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APHIS Resumes Receipt of Petitions for Nonregulated Status

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On March 3, 2025, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) will begin to accept petitions for nonregulated status according to APHIS biotechnology regulations at <u>7 CFR part 340 (2019)</u>.

APHIS biotechnology regulations enable developers to petition for a determination that an "article" is not regulated. The petition process applies only to plants that meet the regulatory definition of "regulated article". In general, a regulated article is an organism or product that has been altered or produced using genetic engineering (1) that has one or more of its components derived from a plant pest or an unclassified or unknown organism; or (2) that APHIS determines is a plant pest or has reason to believe is a plant pest. In contrast, a genome edited organism (e.g., plant, microbe, insect) that is not a plant pest or likely to be a plant pest is not subject to <u>7 CFR part 340 (2019)</u>, unless the organism retains DNA sourced from a plant pest. Similarly, a transgenic organism that is not a plant pest and not likely to be a plant pest and does not contain DNA sourced from a plant pest is not subject to 7 CFR part 340 (2019).

If your modified plant meets the definition of "regulated article" and you would like to petition for nonregulated status, you must provide relevant information, data, and publications that substantiate that the modified plant is unlikely to pose a greater plant pest risk than the unmodified plant from which it was derived. To view the specific requirements and learn how to apply, visit our <u>Petitions Guide</u> (194.58 KB).

We encourage developers to request a pre-submission consultation to review the information APHIS needs to evaluate a petition and reach a decision. Please email requests for a pre-submission consult to BRS.Petitions@usda.gov.

Learn more about Petitions