

Administrative and Legal Committee

CAJ/77/4

**Seventy-Seventh Session
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to be considered by correspondence

ESSENTIALLY DERIVED VARIETIES

Document prepared by the Office of the Union

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EXECUTIVE SUMMARY

1. The purpose of this document is to present proposals for consideration by the Administrative and Legal Committee (CAJ) according to the replies to UPOV Circular E-20/093 of July 9, 2020, and to invite the CAJ to establish the working group on essentially derived varieties (WG-EDV), to approve the terms of reference and the composition of the WG-EDV and to consider a date for the first meeting of the WG-EDV.

2. The CAJ is invited to:

(a) establish the WG-EDV and approve the terms of reference for the WG-EDV, as set out in Annex II to this document, in conjunction with the modified “Policy issues in conjunction with the breeders’ customs and practices” in Annex I of this document;

(b) approve the composition of the WG-EDV, as set out in paragraph 15;

(c) approve the tentative date for the first meeting of the WG-EDV, as set out in paragraph 16; and

(d) request the WG-EDV to propose a timeline for its work at its first meeting, for consideration by the CAJ at its session in 2021.

3. The structure of this document is as follows:

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BACKGROUND

4. The Administrative and Legal Committee (CAJ), at its seventy-sixth session, held in Geneva on October 30, 2019, agreed the matters in the following paragraphs (see below extracts from document CAJ/76/9 "Report", paragraphs 9 to 14).

"Essentially Derived Varieties"

"9. The CAJ considered document CAJ/76/3.

"10. The CAJ noted the background information and developments concerning EDVs, including relevant matters on the 'Seminar on the impact of policy on essentially derived varieties (EDVs) on breeding strategy', as set out in paragraphs 4 to 15 of document CAJ/76/3.

"11. The CAJ noted the information on the presentations and noted the following oral summary by the Chair of the CAJ concerning the outcome of the 'Seminar on the impact of policy on essentially derived varieties (EDVs) on breeding strategy', held on the morning of 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.'

"12. On the basis of the outcome of the EDV Seminar, the CAJ agreed to open up the 'Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention' (document UPOV/EXN/EDV/2) for revision. As a first step, the Office of the Union would:

- “(a) invite members and observers to make contributions by correspondence on policy issues;
- “(b) invite breeders to provide information on customs and practices on EDV; and
- “(c) based on the replies to (a) and (b), prepare a preliminary analysis on the EDVs issues and practices and draft terms of references for a working group on EDV, for comments by the CAJ by correspondence.

"13. On the basis above, the Office of the Union would prepare a document for the consideration at the seventy-seventh session of the CAJ, to be held on October 28, 2020.

"14. The CAJ noted that there had been no developments concerning a possible meeting of the Office of the Union with the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties (CIOPORA), the International Seed Federation (ISF) and the World Intellectual Property Organization (WIPO) in order to explore the possible role of UPOV in alternative dispute settlement mechanisms for matters concerning EDVs, including the provision of experts on EDV matters, and noted that the Office of the Union would not pursue this matter further unless there is a change of circumstances."

PROCEDURE FOR THE REVISION OF THE GUIDANCE ON ESSENTIALLY DERIVED VARIETIES PROVIDED IN DOCUMENT UPOV/EXN/EDV/2 "EXPLANATORY NOTES ON ESSENTIALLY DERIVED VARIETIES UNDER THE 1991 ACT OF THE UPOV CONVENTION"

Developments since the seventy-sixth session of the CAJ

5. In accordance with the procedure for the revision of document UPOV/EXN/EDV/2 agreed by CAJ (see "Background", above), please find below the developments since the seventy-sixth session of the CAJ.

UPOV Circulars E-19/232 and E-19/233 of December 23, 2019

6. The Office of the Union sent Circulars E-19/232 and E-19/233 of December 23, 2019, inviting members and observers to make contributions by correspondence on policy issues and inviting breeders to provide information on policy issues and customs and practices on EDV. The following members and observers sent contributions: European Union, Germany, Japan, Russian Federation, South Africa, Sweden, African Seed Trade Association (AFSTA), Asia and Pacific Seed Association (APSA), CropLife International, Euroseeds, International Association of Horticultural Producers (AIPH), International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), International Seed Federation (ISF), and Seed Association of the Americas (SAA). The contributions by members of the Union and observers in reply to Circulars E-19/232 and E-19/233 are available at <https://www.upov.int/meetings/en/pages/caj77/contributions.html>.

UPOV Circular E-20/093 of July 9, 2020

7. On the basis of the replies to Circulars E-19/232 and E-19/233, the Office of the Union sent Circular E- 20/093 of July 9, 2020, inviting the CAJ to:

- (a) comment on the draft terms of reference for a working group on EDV (WG-EDV) presented in Annex II of Circular E-20/093;
- (b) comment on the preliminary analysis of the EDV issues and practices in Annex III of Circular E- 20/093, prepared on the basis of the contributions by members of the Union and observers in reply to Circulars E-19/232 and E-19/233 of December 23, 2019;
- (c) invite members of the Union and observers to the CAJ to express their interest to be a member of the WG-EDV.

8. The following sections present proposals for consideration by the CAJ, in accordance with the replies to UPOV Circular E-20/093. Those proposals will include the invitation to the CAJ to consider the updated version of the policy issues in conjunction with the breeders' customs and practices, to approve the terms of reference and the composition of the WG-EDV and a tentative date for the first meeting of the WG-EDV.

Policy issues in conjunction with the breeders' customs and practices

9. In reply to Circular E-20/093, the following member of the Union and observers in the CAJ provided comments in relation to the policy issues in conjunction with the breeders' customs and practices presented in Annex III of Circular E-20/093: United States of America, AIPH and a joint contribution from AFSTA, APSA, CIOPORA, CropLife International, Euroseeds, ISF and SAA. Those contributions in reply to Circular E 20/093 are available at https://www.upov.int/meetings/en/pages/caj77/e_20_093.html.

10. The proposals reflecting the comments received on the policy issues in conjunction with the breeders' customs and practices in Annex III of Circular E- 20/093, are presented in manual revision mode and highlighted in grey in Annex I to this document. The cross references to the issues in the subsection "General issues" in Annex I, Appendix I, have been updated to reflect the new numbering in accordance with the comments and the new issues received in reply to Circular E-20/093. In the subsection "Issues concerning specific aspects of the current explanatory notes" in Annex I, Appendix I, the numbers of the issues in the previous version have been kept in square brackets for ease of reference.

Terms of Reference of the Working Group on Essentially Derived Varieties (WG-EDV)

11. According to the replies to Circular E-20/093, there were no proposals to change the text in the draft terms of reference for a working group on EDV (WG-EDV) presented in Annex II of Circular E- 20/093 and reproduced in Annex II of this document.

12. In the comments from the European Union and in the joint contribution reply from AFSTA, APSA, CIOPORA, CropLife International, Euroseeds, ISF and SAA, a suggestion was made to include a tentative timeline for the work of the WG-EDV.

13. In relation to the above comments, section “Modus Operandi” of the terms of reference (paragraph (c)) provides as follows:

“the WG-EDV to report to the CAJ on progress of its work and to seek further guidance from the CAJ, as appropriate;”

14. It is proposed that the CAJ invites the WG-EDV to consider an indicative timeline once it has had the opportunity to meet and consider its mandate in accordance with the terms of reference. The indicative timeline could be included in the WG-EDV report to the CAJ on progress of its work.

Composition of WG-EDV

15. In reply to Circular E-20/093, the following members of the Union and observers in the CAJ expressed an interest to be members of the WG-EDV: Australia, Brazil, Chile, Ecuador, European Union, France, Japan, Kenya, Sweden, United Republic of Tanzania, United States of America, APSA, Association for Plant Breeding for the Benefit of Society (APBREBES), CIOPORA, CropLife International, Euroseeds, ISF and SAA.

Tentative date for the first meeting of the WG-EDV

16. In recognition of the difficulties in organizing physical meetings at this time and taking into consideration that the UPOV Sessions in October 2020 will be held in the form of virtual meetings, it is proposed to hold the first meeting of the WG-EDV in the form of a virtual meeting on December 8, 2020.

17. *The CAJ is invited to:*

(a) *establish the WG-EDV and approve the terms of reference for the WG-EDV, as set out in Annex II to this document, in conjunction with the modified “Policy issues in conjunction with the breeders’ customs and practices” in Annex I of this document;*

(b) *approve the composition of the WG-EDV, as set out in paragraph 15;*

(c) *approve the tentative date for the first meeting of the WG-EDV, as set out in paragraph 16; and*

(d) *request the WG-EDV to propose a timeline for its work at its first meeting, for consideration by the CAJ at its session in 2021.*

[Annex I follows]

POLICY ISSUES IN CONJUNCTION WITH THE BREEDERS' CUSTOMS AND PRACTICES

This Annex contains the following:

- (a) Appendix I: Policy issues; and
- (b) Appendix II: Breeders' customs and practices.

[Appendix I follows]

ANNEX I, APPENDIX I

POLICY ISSUES

GENERAL ISSUES¹

(a) The role of the EDV concept “to maximize benefits to society in terms of maximizing progress in breeding” (see summary by the Chair of the CAJ concerning the outcome of the “Seminar on the impact of policy on essentially derived varieties (EDVs) on breeding strategy”, document CAJ/76/9 “Report”, paragraph 11), and, in particular:

- (i) providing incentives for breeders to use genetic diversity (see issues 5, 6, practices 4, 9, 24);
- (ii) predominant derivation to be considered the key element of the EDV concept (see issues 29, 32, 50, 51, 54, 60, practices 6, 7, 22 and 23);
- (iii) whether mutants should be considered to be EDVs (see issues 18, 21, 25, 29, 32, 64, practices 10, 11, 13, 15);
- (iv) whether “except for the differences which result from the act of derivation” in the Convention should be understood as not setting a limit to the amount of difference that may exist between the initial variety and the EDV (e.g. mutations induced by radiation) (see issues 16,17,18);
- (v) the role of DNA analysis and genetic thresholds in assessing genetic conformity with the initial variety. How many backcrossings should be considered? (see issues 31, 51, 54, 60, 64, practices 22, 23, 28); and
- (vi) impact of modern breeding methods on the EDV concept “evolution of breeding technologies has created new opportunities/incentives for predominantly deriving varieties from initial varieties, more rapidly and at a lower cost” (see draft ToR on outcome of 2019 EDV Seminar and issues 9, 22, 27, 30, 31, 32, 33, 64, practices 5, 9);
- (vii) what should be considered necessary for an EDV to conform with the essential characteristics of the initial variety? (see issues 11, 13, 15, 52, 57);

(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 5, 6, 7, 8, 10, 19, 20, 55, practice 21) and, in particular:

- (i) how a clear and user-friendly guidance could assist in court, arbitration or mediation cases? (issues 7, 53, 54, 61, 64, 65, 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 issues 54, 58, 60, 64, practice 17);
- (iii) whether ~~the role of~~ PVP Offices or its experts may have or not a role in EDV assessment (see issues 41, 53, 65, practice 21); and
- (iv) whether it would be appropriate for the application form for a breeder’s right should to facilitate the disclosure of information on EDV matters on a voluntary basis (see issues 38, 39, 40, 41, 59, practice 21).

¹ The cross references to the issues in the subsection “General issues” have been updated reflecting the new numbering in accordance with the comments and the new issues received in reply to Circular E-20/093. In the subsection “Issues concerning specific aspects of the current explanatory notes” the numbers of the issues in the previous version have been kept in square brackets for ease of reference.

ISSUES CONCERNING SPECIFIC ASPECTS OF THE CURRENT EXPLANATORY NOTES

	PREAMBLE	Contributions by
Issue 1	to consider if the reference to the “Resolution on Article 14(5)” of the 1991 Diplomatic Conference is necessary	RU
Issue 2	to consider reviewing and reducing the text in the Preamble to avoid repetitions	RU
	SECTION I: PROVISIONS OF ESSENTIALLY DERIVED VARIETIES	
	(a) Relevant provisions of the 1991 Act of the UPOV Convention	
Issue 3	to consider removing the provisions of Article 14(5)(ii) and (iii) of the 1991 Act and those in the footnote (page 4).	RU
Issue 4	to consider not to divide relevant provisions on EDVs in subsections (a) and (b)	RU
Issue 5	to explore how the revision of the explanatory notes could address the following “Relatively small changes can have an enormous impact on the initial variety right holder. ‘In the field of plant species, this question of principle is of considerable economic importance, particularly in the horticultural and floral sphere where any new variety — whether it be a mutation or a creation — can become a best seller overnight and capture a market share as large as that held by the original plant variety right holder’. That reality calls for some form of effective enforcement of Intellectual Property rights. Without it, incentives to innovate might vanish.”	AIPH (request of deletion from AIPH)
Issue5 [6]	to address the issue identified by breeders in the survey that “50% of the respondents have rated the effectiveness of the EDV provision in making sure that the breeder of the initial variety get the necessary compensation as being absent or low.”	Joint contribution by breeders
Issue 6 [7]	to consider the scope of the EDV concept in relation to the following policy matters “To a large group of the respondents, the EDV provision has proven to be valuable, nonetheless it is also clear that further clarification is needed. Any attempt to diminish its value by narrowing its scope or otherwise, would greatly endanger the breeding incentive for cross breeding and could possibly lead to a decrease in breeding effort, genetic variation and biodiversity. This will eventually result in fewer varieties for users which might threaten the whole UPOV system.”	Joint contribution by breeders, AIPH
Issue 7 [8]	to consider how to address the needs of small companies in the following comment “small companies note that it is hard for them to get the full picture of the evolution of the EDV concept (interpretation of UPOV Explanatory Notes, court cases with different outcomes). Maybe they would benefit from clearer guidance / more simplified explanatory material from UPOV”	Joint contribution by breeders, AIPH
Issue 8	to consider the role of the EDV concept in relation to the following policy matter: “without a good EDV policy the value of the PVR system will be considerably lower. Protection would be sought through a restricted licensing policy in which the new varieties might no longer be available for small growers.”	AIPH
	(b) Defining an essentially derived variety	
Issue 9	to consider the inclusion of plant breeding innovations such as genome editing in the [definition of EDV]/[EDV concept]	ZA

Issue 10	to address the need for a clear EDV concept considering the following development of DNA technology (New Genetic (Breeding) Techniques) “These technologies allow for speedier breeding and make it arguably easier for subsequent breeders to develop a derived variety. A relatively small genetic variation could be sufficient to fulfil the DUS requirements for a new PVR, whilst in effect the product would remain much the same. In countries with low PBR enforcement or countries that are still members of UPOV 1978 (where the EDV Concept is absent) [...] breeders [...] (owners of the initial variety) may be left empty-handed, and their long term investments compromised.”	AIPH (request of deletion from AIPH)
Issue 10 [11]	to consider how to provide clarity and certainty in relation to the following “respondents note that some further clarity on the concept, on genetic thresholds or on essential characteristics would be welcome. Additionally, concerns have been raised as regards the multiple interpretations of how to apply the EDV concept in different jurisdictions.”	Joint contribution by breeders, AIPH
	Predominantly derived from the initial variety (Article 14(5)(b)(i))	
Issue 11 [12]	to clarify the terms in Article 14(5)(b)(i) concerning “while retaining the expression of the essential characteristics that results from the genotype and combination of genotypes”	EU
Issue 12 [13]	to clarify the explanations in paragraphs 4 and 5	RU
Issue 13 [14]	to clarify the notion of essential characteristics and how they relate or not to DUS characteristics (see paragraph 6)	RU, ZA
	Clearly distinguishable from the initial variety (Article 14(5)(b)(ii))	
Issue 14 [15]	to clarify the notion of “clearly distinguishable” in Article 14(5)(b)(ii) and to consider if the reference to Article 14(5)(a)(ii) in paragraph 7 is relevant	SE, RU
	Conformity with the initial variety in the expression of the essential characteristics (Article 14(5)(b)(iii))	
Issue 15 [16]	to determine how many differences and how important such differences are necessary for an EDV to conform “essentially” with the initial variety	EU, ZA
Issue 16 [17]	to consider removing the sentence “differences should be one or very few” in paragraph 10	EU
Issue 17 [18]	to clarify the meaning of “except for the differences which result from the act of derivation” and whether there can be any differences which do not result from the act of derivation	ZA
Issue 18 [19]	to consider what justifies a limit on the number of differences for purposes of determining whether a variety is essentially derived or not, if the wording “except for the differences which result from the act of derivation” “do not set a limit to the amount of difference that may exist” (e.g. mutations induced by irradiation) (see paragraph 9)	ZA
Issue 19 [20]	to review the explanations in paragraphs 8 to 11 to provide clear guidance concerning the provisions in Article 14(5)(b)(iii)	RU
Issue 20 [21]	to consider how to provide certainty in relation to the following “the existence of an EDV is sometimes hard to prove, and uncertainty exists due to the lack of clarity around the EDV concept and what the unaltered expression of essential characteristics means for a specific crop.”	Joint contribution by breeders
Issue 21 [22]	to consider how to clarify the following “Respondents see that the EDV concept provided by UPOV is a way to solve disputes upfront between breeders. However, the latest UPOV Explanatory Notes on EDV (2017) created confusion among the breeders, particularly if that would mean that mutants of protected initial varieties are no longer seen as EDVs.”	Joint contribution by breeders, AIPH
	Examples on ways in which an essentially derived variety may be obtained (Article 14(5)(c))- paragraphs 12 and 13	

Issue 22 [23]	to consider explaining the term 'induced mutant' in relation to the "techniques of genome editing"	SE
Issue 23 [24]	to review the need to keep the text of Article 14(5)(c), in paragraph 12, as it is already included in Section I (a)	RU
Issue 24 [25]	to consider the need to retain the first sentence in paragraph 13 and whether to review the second sentence to explain that "for example" in Article 14(5)(c) means that those are examples and do not exclude the possibility of an essentially derived variety being obtained in other ways.	RU
	Method of breeding	
Issue 25 [26]	to consider the need to revise the second sentence of paragraph 15 "[.]. For instance, the genetic change may result in a mutant that no longer retains the expression of the essential characteristics that result from the genotype of the initial variety."	DE
Issue 26 [27]	to consider the following revision of paragraph 15 "While the genetic change may result in a mutant that no longer retains the expression of the essential characteristics that result from the genotype of the initial variety, this is rarely the effect of point mutations."	SE
Issue 27 [28]	to consider if the breeding method used should not have an impact on the EDV concept	ZA
Issue 28 [29]	to consider the need to clarify the contents of paragraphs 14 and 15 to facilitate the EDV determination process	RU
Issue 29 [30]	to consider the following proposals in relation to mutants: (a) in the majority of cases mutants are EDVs; (b) Mutants are always predominantly derived; (c) the mutant is completely derived from the initial variety.	EU
Issue 30 [31]	to consider reaching a common understanding on mutagenesis and the different kinds of mutagenesis techniques (e.g. spontaneous or induced mutagenesis provoking a single or several mutations)	EU
Issue 31 [32]	to consider, in relation to backcrossing, if thresholds can be defined to establish predominant derivation and to shift the burden of proof which might not be the case with mutants "The difference between backcrossing and mutation is that in case of backcrossing there are two parent varieties providing each of them their genome. In order to avoid a limitation of the breeder's exemption it is therefore particularly important to draw a borderline regarding the conformity. This can be done by using the terminology 'repeated backcrossing'. It should also be stated that in relation to repeated backcrossing the limitation to 'one or a few differences' would remain an important principle for the conformity assessment." (see also issue 17)	EU
Issue 32 [33]	to consider if the use of new breeding techniques (e.g. targeted mutagenesis) should in all cases lead to the conclusion that the variety is predominantly derived from the initial variety.	EU
Issue 33 [34]	to consider providing a more elaborated explanation of the terms "somaclonal variant" and "selected variant individual" as those terms just indicate the origin of a natural or induced mutant	DE
	Direct and indirect derivation	
Issue 34 [35]	to improve Figure 2 in order to clarify that 'Z' is clearly distinguishable from 'A' but also clearly distinguishable from 'B' to 'Y'.	DE
Issue 35 [36]	to consider the following comment: "While the scheme in Figure 2 is theoretically, and legally, correct, it may be inferred that subsequent derivation lowers the likelihood that EDVs 'further away' from the initial variety A will retain the expression of essential characteristics of "A" and / or conform to "A" in essential characteristics."	SE
Issue 36 [37]	to review paragraphs 17, 18 and 19 in order to avoid repetitions	RU

	(c) Scope of the breeder's right with respect to initial varieties and essentially derived varieties	
Issue 37 [38]	<i>to consider whether the breeder of the initial protected variety should be granted a breeder' right at the same time as the breeder of the EDV, without any additional examination by the authority and that the grant of the breeder's right for the EDV shall not depend on additional conditions except for the designation of a denomination for the EDV and compliance with the formalities and payment of required fees.</i>	RU
Issue 38 [39]	<i>to consider whether information about the origin of the variety be specified in the application form and not be considered a commercial secret</i>	RU
Issue 39 [40]	<p>(a) <i>to consider whether application forms should be amended to disclose from which variety a variety was derived, what the act of derivation was, what are the essential characteristics of the initial protected variety and what are the essential characteristics of the derived variety.</i></p> <p>(b) <i>to consider if the above proposal for the amendment of the application form could provide the basis for the breeder of the protected initial variety to oppose to the application on the basis that the applicant has failed to admit or agree that the variety is an essentially derived variety,</i></p> <p>(c) <i>to consider if the above opposition procedure could provide the basis for the candidate variety be deemed to be essentially derived pending the final determination by the PBR Authority to the contrary.</i></p>	ZA
<u>Issue 40</u>	<u><i>to consider that it would not be appropriate to discuss any requirement for variety origination disclosure requirements to be included in the Explanatory Note on EDV.</i></u>	<u>US</u>
<u>Issue 41</u>	<u><i>to consider that it would not be appropriate to (a) mandate examination practices at national or regional plant variety protection offices and (b) for the working group to craft application forms or processes requiring certain information</i></u>	<u>US</u>
Issue 42 [41]	<i>to consider whether UPOV and UPOV members should develop regulations for the legal registration of the right of the breeder of the initial protected variety in relation to the EDV and options for the operation of this right (see proposal in item 28).</i>	RU
Issue 43 [42]	<i>to consider adding, after Figure 4, that the breeder of the protected derived variety may obtain an authorization for commercialization of the EDV in the form of an exclusive license from the breeder of initial protected variety</i>	RU
<u>Issue 44</u>	<u><i>to consider inclusion of guidance on the variety denomination for an unprotected EDV that an EDV must not have the same variety denomination as its Initial Variety.</i></u>	<u>Joint contribution by breeders</u>
<u>Issue 45</u>	<u><i>to consider if the PVP authority might be requested to confirm that an EDV is distinct from the initial variety.</i></u>	<u>Joint contribution by breeders</u>
	(d) Territoriality of protection of initial varieties and essentially derived varieties	
Issue 46 [43]	<i>to consider, in paragraph [24], replacing the terms "in the territory concerned" by "...in the same territory", to clarify that the territory to which the breeder's right of the initial variety applies should be the same for the initial variety and the EDV.</i>	RU
Issue 47 [44]	<i>to consider adding, at the end of paragraph [24], the following "In case of discrepancy between initial and the derived varieties' protection territories the breeder's right for the initial variety is extended to imported material of derived variety in the protection territory of the initial variety".</i>	RU

	(e) Transition from an earlier Act to the 1991 Act of the UPOV Convention	
Issue 48 [45]	<p>to consider whether paragraph [25], should be amended as follows:</p> <p><i>“Members of the Union which amend their legislation in line with the 1991 Act of the UPOV Convention should cover the extension of the provisions of Article 14(5) to the generally known varieties”</i></p> <p>for members of the Union bound by the 1991 Act to apply provisions of Article 14(5) to all protected varieties regardless of the date of grant.</p>	RU
Issue 49 [46]	to consider removing paragraph [26]	RU
	SECTION II: ASSESSMENT OF ESSENTIALLY DERIVED VARIETIES	
Issue 50 [47]	to consider whether predominant derivation from an initial variety, confirmed by a high genotypic conformity, could be a key requirement for determining EDV.	EU
Issue 51 [48]	to explore the role of DNA analysis for determining, with genetic thresholds, the requirement of “predominantly derived”.	EU
Issue 52 [49]	to consider if for conformity, both genotype and phenotype should be considered; and to explore if a judge could have access to the breeding book and information on phenotypical similarities in order to decide if a variety is an EDV.	EU
Issue 53 [50]	<p>to consider reintroducing in the guidance the concept in document UPOV/EXN/EDV/1, paragraph 15, that the determination of whether a variety is an EDV should:</p> <ul style="list-style-type: none"> (a) be made by the industry and at the end through an arbitration process or by courts; (b) the granting authorities not to play the dispute resolving role; (c) it is up to the holder of a breeder’s right to defend its right; (d) experts from plant variety examination offices could be called as experts by courts. 	EU
Issue 54 [51]	<p>to consider the following on the role of the position papers, for some species, developed by the industry:</p> <ul style="list-style-type: none"> (a) such papers include thresholds on genetic similarities which could trigger the change of the burden of proof as to whether a variety is predominantly derived; (b) such papers do not include thresholds as regards how many characteristics must be similar/different when assessing if a variety is an EDV; (c) a court is not bound by such papers but may take into account implementation practice when assessing a given case. 	EU
Issue 55 [52]	to explore the need for a clearer explanation and criteria to identify a variety could be an EDV to avoid unnecessary law case.	JP

<p>Issue 56 [53]</p>	<p>to consider whether:</p> <ul style="list-style-type: none"> (a) additional expertise regarding the origin of a new EDV variety to be required in rare court cases and only if the parties disagree; (b) the methods of assessment in those court cases to depend on the method establishing the fact of origin and the conditions of commercialization; (c) the settlement of such a dispute between the parties to be considered in accordance with the applicable law. 	<p>RU</p>
<p>Issue 57 [54]</p>	<p>to note that the guidance does not provide for a mechanism to determine whether a variety is essentially derived variety, or not; and therefore to be aware of that it is problematic to construct the concept of essentially derived varieties and make its determination dependent on an undefined number of differences in undefined “essential” characteristics and then leave the determination thereof to breeders with competing interests.”</p>	<p>ZA</p>
<p>Issue 58 [55]</p>	<p>to consider how to address the burden on the breeder of the protected initial variety, in particular, the responsibility and legal expenses to “force” a determination as essentially derived on a variety that was admittedly predominantly derived from the initial protected variety, and often in circumstances where the derived variety is commercialized in competition with the initial variety and causing the breeder initial variety irreparable harm.</p>	<p>ZA</p>
<p>Issue 59 [56]</p>	<p>to consider whether to replace Section II by the following new Section II”</p> <p>“Section II “Registration of protected initial variety’s rights’ extension to essentially derived varieties”</p> <p>“An applicant (breeder) shall indicate the history of breeding (creation) of the variety in the application materials (the application form) for granting the breeder’s right or application materials (the application form) for including the variety in the National List. At the stage of preliminary examination of the application the competent authority of the member of the Union examines the completeness of the information on the new variety and requests additional information if applicable.</p> <p>“A request to determine variety to the category ‘essentially derived varieties’ and to denominate the [initial] variety is prepared by the authority based on the information containing the origin of the variety and DUS examination, and is published in the official Bulletin.</p> <p>“Comments on the application materials submitted within six months after the publication are to be agreed with stakeholders.</p> <p>“The decision of competent authority concerning the determination of variety to the category of essentially derived varieties and denomination of the [initial] variety may be appealed in accordance with national legislation.</p> <p>“In the case of the protection of the initial variety in the territory of the member of the Union, the competent authority request to submit a license agreement with the breeder of the initial variety about the conditions commercialization of the propagating material of the EDV when registering the breeder’s right for EDV.</p> <p>“Interrelation between essentially derived varieties (protected and unprotected by private right) and the protected initial variety is reflected by the competent authority by publishing the information about varieties used in own territory, including the UPOV website.”</p>	<p>RU</p>
<p>Issue 60 [57]</p>	<p>to consider if the “initiatives from the private sector, valuing the work of breeders,” should be encouraged and further developed (see issue 51 above)</p>	<p>Joint contribution by breeders</p>

<u>Issue 61 [58]</u>	<i>to consider “the interest of the alternative dispute resolutions put in place by trade associations.”</i>	<i>Joint contribution by breeders</i>
<u>Issue 62</u>	<i>to consider that standardization of genetic thresholds for EDV may be useful for the international community, yet at the same time UPOV members ultimately should value any such genetic evidence of EDV consistent with their own evidentiary regimes.</i>	<u>US</u>
<u>Issue 63</u>	<i>to consider seeking “to find support for particular examples of EDV, either from case law of member jurisdictions, or from other areas of consensus which the group can elaborate on the terms used in the treaty text (e.g., ‘predominantly derived,’ ‘clearly distinguishable from the initial variety,’ and/or “conforms to the initial variety in the expression of the essential characteristics”, etc.).”</i>	<u>US</u>
<u>Issue 64</u>	<i>to consider that “the process of establishing any useful threshold values for genetic conformity assessments should be mutually arrived at by all interested UPOV members and stakeholders. The costs and impacts on small and medium sized entities should be considered (i.e., is genetic testing so cost prohibitive that small breeders cannot access the technology). Moreover, the working group should consider if certain classes of breeding techniques should trigger a prima facie (but rebuttable) case of ‘predominant derivations.’ Such classes of techniques could include, but not be limited to derivation of mutants by irradiation, point gene edits, or other techniques.”</i>	<u>US</u>
<u>Issue 65</u>	<i>to consider that “ultimate EDV determinations are best left to national courts or to an arbitration process. Any granting authority decision on EDV could be used as rebuttable evidence of an EDV in national courts or arbitration processes. However, [...] the 1991 Act of the Convention does not require offices to carry out EDV determinations, and the working group cannot serve as a means to create such a requirement.”</i>	<u>US</u>

[Appendix II follows]

ANNEX I, APPENDIX II

BREEDERS' CUSTOMS AND PRACTICES

In reply to Circular E-233 with a request to provide information on EDV customs and practices of breeders, the Office of the Union received:

(a) on April 9, 2020, a joint contribution by the International Seed Federation (ISF), the International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), CropLife International, Euroseeds, the Asia and Pacific Seed Association (APSA), the African Seed Trade Association (AFSTA) and the Seed Association of the Americas (SAA) and the survey with the "Summary Report of EDV Survey Results and Comments from 98 actors active in various agricultural crops, ornamentals, fruits and vegetables and from various continents" (joint contribution by breeders);

(b) on May 27, 2020, a contribution from the International Association of Horticultural Producers (AIPH) expressing its support to certain findings in the survey referred to in (a), above.

The following table presents relevant extracts from the survey (see (a) above). The table also illustrates when the contribution of AIPH has indicated support to findings in the survey in the joint contribution by breeders.

BREEDERS' CUSTOMS AND PRACTICES
CONCERNING SPECIFIC ASPECTS OF THE CURRENT EXPLANATORY NOTES

	<i>Joint contribution by ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, SAA</i> An asterisk ("*") in the left column means support expressed by AIPH to the joint contribution.
	PREAMBULE
	SECTION I: PROVISIONS OF ESSENTIALLY DERIVED VARIETIES
	(a) Relevant provisions of the 1991 Act of the UPOV Convention
<i>Practice 1</i>	<i>"majority of respondents (80%) acknowledged the preventive and clarifying effect that the EDV provision of UPOV 1991 Act has had regarding the development and marketing of predominantly derived varieties without an agreement".</i>
<i>Practice 2</i>	<i>"It [EDV provision] has led breeding companies to monitor their practices and there has been an auto-regulation of practices"</i>
<i>Practice 3</i>	<i>"Some breeders mention that the EDV concept is not preventing the development and marketing of EDV's; it is regulating it. The occurrence of spontaneous mutants cannot be prevented anyway"</i>
<i>Practice 4*</i>	<i>"It was also noted that the concept of EDV does not restrict biodiversity but rather enhances it as breeders are incentivized to work with broader germplasm if they want to avoid developing an EDV."</i>
<i>Practice 5*</i>	<i>"the modification of one or more characteristics in an initial variety, for example via the latest breeding methods, does not automatically lead the new variety to be out of the scope of EDVs;"</i>
	<i>Predominantly derived from the initial variety (Article 14(5)(b)(i))</i>
<i>Practice 6</i>	<i>"it does not matter whether the characteristic(s) in which the EDV differs from the protected initial variety is (are) of economic, agronomic or societal importance, essential or trivial. EDV principles remain the same and predominant derivation from an initial variety is a key requirement for a variety to be considered an EDV."</i>
	<i>Clearly distinguishable from the initial variety (Article 14(5)(b)(ii))</i>
	<i>Conformity with the initial variety in the expression of the essential characteristics (Article 14(5)(b)(iii))</i>

	<p><i>Joint contribution by ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, SAA</i></p> <p>An asterisk (“**”) in the left column means support expressed by AIPH to the joint contribution.</p>
Practice 7*	<p><i>“[A] vast majority of respondents declared that it does not matter whether the characteristic(s) in which the EDV differs from the protected initial variety is of economic, agronomic or societal importance. They emphasized that as long as the variety is predominantly derived from the initial variety, it remains “derived from” and should be treated as an EDV.”</i></p>
Practice 8	<p><i>“Some companies indicate that the quality of the characteristics is important when entering into negotiations, with a more important trait the developer of the EDV can ask for a larger portion of the license fee”</i></p>
Practice 9*	<p><i>“Almost all responding companies (more than 90%) consider it negative or very negative if varieties developed with latest breeding methods (such as CRISPR-Cas 9 or other recombinant DNA technologies) and differing in at least one characteristic from the protected initial variety were not considered as EDVs. They are of the opinion that this would give the users of these new technologies a very easy manner to take over varieties which would diminish the incentive to develop new varieties. It is expected that this will lower the development of segregating variation and thus reduce genetic gain.”</i></p>
Practice 10	<p><i>“Some breeders mention that the EDV concept is not preventing the development and marketing of EDV’s; it is regulating it. The occurrence of spontaneous mutants cannot be prevented anyway. Some breeders mention that no one will prevent the commercialization of a truly valuable mutant, but the EDV concept can make sure no one in the industry is damaged by a multitude of unstable or inferior mutants being introduced on the market.”</i></p>
	<p><i>Examples on ways in which an essentially derived variety may be obtained (Article 14(5)(c))</i></p>
Practice 11	<p><i>“If spontaneous mutants or sports were found by growers (e.g. in ornamentals or fruits) there are often contracts in place that require reporting.”</i></p> <p><i>“Some companies report they have contracts with growers for the situation that spontaneous mutants occur.”</i></p>
Practice 12	<p><i>“Other companies have a policy not to develop EDV’s themselves.”</i></p>
Practice 13	<p><i>“Regarding spontaneous mutants that occur in ornamental and fruit crops mostly at the premises of growers, many breeders reply that their policy is to find agreement on commercializing the EDV if there is added value of bringing this mutant to the market.”</i></p>
	<p><i>Method of breeding</i></p>
	<p><i>Direct and indirect derivation</i></p>
	<p>(c) Scope of the breeder’s right with respect to initial varieties and essentially derived varieties</p>
	<p>(d) Territoriality of protection of initial varieties and essentially derived varieties</p>
	<p>(e) Transition from an earlier Act to the 1991 Act of the UPOV Convention</p>
	<p>SECTION II: ASSESSMENT OF ESSENTIALLY DERIVED VARIETIES</p>
Practice 14	<p><i>“Some of those who commented state that when third parties developed EDVs it was possible to agree with the third parties and come to a settlement/license agreement</i></p>
Practice 15	<p><i>“Many companies report that they monitor varieties of other breeders, some do this by use of DNA analysis. Some companies report they have contracts with growers for the situation that spontaneous mutants occur. Other companies have a policy not to develop EDV’s themselves. Some companies don’t see the need for a policy as EDV’s are not an issue in their crops or are considering to develop a policy in the near future. Regarding spontaneous mutants that occur in ornamental and fruit crops mostly at the premises of growers, many breeders reply that their policy is to find agreement on commercializing the EDV if there is added value of bringing this mutant to the market.”</i></p>

	<p><i>Joint contribution by ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, SAA</i></p> <p>An asterisk (“**”) in the left column means support expressed by AIPH to the joint contribution.</p>
Practice 16	<i>“Many companies conduct surveillance in this regard, sometimes with the help of molecular markers. 42% of the respondents have declared that their company has identified third party varieties that are potential EDV of their own protected varieties”</i>
Practice 17	<i>“Most respondents consider that conditions (threshold, protocols, etc...) to classify varieties as an EDV should be developed by breeders or at least with the involvement of breeders familiar with the crops, preferably at the global level in order to avoid differences country by country. Some hold the view that independent authorities should also be involved in such work”</i>
Practice 18	<i>“Some seed breeders consider that having an EDV threshold by the sector is important but state that having the possibility to go for a legal action and a final decision by an independent body (e.g. a court) should be available.”</i>
Practice 19	<i>“Some thought this question was not so easy to answer. Either because some felt that an independent authority would be better placed to delineate objectively between an EDV and the normal offspring from standard crosses; or because some considered that interests between breeders of the initial varieties and developers of EDVs will obviously differ.”</i>
Practice 20*	<i>“Most companies prefer decision by courts or arbitration, but some see also a role for PVP authorities in respect of technical questions.</i>
Practice 21	<i>“It is often said that PVP authorities are expected to have a better (technical) knowledge than courts and/or arbitrators, depending on specific country situation. Therefore, the involvement of PVP offices as experts in a court or an arbitration panel can be valuable. Some would like to see that PVP authorities make a decision regarding potential EDV-status of a variety during the application procedure (which is expected to be cheaper than a court procedure) which could be followed by a procedure to go to court or arbitration. Others are of the opinion that PVP authorities should remain independent and not choose side in a dispute between companies. Furthermore, in a legal dispute many questions will be raised which require legal expertise and go beyond the expertise of a PVP authority, such as the validity of the title(s), the acts of infringement, liability and the level of compensation.”</i>
Practice 22	<i>“many respondents from the seed sector indicated that they make use of the tools developed by the seed industry to prevent and help dispute resolutions.</i>
Practice 23	<i>“ISF and Euroseeds have developed guidelines on EDV, setting genetic thresholds related to perennial ryegrass, maize, oilseed rape, cotton, lettuce and potatoes. https://www.worldseed.org/our-work/trade-rules/#essential-derivation https://www.euroseeds.eu/app/uploads/2019/07/12.0838.pdf”</i>
Practice 24	<i>“82% of the respondents declared that their company did not actively develop varieties that are potential EDV of protected varieties from other companies. The vast majority of breeders try to avoid developing EDVs e.g. by working with their own material when conducting mutagenesis breeding or by performing cross breeding when working with material of competitors. However, some note that it is not the purpose to absolutely avoid EDV development, and they mention that they initiate dialog with the owner of the initial variety when needed.”</i>
Practice 25	<i>“Some note that they do not actively monitor EDV development by third parties.”</i>
Practice 26	<i>“the majority of the respondents do not have a company policy in place to deal with EDV-related issues”</i>
Practice 27	<i>“Many companies have given instructions internally, to their breeders to avoid the making of EDV’s, either by using plant material of other breeders only for making crossings or by doing mutation breeding on own material only.”</i>
Practice 28	<i>“Some companies working with hybrid crops report instructions not to make too many back crossings and to check that the new variety is distinct enough. Some breeders report that although they have no written policy, their staff is aware of the issue.”</i>

DRAFT TERMS OF REFERENCE OF THE WORKING GROUP ON ESSENTIALLY DERIVED VARIETIES
(WG-EDV)

[Reproduced from Annex II of UPOV Circular E-20/093 dated July 9, 2020 – changes are presented in manual revision mode and highlighted in grey]

PURPOSE:

The purpose of the WG-EDV is to draft a revision of the “Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention” (document UPOV/EXN/EDV/2) for consideration by the Administrative and Legal Committee (CAJ).

COMPOSITION:

- (a) to be composed of the members of the Union and the observers agreed by the CAJ;
- (b) other members of the Union would be free to participate at any meeting of the WG-EDV and make comments, where so desired;
- (c) the WG-EDV would revert back to the CAJ if the WG-EDV recommended to invite other observers or experts to any of its meetings; and
- (d) meetings to be chaired by the Vice Secretary-General.

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:
 - “- 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 I of this document ~~III of this Circular~~;
- (b) the WG-EDV to meet at a time and frequency to address its mandate, by physical and/or virtual means, as agreed by the WG-EDV;
- (c) the WG-EDV to report to the CAJ on progress of its work and to seek further guidance from the CAJ, as appropriate;
- (d) WG-EDV documents to be made available to the CAJ.

[End of Annex II and of document]