UPOV
International Union for the Protection of New Varieties of Plants

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A STRATEGY TO ESTABLISH GENETIC SIMILARITY (GS) THRESHOLDS TO SUPPORT ESSENTIALLY DERIVED VARIETY (EDV) EVALUATION: BREEDER PERSPECTIVES ON PROCESS

Document prepared by an expert from the International Seed Federation (ISF)

Disclaimer: this document does not represent UPOV policies or guidance

The annex to this document contains a presentation “A strategy to establish Genetic Similarity (GS) thresholds to support Essentially Derived Variety (EDV) evaluation: Breeder perspectives on process”, to be made by an expert from the International Seed Federation (ISF), at the fourth session of the TWM.

[Annex follows]

International Seed Federation
Seed is Life

A Strategy To Establish Genetic Similarity (GS) Thresholds To Support Essentially Derived Variety (EDV) Evaluation:

Breeder Perspectives on Process

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The EDV Concept

Part of the UPOV 91 Act

An EDV as described by UPOV is…

- (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.

The recent EDV EXN ensures the continued relevance of PVP systems, which play an important role in encouraging innovation in the plant breeding sectors:

- Clarifies how officials consider the relationship between initial varieties and EDVs
- Provides legal certainty for rights' holder of the initial variety
- Clarifies expectations for plant breeders when using PVP-protected material in their breeding programs

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The EDV Concept

The questions facing UPOV members and applicants are the same:

- How can we facilitate EDV assessment?
- How can we communicate best practices to clarify EDV concepts?
- How do we inform discussions on EDV:
  - Note that evaluation of morphology, alone, may not necessarily provide enough information to make an informed decision.

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Breeder Solutions

Breeders should consider EDV ***before*** breeding activity begins

The act of derivation is the primary element of an EDV, i.e., what is the breeding pedigree underlying the new variety?

- Breeding strategies are proprietary and phenotypic interactions with differences of the act of derivation are not always obvious.
- Any combination of breeding approaches may or may not result in an EDV.

DNA marker-based genetic similarity (GS) thresholds provide a tool to inform the breeding process when considering EDVs.

- Thresholds provide a 'trigger' point for next steps, i.e., how similar is a new variety to a previously protected variety?
  - Does *not* guarantee a variety above a threshold is an EDV
  - Considering pedigree is required
  - Convergent breeding may lead to independently bred varieties above threshold
- Once a threshold is triggered, **the burden of proof shifts to the second applicant**

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EDV GS Threshold Elements

Technical Elements To Consider <u>in Order of Occurrence</u>

1. Experts involved?
2. What germplasm to select?
3. What genetic marker panel?
4. What threshold model?
5. What similarity/distance algorithm?
6. Threshold Agreement
7. Implementation

Policy Elements To Consider

- Input / representation from public/private experts from regions important for the species
- Openness and transparency of the process from start to finish at each step
- Legal compliance (IP, Antitrust)
- The implementation is accessible and operational for all breeders; larger/small, public/private

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EDV GS Threshold Elements

Technical Elements To Consider

1. **<u>Experts involved?</u>**
   - <u>Global representation</u> from key countries where the species is important
     - Public and private breeders/experts
     - Seed associations

Policy Elements To Consider

- Broad representation supports all views being heard and considered
- Supports consensus building and alignment

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EDV GS Threshold Elements

Technical Elements To Consider	Policy Elements To Consider

2. **What germplasm to assess?**
• Representative genetics from key countries
  • Represent the relevant genetic backgrounds globally
• It's not necessary to require all known varieties
	• Respect IP protections
	• May require legal agreements
	  • May need to focus on varieties in the public domain

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EDV GS Threshold Elements

Technical Considerations	Policy Considerations

3. **Genetic Marker Panel**
• Do markers exist for the species!
• Markers selected for assay performance, informativeness, & genome coverage
• Describe the relationships of varieties with known pedigrees
• How many markers?
	• Markers need to be public and accessible
	  • Not encumbered by IP (patents)
	  • Public marker panels already exist for many species
	• Harmonize the public marker set globally by species.

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EDV GS Threshold Elements

Technical Considerations	Policy Considerations

4. **What threshold model?**
• Derivation process impacts likelihood of EDV
  • **Mono-parental** derived varieties (*per se* predominantly derived from their IV) resulting from e.g.,:
  • Mutations (induced or spontaneous)
  • Genetic modification induced via breeding approaches and technologies (old and new)
  • **Multi-parental** derived varieties (e.g., repeated back-crossing)
• Be data driven
	• Manage subjectivity where possible
	• Defend the model chosen

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EDV GS Threshold Elements

Technical Considerations	Policy Considerations
5. **What similarity/distance algorithm** • Similarity/Distance? • Allelic, frequency, or haplotype?	• Does not need to be overly sophisticated • A simple algorithm enables all breeder skill levels to run analysis

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EDV GS Threshold Elements

Technical Considerations	Policy Considerations
6. **Threshold Agreement** • Validate in their own breeding programs before agreement • Communicate and test threshold outside of the project team	• Validating externally and communicating the process openly helps build acceptance

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EDV GS Threshold Elements

Technical Considerations	Policy Considerations

7. **Implementation**
• Agreement and adoption by regional, then global seed associations
• Consider publication
	• Once the threshold is set, **all** breeders need to be enabled
	  • Marker panel access
	  • QC guidelines
	  • Control varieties
	  • Genetic similarity calculation method

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Closing Thoughts

- The act of derivation should remain the primary element of EDV evaluations
- Breeders should consider EDV ***before*** beginning breeding activities
- Genetic similarity (GS) thresholds are an actionable tool to evaluate potential EDV, *but not the definitive determinant*.
- An open, transparent, collaborative approach to establishing GS thresholds for EDV creates a path to global threshold acceptance success
- GS thresholds give breeders clarity on EDV for their breeding programs.
  - Soy (2025): https://www.upov.int/edocs/mdocs/upov/en/twm_3/twm_3_9.pdf
  - Wheat (2025): https://www.upov.int/edocs/mdocs/upov/en/twm_3/twm_3_11.pdf
  - Mushroom (2017): https://worldseed.org/wp-content/uploads/2018/04/05042018-ISF-Good-Practices-edv-mushroom-1.pdf
  - Corn (2014): https://worldseed.org/wp-content/uploads/2015/10/ISF_Guidelines_Disputes_EDV_Maize_2014.pdf
  - Corn (2014): https://www.upov.int/edocs/mdocs/upov/en/bmt_14/bmt_14_7_rev.pdf
  - Ryegrass (2009): https://worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Ryegrass_Nov_2009.pdf
  - Cotton (2007): https://worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Cotton_2007.pdf
  - Oilseed Rape (2007): https://worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Oilseed_Rape_2007.pdf
  - Lettuce (2004): https://worldseed.org/wp-content/uploads/2015/10/Guidelines_EDV_Lettuce_2004.pdf
  - Ryegrass (2000): https://link.springer.com/article/10.1023/A:1011361731545

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Thank you!!

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