

**Working Group on Essentially Derived Varieties (WG-EDV)**
**UPOV/WG-EDV/2/2**
**Second Meeting  
Geneva, February 4, 2021**
**Original:** English  
**Date:** January 26, 2021

**JOINT PRESENTATION BY BREEDERS' ORGANIZATIONS AND DISCUSSION IN RELATION TO ISSUES FOR CONSIDERATION**
*prepared by the Office of the Union*
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1. The Working Group on Essentially Derived Varieties (WG-EDV), at its first meeting via electronic means, held on December 8, 2020, considered document UPOV/WG-EDV/1/2 "Work Plan".<sup>1</sup>
2. The WG-EDV agreed, as a first step in informing its work, to invite the breeders' organizations to present an overview of the aspects of document UPOV/EXN/EDV/2 that they would wish to be reviewed to reflect the practice and understanding of breeders on essentially derived varieties and to present proposals on those aspects.
3. The WG-EDV agreed that the joint presentation by the international breeders' organizations that were members of the WG-EDV, be made at its second meeting, followed by discussion and consideration of the presentation by the WG-EDV in relation to the issues identified in Annex II to document UPOV/WG-EDV/1/2 (see [https://www.upov.int/meetings/en/details.jsp?meeting\\_id=60508](https://www.upov.int/meetings/en/details.jsp?meeting_id=60508)).
4. On the basis of the discussion at the second meeting of the WG-EDV, the WG-EDV agreed to request the Office of the Union to prepare a preliminary draft text for a revision of UPOV/EXN/EDV/2 for consideration by the WG-EDV at its third meeting.
5. The WG-EDV agreed the following timeline:

<u>February 4, 2021</u>	Second Meeting of the WG-EDV (by virtual means):  - Joint presentation by breeders' organizations and discussion in relation to issues for consideration. (presentation to be posted at least 1 week in advance of the second meeting)
<u>April/May 2021</u> [date to be decided]	Third Meeting of the WG-EDV (by virtual means):  - consideration by the WG-EDV of a preliminary draft text for revision of UPOV/EXN/EDV/2 (to be posted at least 4 weeks before the third meeting)
<u>June/July 2021</u> [date to be decided]	Consideration of UPOV/EXN/EDV/3/Draft 1 by correspondence (6 weeks for comments)
<u>October 2021</u> [date to be decided]	Fourth Meeting of the WG-EDV (at the fringes of the CAJ session)  - consideration of UPOV/EXN/EDV/3/Draft 2 by correspondence (to be posted 6 weeks before the fourth meeting in English)

6. The joint presentation by the international breeders' organizations is reproduced in Annex I to this document. The narrative of the presentation provided by the breeders' organizations is reproduced in Annex II of this document.

<sup>1</sup> see document UPOV/WG-EDV/1/3 "Report", paragraphs 5 to 9, available at: [https://www.upov.int/meetings/en/details.jsp?meeting\\_id=60508](https://www.upov.int/meetings/en/details.jsp?meeting_id=60508).

7. The following approach is proposed for consideration of this matter at the second meeting of the WG-EDV:

- (a) Introduction of this document;
- (b) Presentation by the international breeders' organizations (25 minutes);
- (c) Comments and questions from the WG-EDV in relation to the issues identified in Annex II to document UPOV/WG-EDV/1/2 (see [https://www.upov.int/meetings/en/details.jsp?meeting\\_id=60508](https://www.upov.int/meetings/en/details.jsp?meeting_id=60508)); and
- (d) Conclusions on a basis for drafting of a preliminary draft text, by the Office of the Union, for a revision of UPOV/EXN/EDV/2 for consideration by the WG-EDV at its third meeting.

8. In order to facilitate discussions at the WG-EDV, the members of the WG-EDV are invited to send comments or questions on the presentation and its narrative, reproduced in Annexes I and II, respectively, to this document by February 2, 2021. Comments or questions that are not received in advance may also be raised at the meeting.

*9. The WG-EDV is invited to consider the joint presentation by the international breeders' organizations, in conjunction with the issues identified in Annex II to document UPOV/WG-EDV/1/2 (see [https://www.upov.int/meetings/en/details.jsp?meeting\\_id=60508](https://www.upov.int/meetings/en/details.jsp?meeting_id=60508)), as set out in paragraphs 7 and 8, above.*

[Annexes follow]

## **Joint presentation of breeders on issues related to EDV**

- UPOV Working Group EDV -

- February 4, 2021 -



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### **Topics**

- 1. Introduction**
- 2. Highest Priority Issues**
- 3. Scenarios**
- 4. Summary Conclusions**



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## 1. Introduction



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## Introduction

- The basic purpose of incorporating the EDV principle into the UPOV 1991 Act was to provide effective protection to a breeder who developed an original genotype (= the Initial Variety) from crossing and selection.
- The EDV principle was meant to provide breeders of Initial Varieties the right over derived varieties with mutations, genetic engineering and changes developed by repeated backcrossing.
- New Breeding Technologies now enable apart from single modifications also multiple modifications of an Initial Variety in one act of derivation and thus have the potential to undermine the protection of the Initial Variety, unless a sufficiently broad interpretation of the EDV principle is agreed upon between UPOV members.

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## Introduction

- Breeders are concerned that the current text of the EXN on EDV suggests a very narrow scope of the EDV principle by indicating that one modification of an essential characteristic might lead to the new variety being out of the scope of the EDV principle.
- For breeders it is important that the revised EXN on EDV
  - Affirm predominant derivation is the key requirement for EDV.
  - Confirm the number of differences between an EDV and its Initial Variety is not necessarily limited to one or very few differences and may include differences in essential characteristics.
  - Clarify the distinct roles and accountabilities relating to EDV.
  - Provide a basis for consistent processes and standards relating to EDV across all UPOV members.

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## 2. Highest Priority Issues to be Addressed by Revising the EXN on EDV



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## **Predominant Derivation**

### **Breeders' Viewpoint:**

- Predominant derivation is the key requirement for EDV
- The primary function of the first condition (i) of art. 14 (5) (b) is to establish a requirement relating to the genetic source of the variety.
- Every variety is derived from its parents, but "predominant" derivation implies that more of the IV is retained in the derived variety (as shown by a high genetic conformity) than what would normally be retained of a parent variety by crossing and selection.
- All mono-parental varieties are predominantly derived from their IV.
- In the case of two or more genomes (multi-parental), predominant derivation may result from selectively retaining the genome of the IV.

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## **Predominant Derivation (cont.)**

### **Important changes required:**

EXN EDV should affirm that fulfilling the requirement of predominant derivation requires a genetic conformity which is higher than the genetic conformity typically obtained by crossing and selection with the IV.

### **Value to Breeders from changes:**

- For a breeder it is important to know what is needed to establish that a variety is predominantly derived from their variety. If a breeder can provide evidence of high genetic conformity in order to serve as an indication of predominant derivation, the burden of proof regarding the essential derivation of the variety should shift to the other party.
- For the vast majority of breeders who wish to stay outside of the EDV scope, it is important to know which acts would result in predominant derivation.

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## Differences and conformity of an EDV with its Initial Variety

### **Breeders' Viewpoint:**

- An EDV shall conform to the Initial Variety (IV) in the expression of essential characteristics, except for those differences resulting from act(s) of derivation.
- The essential characteristics of a variety will differ from one species to another. They may evolve over time as well. They may be of different nature, such as phenotypic, agronomic, end user focused, etc., but they must be useful for the users of the propagating material or of the harvested material and/or directly obtained products.
- Typically, the EDV will retain the expression of essential characteristics from its IV, this is the reason why the IV has been chosen in the development of this EDV.

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## Differences and conformity of an EDV with its Initial Variety (cont.)

### **Breeders' Viewpoint (cont.):**

- Act of Derivation and Impact on the Number of Differences
  - Mono-parental: All differences result necessarily from one or several acts of derivation.
    - ➔ Typically EDVs.
  - Multi-parental: Differences may result either from the random recombination of the different genotypes used, or from one or several acts of derivation only.
    - ➔ When all differences result from the act(s) of derivation only, for example recurrent backcrossing: typically EDVs.
    - ➔ When differences result from random recombination (regular crossing and selection): typically not EDVs.

For both mono-parental and multi-parental EDVs, there can be more than one or very few differences and these may also include differences in essential characteristics.

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## **Differences and conformity of an EDV with its Initial Variety (cont.)**

### **Important changes required:**

EXN on EDV should affirm that the number of differences between an EDV and its IV is not necessarily limited to one or very few differences, taking into account different breeding methods and may also include essential characteristics.

### **Value to Breeders from changes:**

- EXN confirms/validates breeders' viewpoint, that monoparental varieties are typically EDVs.
- EDV principle becomes clearer, more predictable and thus easier to enforce, also for small and medium sized breeders.
- EDV principle provides incentives to breed more diverse varieties.
- EDV principle remains up-to-date with latest technology developments, which allow multiple modifications in one act of derivation, i.e. CRISPR or marker assisted back-crossing.

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## **Clarity on EDV System Roles, Accountabilities and Conditions**

### **Breeders' Viewpoint:**

- Breeders need clarity regarding roles, accountabilities and conditions
  - To make EDV determinations
  - To assert plant variety rights against a putative EDV.
- Holders of plant breeders' rights should be accountable to monitor for EDVs and to determine EDV status among new varieties.

### **Important changes required:**

- Reintroduce content of paragraph 15 of EXN/EDV/1 with additional details.
- Fully clarify roles and accountabilities of different EDV stakeholders.
- Define processes for managing EDV cases, including assessing EDV, relevant guidelines and options for dispute resolution.

### **Value to Breeders from proposed changes:**

Breeders will know who determines EDV and how to assert their rights relating to EDV under the 1991 Act.

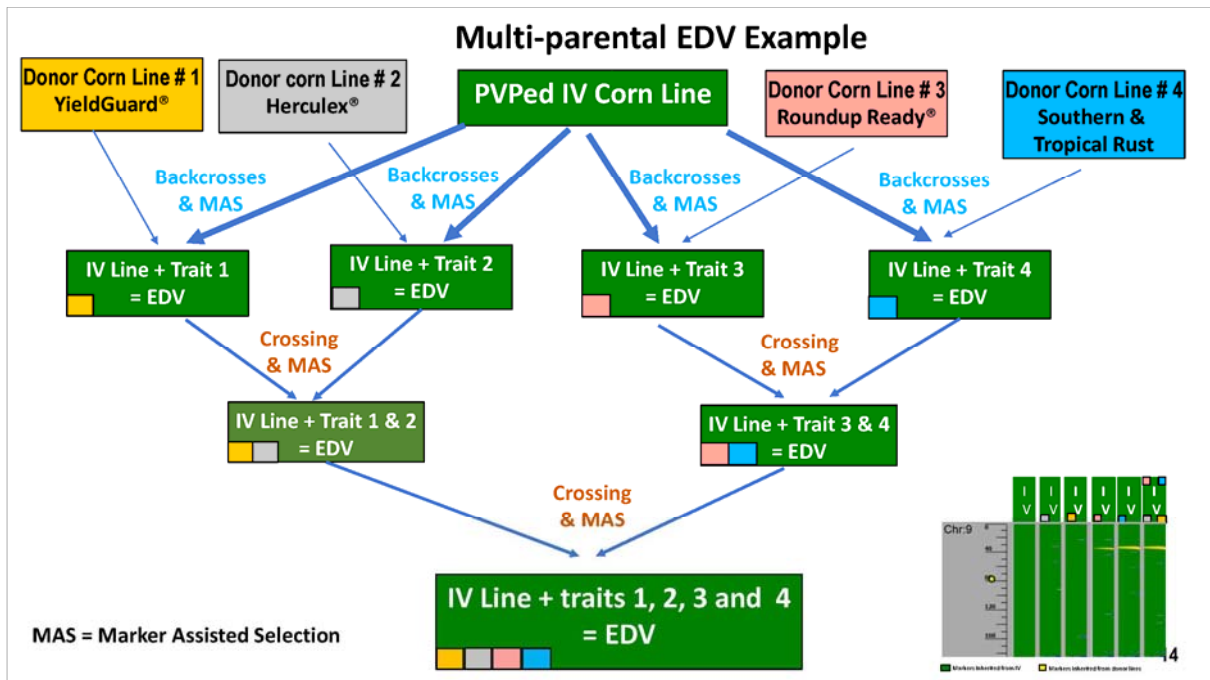
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### 3. Scenarios

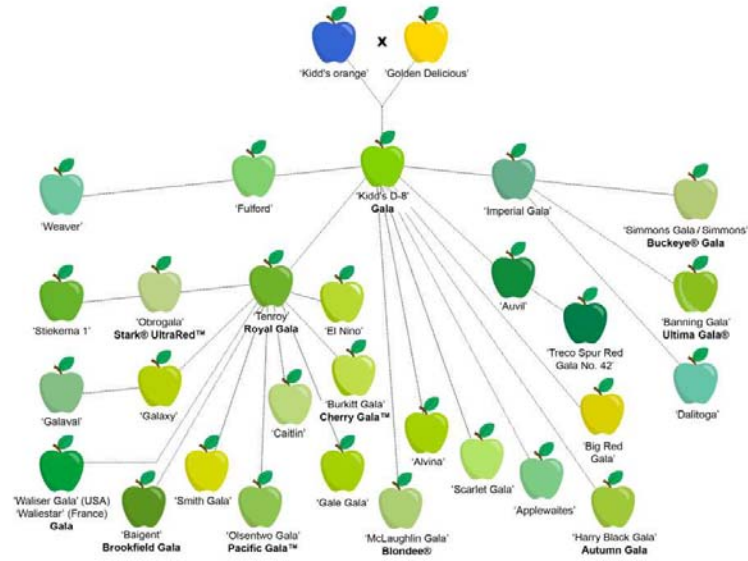


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## Mono-parental EDV example in Apple

A subset of naturally-occurring mutations of 'Kidd's D-8 apple (marketed as 'Gala')



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## 4. Summary Conclusions



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### **Summary Conclusions**

- Breeders gratefully thank UPOV and WG-EDV for the opportunity to share our viewpoints regarding the EDV principle and to identify critical needs when the EXN on EDV is revised.
- The EXN EDV should affirm that predominant derivation is the key requirement and requires a genetic conformity which is higher than the genetic conformity typically obtained by crossing and selection with the IV.
- Breeders need greater clarity and legal certainty upfront regarding the EDV status of new varieties bred by mono-parental derivation or by combining two or more varieties with repeated backcrossing.
- The revised EXN should confirm that the number of differences between an EDV and its IV is not necessarily limited to one or very few, while taking into account different breeding methods and may also include differences in essential characteristics.

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### **Summary Conclusions**

- Therefore, when a new distinct variety exhibits a high degree of genetic conformity to a protected Initial Variety, there is significant reason to consider it essentially derived.
- It is crucial the revised EXN on EDV affirms EDV-related roles and accountabilities in the PBR system and defines processes for managing EDV cases, including assessing EDV, relevant guidelines and options for dispute resolution.
- Guidance in the revised EXN on EDV must clarify how a breeder of a protected Initial Variety can assert his right whether an EDV can be sold or exploited commercially, such as the conditions for shifting the burden of proof to the EDV owner.
- It is vital that consistent processes and standards relating to EDV are implemented and executed across all UPOV members.

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**Thank you for your attention!**



[Annex II follows]

ANNEX II

NARRATIVE OF THE PRESENTATION



**Joint Presentation of breeders on issues related to EDV**

- To the UPOV Working Group EDV -

- February 4, 2021 -

Dear Mr. Chair, dear members of the WG on EDV, I would like to thank you on behalf of the breeding sector for having invited us to give a joint presentation on the EDV principle.

This presentation has been developed through the close cooperation of the International Seed Federation, CIOPORA, Crop Life International, Euroseeds, APSA (Asia and Pacific Seed Alliance), AFSTA (African Seed Trade Association) and SAA (Seed Association of the Americas). We represent the interests of thousands of companies, research institutes and universities active in research, breeding, production and marketing of agricultural, horticultural, ornamental and fruit plant varieties. The presentation is also fully supported by the International Association of Horticultural Producers, AIPH.

We are here today to speak with you with one single voice.

We breeders very much appreciate the opportunity to share with the members of WG-EDV our viewpoints on the EDV principle and our expectations for the

next Explanatory Notes on EDV, which should take into consideration both the original purpose of the EDV principle and the new developments in breeding.

This presentation has 4 chapters, namely a short introduction, then as the main part the list of our highest priorities, followed by two scenarios, that will show why a sufficiently broad EDV principle is important for breeders, and finally a summary and conclusions.

The basic purpose of incorporating the EDV principle into the UPOV 1991 Act was to provide effective protection to a breeder who developed an original genotype - that is an Initial Variety - from crossing and selection.

At the time of the adoption of the UPOV 1991 Act the EDV principle was meant to affirm the scope of protection for breeders of protected Initial Varieties to include certain types of derived varieties with mutations, genetic engineering and changes developed by recurrent backcrossing.

New Breeding Technologies, such as Oligonucleotide Directed Mutagenesis (ODM) or Site-directed nucleases (SDN) such as CRISPR now enable both single and multiple modifications of an Initial Variety in one act of derivation, in a short period of time, and thus have the potential to undermine the protection of the Initial Variety, unless a sufficiently broad interpretation of the EDV principle is agreed upon between UPOV members.

We are concerned that the current text of the Explanatory Notes on EDV suggests a very narrow scope of the EDV principle by indicating that one modification of an essential characteristic might lead to the new variety being

out of the scope of the EDV principle. This was not intended by the drafters of the EDV principle in 1991.

For breeders it is important that the revised Explanatory Notes

- Affirm that predominant derivation is the key requirement for EDV.
- Confirm the number of differences between an EDV and its Initial Variety is not necessarily limited to one or very few differences and may include differences also in essential characteristics.
- Clarify the distinct roles and accountabilities relating to EDV.
- Provide a basis for consistent processes and standards relating to EDV across all UPOV members.

Based on this I'd like now to introduce our highest priorities to be addressed by revising the Explanatory Notes.

The first priority is the clarification of **PREDOMINANT DERIVATION**

It is our viewpoint that

- Predominant derivation is the key requirement for the establishment of an EDV.
- The primary function of the first indent of Article 14 (5) (b) is to establish a requirement relating to the genetic source of the variety.
- Every variety is derived from its parents, but "predominant" derivation implies that a genetic conformity between the new variety and the Initial Variety is given which is higher than the genetic conformity typically obtained by crossing and selection with the Initial Variety.

- It is a matter of fact that all monoparental varieties are predominantly derived from their Initial Varieties.
- In the case of two or more genomes (multi-parental), predominant derivation may result from selectively retaining the genome of the Initial Variety. In this case crop-specific genetic conformity thresholds might be defined in order to establish predominant derivation.

So, the first important change we ask for is that the Explanatory Notes should clarify what is needed to fulfill the requirement of predominant derivation, in the light of the considerations we just presented. This means the Explanatory Notes should affirm that fulfilling the requirement of predominant derivation requires a genetic conformity which is higher than the genetic conformity typically obtained by crossing and selection with the Initial Variety.

We ask for this change because:

- For a breeder it is important to know what is needed to establish that a variety is predominantly derived from their variety. If a breeder can provide evidence of high genetic conformity in order to serve as an indication of predominant derivation, the burden of proof regarding the essential derivation should shift to the other party.
- For the vast majority of breeders who wish to stay outside of the EDV scope, it is important to know which acts would typically result in predominant derivation.
- Before starting a breeding program, using certain techniques, breeders need to have clarity and legal certainty upfront to know if they might be creating an EDV or not. Therefore, it is important that the revised Explanatory Notes is as clear as possible on this.



Now I come to the second priority: This is the clarification of the Differences and Conformity of an EDV with its Initial Variety.

On this point, breeders have the following view:

- An EDV shall conform to the Initial Variety in the expression of essential characteristics, except for those differences resulting from act(s) of derivation. Such differences, which result from the act or acts of derivation, shall not be taken into account when assessing whether the predominantly derived variety is an EDV.
- The essential characteristics of a variety will differ from one species to another. They may evolve over time as well. They may be of different nature, such as phenotypic, agronomic, end user focused, etc., but they must be useful for the users of the propagating material or of the harvested material and/or directly obtained products. Purely cosmetic characteristics shall not be considered essential.
- Finally, typically, an EDV will retain the expression of essential characteristics from its Initial Variety, because those characteristics are the reason why the Initial Variety was chosen as the source to develop this EDV.

We breeders also believe that the number of phenotypic differences between an EDV and its Initial Variety also depends on the act of derivation.

- In Mono-parental varieties, as a matter of fact, all differences result necessarily from one or several acts of derivation. As a consequence, such mono-parental varieties are typically EDVs, even if there are more than one or very few differences, and even if the differences relate to essential characteristics.

- In Multi-parental varieties the differences may result from either the random recombination of the different genotypes used or from one or several acts of derivation only. When all differences result from act(s) of derivation only, e.g., recurrent backcrossing, this will typically result in EDVs. When differences result from random recombination produced by regular crossing and selection, this will typically not result in EDVs.
- In any case, for both mono-parental and multi-parental EDVs there can be more than one or very few differences and they may even include differences in essential characteristics.

So, the second important change we ask for is that the revised Explanatory Notes should clarify that the number of differences between an EDV and its Initial Variety is not necessarily limited to one or very few differences, and may also include differences in essential characteristics, taking into account different breeding methods.

In order to highlight the importance of this interpretation of the EDV principle, I would like to refer to the survey which the breeders' associations made for the preparation of these discussions on EDV.

When asked about the impact on their company if varieties developed with the latest breeding methods (such as CRISPR-Cas 9) and differing in one characteristic from their protected initial variety were NOT considered as EDVs, 91 % of the breeders answered that the impact would be negative or very negative for them.

From this it is clear that the clarification we ask for is important to breeders. If the required clarification has been made,

- The revised Explanatory Notes confirms and validates the breeders' viewpoint, that monoparental varieties are typically EDVs,
- the EDV principle becomes clearer, more predictable and thus easier to enforce, also for small and medium sized breeders,
- the EDV principle provides incentives to breed more diverse varieties, and
- the EDV principle remains up-to-date with latest technology developments, which allow multiple modifications of an Initial Variety in one act of derivation, i.e., CRISPR or marker-assisted back-crossing.

Finally, I would like to remind you of the examples given in the UPOV 1991 Act on what may be an EDV: *“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.”*

- We breeders think that there is a strong indication that use of the methods listed in Article 14(5)(c) will result in an EDV. But the list is not exhaustive, so that an EDV can also be obtained in other ways, such as by New Breeding Technologies.

The third and last priority relates to the clarification of the Roles, Accountabilities and Conditions of the EDV system.

Systems and processes work effectively when roles, accountabilities and conditions are specified.

It is essential for breeders to understand the roles, accountabilities and conditions relating to EDV, in order to make EDV determinations and to assert their rights against a putative EDV.

It is our viewpoint that the holders of plant breeders' rights should be accountable to monitor for EDVs and to determine EDV status among new varieties.

Paragraph 15 in the 1st EDV Explanatory Notes of 2009 was significant by clarifying the roles and accountabilities for establishing whether a variety might be an EDV. Paragraph 15 documented "a common view expressed by UPOV members". The view was "that the existence of a relationship of essential derivation between protected varieties is a matter for the holders of plant breeders' rights in the varieties concerned."

The 2nd EDV Explanatory Notes of 2017 failed to elaborate on or even include Paragraph 15. This omission left breeders and other PBR stakeholders with insufficient clarity regarding several key aspects of the EDV system.

We breeders are of the opinion that it is crucial that the new Explanatory Notes provide breeders with guidance regarding the roles, accountabilities and conditions that determine operational effectiveness and consistent application of EDV globally. The revised Explanatory Notes should define processes for managing EDV cases, including assessing EDV, relevant guidelines and options for dispute resolution.

In this case breeders will know who determines EDV and how to assert their rights relating to EDV.

Now I would like to share two scenarios with you which show the importance of a sufficiently broad interpretation of the EDV principle:

The first scenario refers to recurrent backcrossing and so-called stacking that involves combining two or more traits of interest into a single plant.

In order to respond to the needs of farmers, a corn breeder wants to add 4 essential characteristics to one of its competitor's elite parental inbred line, which I refer to as the Initial Variety.

The desired traits are two insect tolerance genes, one herbicide tolerance gene and one disease tolerance gene.

Each trait is present in a different donor line.

The breeder starts to incorporate each desired trait by backcrossing each donor line with the Initial Variety using the Initial Variety as the recurrent parent.

After 4 or 5 backcrosses, using a set of several thousand of markers, the breeder is able to select the progenies exhibiting the highest genetic similarity with the Initial Variety (95% or more) yet ensuring that each of the 4 resulting EDV inbred lines contain one of the desired genes.

The first round of stacking consists in crossing two-by-two these first generation EDVs and using the same set of markers to assist the selection process, the breeder is able to select the double stack inbred lines which are genetically the closest to the Initial Variety.

The second round of stacking consists in crossing the two double stack EDVs and using again the same set of markers the breeder will select the quadruple stack inbred lines that are genetically the closest to the Initial Variety as shown in the image representing the marker results from Chromosome 9 in the lower right corner.

If carried out efficiently, using glasshouses and trade secret techniques, the final quadruple stacked lines may be obtained in as little as 3 to 4 years.

This operation can be repeated, using different Initial Varietys to start from and with a guaranteed chance of success if the breeder has the necessary skills and equipment.

If, as requested by the breeder's associations, all the traits that have been obtained through one or several acts of derivation are ignored and no other difference in essential characteristics can be found then, all first, second and third generations of derived inbred lines should be considered as EDVs.

And this is the result the 1991 UPOV Convention intended to reach.

The second scenario is about apple breeding and mutations:

The breeding of a new apple variety in a conventional breeding programme by crossing and selection takes usually more than 20 years and a high financial and labour investment. This can to some extent be fast tracked with marker assisted selection and whole genome selection but is balanced again with increasingly complex parental development and pre-breeding steps. A recent example of the development of a new apple variety is Cosmic Crisp, variety denomination WA 38. The breeding at the Washington State University started in 1997 and the first trees were planted for commercial use in 2017, so 20 years.

Apples are inclined to spontaneous mutations, colloquially known as "sports". The picture here shows a number of highly commercially successful sports from the initial variety 'Kidd's D-8', well known as Gala, including the mutant 'Tenroy', which is marketed as Royal Gala.

As a naturally occurring mutation, apple sports can vary widely in their mutations, and express different essential characteristics for apples, such as high fruit colour (increased over colour, darker reds in low light conditions), or seasonal variations (early or later ripening) but can be as extreme as 'McLaughlin

Gala', a yellow colour mutant of 'Kidd's D-8'. All of these mutations compete on the market with their Initial Variety and take away market share and thus decrease return on investment to the original breeder, who spent 20 years to develop the Initial Variety.

Under the narrow interpretation of the current Explanatory Notes, most mutations would not be considered EDV, because a change in an essential feature – e.g., fruit colour is naturally considered important to breeders and as a commercial trait - would put the variety out of the EDV scope. This would harm the original breeder and would discourage true innovation by conventional breeding, which is not the purpose of the EDV principle. Therefore, breeders are of the opinion that mutations are typical examples of EDVs and that this should be clarified in the revised Explanatory Notes.

Now I come to the end and would like to summarize and conclude the presentation.

First of all, on behalf of the breeders I would like to thank UPOV and the members of the WG-EDV for the opportunity to share our viewpoints regarding the EDV principle and to identify critical needs when the Explanatory Notes on EDV is revised.

Our primary requests are:

- The revised Explanatory Notes should affirm that predominant derivation is the key requirement for EDV and requires a genetic conformity which is higher than the genetic conformity typically obtained by crossing and selection with the Initial Variety.

- Breeders need greater clarity and legal certainty upfront regarding the EDV status of new varieties bred by mono-parental derivation or by combining two or more varieties with recurrent backcrossing.
- The revised Explanatory Notes should confirm that the number of differences between an EDV and its Initial Variety is not necessarily limited to one or very few differences and may also include differences in essential characteristics, while taking into account different breeding methods.
- When a new distinct variety exhibits a high degree of genetic conformity to an Initial Variety, there is significant reason to consider it may be essentially derived.
- It is crucial the revised Explanatory Notes affirms EDV-related roles and accountabilities in the PBR system and defines processes for managing EDV cases, including assessing EDV, relevant guidelines and options for dispute resolution.
- Guidance in the revised Explanatory Notes must clarify how a breeder of a protected Initial Variety can assert his right whether an EDV can be sold or exploited commercially, such as the conditions for shifting the burden of proof to the EDV owner.
- It is vital that consistent processes and standards relating to EDV are implemented and executed across all UPOV members.

Thank you very much for your attention!

[End of Annex II and of document]