

Am I Regulated (AIR) Questions and Answers

Q: What is the Am I Regulated (AIR) inquiry process?

A: The AIR inquiry process allows stakeholders to ask APHIS whether an organism developed using genetic engineering meets the definition of a “regulated article,” as defined in [7 CFR § 340.1](#), and is thus subject to regulation for any importation, interstate movement, or release into the environment. For more information about the AIR process, please consult the [Am I Regulated \(AIR\) Process Guide for Submission of AIR Inquiries](#) on the APHIS website.

Q: How do I submit an Am I Regulated (AIR) inquiry for my organism developed using genetic engineering?

A: To submit an AIR inquiry to APHIS, please send a letter of inquiry to AIRinquiry@usda.gov. Your AIR inquiry must contain information about your organism, the genetic engineering methods used to develop your organism, and information demonstrating that the organism does not meet the definition of a “regulated article” as defined in [7 CFR § 340.1](#). For more details about the information required in an AIR inquiry submission, please consult the [AIR guide](#) on the APHIS website.

Q: When will APHIS respond to my Am I Regulated (AIR) inquiry?

A: Depending on the number of pending inquiries, APHIS is generally able to respond within 120 days of receiving a sufficiently detailed letter of inquiry.

Q: Does APHIS regulate non-viable organisms developed using genetic engineering?

A: No, non-viable materials such as cut flowers that are incapable of propagation, are not regulated under 7 CFR part 340 (2019).

Q: My organism developed using genetic engineering is not a plant pest and does not have any foreign DNA inserted into its genome (e.g., the modifications involve gene, base, or prime editing and are limited to deletions, non-templated insertions, replacements and/or rearrangements, or the organism has been modified by untargeted mutagenesis, or all foreign DNA has been removed through segregation or another technique). Is my organism regulated by APHIS?

A: If your organism is not a plant pest or reasonably likely to be a plant pest and has not been modified to contain foreign DNA, then it does not meet the definition of a “regulated article” as defined in [7 CFR § 340.1](#), and it is not regulated. If you are unsure whether your organism developed using genetic engineering meets the definition of a regulated article, you may send an Am I Regulated (AIR) letter of inquiry to AIRinquiry@usda.gov to seek a confirmation of its regulatory status. For more details about the information required in an AIR inquiry submission, please consult the [AIR guide](#) on the APHIS website.

Q: How do I know if an organism developed using genetic engineering, or the donor organism from which inserted DNA is obtained, is a plant pest?

A: In addition to reviewing the definition of “regulated article” in [7 CFR § 340.1](#), developers may also consult the information in [7 CFR § 340.2](#). Please note that taxonomy may have changed since the publication of the list of groups of organisms which are or contain plant pests in § 340.2, and that the list at § 340.2 represents known plant pests when APHIS promulgated the regulation in 1987. If due to a taxonomic change or new discovery, the donor or recipient organism you used to develop your organism does not belong to any of the groups of organisms identified in § 340.2, but still meets the definition of a “[plant pest](#)” in the [Plant Protection Act](#), your organism meets the definition of a regulated article and is regulated under 7 CFR part 340 (2019). If you are unsure whether your organism meets the definition of a regulated article, you may send APHIS an Am I Regulated (AIR) letter of inquiry to seek a confirmation of regulatory status. For more details about the information required in an AIR inquiry submission, please consult the [AIR guide](#) on the APHIS website.