USAID Biosafety Procedures[1]
"First Review, Proposal and Reporting"

Reconciling ADS 201 with Draft ADS 211

USAID's "Biosafety Procedures for Genetic Engineering Research" are still in draft, and are intended to be promulgated as ADS Chapter 211, replacing the current section of ADS 201 regarding the environmental review requirements for biosafety. Until ADS 211 is approved, however, the operative ADS guidance is found in ADS 201.3.12.2(b). This section provides that "if an activity will potentially involve the use of genetically modified organisms in research, field trials, or dissemination, the activity must be reviewed and approved for compliance with applicable U.S. requirements by the Agency Biosafety Committee in Washington before the obligation of funds and before the transfer, testing, or release of biotechnology products into the environment." This guidance further states that a biosafety review is separate from and should precede the Regulation 216 review, although each review informs the other.

The gap between existing Agency biosafety review policies and those intended by the draft ADS 211 is not, in practice, a large one. The draft ADS 211 is essentially an elaboration of the process envisioned by ADS 201 for a biosafety review. Compliance with ADS 201's biosafety review requirements is achieved, therefore, by complying with the requirements of draft ADS 211.

Essential, however, is that ADS 201 specifies the order of the two reviews such that the biosafety review must precede the Regulation 216 review for research, field trials and dissemination of genetically modified organisms (GMOs). In practice, this means that a threshold decision on an activity involving GMOs must be deferred until completion of the biosafety review procedures outlined below. This applies even to contained research.

Summary of Draft ADS 211

Summarized here is draft ADS Section 211.3.1, regarding 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 procedures apply to:

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

USAID-funded GE-product development and implementation partners are prohibited from transferring or releasing GE products prior to obtaining the required written approval from USAID, as detailed in ADS 211.3.1. In addition, applicable national laws (e.g., biosafety, shipping/packaging, sanitary, or phytosanitary standards) must be adhered to.

Regarding the first review of initial transfer, testing, or use (ADS 211.3.1), the responsible actors (grantee /contractor, etc.), shall follow the USAID biosafety review process:

Proposal. The implementing parties must: provide a proposal containing required information on the proposed transfer, testing, or use that the grantee/contractor. The goes to the USAID Cognizant Technical Officer (CTO) or Strategic Objective (SO) Team, before supporting GE products for testing or use, the grantee/contractor must submit a proposal for approval by USAID.

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1 Condensed from the draft USAID Automated Directives System (ADS), Chapter 211 "Biosafety Procedures for Genetic Engineering Research." Summarized here is ADS Section 211.3.1

External Review for USAID. This proposal will be forwarded by the CTO to the USAID Biosafety Officer for external review. The Biosafety Officer will arrange for an external biosafety review of the proposal.

Certification of Host Country Approval. Documentation must be provided 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. 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.

These 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.

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, testing and/or release of the GE product, including any specific conditions imposed by the host country. USAID will not grant approval of the transfer, testing or release in the absence of this letter or letters of approval.