



Mr. Peter Button  
UPOV  
34 chemin des Colombettes  
CH-1211 Geneva 20

30 September 2021

## Contribution in response to UPOV Circular E-21/132

Dear Mr. Button,

The International Seed Federation, CIOPORA, Crop Life International, Euroseeds, APSA (Asia and Pacific Seed Alliance), AFSTA (African Seed Trade Association), SAA (Seed Association of the Americas) represent the interests of thousands of companies active in research, breeding, production and marketing of agricultural, horticultural, ornamental and fruit plant varieties.

Following your request expressed in Circular E-21/132, we would like to provide you with our comments on document UPOV/EXN/EDV/3 Draft 2.

### General Comments

Given the nature of some comments submitted, we think it is appropriate and critical at this moment to recall the fundamental reasons and conditions that led UPOV to undertake the revision of the Explanatory Notes on EDV.

UPOV has sought to encourage the development of standard guidelines on EDVs and to promote a common understanding and deployment of EDV-related provisions among UPOV Members by issuing Explanatory Notes on EDV in October 2009 and April 2017 and by holding EDV seminars in October 2013 and October 2019.

Our industry alliance requested that UPOV open the April 2017 Explanatory Notes for revision to affirm the following guiding principles:

- predominant derivation from an initial variety, as confirmed by a high genotypic conformity, is the key requirement for a variety to be considered an EDV;
- important modifications in the characteristics of an initial variety do not automatically lead to the new variety escaping from being qualified as EDV.

After serious deliberation, the CAJ decided to open the Explanatory Notes for revision.

UPOV Circular E-20/093 (July 9, 2020) clearly specified the terms of reference for the WG-EDV and provided excellent direction regarding the expected scope of the undertaking to revise the EDV Explanatory Notes. Overall direction is provided by the following section (a) of the Modus Operandi:

- (a) “in drafting the revision of document UPOV/EXN/EDV/2, the WG-EDV to consider:
  - (i) the outcome of the 2019 Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy *[see #11 in the CAJ Session Report (CAJ /76/9) from October 30, 2019]*:
    - “Evidence that the current UPOV guidance does not reflect the practice amongst breeders in the understanding of essentially derived varieties;
    - Evolution of breeding technologies has created new opportunities/incentives for predominantly deriving varieties from initial varieties, more rapidly and at a lower cost;
    - Clear indication from presentations and discussions that the understanding and implementation of the EDV concept influences breeding strategy – therefore, it is important that UPOV guidance is tuned to maximize benefits to society in terms of maximizing progress in breeding”; and
  - (ii) the policy issues in conjunction with the breeders’ customs and practices, as set out in Annex III of this Circular;

Appendix I of Annex III, “Preliminary Analysis of EDV Issues and Practices”, of UPOV Circular E-20/093 provides detailed guidance regarding the issues and practices to be addressed by revision of the EDV Explanatory Notes. Section (b) specifies the following:

- (b) To ensure that the EDV guidance plays a clarifying role, prevents disputes and facilitates the breeder of the protected initial variety receiving equitable remuneration or negotiating suitable arrangements with the breeder of an EDV (e.g., cross-licenses) (see issues 6, 7, 8, 10, 20, 21, 52, practice 21) and, in particular:
  - (i) how a clear and user-friendly guidance could assist in court, arbitration or mediation cases (issues 8, 50, 51, practices 18, 21);
  - (ii) the role of DNA analysis and molecular markers in reducing the burden on the breeder of the initial protected variety in EDV assessment (see issue 55, practice 17);
  - (iii) the role of PVP Offices or its experts in EDV assessment (practice 21); and
  - (iv) whether the application form for a breeder’s right should facilitate the disclosure of information on EDV matters (see issues 39, 40, 56, practice 21).

We believe the WG-EDV and the UPOV Secretariat have done an outstanding job to revise the Explanatory Notes and that UPOV/EXN/EDV/3 Draft 2 is fully and effectively responsive to the CAJ’s mandate and expectations as detailed in UPOV Circular E-20/093.

1) Page 3, Preamble, Paragraph 2, proposal from APBREBES

Paragraph 2 of the Preamble should be retained as shown in the current draft because the revised Explanatory Notes on EDV are intended to provide guidance to the UPOV members **and** to a broader set of relevant stakeholders, especially breeders. This was a clearly stated expectation in Section (b) of Appendix I of Annex III (see above). We see no need for Paragraph 2 of the Preamble in this revision “to establish coherence” with the EXN/EDV/2.

2) Page 6, Section I, Paragraph 7, proposal from Mexico

We would recommend keeping the words “or other heritable determinants” because molecular biology research has shown that a plant phenotype may result from more than genes per se. When “or other heritable determinants” is removed, the paragraph no longer covers other types of heritable genomic changes that may occur during plant recombination or might be achieved using new breeding technologies.

3) Page 7, Section I, Paragraph 8, proposal from Mexico

We can agree with the proposal from Mexico to change the word “essential” for “fundamental”. This can bring more clarity to the proposed definition of “essential characteristic”.

4) Page 7, Section I, Paragraph 11, proposal from Mexico

We can agree to change the opening from “A predominantly” to “An essentially” to better describe the derived variety. However, the example proposed does not seem sufficiently clear and may lead to more questions, for example, whether the colour of the corn is an essential characteristic or not. We appreciate the effort to provide examples to the reader of the Explanatory Notes, but if an example will be included, we recommend that a different and less ambiguous example be developed.

5) Comments from Spain: Page 7, Section I, Paragraph 7, and Page 7, Section I, Paragraph 13 and Page 8, Section I, Paragraph 14 and Page 8, Section I, Paragraph 15 and Page 8, Section I, Paragraph 17 and Page 9, Section I, Paragraph 20

In general, we don't agree with the comments from Spain. We believe that the proposed revision of the current Explanatory Notes on EDV is critical to provide greater fairness and legal certainty for breeders, PBR owners, and developers of essentially derived varieties, such as gene-edited varieties, and to restore the balance between the owners of PBR and the owners of Patents, which are commonly used to protect gene-editing technologies and traits.

Arguments are being made that the EDV Principle, which served to restore the scope and strength of a balanced PBR system, must now be ignored or weakened following the pressure of new technologies, such as gene editing. As a matter of fact, it would be totally in contradiction with the spirit that led to the introduction of the EDV concept in the UPOV Convention in 1991 to weaken the system of intellectual property rights granted to the breeder's community simply to serve the particular interests of those who have access to a new technology by permitting them to use predominantly the most elite varieties developed by others and commercialize the resulting varieties freely.

The UPOV 1991 Act is an international Treaty, and as such, allows for some flexibility for each member to enact their national PBR laws and systems. Having said that, it is our view that the Preliminary Draft EXN-EDV is fully in line with the 1991 Act. One of the main reasons for introducing the EDV concept in 1991 were mutations and the imminent launch of transgenic varieties. Such varieties typically differ from their IV in one or more essential characteristics, such as a disease resistance, herbicide tolerance, or flower colour. It takes considerable resources to develop, deregulate and commercialize such GM traits. No breeder would go through the trouble of creating a GMO variety that differs in just a small cosmetic characteristic.

And as such, the approach to classify varieties that differ in one or more essential characteristics from their IV as no longer eligible EDV's is inherently wrong.

Certain text in the current UPOV EXN-EDV was inconsistent with the 1991 Act and soon after its adoption led to great confusion among the global breeding community. It was felt the inconsistency and resulting legal uncertainty had to be addressed by a revised EXN-EDV better aligned with the 1991 Act. To all associations co-signing this letter, it is clear that the new Preliminary Draft represents greater consistency and more fairness and legal certainty compared to the current EXN-EDV.

Dismissing the value and a need for enforcement of the EDV Principle would disincentivize the continuing and considerable investment in global breeding efforts. Adequately resourcing this fundamental breeding (e.g., crossing and selection) remains critical to ensure sustained varietal improvements for agriculture and horticulture and to secure global food security and stable income for countless people in the food, feed, fiber, and floral sectors worldwide.

6) Page 17, Section II, proposal by APBREBES

For the reasons already mentioned under our "General Comments", we do not support the proposal to retain the version of Section II adopted by the Council on April 6, 2017. The new provisions in Section II provide exactly the kind of clear guidance needed to achieve a common understanding and approach relating to EDV among UPOV members and breeders.

That is why the current draft of revised Explanatory Notes on EDV is so important. The mandate and terms of reference for the WG-EDV from the CAJ were very clear on the need to address a number of policy issues and issues relating to breeders' practices through the revision of the Explanatory Notes on EDV. Section II as now revised does that.

7) Page 17, Section III, proposal by APBREBES

For the reasons already mentioned under our "General Comments", we do not support the deletion of Section III as proposed. The new provisions in Section III provide exactly the kind of clear guidance needed to achieve a common understanding and approach relating to EDV among UPOV members and breeders.

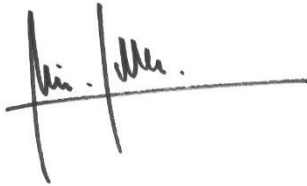
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Closing Remarks

In closing, we hope the WG-EDV will be able to proceed with the current draft 2 of UPOV/EXN/EDV/3 so there is imminent success to achieve the intended purpose by opening the EDV Explanatory Notes for revision and by incorporating essential revisions and crucial new provisions for all stakeholders involved in EDV-related matters.

We are staying at your disposal may you have further questions,

Sincerely Yours,



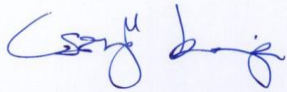
Michael Keller  
ISF Secretary General



Dr. Edgar Krieger  
CIOPORA Secretary General



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