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APHIS Restarts Permitting and Am I Regulated Processes for Products of Biotechnology

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The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is sharing several updates resulting from the 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.

APHIS aims to provide our stakeholders with stability and is re-establishing the regulatory and non-regulatory processes under the pre-May 2020 framework, [7 CFR part 340 \(2019\)](#), including pathways for authorizing regulated activities, commercializing products, and providing compliance oversight for products of biotechnology.

In keeping with our pre-2020 approach, APHIS will restart the *Am I Regulated* process. See [7 CFR part 340 \(2019\)](#) (defining "regulated article"). If you are unsure whether your organism developed using genetic engineering meets the definition of a "regulated article," you may submit an "Am I Regulated" inquiry. Instructions for preparing "Am I Regulated" inquiries are available on our [website](#). If you require further assistance, please send your questions to AIRinquiry@usda.gov.

Additionally, in the coming days, APHIS will resume issuing permits under [7 CFR part 340 \(2019\)](#). If you have already submitted a permit application and wish to remove constructs that do not meet the definition of a “regulated article” and, thus, are not subject to regulation, we encourage you to withdraw your permit application and resubmit it. If you choose to revise your permit application, you can start this process now. The APHIS eFile system enables permit holders to easily clone an application, copy constructs, and then delete those that are not necessary. Simple, step-by step instructions can be found in the [APHIS eFile Job Aid on pages 45-46](#). We will provide additional information on resuming the notification process in the coming weeks.

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

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