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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 Working Group on Essentially Derived Varieties at its fourth meeting to be held, by electronic means, on October 19, 2021

and

the Administrative and Legal Committee at its seventy-eighth session to be held, by electronic means, on October 27, 2021

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#### Note for Draft version

Footnotes will be retained in published document.

Endnotes are background information when considering this draft and will not appear in the final, published document.

New proposals in reply to Circular E-21/110 of July 21, 2021 on document UPOV/EXN/EDV/3 Draft 1 are presented in boxes.

For reference purposes, document UPOV/EXN/EDV/3 Draft 2 "Marked version", which has been posted in the WG-EDV/4 and CAJ/78 webpages, presents the draft revision in the present document UPOV/EXN/EDV/3 Draft 2 to the text of document UPOV/EXN/EDV/2 as follows:

Strikethrough indicates deletion from the text of document UPOV/EXN/EDV/2, agreed by the WG-EDV, by correspondence, on September 1, 2021 (see Circular E-21/110 of July 21, 2021);

<u>Underlining</u> indicates insertion to the text of document UPOV/EXN/EDV/2, agreed by the WG-EDV, by correspondence, on September 1, 2021 (see Circular E-21/110 of July 21, 2021).

Comments of **October 19, 2021**, from **Morocco** with request for consideration by the WG-EDV/4 – posted and circulated to participants at WG-EDV/4 on October 19, 2021

Joint comments of September 30, 2021, from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA received in advance and posted on October 1, 2021

are reproduced in green boxes under the relevant paragraphs

#### **Contents**

| PREAMBLE   | 3        |
|--|----------|
| SECTION I: PROVISIONS OF ESSENTIALLY DERIVED VARIETIES   |          |
| (a) Relevant provisions of the 1991 Act of the UPOV Convention   | 4        |
| Predominantly derived from the initial variety (Article 14(5)(b)(i))   | 5        |
| Conformity in the expression of the essential characteristics of an EDV with its initial variety (Article 14(5)(b)(iii))       | 6        |
| Examples of methods by which an essentially derived variety may be obtained (Article 14(5)(c))  Direct and indirect derivation |          |
| (c) Scope of the breeder's right with respect to initial varieties and essentially derived varieties                           |          |
| (d) Territoriality of protection of initial varieties and essentially derived varieties  | 18<br>18 |
| BECTION II: ASSESSMENT OF ESSENTIALLY DERIVED VARIETIES  |          |
| SECTION III: OPTIONS FOR THE ENFORCEMENT OF BREEDERS' RIGHTS IN RELATION TO ESSENTIALLY DERIVED VARIETIES                      | 19       |
| SECTION IV: FACILITATING EDV UNDERSTANDING AND IMPLEMENTATION  | 20       |
|  |          |

ANNEX: Summary flowchart

#### **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. These Explanatory Notes 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 purpose of this guidance is to assist members of the Union and relevant stakeholders in their considerations in matters concerning essentially derived varieties. 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.

#### Proposal by APBREBES a

Paragraph 2 to be changed as follows: "<u>The purpose of Ft</u>hese Explanatory Notes <u>is to</u> provide guidance on 'Essentially Derived Varieties' under the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV Convention). <del>The purpose of this guidance is to assist members of the Union and relevant stakeholders in their considerations in matters concerning essentially derived varieties.</del> 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."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

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

3. These Explanatory Notes are divided into the following four sections: Section I Provisions of essentially derived varieties; Section II Assessment of essentially derived varieties; Section III Options for the enforcement of breeders' rights in relation to essentially derived varieties; and Section IV Facilitating EDV understanding and implementation.

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.<sup>2</sup> 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 breeding<sup>3</sup> 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.

<sup>2 &</sup>quot;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.

<sup>&</sup>quot;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 one or more genes or other heritable determinants and includes, but is not limited to, morphological, physiological, agronomic, industrial (e.g. oil characteristics) and/or biochemical characteristics.

#### Proposal by Mexico (original in Spanish) b

Paragraph 7 to be changed as follows: "An essential characteristic is a characteristic that results from the expression of one or more genes or other heritable determinants and includes, but is not limited to, morphological, physiological, agronomic, industrial (e.g. oil characteristics) and/or biochemical characteristics."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

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

8. An "essential characteristic" is a characteristic that is essential 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 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.

#### Proposal by Mexico (original in Spanish) c

Paragraph 8 to be changed as follows: An "essential characteristic" is a characteristic that is essential 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 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."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

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

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. A predominantly 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.<sup>d</sup>

#### Proposal by Mexico (original in Spanish) e

Paragraph 11 to be changed as follows: "A predominantly 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. An example is the modification of the color of a grain of white and yellow corn, whereby only the color of the grain is modified and the other morphological characteristics and of value of the initial variety remain unchanged."

#### Reply to the proposal by Mexico from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

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

#### Comment from Spain (original in Spanish) f

"Paragraphs 11 and 13. The phrase 'which may also include differences in essential characteristics' does not appear in Article 14(5)(b)(iii). It is, therefore, entirely interpretative and even inconsistent with Article 14(5)(b)(i). In a case such as the one indicated, where both the conditions under subparagraphs (i) and (ii) are met, and the difference resulting from the derivation is a characteristic such that it results in an essential characteristic, the variety should not automatically be considered as essentially derived, and each case should be reviewed on a case-by-case basis. Indeed, it contradicts what is stated in paragraph 34 to the effect that the titleholder of the initial variety must establish, by DNA-based genetic analysis, the conformity of the supposed EDV variety with the essential characteristics of the initial variety. That is not possible if the difference consists of a characteristic which is itself essential. Otherwise, one would be favoring classic plant breeding technologies and penalizing any technological advance that includes genomic technologies allowing mono-parental breeding. It is important to point out that rights are being granted for new plant varieties that can hardly be said to differ essentially from commonly known varieties. It would be all the more surprising if obstacles were to be placed in the way of granting rights for new varieties that do indeed possess unique essential characteristics in comparison with existing varieties. The meaning of the final wording of this explanatory note is crucial, as it could change the spirit of the Convention as drafted."

### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA on the comments from Spain on Paragraphs 11, 13, 14, 15, 17 and 20

"In general, we don't agree with the comments from Spain. We believe that the proposed revision of the current Explanatory Notes on EDV is critical to provide greater fairness and legal certainty for breeders, PBR owners, and developers of essentially derived varieties, such as gene-edited varieties, and to restore the balance between the owners of PBR and the owners of Patents, which are commonly used to protect gene-editing technologies and traits. Arguments are being made that the EDV Principle, which served to restore the scope and strength of a balanced PBR system, must now be ignored or weakened following the pressure of new technologies, such as gene editing. As a matter of fact, it would be totally in contradiction with the spirit that led to the introduction of the EDV concept in the UPOV Convention in 1991 to weaken the system of intellectual property rights granted to the breeder's community simply to serve the particular interests of those who have access to a new technology by permitting them to use predominantly the most elite varieties developed by others and commercialize the resulting varieties freely.

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

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

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

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

#### Reply from Morocco on the comments from Spain and Mexico on Paragraph 11

- "(A) Morocco agrees with the amended wording of paragraph 11 as proposed in Draft 2 of Document UPOV/EXN/EDV/3. In particular, the sentence 'which may also include differences in essential characteristics' needs to be kept.
- (B) We disagree with the amendment proposal from Spain, which, in our view, is based in a misinterpretation of Article 14(5)(b)(iii) of the 1991 UPOV Convention. According to this Article: (1) all differences which result from the act of derivation are clearly excluded from the comparison ('except for the differences which result from the act of derivation'); and (2) even in connection with those differences that do not result from the act of derivation (and thus can be taken into consideration), there is not a qualitative or quantitative limit as long as the new variety retains the essential characteristics of the initial one ('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'), which puts the focus in the retention of the essential characteristics, regardless of whether there may be differences in (essential or non-essential) characteristics.

The amendment proposed by Spain would entail a denial of the purposes of the 1991 UPOV Convention against free-riding practices that take undue advantage of well-known and successful varieties thanks to techniques such as induced mutagenesis.

- (C) We agree with Mexico's amendment proposal."
- 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.

#### Comment from Spain (original in Spanish) <sup>9</sup>

"Paragraphs 11 and 13. The phrase 'which may also include differences in essential characteristics' does not appear in Article 14(5)(b)(iii). It is, therefore, entirely interpretative and even inconsistent with Article 14(5)(b)(ii). In a case such as the one indicated, where both the conditions under subparagraphs (i) and (ii) are met, and the difference resulting from the derivation is a characteristic such that it results in an essential characteristic, the variety should not automatically be considered as essentially derived, and each case should be reviewed on a case-by-case basis. Indeed, it contradicts what is stated in paragraph 34 to the effect that the titleholder of the initial variety must establish, by DNA-based genetic analysis, the conformity of the supposed EDV variety with the essential characteristics of the initial variety. That is not possible if the difference consists of a characteristic which is itself essential. Otherwise, one would be favoring classic plant breeding technologies and penalizing any technological advance that includes genomic technologies allowing mono-parental breeding. It is important to point out that rights are being granted for new plant varieties that can hardly be said to differ essentially from commonly known varieties. It would be all the more surprising if obstacles were to be placed in the way of granting rights for new varieties that do indeed possess unique essential characteristics in comparison with existing varieties. The meaning of the final wording of this explanatory note is crucial, as it could change the spirit of the Convention as drafted."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

(same reply as the one reproduced under paragraph 11 for the comments of Spain)

#### Reply from Morocco on the comments from Spain on Paragraph 13

- "(A) For the same reasons explained above in connection with paragraph 11, we disagree with the amendment proposal from Spain. Indeed, during the discussions that led to the 1991 UPOV Convention the German delegation proposed to specify that an essentially derived variety should differ from the original one only in one or few characteristics. Such proposal was rejected, which makes it clear that the intent of the 1991 UPOV Convention was to not establish a limit on the number of differences between the original variety and the essentially derived one.
- (B) The comment of Spain according to which this revised version would put 'obstacles' to 'granting rights for new varieties that do indeed possess unique essential characteristics in comparison with existing varieties' is blatantly incorrect. An EDV can indeed be protected by plant variety rights. In fact, for being considered an EDV it is necessary that the variety in question meets the distinguishability requirement [as expressly stated in Article 14(5)(b)(ii): 'it is <u>clearly distinguishable</u> from the initial variety']. Otherwise, we would be talking about the same variety or a non-clearly distinguishable variety in the sense of Article 14(5)(a)(ii).
- (C) This is in line with what happens with other intellectual property rights, as it is the case of patent dependency. A new invention that meets the novelty, inventiveness and industrial application requirements may be patentable, but as long as its exploitation requires using a previous patent it will require the authorisation of the owner of the original patent. This same principle underlies the EDV concept under the 1991 UPOV Convention, as it is clear from the discussions held prior to its adoption.
- (D) In summary, the EDV concept is not conceived for cases of mere cosmetic changes (as Spain seems to suggest), since those would already be dealt with in Article 14(5)(a)(ii), but for cases of clearly distinct varieties (which may include differences in essential characteristics) that may be eligible for PVR protection."
- 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.

#### Comment from Spain (original in Spanish) h

"Paragraph 14. By this definition, only classic plant-breeding technologies would be taken into account. All available technologies are needed to meet the enormous challenges facing agriculture. Breeders cannot and should not be penalized for using the new technologies available to them. Let us recall the mission of UPOV, as set forth on its website: "To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society." The system must, therefore, promote the development of new varieties to meet the challenges facing society by encouraging new plant breeders with new techniques and ensuring that they may, in turn, take advantage of the UPOV system to make their varieties available to farmers."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

(same reply as the one reproduced under paragraph 11 for the comments of Spain)

#### Reply from Morocco on the comments from Spain on Paragraph 14

"The comments from Spain should be rejected. This paragraph is not penalizing new technologies. On the contrary, it aims to provide certainty on the EDV concept and to protect plant breeders from third parties that may benefit from original plant varieties to easily create new ones by simple acts of derivation. Again, this point is not disincentive to development (just like patent dependency is not a disincentive to technology improvement in other fields), but quite the opposite."

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.

#### Comment from Spain (original in Spanish) i

"Paragraph 15. Possible methods are included, but it should not be assumed that the end result will automatically be an EDV. Rather, results should be assessed on a case-by-case basis."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

(same reply as the one reproduced under paragraph 11 for the comments of Spain)

#### Reply from Morocco on the comments from Spain on Paragraphs 15 and 17

- "(A) The comment of Spain must be rejected and the wording of the draft has to remain unchanged. Mutations (whether induced or spontaneous) have always been acknowledge as a paradigmatic example of predominant derivation within the horticultural community.
- (B) In addition, paragraph 17 uses the term 'typically', which leaves sufficient room for those exceptional cases where even if this technique is being used, the result might not be an EDV."
- 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.

#### Proposal from Spain (original in Spanish) j

To delete paragraph 17.

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

(same reply as the one reproduced under paragraph 11 for the comments of Spain)

#### Reply from Morocco

(same reply as the one reproduced under paragraph 15 in relation to the comments of Spain)

#### 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.

#### Proposal from Spain (original in Spanish)k

"The last sentence of paragraph 20 reads 'Variety C is essentially derived from initial variety A, but is predominantly derived from variety B.' On the basis of that conclusion, the following tables should be amended as follows:"

Figures 2, 3, 4, 5, tables 3: predominantly derived from AB

Figures 2, 3, 4, 5, tables 6: predominantly derived from A Z-1

(proposed changes appear in [] in the relevant Figures/tables)

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

(same reply as the one reproduced under paragraph 11 for the comments of Spain)

#### Reply from Morocco on the comments from Spain on Paragraph 20

"The comments from Spain should be rejected."

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"

## Initial Variety "A" bred by Breeder 1

- not essentially derived from any other variety



#### **Essentially Derived Variety "B"**

bred by Breeder 2

- predominantly derived from "A"
- clearly distinguishable from "A"
- conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation

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

## **Initial Variety "A"** bred by *Breeder 1*

- not essentially derived from any other variety



#### **Essentially Derived Variety "B"**

bred by Breeder 2

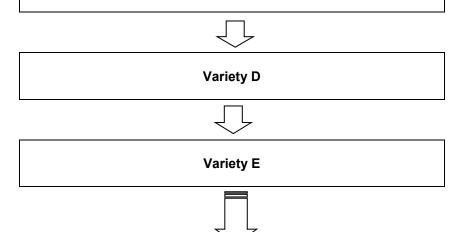
- predominantly derived from "A"
- clearly distinguishable from "A"
- conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation



#### **Essentially Derived Variety "C"**

bred by Breeder 3

- predominantly derived from "A" [A B]k
- clearly distinguishable from "A"
- conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation



### Essentially Derived Variety "Z" bred and protected by *Breeder N*

- predominantly derived from "A"[-A Z-1]k
- clearly distinguishable from "A"
- conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation

- 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 (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 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

### Initial Variety "A" (PROTECTED) bred and protected by Breeder 1 **Essentially Derived Variety "B"** bred and protected by Breeder 2 Commercialization:4 - predominantly derived from "A" authorization of - clearly distinguishable from "A" Breeders 1 and 2 required - conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation **Essentially Derived Variety "C"** bred and protected by Breeder 3 Commercialization:4 authorization of Breeders 1 and 3 required - predominantly derived from "A" [A B]k (authorization of Breeder 2 - clearly distinguishable from "A" not required) - conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation Variety D Variety E **Essentially Derived Variety "Z"** bred and protected by Breeder N Commercialization:4 authorization of - predominantly derived from "A" [-A Z-1]k **Breeders 1 and N** required - clearly distinguishable from "A" (authorization of Breeders 2, 3, - conforms to "A" in the expression of its essential etc. not required) characteristics, except for the differences resulting

from the act(s) of derivation

<sup>4 &</sup>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.

Figure 4: Initial Variety protected and EDVs NOT protected

### Initial Variety "A" (PROTECTED) bred and protected by Breeder 1 **Essentially Derived Variety "B"** bred by Breeder 2 but NOT protected Commercialization:<sup>5</sup> - predominantly derived from "A" authorization of - clearly distinguishable from "A" Breeder 1 required - conforms to "A" in the expression of its essential (authorization of Breeder 2 characteristics, except for the differences resulting not required) from the act(s) of derivation **Essentially Derived Variety "C"** bred by Breeder 3 but NOT protected Commercialization:5 authorization of Breeder 1 required - predominantly derived from "A" [A B]k (authorization of Breeders 2, 3 - clearly distinguishable from "A" not required) - conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation Variety D Variety E **Essentially Derived Variety "Z"** bred by Breeder N but NOT protected Commercialization:5 authorization of - predominantly derived from "A" [-A Z-1]k Breeder 1 required - clearly distinguishable from "A" (authorization of Breeders 2, 3, - conforms to "A" in the expression of its essential N etc. not required) characteristics, except for the differences resulting

from the act(s) of derivation

<sup>&</sup>lt;sup>5</sup> "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

**Initial Variety "A"** (NOT PROTECTED) bred by Breeder 1 **Essentially Derived Variety "B"** bred and protected by Breeder 2 Commercialization:6 authorization of Breeder 2 required - predominantly derived from "A" (authorization of Breeder 1 not - clearly distinguishable from "A" required) - conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation **Essentially Derived Variety "C"** bred and protected by Breeder 3 Commercialization:6 authorization of Breeder 3 required - predominantly derived from "A" [A B]k (authorization of Breeders 1 and - clearly distinguishable from "A"
- conforms to "A" in the expression of its essential 2 **not** required) characteristics, except for the differences resulting from the act(s) of derivation Variety D Variety E **Essentially Derived Variety "Z"** bred and protected by Breeder N Commercialization:6 authorization of **Breeder N** required - predominantly derived from "A" [-A Z-1]k - clearly distinguishable from "A" (authorization of Breeders 1, 2, 3, etc. not required) - conforms to "A" in the expression of its essential characteristics, except for the differences resulting from the act(s) of derivation

<sup>&</sup>lt;sup>6</sup> "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 variety denomination shall not be identical 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."

<sup>&</sup>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

#### Proposal by APBREBES I

"Section II of the draft Explanatory Note on Essentially Derived Varieties under the 1991 Act of the UPOV Convention should not be changed. The version adopted by the Council on April 6, 2017 should be retained."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

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

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

- 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. It is a matter for the titleholder of the initial variety to evaluate new varieties commercialized by others and to determine if a new variety may have been essentially derived from their initial variety(ies). Independent experts may be consulted in the process to establish whether a variety is or is not essentially derived from another variety. Such independent experts may exist in plant related institutes, laboratories, etc.. The institutions that provide services for alternative dispute settlement mechanisms relevant for breeders' rights (see document UPOV/INF/21 "Alternative Dispute Settlement Mechanisms", Section II Information on Alternative Dispute Settlement Mechanisms for Breeders' Rights) may be a source of information on such independent experts.

SECTION III: OPTIONS FOR THE ENFORCEMENT OF BREEDERS' RIGHTS IN RELATION TO ESSENTIALLY DERIVED VARIETIES

#### Proposal by APBREBES <sup>m</sup>

"Section III of the draft Explanatory Note on Essentially Derived Varieties under the 1991 Act of the UPOV Convention should be deleted. Any advice to titleholders on how to enforce their rights should be excluded from the Explanatory Note."

#### Reply from ISF, CIOPORA, CropLife International, Euroseeds, APSA, AFSTA, and SAA

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

That is why the current draft of revised Explanatory Notes on EDV is so important. The mandate and terms of reference for the WG-EDV from the CAJ were very clear on the need to address a number of policy issues and issues relating to breeders' practices through the revision of the Explanatory Notes on EDV. This Section III added to the Explanatory Notes is directly on point."

- 36. 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 reversal of the burden of proof. In such situations, the breeder of the putative EDV should 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.
- 37. The titleholder of the initial variety (IV) has several options available to assert their right against the breeder of an EDV. If the titleholder believes a new variety is predominantly derived from their variety, the IV titleholder may inform the putative EDV owner that there is a strong indication of essential derivation and whether a commercial license is required and available. If the parties are not able to reach agreement, the IV titleholder may choose to pursue one or more of the following options:
  - (a) The IV titleholder may seek to prove the new variety's EDV status by undertaking a formal review and decision with an independent technical panel using a framework and criteria established by breeders' organizations;
  - (b) The IV titleholder and the EDV owner may agree to submit the matter to mediation and/or arbitration to resolve any dispute (see document UPOV/INF/21 "Alternative Dispute Settlement Mechanisms");
  - (c) The IV titleholder may take relevant actions before the competent tribunal to enforce their rights. (see document UPOV/EXN/ENF "Explanatory Notes on the Enforcement of Breeders' Rights under the UPOV Convention").
- 38. 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 IV: FACILITATING EDV UNDERSTANDING AND IMPLEMENTATION

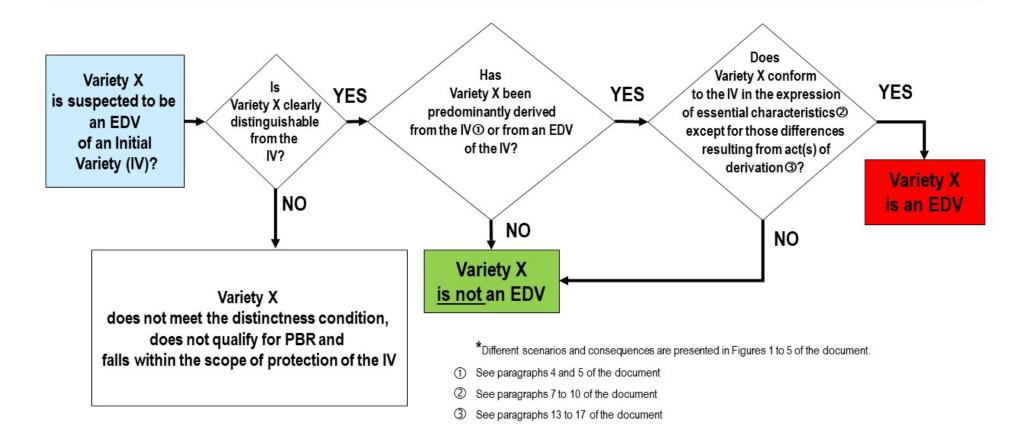
- 39. The Council approved in 2020 the establishment and terms of reference for the Technical Working Party on Testing Methods and Techniques (TWM). The tasks of the TWM, as directed by the Technical Committee, include to "(i) Provide a forum for discussion on the use of biochemical and molecular techniques in the consideration of essential derivation and variety identification."
- 40. UPOV has established a section on its website (UPOV SYSTEM: Legal Resources: Jurisprudence: <a href="http://www.upov.int/about/en/legal\_resources/case\_laws/index.html">http://www.upov.int/about/en/legal\_resources/case\_laws/index.html</a>) 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.

[Appendix follows]

#### **APPENDIX**

#### SUMMARY FLOWCHART

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



#### UPOV/EXN/EDV/3 Draft 2

#### **ENDNOTES**

- <sup>e</sup> The comments from Mexico are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix II.
- <sup>f</sup> The comments from Spain are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix III.
- <sup>g</sup> The comments from Spain are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix III.
- <sup>h</sup> The comments from Spain are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix III.
- <sup>1</sup> The comments from Spain are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix III.
- <sup>j</sup> The comments from Spain are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix III.
- <sup>k</sup> The comments from Spain are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix III.
- <sup>1</sup> The comments from APBREBES are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix IV.
- <sup>m</sup> The comments from APBREBES are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix IV.

<sup>&</sup>lt;sup>a</sup> The comments from APBREBES are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix IV.

<sup>&</sup>lt;sup>b</sup> This proposal from Mexico for the Spanish version affects also the other language versions. The comments from Mexico are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix II.

<sup>&</sup>lt;sup>c</sup> This proposal from Mexico for the Spanish version affects also the other language versions. The comments from Mexico are reproduced in document UPOV/WG-EDV/4/2, Annex, Appendix II.

<sup>&</sup>lt;sup>d</sup> The WG-EDV, at its third meeting, agreed that the Office of the Union should invite the WG-EDV to provide examples to be included, if appropriate, in the revision of paragraph 11 of document UPOV/WG-EDV/3/2, Annex I (see document UPOV/WG-EDV/3/3 "Report", paragraph 17). An invitation to provide examples on paragraph 11 of document UPOV/EXN/EDV/3 Draft 1 was included in Circular E-21/110 inviting the WG-EDV to consider document UPOV/EXN/EDV/3 Draft 1. The comments from ISF, CIOPORA, CropLife International, APSA, SAA, AFSTA and Euroseeds contain also examples to help the understanding of the proposed revision of the Explanatory Note on Essentially Derived Varieties but are not included in the revision of document UPOV/EXN/EDV/3 Draft 1 (see Annex, Appendix V to document UPOV/WG-EDV/4/2).