ADS 211: Biosafety Procedures for Genetic Engineering Research

Draft USAID Guidance

Activities Covered

- Transferring genetically engineered products to a developing country for release outside a contained facility
- Field testing livestock vaccines in a LDC
- Field testing crop varieties in a LDC
- Testing or releasing GE bioremediation products in LDCs

Activities *not* covered

- Genetically engineered human pharmaceuticals, incl. vaccines, which undergo FDA approval, thus already reviewed for potential environmental impact
- Use of GE products in contained facilities such as labs, which are subject to existing NIH guidelines…

Responsibilities

- EGAT appoints Agency Biosafety Officer, responsible for:
  - Assisting CTOs or SO Teams in implementing ADS 211
  - Supporting MEO, REO, BOE in incorporating external biosafety reviews into Agency env. Procedures
- CTOs & SOTs ensure full compliance with ADS 211

Policy & Procedures

- Grantees are prohibited from transferring or releasing GE products prior to obtaining required written procedures as detailed
- Proposal review – info required is in Reference Document to ADS 211
- External Review required
- Host Country approval required of designated national authority

USAID Determination

- Upon receipt of above, Agency Biosafety Officer submits to CTO/SOT a recommendation
- SOT/Mission submits recommendation, with IEE, to BEO of geographic Bureau
- BEO, in consultation with Biosafety Officer, MEO, REO, makes threshold determination, provides to SOT, CTO, etc.
- CTO/SOT conveys to grantee or contractor in writing the determination and any conditions