ABSTRACT

The concept of Essentially Derived Varieties (EDVs) was introduced in the 1991 Act of the UPOV Convention with the aim of providing an effective incentive for plant breeding that would maximize progress in the development of new, improved varieties for the benefit of society.

The purpose of the Seminar is to consider the impact of EDV policy on breeding strategies and the consequences for the development of new, improved varieties of plants. The Seminar will provide perspectives covering various breeding methods and different types of plants. The Seminar is expected to assist the Administrative and Legal Committee (CAJ) in its review of the guidance on EDV provided in document UPOV/EXN/EDV/2.
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Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy*

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**Plant breeding and the EDV concept: challenges of the past, opportunities for the future?**
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**UPOV guidance on EDV**
Ms. Yolanda Huerta,
Legal Counsel and Director of Training and Assistance, UPOV

**SESSION II: IMPACT OF EDV CONCEPT ON PLANT BREEDING**

**Outlook for agricultural crops**
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**Outlook for ornamental plants**
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**Outlook for vegetables**
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*The views expressed in the papers and discussion summaries of the Seminar are those of the speakers and/or participants and are not necessarily those of the International Union for the Protection of New Varieties of Plants (UPOV).*
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Mr. Peter Button, Vice Secretary-General, UPOV

**SESSION I: TO AN EDV CONCEPT FOR THE PRESENT AND THE FUTURE**
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**Plant breeding and the EDV concept: challenges of the past, opportunities for the future?**
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**UPOV guidance on EDV**
Ms. Yolanda Huerta, Legal Counsel and Director of Training and Assistance, UPOV

**SESSION II: IMPACT OF EDV CONCEPT ON PLANT BREEDING**
Moderator: Mr. Anthony Parker, Chair, Administrative and Legal Committee (CAJ), UPOV

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Ms. Emma Brown, Business Development Manager, Plant & Food Research, New Zealand

12:00  
**Panel discussion and questions**

12:25  
**Closing remarks**
Mr. Anthony Parker
Good morning and welcome to this Seminar on the Impact of Policy on Essentially Derived Varieties on Breeding Strategy.

The topic of essentially derived varieties (EDVs) is a very important issue within UPOV. Indeed, it goes to the very heart of UPOV’s mission, which is to encourage the development of new varieties of plants for the benefit of society. The UPOV Convention was introduced with the focus on providing benefits for farmers and society. A cornerstone of the UPOV Convention - the breeder’s exemption - exemplifies this by ensuring that breeders have access to the best germplasm with which to do their plant breeding in order that plant breeding progress is maximized.

The concept of EDVs was introduced in the 1991 Act of the Convention with exactly the same purpose of maximizing benefit to society, by ensuring that there is an incentive for long-term, sustainable plant breeding that will deliver high-performing varieties to farmers and therefore benefit for society.

The aim of the seminar today is to consider how the policy on EDVs will impact on breeding strategies. We have a great opportunity to look across different crop types: agricultural, ornamental, fruit, and vegetables, to see what that impact might be.

The objective at the end of this seminar will be to take the lessons that we learn into the work of the UPOV Administrative and Legal Committee when reviewing its guidance on this issue.

The seminar is divided into three parts:

- The first session looks at the EDV concept at present and for the future.

- The second session will look at the impact of the Policy on EDV for Breeding Strategies. As I mentioned, it will look at this from different angles, from the agricultural, ornamental, fruit, and vegetable perspectives. We are very fortunate to have speakers that can knowledgeably share breeders’ perspectives on this issue.

- Finally, we will end with a panel discussion with all the speakers on the podium to have a discussion. However, it is important for the success of this seminar that you, the participants, ask questions to the panel in that session.
I would like to thank all the speakers. We are really delighted with the quality of the speakers that we have attracted, who have come from all around the world to represent different geographies as well as different crops types and many thanks also to our moderator, Mr. Anthony Parker.

I would like also to thank you, the participants, because this is an event designed for you to participate and learn from the discussions on essentially derived varieties. I am delighted to see such a high level of participation and welcome you all to this event.
SESSION I

TO AN EDV CONCEPT FOR THE PRESENT AND THE FUTURE

Plant breeding and the EDV concept: challenges of the past, opportunities for the future?

Key note Speaker: Mr. Sven J.R. Bostyn, University of Copenhagen, Faculty of Law, Centre for Advanced studies in Biomedical Innovation Law (CeBIL), Denmark

UPOV guidance on EDV

Ms. Yolanda Huerta, Legal Counsel and Director of Training and Assistance, UPOV
Essentially Derived Varieties: Challenges of the past and opportunities for the future

Mr. Sven J.R. Bostyn  
*University of Copenhagen, Faculty of Law,  
Centre for Advanced studies in Biomedical Innovation Law (CeBIL), Denmark*

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1. Introduction

In this contribution, I will provide an overview of the concept of “Essentially Derived Varieties” (EDV’s) under the UPOV Convention 1991, the challenges it has presented both to UPOV and users of the UPOV system, and will attempt to provide some guidance for the future.

As we will see in what follows, the concept of EDV’s is not only framed in a quite difficult language in the statute, but it has proven to be equally difficult to apply. Moreover, consensus on the exact interpretation of the concept, missing in the provisions of the UPOV 1991 Convention, and left for later implementation by courts and/or Guidelines has equally been a challenging task.

In this contribution, I will first provide a short overview of what the concept EDV entails. Subsequently, I will briefly explain how it works. I will then continue with a quest into the rationale of the EDV concept, indispensable to understand its deeper goals and necessary to grasp with a view to come to a reasoned judgement as to how the concept should be interpreted/implemented in the future. I will then give some thoughts on the way forward with the EDV concept with a view to assist the legislature in developing the next steps.

2. Essentially Derived Varieties: What?

In order to understand what the concept of essentially derived varieties (EDV’s) means, it is good to start with the text of the UPOV 1991 Convention.

EDV’s are covered by Art. 14(5) UPOV1991, which states:

“Art. 14(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.
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.

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 aforementioned three conditions, i.e., that the EDV is predominantly derived from the initial variety, it is clearly distinguishable therefrom and 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 must be cumulatively fulfilled.

The problem is now that for none of those three criteria, clear definitions have been provided. There is general consensus, not only in the literature, but also amongst users of the system, that the provision has a somewhat byzantine complexity.

The UPOV 1991 Convention does provide a couple of examples of breeding techniques that may result in EDV, in particular:

- 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
3. How does the system work?

If the normal protection requirements (novelty, distinctness, uniformity and stability) are fulfilled, the breeder of an essentially derived variety is granted a plant variety right and may thus assert all rights resulting from variety protection against any third party.

However, the marketing of the derived variety requires the authorization of the breeder of the initial variety, from which it was essentially derived. The result is that the “breeder” who desires to commercially exploit an essentially derived variety requires the permission of the owner of the initial variety, and is thus dependent on the initial variety, so as to provide the developer of the initial variety some of the reward for his “efforts” to create the initial variety which was depended on for the creation of the new variety.

Also observe that there is a difference between UPOV and the Community plant variety rights (CPVR)\(^1\) in respect of EDV’s:

UPOV: “(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”

CPVR Art. 13(6)(a): “(a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety”

UPOV: “(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.

CPVR Art. 13(6)(c): “(c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety.

The jury is still out there as to whether the differences between the UPOV and CPVR have a substantive effect. It has been said that the CPVR must be interpreted in the light of the UPOV Convention. But surely the difference in text should be given some meaning. For purposes of this contribution, I let this question to rest.

Essentially Derived Varieties: Why?

The Plant Breeders Rights (PBR) system is a sui generis right that has a rather wide range of idiosyncratic provisions and requirements that cannot be found in other intellectual property rights (IPRs) and for that reason alone, it is rather different from those other IPRs. That has partly to do with the very specific nature of breeding. Plant breeding is an incremental and iterative process. Plant breeders use and build upon the work of previous plant breeders and rely on existing plant varieties for the initial source of genetic variation.

That also implies that for breeders, access is paramount. That in turn explains why the PBR system under UPOV has introduced the full breeders’ exemption. Under that exemption, breeders are not only allowed to use the protected variety for purposes of developing new varieties, but can only commercialise such new varieties without having to pay any form or compensation to the right holder of the variety which was used in creating the new variety.

Absent any form of specific protection, plant variety right holders are hence not capable of preventing competitors to use their protected variety for breeding a competing product, and for commercialising the same.

The full breeder’s exemption is unique to the PBR system, and no other IP systems provide such rather extensive lack of control for right holders. The copyright system has a number of fair dealing exceptions, amongst which the one for study and research and a private copy exception, but these exceptions are much narrower than the full breeder’s exemption, as they are limited in scope and all of them must fulfil the so-called three step test under Art. 9(2)

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3 “Article 15 Exceptions to the Breeder’s Right: (1) [Compulsory exceptions] The breeder’s right shall not extend to (i) acts done privately and for non-commercial purposes, (ii) acts done for experimental purposes and (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.”


5 See for instance Article 5(3)(a) Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, OJ L 167, 22/06/2001 P. 0010 – 0019: “(a) use for the sole purpose of illustration for teaching or scientific research, as long as the source, including the author’s name, is indicated, unless this turns out to be impossible and to the extent justified by the non-commercial purpose to be achieved.”

6 See for instance Article 5(2)(b) Directive 2001/29/EC: “(b) in respect of reproductions on any medium made by a natural person for private use and for ends that are neither directly nor indirectly commercial, on condition that the right holders receive fair compensation which takes account of the application or non-application of technological measures referred to in Article 6 to the work or subject-matter concerned.”
Berne Convention\(^7\), according to which “It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.” Patent law has a research exemption\(^8\), and in Europe some countries have introduced a limited breeders’ exemption. The latter exemption allows third parties (and hence also competitors) to use a patented plant for the development of a new plant (variety), but any commercialisation of such new plant (variety) would still require the consent and hence license of the patent holder\(^9\). With the limited breeder’s exemption in patent law, access to plant material is guaranteed, whilst at the same time protection of the legitimate interests of the patent holder is also safeguarded.

It is not difficult to see that the existence of a full breeder’s exemption is not easy to reconcile with an effective protection for the innovation activity in new plant varieties. A basic economic principle underlying virtually all IP rights is that in the absence of any enforceable kind of right, market players will have no incentive to invest in new innovative activity\(^10\). Even though the full breeder’s exemption does not take away all enforcement options for the plant variety right holder, it does in effect take away any possibility to enforce his/her right against any third party who wishes to use the protected variety to develop a competing variety on the basis of the protected variety. Effective protection is de facto limited to enforcement against third parties who deal with the protected variety as such or with parts thereof\(^11\).


\(^8\) In most cases inspired by the limited breeder’s exemption introduced in the so-called UPC system, see Art. 27(c) Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1–40: “The rights conferred by a patent shall not extend to any of the following: […] (c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties.” The UPC system has not yet entered into force, however.


\(^11\) Article 14 UPOV 1991: “(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.”
There is a rationale, however, for having a breeder’s exemption, as access to plant material for further development in the plant sector was deemed essential and imperative. The full breeder’s exemption has most definitely ensured this free access, but at quite a high price, i.e., that competitors developing mutations based on the protected variety can do so without inhibition, effectively eating profits away from the plant variety right holder. That in turn may have rather negative consequences on the preparedness of breeders to go through the laborious process of filing for PBR protection in the first place, for the economic reasons referred to above.

An old European case from 1985 in fact illustrates this problem very well. In the Pitica/Kyria case12, the issue was whether a plant variety right holder of certain varieties of roses could exert influence over the rose varieties developed by a licensee of the plant variety right holder, where those new rose varieties were mutations developed on the basis of the protected varieties. The European Commission held that this was not possible, as there was a breeders’ exemption in the first place, preventing enforcement of plant variety rights against third parties, and secondly, the licensee would be entitled to his own plant variety rights for those mutant roses, and under European competition law, there was no possibility to tie the licensee, being entitled to his own plant variety rights, into an obligation to transfer any such rights to the licensor.

That case illustrates perfectly the conundrum with which the PBR system is confronted. Even though the case predates the introduction of the EDV concept, it is nevertheless still relevant even in the context of EDV’s.

Indeed, in view of the above constraints within the PBR system under UPOV, it was felt that something needed to be done to protect the legitimate expectations and rights of the plant variety right holders. That led to the development of the EDV concept, as that system would allow the right holder to exercise his/her rights against a competitor who brought on the market a variety that is deemed to be an essentially derived variety. The rationale was hence to extend the scope of protection of the plant variety right holder so as to allow him/her to enforce his/her rights and protect his/her investment in the innovative activity of developing new varieties.

Understanding that rationale is crucial with a view to further evaluate how such EDV concept needs to be implemented. As was illustrated with the abovementioned Pitica/Kyria case, the introduction of an EDV system should allow the right holder to enforce his rights against third parties who simply develop a mutation without much more. As it was said in the EC Decision, a new variety, for instance a new mutation, can instantly create a new market, and may consequently very quickly eat away any profit for the original plant variety right holder:

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“Where, as in the case of the variety Pitica / Kyria13, a natural mutation is discovered by a third party on a plant of a parent variety already protected in the name of an original breeder, the problem arises of determining the extent of the respective rights of each party — third party discoverer and original breeder — under the law, in the new variety resulting from that mutation. 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, for example, by Baccara in its day or Sonia at the present time.”

Prior to the 1991 UPOV Convention, the existence of the full breeder’s exemption and the fact that enforcement of plant variety rights against third party breeders using the protected variety for developing and marketing a new variety was hardly possible, has slowly become more of a problem also for other reasons, even though it was not initially. Traditional plant breeding was an incremental and time-consuming process, and the lack of enforcement possibilities combined with a full breeders’ exemption did consequently not hurt right holders that much, as mere access to the protected variety for breeding a new variety would still require a certain amount of time, during which the right holder had a de facto protection on the market. The advent of new breeding technologies, such as molecular technologies, genetic engineering and gene editing technologies have made this lead time advantage in the market disappear, as those new technologies lead much faster to a new variety. That would allow competitors to take advantage of the breeder’s exemption under which they are allowed to use the protected variety for breeding a new one and bring it to market, to enter much quicker into competition with the right holder: “A hypothetical example of this is a protected orange variety that has been used to create a new orange variety which is identical in shape, colour and taste to the protected variety. Generally, even if the difference between the two varieties is that the new variety has a different leaf colour, it is eligible for plant variety rights protection because it is distinct from the protected variety14.”

Introducing a feature in the PBR system allowing the right holder to enforce his rights vis-à-vis third party developers using the protected variety was an obvious means to provide a more effective form of PBR protection.

A further argument why right holders were unhappy with the very limited enforcement possibilities under the PBR system was the very narrowly interpreted requirement of distinctness. Under Art. 6(1)(a) UPOV Convention 1978, “the variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common

13 Para 8 of the Decision.
knowledge at the time when protection is applied for.” 15. It was argued that it was too easy to satisfy this requirement, as the assessment of distinctiveness is based on physically observable ‘morphological or physiological’ differences.16. Such a low threshold implies in turn that, absent any further enforcement mechanism, any minor change could potentially suffice to obtain a new plant variety right, which would then make it fall outside of the scope of the plant variety right from which it is distinct in a minimum fashion.

Another, and often overlooked rationale for introducing the EDV concept, is the fact that the patent system became more and more “popular” as a means to obtain IP protection, and to some extent at the expense of the PBR system. Patent protection, available for both genetically modified and more traditionally grown plants (provided it is not an essentially biological process for the production of plants17), provides an enforceable right. Patent protection has always been broader than mere copying. The patent system applies a doctrine of equivalence18, under which more can fall within the scope of the patent than what has been literally claimed in the patent document. The doctrine of equivalence is based on the premise that the patent extends to those embodiments which, even though not literally claimed, must have meant to have been included within the scope of the patent when the patent applicant used the specific wording of the patent claims in defining his invention. Those features that go beyond what has been literally claimed provide a reasonable extension of the scope of protection. In the UK, the exercise is often called “purposive construction”, which means that “a patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.”19

15 Under Art. 7 UPOV 1991, “the variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application.”
16 Jay Sanderson, op.cit., 209.
18 See for instance Art. 69 EPC and the Protocol on the Interpretation of Article 69 EPC of 5 October 1973, as revised by the Act revising the EPC of 29 November 2000.
Moreover, prior to the advent of the limited breeders’ exemption in patent law, patent protection did not allow competitors to use the patent protected plant (encompassing plant varieties) with a view to develop a competing new variety and market the same\textsuperscript{20}. The availability of an IP right that can effectively be enforced against competitors makes that IP right much more attractive to innovators than one that is not or very difficult to enforce. That has posed a more existential threat to the PBR system, which was put under pressure to provide an IP system that allows right holders to effectively enforce their rights vis-à-vis third parties using their protected varieties to develop and market competing products.

Yet another reason that could be given to defend the introduction of an EDV concept is related to scope of protection. Under patent law, as we have just seen, the scope of protection extends beyond what has been literally protected. That allows the patent holder to claim beyond the literal wording of the claim, which is partly informed by the fact that language has its inherent limitations, and as inventions need to be expressed in words in order to attain patent protection, this imperfection has an inevitable effect on how the invention is claimed.

One would have thought that a similar doctrine, akin to the doctrine of equivalence, could have been developed for plant variety rights. That has been said not be feasible, due to the very specific requirements within the PBR system\textsuperscript{21}. One of those is the requirement of distinctness. As we have seen, that requirement has been interpreted in such a way that a very narrow difference could lead to a distinct variety, capable of attaining a right in its own. There is clearly some truth in this argument, but it must be added that also under patent law, the mere fact that an allegedly infringing product has attained its own patent right is not in all circumstances in itself a successful argument to claim that there is no infringement by equivalence. As that is true for patent law, one could argue mutatis mutandis that nothing would prevent the scope of protection of a plant variety right to extend into other plant varieties which have attained separate protection in their own right. As we have seen when we explained the EDV concept, the UPOV Convention takes this view actually also as a starting point, as an EDV is a plant variety that is distinct from the protected variety. It must be added though that the exact scope of the doctrine or equivalence is, many years after its introduction in various jurisdictions, still a highly debated subject, regularly leading to referrals to the highest courts for further clarification. In that context, it was probably wise to introduce a statutory binding concept and test to determine scope in the PBR system, as this is an area where case law is very sparse and litigation is the exception. However, it did not help that the EDV concept came without much further clarification or implementation.

\textsuperscript{20} Some people have suggested that using the patent protected plant to develop a new variety could have fallen under the research exemption in patent law. I have for many years argued that at least in most jurisdictions, this would in fact not have been possible, as the research exemption in many countries does not cover activities with the patented subject matter to develop and market another product, and to that effect invoking the research exemption in this context amounts to an erroneous interpretation of the law.

\textsuperscript{21} Mark D. Janis & Stephen Smith, Technological Change and the Design of Plant Variety Protection Regimes, 82 Chi.-Kent L. Rev., 2007, (1557) at 1591.
The reasoning developed in the above is the context within which one has to see the introduction of the EDV concept. Any interpretation of the EDV concept that would de facto hollow out effective enforcement of plant variety rights against third parties would in effect hollow out the raison d’être of the PBR system, and it is difficult to envisage that the legislature, when devising the EDV concept, would have had that goal in mind, as that would in effect not mitigate the existential threat to the system. Following from that, any interpretation of the EDV provisions in a way that they in effect not provide an effective form of enforcement, for instance by limiting the EDV concept to a very narrow scope of situations, with the exclusion of a plethora of situations where the third party who uses the protected variety develops and markets a competing variety, would in my view be contrary to the rationale of introducing a concept with aimed at allowing enforcement of IP rights, and secondly, would in my view also do not do justice to the reasonable expectations of right holders of such IP rights. I will come back to this later in this contribution.

That brings us then to the next question of how to implement an EDV system so as to give it a proper and functioning effect?

5.

How should the EDV concept be implemented?

5.1 Introduction

The next step in the reasoning is then to go into more depth as to how an EDV concept should be put in practice. That has been a very difficult issue for as long as the EDV concept exists. At least one reason why it has proven to be so difficult to implement is that the entire concept of EDV’s is “a hybrid concept: creating scientific, legal and pragmatic questions.”\textsuperscript{22} Another reason is also that the statutory text is notoriously difficult to understand.\textsuperscript{23}

Rather opposite views exist on this issue. Some have argued that the EDV concept should be interpreted very narrowly, i.e., that only those new varieties which have one or very few modifications from the initial variety can fall within the scope of protection of the right holder.


\textsuperscript{23} See also, P.A.C.E. van der Kooij, Afgeleide rassen Anno 2008, Agrarisch Recht, nr. 7/8, July – August 2008, p.311-317;
of the initial variety. In that context, reference is sometimes made to “plagiarism.” Others argue that limiting the EDV protection mechanism to “plagiarism”\textsuperscript{24} would be tantamount to introducing no additional scope of protection whatsoever in any meaningful way\textsuperscript{25}. I would agree with the latter position, for reasons I will elaborate on further below.

5.2 The UPOV 2017 Explanatory notes

Before we go further, it is useful to explain the current position of UPOV vis-à-vis the EDV concept, as that has been laid down in the 2017 Explanatory Notes\textsuperscript{26}.

To be essentially derived, a second plant variety must be ‘predominantly derived’ from the initial variety, be clearly distinguishable from the initial variety and express genetic conformity to the initial variety in the expression of the essential characteristics that result from the genotype.

There are hence three conditions that need to be cumulatively fulfilled, i.e., ‘predominantly derived’, the variety must be ‘clearly distinguishable’ ‘essential characteristics’ and ‘conforms to the initial variety’. The problem is, however, that the UPOV Convention does not contain any definition of what is ‘predominantly derived’, what are ‘essential characteristics’ and what it means that the essentially derived variety ‘conforms to the initial variety’.

Article 14(5)(c) provides some examples of what could be deemed to be essentially derived varieties, i.e., “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 Explanatory Notes further say that

“5. The phrase “while retaining the expression of the essential characteristics” requires that the expression of the essential characteristics conforms to and be derived from the initial variety.

\textsuperscript{24} Noel Byrne, Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties, Centre for Commercial Law Studies, London, 1994, p. 55; Charles Lawson, Plant breeder’s rights and essentially derived varieties: still searching for workable solutions, E.I.P.R. 2014, 36(8), 499-517; Australian Plant Breeder’s Rights Act 1994, s. 4(c): “[…] (c) it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety.”

\textsuperscript{25} CIOPORA Position on Essentially Derived Varieties as approved by written procedure in May / June 2016, downloadable at https://docs.wixstatic.com/ugd/53e3d5_a6fec4442fce4747a945a1303817eb75.pdf

\textsuperscript{26} Explanatory Notes On Essentially Derived Varieties Under The 1991 Act Of The Upov Convention, 6 April 2017, Upov/Exn/Edv/2.
6. The following might be considered in relation to the notion of “essential characteristics”:

(i) essential characteristics, in relation to a plant variety, means heritable traits that are determined by the expression of one or more genes, or other heritable determinants, that contribute to the principal features, performance or value of the variety;

(ii) characteristics that are important from the perspective of the producer, seller, supplier, buyer, recipient, or user;

(iii) characteristics that are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics;

(iv) essential characteristics may or may not be phenotypic characteristics used for the examination of distinctness, uniformity and stability (DUS);

(v) essential characteristics are not restricted to those characteristics that relate only to high performance or value (for instance, disease resistance may be considered as an essential characteristic when the variety has susceptibility to disease);

(vi) essential characteristics may be different in different crops/species.”

Somewhat mysteriously, the Explanatory Notes continue by saying that “7. The phrase “it is clearly distinguishable from the initial variety” establishes that essential derivation is concerned only with varieties that are clearly distinguishable, in accordance with Article 7, from the initial variety and which are accordingly protectable.” That is from a legal perspective somewhat difficult to follow, as there is not only the requirement of distinctiveness to fulfil to attain plant variety protection, but also uniformity and stability.

It emanates from the paragraphs 9 and 10 of the Explanatory Notes that UPOV had a rather narrow scope of the EDV concept in mind:

“9. The words “except for the differences which result from the act of derivation” do not set a limit to the amount of difference which may exist where a variety is considered to be essentially derived. A limit is, however, set by Article 14(5)(b)(i) and (iii). The differences must not be such that the variety fails “to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety”.”
10. The examples given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few. However, if there are only one or few differences that does not necessarily mean that a variety is essentially derived.”

5.3 The way forward

Everything in the above Explanatory Notes text, and in particular in paragraphs 9 and 10, seems to suggest that only in very limited cases it could be concluded that there is an EDV. As we have already set out earlier in this contribution, it is very questionable whether that was the intention of the legislature. We develop a more foundational legal argument to prove this in what follows.

In order to determine the intention of the legislature – which is admittedly not very easy in this particular case – we will revert to conventional means of determining the intention. In that context, the Vienna Convention on the law of treaties27 may help us further in determining the meaning of the EDV concept. According to article 32, “Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) Leaves the meaning ambiguous or obscure; or (b) Leads to a result which is manifestly absurd or unreasonable.”

I think it is fair to say that the text of Art. 14(5) UPOV 1991 in itself does not allow us to derive a very clear meaning of the scope of the EDV concept. If it would have been very clear, the quest for its exact scope and interpretation would have been finalised by now.

That means that we need to look for supplementary means of interpretation, which is expressly allowed under Art. 32 of the Vienna Convention on the law of treaties. Further according to that same Art. 32, we are allowed to look at the preparatory works to find clarification in what is otherwise unclear or ambiguous.

The UPOV Convention and its preparatory works make no reference to this criterion of one or very few. To the contrary, a suggestion to limit the scope of the EDV concept to very few differences was explicitly rejected during the UPOV 1991 Conventions negotiations. Indeed, the German delegation made the following proposal: “(b) For the purposes of subparagraph (a)(iv), a variety shall be considered to be an essentially derived variety when (i) it is the direct descendent of another variety (“the initial variety”) and retains, subject to a very small number of

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modifications, the expressions of the characteristics which result from the genotype or combination of genotypes of the initial variety and (ii) it is clearly distinguishable from the initial variety.  

This proposal was rejected by a large majority: “The proposal of the Delegation of Germany, reproduced in document DC/91/92, concerning the definition of essentially derived varieties was rejected by four votes for, 14 votes against and two abstentions.”

The implication of that rejection is that it is rather difficult to maintain that it was the intention of the legislature to limit the scope of the EDV concept to only one or very few differences. That in turn means that the legislature must have had a broader scope in mind. How broad that scope exactly is, is not clear from the preparatory works, but could probably be derived from a teleological interpretation of the intentions of the legislature.

To that effect, the preparatory works inform us that the aim of the revision of the UPOV Convention was, amongst other goals, to “strengthen the rights of the breeder.” Even though that such goal still does not clearly inform us of the exact scope, putting the two arguments together leads one to the conclusion that the aim of the legislature was to provide a more extensive scope of protected to the right holders, and in doing so that any interpretation of the EDV concept that would be narrowly interpreted, would not be in line with the intention of the legislature as per the preparatory works.

That leads to the conclusion that a test of “plagiarism” is not an interpretation in conformity with the intention of the legislature.

That is further informed by the fact that the use of the wording plagiarism, which has become a staple word in much of the literature on this issue, does in fact not do any favours to the ones who would like to use it as a means to give meaning to the EDV concept. It stems from a different IP right (copyright), which has a very different rationale, an entirely different functioning, and as said before, it has much narrower exceptions to the rights of the copyright holder. It is in general never a good idea to randomly transplant legal concept from other legal systems, and it is particularly ill informed if the system it has been taken from functions very differently and has a rather divergent rationale, as is the case for copyright law.


29 Point 1092 of the Records, page 344.

30 UPOV, Doc. IOM/IV/2, Introduction, sub B. 5. (i).

31 See also, Mark D. Janis & Stephen Smith, Technological Change and the Design of Plant Variety Protection Regimes, 82 Chi.-Kent L. Rev., 2007, (1557) at 1592.
There are also other reasons why using the term “plagiarism” as a standard for EDV implementation is not necessarily a good idea. The wording “plagiarism” is interpreted as being equivalent to “only a few minor differences”. However, the one does not necessarily follow from the other. Under copyright law, where the term plagiarism seems to have been taken from, there is no such rule that there is only plagiarism or copyright infringement if there are only a few minor differences. Even though there are national differences when it comes to interpreting copyright infringement provisions, it could be said in general that there is copyright infringement if the “whole or substantial part” of the protected work has been copied. The words “whole or substantial part of the work” constitute both a quantitative and qualitative criterion, meaning that it is not necessarily a question of only a few minor differences. In some cases, more or less will be required. Also for that reason, invoking a concept of “plagiarism” as a test for implementing the EDV concept is difficult to justify.

Based on this rather logical argument, combined with the conventional interpretation of Convention provisions carried out in the previous paragraphs, leads to the inevitable conclusion that a test of “plagiarism” is not only not an interpretation in conformity with the intention of the legislature, but it is also not advisable to use it as a test for interpreting the EDV concept, as it is a legal concept foreign to and incompatible with the PBR system.

I illustrate the point further with a couple of examples. Mutations, but also new breeding techniques (NBT) do not aim at plagiarism, but could and should nevertheless still fall under the EDV concept. It is difficult to see how a colour mutation could aim at plagiarism. Equally so, it is also difficult to see how gene-editing techniques using CRISPR-Cas could aim at plagiarism. But in both cases, such new varieties could still be an EDV, at least in our view.

Marker assisted breeding is an area which exemplifies how a test of plagiarism proves to be inadequate for determining essential derivation. A breeder can select a molecular marker profile that is ‘sufficiently different’ from the initial variety. An example given in the literature is the following: “If the threshold for variety Y is 90 per cent, it may be possible to ensure that subsequent varieties will show genetic thresholds 85 per cent or less, despite there only being minor changes made to the initial variety. While the new plant variety may be quantitatively outside the boundary established for essential derivation, it may still draw on the important or essential features of the existing variety for its commercial appeal to the industry.”

In a test of essential derivation that would be based on “plagiarism”, even if one would know what that

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34 Jay Sanderson, op.cit., 221
exactly means under the PBR system, quod non, such a derivation might not be a plagiarism, and hence an essentially derived variety, even though it still derives most of the crucial and essential features from the protected initial variety.

I continue with the example of the Arctic Apple®

What is the Arctic Apple®? According to the developers of the new variety, “when the cell of a typical apple is ruptured – for example, by biting, slicing or bruising – polyphenol oxidase (PPO) found in one part of the cell mixes with polyphenolics found in another part of the cell. (PPO is a plant enzyme. Polyphenolics are one of the many types of chemical substrates that serve various purposes, including supplying its aroma and flavour). When PPO and polyphenolics mix, brown-toned melanin is left behind. Arctic® apples produce practically no PPO so that enzymatic browning reaction never occurs. This means Arctic® apples’ polyphenols aren’t burned up when the apple is bitten, sliced, or otherwise bruised.” Further according to the developers, the result was achieved by identifying the four genes that are responsible for apple browning, and by gene silencing to turn down the expression of PPO.

One can now have two different views as to whether this Arctic Apple® should be seen as an EDV from an initial variety or not.

**View 1:** This is an EDV as it – except for the differences which result from the act of derivation - conforms to the initial variety in the expression of the essential characteristics. It is an example in Art 14.5 (c): a natural or induced mutant, […] or transformation by genetic engineering.

**View 2:** This is NOT an EDV as a variety cannot be declared an EDV whenever it contains an important characteristic which differentiates it from the initial variety and adds to the performance or value of the variety.

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35 Picture used for research purposes and obtained from https://www.arcticapples.com/how-did-we-make-nonbrowning-apple/
36 Ibidem.
37 Ibidem.
Under a test focusing on “plagiarism”, even if we would know what that exactly entails in the context of plant varieties, quod non, it would likely be concluded that View 2 would be the correct one. It is not difficult to see how this could in effect take away a considerable chunk of the profits of the plant variety right holder in the initial variety, even though the derived variety has been developed solely on the basis of the initial variety.

Following the first View, and giving an interpretation and scope that goes beyond “plagiarism” would allow the right holder of the initial variety to claim against the person marketing the derived variety.

A study carried out recently by the New Zealand government is rather interesting in this regard38. The study evaluates four options to implement the EDV concept into national law. I focus here on Option 3, which the government declined to put into effect.

“Option 3: Define an EDV as a derived variety that retains one or more of the commercially valuable characteristics of the initial variety

254. Under this option, any derived variety that retained all of the “essential characteristics” of the initial variety would be deemed to be an EDV. In this context, an “essential characteristic” could be defined as one that provides commercial value to the variety. This would be a broader definition of an EDV than under Option 2.

255. The effect of this approach would be that derived varieties that are “copycat” varieties and derived varieties that are genuine improvements would be deemed to be EDVs. For example, a derived variety that possessed all the essential characteristics of the initial variety would be an EDV even if it possessed one or more essential characteristics not present in the initial variety. On the other hand a derived variety where one or more of the essential features of the initial variety are not present would not be an EDV.

256. In effect, this option could mean that most varieties that are “genuine improvements” would be EDVs. If the PVR over an initial variety extends to derived varieties that are “genuine improvements” this could discourage breeders from using PVR protected varieties in their breeding programs, where they did not own the PVR in those varieties. This could unreasonably favour breeders who already own many PVRs, as they are free to use their own protected varieties in their breeding programs. They would not have to seek permission to commercialise any EDVs they develop from them.

257. Adopting this option could therefore actually reduce the incentive for some breeders to develop new varieties. It could potentially act as a barrier for entry to the plant breeding industry. New entrants would not own any PVRs, and may only be able to use varieties that are no longer, or were never protected by PVRs in their breeding programs.\(^{39}\)

The reason why I included the above reasoning is that it provides some interesting insights. The Option indeed suggests that allowing an interpretation as laid out provides a stronger protection for the plant variety right holder of the initial variety. The government seems to conclude, however, that this is not a desirable solution, as it could unreasonably favour breeders who already have many plant variety rights, and could hence reduce incentives for breeders to develop new varieties. This is unfortunately the type of reasoning that does not bring us very far. It is an inevitable consequence of an effective and enforceable IP right that it could potentially affect subsequent development. But that is true for all IP rights, and plant variety rights are not that fundamentally different from other IP rights that they should only attain IP protection which is virtually not enforceable. PBR already provides for guaranteed access, one of the corner stones of the right. The point is that an IP right that is very difficult or impossible to enforce effectively against competitors takes away all incentives to innovate in the first place. And if there is no initial innovation, there will be no subsequent innovation. The reasoning followed by the New Zealand government, and for that matter by all governments who have decided that there should be a very narrow interpretation given to the EDV concept, seems to try to marry two inherently incompatible concepts, i.e., providing an IP right with a view to stimulate innovation in breeding, but on the other hand not allowing such IP right holders to effectively enforce the IP rights so obtained. It is very difficult if not impossible to square this circle, reason also why the “plagiarism” test cannot provide an adequate form of protection. It is also reason why until and unless a broader interpretation is being given to the EDV concept, users will continue to question the fairness of the system and the suitability of it for their business activities. If no changes are made, the EDV concept will continue to haunt the legislature for many years to come.

For that reason, and adding to what I have said earlier, a broader interpretation of the EDV concept is required.

\(^{39}\) Ibidem, at p.70.
5.4 Which test to apply?

The fact that after many years of discussion we have not yet come close to a consensus on the parameters of the EDV concept, together with a rapidly changing technological environment, means that it is time for something different, as most of the suggestions made in the past were mostly circling around the same idea of introducing a very limited scope of the EDV concept, leading to many cases where economically damaging derivations were not deemed to fall within the EDV concept, and remained hence outside of the reach of the right holder to the initial variety. There is now at least some evidence that this model has not been satisfactory to many users of the system, and the UPOV system is made for the users. That in turn implies that if the system does not satisfy an increasing number of users, change must be made.

What change is then the next question. As we have set out in the previous section, the rationale of the introduction of the EDV concept was to strengthen the rights of the breeder. As we have also established in the previous section, plagiarism is not a correct and recommended interpretation of the EDV concept. Which interpretation is then more preferred?

My suggestion would be that any variety that retains the essential characteristics of the initial variety should be considered to be an EDV. That is in my view the only interpretation which 1) gives effect to the desire of the legislature to strengthen the rights of the breeder and 2) provides an effective plant variety right to the right holder of the initial variety.

I develop here two possible tests to determine whether a variety is an EDV or not.

The first test is in fact derived from patent law. Even though I have in what precedes gone to considerable lengths arguing that legal transplants from other IP rights are often ill-advised, I nevertheless think that taking inspiration from the doctrine of equivalence test in patent law is an acceptable way forward. First of all, as is the EDV concept, the doctrine of equivalence is also a hybrid concept “creating scientific, legal and pragmatic questions”. Secondly, fundamentally the issue of establishing whether a plant variety is an EDV and establishing whether an allegedly infringing product is equivalent to a patented one, is very much the same if not identical kind of exercise/evaluation. Thirdly, even though the argument has been raised that the EDV concept is special as the EDV needs to be distinct from the initial variety, creating an allegedly unique IP situation, I have argued in this contribution that I do not think that this is a situation which is much different from what happens under the doctrine of equivalence, as a patent on the allegedly infringing product does not necessarily take away the fact that it can still infringe an earlier patent. I therefore think that it is an allowable argument to take at least inspiration from the doctrine of equivalence under patent law.
I use herein for convenience reasons the most recent doctrine of equivalence test developed by the UK Supreme Court in the Actavis v Eli Lilly case. The test developed in this case is the following:

“ii) In deciding whether a variation is immaterial, one should ordinarily ask three questions:

a) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?

b) If yes, would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

c) If yes, would a reader of the patent have concluded that the patentee nevertheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?”

I now reword the above questions for purposes of the EDV concept:

“ii) In deciding whether a variety is an EDV, one should ordinarily ask three questions:

a) Notwithstanding that it is not within the literal meaning of the relevant initial variety, does the derived variety achieve substantially the same result in substantially the same way as the initial variety, i.e. does it retain the essential characteristics of the initial variety?

b) If yes, would it be obvious to the person skilled in the art, knowing the initial variety, but knowing that the derived variety achieves substantially the same result as the initial variety with the exception of the derivation, that it does so in substantially the same way as the initial variety by using the essential characteristics of the initial variety?

c) If yes, would the skilled person studying the initial variety have concluded that the plant variety right holder for the initial variety nevertheless intended that strict compliance with the literal meaning of the relevant characteristics of the initial variety was an essential requirement of the plant variety right application?

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41 Ibidem, paragraph 66.
If the answer to the last question is no, then the derived variety is an EDV.

A second possible test is based on the work of Jerome Reichman\(^{42}\). He has suggested quite a few years ago a so-called liability system as a replacement for the patent system, which he argued was rather inefficient, as it grants too many patents which are only marginally different from what is already in the state of the art. His argument, which I do not comment further on in this contribution, is that the quality of examination is low, leading to too many patents of questionable quality being granted. He refers in this context to “subpatentable innovation”. Those patents put a burden on society, as patents can be enforced, and patent rights can be exercised, leading to potentially monopolistic pricing, which brings additional costs for society. His idea was to replace the system with a type of liability system, where inventors can claim some sort of exclusive right into their inventions, but they could not prevent third parties from using their inventions for further development. Third parties using the inventions for further development would then be liable to compensate the original inventor for the use of the invention.

A similar system could be used for plant varieties. Even though the system devised by Reichman assumes that there is no one with an IP right, I think that the system can still be useful and applied in cases where there is an IP right, but where there is free access to the protected material. In that sense, my suggested solution combines features of IP rights and the liability system developed by Reichman. I think that is defendable, as the specific nature of plant variety rights, which allow competitors to use the protected material for breeding and market the new variety without compensation provided it is not an EDV, fits within the liability system, which excludes any full exclusionary right. Indeed, the PBR system does not provide a fully exclusionary right, for the reasons mentioned.

I start again from a rather broad definition of what is an EDV, also as this is in line with the intention of the legislature, as set out earlier. All varieties which use the essential characteristics of the initial variety would be deemed to be EDVs. I also retain the concept that the developer of the initial variety obtains some sort of exclusivity in the new initial variety. All the developers of such EDVs would then be under an obligation to pay compensation to the initial variety right holder for the use of the initial variety in the development of their EDVs. Such a system would catch multiple birds with one stone.

1) It gives meaning to the EDV concept as laid down in the treaty.

2) The developer of the initial variety receives compensation for the use of his variety.

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3) The developer of the initial variety is capable of sharing in the proceeds of the EDV which has been developed on the basis of the initial variety and which EDV will in many cases be in competition with the initial variety. By providing an obligation to give compensation to the initial variety right holder, the loss of profits which typically accompanies the entering into the market of the competing EDV can at least be compensated, introducing an element of fairness into the system.

4) It respects the one of the fundamental principles underlying the PBR system that guarantees access to germplasm for further breeding.

6. Conclusion

In this contribution I have argued that the rationale of the legislature in developing an EDV concept under the UPOV 1991 Convention was to strengthen the rights of breeders. That brings with it that a very narrow interpretation of the EDV concept is contrary to the intention of the legislature.

I have in this connection also argued that an interpretation limiting the EDV concept to “plagiarism” is contrary to the intention of the legislature, using conventional means of interpreting international treaties. That comes besides and above the conclusion that, absent any specific definition of what is understood by “plagiarism” in PBR law, and taking into account that the concept is transplanted from a rather different legal system which additionally functions very differently from the PBR system, invoking this standard is ill-advised.

I have further explained that a narrow interpretation given to the EDV concept, seems to try to marry two inherently incompatible concepts, i.e., providing an IP right with a view to stimulate innovation in breeding, but on the other hand not allowing such IP right holders to effectively enforce the IP rights so obtained. It is very difficult if not impossible to square this circle, reason also why the “plagiarism” test cannot provide an adequate form of protection. Until and unless a broader interpretation is being given to the EDV concept, users will continue to question the fairness of the system and the suitability of it for their business activities. If no changes are made, the EDV concept will continue to haunt the legislature for many years to come.
I have finally argued that, using as a starting point a wider interpretation of the EDV concept, whereby a variety is an EDV if it uses all essential characteristics of the initial variety, a number of tests could be developed which can assist users in understanding the concept. One test was based on the doctrine of equivalence in patent law, a doctrine which is in reality not that much different from the EDV concept, and which stems moreover from a rather similar background, as it is also a hybrid concept, founded in a combination “scientific, legal and pragmatic questions”. A second test was based on the idea of a liability rights system, whereby the developer of an EDV can develop and commercialise such EDV, but would be under an obligation to provide compensation to the right holder of the initial variety. That does justice to the legitimate expectations from the plant variety right holder of the initial variety of being able to enforce his rights against competitors and receive compensation from such third parties for the use of his initial variety. At the same time, it respects the important principle of access to germplasm for purposes of breeding, and it gives the subsequent breeder the freedom to develop competing varieties.

I hope that this contribution will inspire the legislature in the next phase of implementing an effective and workable EDV system under UPOV 1991.
UPOV guidance on EDV

Ms. Yolanda Huerta

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The concept of essentially derived varieties (EDV) was introduced in the 1991 Act of the UPOV Convention with the aim of providing an effective incentive for plant breeding that would maximize progress in the development of new, improved varieties for the benefit of society.

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 (1991 Diplomatic Conference), adopted the following resolution:

“Resolution on Article 14(5)

“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.”

Several meetings and deliberations have taken place in UPOV with the view of developing guidance to increase the understanding of the EDV concept. This is an ongoing process, the last version of the EDV guidance was adopted in 2017 by the UPOV Council (see document UPOV/EXN/EDV/2 at https://www.upov.int/explanatory_notes/en/).

We are at a crucial moment of reflection on this topic. The information presented at this Seminar will assist during the deliberations at the Administrative and Legal Committee (CAJ) of UPOV meeting this afternoon. The CAJ will review whether there is a need or not to open up discussions on this subject.

In this context, it is useful to recall the purpose of the EDV concept. It ensures sustainable plant breeding development by providing effective protection for the breeder and encourages cooperation between breeders and developers of new technologies.

It is important to develop EDV guidance that will provide certainty and clarity to enable cooperation and agreements between breeders for the PVP system to have the effect that was designed for: the development of new varieties of plants, for the benefit of society.
The context of this topic is presented in the above slide: there is a Breeder 1 that has developed an initial variety “Variety A” using other varieties and a lengthy breeding process of several years. Then, we have the situation where from that initial variety, another variety is developed “Variety B” by Breeder 2.

In order for the EDV concept to apply, there are three important elements provided under 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.”
In the scenario presented in the above slide, if Breeder 2 wants to commercialize essentially derived “Variety B”, Breeder 2 will need to have the authorization of Breeder 1, the breeder of the initial variety “A”, but that legal dependency would only take place if the initial variety is protected.

The key elements of the EDV concept in the Convention are: predominantly derived, clearly distinguishable and conformity in the expression of the essential characteristics.

If we look into whether essentially derived varieties can be protected, the answer is yes. What are the conditions to grant protection for the essentially derived variety? They are the same conditions as for any other candidate variety that will be presented to any national or regional office of plant breeders’ rights: novelty, distinctness, uniformity and stability. UPOV has developed a lot of guidance on the topic of conditions of protection (see at https://www.upov.int/upov_collection/en/).

The second question: can the essentially derived variety be commercialized? For that question, we know that the 1991 Act of the Convention provides this legal dependency, so the breeder of the EDV will require the authorization of the holder of the right of the initial variety to commercialize the EDV. I will introduce in the following slide the context of what is in the current EDV guidance adopted in 2017.

Slide 2

**ESSENTIALLY DERIVED VARIETY?**
I would like to highlight with the above slide that we have two varieties: one variety might be considered to be essentially derived from the other variety because the only difference is in the color of the basal part of the stem. We can observe some elements that could be considered “essential” characteristics, while other elements may not be “essential”. What are the elements in the current guidance that might give insights on the possible way forward?

The current guidance provides that there are two possible starting points:

“29. Both predominant derivation (e.g. evidence of genetic conformity with the initial variety) and conformity on the essential characteristics (e.g. evidence on conformity in the expression of the essential characteristics of the initial variety) are possible starting points in providing an indication that a variety might be essentially derived from the initial variety.

“30. In some situations, relevant information provided by the breeder of the initial variety on predominant derivation and/or on conformity on the essential characteristics might be used as the basis for the reversal of the burden of proof. In such situations, the other breeder might need to prove that the other variety is not essentially derived from the initial variety. For instance, the other breeder would need to provide information on the breeding history of the other variety to prove that the variety was not essentially derived from the initial variety.”

In relation to “predominant derivation”, we know that there are practices between breeders where molecular markers have been used to provide initial evidence of genetic conformity with an initial variety. Another possible starting point is the conformity with the essential characteristics of the initial variety, and then again when there is evidence of such a conformity, breeders involved have also come together to find possible agreements.

What is the current guidance telling us about the notion of predominantly derived?

Document UPOV/EXN/EDV/2 contains the following:

“4. The requirement of predominant derivation from an initial variety means that a variety can only be essentially derived from one initial variety. The intention is that a variety should only be essentially derived from another variety when it retains virtually the whole genotype of the other variety. A derived variety could not, in practice, retain the expression of the essential characteristics of the variety from which it is derived unless it is almost entirely derived from that initial variety.”
Another part of the current guidance addresses the notion of essential characteristics. Document UPOV/EXN/EDV/2 contains the following:

“6. The following might be considered in relation to the notion of “essential characteristics”:

(i) essential characteristics, in relation to a plant variety, means heritable traits that are determined by the expression of one or more genes, or other heritable determinants, that contribute to the principal features, performance or value of the variety;

(ii) characteristics that are important from the perspective of the producer, seller, supplier, buyer, recipient, or user;

(iii) characteristics that are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics;

(iv) essential characteristics may or may not be phenotypic characteristics used for the examination of distinctness, uniformity and stability (DUS);

(v) essential characteristics are not restricted to those characteristics that relate only to high performance or value (for instance, disease resistance may be considered as an essential characteristic when the variety has susceptibility to disease);

(vi) essential characteristics may be different in different crops/species.”

The following extract of document UPOV/EXN/EDV/2 reflects the understanding in 2017 of the differences in essential characteristics:

“9. The words “except for the differences which result from the act of derivation” do not set a limit to the amount of difference which may exist where a variety is considered to be essentially derived. A limit is, however, set by Article 14(5)(b)(i) and (iii). The differences must not be such that the variety fails “to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety”.

“10. The examples given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few. However, if there are only one or few differences that does not necessarily mean that a variety is essentially derived. The variety would also be required to fulfil the definition stated in Article 14(5)(b).
“11. The derived variety must retain almost the totality of the genotype of the initial variety and be different from that variety by a very limited number of characteristics.”

I would like to end the introduction of the context with an image that was presented in a previous EDV Seminar in 2013 (see at https://www.upov.int/meetings/en/details.jsp?meeting_id=29782).

**Slide 3**

The above example relates to a spontaneous mutation of Dianthus. Is it an essentially derived variety, yes or no?

It is important to observe what is happening in the real world: what are the situations that breeders are facing? what is their practice? what is their understanding of the EDV concept?

I would like to summarize by noting that the development of guidance to increase the understanding of the EDV concept is an ongoing process.

The purpose of the Seminar is to consider the impact of EDV policy on breeding strategies and the consequences for the development of new, improved varieties of plants.

The Seminar will provide perspectives covering various breeding methods and different types of plants. Today’s Seminar is expected to assist the CAJ in its review of the current guidance in document UPOV/EXN/EDV/2.
SESSION II

IMPACT OF EDV CONCEPT ON PLANT BREEDING

**Outlook for agricultural crops**
Ms. Magali Pla, Deputy Manager of Industrial Property, Limagrain, France

**Outlook for ornamental plants**
Mr. Micha Danziger, Danziger “Dan” Flower Farm, Israel

**Outlook for vegetables**
Mr. Laurens Kroon, Head of Research, Bejo, Netherlands

**Outlook for fruit**
Ms. Emma Brown, Business Development Manager, Plant & Food Research, New Zealand
Impact of EDV Concept on Plant Breeding:
Outlook for agricultural crops

Ms. Magali Pla
Deputy Manager of Industrial Property,
Limagrain, France

Limagrain

Limagrain is an international seed group owned by a French Cooperative. It has been founded and is managed by French farmers. It represents nearly 2,000 farmer members and more than 10,000 employees. The group is No. 4 seed company worldwide with nearly 2.5 billion Euros in sales and has subsidiaries in 56 countries. It invests 14.3% of sales in research.

Limagrain is specialized in seeds and cereal products through its different Business Units (BUs) creating unique integrated cereal chains.

Limagrain Coop, the mother company, focuses on the plant production activities of its coop members. The BUs in Field Seeds and Vegetable seeds are covering seed activities from breeding research to business and serve the needs of farmers, vegetable growers and vegetable processors. The Cereal Ingredients activity is for the agri-food industry, the Bakery Products division sells directly to consumers, finally, the Garden Products activity serves the needs of gardeners.

More specifically in the seed sector, the Limagrain Vegetable Seed is No. 2 worldwide with 678 M€ of consolidated sales contributed to the Group. It breeds more than 30 species, including tomato, carrot, melon, cauliflower, and bell pepper seeds. Through six BUs all over the world, Limagrain Field Seeds works on about ten crops. Amongst them, corn, wheat, sunflower and rape seeds, contributes for 1,302 M€.

In the following part, I will develop Limagrain view on the EDV principle and its implementation on plant breeding in agriculture crops.
What “Essentially Derived Variety principle” (EDV principle) means for Limagrain?

The process of essential derivation from an initial variety (INV) is based on three pillars that we will refer below as “EDV principle”.

The first pillar is the “EDV purpose”, the second one is the “EDV legal framework” and the third one is the “EDV implementation guidelines”. All three pillars are interconnected and the ignorance of one of them is detrimental to the whole EDV principle.

Variety creation is a long and risky process requiring an important human and financial investment over time. Specific skills, access to germplasm, up to date infrastructure and a sustainable mid to long term vision are key requirements for success. The breeder’s exemption, as introduced by UPOV for the creation of new variety from the available existing variability, allows all breeders to benefit from the genetic progress made by the entire breeding community and to enlarge and mix a large scope of genetic variability.

The “EDV purpose” is fundamental as it provides the original intention of the member states delegates who, back in 1991 in Geneva, had the objective of strengthening the breeder’s right and introduced the idea of dependency of the breeder of the EDV to the holder of the title of the INV (Records of the Diplomatic Conference for the revision of the International Convention for the protection of new varieties of plants, Geneva, 1991).

Because of the large investment on variety creation, the initial breeder’s contribution to a new variety needs to be acknowledged whenever such contribution is predominant in that new variety, which leads to an EDV. As such, an EDV can be seen as an improvement of the INV. Consequently, the mere addition of a trait in an INV cannot prevail on the predominant use of that INV, whatever the importance of this trait.

The “EDV legal framework”, is the legal expression of the original purpose. It allows the title holder of the protected INV to get a fair return on the investment whenever his variety is EDV of the INV. Article 14 (5) on the Act of the UPOV Convention 1991 is providing an extension of the breeder scope right and a legal definition of EDV.

The definition lists three conditions which need to all be fulfilled by a variety to be qualified as EDV. In a nutshell, the variety needs to be predominantly derived from the INV, distinguishable from the INV and to conform, except for the differences which result from the derivation, to the INV in the expression of the essential characteristics that result from the genotype.
From our viewpoint, it is critical that EDV definition be implemented and interpreted in a harmonized way at national levels in order to remain in full alignment with the EDV purpose. Besides, EDV principle is a matter of scope of protection and enforcement rights. Therefore, it is to the holder of a title to decide whether he defends his right or not before the competence of the judiciary power and not before national plant variety rights’ authorities, which are mandated to grant titles.

The third pillar are the EDV implementation guidelines that provide practical rules and tools to qualify an EDV status.

These guidelines can be developed in house by breeders or agreed at the level of the sector eventually crop by crop. As an example, for the maize sector agreed on breeding tools based on threshold of genetic distance and specific set of markers to assess such distance. Such tools are available in International Seed Federation (ISF) crop guidelines.

We can also refer to rules available in the ISF view on IP (2012) and Regulation for the Arbitration of Disputes. One of such important rules the sector agreed on at ISF level, states that the burden of proof is placed on the breeder of the putative EDV, on the basis of data provided by the breeder of INV, to prove the non-predominant use. This rule is essential for an efficient respect of the legal framework.

Finally, EDV further means for Limagrain a virtuous long-term effect for the sector. If on the one hand it is important that the entire breeding community can use the most advance genetic sources for further breeding, on the other hand it is important that a broad genetic variability be created. Thanks to the implementation of the EDV principle, we believe there is a good balance between the opportunity to access to genetic elite resources and the creation of a certain level of genetic diversity between commercialized varieties. As such, EDV eventually contributes to the promotion of innovation.

**In this context, Limagrain aims to develop varieties taking into account the UPOV EDV principle.**
How Limagrain implements EDV principle?

Limagrain has **four basic rules** related to EDV implemented on breeding programs.

The first one is the Germplasm qualification process. It consists in Databases with “Freedom To Operate” criteria related to legal, IP, regulatory etc... topics. Such criteria can include EDV/Non-EDV status. The germplasm needs to qualify and get a “valid passport” for breeding and commercialization.

Second, when writing contracts (e.g. research collaboration) we use, whenever possible, **EDV based definitions** in order to define what one can do or not do, who owns what, etc. and to protect the interest of each breeder party. This is mainly the case in private agreements between companies, to have access to protected INV owned by third party, for breeding, trait development and commercialization. This specific use might go beyond the EDV purpose, but it shows that EDV principle is acknowledged by Limagrain and, to some extent, the breeding community it is dealing with.

The third rule relates to **practical breeding process and tools** used for the development of new varieties from the existing variability. We generally rely on standard breeding schemes to avoid similarity risks. Such “secured” **breeding schemes** rules is adopted for example in wheat and in corn. For this latter crop, we systematically avoid cross between sister lines when such lines come from the same commercialized hybrid.

We also rely on the use of molecular tools during a breeding program. This can be either an internal set of markers, like for example in wheat, or industry agreed set of markers, like in maize. Indeed, in the maize community EDV debates in the 1990’s resulted in adoption of a common set of guidelines based on homology (1-D) between varieties based on Rogers' distance. A public set of SNP markers is used to define 3 pragmatic zones based on homology:

- A **red zone** (homology>0.95), the homology with the INV is so high that we assume that such INV must have been used to create the new line. There are strong indications that the new line is declared predominantly derived from the INV.

- An **orange zone** (0.91<homology<0.95), the homology found is judged to be sufficient evidence to justify a “reversal of the burden of proof”: the accused party has to open breeding books and demonstrate that the INV was not used to create the new line.

- A **green zone** (D<0.91), the homology with the INV is low enough so we assume the new line is a new Initial Variety. It is reciprocal to the red zone.
This practical tool is used, in the frame of an in-house FTO-specific procedure and according to potential contract obligation and restriction, for:

- monitoring the genetic distance between both parents (hybrid we have access to and our own line) used to create new breeding populations to avoid narrow crosses in order to avoid potential EDV cases.

- monitoring the genetic distance between progenies and parents in order to identify and discard early potential EDVs.

Finally, the last and fourth rule is dealing with trait introgression practice. Trait introgression are used to improve a given variety by transferring inheritable traits of interest. Such introgression will be achieved by using Limagrain own germplasm or variety. The variety is then expected to lead to an EDV of Limagrain proprietary varieties assuming it fits with the EDV definition provided above. Trait driven by alleles able to restore fertility (Rf) induced by cytoplasmic male sterility in corn, or alleles for insect tolerance trait in wheat are few possible examples of trait introgressed by backcrossing.

**Perspectives in the context of New Breeding Technologies (NBTs) and Conclusion**

This last part is dealing with the perspectives of the EDV principle in the context of the occurrence of the NBTs.

We believe the EDV principle is independent of the technology used to create a trait. Therefore, even in a context wherein NBTs will be used for trait development, Limagrain will keep on the same practice as described above that is, trait creation or introgression will only be made in our own germplasm, to improve our own plant material, irrespective of the technologies used (tilling, GM technologies, NBTs, etc.). However, such position can only be applicable if the EDV legal framework and its interpretation remain in line with the EDV purpose of the 1991 Act of the UPOV Convention.

In conclusion, this paper shows that Limagrain breeding process respects and takes fully into account the EDV principle, that is, the purpose, the legal framework and the implementation tools and rules. Limagrain recognizes the contribution of the protected INV for the creation of a new variety, whenever such contribution is predominant and whatever the technology used to achieve that new variety.

The UPOV “EDV principle” needs to be reaffirmed and seed business needs to rely on an internationally harmonized EDV legal framework which does not impair EDV principle.
Impact of EDV Concept on Plant Breeding:
Outlook for ornamental plants

Mr. Micha Danziger
Danziger “Dan” Flower Farm,
Israel

Danziger – Short Introduction

Micha Danziger (Chairman of the Board) of Danziger “Dan” Flower Farm (since 1953), the second generation of an Israeli family owned global company specializing in the breeding, production and marketing of hundreds of new horticultural varieties of cut flowers, annuals and perennials. Danziger’s R&D center is located in Israel, and additional R&D sites in Kenya, Colombia and the United States of America. Danziger has been a CIOPORA member for many years.

Micha Danziger serves also as the CEO of Danziger Innovations (NBT company with a Genome editing technology for site specific mutations, an affiliate of Danziger), and also serves as Chairman of the Board of Equinom and Israeli advanced breeding company focused on breeding of orphan crops (such as sesame) and high protein crops (“smart food seeds by design”).

The essence of the EDV concept

It takes many years and enormous funds to breed, introduce and market a successful variety. In order to maintain the source of innovation we must have a sufficient return on investment through appropriate intellectual property (IP) protection.

In vegetatively reproduced ornamental crops, the EDV concept is all about mutants (and a bit genetically modified organisms (GMOs)).

Many new ornamental varieties are the basis for the development of mutants (natural, induced or otherwise developed by new breeding techniques - NBT). Creating a mutant may be quick and easy in some aspects (such as traditional breeding).
Yet, creating a mutant may be more complex and expensive in other aspects (such as New Breeding Techniques).

However, in both cases, developers of mutants deliberately choose a valuable initial variety as the source of their mutant, as they wish to benefit from its genetics and marketing added value.

For this reason the initial breeder should be commercially compensated.

A clear EDV definition is required

A sufficiently broad and clear EDV definition is required in order to avoid lack of stability in the IP regime. For example, see 2 completely opposite court rulings in respect to the exact same varieties, that Danziger was involved in (The Million Stars – Blancanieves cases).

While defining the absolute EDV it is important to take into consideration the interests of traditional ornamental breeders and innovative EDVs developers and to balance them.

Court cases and EDVs

Conducting IP court cases are time consuming and very expensive (legal fees, genetic analyses, expert opinions). Most of the ornamental breeders don’t have the resources to spend so much time and money on court cases, as we breeders prefer to work in the field and breed rather than being in court rooms.

This path can be taken only in extreme cases, protecting a very unique and successful variety. This was the case with Danziger’s Million Stars® Gypsophila variety.

We at Danziger had to face several court cases in order to protect ours’ and our lawful customers’ legal rights.

Example of one unique court case can be given in the matter of Million Stars vs. Blancanieves (Gypsophila). In Court no. 1, the variety declared to be an EDV, having 17 morphological differences compared to Million Stars. All differences were proven to be a result of the act of derivation (chromosome doubling). In Court no. 2, an opposite decision was ruled. Blancanieves was found not to be an EDV due to the number of differences.
A Broader Scope of EDV Concept should be adopted

Varieties derived from an initial variety, but not retaining all the essential characteristics of the initial variety, and even if all morphological differences result from the act of derivation – may not be considered an EDV according to the UPOV current Explanatory Notes (EXN) on EDV.

According to UPOV Explanatory Notes today the differences between the EDV and the Initial Variety should be “one or very few”.

According to UPOV Explanatory Notes, today if a variety does not retain the (= all) “essential” characteristics of the initial variety, it will not be an EDV.

In our point of view the number of differences or their nature does NOT matter – if you created a mutant (or GMO) out of an initial variety – it is an EDV, as long as the differences are a result of the act of derivation.

Excluding most mutants and GMO’s from the EDV concept by way of a very narrow definition of EDV would be harmful to initial breeders.

We can mention some examples which we find awkward (typical in ornamentals) that would not be EDV’s under the current Explanatory Notes of UPOV (EXN):

- Color mutants
- Longer shelf life
- Different growth habit
- Disease resistance/tolerance

Just imagine that a color mutant is not an EDV!

This is the most common mutant in the ornamental industry, which many times is very easy to create.

New Breeding Techniques (NBT) and EDV

We believe varieties resulting from NBT are mutations, exactly as natural /“old fashion” mutations are, because they retain almost the whole genome of the initial variety.

The reason to choose a specific initial variety and use a NBT to modify it is the initial varieties’ advantages. Otherwise – please feel free to use an open unprotected variety.
In our opinion - **the type of technology creating a mutant doesn't matter.** Whether “old fashion” mutation breeding or NBT- it is still a mutant and the developer should commercially compensate the initial breeder. We understand that NBT can result in significant improvements compared to the initial variety, but still the overwhelming part (100% minus a tiny fraction) of the genome of the new variety comes from the initial variety, and we feel it would be unfair to the breeder of the new variety not to respect this.

Danziger holds this opinion even though we have in Danziger Innovations a patented NBT called “MemoGene®”, allowing a site specific deletion technology.

**Breeding Aspects and implications**

The Danziger group respects the IP of others as we expect others to respect our IP.

We honor IP rights as we understand the importance of the protection, granting return of investment to the breeder for many years of investment of time, funds, manpower in the breeding, sales, marketing and commercialization of a new variety.

We honor IP rights as we want the genetic germplasm to evolve.

Therefore, should Danziger want to use another breeders patented variety (for example a variety with a utility patent), Danziger will request a license from the other breeder and will sign a binding agreement that authorizes use.

We at Danziger don’t create mutants/EDV’s using classical breeding nor NBT’s without the permission of the initial breeder, and we don’t intend to do so.

Therefore, we hope that the narrow interpretation of UPOV for the EDV concept will NOT stay as is, as the risk of the current interpretation is that it will lead ALL breeders to take advantage of the “legal loophole” whereby mutant breeders can get away without having the initial breeder’s authorization.

As emphasized – we are totally against this.
Commercial Aspects and implications

EDV can ensure a fair return on investment to the breeder of the Initial Variety.

Due to growing competition worldwide, and the ongoing consolidations – amongst small and medium breeders, many of them highly innovative, will not have the resources to compete with the big companies, surely not in courts, and surely not if the law is unclear and the result of a dispute is unpredictable.

Small - medium size breeders will face great difficulty protecting their varieties, and hence the genetic resources and progress will be compromised.

As already mentioned, breeding of a new variety may take many years of enormous investments in capital and human resources of the breeders. Launching a new variety will also require many years of investment of the sales and marketing teams from trials to semi-commercial and until a commercial phase is reached. Even then, in our modern world, most of the ornamental varieties last between 3-5 years. Sometimes they are out of the catalog even before they are granted with a PBR.

Mutants can easily harm the success of the very unique variety having this WOW effect which may allow it to survive and be a leading variety for many years.

In order to provide an indication of extent of mutant breeding, CIOPORA approached some European breeders in the ornamental market.

The figures shown here are estimates, of the percentage of mutant varieties on the market within each crop group.

These give some idea on the extent of mutant breeding in the industry.

In Chrysanthemum for example some indication show that when there is a top variety on the market which mutates easily, the percentage can be as high as 80%.

This was the case with the Reagan series some years ago.

So, in average we estimate 50% of Chrysanthemum varieties are mutants.

When color mutants will not be protected anymore by the PBR of the original variety the percentage will rise further.
Due to the fact that part of the mutants are not commercialized at the moment, because they are too close to the initial variety.

But in case of another owner (mutant finder) he will argue it is an important characteristic change and commercialize it.

Yet we argue that the importance of the characteristic is not of relevance for the EDV distinction. Achieving a good and successful variety is not an easy task, and it costs a fortune. If we as breeders invest this fortune and take all those risks, we must have a substantial return on this investment.

Granting the right for a mutant to be commercialized in the market without compensating the breeder of the initial variety will dramatically shorten the return of investment, and will cause demoralization of breeders to create new and novel varieties to the benefit of the world. Initial breeders should be given the right to control the commercialization of mutants (and GMOs) of their own bred varieties.

EDV developers and the initial breeder should negotiate the terms of commercialization of EDVs and the initial breeder should be compensated for the use of its genetics to create new varieties. Negotiation between breeders – and case by case value will be determined between the parties based on commercial value and WOW effect.

A fair and balanced solution is needed since EDV concept has huge commercial impact on the industry.

It is compulsory that the owner of the initial variety will give his consent to commercializing the derived variety. This stems from the clear fact that those who modified the initial variety, intentionally modified the initial variety, due to its attributes, they did not choose to modify a different open variety. This intention, creates the obligation for the mutant variety holder to approach the breeder of the initial variety, to discuss rights and terms of commercialization, and profit share subject to each parties efforts, as is customary in the patent arena.
Conclusion

Would it be reasonable to take a pencil and add an eraser at the end or change the color of the pencil and claim that this is a NEW product?

Would it be honest to create a mutant in a fruit variety which a breeder worked on for over a decade, improve or modify it a little bit, and then claim this was a totally NEW variety?

Or maybe modify only the color of a flower and claim this was an entirely NEW flower?

These case, in which a **new variety is produced with only ONE parent**, and IS NOT produced via sexual reproduction, as such **NOT an independent** NEW variety but rather **it IS AN EDV**.

Today, as our world of breeders expands to many countries the significance of EDV’s and incorporation in all the various legal systems around the globe has become imperative.

Summary

When **vegetative** propagation is the chosen propagation method:

1. **Any and ALL** mutants are EDV’s

2. A mutant is a new variety that has **only ONE parent**

3. **ALL** mutants, irrespective of number and type of modifications different from initial variety, **IS AN EDV**

4. Breeder of initial variety and EDV breeder will negotiate the proportion of each breeders contribution to the financial added value to the EDV.

5. As 28 years have passed, the time has come for UPOV’s to amend the Explanatory notes on EDV’s under the 1991 act of the UPOV convention.

These notes must reflect the present and prepare for the future, taking into consideration the rights of the Initial Breeder in the name of progress and innovation.

Today, as our world of breeders expands to many countries the significance of EDV’s and incorporation in all the various legal systems around the globe has become imperative.
Impact of EDV Concept on Plant Breeding:

Outlook for vegetables

Mr. Laurens Kroon
Head of Research, Bejo,
Netherlands

Bejo, breeder of vegetable seeds for the professional grower

Bejo is a leading company in breeding, production and sales of vegetable seeds. With operations in more than thirty countries, we are an internationally oriented family business. Our 1,800 employees are dedicated to developing the best vegetable varieties for the present and the future. We’ve expanded over the years in an organic, ongoing process, shaped by interaction between growers, dealers, supply chain partners and our own employees. All our partners have the freedom, within their own local market, to get the most out of our products.

Together for the long term

We build long-term relationships with our customers rather than going for quick wins. Our representatives are in close communication with growers, exchanging views and listening to their concerns. By keeping our ear to the ground, we can provide better support and advice for real and lasting crop results. We learn every day from experience. We want to know what is happening on the field and in the market. We use this practical knowledge to develop new varieties and produce seeds with better characteristics for growers and the chain.

Raising the bar with innovations

We invest considerably in research. Just as we were ahead in the 1960s in applying modern breeding techniques, we never stop actively exploring all new technologies. The more we learn about plants, right down to the DNA level, the more able we are to develop new varieties faster and more accurately than ever. This means varieties with even better growth characteristics that are well suited to sustainable farming. And it results in crops that meet growers’ needs and vegetables that appeal to consumers.
Harvesting now and fifty years from now

As the world population increases and more mouths need to be fed, there is a steadily growing need for good, healthy food. We contribute with our expertise and by further improving our breeding methods. We stay close to nature. We feel that the world’s scarce natural resources deserve protection, so that growers can harvest from healthy, fertile soil, now and in fifty years’ time. That’s why we are always looking for new, more sustainable farming methods and why we invest in a broad range of organic vegetable seeds.

Quality: the best seeds and the best varieties

We look with confidence to the future. As a family business, we continue to do what we have always done: produce the best seeds and create the best varieties for healthy, flavourful, sustainably grown vegetables. Working together with growers and partners in the supply chain to give good initiatives room to grow: that’s our passion. That’s Bejo quality.

Variety protection

Value of Breeder’s Exemption in vegetable breeding

Development of new, advanced vegetable varieties requires the use of a wide range of germplasm by the breeder. This can come from his/her own breeding pool, from genetic resources available at Genebanks and even from competitor varieties. By using the top varieties in the market and combining the best traits and genetics with the breeders own genepool, breeders are constantly raising the bar with improved varieties that suit the market’s needs even better.

The “breeder’s exemption” in the UPOV Convention enables plant diversity to be available for further breeding activities because acts done for the purpose of breeding other varieties are not subject to any restriction by the breeder. This reflects the fact that access to protected varieties contributes to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society¹.

The protection of the variety itself ensures that the breeding company can benefit from their hard work. Developing a variety can take 10 to 15 years, especially in biannual crops like cabbage, carrot, onion and red beet that Bejo works on. To develop varieties for the range of markets that we serve with our sales network, a substantial financial input is required.

¹ UPOV Frequently Asked Questions https://www.upov.int/about/en/faq.html#QR20
Hundreds of highly skilled professionals are working around the globe to combine high tech solutions and the breeder’s eye for variety development. Over 15% of our annual turnover is put into this process, and without good variety protection, getting a good return on this investment would be impossible.

*The definition of variety in the 1991 Act of the UPOV Convention, Article 1 (vi) states that “variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be “defined by the expression of the characteristics resulting from a given genotype or combination of genotypes [...].” The notion of “combination of genotypes” covers, for example, synthetic varieties and hybrids*.2

Trait patents can give an additional layer of protection over multiple varieties. There is much debate on the effect of patents on breeding material and the potential block on access to innovations that this may lead to. Bejo is of the opinion that PVP is the most preferred option for protection of the breeder’s interest. Patents on traits like disease resistance are pursued, but only to protect years (or even decades) of research in resistance mechanisms and trait introgression in elite breeding material from wild germplasm. We believe that products from Essentially Biological Processes (EBP’s) should not be patentable. Bejo is part of the International Licensing Platform (ILP), an organization that regulates access to patented traits of the ILP-members at a fair rate.

*Patents and plant breeders’ rights are separate intellectual property rights with different conditions of protection, scope and exceptions. Breeders can use plant breeders’ rights, patents or other forms of intellectual property rights, or a combination to the extent that such systems are available in the territory concerned. Nowadays, with recent technological developments, for example the rising number of gene-related patents and rapid progress in the field of genetic engineering, patents and plant breeders’ rights are more interlinked*.3

**Variety protection in hybrid vegetable crops**

A hybrid or F1 variety is a variety that is developed by combining traits from two elite breeding lines. One of the lines is used to produce the F1 seed on (mother line), the other line is used as a pollinator (father line). Both lines are developed by inbreeding to create a level of homozygosity in the parental line. The more homozygous (or genetically uniform) both lines are, the more uniform the hybrid variety will be. This results in a product for the farmer that is uniform in shape, color, harvest time and disease resistance.

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2 UPOV Frequently Asked Questions https://www.upov.int/about/en/faq.html#QR20

3 UPOV Frequently Asked Questions https://www.upov.int/about/en/faq.html#QR20
Many hybrids are protected through PVP on the parental lines. A hybrid variety can only be (re)produced by using both parental lines. As only the hybrid seed is sold, competitors have no access to the parents, so they can only use the F1 hybrid as starting material in their breeding program. Crossing or inbreeding with the hybrid will lead to a lot of diversity in the chromosome content of the gametes because of cross-overs. This means it will be nearly impossible to re-create the hybrid variety for a competitor, but the hybrid variety can be used as a source to cross in quality traits into the competitor’s germplasm. The chances that the use of the hybrid in the competitors breeding scheme will lead to an EDV in vegetable breeding are very slim, unless the competitor makes a deliberate effort to make a copycat variety. This can be achieved for instance by making a detailed DNA-analysis of the initial variety and design a new combination of parental lines from the offspring of the initial variety that mimic the initial variety when crossed.

**Variety protection in OP varieties**

For OP, or Open Pollinated varieties, the situation is quite different. With these varieties, only one line is used in propagation and seed production. The resulting seed is created by selfing or mass pollination. For a competitor, the genetics can be used under the Breeder’s Exemption to cross with their own breeding material. Using the initial variety for repeated backcrossing, or selecting new lines from the variation within the initial variety are processes that (may) lead to an EDV. For Bejo, lettuce is one of the few crops that is only available in OP varieties.

**New Breeding Techniques and EDV**

One of the main opportunities with New Breeding Techniques (NBT’s) like CRISPR-cas gene editing, is the ability to edit a significant trait in an existing variety (at least if the current legislation in your country of residence permits the use of these techniques in product development). For instance in lettuce, resistance to Bremia (downy mildew) is a valuable make-or-break trait in the market. Breeding for resistance against this pathogen requires a lot of input from both Breeding and Research, and involves crossing in resistance genes from wild relatives of lettuce and testing this against a wide range of isolates of the pathogen. Basically, it is a rat race between the breeder and the pathogen, because often the pathogen overcomes the resistance within 3 to 5 years. In a new approach, NBT’s can be used to target susceptibility genes in lettuce, possibly creating a durable form of disease resistance against Bremia.

However, this also causes a concern at breeding companies that NBT’s could be employed by competitors or even Tech companies to edit their top varieties in the market. According to some interpretations of the EDV Explanatory Notes, adding a single innovative trait like durable Bremia resistance in a commercial variety would qualify the resulting product as a non-EDV.
That would mean that the developer of the initial variety would get no additional revenue of their breeding effort, market development and investment in public-private research initiatives, while their varieties are replaced in the market by the improved ones.

A good balance between Plant Variety Protection and open (breeding) innovation is essential to make sure that all parties involved will receive a fair return of the investments that they have made. This will result in continued improvement of vegetable varieties to the benefit of both growers and consumers.
Impact of EDV Concept on Plant Breeding:

Outlook for fruit

Ms. Emma Brown
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Abstract

The introduction of the Essentially Derived Varieties (EDV) provision in the 1991 Act of the UPOV Convention (UPOV91) was a step change intended to balance the rights of breeders, regardless of breeding techniques and technologies employed, with the interests of the breeders of initial varieties and EDVs. Its introduction was a timely future proofing of the UPOV convention concurrent with the introduction and development of new breeding techniques. It is now appropriate to consider whether its application is still effective today.

A protectable EDV must be clearly distinguishable from the initial variety. The requirement for distinctness is fundamental to our Plant Variety Rights (PVR) system and creates the “bright-line” test between an EDV and an initial variety. As a discrete variety an EDV is in principle eligible for PVR protection. If it is not clearly distinguishable from the initial and other varieties of common knowledge then it cannot receive separate PVR protection but falls automatically within the scope of the earlier protected variety.

The prevention of plagiarism or copycat breeding is a question of distinctness. If a new variety is not clearly distinguishable from a protected variety then its commercialisation is a direct infringement. The fact that an EDV needs to be distinct from its initial variety clearly means that a copycat can never enjoy PVR protection in its own right as a copycat already lacks distinctness. This protects and enables innovation, regardless of breeding techniques and technologies employed, and the interests of breeders of initial varieties and EDVs are balanced as a new and clearly distinguishable variety is eligible for PVR protection.

However, due to the mixed model of implementation of the EDV provision internationally, even within the legislation of countries ratified with UPOV91, there is a very real possibility that a candidate variety would be considered an EDV in some countries, and not in others.
Over time, UPOV has developed guidance on the EDV provision. The first UPOV explanatory note (EXN) on the EDV provision was adopted in 2009, 18 years after the introduction of the provision itself. While that EXN was almost immediately opened for revision, it then took until 2017 (26 years after the adoption of UPOV91) for the second (and current) EXN on EDVs to be adopted. It is critical that we do not underestimate the important influence that the EXN can and does have, both on implementation of current national laws, and the shaping of new legislation and national policies.

New fruit varieties have breeding and development lead times of decades. Breeding programmes being undertaken today are 10-20 years away from delivering new varieties to consumers - but we need clarity now on how the legislation on which we rely to protect our innovation will be implemented. We are also at a crossroads for integration of breeding techniques, with the rapid development of new and potentially undetectable techniques, accompanied by shifting public perception of the science behind those new breeding techniques.

Plant breeders around the world want to be able to deliver new and innovative varieties, creating benefit for society and to receive a fair share of benefit on those innovations. To best enable breeders to continue to deliver innovation we request certainty from UPOV on the rights granted regardless of the breeding strategies employed. It seems timely for a clarification of the EDV concept within an updated EXN, which would clearly affirm the following 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 no automatically lead to the new variety escaping from qualification as an EDV.

Introduction

The concept of Essentially Derived Varieties (EDV) was first introduced into international law by the International Union for the Protection of New Varieties of Plants (UPOV) in the 1991 Act of the UPOV Convention (UPOV91) in the form of 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 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.” (EDV Provision).

The introduction of the EDV provision was a step change intended to balance the rights of breeders regardless of breeding techniques and technologies employed, and the interests of the breeders of initial varieties and EDVs. Its introduction was a timely future proofing of the UPOV convention concurrent with the introduction and development of new breeding techniques.

No concept of EDVs was contemplated in international law preceding UPOV91, respectively the 1978 Act of the UPOV Convention (UPOV78) and 1961 Act of the UPOV Convention (UPOV61). As the national legislation adopted by the member countries reflects the UPOV Act they have ratified, today there is considerable variability on whether and how EDVs are provided for among UPOV members. Those countries, such as New Zealand, which remain ratified with UPOV78 still operate today with no EDV concept or provision. Those member countries who are ratified with UPOV91 have adopted various models of the EDV concept, further influenced in some cases by the timing of adoption or updating of the EDV provisions coincident with any prevailing UPOV explanatory note (EXN). Further, the UPOV family has grown over time with each member’s EDV position being influenced by a mix of history, perspective, and the point in time at which they joined the conversation.

Evolution of breeding strategies

Over the 58 years since the 1961 Act of the UPOV Convention was adopted there has been measurable evolution in breeding strategies, regulatory environments, public perception, and the science behind breeding technologies.

In the era of the first two Acts of the UPOV convention breeding strategies largely consisted of conventional crossing, including deliberate outcrossing and backcrossing strategies. For fruit species this means long periods of evaluation and extensive lead times between undertaking crossing and having a variety ready for commercialisation. For example:
Apples and pears – 20+ years
→ Blueberries – 15-20 years
→ Raspberries – 10-15 years
→ Kiwifruit – 15-20 years
→ Stonefruit (apricot, peach, cherry etc) – 15-20 years
→ Table grapes – 15-20 years
→ Citrus – 15-20 years
→ Strawberries – 10-15 years

For some fruit species, such as apples, naturally occurring mutations are common. These are commonly referred to as sports. Sports and mutations in apple have brought forward valuable new varieties with characteristics of benefit to both consumers and growers (see Gala Case Study).

Conversely, the propensity for natural mutation in some species presents “quality control” challenges, requiring breeders and variety developers to take active measures to ensure the consistency and integrity of their varieties. The increasing use of techniques such as tissue culture propagation, which has been widely used in some crops for decades, and with advances in the methodology now being used in a broader range of fruit crop species, is a case in point. Rigorous standards and measures to guard against unintended somaclonal mutation are required to ensure sub-quality plants are not introduced. For example, in raspberry tissue culture plant propagation operators are careful to ensure trueness to type, ensuring a known common mutation is not introduced through sub-optimal techniques. This mutation has significant implications in fruit quality that can result in poor productivity or rejection of fruit for high quality market uses.

The step change between UPOV78 and UPOV91 that saw the first introduction of the broad EDV concept responded to the continued evolution of breeding techniques that occurred within the intervening 13 years, and in some part was also applying foresight to how outcomes of the new breeding techniques that were in vogue at the time (genetic modification) would need to be accommodated within the PVR system. Although with hindsight we might now conclude that certainly in the context of fruit breeding strategies “in the late 1990’s public scepticism cast genetic modification as the answer to the question no-one was asking” (David Hughes, Chief Executive Officer, PFR, 03/09/2019).

The state of change in breeding strategies, related regulatory environments, public perception, and the science behind breeding technologies, was recognised and in 1991 UPOV had the objective of an immediate requirement to start the discussion on the details of the EDV concept. However, this did not commence until 2007.
Conventional crossing was still the dominant breeding strategy employed in fruit species at the time of the introduction of the EDV concept, with naturally occurring mutations varying in commonality by species. In parallel, research and development in new breeding techniques was under active development. Bringing us to today where we now see the results of those evolved versions of breeding methodologies in use in fruit breeding strategies.

A strength and benefit of UPOV from a legal and commercial standpoint is the provision of model international law that enables member countries freedom to customise their national law. However, in the case of adoption of the EDV provisions this has created a mixed result. Due to the various timelines to ratification of UPOV91 and variability in implementation of the EDV concept in the legislation of countries ratified with UPOV91 there is a very real possibility today that a candidate variety would be considered an EDV in some countries and not in others.

With the seemingly subjective nature of the definition of EDVs and the variability in national legislation, confusion in roles and accountabilities can arise between breeders of initial varieties and discoverers of EDVs. Such confusion can lead to disputes; cases that illustrate this which have come to public attention include those around ‘Cripps Pink’ apple, and ‘Nadorcott’ and ‘Tango’ mandarin.

The first EXN on the EDV provision was adopted in 2009, 18 years after its introduction. While that EXN was almost immediately opened for revision it then took until 2017 (26 years after the adoption of UPOV91) for the second (and current) EXN on EDVs to be adopted. It is critical that we do not underestimate the important influence that the EXN can and does have, both on implementation of national laws, and in the shaping of new legislation and national policies.

The opportunity for any of the member countries to review, amend, or adopt new legislation and national policies is a rare one. When any member country does have this opportunity, it is to UPOV91 to which they look for guidance, however not in isolation. Member countries look to the EXN and additional explanatory notes adopted by UPOV and to the national laws of other member countries to observe how the convention has been given effect. New Zealand, for example, is currently ratified with UPOV78 and is in the process of legislative review and the accountable Government body has prepared an options paper for public review and submission. The preferred option, concerning definition and provision for EDV, highlights the respect and influence of UPOV and the EXN on the creation of relevant legislation. The preferred option put forward focused on the difference and the significance of the difference between an EDV and the initial variety rather than the genetic similarity.
Accepting that within many countries the current regulatory environment reflects a low or no acceptance of genetic modification, it appears that science and public perception is moving forward. The rate of change in the science and the rate of positive change of public perception are observed to be accelerating. In this context, the EDV concept that created such a step change from 1978 to 1991 will now likely be tested even more in the next 10, 20, or 50+ years. The EXN deserves to be revisited to ensure the balancing of the scope of outcomes of new breeding techniques and traditional breeding is still well-served, and the interests of the breeders of initial varieties and EDVs are balanced.

Many breeding companies are advancing swiftly towards a future where their overarching breeding strategies are not fixed within one methodology, but may employ a combination. The multidisciplinary approach is motivated to increasingly fast track and deliver new innovative varieties, augmenting conventional breeding with marker assisted selection and whole genome selection among other techniques.

It is essential that users of our PVR regime have clarity, transparency, and certainty regardless of the breeding strategies they employ. Our system relies heavily on integrity, and therefore confusion amongst breeders and in the market place benefits no one, least of all consumers.

A protectable EDV must be clearly distinguishable from the initial variety. The requirement for distinctness is fundamental to our PVR system and draws the line between an EDV and a variety which is not clearly distinguishable from the protected variety. As a discrete variety, an EDV is in principle eligible for PVR protection. If it is not clearly distinguishable from the initial and other varieties of common knowledge then it cannot receive separate PVR protection but falls automatically within the scope of the earlier protected variety. The prevention of plagiarism or copycat breeding is a question of distinctness. If a new variety is not clearly distinguishable from a protected variety then its commercialisation is a direct infringement. The fact that an EDV needs to be distinct from its initial variety clearly means that a copycat can never enjoy PVR protection in its own right as a copycat already lacks distinctness.

The status quo also creates issues around enforcement. How can the owner of a variety with PVR protection hope to enjoy and enforce their rights for the limited period of time in which they have them if equivalent rights are granted to varieties which can hardly be differentiated from the pre-existing protected variety?

The following case studies illustrate real situations where the EDV concept and the way that it is applied affect plant variety innovation, consumer benefit, and the interests of the breeders of initial varieties and EDVs.
Gala Case Study

The apple variety ‘Kidd’s D-8’, marketed as Gala, was bred through conventional crossing in New Zealand. Gala fruit are well known to consumers around the world. Since its release in the 1970’s there has been a proliferation of sports (Figure 1). There is a degree of technical difficulty in identifying a sport with potentially beneficial characteristics, propagating successive generations, and confirming uniformity and stability. Given this proliferation, it seems inevitable for consumer confusion to arise and the significant cannibalisation of the market of the initial variety has resulted. The allowance of the use of the marketing name Gala in a wide range of denominations and marketing names also suggests exacerbation of that confusion and loss of market share.

As can be seen in the representation in Figure 1, the high degree of genetic conformity to the initial variety is inherent when varieties are developed in this way. It is also interesting to note the pattern among the distinct characteristics of the respective EDV’s of ‘Kidd’s D-8’; they are predominantly high fruit colour mutants or with fruit harvest-season variations from the initial variety, some of these would of course fit the definition of an EDV as a “copycat”. However, note the variety marketed as Blondee™ which is a yellow colour mutant, is this still an EDV? Arising as a sport it has, by definition, a high degree of genetic conformity but due to a substantial change in an important characteristic - it could not be considered a copycat.

![Figure 1: A subset of the naturally occurring mutations of ‘Kidd’s D-8’ apple](image-url)
Pink Lady® Case Study

Increasingly we are seeing commercialisation models for fruit crops that bundle intellectual property. A high profile and highly successful example of this is the Pink Lady programme, where the apple variety ‘Cripps Pink’ is marketed as Pink Lady®. The intellectual property bundled in this commercialisation model includes PVR, a registered trade mark and by-lines, a brand strategy and grower support.

Since the release of the initial variety ‘Cripps Pink’, naturally occurring sports have been discovered and developed. These new varieties have been selected for improved characteristics such as better fruit colour and higher disease resistance. A range of the sports have been granted PVR. Even though they are EDVs they have been found to be to be distinct from the initial variety. This is consistent with the EDV concept providing a balance in the interests of the breeders of initial varieties and EDVs.

However, most fundamentally for Apple and Pear Australia Limited (APAL), the owner of the brand, the fruit produced and sold from these varieties are not marketed as Pink Lady® unless they meet the brand guidelines for consumer eating experience. This ensures there is no consumer confusion as, regardless of the variety, the fruit supplied to the market meets the Pink Lady® brand promise. A very different scenario to what was seen in with the proliferation of ‘Kidd’s D-8’ sports and use of the marketing name Gala.

Arctic® Apples Case Study

2017 saw the first commercial crop of Arctic® Golden harvested in the United states of America. This has been followed by Arctic® Granny and Arctic® Fuji with Arctic® Gala in development. These are the first genetically modified fruits to be bought to the market with a consumer focused trait. These varieties have all been modified in the same way to essentially turn off the process that causes apple flesh to go brown when cut or bruised. These varieties have a strong consumer facing brand built around the Arctic umbrella trade mark and use of the key elements of the original variety denomination or marketing name, the modified trait has consumer appeal with brand messaging around sustainability and reducing food waste.

Regardless of personal views on the controversial topic of genetic modification, or the value in a non browning apple, the question to be considered is why these initial varieties were selected by Okanagan Specialty Fruits. They explain why on their website “we took three of North America’s top varieties and improved them with the non-browning trait” – they have taken three, soon to be four, very familiar apple varieties, well established with consumers, leveraging on that familiarity and establishment with a single difference. With the potential
controversy surrounding bringing a genetically modified fruit to market, opting for initial varieties which already have an established consumer following is a well thought through strategy. The marketing approach around these new fruits being essentially everything you love about these varieties but better. This one difference makes it potentially an easier leap for some consumers into accepting genetic modification. It also suggests that Okanagan Specialty Fruits have made a considered choice in selecting varieties well outside any proprietary position and PVR protection, and therefore sidestepping the potential controversy of taking another parties’ proprietary variety and making one change to create the new product.

Conclusion

Why now? The member countries look to UPOV to guide them and provide the bedrock to their respective national laws. New fruit varieties have lead times of decades, the results of breeding programmes being undertaken today are 10-20 years away from reaching consumers but breeders need clarity now on how the international law on which we rely to protect our innovation will be implemented. We are also at a crossroads for new breeding technologies with rapid development of new and potentially undetectable techniques and shifting public perception – potentially with greater market acceptance of fruits arising from multi-disciplinary breeding methodologies.

We have taken a journey through the evolution of our UPOV legislation with respect to Essentially Derived Varieties, the breeding strategies employed, and the other influences of the times. From UPOV78 where there was no EDV provision and breeding largely consisted of conventional crossing with a few examples by species of naturally occurring mutations. To UPOV91 with a broad, well-intended, EDV definition and the continuance of those breeding strategies alongside the introduction of new breeding techniques, and into this era largely dominated by genetic modification, which has had a slow rate of adoption in fruit crops. Then to the introduction of the second explanatory note in 2017 and the effects, perhaps unintended, on the implementation of the EDV provisions in national legislation at a time when again in addition to conventional crossing, naturally occurring mutations, and an increasing expansion in the landscape of new breeding techniques is occurring with accelerated scientific advances and evolving public perception. Barriers to investment are greatly raised when following a conventional breeding strategy and 20+ year lead times a newly released variety may immediately be used to develop a new variety with new breeding techniques.

Plant breeders around the world want to be able to deliver new and innovative varieties – delivering for the benefit of society and to receive a fair share of benefit on those innovations. To best enable breeders to continue to deliver innovation we request certainty from UPOV in the rights granted regardless of the breeding strategies employed. It seems timely for a clarification of the EDV concept which would clearly affirm the following 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.

Given the influence the EXN can and does have on the national laws being implemented by the UPOV members, our preferred position would be its pragmatic suspension until such time as it can be reconsidered. We believe this would be well supported by the international breeding community. We respectfully request that the EXN is reconsidered taking into account the information and presentations received in the UPOV Seminar on the Impact of Policy on Essentially Derived Varieties on Breeding Strategy.
Panel Discussion

Anthony Parker
(moderator)

Very informative morning. I think everyone probably shares that same sentiment. We’d like to start the third portion of our session, which is a question and answer. When you pose the question, state your name to whom you wish the question to be directed.

Michael Kock
Vice President, Innovation Catalyst, Basel, Switzerland

My name is Michael Kock. I have a question either to Yolanda or Sven or you.

I think we are facing here a dilemma. On one hand, we don’t want to encourage plagiarism, but we still, I believe, want to encourage new breeding innovation. It’s also a dilemma between the term predominantly, which seems to be more quantitative, and the term essentially, which seems to be more qualitative. What we have seen in the patent area, you can spend years and years to try to delineate one from the other. I was wondering whether there was any time spent to look into the flexibility of a system like free access but not access for free. Laurens mentioned the licensing platform in the patent area. That could maybe be built on Article 17.2 of the UPOV Convention where access can be granted so that we are not looking on either is it in or is it out, but trying to find a more robust mechanism on how to facilitate access. Has that been investigated already as a potential solution?

Anthony Parker
(moderator)

That’s an excellent question. And maybe we’ll start off with our guest speaker to start. And, Yolanda, if you have something to add towards the end.

Sven J.R. Bostyn
(speaker)

I have the pleasant task of trying to answer the unanswerable question. I think it’s a very good question, indeed, because I think actually my second kind of intellectual exercise I was referring to was more or less going into that direction of maybe facilitating access because that’s probably a very efficient way of dealing with it because any other solution that you try to develop is inevitably going to hit some kind of analysis evaluation that is going to be of a
qualitative nature for the reasons exactly you say, Michael. Also, my intellectual exercise is getting inspired from the patent system where we do a qualitative analysis when it comes to equivalence. That always, inevitably, presents problems. But it’s not, of course, something that is not possible because, clearly, it is done in other intellectual property rights. And for that matter, it’s also in all other intellectual property rights which expands scope to be literally the same.

This quantitative and qualitative analysis, it is happening already in other intellectual property rights. But, of course, if you want to avoid getting dragged into lengthy debates as to what is qualitative and how far is it qualitative, then, of course, you can maybe make it easier and just grant an access system, indeed. And that would maybe not be such a bad idea because, of course, the whole UPOV system is based on access, and if you just made sure that there is some kind of access mechanism where people pay. But you will never be able to avoid entirely a qualitative evaluation. People still want to know when they have to pay and people might still say I don’t have to pay because I haven’t derived it. There will still always be an element of evaluating what it’s derived from. I think it’s a conundrum that is, in that sense, unresolvable. I can’t make it easier than it is, I’m afraid.

Anthony Parker

(moderator)

Yolanda, do you have anything to add?

Yolanda Huerta

(speaker)

Just to comment that your reflection on the concept that you just pointed out is ongoing, but the link to Article 17, paragraph 2, of the Convention, is not something that has been considered in this particular context.

Anthony Parker

(moderator)

Thank you very much. And thank you for being the brave person to pose the first question. Maybe if I ask the audience here, when you do pose your question, very direct, succinct, to the point, so we can get as many questions in as possible in this period of time.
Ángela Martínez López  
*Euroseeds*

From Euroseeds, formerly known as the European Seed Association.

I do not have a specific question now. I would just like to take the opportunity that this seminar offers and contributes as well to complete the general picture on EDVs for us to take home today, with a brief mention to EDVs in the specific case of potato crops. I won’t plunge into the details. I would just like to draw your attention to an EDV study on potato that was conducted by Euroseeds a few years ago.

To set the background, it was the Euroseeds section on potatoes that decided to embark on a specific project devoted to the investigation of genetic variability in potatoes. The study lasted around four years. Based on the results arising therefrom, it was agreed that the similarity coefficient for predominant derivation should be set at 92 percent. And well, in sum, the conclusions of this study materialized in a tangible Euroseeds position paper on EDVs in potatoes. We can agree that it is important that we disseminate our relevant findings in view that, for instance, judges resort to these types of interprofessional agreements as some sort of guidance which, despite not being legally binding, can nonetheless certainly prove helpful. I can only invite you to have a look at it as it is published now in the Euroseeds official website in our resource area under the section potatoes. Thank you.

Anthony Parker  
(*moderator*)

Thank you for that comment and the information on where to find the information that you alluded to with respect to potatoes and EDV. But could we have maybe some questions?

José Ignacio Cubero Salmeron  
*Professor of Genetics and Plant Breeding (emeritus), Universidad de Córdoba, Eurogenetic, Eurosemillas, Córdoba, Spain*

I think for a big company, it is not a problem the question of EDVs because the practice since the beginning of the last century, it is to substitute one variety by the next one with one more gene introgressed in the past, intercrossed now perhaps with genetic engineering. Then, for a big company, it is not a problem. It is not a problem to have an EDV or an initial variety because they are substituting the initial varieties with a secondary variety and the third variety. Every five years we can say that. The big problem, it is for the small companies that have to access nice varieties, important varieties, or not so important, with their desire of modifying them. If not allowed, the big companies will smash in the courts and in the trials the small
and medium sized companies. It will be in their hands if the EDV concept is understood in the broad sense, as it is suggested by many people. It will help the big companies, the companies who have already protected varieties. If not, the small and medium companies will be lost and the breeding for them will be out.

Anthony Parker
(moderator)

Thank you. Very interesting comment. I’ll ask Sven, maybe you could just share your thoughts on what has been said. And maybe if we could have someone from one of the breeding companies afterwards step forward and provide a response.

Sven J.R. Bostyn
(speaker)

Thank you very much. I think it was a very important observation, that I also tried to emphasize during my speech. I think systems have to be made for the users, and then as much as possible for all users. But I think what we quite often overlook, and I have a lot of experience myself in patent law, which has become a system that is largely for big players because of the sheer cost of it. But, of course, the plant variety rights system is actually inherently a system that is made for everyone and it should remain that way. But, obviously, you have to make it useful for everyone. If you devise it in a way or if you interpret it in a way that it basically takes away the profit for SME companies of getting benefit from their innovation, then, obviously, it doesn’t make any sense anymore. That’s why I think emphasis should be put on the importance of SMEs as innovators. Because we have to be honest, in a number of technologies, it’s big industry that shows the way. But in plant variety rights, it’s actually SMEs that show the way. Most innovations are probably taking place in SMEs and not in – well, obviously, big companies always do innovation, but the kind of day-to-day innovation is more taking place in SME companies because big companies will probably – and I’m not insulting anyone because, of course, Limagrain is big.

Magali Pla
(speaker)

It depends of what you mean by big.
**Sven J.R. Bostyn**  
_(speaker)_

But some of the major players – and I don’t want to mention any names because it’s always politically sensitive and also because they’re all been taken over by someone else at some point – they obviously go for the big profits probably and not necessarily for – well let me put it this way, a lot of companies go for a combination, and amongst them SMEs, of sustainable and innovation, and that is not necessarily what some of the biggest players are doing, and in that sense, I think it’s important that we maintain a system that stimulates innovation for SMEs.

**Magali Pla**  
_(speaker)_

Just to complete what Sven just said. I believe that there is always the possibility to discuss between companies, a small or a big company, to obtain a kind of negotiation, an access through negotiation. This is still always possible.

**Anthony Parker**  
_(moderator)_

Thank you for that.

**Raimundo Lavignolle**  
Chairman of the Board, National Seed Institute (INASE), Ministry of Production and Labor - Secretariat of Agroindustry, Buenos Aires, Argentina

Well, I’m going to have to start by apologizing because there are a number of things I might not grasp fully. But taking into account the fact that there are no limitations in what plant breeders can do, I think we need some more information. How is it possible that an EDV has a different impact on small and large companies. I don’t understand this. Thank you.

**Anthony Parker**  
_(moderator)_

Someone from our industry representatives like to tackle that question?
Laurens Kroon
(speaker)

I think that both small and large companies will be affected by an EDV variety. I don’t see that it’s really a difference. Maybe the big companies have more power to survive it or they have a broader base for the program. And in that way, a smaller or a medium sized company would suffer bigger effects if their main varieties are targeted in this way. Does that answer your question?

Anthony Parker
(moderator)

I think this will be the last question. We are running very tight on time and we do have to summarize the session this morning.

Roberto Manno
Partner, Weblegal.it, Barletta, Italy

I was raising some questions but maybe horizontally. Because, in my view, the Explanatory Notes, the last version, were quite defining, well a practical approach and there was concern, but what was the possible review bearing in mind a more specific point which is to what extent the initial variety owner should have the possibility to control the variety? Or, in other words, does he have a veto power or is there always the possibility to commercialize the EDV variety also based on the payment of an equitable remuneration or something like that. Because this is also something which is on a practical point always conflictual.

Anthony Parker
(moderator)

Thank you for that question. Maybe we should start with one of our breeder companies to elaborate on some of the arrangements that you might have in place for EDVs.

Micha Danziger
(speaker)

I can answer it. I said it in my presentation that there should be a way that both parties will enjoy the new innovation of the EDV and it has to be in accordance to the contribution of the new trait that the new breeding technology brought to the product that was produced by the initial breeder. There are ways to do it and actually I think the people from the seed industry, they already found a way that all the patents are out there, and you can maybe elaborate a bit.
Each company can buy traits or patents, negotiate on it, and if they don’t reach an agreement, there is the baseball system to find a solution. It enhances the progress of the industry and contributes to the public and at the end of the day, that’s the idea of UPOV, I think.

**Anthony Parker**

*(moderator)*

Thank you very much for that response. I think that’s probably a good one to close our Q&A portion of this session.

Finally, I’d like to thank the participants in this room. I think you exceeded our expectation in the number of participants. Very pleased to see many faces here who will also be in the CAJ this afternoon because we have to remember the whole point of this seminar is to help us in our deliberations with the CAJ to figure out, to find a path forward what will we do with this EDV concept. I think we’re now armed with a lot of new information that will help us in our deliberations. Once again, thank you so much for attending, for your time, your attention and your contribution.
Closing Remarks

Mr. Anthony Parker
Chair, Administrative and Legal Committee (CAJ), UPOV

UPOV EDV SEMINAR - SUMMARY

Evidence that the current UPOV guidance does not reflect the practice amongst breeders in the understanding of essentially derived varieties (EDV).

Evolution of breeding techniques has created new opportunities/incentives for predominately deriving varieties from initial varieties, more rapidly and at a lower cost.

Clear indication from presentations and discussions that the understanding and implementation of the EDV concept influences breeding strategy – therefore, it is important that UPOV guidance is tuned to maximize benefits to society in terms of maximizing progress in breeding.
Mr. Peter Button was appointed Vice Secretary General of UPOV on December 1, 2010, having previously held the role of Technical Director at UPOV since 2000.

Mr. Button graduated from the University of Warwick with a B.Sc. Honors degree in Biological Sciences.

From 1981 to 1987 he worked for Twyford Seeds Ltd., a plant breeding company, in the development of new cereal varieties. From 1987 he was the general manager of a new company that was established to develop micropropagation systems for the commercial production of seed potatoes and soft fruit stocks. In 1996, Mr. Button joined the British Society of Plant Breeders Ltd. (BSPB) as Technical Liaison Manager. In 1998, he became Technical Liaison Officer for the Plant Variety and Seeds Division of the UK Ministry of Agriculture, Fisheries and Food.
Mr. Sven J.R. Bostyn (LLB, Lic. Jur., LLM, PhD) is Associate Professor of Biomedical Innovation Law at the Centre for Advanced Studies in Biomedical Innovation Law (CeBIL http://cebil.dk ), Faculty of Law, University of Copenhagen, an Assistant Professor of Intellectual Property Law at the Institute for Information Law (IVIR) of the University of Amsterdam, and consultant in IP. He is also a regular guest professor at CEIPI in Strasbourg. He graduated cum laude in Law at the University of Gent (Belgium), obtained a summa cum laude postgraduate Masters in Law degree at the University of Stockholm (Sweden), and successfully defended his PhD in law at the University of Maastricht in 2001, where he was a lecturer from 1996 until 2003. His PhD studied the enabling disclosure requirement in patent law for biotechnological inventions in Europe and the United States of America, and has been widely acclaimed for its quality and relevance.

He is specialized in all areas of IP law, a world authority in the area of patent law relating to pharmaceuticals, biotechnology, medical devices, software and SPC’s, and also a world authority in the area of plant patents and plant variety rights. He is also an expert in regulatory exclusivities (data and market exclusivity) in the area of pharmaceuticals in general, and orphan drugs and antibiotics in particular, and in trade secret law. Sven is the author of more than 60 single authored scientific peer reviewed publications, amongst which two widely acclaimed monographs.

He was member of a Scientific Advisory Committee at the Dutch Royal Academy of Sciences (Gene Patents Committee, 2002-2003) and was between 2013 and 2016 the Chair of the Expert Committee at the European Commission on the development and implications of patent law in the field of biotechnology and genetic engineering, after having been a member of and Rapporteur at an earlier European Commission Expert Group (2003-2006). Besides the European Commission, he has also advised both the Belgian and Dutch governments on policy matters regarding patentability of biotechnological and software inventions. He is often consulted as an expert in patent law, regulatory exclusivities and licensing matters, by government institutions and by practitioners in the framework of litigation.

Sven has additionally more than 14 years of experience in private practice. He has worked for multinational and boutique law firms. His main practice was/is in patent law and regulatory exclusivities, with particular emphasis on life sciences and green biotech.

He is a frequent speaker at international conferences organized by commercial conference agencies, (inter)national government agencies and academic institutions (more than 230 invited speeches).

Aside from being native in Dutch, he is fluent in French, English, German and has a working proficiency of Italian and Swedish, and is now in the process of acquiring proficiency in Danish.
Yolanda Huerta works since 2001 at the International Union for the Protection of New Varieties of Plants (UPOV) and acts as Legal Counsel, directs the organization of the governing bodies of UPOV, as well as directs and organizes the implementation of the UPOV training and assistance strategy.

Ms. Huerta provides strategic and legal advice on international, administrative, constitutional, and contract law relating to the Organization, as well as providing guidance in drafting legislation governing plant breeders’ rights and explanations on the provisions of the UPOV Convention.

Professional experiences include Legal Officer at the World Intellectual Property Organization (WIPO), dealing with depositary functions of the treaties administered by WIPO and with normative activities, research and giving legal advice to governments in the field of patents, trademarks, geographical indications, integrated circuits, biodiversity, electronic commerce and alternative dispute resolution matters. Previously, lawyer in the Intellectual Property Department, Bufete Mullerat & Roca, Barcelona, Associate Professor at the Faculty of Law, University of Barcelona, Director of Legal Affairs, RES International, Ottawa, responsible for projects involving international law, intellectual property and transfer of technology matters in Latin America.

Ms. Huerta is Licenciada en Derecho (LL.B.) from the University of Barcelona, and holds a LL.M., International Law, from the University of Montreal. She has published several articles and given lectures on different topics in the field of international intellectual property law.
Magali is currently Deputy Manager of the Industrial Property Department of Group Limagrain. In particular, she is in charge of the field seeds industrial property within this department. She is a member of intellectual property committees of several seed associations, the International Seed Federation (ISF), Euroseeds and the French national seed association UFS (Union française des semenciers).

Within Limagrain, her role is to manage the protection of innovation in matters linked to breeding and biotechnology research, and to participate in setting global IP strategy and positions. This covers activities related to Patent and Plant Breeders Rights. Beyond the pure IP aspects, Magali has built, through her 10 year experience at Limagrain, a solid knowledge on technical matters, from breeding to genome modifications.

Before joining Limagrain, Magali had been working for six years as IP counsel at the Institut National de la Recherche Agronomique.

She also holds an International Industrial Studies Diploma in “Patents” from CEIPI, a Master in Molecular Biology and Genetics and a PhD in Plant Molecular Biology from University Paris XI (FR). During her PhD, she worked on the genetic determinism of cytoplasmic male sterility in plant. She also worked in non-plant related topics, during her postdoctoral research at Brandeis University (USA), to decipher genetic pathway in training and memory in Drosophila.
Danziger was established as a family business in 1953. Micha is the second generation in the farm that today has the 3rd generation included in the management team.

Micha has over 45 years of experience in the agriculture, floriculture and breeding industries.

Chairman of the board, owner and founder of Danziger a leading global floriculture company, established as a family business in 1953.

Background

- Chairman of the Board, The Danziger Group
- Co-owner of Beauty Line Ltd. (Kenya)
- Co-owner of Beauty Line Guatemala S.A.
- CEO and co-owner of Danziger Innovations Ltd.
- Co-owner, shareholder and Chairman of the Board of Directors of Equinom Ltd.
- Member of The Board of Governors, The Hebrew University of Jerusalem

Experience

- 1980 – 2016 Co-CEO at Danziger
- 1977 – 1980 Partner at Danziger “Dan” Flower
- 2001 – present Co-owner of Beauty Line Ltd. (Kenya)
- 2008 – present CEO and co-owner of Danziger Innovations Ltd.
- 2012 – present Co-owner, shareholder and Chairman of the Board of Directors of Equinom Ltd.
- 2013 – present Co-owner of Beauty Line Guatemala S.A.

Qualifications

- Agricultural studies (B.Sc) at the Hebrew University in Jerusalem.
Laurens Kroon is Head of Research at Bejo Zaden, based in Warmenhuizen, in the Netherlands. Bejo is a leading company in breeding, production and sales of vegetable seeds. With operations in more than thirty countries, it is an internationally oriented family business with over 1,700 employees.

Dr. Kroon holds a M.Sc. Degree in Plant Breeding and Crop Protection, from Wageningen University and obtained his PhD in 2010 based on his thesis: The genus Phytophthora, phylogeny, speciation and host specificity. He is a member of the IP committees of Euroseeds (2013) and the International Seed Federation (2015).
The New Zealand Institute for Plant and Food Research Limited (Plant & Food Research) is a Crown Research Institute (CRI), which was formed in 2008 from the amalgamation of two other New Zealand CRI’s. While as a CRI it is a government owned company Plant & Food Research, it is operated as a corporate entity. Our purpose is to enhance the value and productivity of New Zealand’s horticultural, arable, seafood, and food and beverage industries, to contribute to economic growth and the environmental and social prosperity of New Zealand. Plant & Food Research operates a wide variety of plant breeding programs in the fruit, arable, and ornamental sectors with breeding programs located both in New Zealand and offshore.

The Plant Varieties Team is tasked with taking a cross-functional approach combining science/technical competence, legal approaches, and business acumen to maximize profitability and business opportunities for new plant varieties. To enable the business opportunities for both Plant & Food Research and our commercialization partners the Plant Varieties Team is also responsible for securing and maintaining robust defensible Plant Variety Intellectual Property for these new plant varieties within the various legislative frameworks around the world.

**Highlights**
- Collaborating in Hot Climate apple and pear breeding program with Plant & Food Research, IRTA and Fruit Futur in Spain and T & G Global as the strategic commercialization partner. Utilizing conventional plant breeding techniques to create high-quality apple and pear varieties with excellent consumer appeal and eating experience, producing apples and pears specifically designed to be produced in hot climate environments.
- Developing an umbrella brand within a joint venture company, Pacific Berries, for a suite of raspberry varieties with the initial audiences of growers and buyers with the potential extension to consumer recognition and differentiation of premium process raspberries.

**Background**
- 2010 – 2014  Intellectual Property Coordinator, Plant Varieties Team, Plant & Food Research
- 2014 – present  Business Development Manager, Plant Varieties Team, Plant & Food Research

**Qualifications**
- Bachelor of Science, Horticultural Science and Physiological and Molecular Plant Biology – Massey University, New Zealand
- Master of Science, Horticultural Science - Massey University, New Zealand
- Introduction to the UPOV System of Plant Variety Protection under the UPOV convention – UPOV
- New Zealand Diploma in Business - Eastern Institute of Technology, New Zealand
- Inaugural Graduate, IP Competence Certificate, CIOPORA Academy
Liste des participants / List of participants / Teilnehmerliste / Lista de participantes
(dans l’ordre alphabétique des noms / in the alphabetical order of the surnames / in alphabetischer Reihenfolge der Namen / por orden alfabético de los apellidos)
Établie par le Bureau de l’Union / prepared by the Office of the Union / vom Verbandsbüro erstellt / preparada por la Oficina de la Unión

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