



## ADS Chapter 211

# Biosafety Review Procedures for the Research, Testing, and Use of Genetically Engineered Organisms

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ADS 211 – Biosafety Review Procedures for the Research, Testing, and Use of  
Genetically Engineered Organisms  
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## 211.1 OVERVIEW

Effective Date: 11/15/2018

USAID supports the use of safe, legal, effective technologies to advance development objectives. Where appropriate, this may include Genetically Engineered (GE) organisms (also known as Genetically Modified Organisms (GMO), Living Modified Organisms (LMO), transgenic organisms, biotech organisms, etc.). These are defined as living organisms into which scientists have intentionally introduced genetic material, using a range of potential technological approaches.

To ensure the safety of USAID activities that develop, test, or use GE organisms, the biosafety review procedures outlined in this ADS chapter are intended to:

- Describe the process by which USAID reviews the biosafety of proposed activities involving GE organisms;
- Identify officials authorized to determine potential human, animal, or environmental risks of activities involving GE organisms on behalf of USAID; and
- Ensure that USAID effectively identifies, reduces, and manages potential risks that GE organisms may pose to human, animal, or environmental health.

To accomplish these goals, the USAID Biosafety Review process draws upon internationally recognized biosafety data requirements, risk assessment practices and harmonized standards to identify, minimize, and mitigate potential risks posed by USAID-funded activities that research, test, or use GE organisms in an international development context. In doing so, the Biosafety Review process adheres to robust standards comparable to those applied by U.S. regulatory agencies, while maintaining flexibility for activities conducted in USAID partner countries to navigate the specific regulatory requirements prescribed by local biosafety authorities.

The biosafety review process described in this ADS chapter is not intended to examine the overall scientific quality or development potential of a proposed activity involving GE organisms, as these are reviewed during program planning and implementation.

Additionally, the biosafety review process described in this ADS chapter does not fulfill USAID environmental review requirements set forth under [ADS 204, Environmental Procedures](#). Instead, this biosafety review is intended to precede and inform subsequent USAID environmental reviews. As such, the biosafety review limits analysis to environmental or health risks specifically posed by GE organisms; it does not consider the broader set of non-GE interventions (i.e. pesticide or fertilizer application, irrigation, construction, waste disposal, etc.) by which a proposed activity involving GE organisms may impact the environment.

**211.2 PRIMARY RESPONSIBILITIES**

Effective Date: 05/04/2020

a. The **Assistant to the Administrator (AtA) for the Bureau for Resilience and Food Security (RFS)** is responsible for appointing, in writing, an Agency Biosafety Officer (ABO). The ABO must be a U.S. Government employee qualified to fulfill inherently governmental functions who is based in Washington, DC.

b. The **Agency Biosafety Officer (ABO)** oversees and approves the required biosafety review procedures described in this ADS chapter, and serves as the focal point of contact for USAID activities involving research, testing, or use of GE technologies. Specifically, the ABO:

- Determines whether or not an activity is subject to USAID biosafety review requirements;
- Identifies the technical expertise necessary to fulfill USAID biosafety review requirements, and coordinates across Operating Units to ensure that relevant staff (or, if necessary, external) expertise is applied during the biosafety review process;
- Approves the Biosafety Risk Determination document, which summarizes the results of the biosafety risk assessment;
- Clears any [22 CFR 216](#) environmental review documents pertaining to activities that require USAID biosafety review, before such activities may proceed (relevant documentation may include, for example, an Initial Environmental Examination (IEE), IEE Amendment, or Environmental Assessment (EA));
- Ensures that Agency queries regarding biosafety are answered in a timely manner by monitoring and responding to emails submitted to **biosafety@usaid.gov**;
- Ensures that Agreement Officers, Contracting Officers, Agreement Officer's Representatives, and Contracting Officer's Representatives, Activity Managers, or Assistance Objective Teams receive appropriate technical support in implementing biosafety monitoring and mitigation conditions during the award period; and
- May appoint one or more qualified Deputy Agency Biosafety Officers (DABOs) to ensure timely decision-making.

c. **USAID Bureaus** will appoint, at the ABO's request, a technical advisor with sufficient knowledge to oversee or inform biosafety review of proposed activities pertaining to that Bureau's area of expertise (e.g. the Global Health Bureau to advise on the testing or use of GE vaccines; or the Bureau for Food Security to advise on the

testing or use of GE crops).

**d. Agreement Officer's Representatives and Contracting Officer's Representatives (AORs/CORs), Activity Managers (AMs), and Assistance Objective Teams** responsible for a proposed activity involving GE organisms are responsible for:

- Informing the relevant AO/CO and Mission, Regional, or Bureau Environmental Officer (MEO/REA/BEO) or Advisor if the proposed activity involves GE organisms;
- Working with the ABO, the relevant MEO/REA/BEO, and the contractor/recipient, as appropriate, to execute the biosafety review procedures described in this ADS chapter; and
- Ensuring full compliance with Agency biosafety procedures in the design and implementation of all activities involving GE organisms.

**e. The Mission, Regional, or Bureau Environmental Officer or Advisor (MEO/REA/BEO)** responsible for environmental review of a proposed activity involving GE organisms must:

- Work closely with the ABO and relevant AM/AOR/COR to implement the required biosafety review procedures;
- Take into consideration the ABO's Biosafety Risk Determination when assisting in development of environmental review documentation in fulfillment of [22 CFR 216](#) requirements (e.g. an IEE, IEE Amendment, or EA); and
- Obtain the ABO's clearance on any [22 CFR 216](#) environmental review documentation pertaining to activities that require biosafety review.

**f. The Agency Environmental Coordinator (AEC), together with the AA or Mission Director (MD)** of the Operating Unit sponsoring the relevant GE activity, are responsible for mediating any disagreements regarding the incorporation of the Biosafety Risk Determination into subsequent Agency Environmental Review as required under [ADS 204, Environmental Procedures](#).

### **211.3 POLICY DIRECTIVES AND REQUIRED PROCEDURES**

Effective Date: 11/15/2018

Biosafety review is the process by which USAID assesses the potential for a proposed activity involving GE organisms to result in human, animal, or environmental harm (see [ADS 211saa, Biosafety Review Process Flow Chart](#)). Note that except in extraordinary circumstances, USAID will not approve research, testing, or use of GE organisms in countries lacking appropriate, enabling biosafety policies, laws, or

regulations.

### **211.3.1 Applicability of Biosafety Review Requirements to USAID Activities**

Effective Date: 11/15/2018

All USAID-funded activities conducted outside the United States that involve the research, testing, or use of GE organisms (including GE plants, animals, or microorganisms) are subject to the biosafety review requirements described in this ADS chapter.

USAID activities not subject to biosafety review include:

- Activities that do not involve GE organisms;
- Activities conducted within the United States, as these are already subject to regulation and oversight by appropriate U.S. authorities;
- Activities involving the procurement or distribution of GE commodities (such as grain for food or feed), as these are already subject to applicable U.S. and foreign laws;
- Research, testing, or use of nonliving products derived from GE organisms (such as pharmaceutical or industrial products); and
- Activities involving GE organisms that were awarded prior to the issuance of this ADS chapter, but which underwent comparable assessment of biosafety risks.

Given the rapid pace of biotechnological innovation, novel methods of introducing targeted genetic changes into living organisms (e.g. CRISPR and other genome editing technologies) are being developed that may confound current definitions of what is or is not a “GE organism”. In these (or other) cases where applicability of biosafety review requirements is uncertain, the ABO will determine on a case-by-case basis, and in accordance with evolving biosafety risk assessment best practices (including whether the proposed activity would be regulated as a GE organism according to U.S. or partner-country standards), whether USAID biosafety review requirements apply to a particular activity or technology (see **211.3.3** for details).

### **211.3.2 Overview of the Biosafety Review Process**

Effective Date: 11/15/2018

The biosafety review process includes the following six steps (see [ADS 211saa](#)):

1. The AM/AOR/COR and MEO/REA/BEO of the activity request a preliminary consultation with the ABO, who determines whether biosafety review is necessary (see **211.3.3**).

2. If a biosafety review is necessary, the AM/AOR/COR prepares the Activity Biosafety Summary and accompanying documentation, in close consultation with the contractor/recipient, if appropriate, and submits it to the ABO (see **211.3.4**).
3. The ABO ensures that potential biosafety risks of the activity are assessed by appropriate experts (see **211.3.5**).
4. The ABO approves a written USAID Biosafety Risk Determination (see **211.3.6**).
5. The AM/AOR/COR and MEO/REA/BEO incorporate the ABO's Biosafety Risk Determination and partner-country biosafety authorization into a subsequent USAID environmental review under [ADS 204](#) (see **211.3.7**).
6. If appropriate, the ABO may continue to provide follow-up technical assistance to the AM/AOR/COR and MEO/REA/BEO after the biosafety review has been completed (see **211.3.8**).

Further detail on each of the six steps is described below, and illustrative examples of how biosafety review requirements are fulfilled throughout the program planning and implementation cycle can be found in **211.5.c**.

### **211.3.3 Preliminary Consultation with the ABO**

Effective Date: 11/15/2018

Upon consideration of any new activity involving GE organisms, and prior to environmental review of the activity under [ADS 204](#), the AM/AOR/COR and MEO/REA/BEO must consult with the ABO to determine whether Biosafety Review is necessary. To initiate this process, the AM/AOR/COR should email a short description of the proposed activity involving GE organisms to [biosafety@usaid.gov](mailto:biosafety@usaid.gov). In this context, a "new" activity may be:

- A new funding opportunity being developed for solicitation;
- A proposal or application under consideration for award;
- A new GE activity under an existing award; or
- A proposed activity involving a GE organism whose scope varies from what was previously approved under the IEE for an existing activity (e.g. a significant change in the approved host organism, transgene construct, release location, release protocol, or scale of release).

Upon receiving an email query at [biosafety@usaid.gov](mailto:biosafety@usaid.gov), the ABO will determine on a case-by-case basis whether biosafety review is required for a proposed activity. A variety of factors may influence this determination, but in general activities will fall into the following categories:

<b>Type of Activity</b>	<b>Typical Biosafety Review Requirement</b>
An activity involving GE organisms that will be conducted solely in the United States.	<b>Not Required</b>
Trainings, workshops, or technical assistance activities which do not themselves research, test, or use GE organisms.	<b>Not Required</b>
Procurement or distribution of GE commodities (such as grain for food or feed).	<b>Not Required</b>
Research, testing, or use of nonliving products derived from GE organisms (such as pharmaceutical or industrial products).	<b>Not Required</b>
Activities involving technologies the ABO determines do not meet the definition of "Genetically Engineered."	<b>Not Required</b>
Research, testing, or use of GE organisms in physically contained and controlled facilities such as laboratories, greenhouses, or animal rearing facilities.	<b>Required</b>
Research, testing, or use of GE organisms under confined field conditions.	<b>Required</b>
Environmental release of a GE organism without containment or confinement.	<b>Required</b>
Dissemination or use of a GE organism that has already received partner-country regulatory approval for environmental release.	<b>May Be Required</b> <i>(Depending on the availability and sufficiency of biosafety review information issued by U.S. and/or partner-country regulatory authorities.)</i>



Type of Activity	Typical Biosafety Review Requirement
Activities involving GE organisms that USAID funds through a program contribution to a Public International Organization award.	<p style="text-align: center;"><b>May Be Required</b> <i>(Depending on the award provisions.)</i></p>

If the ABO determines that biosafety review is necessary, implementation of the proposed activity must not proceed until the biosafety review process has been completed.

Depending on the nature of the proposed activity, the ABO may delegate responsibility for subsequent steps of the biosafety review process to technical advisors within an appropriate Bureau or Mission, or to external experts. For example, an activity proposing to develop or disseminate a GE vaccine for humans might be referred to an appropriate Global Health Advisor, while an activity involving GE crops might be referred to technical experts in the Bureau for Food Security.

#### **211.3.4 The Activity Biosafety Summary**

Effective Date: 11/15/2018

If the ABO determines that an activity is subject to USAID biosafety review requirements, an Activity Biosafety Summary must be completed. The purpose of the Activity Biosafety Summary is to provide sufficiently detailed technical information about the proposed activity so that the ABO can effectively assess the likelihood that it will result in harm to humans, animals, or the environment.

The AOR/COR/AM is responsible for developing and submitting an Activity Biosafety Summary document to the ABO (or designee)—often in close consultation with the contractor or recipient (as appropriate). The ABO will work with the AOR/COR/AM and MEO/REA/BEO to determine the structure and content of the Activity Biosafety Summary, but in general it should describe, with supporting documentation:

- The GE organism (including details of the host organism and the engineered construct) and its intended use;
- Implementation details of the proposed activity;
- The degree of human and environmental exposure likely to arise as a result of the activity;
- Any potential environmental or health hazards posed by the GE organism;
- Proposed mitigation and monitoring measures; and

- Partner-country regulatory documentation required by the competent local authorities, as appropriate in consultation with the ABO.

Though all Activity Biosafety Summaries will provide information on these general categories, the supporting data requirements will vary depending on the type of GE technology and the nature and scale of the proposed activity. Further details regarding the specific structure and content of the Activity Biosafety Summary are provided in the Biosafety Summary Guidelines for Activities Involving GE Organisms, or may be determined by the ABO during the preliminary consultation depending on the nature of the activity.

### **211.3.5 Biosafety Risk Assessment**

Effective Date: 11/15/2018

Once the AOR/COR/AM submits the Activity Biosafety Summary and accompanying documentation to the ABO, the ABO (or designee) will use it as the basis to conduct a Biosafety Risk Assessment. A Biosafety Risk Assessment is the process by which USAID determines the potential for a proposed activity to harm environmental, human or animal health and suggests appropriate monitoring or mitigation steps to manage those risks.

The Biosafety Risk Assessment may consider a number of factors that influence the degree of risk a GE organism poses to human, animal, or environmental health. These primarily include:

- The degree to which humans, animals, or the environment will be exposed to the GE organism during the course of the proposed activity;
- Evidence regarding the potential harm the GE organism could cause to human or animal health (such as pathogenicity, toxicity, or allergenicity);
- Evidence regarding the potential harm the GE organism could cause to the environment (such as weedy persistence, unintended gene flow to other organisms, or impacts on non-target organisms); and
- The capacity of local biosafety authorities to effectively regulate the proposed activities.

To perform the Biosafety Risk Assessment, the ABO (or designee) reviews the Activity Biosafety Summary and accompanying partner country documentation, and may consult any additional materials necessary to inform assessment of potential risks according to internationally recognized best practices for biosafety risk assessment. In some cases, the ABO may, at their discretion, arrange for external review of the Activity Biosafety Summary by one or more outside experts.

### **211.3.6 The Biosafety Risk Determination**

Effective Date: 11/15/2018

The Biosafety Risk Assessment process culminates in a written Biosafety Risk Determination document, signed by the ABO, which:

- Advises whether the proposed activity should be approved (with or without conditions), modified, or rejected;
- Contextualizes and justifies the ABO's recommendation by referencing and synthesizing sources that informed the biosafety review process;
- Recommends mitigation and monitoring conditions that should be considered during subsequent USAID environmental review in order to minimize biosafety risk; and
- Provides sufficient detail to inform the AOR/COR/AM and MEO/REA/BEO's subsequent development of an appropriate Threshold Determination during environmental review under [ADS 204](#).

Once complete, the ABO shares the Biosafety Risk Determination with the AOR/COR/AM and MEO/REA/BEO, who are responsible for fulfilling subsequent environmental review requirements for the proposed activity.

### **211.3.7 Incorporate Biosafety into Subsequent Environmental Review**

Effective Date: 11/15/2018

The biosafety review process is intended to precede and inform USAID's environmental review (as described in [ADS 204](#)) for activities involving the research, testing, or use of GE organisms. Therefore, if [22 CFR 216](#) environmental review documentation (e.g. an IEE, IEE Amendment, or EA) states that a determination will be made regarding activities involving GE organisms, then:

- The AOR/COR/AM responsible for developing the environmental review document must:
  - Reference the Activity Biosafety Summary and USAID Biosafety Risk Determination documents in order to populate activity information, implementation details, and biosafety risk factors of activities involving GE organisms;
  - Ensure that the Biosafety Risk Determination's assessment of potential human, animal, or environmental health risk directly informs the relevant Threshold Determination; and
  - Incorporate into the environmental review documentation any biosafety

mitigation conditions or monitoring plans that are recommended in the USAID Biosafety Risk Determination and/or required by the partner country.

- Appropriate authorization documents must be obtained from the country or countries in which the activity will be conducted—for example, a permit or other regulatory decision issued by the competent National Biosafety Authority. The [22 CFR 216](#) environmental review document must include, as attachments, all biosafety permits or documentation required by the partner country (in English, or with a clear English translation), including any monitoring, mitigation, or other conditions imposed by local authorities. Until USAID receives such documentation of partner-country approval, the biosafety review process cannot be completed and the activity will not proceed.
- The ABO must clear the [22 CFR 216](#) environmental review document prior to the final BEO clearance. Both clearances are required before any activity involving a GE organism may proceed. In the event of a disagreement between the ABO and MEO/REA/BEO, any dispute will be mediated by the Agency Environmental Coordinator (AEC), in consultation with the Assistant to the Administrator or Mission Director of the Operating Unit responsible for the activity in question.

Note that if the ABO, in consultation with the MEO/REA/BEO, determines that a significant effect on the environment may result from the release of a particular GE organism, further analysis beyond the biosafety review process may be appropriate under [ADS 204](#) environmental assessment protocols.

### **211.3.8 Continued Biosafety Support During Activity Implementation**

Effective Date: 11/15/2018

After completion of the biosafety review process, the AOR/COR/AM or MEO/REA/BEO of an activity involving GE organisms may email the ABO at [biosafety@usaid.gov](mailto:biosafety@usaid.gov) to request technical assistance to ensure effective implementation of biosafety mitigation and monitoring conditions described in the IEE or EMMP. Such technical support may include, for example:

- Communicate to the awardee the biosafety threshold determination and any associated monitoring or mitigation measures for an activity involving GE organisms;
- Provide guidance to the AOR/COR/AM or MEO/REA/BEO on how to ensure compliance with biosafety monitoring and mitigation measures required by the activity IEE;
- Identify sources of expertise to implement monitoring, mitigation, or assessment measures required by the [22 CFR 216](#) environmental review documentation that extend beyond the capacity of the AOR/COR/AM or MEO/REA/BEO to implement directly (such as independent CFT field inspections, or an

Environmental Assessment if required in accordance with [ADS 204](#)); or

- Assist in the development of appropriate guidance to mitigate negative impacts, in the unlikely event that implementation of an activity involving GE organisms results in negative consequences to human, animal, or environmental health.

Additionally, in some cases monitoring or mitigation conditions stated in the activity IEE or EMMP may require ongoing involvement of the ABO (e.g. to periodically review partner-country permits or biosafety compliance reports) as a condition of implementation.

## 211.4 MANDATORY REFERENCES

### 211.4.1 External Mandatory References

Effective Date: 11/15/2018

- [22 CFR 216, Agency Environmental Procedures](#)
- [Section 117 of the Foreign Assistance Act of 1961, as amended](#)

### 211.4.2 Internal Mandatory References

Effective Date: 11/15/2018

- [ADS 204, Environmental Procedures](#)

## 211.5 ADDITIONAL HELP

Effective Date: 11/15/2018

- [ADS 211saa, Biosafety Review Process Flow Chart](#)
- [ADS 211sab, Illustrative Examples of ADS 211 Implementation Throughout the Program Cycle](#)

## 211.6 DEFINITIONS

Effective Date: 05/04/2020

See the [ADS Glossary](#) for all ADS terms and definitions.

### Agency Biosafety Officer

Appointed by the [AtA/RFS](#) to provide assistance in the implementation of USAID biosafety policy and procedures. (**Chapter 211**)

### biosafety

The prevention of harm to human, animal, or environmental health. (**Chapter 211**)

### biosafety risk determination

A document which summarizes the findings of the ABO's Biosafety Risk Assessment of

a proposed activity involving GE organisms, and recommends whether the activity should be approved (with or without conditions), modified, or rejected. **(Chapter 211)**

**biosafety review**

The overarching process by which USAID assesses the potential for a proposed activity involving GE organisms to result in harm to human, animal, or environmental health. **(Chapter 211)**

**biosafety risk assessment**

The step in the USAID biosafety review process in which the ABO (or a designee) uses the Activity Biosafety Summary and other supporting information as the basis to assess, on behalf of USAID, the potential for a proposed activity involving GE organisms to harm human, animal or environmental health. This process is summarized in a written Biosafety Review Determination. **(Chapter 211)**

**biosafety summary**

Document produced during the USAID biosafety review process which provides sufficiently detailed technical information about a proposed activity involving GE organisms to assess the likelihood that it will result in harm to humans, animals, or the environment. **(Chapter 211)**

**Confined Field Trial (CFT)**

In the context of activities involving GE organisms, an activity conducted in confined but non-contained facilities (for example, a fenced field rather than a laboratory) but in a limited area. The trial is physically and biologically contained through several approaches to eliminate movement of genetic material outside the trial site (isolation distances, surveillance, restricting flowering, nets, etc.) **(Chapter 211)**

**contained use**

In the context of activities involving GE organisms, use of GE organisms in a physically contained facility such as a laboratory, hospital, or greenhouse. **(Chapter 211)**

**dissemination**

In the context of activities involving GE organisms, the larger-scale multiplication and distribution of a GE organism that has been approved for environmental release. **(Chapter 211)**

**environmental release**

In the context of activities involving GE organisms, the open and deliberate introduction of genetically engineered organisms into the environment, such as the provision of plants/seeds to farmers. This does not include food commodities that are intended for consumption rather than cultivation. **(Chapter 211)**

**genetically engineered (GE) organisms**

For the purposes of USAID, genetically engineered organisms (sometimes referred to

as Genetically Modified Organisms (GMO), Living Modified Organisms (LMO), transgenic organisms, biotech organisms, etc.) are defined as those plants, animals, or microorganisms that have been modified by recombinant DNA (rDNA) techniques to create transgenic organisms that have new traits. (**Chapter 211**)

**microorganisms**

Microorganisms are microscopic entities capable of carrying on living processes. Types of microorganisms include bacteria, fungi, protozoa, and viruses. (**Chapter 211**)

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