USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

DOCUMENT ID:
BRS-GD-2025-0002

DATE:
February 7, 2025

AM I REGULATED? (AIR) PROCESS GUIDE FOR SUBMISSION OF AIR INQUIRIES

The information contained in this document is intended solely as guidance. Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations.

Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement.

Following the guidance contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

4700 River Road
Riverdale, MD 20737

GUIDE INFORMATION

ISSUING AGENCY/OFFICE:	Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS)
TITLE OF DOCUMENT:	Am I Regulated? (AIR) Process Guide for Submission of AIR Inquiries
DOCUMENT ID:	BRS-GD-2025-0002
DATE OF ISSUANCE:	February 7, 2025
REPLACES:	October 31, 2019
SUMMARY:	This document provides instructions on how to submit an Am I Regulated request.
DISCLAIMER:	The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document isintended only to provide clarity to the public regarding existing requirements under the law or agency regulations.

TABLE OF CONTENTS

INTRODUCTION

If you are unsure whether your modified 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 modified organism from APHIS through a letter. This Guide provides instructions on how to submit an Am I Regulated request.

SUBMISSION INSTRUCTIONS

Send a signed letter containing the information described below to:

ADDRESS THE LETTER OF INQUIRY TO:

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd
Riverdale, MD 20737

EMAIL YOUR LETTER OF INQUIRY TO:

AIRinquiry@usda.gov

APHIS will provide a written response within 120 days of receiving a sufficiently detailed letter of inquiry, except in circumstances that could not reasonably have been anticipated. Upon completion, APHIS will post letters of inquiry and responses on the APHIS BRS website, typically, within 1-2 business days of providing the response to the developer, with any information claimed as Confidential Business Information (CBI) or personal identifying information redacted, as appropriate.

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 you used or intend to use to confirm 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. Any retention of plant pest sequence that was intentionally or unintentionally inserted into the product (e.g., as part of the modification process) would meet the definition of a regulated article. Provide sufficient detail to enable APHIS to assess the efficacy of the methodology used, or that you will use, to confirm the absence of plant pest sequence in the final product.

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 complete the review of your inquiry until we have received all the required documents. Please consult the link below for instructions on 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 the **Guide for Claiming Confidential Business Information**

VERSION HISTORY

Date	Version Updates
2/7/25	Update to new template, formatting, and link corrections.
10/31/19	Original version.