

# ASTA GUIDANCE ON COMMUNICATION REGARDING PLANT VARIETY PROTECTION SEED DEPOSITS CONTAINING BIOTECHNOLOGY EVENTS

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## BACKGROUND

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When a Plant Variety Protection (PVP) application is made for a plant variety, the applicant must provide a seed deposit to the U.S. Department of Agriculture (USDA) of that variety and, for a hybrid, a deposit of each plant line necessary to produce the hybrid. These seed deposits are securely held at the National Plant Germplasm System's (NPGS) National Center for Genetic Resources Preservation in Fort Collins, Colorado.

Some of the PVP seed deposits contain Event(s)<sup>1</sup> developed using the tools of modern biotechnology. Currently, PVP applicants are not required to inform USDA whether the seed deposit associated with that PVP application contains an Event(s). There could be regulatory implications if a PVP seed deposit does contain an Event(s), particularly if that Event or material containing the Event(s) is within the scopes of USDA and Environmental Protection Agency (EPA) regulations under the Coordinated Framework. There could also be patent(s) associated with the Event. In addition, some PVP seed deposits may have additional intellectual property associated with the deposit, in particular a U.S. utility patent(s) on the variety.

## ASTA GUIDANCE FOR PVP APPLICANTS

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The goal of this guidance is to facilitate voluntary communication concerning certain existing patents and regulatory status of PVP seed deposits when a PVP certificate expires. Toward this end, ASTA provides the following guidance to its members on how to communicate information to USDA regarding existing U.S. utility patent(s) on the variety<sup>2</sup> and the regulatory status of PVP seed deposits that contain Events.

At the time of PVP application, ASTA recommends that the PVP applicant commit, in writing<sup>3</sup>, to provide to USDA the following information.

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### THE PRESENCE OF EVENT(S) IN THE PVP SEED DEPOSIT.

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At the time the PVP seed deposit is made, the applicant informs the US PVP Office and the NPGS whether or not there is an Event(s) in that PVP seed deposit<sup>4</sup>. The PVP applicant informs the PVP

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<sup>1</sup> An Event is defined as: A single insertion of a nucleic acid construct into a specific site in a plant's chromosome that is regulated under the U.S. Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework).

<sup>2</sup> NPGS requestors should take note that their order may contain accessions that are protected by intellectual property rights other than that described in this guidance.

<sup>3</sup> Standard forms for all of the written communication to USDA accompany this guidance.

<sup>4</sup> This information refers to the intentional existence of an Event in a PVP seed deposit. It does not refer to either adventitious presence or low level presence in the seed being deposited.

Office and the NPGS through the standard statement attached to the PVP seed deposit form, ST-472, *National Center For Genetic Resources Preservation Deposit Form For Plant Variety Protection Voucher Sample*.

The applicant agrees that such information can be put into the Germplasm Resources Information Network (GRIN) by USDA.

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### DECLARATIONS IN ADVANCE OF PVP CERTIFICATE EXPIRY

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The PVP certificate holder agrees to provide the following written information six months prior to the expiration of the PVP certificate. The PVP certificate holder agrees to provide this information, using the accompanied standard form.

1. The PVP certificate holder informs the US PVP Office and the NPGS that there will be/will not be an EPA registration associated with the Event at the time the PVP certificate expires;
2. The PVP certificate holder informs the US PVP Office and the NPGS that there will be/will not be a USDA deregulation decision associated with the Event at the time the PVP certificate expires;
3. The PVP certificate holder informs the US PVP Office and the NPGS of the identity of the Event(s) contained in the PVP seed deposit<sup>5</sup> ; and
4. The PVP certificate holder agrees to provide written information to the US PVP Office and the NPGS that identifies if there is a U.S. utility patent(s) on the variety in the PVP seed deposit.

The PVP certificate holder agrees that such information can be put into GRIN by USDA.

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### LINKS TO STANDARD FORMS

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1. PLANT VARIETY PROTECTION APPLICANT: COMMITMENT TO PROVIDE INFORMATION TO USDA
2. PVP SEED DEPOSIT DECLARATION: PRESENCE OF EVENT(S) IN PVP SEED DEPOSIT
3. PVP SEED DEPOSIT DECLARATION IN ADVANCE TO PVP EXPIRY

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<sup>5</sup> The identity of the Event will include the Phenotype/Event designation in the USDA table of regulatory decisions found at : [http://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml](http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml)