



BACKGROUND AND RESOURCE APPENDIX

ASTA POSITION PAPER ON ADDRESSING EDV SYSTEM ROLES, ACCOUNTABILITIES AND CONDITION

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From 1991 Act of UPOV Convention

BACKGROUND

Introduction

The International Convention for the Protection of New Varieties of Plants (UPOV) is critically important to the U.S. seed industry's ability to conduct business, protect intellectual property rights, and provide leadership in plant breeding globally. Since UPOV issued Explanatory Notes on Essentially Derived Varieties (EDV) in 2017, the seed industry has raised questions and expressed concerns about how EDV is being implemented.

At their meeting in October 2019, the UPOV Administrative and Legal Committee agreed to open those EDV Explanatory Notes for input and revision. The revised guidance will have a lasting impact on U.S. seed companies with commercial operations both in the U.S. and in UPOV member countries worldwide that have adopted the 1991 Act. ASTA is working with global and regional seed industry associations and other stakeholders to influence the revised Explanatory Notes so the principle of EDV will be appropriately and consistently applied to ensure appropriate protection for all sexually and asexually propagated plant varieties.

Essential Derivation

The principle of essentially derived varieties represented a significant addition to the UPOV Convention's revised Act of 1991 and an important improvement to plant breeders' rights (PBR) and plant variety protection (PVP) across UPOV member countries. Under the UPOV Act of 1978, breeders using a protected variety as a breeding source have sole and independent ownership rights on any progeny variety deemed distinct from the protected variety without regard to its derivation from or genetic conformity to an initial variety (IV). In particular, breeders were anticipating the deployment of transgenesis for plant improvement and were concerned biotech companies might create transgenic versions of protected varieties and then pursue freedom to operate under the breeder's exemption.

The provisions of UPOV '91 establish a balanced form of PBR/PVP so breeders who invest in the development of protected varieties may benefit from additional rights regarding EDVs derived from their protected IV. This is because the owner of the PBR/PVP for the IV determines whether an EDV of the IV may be exploited commercially.

Implementation of the EDV principle supports both the intellectual property rights (IPR) of the initial breeder and, at the discretion of the owner of the IV, the commercial interests of those who breed or discover varieties that are essentially derived from the IV. The condition of discretionary ownership to an EDV provides a balance of IPR granted to the owner of the IV and to anyone who subsequently breeds or discovers an EDV under the breeders' rights principle.

UPOV Explanatory Notes on EDV

In March 1991, the UPOV Diplomatic Conference requested the UPOV Secretary-General "to start work immediately . . . on the establishment of draft standard guidelines on essentially derived varieties". The International Association of Plant Breeders (ASSINSEL)¹ assumed responsibility to develop technical guidelines on a crop-by-crop basis. On October 22, 2009, UPOV/EXN/EDV/1, entitled "Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention" was adopted by the UPOV Council. Later, on April 6, 2017, Document UPOV/EXN/EDV/2, entitled "Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention", was issued by UPOV. The purpose of the guidance issued was "to assist members of the Union and relevant stakeholders in their considerations in matters concerning essentially derived varieties."

¹ In 2002, ASSINSEL merged with the International Seed Trade Federation (FIS) to form the International Seed Federation (ISF).

UPOV Member Countries which implemented the 1991 Act have had few practical reasons or opportunities to translate the EDV Standard and EDV Explanatory Notes into common practice. A limited number of UPOV Members have formally defined and implemented EDV oversight and processes within their regulations under a PBR/PVP Act compliant with UPOV '91.

Despite the lack of implemented EDV oversight and processes, we are aware of only a few public disputes over EDVs, which led to judicial or arbitration cases. An industry-wide¹ EDV Survey (2019) found a majority of breeders understand the EDV concept and respect the principle of EDV. Additionally, breeders reported they follow internal breeding guidelines to avoid developing EDVs. If an EDV should result, breeders responded that they usually contact the owner of the IV to seek a commercial license.

The International Seed Federation (ISF) has established Guidelines for the Arbitration of EDV Disputes and also practical EDV Methodologies and Action Thresholds. Based on industry agreement, these are defined for only 6 crops (corn/maize, cotton, lettuce, oilseed rape, potato², and perennial ryegrass). Therefore, there is currently a limited framework in place to handle EDV disputes.

Evaluating Predominant Derivation and Genetic Conformity

An essentially derived variety (EDV) is a variety predominantly derived from an initial variety (IV), or from an EDV of that IV, and clearly distinguishable from the IV. Except for genotypic and phenotypic differences that result from the act of derivation, the EDV conforms to the IV regarding its essential characteristics.

A fundamental element of proof required to establish EDV status is demonstrating the condition of predominant derivation. Comparisons of morphology or phenotypically expressed characteristics do not represent meaningful measures of predominant derivation and genetic conformity because the genetic basis of morphological expression of many, if not most, DUS characteristics is unknown.

Unlike simply-inherited traits such as pathogen resistance, comparisons of almost all other agronomically important traits are generally uninformative and possibly misleading when assessing genetic conformity given their complex multi-genic control.

DNA analysis overcomes the confounding variation in the expression of morphological characteristics caused by differences in environmental and field conditions from year to year and location to location. DNA analysis can determine if and to what extent a breeder has used another breeder's protected variety, or an EDV thereof, to derive a new variety, in itself an important consideration for determining EDV status.

Consequently, DNA-based genetic analysis is the principal means to measure genetic conformity and to provide an exacting test of pedigree.

¹ International Seed Federation (ISF), International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), Crop Life International (CLI), Euroseeds, Asia and Pacific Seed Alliance (APSA), African Seed Trade Association (AFSTA) and Seed Association of the Americas (SAA)

² developed by the European Seed Association, now Euroseeds.

KEY TERMS

1. **Essentially-Derived Variety (EDV):** EDV is a specific term introduced in Article 14 of the 1991 Act of the UPOV Convention. A new variety will be an EDV when it was 'mostly' or 'predominantly' bred, developed or derived from a PBR/PVP protected variety and the new variety is clearly distinguishable from the protected initial variety (IV). Except for differences associated with derivation, the EDV should conform to the essential characteristics of the IV. An EDV can be derived directly from an IV, indirectly from another EDV, but in any case, the IV owner has commercial rights in the EDV.
2. **Initial Variety (IV):** An IV is a plant variety protected by PBR/PVP which is not itself an EDV.
3. **Distinct, Uniform and Stable (DUS):** These are the criteria any new variety, either IV or EDV, must meet during PBR/PVP examination in order to qualify for variety protection. Even though an EDV is derived from an IV and may show genetic conformity to the IV, an EDV can qualify for PBR/PVP protection if it meets the DUS conditions. DUS can be determined via morphological, physiological or genetic traits/descriptions.
4. **Variety Breeding vs. Discovery:** EDVs can originate via multiple pathways. As a first step, a breeder selects breeding parents with the goal to retain positive features from each parent. Subsequently, there are various breeding methods, for example, marker assisted selection, producing doubled haploids, backcrossing, and induced mutagenesis, that can result in the development of an EDV from an IV. More targeted approaches, such as gene editing and traditional biotech, create genetic changes to the IV that may result in the development of an EDV such as a disease resistant variety. While rare, a spontaneous mutation can lead to a stable genetic change, such as an alteration in flower color. The discovered variety is considered an EDV of the protected IV. Both bred and discovered EDVs are considered to be derived from an IV.
5. **Ownership vs. Rights to Commercialize:** PBR/PVP rights in the IV extend to an EDV derived from the IV per UPOV '91 Article 14(5)(a)(i), enabling the IV owner to exclude the EDV owner from the commercial activities specified in UPOV '91 Article 14(1) – (4). Practically speaking, this means that the owner of an EDV may be granted PBR/PVP rights in accordance with UPOV '91 Article 14(1) – (4), but still needs authorization from the owner of the protected IV to perform commercial activities. The owner of an EDV not protected by PBR/PVP also needs authorization from the IV owner to perform commercial activities. Likewise, the PBR/PVP for the IV does not entitle the IV owner to commercialize an EDV derived from that IV regardless of whether the EDV is or is not protected by PBR/PVP.
6. **Molecular Markers:** DNA-based genetic analysis of varieties is currently accepted by UPOV under specific circumstances as an element of the PBR/PVP process to determine varietal Distinctness (as part of DUS) for eligibility to be a protected cultivar. When determination of essential derivation is required, DNA-based genetic analysis serves to measure genetic conformity and prove if a new variety is predominantly derived from a protected variety. A variety judged distinct by DUS would likely be an EDV when DNA-based genetic analysis demonstrates predominant derivation. To avoid having a new distinct variety later classified as an EDV, breeders should use molecular markers to screen and select new varieties that exhibit reduced genetic conformity to the IV.

Act of 1991 of the UPOV Convention

Article 14 - Scope of the Breeder's Right

- (1) [*Acts in respect of the propagating material*] (a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:
- (i) production or reproduction (multiplication),
 - (ii) conditioning for the purpose of propagation,
 - (iii) offering for sale,
 - (iv) selling or other marketing,
 - (v) exporting,
 - (vi) importing,
 - (vii) stocking for any of the purposes mentioned in (i) to (vi), above.
- (b) The breeder may make his authorization subject to conditions and limitations.
- (2) [*Acts in respect of the harvested material*] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.
- (3) [*Acts in respect of certain products*] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.
- (4) [*Possible additional acts*] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(a) shall also require the authorization of the breeder.
- (5) [*Essentially derived and certain other varieties*] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to
- (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,
 - (ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and
 - (iii) varieties whose production requires the repeated use of the protected variety.

- (b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety (“the initial variety”) when
- (i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
 - (ii) it is clearly distinguishable from the initial variety and
 - (iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.
- (c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

Article 17 - Restrictions on the Exercise of the Breeder’s Right

- (1) [*Public interest*] Except where expressly provided in this Convention, no Contracting Party may restrict the free exercise of a breeder’s right for reasons other than of public interest.
- (2) [*Equitable remuneration*] When any such restriction has the effect of authorizing a third party to perform any act for which the breeder’s authorization is required, the Contracting Party concerned shall take all measures necessary to ensure that the breeder receives equitable remuneration.