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APHIS Reinstates Notifications for Products of Biotechnology

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The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) will begin to accept and process notifications for the introduction of certain modified plants that meet the regulatory definition of "regulated article" under 7 CFR 340 (2019) on February 7, 2025. We are restarting the notification procedure following a December 2, 2024, ruling by the U.S. District Court for the Northern District of California vacating the May 2020 final rule (7 CFR part 340) for organisms developed using genetic engineering.

Notifications are a streamlined alternative to permits for regulated articles meeting specified eligibility criteria and pre-defined performance standards under [7 CFR § 340.3](#). Beginning February 7, 2025, you may submit notifications electronically through APHIS eFile. For information on plants that are eligible for the notification process and how to apply, please view our [Notification Guide](#). To apply for a notification, you must provide information that demonstrates your introduction meets the performance standards under [7 CFR § 340.3](#). If you are interested in seeking feedback on the procedures you will use to demonstrate compliance with the performance standards in advance of February 7, 2025, please submit them to BRSPermits@usda.gov.

Please know that if an organism does not meet the regulatory definition of "regulated article," it is not subject to APHIS' biotechnology regulations (i.e., such organisms do not require a permit or notification prior to introduction). For example,

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 [7 CFR part 340 \(2019\)](#), 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 \(2019\)](#). Developers may voluntarily seek a letter confirming that an organism is not subject to regulation by submitting an [Am I Regulated](#) inquiry.

We appreciate your patience as we adjust processes to keep American agriculture safe and at the forefront of science and innovation.

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