













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

10 August 2020

Contribution in response to UPOV Circular E-20/093

Dear Mr. Button,

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

Following your request expressed in Circular E-20/093, we would like to provide you with our comments on the Terms of Reference for WG-EDV, expression of interest and EDV issues and practices.

 <u>Draft Terms of Reference of the Working Group on Essentially Derived Varieties</u> (WG-EDV) – Annex II

We are very pleased to see the intent of the Terms of Reference of this new WG. The only proposal we have is to add an indicative timeline to better prepare Parties and Observers to the work schedule.

2) Expression of interest

We thank you for giving the opportunity to observers to be part of the WG-EDV. The following persons would like to be part of the WG-EDV:

- Mr Edgar Krieger CIOPORA
- Mr Jan de Riek CIOPORA
- Mrs Wendy Cashmore CIOPORA

- Mr Marcel Bruins CropLife International
- Mrs Szonja Csörgő Euroseeds
- Mrs Judith de Roos Euroseeds
- Mrs May Chodchoey APSA
- Mrs Hélène Khan Niazi ISF
- Mrs Magali Pla ISF
- Mr Jean Donnenwirth ISF
- Mr John Duesing ISF
- Mr Stevan Madjarac SAA
- Mr Diego Risso SAA

3) Comments on the issues – Annex III

We are pleased to communicate to you our comments on the preliminary analysis on the issues related to EDV practices and policies, which accompany this letter. We have also proposed a classification of these issues depending on their importance for the consideration of the future WG-EDV.

Moreover, we would like to highlight some points from our contribution which were not present in the preliminary analysis but we still prefer to be discussed by the WG-EDV.

a) Variety denomination of an unprotected EDV

The next version of the EXN would benefit from the inclusion of guidance on the variety denomination for an unprotected EDV. An EDV is a separate variety and distinct from its Initial Variety, so that it must not have the same variety denomination as its Initial Variety. In case of a protected EDV there is a logical consequence of the procedure to register the name of the EDV once it has passed the DUS-test. In case of an unprotected EDV there is no automatic check by the PVP authority, but they might be asked to confirm that the EDV is not the same as the initial variety and therefore cannot have the same denomination.

b) Non protection of the EDV

If the EDV is not protected there is no automatic check by the PVP authority to confirm that the EDV is distinct from the initial variety, but on request they might be asked to confirm that the EDV is not the same as the initial variety.

We would like to take this opportunity to reiterate the important conclusions from the survey we conducted:

- 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;
- 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.

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

Michael Keller ISF Secretary General Dr. Edgar Krieger CIOPORA Secretary General Giulia di Tommaso President & CEO Crop Life International

Gulia D' Commano

Szonja Csörgő Euroseeds IP Director

Kanokwan Chodchoey APSA Executive Director

Justin Rakotoarisona AFSTA Secretary General Diego Risso SAA Executive Director

Comments on Appendix III

PRELIMINARY ANALYSIS OF EDV ISSUES

PREAMBLE:

Issue 1	to consider if the reference to the "Resolution on Article 14(5)" of the 1991	RU
	Diplomatic Conference is necessary	

Response:

The EDV Task Force has no position on this issue.

Issue 2	to consider reviewing and reducing the text in the Preamble to avoid	RU
	repetitions	

Response:

The EDV Task Force has no position on this issue.

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	RU
	Act and those in the footnote (page 4).	1

Response:

The EDV Task Force has no position on this issue.

	Issue 4	to consider not to divide relevant provisions on EDVs in subsections (a) and (b)	RU
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Response:

The EDV Task Force has no position on this issue.

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
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Response:

This issue should be removed from consideration by the WG-EDV.

This Issue regarding "effectiveness of the EDV provision" must be considered and addressed by the WG-EDV.

Issue 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 de-crease 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 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 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

Response:

These three related issues require more clarity and guidance in the revised EXN. They should be considered and addressed by the WG-EDV.

a) Defining an EDV

Issue 9	to consider the inclusion of plant breeding innovations such as genome editing in the [definition of EDV]/[EDV concept]	ZA
Issue 23	to consider explaining the term 'induced mutant' in relation to the "techniques of genome editing"	SE
Issue 28	to consider if the breeding method used should not have an impact on the EDV concept	ZA
Issue 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 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 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	
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Issues 9, 23, 28, 31, 32 & 33 all relate to breeding methods for varietal improvement. These are high priority issues and must be considered and addressed by the WG-EDV.

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
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Response:

This issue should be removed. It will be addressed effectively when the WG-EDV considers and addresses the high priority issues #9, 23, 28, 31, 32 and 33.

• Predominantly derived from the initial variety

Issue 12	to clarify the terms in Article 14(5)(b)(i) concerning "while retaining the	EU
	expression of the essential characteristics that results from the genotype	
	and combination of genotypes"	

Response:

This is a high priority issue and must be considered and addressed by the WG-EDV.

Issue 13	to clarify the explanations in paragraphs 4 and 5	RU	ĺ
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Response:

This issue should be considered and addressed by the WG-EDV. It would be beneficial to consider alignment of language in paragraphs 4 and 5.

Issue 14	to clarify the notion of essential characteristics and how they relate or not to DUS characteristics (see paragraph 6)	RU, ZA
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Response:

We recommend there is no need to further clarify paragraph 6(iv) of the current EDV EXN. The EXN cannot be so specific as to include elements for each crop. This is a high priority issue and must be considered and addressed by the WG-EDV.

• Clearly distinguishable from the initial variety

Issue 15	to clarify the notion of "clearly distinguishable" in Article 14(5)(b)(ii) and	SE, RU
	to consider if the reference to Article 14(5)(a)(ii) in paragraph 7 is	
	relevant	

Response:

This issue should be considered and addressed by the WG-EDV because paragraph 7 needs to be clarified.

• Conformity with the initial variety in the expression of the essential characteristics

Issue 16	to determine how many differences and how important such differences	EU, ZA
	are necessary for an EDV to conform "essentially" with the initial variety	

Response:

This is a high priority issue and must be considered and addressed by the WG-EDV.

Issue 17	to consider removing the sentence "differences should be one or very few"	EU
	in paragraph 10	

Response:

This issue is a high priority and should be considered and addressed by the WG-EDV. It would be beneficial to consider alignment of language in paragraphs 10 & 11.

Issue 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	ZA
	from the act of derivation	

Response:

This is a high priority issue and must be considered and addressed by the WG-EDV.

Issue 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
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Response:

This issue should be considered and addressed by the WG-EDV.

Issue 20	to review the explanations in paragraphs 8 to 11 to provide clear	RU
	guidance concerning the provisions in Article 14(5)(b)(iii)	

Response:

This issue should be considered and addressed by the WG-EDV.

Issue 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
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This issue should be considered and addressed by the WG-EDV.

Issue 22	to consider how to clarify the following "Respondents see that the EDV	Joint
	concept provided by UPOV is a way to solve disputes upfront between	contribution
	breeders. However, the latest UPOV Explanatory Notes on EDV (2017)	by breeders
	created confusion among the breeders, particularly if that would mean	& AIPH
	that mutants of protected initial varieties are no longer seen as EDVs."	

Response:

This issue regarding the EDV concept is a high priority and must be considered and addressed by the WG-EDV to resolve confusion.

Issue 23 Note: see the grouping under issue 9 on page 5

• Examples on ways in which an EDV may be obtained

1	ssue 24	to review the need to keep the text of Article 14(5)(c), in paragraph 12, as it	RU
		is already included in Section I (a)	

Response:

The EDV Task Force has no position on this issue.

Issue 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	RU
	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.	

Response:

The EDV Task Force has no position on this issue.

Method of breeding

Issue 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	DE
	retains the expression of the essential characteristics that result from the genotype of the initial variety."	

Response:

This issue should be considered and addressed by the WG-EDV.

Issue 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	
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This issue should be considered and addressed by the WG-EDV.

Issue 28 Note: see the grouping under issue 9 on page 5

Issue 29	to consider the need to clarify the contents of paragraphs 14 and 15 to	RU
	facilitate the EDV determination process	

Response:

This issue should be considered and addressed by the WG-EDV.

Issue 30	to consider the following proposals in relation to mutants: (a) in the majority of	EU
	cases mutants are EDVs; (b) Mutants are always predominantly derived; (c)	
	the mutant is completely derived from the initial variety.	

Response:

This issue should be considered and addressed by the WG-EDV.

Issue 31 Note: see the grouping under issue 9 on page 5

Issue 32 Note: see the grouping under issue 9 on page 5

Issue 33 Note: see the grouping under issue 9 on page 5

Issue 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	
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Response:

This issue should be removed from WG-EDV consideration. The two terms are included in the 1991 Act solely as examples of methods used to develop improved plant varieties that may lead to an essentially derived variety. A more elaborated explanation of the two terms is unnecessary and would be irrelevant.

• Direct and indirect derivation

Issue 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

Response:

This issue should be removed from WG-EDV consideration as the proposal is not correct.

Issue 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 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
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This issue would add confusion to the scheme and should be removed from WG-EDV consideration.

Issue 37	to review paragraphs 17, 18 and 19 in order to avoid repetitions	RU
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Response:

This issue should be considered and addressed by the WG-EDV.

b) Scope of the breeder's right with respect to initial varieties and EDV

Issue 38	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.	RU
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Response:

This issue seems to go beyond the scope of the 1991 Act. This issue should be removed from consideration by the WG-EDV.

to consider whether information about the origin of the variety be specified in the application form and not be considered a commercial secret	RU
application form and not be considered a confinercial secret	

Response:

This issue is not related to EDV and should not be addressed by the WG-EDV in the revision of the Explanatory Notes. This issue should be removed.

Issue 40	(a)	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.	ZA
	(b)	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,	
	(c)	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.	

This topic is outside the scope of the Convention and should not be addressed by the WG-EDV in the revision of the EXN. This issue should be removed.

Issue 41	to consider whether UPOV and UPOV members should develop regulations	RU
	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).	

Response:

We don't see a need for this issue to be addressed by the WG-EDV in the revision of the EXN. This issue should be removed.

Issue 42	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	RU

Response:

We don't see a need for this issue to be addressed by the WG-EDV in the revision of the EXN. This issue should be removed.

c) Territoriality of protection of initial varieties and EDV

Issue 43	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	RU
	right of the initial variety applies should be the same for the initial variety and the EDV.	

Response:

We don't see the need for this clarification. This issue should be removed from consideration by the WG-EDV.

Issue 44	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".	RU
	variety in the protection territory of the initial variety.	

Response:

This issue should be considered and addressed by the WG-EDV.

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

Issue 45	to consider whether paragraph [25], should be amended as follows:	RU
	"Members of the Union which amend their legislation in line with the 1991 Act of the UPOV Convention should cover extension of the provisions of Article 14(5) to the generally known varieties"	
	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.	

This issue should be considered and addressed by the WG-EDV, but we request further clarification on the need and purpose of the proposed text.

Issue 46	to consider removing paragraph [26]	RU
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Response:

We don't agree to remove this paragraph. This issue should be removed from WG-EDV consideration.

SECTION II: ASSESSMENT OF EDV

Issue 47	to consider whether predominant derivation from an initial variety, confirmed by	EU
	a high genotypic conformity, could be a key requirement for determining EDV.	

Response:

This issue is a high priority and must be considered and addressed by the WG-EDV.

Issue 48	to explore the role of DNA analysis for determining, with genetic thresholds,	EU
	the requirement of "predominantly derived".	

Response:

This issue is a high priority and must be considered and addressed by the WG-EDV.

Issue 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
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Response:

This issue should be considered and addressed by the WG-EDV.

Issue 50	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:	EU
	(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.	

This issue is a high priority and must be considered and addressed by the WG-EDV.

Issue 51	to consider the following on the role of the position papers, for some species, developed by the industry:	EU
	 (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.	

Response:

Addressing this issue in the revised EXN would provide important support for what industry has done and is developing to provide appropriate solutions. This issue should be considered and addressed by the WG-EDV.

Issue 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

Response:

This issue should be considered and addressed by the WG-EDV.

Issue 53	to consider whether:	RU
	(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.	

Response:

This proposal goes beyond what an EXN can recommend to UPOV members. This issue should be removed from consideration by the WG-EDV.

Issue 54	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."	ZA
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This is a complaint rather than an issue. The substance of this complaint will be addressed by the WG-EDV as it handles related issues included in this compilation. This issue should be removed from consideration.

Issue 55	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.	ZA
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Response:

This issue seeks to revise conditions of international (WIPO) and national law. It is outside the scope of the revised EXN and should be removed from WG-EDV consideration.

Issue 56	to consider whether to replace Section II by the following new Section II	RU
	"Section II "Registration of protected initial variety's rights' extension to essentially derived varieties"	
	"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.	
	"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.	
	"Comments on the application materials submitted within six months after the publication are to be agreed with stakeholders.	
	"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.	
	"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.	
	"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."	

The proposal represented in this issue goes beyond the scope of Explanatory Notes for the 1991 Act of UPOV Convention. This issue should be removed from WG-EDV consideration.

Issue 57	to consider if the "initiatives from the private sector, valuing the work of breeders," should be encouraged and further developed (see issue 51	Joint contribution
	above)	by breeders

Response:

This issue is a high priority and must be considered and addressed by the WG-EDV.

Issue 58	to consider "the interest of the alternative dispute resolutions put in place by trade associations."	Joint contribution
		by breeders

Response:

This issue is a high priority and must be considered and addressed by the WG-EDV