Example Scenarios: **How do I apply ADS 211 Biosafety Review requirements to my program?**

In this scenario…	*(Examples)*	… how do I fulfill ADS 211 Biosafety Review requirements?

1) I don't know what a Genetically Engineered (GE) organism is, or whether my activity triggers ADS 211 Biosafety Review requirements.	• *E.g.*— I am anxious that I should be doing something about all these new **ADS 211** Biosafety requirements, but I majored in 17th Century French painting with a minor in accounting, and I am totally confused about whether these requirements apply to me or the activities I manage.
	
	• *E.g.*— The contractor for my agricultural value-chain program wants to disseminate a bio-fortified vegetable that is highly resistant to drought and heat. I'm not sure whether this counts as a GE organism or not,[1] or whether it triggers **ADS 211** biosafety review.
		• Review **ADS 211**—particularly:
		  ○ **ADS 211.1** ("Overview") and
		  ○ **ADS 211.3.1** ("Applicability of Biosafety Review Requirements to USAID Activities").
		• Check with your MEO/BEO.
		• If you are still confused, consult with the ABO.
		• Note that the vast majority of USAID awards and activities do not involve GE organisms and will not trigger **ADS 211** Biosafety Review requirements.

2) I am developing a Notice of Funding Opportunity (NOFO) that may include activities involving GE organisms, but I'm not yet sure exactly what those activities might be.	• *E.g.*— I am developing a new funding opportunity that calls for creative solutions to development challenges. I want offerors to be able to propose GE solutions if they think that's the best available tool, but it's not a requirement and I'm not sure what approaches they might suggest.	• Consult the ABO early in NOFO development. • If activity details are insufficient for the ABO to assess potential biosafety risks at the pre-solicitation phase, the ABO will likely recommend that you include a "Negative Determination w/ Conditions" in the IEE, stipulating that if applicants propose any activity involving a GE organism, a biosafety review must be completed before initiation of that activity.

[1] Note that "bio-fortification" is a generic process by which the nutritional quality of food crops is improved. This can be accomplished through a variety of scientific approaches, including conventional crop breeding, agronomic practices, or genetic engineering. ADS 211 would only apply to bio-fortified crops generated using GE approaches.

		• The ABO may also have helpful suggestions regarding what information your solicitation should require applicants to submit as part of their application package if they propose to work with GE organisms, in order to streamline the biosafety review process. • Initiate biosafety review if/when an applicant proposes activities involving GE organisms. • Subsequently incorporate any biosafety review recommendations into an IEE Amendment that specifically covers the proposed activity involving GE organisms. • Implementation of the activity involving GE organisms may proceed once the conditions of the IEE Amendment are met.
3) I am developing a NOFO that will implement activities involving GE organisms, whose details are known at the time of solicitation.	• *E.g.*— My office is developing an IEE for a new activity that will disseminate insect-resistant *Bt* maize to combat Fall Armyworm in South Africa. • *E.g.*— My office conducted a BAA on innovative approaches to disease control in my partner country, and is now in discussion with a private-sector biocontrol company that proposes releasing GE mosquitos to control vector-borne diseases.	• Consult the ABO early in NOFO development. • If sufficient detail is known about the activity at the pre-solicitation/project design phase, the ABO may conduct the biosafety review based on the NOFO's program description. • Incorporate any biosafety review recommendations into the IEE for the NOFO. Award and implementation of the activity may proceed according to usual protocols.
4) The AO issued an NOFO (with accompanying IEE) that did not anticipate triggering ADS 211	• *E.g.*—The AO issued a NOFO for an agricultural value chain project. At the time the possibility of GE technologies	• Consult the ABO as soon as you realize you may want to issue an award for activities involving GE organisms.

requirements—but we've unexpectedly received a compelling application that proposes using GE organisms.	didn't occur to me, but the apparently successful application includes, among other things, technical support for seed companies to produce and disseminate GE rice and papaya seed. It's a great application, but the original IEE I developed doesn't include any provision for activities involving GE crops, and I'm not sure whether it's even legal to sell or cultivate them in my partner country.	• If sufficient details about the activity are included in the application, the ABO may be able to conduct the biosafety review for the proposed activity. (If details are insufficient, see Scenario #3 above.) • Incorporate the biosafety review recommendations into the IEE (or, depending on the award timeline, into a subsequent IEE Amendment that covers the elements of the activity involving GE organisms). • Implementation of the GE activity may proceed once the biosafety conditions of the relevant IEE Amendment have been met.
5) I manage an existing award that did not previously implement activities involving GE organisms, but wants to begin doing so.	• *E.g.*— The livestock value-chain program I manage is in its third of five years. Recently, the biosafety regulatory authority in my partner country approved release of the country's first GE cow, which is resistant to a disease that dramatically increases economic risk to pastoralists. In its final two years, this project wants to refocus its existing breed improvement efforts to take the new GE cow to scale in the resilience zone worst affected by the disease.	• Consult the ABO as soon as you realize your award may evolve to include activities involving GE organisms. • Complete the biosafety review process for the new or modified element of the project that will now involve GE organisms. • Incorporate the biosafety review recommendations into an IEE Amendment that covers the new activity elements that involve GE organisms. • Implementation of new GE activities may proceed once the conditions of the IEE Amendment have been met.
6) I manage an award or NOFO whose existing IEE already covers activities involving GE organisms, but which now proposes to modify the scope of	• *E.g.*— The AO issued an NOFO calling for applicants who are able to perform confined field trials (CFTs) of a GE crop at an approved research site. But the	• Consult your IEE; it may already include guidance on how to proceed. Consult the ABO if you have any questions or want to confirm your interpretation.

those activities to include a different:
• **Organism**
• **Genetic construct**
• **Geographic area**
• **Scale of environmental or human exposure (*e.g.* shifts between contained, confined, or environmental release; or introduces substantial change to an approved release protocol).**
	apparently successful applicant wants to test the product in multiple agro-ecologies, and is therefore proposing CFTs at two additional locations. They also want to test a second, more effective version of the transgene construct than was covered in the original IEE.
	
	• *E.g.*— My office supports an ongoing R&D project that is testing a GE insect capable of controlling important vector-borne diseases. Research has been successfully completed, the data look encouraging, and the project is now planning for regulatory submission to local biosafety authorities and subsequent release of the GE insect into the environment as part of a country-wide disease control effort.
		• An additional round of Biosafety Review may be necessary to re-assess the risk of the activity in light of the proposed change in scope. Depending on the proposed change:
		  ○ …review might be expedited (*e.g.* adding a new confined trial site for an organism/construct that was already previously approved);
		  ○ …or review might require a substantial re-assessment of risks (*e.g.* for a proposed shift from confined research to full environmental release).
		• If appropriate, incorporate any new biosafety review recommendations into an IEE Amendment that addresses the modified scope of the activity.
		• Implementation of the modified GE activity may proceed once the conditions of the IEE Amendment have been met.

7) I manage a NOFO or award whose existing IEE covers activities involving GE organisms, and which repeats the same or similar activities multiple times (*e.g.* Confined Field Trials).	• Last year, the project I managed implemented the country's first-ever Confined Field Trial of virus-resistant cassava. This year, they want to repeat the activity to get a second season of field data and validate the disease resistance trait.	• Consult your IEE; it likely already includes guidance on how to proceed. Consult the ABO if you have any questions or want to confirm your interpretation. • Although requirements can vary depending on the context, in general, once an activity has undergone biosafety review, repeated iterations of that activity do not require repeated biosafety review so long as the appropriate partner-country approval documentation is in place, and the approved organism, genetic construct, geography, and release scale/protocol remain the same.

		• If any of the above factors changes, refer to Scenario #6 above.

Key Takeaways:

- As a given activity is designed and implemented, and as it evolves to adapt to dynamic circumstances in-country, ADS 211 Biosafety Review requirements can potentially be triggered and implemented at any point in the program design and implementation cycle—from the pre-solicitation design phase, to the pre-award selection phase, through the implementation phase of an assistance or acquisition mechanism.

- Consult with the ABO as soon as you realize your planned or ongoing activity may involve GE organisms. The ABO can provide tailored guidance on whether and how to proceed with a biosafety review, or how to comply with the biosafety measures already included in your IEE.

- Biosafety Review precedes and informs environmental review—but ultimately the IEE generated according to **ADS 204** is the document that officially governs environmental compliance (including biosafety compliance) by USAID activities. Your activity IEE should therefore incorporate any recommendations from the biosafety review, and an activity involving GE organisms may not proceed until the IEE conditions have been met.