Plant Variety Rights Act 1987 review: Options Paper

Name	Wandy Cashyanya
Name	Wendy Cashmore,
Email	Wendy.cashmore@plantandfood.co.nz
Organisation/Iwi	The New Zealand Institute for Plant and Food Research Limited a Crown Research Institute established under the Crown Research Institutes Act 1992 120 Mt Albert Road, Sandringham, Auckland 1025, New Zealand Plant breeder/developer, licensee and licensor, supporter of Wai262 recommendations, with a strong vested interest in the continuing success of growers, supply chain entities, marketers and other developers of economic value leveraging innovation including through proprietary plant varieties.
The Privacy Act 1993 applies to submissions. Please check the box if you do <u>not</u> wish your name or other personal information to be included in any information about submissions that MBIE may publish.	
MBIE intends to upload submissions received to MBIE's website at www.mbie.govt.nz . If you do not want your submission to be placed on our website, please check the box and type an explanation below. I do not want my submission placed on MBIE's website because [Insert text]	
Please check if your submission contains confidential information:	
I would like my submission (or identified parts of my submission) to be kept confidential, and have stated my reasons and grounds under the Official Information Act that I believe apply, for consideration by MBIE.	

Preface

In preparing this submission we have consulted with stakeholders domestically and internationally, including advisors with whom we have a direct relationship such as CIOPORA (the International Association of Breeders of Asexually Reproduced Horticultural Varieties), and the law firm specialising in intellectual property law, AJ Park, who represent us on a number of matters. As a result of those interactions we have been able to inform our submission with a diversity of experiences and viewpoints.

In that context, before responding to the full set of questions The Ministry of Business, Innovation and Employment (MBIE) seeks in this submission on the options for changes to the Plant Variety Rights Act, we respectfully draw your attention to the "General Comments" provided in the independent submission made by AJ Park. These are provided below for your reference.

"General comments

As an initial point, we would like to comment on the 'social contract' aspect of PVRs. The options paper implies that the social contract involves a monopoly being granted in exchange for immediate access to plant material. This is not the bargain that applies to other IP rights such as patents or designs. For those IP rights, the inventor is given a limited monopoly period in exchange for making

the information about their invention or design public. The availability of that information allows others to build on that knowledge and develop further innovations. When the monopoly period is over, the invention or design becomes available for general use. When a PVR is granted, IPONZ publishes a variety description providing information about the innovative features of the plant. The breeder's exemption allows other parties to use this information to develop new varieties. We submit that this fulfils the social contract for PVRs and the PVR owner is not required to give the public immediate access to plant material.

The options paper also seems to be underpinned by an expectation that the owner of a PVR can enter into a licence agreement or other contract that is exempt from certain competition law provisions. For example, that a PVR owner is free to include provisions restricting the use of harvested material. However, MBIE has proposed amending the Commerce Act to remove the IP exception provisions, see https://www.mbie.govt.nz/have-your-say/review-of-section-36-of-the-commerce-act-and-othermatters/. Australia has recently repealed their equivalent provisions and it is likely that New Zealand will follow suit. Therefore, it is inaccurate to assess the proposed options on the basis that contracts between parties will be a suitable alternative to legislative provisions."

It is our strong view that the matters covered in this content are highly relevant to the further development of the NZ PVRA beyond this Options stage. We fully support the positon put forward by AJ Park on the applicable nature of the "social contract" in this legislation and that it is inaccurate to assume that contractual measures would be a suitable alternative to manage provisions that are not provided for in the legislation - for example, control of harvested material.

Objectives of the PVR Act

Do you have any further comment to make on the objectives of the PVR Act?

We support the recommendation that the word 'dissemination' be replaced with 'use' in objective (a). The revised objective would be as follows:

to promote innovation and economic growth by incentivising the development and use of new plant varieties while providing an appropriate balance between the interests of plant breeders, growers and society as a whole;

We still support further clarification of the definition of 'appropriate balance' in the context of this objective.

We support the movement from "Treaty consistency" to "Treaty compliance" and look for alignment to other international instruments as well e.g. Nagoya Protocol, CBD

With the above considerations taken into account, we consider the objectives sufficiently clear. Our rationale for this support is underpinned by a strong belief that a well-articulated, transparent, enforceable, and accessible PVR regime is a valuable and essential component of a modern, fit for purpose commercial operating environment in an innovation-driven economy such as New Zealand.

Meeting our CPTPP obligations

Do you agree with our analysis and conclusion of the CPTPP options? If not, why not?

We disagree with the conclusion that Option 2 (giving effect to UPOV 1991) is the optimal/only option because we are not convinced that Treaty of Waitangi compliance and acceding to UPOV 1991 are mutually exclusive. We maintain that there are very significant benefits for New Zealand to be gained by New Zealand being seen to accede to UPOV 1991; for example, a primary consideration for users of Plant Breeders Rights legislation internationally when developing varieties is the relevant intellectual property legislation available in each territory. Those users tend to give priority to countries that are signatories to the UPOV 1991 Convention as they believe this demonstrates that country's commitment to supporting modern Plant Breeders Rights or Plant Variety Rights legislation.

Paragraph 43 of the Options Paper acknowledges that acceding to UPOV 1991 could be Treaty of Waitangi compliant and we believe it is important that Government address the necessary policy development to achieve this. We welcome and are encouraged by the whole of government approach announced 30 August 2019 to Waitangi Tribunal claim 262.

Further:

Article 5(2) of UPOV 1991 provides that "the grant of the breeder's right shall not be subject to any further or different conditions" than listed criteria of newness; distinctness; uniformity; stability.

Some clues as to how New Zealand might reconcile the twin objectives of accession to UPOV 1991 and complying with the Treaty of Waitangi emerge from the following:

- 1) "Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)", adopted at UPOV's thirty-seventh ordinary session on October 23, 2003 acknowledges that considerations consistent with the CBD (of which New Zealand is a signatory), such as declarations that the genetic parental material has been lawfully obtained, can exist side-by-side with UPOV 1991 provided that they do not form an additional criterion for grant, but that they should be the subject of separate legislation, "since the legislation on access to genetic material and the legislation dealing with the grant of breeders' rights pursue different objectives, have different scopes of application and require a different administrative structure to monitor their implementation, UPOV considers that it is appropriate to include them in different legislation, although such legislation should be compatible and mutually supportive".
- 2) The subsequent Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (of which New Zealand is not a signatory) establishes mechanisms for access to genetic resources and the fair and equitable sharing of the benefits derived from the use thereof, including the traditional knowledge associated with those genetic resources.

Whilst the Nagoya Protocol is structured to operate on a country-to-country basis, it could be mirrored within a domestic setting: requiring that prior informed consent from the relevant kaitiaki be obtained before utilising taonga species or mātauranga Māori, and requiring a benefit sharing arrangement to be in place before such use. As separate piece of domestic legislation could thus be enacted to broadly define the rights of Māori as tangata whenua in respect of taonga species and mātauranga Māori, which would thus facilitate New Zealand's accession to UPOV 1991, so long as it did not create an additional condition to the grant of PVRs under the PVR Act. If informed consent and benefit sharing would already have had to be established in respect of any taonga species used as a breeding parent or mātauranga Māori used to inform that breeding,

3

4

Treaty compliance – criteria for analysis

Do you agree with the criteria that we have identified? Do you agree with the weighting we have given the criteria? If not, why not?

We agree with the criteria identified. We believe the weighting of each of the criteria would be equal when indigenous property rights are meaningfully addressed within the wider policy framework that Government is addressing.

Treaty compliance - key terms

Do you agree with our proposed approach to these key terms?

Do you have any comments on the principles listed above and how they might apply in practice? For example, would it be useful to specifically list non-indigenous species of significance?

We think it would be useful to give a clearer definition of indigenous and non-indigenous species of significance for Māori. This would give all interested parties more certainty about whether the new requirements around Treaty compliance apply to breeding programmes from inception and throughout the variety development process. We were engaged in and supportive of the open discussion in the hui convened by MBIE in early August 2019 that a possible role of an advisory committee is facilitation of the kaitiaki relationship so each party whether a breeder/entity/iwi/hapu has access to a body of knowledge - and a useful/valuable and live registry comes to pass. This will be a relevant, accessible, and valuable resource for users of the system whether they be domestic or international.

Treaty compliance – options analysis

Do you agree with the proposed options? Are there alternatives we have missed?

Do you agree with our analysis and conclusions? If not, why not?

The options paper acknowledges that the working party's preferred option is more uncertain than the status quo for breeders. We submit that all of the options presented in the paper create uncertainty for all stakeholders in their current form and further work is required. Greater clarity in this decision making process could be achieved if there was an overarching indigenous property right to which the PVRA referred for governance. As acknowledged in 2 we welcome and are encouraged by the whole of government approach announced 30 August 2019 to Waitangi Tribunal claim 262.

Pre-grant consideration only of Treaty compliance would be our preferred option contingent upon:

- Clarity on the genera and species in which a kaitiaki interest exists;
- The possibility of a PVR grant being available to a new variety of any species with refusal only contemplated in those instances where, despite the parties best endeavours, a kaitiaki interest cannot be protected in a meaningful and mana enhancing way;
- Compliance with UPOV 1991. Our position is that adoption of PVRA provisions
 that would not enable New Zealand to accede to UPOV 1991 would also result in
 New Zealand no longer being compliant with UPOV 1978 to which it is a
 signatory. This could be problematic to TRIPS compliance.
- The Māori/Kaitiaki Committee being sufficiently resourced to successfully implement the requirements of the legislative changes.

UPOV 91 alignment - criteria for analysis

Do you have any comment to make about our approach to, and criteria for, the preliminary options analysis in this paper?

In general, it concerns us that MBIE appear to be opting for the lowest level of protection within the framework of the UPOV 1991 Act. We note the opportunity the UPOV framework provides for flexibility for development of domestic legislation – but suggest that in the Options presented MBIE is failing to take a customised *leadership* position to develop legislation that will be resilient, enduring, and relevant as the industry it serves grows in value and importance for New Zealand even beyond its current value.

To better develop alignment with UPOV 1991 <u>and</u> to reflect modern commercial practice we believe further development of the concept and extent of public availability of propagating material and harvested material is warranted. Many new plant varieties are of course intended to be planted in home gardens by the general public. The greater value for New Zealand (as acknowledged by the authors of the Sapere Research Group report) is however delivered by those varieties that are made available to professional growers for the purpose of producing harvested material and products for consumers. Availability of that harvested material and further processed product to the general public should be considered sufficient to meet the social contract of supply to the market implicit in the grant of PVR for those varieties. Modern production and marketing programmes that match production to market demand are a key success factor for New Zealand's fruit industries; instrumental in minimising food waste and avoiding the traditional boom-bust cycle of over-planting leading to unsustainable production economics for those productive sectors. Requiring that propagating material be available to the general public fundamentally undermines that approach.

Specifically, in respect of the criteria around compulsory licences we believe these provisions warrant a more fundamental revision than simply proposing unspecified amendments to the "grace period" and the provisions of 21(3). Further we note that the references in paragraphs 138b and 144 of the Options Paper are not a balanced representation of the purpose of compulsory licensing provisions. References to unspecified "unfair practices" and "behaviours" are made without evidence or examples and appear blind to the countervailing issue of those provisions being utilised by opportunists seeking to obtain benefit from other parties' investment in the development and deployment of innovative intellectual property.

Again we note the willingness of the Vice Secretary-General of UPOV, Mr. Peter Button, to provide assistance (as noted in section 2) in exploring options on how the UPOV Convention and the Treaty of Waitangi could be implemented in a mutually supportive manner. Therefore we submit that depth of experience and knowledge is readily available to MBIE to fully align the New Zealand domestic legislation with the UPOV 1991 framework, and there is no bar to going further than the minimum compliance options considered by MBIE to date.

Definitions – breed

Our preferred option is to incorporate the definition of "breed" that was considered in the previous review to address concerns around discovery of varieties in the wild.

Do you agree? If not, why not?

We support the approach set out in UPOV 1991 "With regard to "discovered and developed", a discovery might be the initial step in the process of breeding a new variety. However, the term "discovered and developed" means that a mere discovery, or find, would not entitle the person to obtain a breeder's right. Development of plant material into a variety is necessary for a breeder to be entitled to obtain a breeder's right. A person would not be entitled to protection of an existing variety that was discovered and propagated unchanged by that person."

8 Definitions – general

Do you have any comments on the definitional issues discussed in this Part?

We support the UPOV 1991 definitions

9 Scope of the breeder's right

Do you have any comments about these new rights required by UPOV 91?

We support the full scope of rights as provided for by UPOV 1991, including coverage of harvested material and products that are obtained directly from material of a protected variety

Exceptions to the breeder's right

Do you have any comments about the exceptions required by UPOV 91?

We support the exceptions provided under UPOV 1991

Term of the right

10

11

12

Do you agree with the proposed options? Are there alternatives we have missed?

Do you agree with our analysis and conclusions? If not, why not?

Our preference is option 2 with the suggestion that the term of rights in New Zealand is harmonised with the EU legislation. The cost objection expressed in paragraph 209 of the Options Paper is offset by the fact that growers and consumers have the choice of many varieties, including those without PVR, and freedom to choose among them according to their individual assessment of relative cost/benefit.

Essentially derived varieties

Do you agree with the proposed options? Are there alternatives we have missed?

Do you agree with our analysis and conclusions? If not, why not?

We do not support the proposed option 2 and note that participants at the MBIE Hui in Wellington on August 5 & 6 were in agreement that this was the least favoured option. As an example a naturally arising mutation of a red rose variety that produced pink flowers might not be considered to be a "copy cat" variety, when it is clearly an EDV in accordance with the intent and the wording of UPOV 1991.

In our view there is an opportunity to ensure the updated plant varieties legislation is contemporary, resilient, and forward-thinking to accommodate future evolution of the sector and industries it serves, including the potential for new breeding technologies (such as gene editing) that could enable quick and inexpensive changes to protected varieties.

We would support Option 1 on the proviso that some further work to give certainty to Breeders is carried out. Our view is that the UPOV 1991 definition is clear but the UPOV explanatory note (EXN) in respect of this has introduced uncertainty and should be withdrawn. UPOV are holding a seminar in October on The Impact of Policy on Essentially Derived Varieties on Breeding Strategy - the UPOV national council will consider whether to open the EXN for revision following this seminar. A letter representing the majority of breeders internationally position on EXN is provided along with this submission.



Option 3 could be workable however agreement on the definition of "essential characteristics" is considered problematic

We suggest that an EDV concept is established and implemented through an objective approach and a clear and self-evident definition. We support that the EDV concept should establish dependency for varieties, which are phenotypically distinct and predominantly derived from the initial variety (i.e. the protected variety).

We perceive the concepts and supporting rationale set out in the CIOPORA Position Paper "Essentially Derived Varieties" is a useful and objective basis for development of an appropriate EDV concept.

For reference:

https://docs.wixstatic.com/ugd/53e3d5_a6fec4442fce4747a945a1303817eb75.pdf

Rights over harvested material

Do you agree with the proposed options? Are there alternatives we have missed? Do you agree with our analysis and conclusions? If not, why not? We do not support the proposed option one.

The role of propagator and propagating material is less pre-eminent in contemporary business and operating environment of harvested material.

The Sapere report shows that that the value and investment in plant variety innovation in New Zealand actually revolves around the production of harvested material rather than propagating material.

Our preference is for option 3.

Further, the definition of harvested material should specifically include pollen.

We strongly support the extension of the rights to cover harvested material and products made from the harvested material of the protected variety and suggest that need could be met by a well-articulated "scope of the breeder's right" compared with attempting to carve in, or out, certain categories or parts of the protected variety of plant of any species in any specific harvested material or end use context.

Farm saved seed

Do you agree with the proposed options? Are there alternatives we have missed?

Do you agree with our analysis and conclusions? If not, why not?

We support Option 2.ii

We note that this needs to facilitated by an appropriate contractual chain of command among participants and a model that allows for opt in on a case by case basis rather than a prescriptive model.

Compulsory licences – general issues

Do you agree with the discussion and the proposals in relation to the five issues discussed above? If not, why not?

Other than the two substantive issues below, are there other issues we have missed?

14

We do not support any of the proposed options.

Other issues we have missed? Yes, we think there is a substantive gap in consideration of the value creation around harvested material, and its availability to the general public. That oversight, in the context of the scope of the breeder's right is a problem in itself (please see response and input provided at 13) and creates ramifications in the context of consideration of flow the benefits of new varieties to society.

Please consider the following.

In our view, *if included at all*, any proposal for compulsory licensing should be available only when the rights holder is not putting the protected variety into use at all in New Zealand or where there is a case to be made that a compulsory licence is necessary to mitigate a risk to human health, animal welfare, biodiversity, or food security in New Zealand. On this basis, *then* we agree:

- a well-articulated and clear process for making and considering compulsory license applications would be required
- that applicants for compulsory licences *must* demonstrate their prior efforts to obtain a licence via good faith negotiation with the rights holder
- that any Compulsory Licence issued must limit the use of propagating material to domestic NZ use only. We further submit that this restriction should also include limiting export of harvested material to allow only processed or derived products meaningfully differentiated from current export formats or intended final uses.

In this context, we disagree strongly with the recommendation not to include a public interest test and with the assessment that underpins that recommendation. Our reasons for this and our proposal for a new option are outlined below.

We submit that *if* compulsory licensing is to be retained, the best option for managing consideration of such licences is to adopt the UPOV 1991 model and add a test for public interest which specifically allows for assessment of the balance of the interests of rights holders and the desire to not unreasonably limit innovation.

In appropriately developing approaches to consider that balance, it might be that a differential assessment of compliance may be of value - depending on whether the genuine public interest in the variety relates to:

- growing the *plant* per se (primarily an issue for ornamental species)
- access to the harvested material (the major interest for food crops such as fruits)
- access to *products derived from harvested material* (applies to process crops such as hops or wine grapes)

If it is determined that compulsory licensing provisions are to be retained we agree that the ability of a commissioner to grant a compulsory licence in *specific* circumstances could play a role in giving substance to the balance of the interests of rights holders and the desire to not unreasonably limit innovation noted in the Options Paper. We do not agree that the qualifying conditions for a Compulsory Licence set out in the options paper are suitable to achieve this.

We submit that the current narrow focus of Section 21 on the availability of reproductive material does not fully reflect the scope of public interest in plants and plant material. We do not believe that having "reasonable quantities of reproductive material" available to the public is a suitable uniform measure of compliance with the "social contract" component of PVR because it does not take into account the variety of "conditions" or "social" outcomes sought by society with respect to different plants. Please also see the

Compulsory licences - grace period 16 Do you agree with the proposed options? Are there alternatives we have missed? Do you agree with our analysis and conclusions? If not, why not? If there is to be retention of a compulsory licensing provision, our preference is Option 2. Three years from grant is an unreasonably short time for product development for innovative plant varieties e.g. crops with long propagation timeframes plus multiple years of growth before coming into production. By implication, a short grace period also unreasonably favours anticompetitive behaviours by parties unwilling to risk investment themselves in breeding, but willing to "coat tail" or presumptively disrupt a variety developer's risk/reward early in the product life cycle. Compulsory licences – section 21(3) 17 Do you agree with the proposed options? Are there alternatives we have missed? Do you agree with our analysis and conclusions? If not, why not? In the context of the content provided in 15 our preference is Option 2, to repeal Section 21(3) if compulsory licensing provisions were to be retained. **Enforcement – infringements** Do you agree with the discussion and the proposals in relation to the four issues 18 discussed above? If not, why not? Should the PVR Act provide that infringement disputes be heard in the District Court? Are there others issues relating to infringements that we have missed? We support the statements at paragraphs 413, 423, and 430 in the options paper and that PVR owners have freedom to choose the Court of competent jurisdiction e.g. the High Court consistent with hearing disputes under other Intellectual Property Rights Legislation. **Enforcement – offences** 19 Do you agree with the proposed options? Are there alternatives we have missed? Do you agree with our analysis and conclusions? If not, why not? If the assumptions of 447 with respect the applicability of the Fair Trading Act 1986 are correct, then we support option 3. Exhaustion of the breeder's right 20 Do you have any comments about the exhaustion provision required by UPOV 91? We support the exhaustion provision required by UPOV 1991.

Do you have any comments about the cancellation and nullification provisions required

by UPOV 91, and MBIE's additional proposals discussed in this section?

Cancellation and nullification of the breeder's right

We support the conclusion set out in 451. We largely accept the conclusions from 452 to 484 but have concerns that there should be a balance of time being of the essence and the evidence requirements to minimise the opportunity for alleged infringers to draw out the legal process by spurious counterclaim as set out in 485.

Extending coverage to algae

22

23

24

Do you have any comments to make about whether or not algae should be included within the definition of "plant" for the purposes of the PVR regime?

We would be supportive of the extension of the definition of plant to include algae for the purposes of the PVR regime.

Provisional protection

Do you agree with our preferred option for dealing with provisional protection? If not, why not?

Retention of the status quo as it is legislated and regulated under the NZ PVRA 1987 is preferred; this pragmatic approach reflects the nature of activity in the industry the PVRA serves and works well with complementary legislation governing commercial activity in New Zealand. Regulatory clarity could be provided.

Maintaining the current scope of provisional protection as it is provided under the NZ PVRA 1987 ensures a breeder can start infringement proceedings during the period of provisional protection; which in turn provides confidence to breeders to release their varieties at an early stage. This provides benefit from timely access to new varieties with improved traits to all parties in the production, supply, and marketing chain, as well as consumers – and therefore society as a whole.

Transitional provisions

What is your view on the options presented here in relation to this issue? Are there alternatives we have missed?

How should transitional provisions apply to EDVs?

We support option 1, new rights, *not obligations*, apply to all existing grants and applications when the changes come into force.

Other comments

We look forward to further engagement in the development of the draft legislation.





CIOPORA Position

on

Essentially Derived Varieties

as approved by written procedure in May / June 2016

Key Statements:

- CIOPORA requests that the EDV concept is clarified through an objective approach and a clear and self-consistent definition, which meets the objective to balance the scope of new breeding techniques and traditional breeding.
- CIOPORA maintains that for vegetatively reproduced ornamental and fruit varieties the EDV concept shall establish dependency for varieties, which are phenotypically distinct and predominantly derived from the Initial Variety.
- The degree of the phenotypic similarity and the number of phenotypic differences between the EDV and the Initial Variety shall not be taken into consideration for the establishment of dependency, but for the assessment of distinctness.
- Predominant derivation is given if material of the Initial Variety has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists.
- The methods and required degrees of genetic conformity should be established crop-by-crop on the basis of state of the art protocols agreed upon by a panel of experts, including representatives of the breeders of the crop concerned, and has to be proven by the title holder of the Initial Variety in case of dispute and litigation.
- CIOPORA maintains that mutants and GMOs as far as they are distinct from the Initial Variety – are EDVs, whenever they retain a very high





genetic conformity to the Initial Variety as established by the panel of experts, because mutants and GMOs per definition are predominantly derived from the Initial Variety.

- CIOPORA maintains that the outcomes of repeated back-crossing as far as they are distinct from the Initial Variety – are EDVs in case they retain a very high genetic conformity to the Initial Variety as established by the panel of experts.
- CIOPORA recognizes that there is a realistic possibility that with advancing technologies it might become possible to create independent varieties by new methods, in particular genetic engineering.

Full Text:

1. Essentially Derived Varieties

According to Article 14 (5) (a) of the UPOV 1991 Act, varieties, which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety, fall under the protection of the protected variety.

According to Article 14 (5) (b), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived from the initial variety¹, 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 variety²,

¹ Predominant derivation means that the variety can only be essentially derived from one variety.

² The expression of the essential characteristics that result from the genotype or combination of genotypes is not a synonym for "phenotype", because phenotype is to a high degree influenced by the environment. The expression of genotype is in fact a chemical process in the cell, through which a part of the genotype ("gene") codifies a certain trait. Such trait is the direct expression of the genotype.

CIOPORA UNITING BREEDERS, PROTECTING INNOVATION



- (ii) it is clearly distinguishable from the initial variety³ 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 variety⁴.
- (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 engineering⁵.

2. The current EDV-concept under the UPOV 1991 Act

Very reason for the introduction of the EDV concept in the UPOV 1991 Act was to strengthen the breeders' right, particularly by creating a balance between biotechnology inventors and traditional breeders and by bringing mutations under the scope of protection of their Initial Variety. The wording of the EDV provision (14 (5) (a) of the UPOV 1991 Act) gives room for interpretation as to what are the requirements of an EDV.

CIOPORA has tried to clarify the current EDV concept by establishing a detailed position on EDV in January 2008.

CIOPORA notes that some want to limit the EDV concept to varieties, which can be distinguished from the Initial Variety by a very limited number of characteristics (typically by one). Such interpretation limits the EDV concept as far as even possible and does not achieve UPOV's objective to create a balance between biotechnology inventors and traditional breeders and to bring mutations under the scope of protection of their Initial Variety. Taking into consideration that an EDV per definition must be clearly distinguishable from the Initial Variety, which requires as a minimum a difference in one characteristic, under such interpretation only varieties which have exactly one difference compared to their Initial Variety could be considered to be an EDV. This approach does not support innovation.

³ For the concept of "clearly distinguishable / distinct" refer to the Position Paper on Minimum Distance.

⁴ This sentence does not add to clarity, but is superfluous.

⁵ This list indicates the intention of the authors that mutations and GMOs and varieties resulting from backcrossing (where the Initial Variety is obviously used as recurrent parent) are typical examples of EDV.





3. The desired EDV concept

CIOPORA requests that the EDV concept is clarified through an objective approach and a clear and self-consistent definition, which meets the objective to balance the scope of new breeding techniques and traditional breeding.

Such objective approach shall be based on the genetic conformity of the varieties concerned. Phenotypic components shall be taken into consideration only as far as the distinctness of the respective varieties is concerned.

Particularly the entanglement of dependency and plagiarism is a mistake in the conception of the EDV provision. Plagiarism is not a question of derivation or dependency, but rather a question of Minimum Distance and direct infringement. If a variety in its phenotype very much resembles a protected variety, it is not clearly distinguishable from the protected variety, and its commercialization is a direct infringement, irrespective whether the new variety is (essentially) derived from the protected variety or not.

Additionally, phenotype is, by definition, what results from the expression of an organism's genes as well as the influence of environmental factors and the interactions between the two. The degree of phenotypic similarity is the result of a subjective evaluation, strongly influenced by variations based on environmental and judgmental factors.

Finally, the wording of the UPOV 1991 Act with regard to the requirement and level of phenotypic conformity between an Initial Variety and its EDV is unclear and contradictory. In Article 14 (5) (b) (i) a general conformity seems to be required, while Article 14 (5) (b) (iii) provides that the EDV must conform to the Initial Variety in the expression of the essential characteristics, except for the differences which result from the act of derivation⁶.

CIOPORA, therefore, maintains that Article 14 (5) (b) (i) of the UPOV 1991 Act does not establish phenotypic similarity as a pre-condition for EDV (because the interaction with the environment is not taken into account), but specifically and expressly refers to genotype⁷.

⁶ Contrary to that, in the PVR law of the European Community (Regulation 2100/94) and some other countries, this contradiction does not exist, since the phrase "while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety" of Art. 14 (5) (b) (i) has not been included in Art. 13 (6) (a) of Regulation 2100/94. Nevertheless, Regulation 2100/94 has been accepted by UPOV as being in line with the UPOV 1991 Act.

⁷ Obviously, at the time when the UPOV 1991 Act was drafted, genotype could not been described other than in relation to its expression.





CIOPORA, therefore, is of the opinion that close phenotypic similarity must not be a precondition for a variety to be considered to be an EDV. However, a close phenotypic similarity can be an indication for essential derivation.

Instead, CIOPORA maintains that for vegetatively reproduced ornamental and fruit varieties the EDV concept shall establish dependency for varieties, which are phenotypically distinct and predominantly derived from the Initial Variety.

The degree of phenotypic similarity and the number of phenotypic differences between the dependent and the Initial Variety shall not be taken into consideration for the establishment of dependency, but for the assessment of distinctness.

3.1 Distinctness

An EDV shall be phenotypically distinct from its Initial Variety. For the assessment of Distinctness the Position Paper of CIOPORA on Minimum Distance of 2 April 2014 shall apply.

3.2 Predominant derivation

An EDV shall be predominantly derived from its Initial Variety.

Predominant derivation is given if material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety, has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists.

A variety can only be *predominantly* derived from *one* variety, as Article 14 (5) (b) (i) UPOV 1991 Act stipulates the EDV must be predominantly derived from the Initial Variety.

The methods and required degrees of genetic conformity should be established crop-by-crop on the basis of state of the art protocols agreed upon by a panel of experts, including representatives of the breeders of the crop concerned, and has to be proven by the title holder of the Initial Variety in case of dispute and litigation.

CIOPORA maintains that mutants and GMOs – as far as they are distinct from the Initial Variety – are EDVs, whenever they retain a very high genetic conformity to the





Initial Variety as established by the panel of experts, because mutants and GMOs per definition are predominantly derived from the Initial Variety.

CIOPORA maintains that the outcomes of repeated back-crossing – as far as they are distinct from the Initial Variety – are EDVs in case they retain a very high genetic conformity to the Initial Variety as established by the panel of experts.

4. Burden of proof

For the sake of establishing the existence of an EDV the following requirements are to be fulfilled:

- Distinctness
- Use of Material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety (derivation),
- Very high degree of genetic conformity (predominant derivation)

With regard to the burden of proof it is up to the plaintiff (holder of the Initial Variety) to prove distinctness and the very high degree of genetic conformity, as defined above. Proving the necessary degree of genetic conformity establishes also a prima facie evidence that material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety has been used. Nevertheless, a close phenotypic similarity may also call for an assessment of the degree of genetic conformity by the parties or the court.

An EDV is dependent on its protected Initial Variety. As a consequence, the commercialization of the EDV requires the authorization of the title holder of the Initial Variety during the duration of its protection.















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

12 August 2019

Request for revision of the UPOV/EXN/EDV/2, Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention adopted on April 6, 2017

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.

The adoption of the Explanatory Notes on Essentially Derived Varieties (EXN EDV) in 2017, particularly part b) "Defining an essentially derived variety" (points 4 to 19) has raised deep concerns among the breeding industries. The current text of the EXN EDV suggests a very narrow scope of the EDV concept, inter alia by indicating that one modification of an essential characteristic might lead to the new variety being out of the scope of the EDV concept. This would greatly endanger the breeding incentive and could possibly lead to a diminution of biodiversity, breeding effort, and eventually resulting in less choices available for the users of varieties and threatening the whole UPOV system.

Aware of the danger of such narrow scope of the EDV concept, which would be contrary to the original intention of the EDV concept put in place in 1991, ISF, CIOPORA, CLI, Euroseeds, APSA, AFSTA, SAA would like to request a clarification of the EXN EDV which should clearly affirm the following guiding principles:

- predominant derivation from an initial variety, as confirmed by a high genotypic conformity, is a key requirement for a variety to be considered an EDV;
- important modifications in the characteristics of an initial variety do not automatically lead to the new variety escaping from being qualified as EDV.

ISF, CIOPORA, CLI, Euroseeds, APSA, AFSTA, SAA would like to request that the revision of the EXN EDV is put onto the agenda of the 76th session of the Administrative and Legal Committee taking place on the 30th of October 2019.

We are forwarding this request to some UPOV members.

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

Sincerely Yours,

Michael Keller ISF Secretary General

Howard Minigh President & CEO Crop Life International

Dr. Edgar Krieger CIOPORA Secretary General

Szonja Csörgő Euroseeds IP Director

Kanokwan Chodchoey APSA Executive Director Justin Rakotoarisona AFSTA Secretary General

Diego Risso

SAA Executive Director

Copy: Anthony Parker, Canadian PVP Office, Chairman of the CAJ