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DRAFT (Revision)

EXPLANATORY NOTES ON ESSENTIALLY DERIVED VARIETIES UNDER THE 1991 ACT OF THE UPOV CONVENTION

Document prepared by the Office of the Union

to be considered by

the Consultative Committee and the Council by correspondence

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Note for Draft version

The Administrative and Legal Committee (CAJ), at its seventy-eighth session, held via electronic means on October 27, 2021, approved the proposed revision to document UPOV/EXN/EDV/2 as presented in this document (see document CAJ/78/13 "Report", paragraphs 16 and 18).

The Council, at its fifty-fifth ordinary session, held via electronic means on October 29, 2021, agreed that a draft of document UPOV/EXN/EDV/3, as approved by the CAJ, be circulated for approval by the Consultative Committee and adoption by the Council by correspondence (see document C/55/18 "Report", paragraph 47).

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PREAMBLE

1. The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, held in Geneva from March 4 to 19, 1991 (Diplomatic Conference), adopted the following resolution:

"Resolution on Article 14(5)¹

"The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to 19, 1991, requests the Secretary-General of UPOV to start work immediately after the Conference on the establishment of draft standard guidelines, for adoption by the Council of UPOV, on essentially derived varieties."

2. The purpose of these Explanatory Notes is to provide guidance on "Essentially Derived Varieties" under the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV Convention). The only binding obligations on members of the Union are those contained in the text of the UPOV Convention itself, and these Explanatory Notes must not be interpreted in a way that is inconsistent with the relevant Act for the member of the Union concerned.

3. These Explanatory Notes are divided into the following three sections: Section I Provisions of essentially derived varieties; Section II Assessment of essentially derived varieties and Section III Facilitating EDV understanding and implementation.

¹ This Resolution was published as "Final Draft" in document DC/91/140 (see Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, UPOV Publication No. 346 (E) "Further instruments adopted by the Conference", page 63.

SECTION I: PROVISIONS OF ESSENTIALLY DERIVED VARIETIES

(a) Relevant provisions of the 1991 Act of the UPOV Convention

THE RIGHTS OF THE BREEDER

Article 14

Scope of the Breeder's Right

[...]

(5) [Essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4)* shall also apply in relation to

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

(ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and

(iii) varieties whose production requires the repeated use of the protected variety.

(b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) 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.

* The provisions in Article 14(1) to (4) of the 1991 Act of the UPOV Convention are as follows:

(1) [Acts in respect of the propagating material] (a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

- (i) production or reproduction (multiplication),
- (ii) conditioning for the purpose of propagation,
- (iii) offering for sale,
- (iv) selling or other marketing,
- (v) exporting,
- (vi) importing,
- (vii) stocking for any of the purposes mentioned in (i) to (vi), above.

(b) The breeder may make his authorization subject to conditions and limitations.

(2) [Acts in respect of the harvested material] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.

(3) [Acts in respect of certain products] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.

(4) [*Possible additional acts*] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(*a*) shall also require the authorization of the breeder.

(b) Defining an essentially derived variety

Article 14(5)(b) of the 1991 Act of the UPOV Convention

(b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Predominantly derived from the initial variety (Article 14(5)(b)(i))

4. Predominant derivation concerns the genetic source of the essentially derived variety. The requirement of predominant derivation from an initial variety, or from a variety that is itself predominantly derived from the initial variety, is the key requirement for a variety to be considered an EDV. Predominant derivation implies that a variety can only be derived from one initial variety.

5. "Predominant" derivation means that more of the genome of the initial variety is retained than would be retained by normal crossing and selection with different parents.² A variety should only be considered predominantly derived from the initial variety if it retains almost the whole genome of its initial variety. However, a high degree of genetic conformity alone does not automatically mean that a variety has been predominantly derived. For example, progenies obtained from the same cross may have a high degree of genetic conformity but none of these progenies obtained should be considered as the initial variety of the other nor as predominantly derived from the other. Convergent breeding³ may also result in a high degree of genetic conformity between two varieties that were developed from different parents without either of the varieties being an initial variety from which the other had been predominantly derived.

² "Normal crossing and selection" means crossing two or more phenotypically and genetically different parents for the purpose of developing a segregating population for testing and selection.

³ "Convergent breeding" occurs when different breeders select independently, within a common pool of germplasm, towards similar plant types having common characteristics (e.g., maturity, plant stature, suitability for mechanical harvesting). As a result of convergent breeding, two varieties bred from the common pool may exhibit a high degree of genetic conformity even though neither variety was predominantly derived from the other.

In that respect,

- (a) Varieties with a single parent ("mono-parental" varieties) resulting, for example, from mutations, genetic modification or genome editing are *per se* predominantly derived from their initial variety.
- (b) Varieties involving the use of two or more parents ("multi-parental" varieties) may be predominantly derived from one parent (the initial variety) by selectively retaining the genome of the initial variety, for example through repeated backcrossing. In this case, crop-specific genetic conformity thresholds might be defined in order to determine predominant derivation, i.e. beyond a level that would be obtained by normal crossing and selection with the initial variety.

Clearly distinguishable from the initial variety (Article 14(5)(b)(ii))

6. The phrase "it is clearly distinguishable from the initial variety" establishes that essential derivation is concerned only with varieties that are distinct, in accordance with Article 7, from the initial variety.

Conformity in the expression of the essential characteristics of an EDV with its initial variety (Article 14(5)(b)(iii))

7. An essential characteristic is a characteristic that results from the expression of the genotype and includes, but is not limited to, morphological, physiological, agronomic, industrial (e.g. oil characteristics) and/or biochemical characteristics.

8. An "essential characteristic" is a characteristic that is fundamental for the variety as a whole. It should contribute to the principal features, performance or value for use of the variety and be relevant for one of the following: the producer, seller, supplier, buyer, recipient, user of the propagating material and/or of the harvested material and/or of the directly obtained products and/or the value chain.

9. An essential characteristic may or may not be a characteristic used for the examination of distinctness, uniformity or stability (DUS) and/or used for the examination of value for cultivation and use (VCU).

10. Essential characteristics are specific to each crop or species and may evolve over time.

11. An essentially derived variety typically retains the expression of essential characteristics of the variety from which it is derived, except for those differences resulting from act(s) of derivation, which may also include differences in essential characteristics.

12. The degree of conformity of the putative EDV to the initial variety should be assessed on the basis of the expression of the essential characteristics which result from the genotype of the initial variety. The conformity to the initial variety excludes the differences which result from the act(s) of derivation. Changes in the expression of multiple characteristics can result from different successive acts of derivation or may be obtained simultaneously. For example, predominant derivation may result from multiple backcrosses or may be achieved by fewer backcrosses, combined with targeted selection methods.

13. Article 14(5)(b)(iii) does not set an upper limit as to the number of differences which may exist where a variety is still considered to be essentially derived. The number of differences between an EDV and the initial variety is therefore not limited to one or very few differences but may vary taking into account different methods of derivation. The differences may also include essential characteristics.

14. Differences resulting from act(s) of derivation are disregarded for the purpose of determining the EDV status of a variety. In that regard, the following clarification is provided:

- (a) In the case of mono-parental varieties, all differences necessarily result from one or more act(s) of derivation, meaning that all differences are excluded from consideration of the EDV status.
- (b) In the case of a multi-parental variety, the differences between that variety and any of its parent varieties may result from normal crossing and selection or from one or more of the methods of derivation described in paragraphs 15 and 16. Therefore, when determining the EDV status of such a multi-parental variety in relation to one of its parent varieties, it is important to establish whether there have been one or more acts of derivation.

Examples of methods by which an essentially derived variety may be obtained (Article 14(5)(c))

15. The Convention provides the following examples of methods by which an essentially derived variety may be obtained:

- selection of a natural or induced mutant, or of a somaclonal variant;
- selection of a variant individual from plants of the initial variety;
- backcrossing;
- transformation by genetic engineering.

In the case of "backcrossing", it is understood that this means repeated backcrossing to the initial variety.

16. The use of the words "for example" in Article 14(5)(c) clarifies that the list of methods is not exhaustive. The examples of methods provided in Article 14(5)(c) correspond to the methods known in 1991. Since then, breeding methods have evolved and techniques, such as genome editing, have emerged. Other breeding methods that could lead to the development of essentially derived varieties may be developed. Any such methods should be considered, if relevant to Article 14(5)(c).

17. The exclusive use of one or more of the methods in paragraphs 15 and 16 would typically result in essentially derived varieties.

Direct and indirect derivation

18. The wording of Article 14(5)(b)(i) explains that essentially derived varieties can be predominantly derived from a variety that is itself predominantly derived from the initial variety, thereby indicating that essentially derived varieties can be obtained, either directly or indirectly, from the "initial variety". Varieties can be predominantly derived from the initial variety "A", either directly, or indirectly via varieties "B", "C", "D", or "E" ... etc., and will still be considered essentially derived varieties from variety "A" if they fulfill the definition stated in Article 14(5)(b).

19. In the example in Figure 1, variety B is an essentially derived variety from variety A and is predominantly derived from variety A.

20. Essentially derived varieties can also be indirectly obtained from an initial variety. Article 14(5)(b)(i) provides that an essentially derived variety can be "predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety." In the example in Figure 2, Variety C has been predominantly derived from variety B, variety B being itself predominantly derived from variety A (the initial variety). Variety C is essentially derived from initial variety A, but is predominantly derived from variety B.

21. Irrespective of whether variety C has been obtained directly from the initial variety A or not, it is an essentially derived variety from variety A if it fulfills the definition stated in Article 14(5)(b).

(c) Scope of the breeder's right with respect to initial varieties and essentially derived varieties

1991 Act of the UPOV Convention

Article 14 (5) (a) (i)

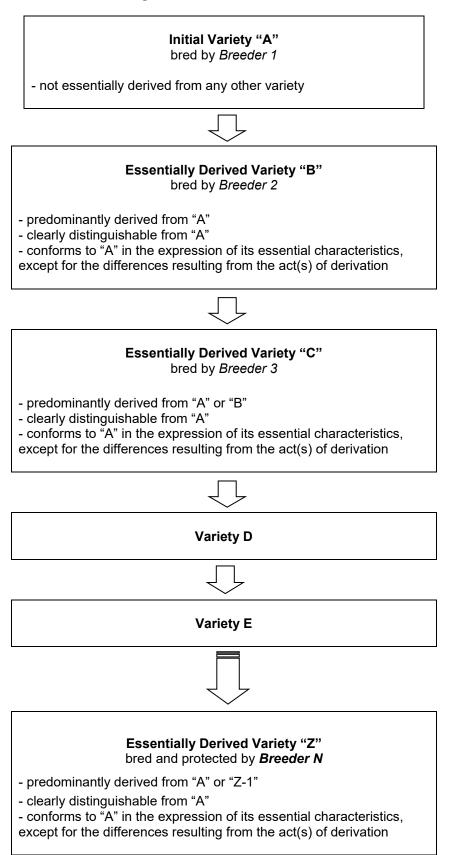
(5) [*Essentially derived and certain other varieties*] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

22. The relationship between the initial variety (variety A) and an essentially derived variety (varieties B, C, etc.) is irrespective of whether a plant breeder's right has been granted to those varieties. Variety A will always be the initial variety for varieties B, C, etc., and varieties B, C, etc., will always be essentially derived varieties from variety A. However, only if the initial variety is protected, will the essentially derived varieties B, C, etc., fall within the scope of protection of the initial variety.

Figure 1: Essentially Derived Variety "B"

Figure 2: EDV "C", "D" to "Z"



23. Essentially derived varieties are eligible for plant breeders' rights in the same way as for any variety, if they fulfill the conditions established in the Convention (see Article 5 of the 1991 Act of the UPOV Convention). If an essentially derived variety is protected, it is necessary to obtain the authorization of the breeder of the essentially derived variety as provided in Article 14(1) of the UPOV Convention. However, the provisions of Article 14(5)(a)(i) extend the scope of the right set out in Article 14(1) to (4) of the protected initial variety to essentially derived varieties. Therefore, if variety A is a protected initial variety, the acts included in Article 14(1) to (4) concerning essentially derived varieties require the authorization of the titleholder of variety A. In this document the term "commercialization" is used to cover the acts included in Article 14(1) to (4). Thus, when there is a plant breeder's right on both the initial variety (variety A) and an essentially derived variety (variety B), the authorization of both the breeder of the initial variety (variety A) and the breeder(s) of the essentially derived variety B).

24. If an essentially derived variety (variety B) is not protected in its own right, the acts included in Article 14(1) to (4) concerning variety B undertaken by the breeder of variety B, or any third party, would require the authorization of the titleholder of variety A.

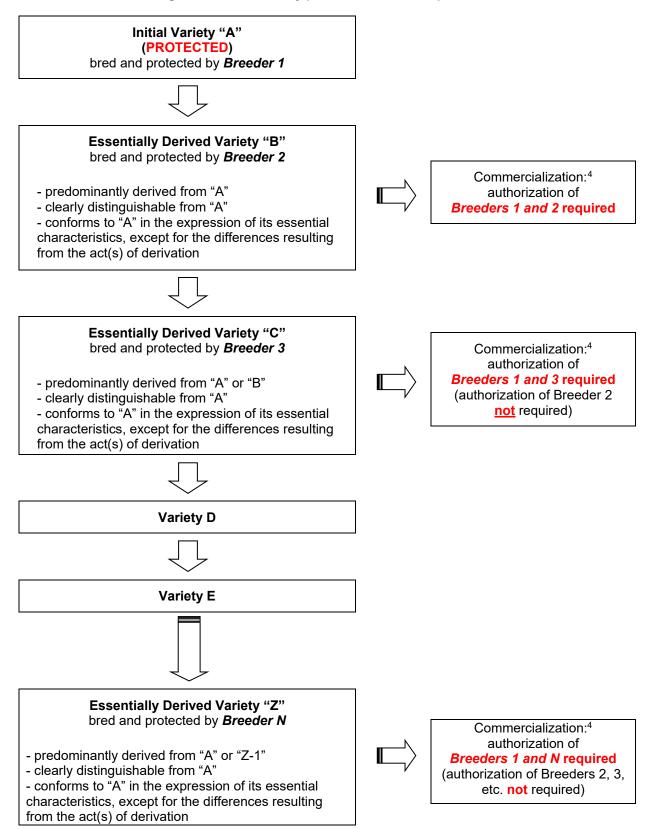
25. Once the plant breeder's right of the initial variety (variety A) has ceased, the authorization of the breeder of the initial variety is no longer required for the commercialization of variety B. In such a situation, and if the plant breeder's right of the essentially derived variety is still valid, only the authorization of the titleholder of the essentially derived variety B would be required for the commercialization of variety B. Furthermore, if the initial variety A was never protected, only the authorization of the titleholder of the essentially derived variety B would be required for the titleholder of the essentially derived variety B would be required for the titleholder of the essentially derived variety B would be required for the titleholder of the essentially derived variety B would be required for the titleholder of the essentially derived variety B would be required for the commercialization of the titleholder of the essentially derived variety B would be required for the commercialization of the titleholder of the essentially derived variety B would be required for the commercialization of the titleholder of the essentially derived variety B would be required for the commercialization of the titleholder of the essentially derived variety B would be required for the commercialization of variety B.

26. The titleholder of variety 1 might obtain a "putative EDV" that it considers to be an essentially derived variety (2). The titleholder of variety 1 may claim that the acts included in Article 14(1) to (4) concerning the "putative EDV" undertaken by any third party, would require the authorization of the titleholder of variety 1. However, there is no guarantee that the "putative EDV" will be accepted as an essentially derived variety 2 by those third parties.

Summary

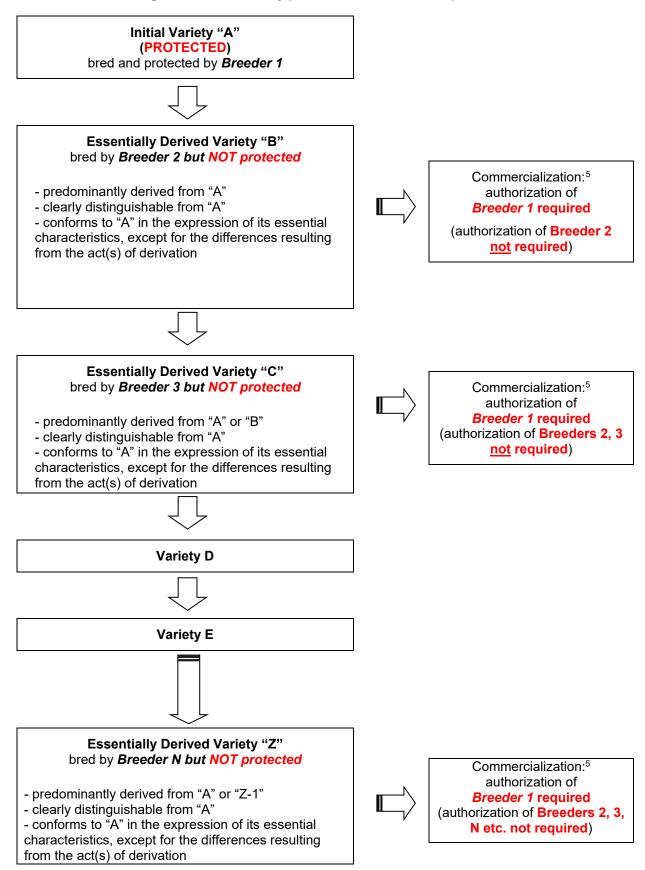
27. Figures 3, 4 and 5 provide a summary of the situations described above. It is important to note that the scope of the breeder's right is only extended to essentially derived varieties in respect of a protected initial variety. In that regard, it should also be noted that a variety which is essentially derived from another variety cannot be an initial variety (see Article 14(5)(a)(i)). Thus, in figure 3, the rights of Breeder 1 extend to EDV "B", EDV "C" and EDV "Z". However, although EDV "C" is predominantly derived from EDV "B", Breeder 2 has no rights as far as EDV "C" is concerned. In the same way, Breeders 2 and 3 have no rights as far as EDV "Z" is concerned. Another important aspect of the provision on essential derivation is that no rights extend to essentially derived varieties if the initial variety is not protected. Thus, in figure 4, if variety "A" was not protected or if variety "A" is no longer protected (e.g., because of expiration of the period of protection, or cancellation or nullification of the plant breeders' rights), the authorization of Breeder 1 would no longer be required to be able to commercialize varieties "B", "C" and "Z".

Figure 3: Initial Variety protected and EDVs protected



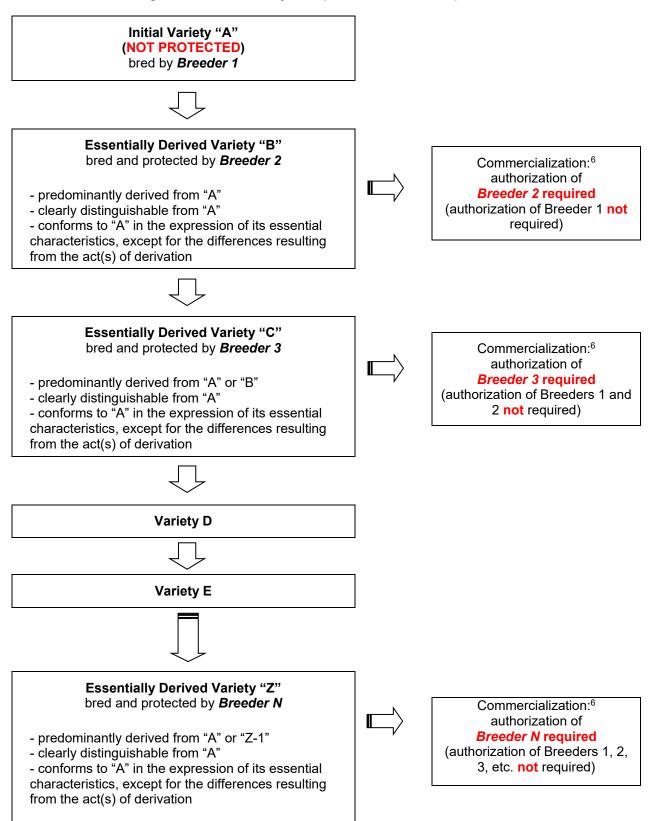
⁴ "Commercialization" encompasses the acts concerning a protected variety which require the authorization of the breeder according to Article 14(1) to (4) of the 1991 Act of the UPOV Convention.

Figure 4: Initial Variety protected and EDVs NOT protected



⁵ "Commercialization" encompasses the acts concerning a protected variety which require the authorization of the breeder according to Article 14(1) to (4) of the 1991 Act of the UPOV Convention.

Figure 5: Initial Variety NOT protected and EDVs protected



⁶ "Commercialization" encompasses the acts concerning a protected variety which require the authorization of the breeder according to Article 14(1) to (4) of the 1991 Act of the UPOV Convention.

(d) Territoriality of protection of initial varieties and essentially derived varieties

28. The scope of the breeder's right applies only to the territory of a member of the Union where the breeder's right has been granted and is in force. Therefore, the breeder of an initial variety only has rights in relation to an essentially derived variety if the initial variety is protected in the territory concerned. Furthermore, the breeder of an essentially derived variety only has rights in relation to that variety if it is protected in its own right in the territory concerned, or if the breeder of the essentially derived variety is also the breeder of the initial variety and the initial variety is protected in the territory concerned.

(e) Variety denomination of essentially derived varieties

29. An EDV is a variety and may require a variety denomination. Regardless of whether an EDV is protected in its own right or not, the denomination that is used for the variety should be in accordance with the Explanatory Notes on Variety Denominations under the UPOV Convention (document UPOV/EXN/DEN) and, in particular, should be different to the denomination of the initial variety.

(f) Transition from an earlier Act to the 1991 Act of the UPOV Convention

30. Members of the Union which amend their legislation in line with the 1991 Act of the UPOV Convention may choose to offer the benefits of the 1991 Act to varieties which were protected under an earlier law. Thus, it is possible for members of the Union to offer the scope of protection provided by Article 14(5) to varieties which were granted protection under an earlier law. However, it should be noted that the conferring of the new scope of rights on a previously protected initial variety could impose new requirements concerning the commercialization^{*} of essentially derived varieties, for which the breeder's authorization was not previously required.

31. One means of dealing with such a situation is the following: for varieties for which protection was granted under the earlier law and for which there is a remaining period of protection which falls under the new law, to limit the scope of rights on a protected initial variety to essentially derived varieties whose existence was not a matter of common knowledge at the time that the new law came into effect. With respect to varieties whose existence is a matter of common knowledge, the General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants (Document TG/1/3) explains the following:

"5.2.2 <u>Common Knowledge</u>

"5.2.2.1 Specific aspects which should be considered to establish common knowledge include, among others:

"(a) commercialization of propagating or harvested material of the variety, or publishing a detailed description;

"(b) the filing of an application for the grant of a breeder's right or for the entering of a variety in an official register of varieties, in any country, which is deemed to render that variety a matter of common knowledge from the date of the application, provided that the application leads to the grant of a breeder's right or to the entering of the variety in the official register of varieties, as the case may be;

"(c) existence of living plant material in publicly accessible plant collections.

"5.2.2.2 Common knowledge is not restricted to national or geographical borders."

[&]quot;Commercialization" encompasses the acts concerning a protected variety which require the authorization of the breeder according to Article 14(1) to (4) of the 1991 Act of the UPOV Convention.

SECTION II: ASSESSMENT OF ESSENTIALLY DERIVED VARIETIES

32. The purpose of this Section is to provide guidance on assessing whether a variety is essentially derived and not whether the variety meets the requirements for the grant of a breeder's right.

33. A decision on whether to grant protection to a variety does not take into account whether the variety is essentially derived or not: the variety will be protected if the conditions for protection as set out in Article 5 of the UPOV Convention are fulfilled (novelty, distinctness, uniformity, stability, variety denomination, compliance with formalities and payment of fees). If it is established that a variety is an essentially derived variety, the breeder of that essentially derived variety still has all rights conferred by the UPOV Convention. However, the breeder of the protected initial variety will *also* have rights in that variety irrespective of whether the essentially derived variety is protected or not.

34. With regard to establishing whether a variety is an EDV, the existence of a relationship of essential derivation between varieties is a matter for the titleholder of the breeder's right in the initial variety concerned. The titleholder of the initial variety may establish predominant derivation (e.g., evidence of genetic conformity with the initial variety by DNA-based genetic analysis) or conformity of the essential characteristics. These are both possible starting points in providing an indication that a variety might be essentially derived from the initial variety.

35. In some situations, relevant information provided by the breeder of the initial variety on predominant derivation and/or on conformity of the essential characteristics might be used as the basis for the breeder of the putative EDV to be required to prove that their variety is not essentially derived from the initial variety. For instance, the breeder of the putative EDV would need to provide information on the breeding history of their variety to prove it was not essentially derived from the initial variety.

36. The 1991 Act of the UPOV Convention does not prescribe or specify a role for the PBR authority to arbitrate and settle EDV-related matters. Therefore, the PBR authority is not required to manage and resolve EDV-related disputes, including when and how the titleholder of an initial variety asserts their right against commercialization of an EDV.

SECTION III: FACILITATING EDV UNDERSTANDING AND IMPLEMENTATION

37. The Council approved in 2020 the establishment and terms of reference for the Technical Working Party on Testing Methods and Techniques (TWM). The tasks of the TWM, as directed by the Technical Committee, include to "(i) Provide a forum for discussion on the use of biochemical and molecular techniques in the consideration of essential derivation and variety identification."

38. UPOV has established a section on its website (UPOV SYSTEM: Legal Resources: Jurisprudence: <u>http://www.upov.int/about/en/legal_resources/case_laws/index.html</u>) where case law relevant to plant breeders' rights, including case law concerning essentially derived varieties, is published. The Office of the Union welcomes the submission of summaries of recent decisions and/or, if possible, a direct link to the full text of the decision.

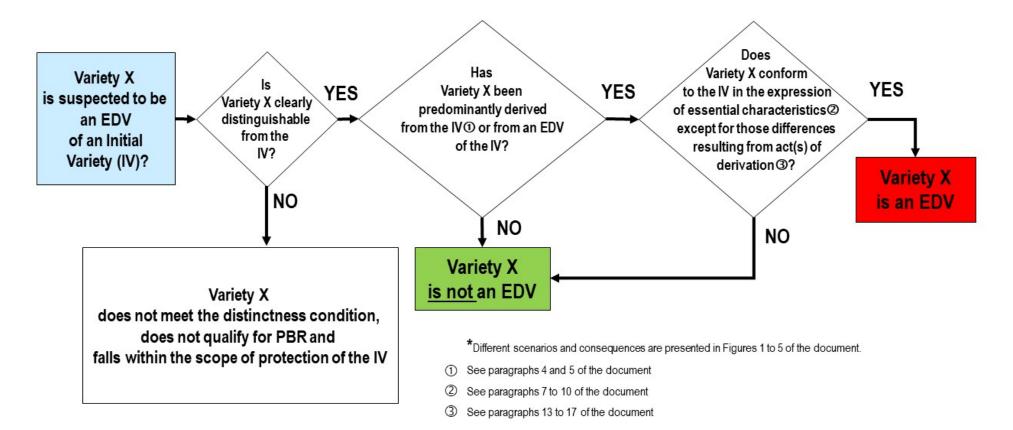
[Annex follows]

UPOV/EXN/EDV/3 Draft 3

ANNEX

SUMMARY FLOWCHART

When does a New Variety qualify as an EDV under the 1991 Act of the UPOV Convention?*



[End of Annex and of document]