

## UPOV Releases Explanatory Notes Further Defining Protection for Essentially Derived Varieties

February 5, 2024

On October 27, 2023, the International Union for the Protection of New Varieties of Plants (UPOV) released its third set of explanatory notes on essentially derived variety (EDV) protection. In this alert, we provide a brief history of EDV protection and plant variety protection (PVP), and we describe how the new explanatory notes may affect the rights of US and international certificate holders.

### PVP review

PVP certificates provide patent-like protection for breeders of new, distinct, uniform, and stable plant varieties, PVPs – also known as plant breeder’s rights (PBRs) in other jurisdictions – are the most widely available legal tool for protecting plant inventions internationally – and in many geographies, they are the only form of protection available for non-genetically modified plants that are produced through traditional breeding techniques.

Registration and protection are coordinated by UPOV, which provides a framework for protecting plant inventions across its 78 member states. In the US, PVPs are administered by the US Department of Agriculture – this form of IP protection is separate from the utility and plant patent protection that is available through the US Patent and Trademark Office. (A more detailed comparison between these different rights can be found [in this 2019 article](#).)

PVP certificate holders can exclude others from selling, importing/exporting, sexually or asexually multiplying the variety, or producing hybrid crops.<sup>1</sup> Holders also can prevent the unauthorized use of marked seed for propagation or stocking of a variety, or even dispensing of a variety without notice of its protection.<sup>2</sup>

### Breeder’s exemption to PVP

PVP is, however, subject to certain important exceptions, including the “research” or “breeder’s rights” exemption, which permits the use of a PVP-protected variety for plant breeding or other research.<sup>3</sup>

The research exemption was intended to strike a balance between **breeder exclusivity** of protected varieties, and **breeder access** of protected genetics for development of future varieties. This initial attempt to simultaneously advance exclusivity and access, however, significantly limited certificate holders’ ability to enforce their rights against even minor variants of protected varieties, and it led to real and perceived commercial abuses.

### Evolution of EDV protection

In 1991, UPOV introduced structural changes to its proposed PVP framework that extended enforceability of PVP certificates

beyond the initial variety to also cover “[essentially derived varieties](#).” In the US, Congress adopted UPOV’s guidance with the passage of the [Plant Variety Protection Act Amendments of 1994](#), which defined an EDV as a variety that:

- “(i) is **predominantly** derived from another variety (referred to in this paragraph as the ‘initial variety’) or from a variety that is 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) is **clearly distinguishable** from the initial variety; and
- (iii) except for differences that result from the act of derivation, **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.”<sup>4</sup>

Since its introduction, interpretation of this language, and hence the scope of the EDV protection, has been hotly debated. Under pressure from the plant breeding community and UPOV members to provide guidance, UPOV has so far issued **three** explanatory notes on EDVs.

### First explanatory note (2009)

UPOV provided examples of how EDVs may be directly or indirectly obtained. Using a hypothetical “Variety ‘A’” as the initial variety, [the first explanatory note](#) explains how “Variety ‘B’” and “Variety ‘C’” – which were predominantly derived from “Variety ‘A’” – would be considered EDVs if they also<sup>5</sup>:

1. Retained expression of the essential characteristics of “Variety ‘A’.”
2. Were clearly distinguishable from “Variety ‘A’.”
3. Conformed to “Variety ‘A’” in essential characteristics, except for the differences from the act of derivation.

### Second explanatory note (2017)

UPOV’s [second explanatory note](#) explained that the requirement for “predominant derivation” meant that a variety only could be essentially derived from **one** initial variety, suggesting that EDVs were limited to new varieties that retained virtually the whole genotype of the initial variety. Along these lines, UPOV indicated that:

1. The differences resulting from the act of derivation should be one or very few.<sup>6</sup>
2. The differences must not be such that the variety fails to retain the expression of the essential characteristics of the initial variety (i.e., traits contributing to the principal features, performance or value of the variety).<sup>7</sup>

### Third explanatory note (2023)

The [third and most recent explanatory note](#) (EXN3), published by UPOV in October 2023, has at least two interpretive notes that notably expand or contradict prior guidance.

The first notable interpretive note relates to the requirement that an EDV be “predominantly derived” from the initial variety<sup>8</sup>:

- **Mono-parental:** In EXN3, UPOV indicated that varieties developed from a single parent (i.e., “mono-parental” varieties), such as those developed from mutations, genetic modification or genome editing, are considered per se predominantly derived from the initial variety.<sup>9</sup>

- **Multi-parental:** In contrast, EXN3 did not change UPOV's earlier proposed framework for evaluating multi-parental varieties based on predetermined<sup>10</sup> similarity thresholds between the proposed EDV and the initial variety.<sup>11</sup>

The second interpretive note in EXN3 relates to the requirement that an EDV conform to the "essential characteristics" of the initial variety<sup>12</sup>:

- **No upper limit to number of genetic differences:** In EXN3, UPOV indicated that there is no upper limit as to the number of genetic differences that an EDV may display, while still "conforming" to the essential characteristics of the initial variety.
- **Genetic differences in EDV can include essential characteristics:** EXN3 further indicated that genetic differences resulting from the derivation also may include those characteristics deemed "essential" to the initial variety.<sup>13</sup>

These interpretive notes likely will be met with mixed reactions. Clarification that mono-parental EDVs qualify as predominantly derived varieties per se may be welcome news to certificate holders of major crop varieties that undergo genetic modification prior to commercialization (e.g., the addition of popular herbicide or insect resistance traits via transformation and/or gene editing). Industry groups generally have been content with UPOV's proposed similarity threshold framework for analyzing multi-parental EDVs, but they may be disappointed that EXN3 failed to provide any additional guidance for how these should be established across multiple species and jurisdictions.

The long-term effect of UPOV's proposed interpretive changes to "essential characteristics" is uncertain. The removal of an upper limit on the number of genetic differences that can be introduced to EDVs arguably blurs the line between EDV protection and the breeder's exemption. This is particularly true for mono-parental varieties, which are considered to be per se predominantly derived from initial varieties, and therefore not subject to the natural limits that could be imposed by similarity thresholds used in evaluating multi-parent varieties.

The distinction between an EDV and a variety falling under the breeder's exemption is further complicated by UPOV's indication that an EDV's genetic differences can extend even to changes of essential characteristics – features that arguably defined the initial variety in the first place. When viewed together, the proposed interpretive changes could end up significantly limiting the scope of the PVP breeder's exemption – and thus expanding the scope of a PVP holder's EDV rights, particularly for those working primarily with mono-parental varieties modified via genetic and/or gene editing tools.

## Effect on US applicants

Changes in UPOV text do not automatically have the force of law in the United States. The US is a member of the 1961 UPOV Convention, and adheres to the 1991 text, which includes the original expansion of protection for EDVs. The UPOV convention text, however, is not self-executing, and had to be separately enacted by Congress via passage of the Plant Variety Protection Act, and its subsequent amendments.

Moreover, UPOV's explanatory notes make it clear that the only binding obligations on members of the union are those contained in the text of the UPOV Convention itself, and that the explanatory notes "must not be interpreted in a way that is inconsistent with" the relevant act, which is the 1991 Act of the UPOV Convention.<sup>14</sup> UPOV's explanatory notes therefore have no current binding legal effect on US PVP certificates – however, in PVP litigation it can be expected that litigants may point to explanatory notes in support of arguments. Enactment of UPOV recommendations into law would require either changes to the Plant Variety Protection Act and/or PVP regulations through legislation.

The US Department of Agriculture's Plant Variety Protection Office has reviewed the explanatory notes, but it has not yet advanced any rule changes to effectuate them.

Other member states similarly will have to roll out legislation and rules implementing new EDV guidance. UPOV's explanatory notes

are thus unlikely to drastically affect US PVP rights in the short term, but they may ultimately result in broader protection and more predictable outcomes for PVP certificate holders, with a breeder's exemption of reduced scope.

#### Notes

1. 7 USC § 2541(a)(1)-(10).
2. *Id.*
3. 7 USC § 2544.
4. 7 USC § 2401(a)(4)(A)(i)-(iii), emphasis added.
5. Figures 1 and 2 of Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention, published October 22, 2009.
6. Section I(c)(10) of Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention, published April 6, 2017.
7. *Id.*, Section I(c)(9).
8. International Convention for the Protection of New Varieties of Plants (1991) at Article 14(5)(b)(i); see also corresponding US statutory language at 7 USC § 2401 (a)(4)(A)(i), as reproduced supra.
9. Section I(b)(5) of Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention, published October 27, 2023.
10. The International Seed Federation in 2012 proposed [similarity tests based on genetic similarity between the EDV and the protected plant](#); see also F.A. van Eeuwijk and J.R. Law, "Statistical Aspects of Essential Derivation, with Illustrations Based on Lettuce and Barley," 137 EUPHYTICA 129 (2004).
11. Section I(b)(5) of Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention, published October 27, 2023.
12. International Convention for the Protection of New Varieties of Plants (1991) at Article 14(5)(b)(iii); see corresponding US statutory language at 7 USC § 2401(a)(4)(A)(iii), as reproduced supra.
13. Section I(b)(19) of Explanatory Notes on Essentially Derived Varieties Under the 1991 Act of the UPOV Convention, published October 27, 2023.
14. *Id.*, Preamble.

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