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ENCAP FACTSHEET

USAID'S BIOSAFETY PROCEDURES AND THEIR RELATIONSHIP TO LIFE-OF-PROJECT ENVIRONMENTAL COMPLIANCE

CONTENTS

1. INTRODUCTION: BIOSAFETY REVIEWS, ADS 211 & USAID'S BIOSAFETY PROCEDURES

USAID requires that a specific biosafety review be conducted prior to the use of USAID funds to support or otherwise facilitate field testing or open release of bioengineered organisms outside the US. The biosafety review informs the pre-implementation *environmental* review process required by 22 CFR 216 (Reg. 216).

The biosafety review process and its relationship to Reg. 216 are currently defined by ADS 201.3.11.2b. More detailed guidance is in final development/review and will be issued as ADS 211 "Biosafety Procedures for Biotechnology Research, Testing and Use." ADS 211 will expand upon the current ADS 201 requirements.

ADS 211 will establish certain implementation and follow-up requirements for activities requiring biosafety review. It also will address appropriate Reg 216 determinations for activities other than field testing and release that involve bioengineered organisms.

Currently, Africa Bureau is following the process and requirements established by the ADS 211 draft. Compliance with the draft ADS 211 requirements assures compliance with the current requirements set out in ADS 201.

For the purposes of this Factsheet, the requirements established by draft ADS 211 are collectively termed USAID's Biosafety Procedures. The factsheet is based on the February 2009 ADS 211 draft.

2. ABOUT THIS FACTSHEET

This factsheet is a summary of the most important elements of the draft ADS 211, with additional information regarding the relationship between the biosafety procedures and USAID's Reg. 216-based environmental procedures. It is not official agency guidance.

This factsheet assumes familiarity with USAID's mandatory environmental procedures, including Reg. 216. See the resources section for concise briefing materials on these topics.

3. WHAT "BIOENGINEERED ORGANISMS" ARE COVERED?

The Biosafety review process applies to "living organisms modified by genetic engineering techniques" and includes, e.g., plants, microorganisms, live animal vaccines (if used outside a contained area *and* not approved in the US), animals, and insects.

The review process specifically does not apply to (1) food commodities for consumption which have been grown and approved as safe in the US; (2) non-infectious DNA fragments for laboratory or diagnostic use; or (3) live animal vaccines that are approved in the US.

The Feb. 2009 ADS 211 draft does not address human

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vaccines or pharmaceuticals, whether human or animal.

4. WHICH ACTIVITIES REQUIRE A BIOSAFETY REVIEW?

Biosafety review is required when USAID funds will directly support or otherwise facilitate the **field-testing** or **open release** of the types of bioengineered organisms noted above. *This includes support for the procurement or transport of such organisms even if USAID has no direct involvement in their actual field testing or release.*

Biosafety review is NOT required for:

- Research with bioengineered organisms in physically contained buildings such as laboratories, hospitals, greenhouses or barns. (However in this case, the Reg. 216 Initial Environmental Examination (IEE) or Environmental Assessment (EA) will generally require that grantees/contractors follow *US National Institute of Health Guidelines on Research Involving Recombinant DNA Molecules. See below.)*

- Training, workshops and other activities related to capacity-building for biotechnology research, use, and regulation.

However, all of these activities are subject to environmental review under 22 CFR 216. See sections 7 & 9.

5. THE BIOSAFETY REVIEW PROCESS FOR FIRST FIELD TEST OR OPEN RELEASE

Biosafety review prior to a proposed first field test or open release into the environment of a bioengineered organism proceeds as follows:*

A. Proposal. *Before transferring* bioengineered organisms to a developing country for confined field testing or release, the grantee/contractor must submit to the USAID Activity Manager, COTR or Technical Team either:

- A proposal for the confined field trial or release of the bioengineered organism (for required proposal content, see mandatory ADS 211 reference, USAID *Biosafety Proposal and Reporting Requirements, Part I); or*

- A copy of the biosafety application submitted to the host country government, along with any supplemental information requested by USAID.

B. External review. The Activity Manager or COTR will forward the proposal to USAID's Agency Biosafety Officer, who will arrange and coordinate review of the proposal, generally by 3–5 external experts. The review is limited to assessment of risks to human health and the environment.

C. Host country approval. The grantee/contractor must also submit to the USAID Activity Manager, COTR or technical team documentation certifying approval of the field trial or release by the relevant authority in the host country. USAID will not grant biosafety approval without documentation of host country approval.

Except in extraordinary circumstances, USAID will not approve field testing or open release of bioengineered organisms in countries lacking biosafety regulations or laws.

D. Biosafety determination. Once the host country approval has been received and the external review is complete, the Agency Biosafety Officer will submit to the Activity Manager, COTR, or Technical Team a *recommendation* based on the external review. The recommendation (the "biosafety determination") is to approve, modify or disapprove the proposed activity.

**However, where the host country has already "fully approved" the bioengineered product/application in question (i.e., it is no longer subject to specific regulatory procedures), streamlined biosafety review procedures may be approved.* See below.

6. WHAT ABOUT SUBSEQUENT, IDENTICAL, FIELD TESTING OR OPEN RELEASE?

For subsequent field testing or open release of a bioengineered organism (1) in the same country and (2) under nearly identical conditions, the grantee/contractor may, in lieu of a full proposal, submit to the COTR or technical team a one-page notification (see mandatory ADS *211 reference USAID Biosafety Proposal and Reporting Requirements, Part III)* and a letter of approval from the host country authority.

7. HOW DOES A BIOSAFETY REVIEW RELATE TO LIFE-OF-PROJECT ENVIRONMENTAL COMPLIANCE?

PRE-IMPLEMENTATION ENVIRONMENTAL REVIEW (REG. 216)

Activities requiring a biosafety review are typically a component of a larger project or program. Each component of the overall project/program must be covered by *duly approved* Reg. 216 documentation* prior to implementation of that component. The biosafety review informs the recommended determination and conditions for the components involving bioengineered organisms:

- If a biosafety review has already been conducted at the time the IEE or EA governing the overall project is being developed, (1) the IEE/EA must document the biosafety determination, and (2) any relevant conditions from the biosafety review must be written into the IEE/EA.

- More often, however, not enough is known regarding the activity(ies) that require a biosafety review to undertake the review prior to development of the IEE/EA for the parent project. In this case, the IEE would either:

a) establish a **Negative Determination** for these activities subject to the **condition** that, prior their implementation, a biosafety review must be conducted and approved, and the IEE then amended to reflect the results of the biosafety review, *including any attendant conditions*; OR

b) **defer** a determination for these activities. Functionally, this is identical to the scenario above: before the activities can be implemented, a biosafety review must be conducted and approved. The IEE must then be amended to reflect the results of the biosafety review, *including any attendant conditions.*

Note: PERSUAPs and Biosafety Reviews are different. Any activity involving the procurement or use of pesticides (including fungicides, fumigants, herbicides, and/or insecticides requires a Pesticide Evaluation Report and Safe Use Action Plan (PERSUAP). The PERSUAP forms part of the IEE and satisfies the specific Reg. 216 requirements for environmental review of pesticide activities. As such, the biosafety review and the PERSUAP serve distinct purposes; one cannot be substituted for the other.

**an IEE, EA or Request for Categorical Exclusion.*

IMPLEMENTATION

ADS 211 requires that the COTR or technical team inform Grantees/Contractors in writing of the Reg. 216 threshold determination made for the activity and of any attendant biosafety/environmental management and monitoring conditions.

As with all USAID activities:

- The COTR/Activity Manager must assure that IEE/EA conditions are incorporated in contract/grant instruments.
- Contractors/Grantees must implement IEE/EA conditions and Team Leaders/COTRs/Activity Manager must assure that these conditions are implemented over the life of the activity.

FOLLOW-UP

An **"end of trial report**" is due within six months of completion of the proposed activities. Biosafety/ environmental compliance is a key focus of this report; see the ADS 211 Mandatory reference *USAID Biosafety Proposal and Reporting Requirements, Part II*).

8. REQUIREMENTS FOR SHIPPING BIOENGINEERED ORGANISMS

With the exception of bulk food commodities, shipments of bioengineered organisms must be clearly labeled, requirements for their safe handling, storage, transport, and use clearly listed; and a contact point provided.

Grantees/contractors must obey any international or national regulations that may apply. In some countries, regulatory authorities require biosafety approval for the import or transshipment of bioengineered organisms even if destined for contained use.

9. BIOSAFETY REVIEW REQUIREMENTS & TYPICAL REG. 216 THRESHOLD DETERMINATIONS FOR ACTIVITIES INVOLVING BIOENGINEERED ORGANISMS

The table below summarizes biosafety review requirements and provides typical Reg. 216 threshold determinations for activities involving bioengineered organisms. These typical determinations will not hold in all circumstances.

If you are unsure whether an activity requires a biosafety review, please consult with the Agency Biosafety Officer.

Activities	Compliance requirements and notes
Biotechnology capacity-building Training or capacity building in the area of biotechnology research Development and dissemination of biotechnology information Technical assistance to support biotechnology policy and regulatory development	**Biosafety Review Required?** NO **Reg. 216 Threshold Determination** Categorical Exclusion or Negative Determination with conditions *Biotechnology policy and regulatory development will rarely qualify for a categorical exclusion, as these activities have significant influence on the future risks of host country biotechnology use to the environment and human health.*
Contained research Research on bioengineered crops, animal vaccines, microbes, or animals in physically contained buildings such as hospitals, laboratories, greenhouses, or barns.	**Biosafety Review Required?** NO **Reg. 216 Threshold Determination** Categorical Exclusion or Negative Determination with conditions *Conditions will typically specify that Grantees/contractors must follow the National Institute of Health Guidelines on Research Involving Recombinant DNA Molecules. www4.od.nih.gov/oba/rac/guidelines/guidelines.html.*

Activities	Compliance requirements and notes
Products/Applications fully approved in host country Activities involving only bioengineered products already fully approved in the host country, i.e. no longer subject to specific regulatory procedures	**Biosafety Review Required?** Yes, but streamlined procedures may be approved **Reg. 216 Threshold Determination** Unknown; varies.
Field testing and open release -Field testing of bioengineered crops -Pen testing of bio-engineered animal vaccines -Field tests of bioengineered microorganisms for bio-remediation, biopesticides, biofertilizer, or other uses -Commercial or widespread promotion or dissemination of bioengineered crops or animal vaccines -Research on bioengineered crops, animal vaccines, microbes, or animals not conducted in physically contained buildings such as laboratories or barns.	**Biosafety Review Required?** YES **Reg. 216 Threshold Determination** Positive Determination, or Negative Determination with conditions *A proposal for release will most often also require public notice as part of the environmental review process (See 216.6(e)).* *For the biosafety review, grantee/contractor must submit documentation demonstrating approval by the host country authorities of the proposed confined field trial or open release*

10. RESOURCES

BIOSAFETY:

- **http://inside.usaid.gov**/EGAT/off-esp/techareas/biotech/pub_resource/index.htm contains a number of useful resources for USAID staff on Biosafety, Biotechnology, and GMOs.

- ***NIH Guidelines for Research Involving Recombinant DNA Molecules***
  (www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)

  The NIH Guidelines *specify practices for constructing and handling: (i) recombinant DNA molecules and (ii) organisms and viruses containing recombinant DNA molecules, including: comprehensive guidance for risk assessments, experimental protocol design, requirements for containment facilities and equipment, and roles and responsibilities of institutions and researchers involved in biotechnology research.*

- **The Cartagena Protocol on Biosafety**
  (www.biodiv.org/biosafety/default.asp)

  The international agreement governing biotechnology and GMOs, the Cartagena Protocol was adopted as a supplementary agreement to the Convention on Biological Diversity. The Protocol defines a comprehensive regulatory system for the safe transfer, handling and use of GMOs subject to trans-boundary movement. The Protocol website includes useful references, including a Biosafety Clearing-House to facilitate information exchange on GMOs and to assist countries in the implementing the Protocol.

- **CDC/NIH: *Biosafety in Microbiological and Biomedical Laboratories***
  (www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

  This is a standard reference for laboratory biosafety practices and procedures and includes guidance for containment of biohazards, facility design, transport and transfer of biohazardous materials, and reporting requirements.

- **WHO *Laboratory Biosafety Guidelines***
  (www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf)

  These World Health Organization guidelines address risk assessment; laboratory design and operations; laboratory equipment requirements; safe laboratory techniques; transport of infectious materials; chemical, electrical, and fire safety; and safety training requirements.

- **American Biological Safety Association (ABSA)**
  (www.absa.org)

  ABSA was founded in 1984 to represent the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety in formation. ABSA publishes a quarterly journal, Applied Biosafety*, and other biosafety publications; conducts training courses and convenes an annual Biosafety Conference; provides a certification program for biosafety professionals; and keeps a registry of accredited practitioners.*

- **European Biosafety Association** (www.ebsa.be)

  The European Biosafety Association represents biosafety professionals in Europe. Their website contains news and recent developments in the biosafety community. They also host working groups and publish a regular newsletter.

USAID'S ENVIRONMENTAL PROCEDURES:

- **Life of project environmental compliance.** See ENCAP's *USAID Environmental Procedures Briefing for Mission Staff* at www.encapafrica.org/meoEntry.htm.

  Reg 216, IEEs, EAs and threshold determinations. Visit the on-line *IEE Assistant* at www.encapafrica.org/assistant.htm.