

	United States Department of Agriculture Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control: AIR Guidance
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Am I Regulated (AIR) Process Guidance for Submission of AIR Inquiries		Effective Date: 09/05/2018

USDA-APHIS-BRS

If you are unsure whether your genetically engineered (GE) organism meets the definition of a regulated article as described in 7 CFR part 340, prior to proceeding with an application for a notification or permit, you may seek a confirmation of regulatory status of the GE organism from USDA by sending a signed letter containing the information described below to:

Address the letter of inquiry to:

Dr. Michael J. Firko
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98
Riverdale, MD 20737

Send the letter of inquiry to:

Ms. Cynthia A. Eck
Document Control Officer
Biotechnology Regulatory Services
4700 River Rd, Unit 146
Riverdale, MD 20737

OR

Email your letter of inquiry to:
AIRinquiries@aphis.usda.gov

Your letter of inquiry must include:

- Developer (Responsible Party) name and contact information, including email address.
- Taxonomic description of organism (genus, species, and subspecies, if relevant).
- Description of intended phenotype(s).
- Description of intended activity (movement or release).
- Description of intended genetic change in final product (e.g., insertion, deletion, substitution, other).
- Description of vector or vector agent used to induce genetic change in the organism (e.g., biolistic delivery, disarmed *Agrobacterium*, nuclease).
- Name of construct(s)
- Description of construct, including the following information for all elements, in order in which they occur in construct:

- Element type(s) (e.g., operators, promoters, origins of replication, terminators, ribosome binding regions);
 - Element name(s) (e.g., 35S, catalase, Tnos);
 - Organism from which element is derived (species or virus strain); and
 - Brief description of genetic element's function.
- Description of scientific methodology that you used or intend to use to confirm that the intended genetic changes were achieved.

Scientific Methodology and Supporting Data

If your letter of inquiry describes a final product that has, or will have, no DNA insertions, please describe the scientific methodology that you used, or intend to use, to confirm that assertion. Provide sufficient detail to enable USDA to assess the efficacy of the methodology.

If your letter of inquiry includes molecular data to support the claims made in your inquiry, please provide a brief summary of the scientific methodology used to generate the data as well as the data presented in an appropriate form to substantiate those claims.

Inquiries Regarding the Movement of Plant Parts

Some AIR inquiries involve the movement of plant parts derived from regulated articles, for example, the importation of cut flowers. If your AIR inquiry involves the movement of a plant part, please include evidence to support any claims that the plant part will not persist in the environment without human assistance.

Confidential Business Information

If your letter of inquiry, as well as any follow-up documentation that you provide, does not contain Confidential Business Information (CBI), it must be marked “**Does Not Contain CBI**”.

If your letter of inquiry, as well as any follow-up documentation that you provide, contains CBI, you must submit a CBI version, a CBI-deleted version and a CBI justification. **We will not initiate the review of your inquiry until we have received all of the required documents.** Please consult the two links below for instructions for preparing these required documents. You will receive verification that your letter of inquiry has been received.

For detailed instructions for preparing documents containing CBI, please refer to pages 9 and 10 in the BRS User's Guide: General Document Preparation Guidelines for Submission to BRS:

[**BRS User's Guide: General Document Preparation Guidelines for Submission to BRS**](#)

[**Confidential Business Information Guidance Instructions**](#)