UPOV

International Union for the Protection of New Varieties of Plants

SEMINAR ON THE INTERACTION BETWEEN PLANT VARIETY PROTECTION AND THE USE OF PLANT BREEDING TECHNOLOGIES

March 22, 2023

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Geneva, March 22, 2023

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Mr. Gert Würtenberger, Chairman of the GRUR Expert Committee on the Protection of Plant Varieties (Vorsitzender des GRUR Ausschusses für den Schutz von Pflanzenzüchtungen) and Lawyer, Meissner Bolte, Munich, Germany

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Ms. Erin Wallich, Intellectual Property Manager, Summerland Varieties Corporation, Summerland, Canada, on behalf of ISF, CropLife International, CIOPORA, APSA, AFSTA, SAA and Euroseeds

16.45 – 16.55 **Diversity of breeding technologies and impact for plant variety protection**
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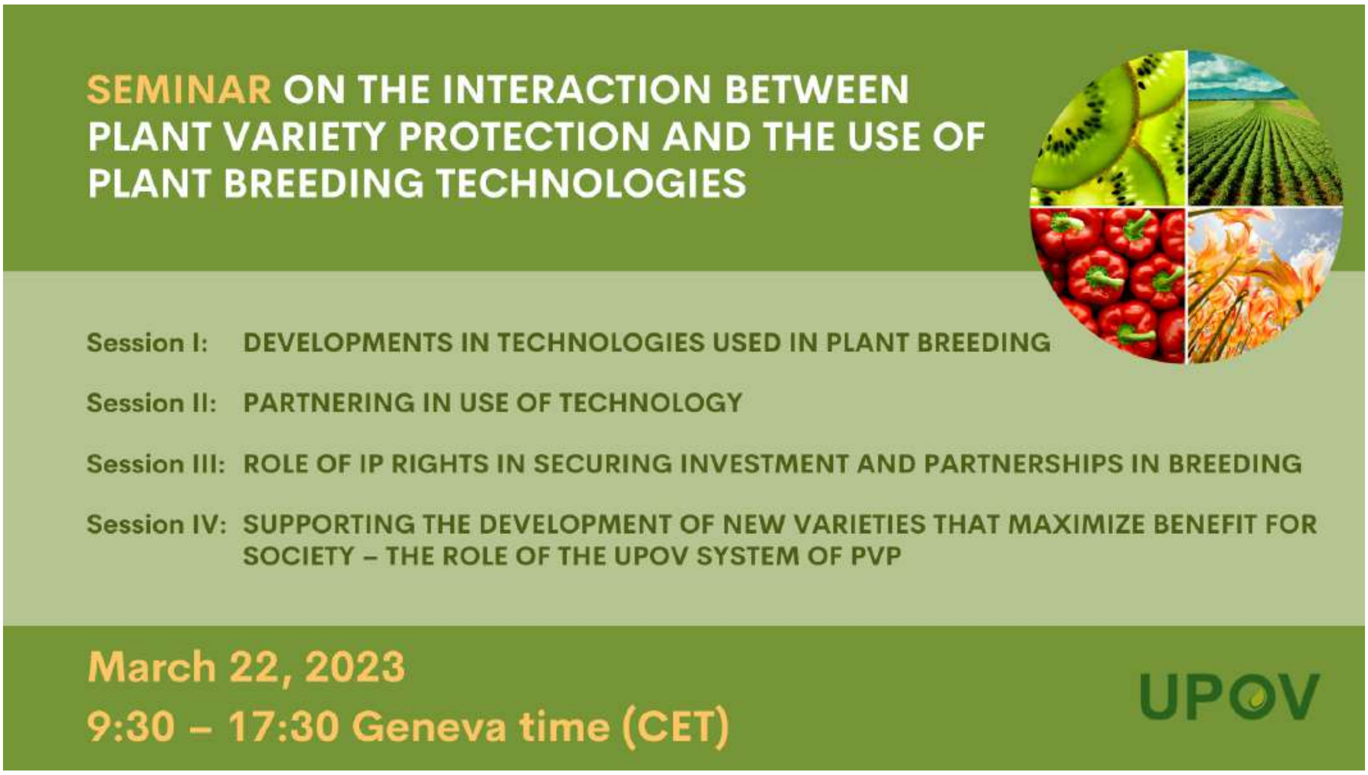
16.55 – 17.20 **Discussion with speakers of Session IV**

17.20 – 17.30 **Closing remarks**
Mr. Yehan Cui, President of the UPOV Council



WELCOME AND OPENING REMARKS

Mr. Peter Button
Vice Secretary-General, UPOV

Mr. Yehan Cui, President of the UPOV Council,

Dear Participants, Dear Friends and Colleagues,

Warmest greetings to everyone. Thank you all for joining us here in Geneva or online! It is a great pleasure to speak to you at the opening of this Seminar on the interaction between plant variety protection and the use of plant breeding technologies.

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The theme for today is a culmination of the topics that UPOV has considered in seminars held in the last two years.

In 2021, we organized a seminar to examine the policies and strategies that plant breeding and plant variety protection are supporting in UPOV members.

All contributors highlighted that plant breeding and improved varieties were an important part of the solution to key policy challenges; a solution that could help to achieve important goals in food security, sustainable agriculture, economic development and improving the livelihood of farmers, including smallholder farmers.

A topic that was frequently mentioned was the impact of climate change and the need for agriculture to adapt to - and to mitigate - climate change. It was clear that plant breeding and, therefore, UPOV had an important role to play in addressing this issue.

The seminar that was organized to consider that topic highlighted that the UPOV system enables plant breeders to provide farmers with the varieties they will need to feed the world in the face of climate change. It also recalled that plant breeding is a long-term process that requires long-term investment from public institutions and from private companies. Plant breeders need an enabling environment that promotes innovation and supports the conservation and utilization of genetic resources.

It is clear from those events that there has never been a time when plant breeding and plant variety protection have been more important. Which brings us to today's event.

One of the key findings from the IPCC's special report on climate change and land was that increasing food productivity is one of the most effective climate responses at our disposal. However, we will have to increase productivity while being more sustainable. The use of technology in plant breeding will clearly be crucial to meet that challenge. And when we talk about technology in plant breeding, it ultimately comes down to the genetics that are provided to farmers when planting their crops.

We know that single genes can have a huge impact. The dwarfing gene in wheat that underpinned Norman Borlaug's Green Revolution is an example that will be familiar to most of you. Another example was the creation of new varieties of Canola with low glucosinolate and low erucic acid content, which transformed a plant of limited agricultural interest into a crop that could be used to feed animals and then an oil fit for humans. It also changed the color of the summer landscape in many countries. However, farmers do not choose genes, they choose varieties, because they need the complete package of genes that forms a variety - adapted to their circumstances - to produce a successful crop. Returning to the varieties of Norman Borlaug, we need to remember that the success of the green revolution was achieved by combining characteristics in wheat; the dwarfing gene needed to be combined with disease resistance genes and with high yield potential. It was not simply a case of introducing the dwarfing gene into existing varieties.

The UPOV system recognizes the need for plant breeders to develop varieties, rather than individual genes. On the other hand, it is clear that the UPOV system needs to incentivize genetic innovation. One of the key drivers for revising the UPOV Convention in 1991 was to respond to advances in plant breeding technologies, including genetic modification. The creation of the essentially derived variety – or EDV – concept was to encourage cooperation between plant breeders and technology developers. Plant breeding technology has moved on and new techniques, such as gene editing, are now an important tool for plant breeders. One of the important topics for today will be whether the UPOV system is *creating the right environment for the plant breeding and agriculture of tomorrow to thrive.*

Farmers and all of us as citizens of the world need the most rapid progress in plant breeding. Plant breeders conceived the UPOV system with the breeder's exemption as a corner-stone so that plant breeding progress would be maximized – they clearly did not conceive this concept to maximize their profits. The EDV concept was also introduced with the same philosophy; not to maximize profits of plant breeders but to ensure that plant breeding progress would be sustainable and would be maximized in the long-term. And I would like to end by recalling that farmers and plant breeders depend on each other – and apart from that, they have one important thing in common; they both need to be in it for the long-term or the rest of us all face the consequences.

So, against this background, I am looking forward to hearing different perspectives on the interaction between plant variety protection and the use of plant breeding technologies and how this can deliver the best outcomes for plant breeding and farming for the future.

Ladies and Gentlemen,

I am delighted to have such a wide range of well-qualified experts to talk on this subject and I am sure that we will have an enlightening seminar that will feed the discussions in UPOV.

Please take this opportunity to engage and to learn from one another.

It is your engagement that will help to shape the UPOV system to meet the challenges ahead.

Thank you very much and best wishes for a productive seminar.

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SESSION I:

DEVELOPMENTS IN TECHNOLOGIES USED IN PLANT BREEDING

Moderator: Mr. Yehan Cui, President of the UPOV Council

Induction Gene-based DH Breeding for Multicrops
Mr. Chen Shaojiang, Professor, Department of Genetics and Breeding, China Agricultural University, China

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Discussion with speakers of Session I

INDUCTION GENE-BASED DH BREEDING FOR MULTICROPS

Mr. Chen Shaojiang
Professor, Department of Genetics and Breeding, China Agricultural University, China

INTRODUCTION

UPOV's mission is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants for the benefit of society. A new variety should go through Distinctness, Uniformity and Stability (DUS) testing before authorization for use as in a main crop. In general, DUS testing of main crops requires varieties that are genetically homozygous and that have an identity.

As we know that hybrid varieties such as maize and tomato hybrids can be developed by crossing two homozygous inbred lines, hybrids show strong heterosis, which is beneficial for yield improvement. For non-hybrid crops, such as wheat, homozygous lines are also necessary for developing new varieties. Thus, in both hybrid and non-hybrid varieties, breeding of the homozygous lines are an essential procedure.

To develop the homozygous lines, the conventional procedure is time-consuming and generally needs continuous generation by generation selfing to reduce the heterozygosity and to purify the genes. In comparison with traditional breeding, doubled haploid (DH) technology can be used to generate homozygous lines with highly uniform traits in only two generations through the procedure of haploid induction and haploid chromosome doubling, thus, significantly accelerating the breeding cycle and benefiting variety protection.

For crops, chromosomes exist in double-sets in a normal cell (2n), while a haploid has only one set of chromosomes (n). How to obtain a haploid is the first step of DH breeding. Generally, a haploid can be obtained by anther, pollen or ovule culture. Nevertheless, this method is feasible in only limited species, but it does not work well due to the low efficiency, genotype-dependence and complex operation. In maize, the most successful way to breed is intraspecies induction by haploid inducers, the original one is stock6 found by Dr. Coe, which can trigger the female parent to generate the maternal h aploid at about a 1–3% ratio by using the inducer as a male pollinator.

DH BREEDING IN MAIZE

DH technology in maize contains three key steps: (1) haploid induction, a haploid inducer was used as a male parent to cross with any breeding germplasms; (2) identification of haploids with markers; and (3) doubling of the haploid chromosome to recover the ploidy level of the haploid to a normal status. Through these procedures, we can get genetically homozygous DH lines. The DH technology above has several advantages, especially genotype independence and easy operation.

Key developments in DH technology have been made in recent decades. ***The first key development*** is that a high induction rate of haploid inducers has been achieved. Elite inducers have a haploid induction rate of about 10% or higher. Further, a high oil inducer, with an induction rate of about 8–10% and kernel oil content of 8%, could be used as a new maker in automatic haploid screening.

The second key development is the high efficiency of haploid screening makers. Since the haploid is only a small part of the F1 seed in the DH system, effective identification of haploids is the next key step. Simply, we can identify the haploids by their typical phenotypes, such as short plant height, narrow leaves and male sterility, however, this way is not efficient. The ideal way is to find the haploids at the seed stage. To this end, the use of the ***R1-nj*** gene marker in haploid inducers has been confirmed as effective, which can realize haploid identification at seed stage by the xenia effects of the marker. The seeds with purple aleurone but white embryos were haploids. However, the ***R1-nj*** color marker is not as clear in certain environments and the genetic backgrounds of the females will inhibit the genes.

To overcome the difficulties, we propose a new marker system of haploid identification by kernel oil content. Considering that kernel oil is mainly distributed in embryos and high oil kernel content has larger embryos. We have developed high-oil haploid inducers. By pollinating with high-oil haploid inducers, the hybrid diploid seed oil content is significantly higher than that of haploids. With this discovery, we have developed an automatic nuclear magnetic resonance (NMR)-based haploid kernel screening system – haploids can be identified automatically by oil content with an accuracy of over 90%.

The third key development is large-scale haploid doubling. As most of the haploids have no pollen, recovery from haploid to diploid by chromosome doubling is another key step in DH breeding. Generally, haploids have very low spontaneous chromosome doubling due to their high sterility. Thus, different artificial chromosome doubling methods are necessary to increase efficiency. Now, haploid embryo doubling has been engineered to generate DH lines on a large scale all year round.

DH technology has been used in maize breeding worldwide. In China, DH breeding has been used by most of the main seed companies. Moreover, several DH service companies have provided professional production of DH lines for small seed companies to replace the traditional inbred line development model. Millions of DH lines have accelerated breeding and rapidly increased the DH hybrid varieties released.

The fourth key development is the cloning of important induction genes. Up to now, several genes have been cloned. We have cloned the two key genes, the first gene, ***ZmPLA1***, also named ***MTL/NLD***, encodes a phospholipase, and the second gene, named ***ZmDMP***, encodes a protein of unknown function. The haploid induction rate can be dramatically increased from 2% to 7% by the interaction of the two genes. Can the successful story of DH technology in maize be copied to other crops? The cloning of the two key induction genes paves the way to establish a similar DH system in muti-crops.

INDUCTION GENE-BASED DH SYSTEM IN MULTI-CROPS

We found the two genes, ***ZmPLA1*** and ***ZmDMP***, were conserved among different crops. ***ZmPLA1*** is mainly conserved in monocot plants, such as wheat, sorghum, rice and millet, where the sequence identity is higher than 75%. So we tried to test whether mutation of ***ZmPLA1*** homologues could also result in haploid induction in other crops. By knocking out similar genes in wheat, wheat haploid inducers have been developed with a maternal haploid induction rate as high as 20%. In the same way, haploid inducers have been developed in both rice and millet, with a haploid induction rate of 2%.

Interestingly, the gene ***ZmDMP*** was found to be conserved among dicot plant species. Some species have a sequence identity higher than 60%. In tomatoes, we found that the ***DMP*** homologues gene mutant could produce haploids at a rate of about 2%. Further, the small size of the seeds makes it difficult for haploid identification, we have determined the haploid identification system and obtained tomato DH lines. Thus the ***DMP-gene*** based DH system has been established, which will accelerate and reshape the breeding procedure in tomato breeding. Similarly, we also found that haploids can be induced successfully and the haploid induction rate was about 1-2% in rapeseed and tobacco.

Based on the work above, we predict that the system can be used to develop new varieties in the commercial breeding of more crops.

SUMMARY

The successful application of DH breeding has already accelerated the process and reshaped the mode of maize breeding. The application of an induction gene-based DH system in multi-crops would be promising for a revolution of the breeding model of homozygous lines and varieties in different ways, which would benefit DUS testing and protection of variety rights.

Incidentally, some new DH technology-based breeding technologies such as genome selection, gene editing and hybrid seed cloning have been developed. Combining technologies would have the potential to deliver more powerful assistance to breeding and new possibilities for plant variety protection.

Presentation made at the Seminar

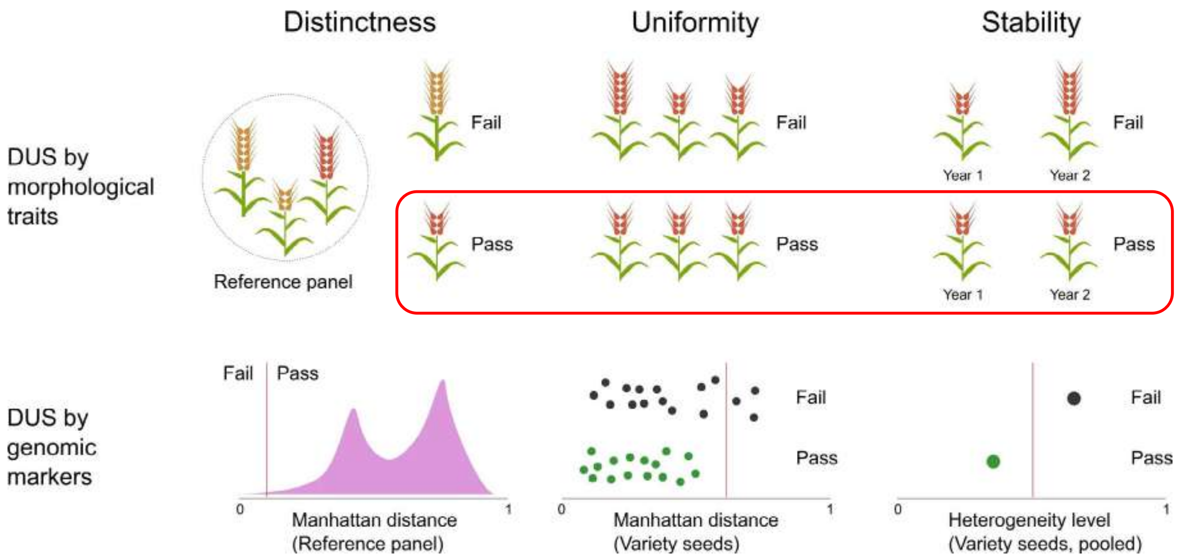
Induction Gene-based DH Breeding for Multicrops

Shaojiang Chen
China Agricultural University

Outlines

- Introduction
- DH breeding in maize
- Induction gene-based DH breeding in multicrops
- Summary

PartI Introduction



For protection of variety's right in main crops, genetic homozygous lines are essential for DUS test.

Yang *et al*. 2021

Hybrid crops

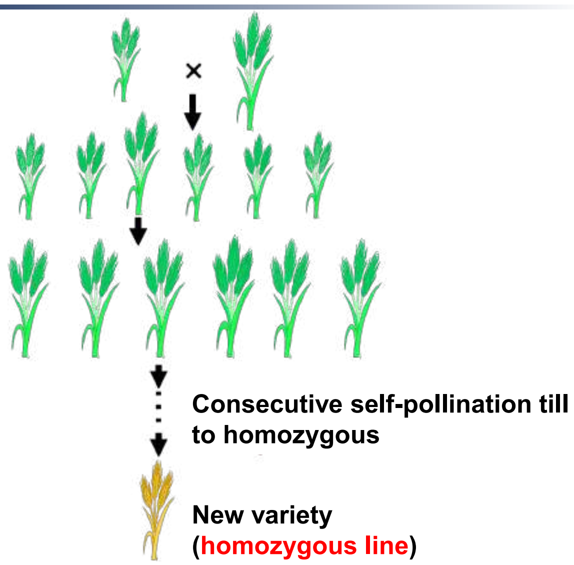
Ye478 Female Parent | Yedan13 Hybrid | Dan340 Male Parent

Breeding of hybrid vatiety in maize needs male and female homozygous parent inbred lines

Non-hybrid crops

Rice

Wheat

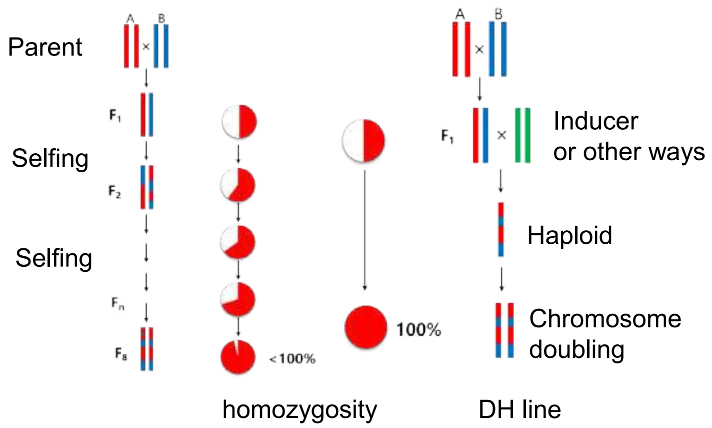


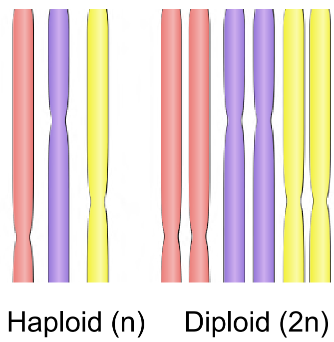
For non-hybrid crops, it needs to be self-pollinated generations to obtain homozygous lines for conventional variety

How to develop homozygous lines in breeding

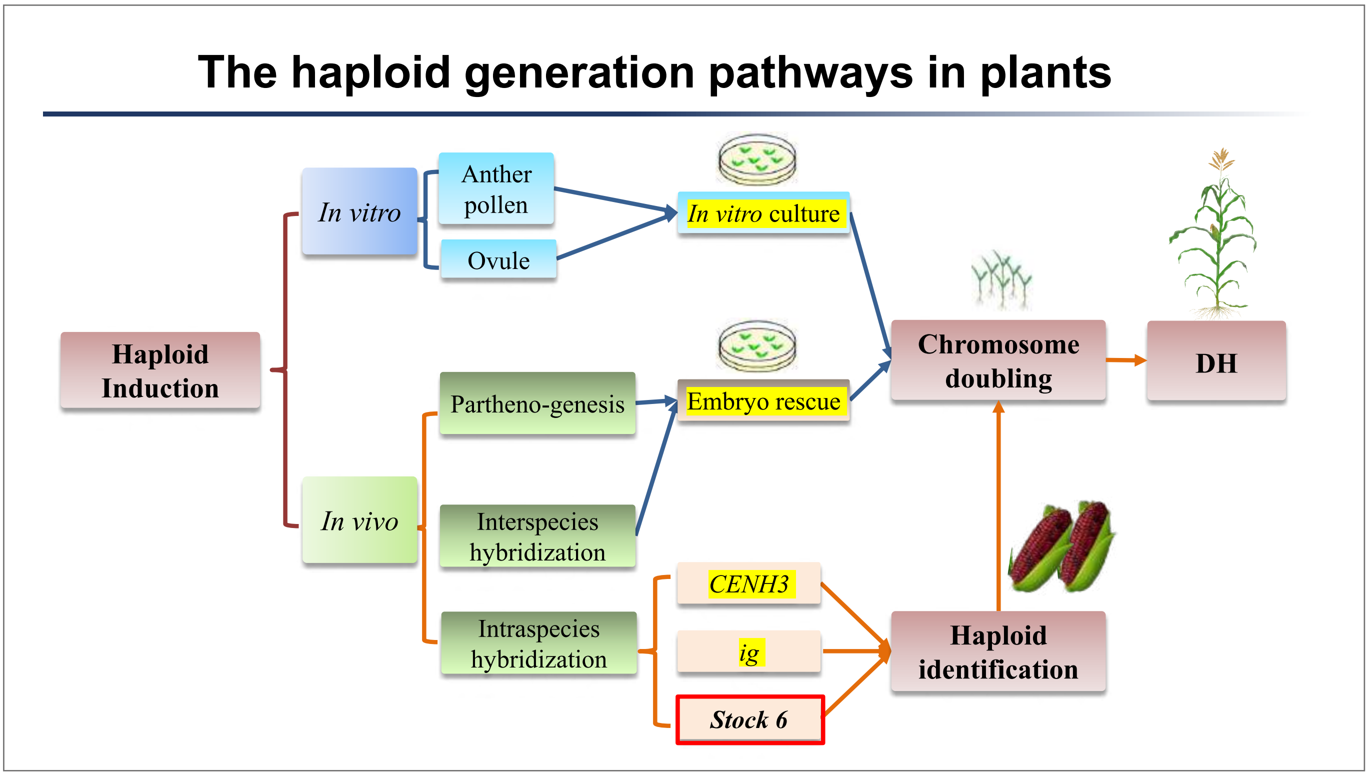
Conventional method

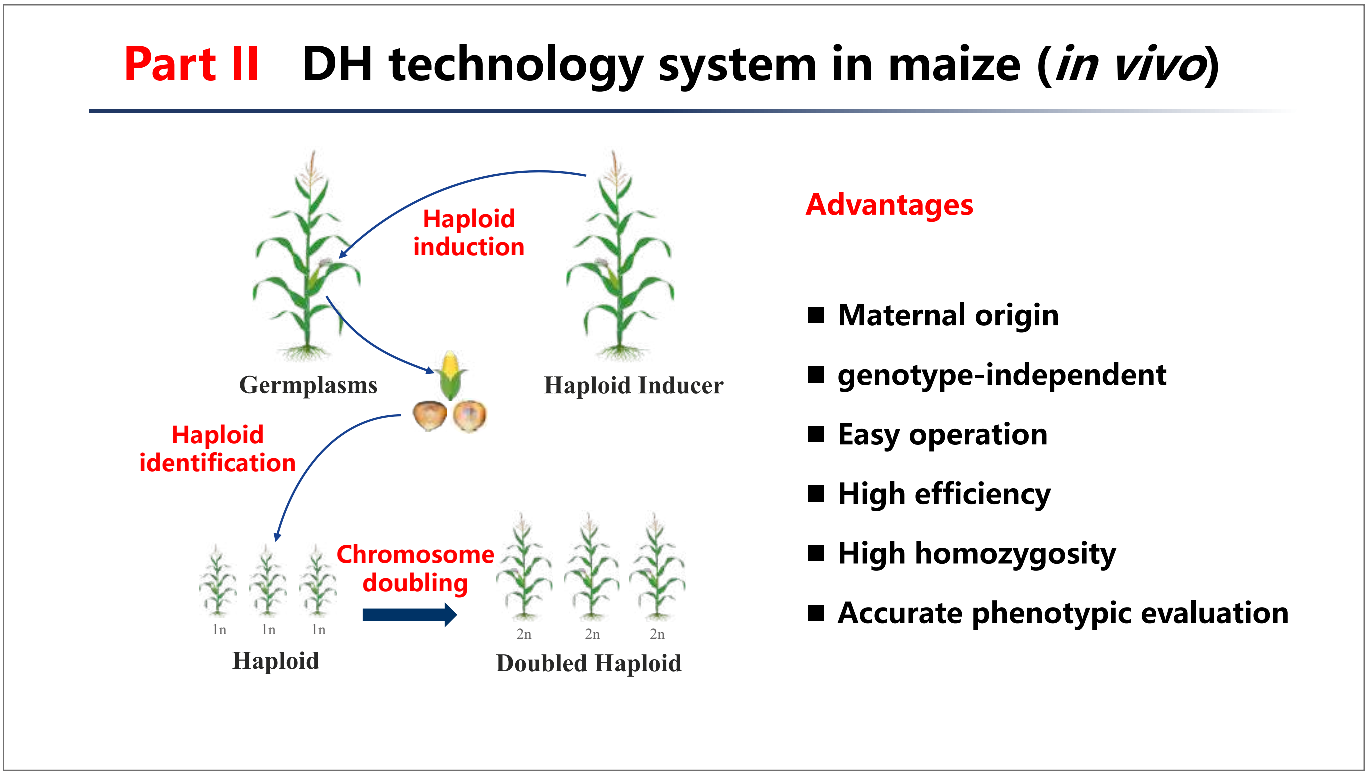
DH technology





1.Tradition way needs continious selfing about 8 or more generations
2. DH way can achieve the homzygous lines in only 2 generations via haploid and chromosome doubling.
-----Accelerating breeding cycle


The haploid generation pathways in plants
Haploid Induction
In vitro
Anther pollen
Ovule
In vitro culture
In vivo
Partheno-genesis
Interspecies hybridization
Intraspecies hybridization
Embryo rescue
CENH3
ig
Stock 6
Chromosome doubling
Haploid identification
DH

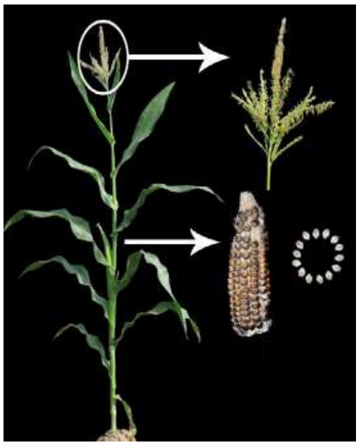

Part II DH technology system in maize (in vivo)
Haploid induction
Germplasms
Haploid Inducer
Haploid identification
Chromosome doubling
1n 1n 1n
Haploid
2n 2n 2n
Doubled Haploid
Advantages
Maternal origin
genotype-independent
Easy operation
High efficiency
High homozygosity
Accurate phenotypic evaluation

Key progress1: High induction rate haploid inducers

Regular inducer

Induction rate~>10%

High-oil inducer



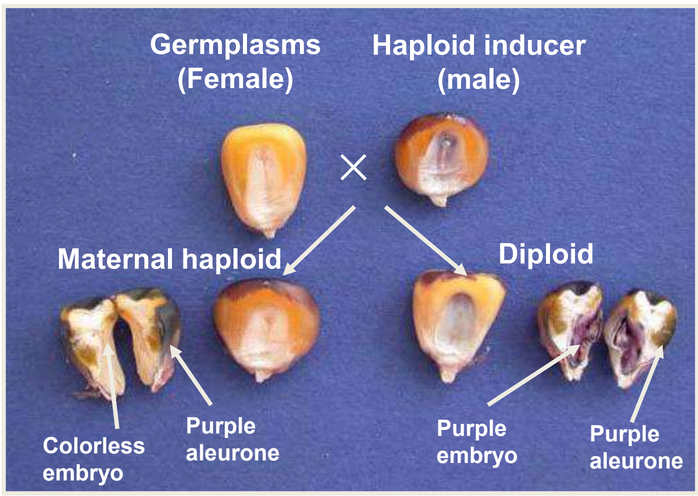
Induction rate~8-10%

kernel oil content ~ 8-10%

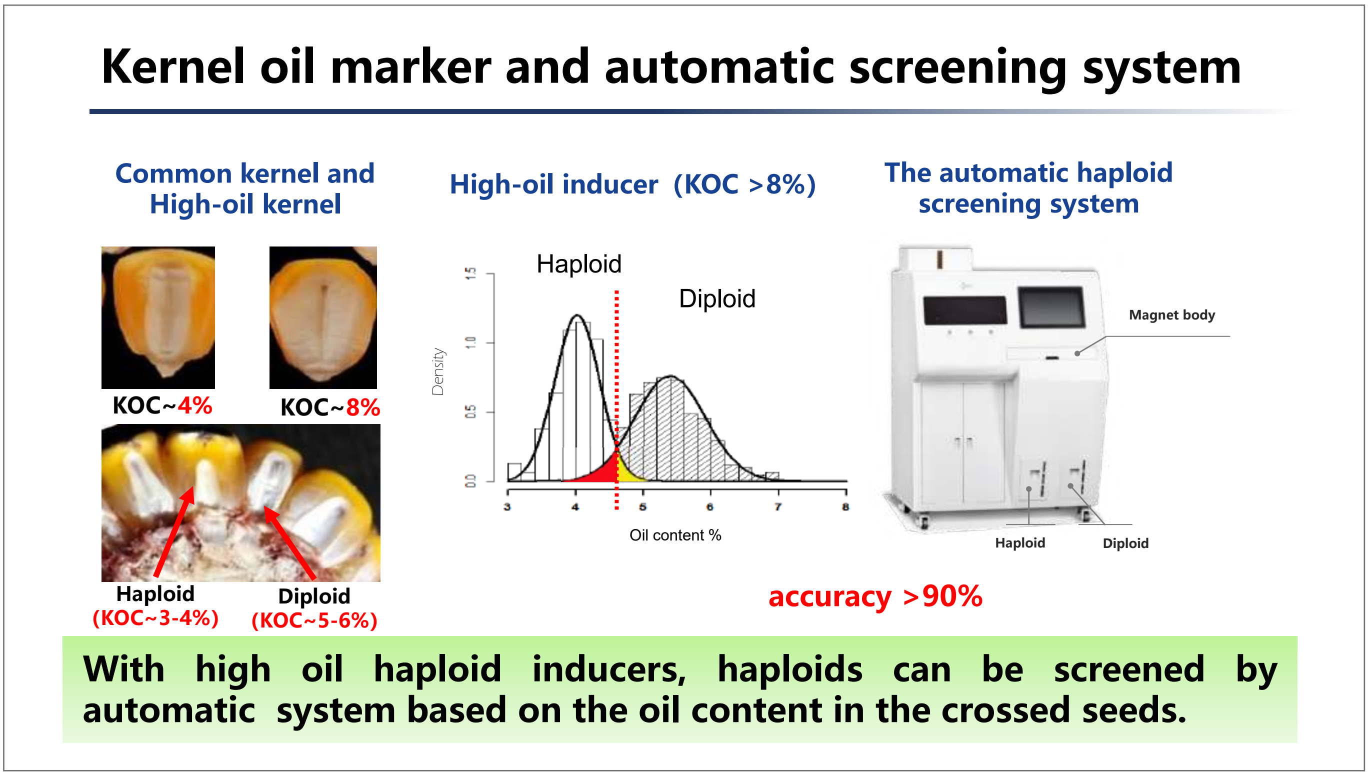
Inducers as male parent can trigger maternal haploid in large scale in different breeding germplasms

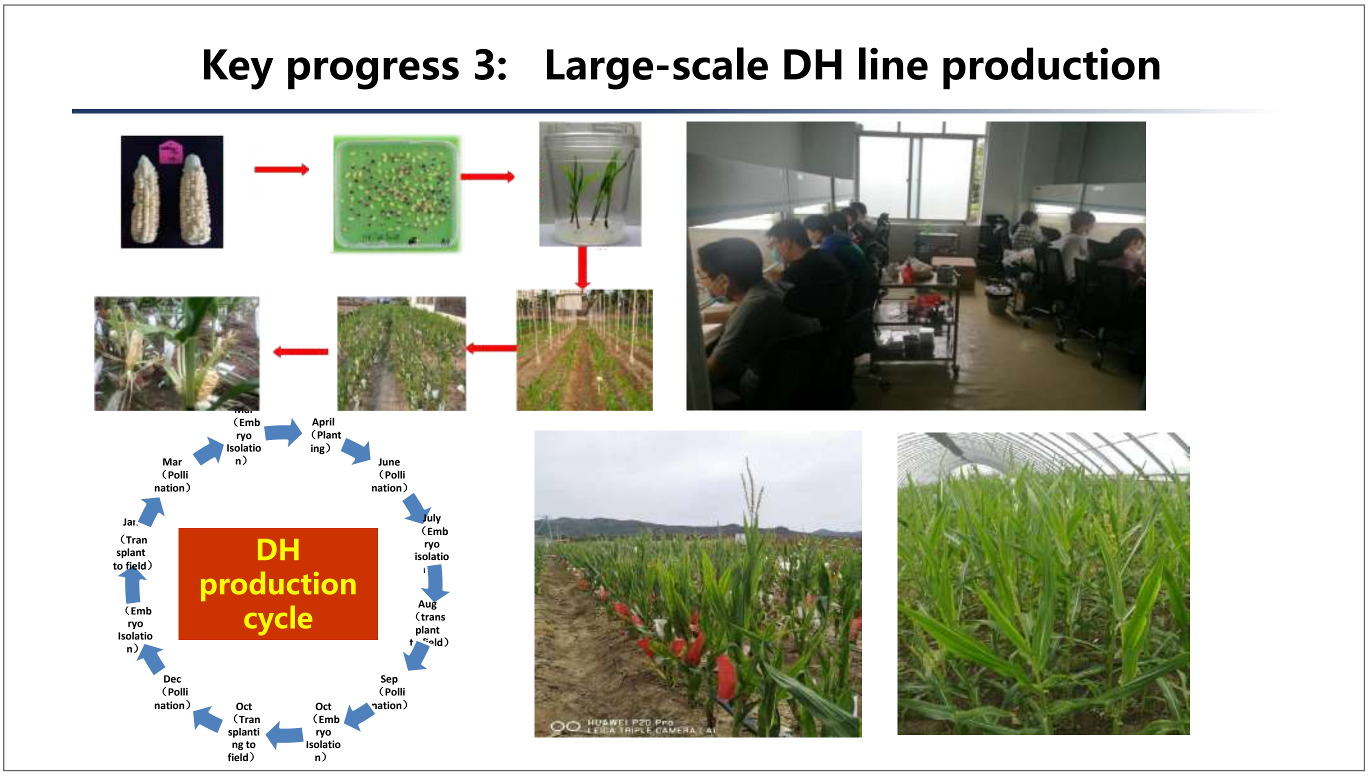
Key progress2: High efficency identification systems

Haploid **Diploid**



***R-nj* color system**, **Sarkar and Coe, 1966**


Kernel oil marker and automatic screening system
Common kernel and High-oil kernel
KOC~4%
KOC~8%
Haploid (KOC~3-4%)
Diploid (KOC~5-6%)
High-oil inducer (KOC >8%)
Haploid
Diploid
Density
Oil content %
The automatic haploid screening system
Magnet body
Haploid
Diploid
accuracy >90%
With high oil haploid inducers, haploids can be screened by automatic system based on the oil content in the crossed seeds.


Key progress 3: Large-scale DH line production
DH production cycle
April (Planting)
June (Pollination)
Mar (Pollination)
Aug (trans plant to field)
Sep (Pollination)
Oct (Embryo Isolation)
Oct (Transplanting to field)
Dec (Pollination)

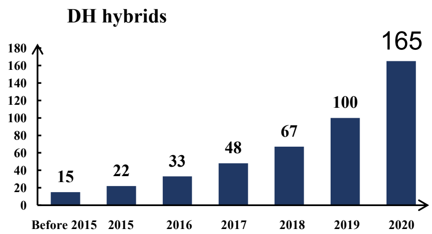
DH technology in commercial maize breeding

1. Seed companies using DH technology

… …

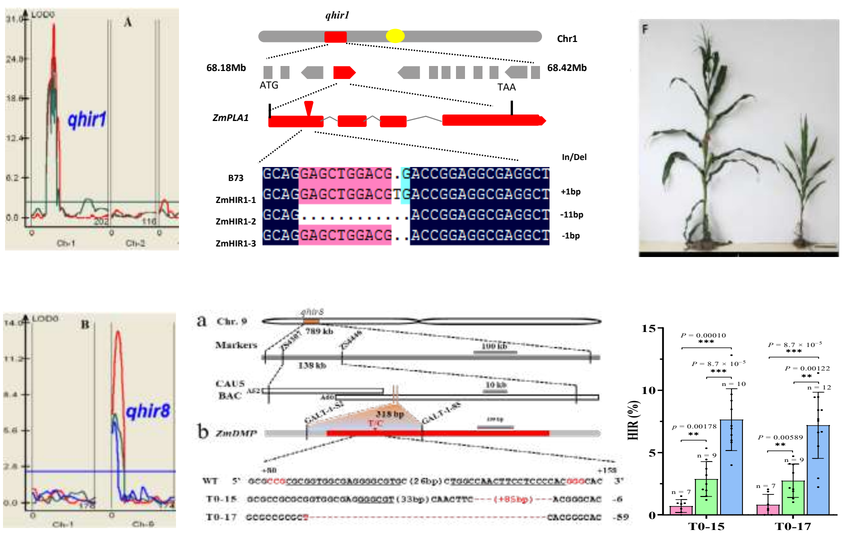
2. DH service

… …



DH technology has been successfully used in large scale and hybrids from DH lines have replaced the traditional ones rapidly in maize breeding over the past decades.

Key progress 4: Cloning of induction genes



ZmPLA1

ZmDMP

Contributes to about 90% of HIR

Liu *et al.*2017; Zhong *et al.* 2019

The finding above confirmed that the system is actually “Induction gene-based DH system”

Part III Induction gene-based DH technology in multicrops

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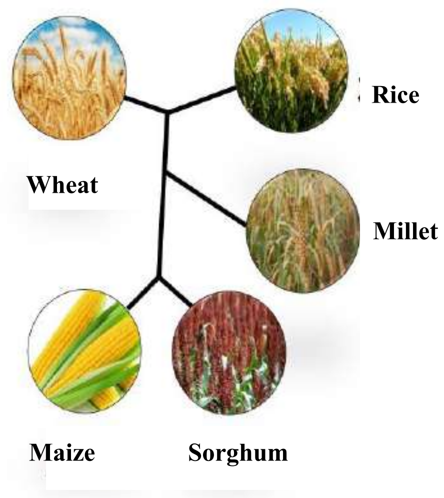
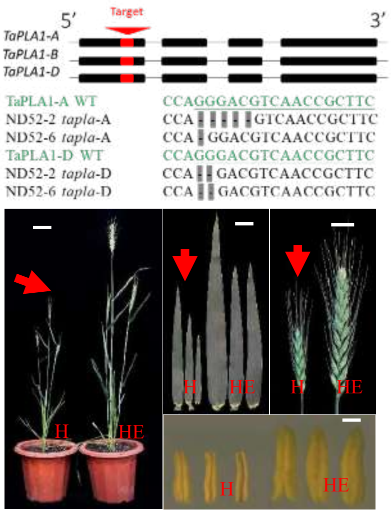
MTL/PLA1/NLD -based DH system in cereal crops



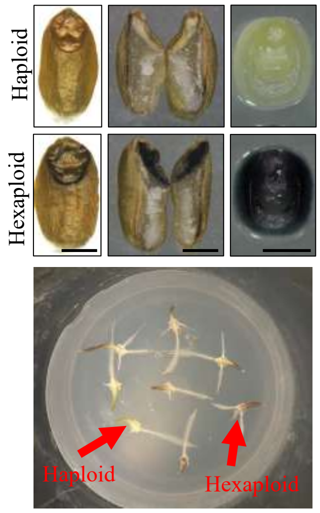
Crops		Amino acid sequence identity (%)
Sorghum		90.39
Millet	√	84.32
Indica rice	√	77.05
Wheat	√	76.78
Japonica	√	76.16

The induction gene has homologous gene in different monocot cereal crops like wheat etc.

MTL/PLA/NLD-based DH system in wheat



Wheat haploid induction
HIR ~ 10-20%

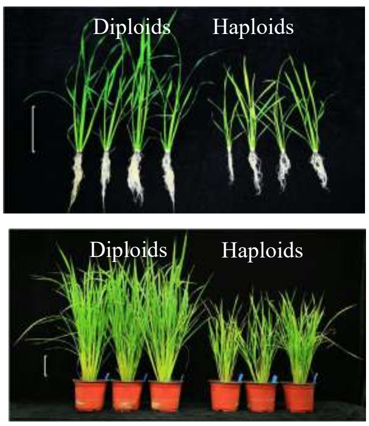


Haploid identification
Accuracy ~ 97.7%

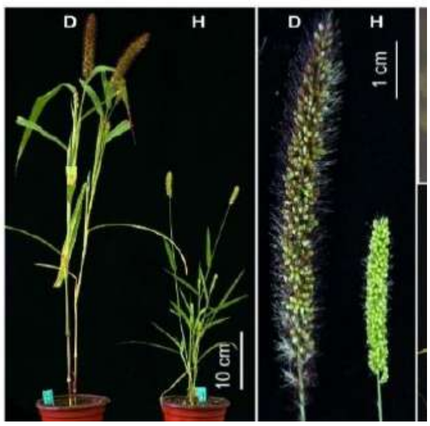
Chromosome doubling
Doubling rate > 90%

Liu *et al*., 2019
Qi *et al*., 2023

MTL/PLA1/NLD-based haploid induction in rice and millet



Rice
HIR ~ 2-6%



Foxtail millet
HIR ~ 2.8%

Yao *et al*., 2018

Cheng *et al*., 2021

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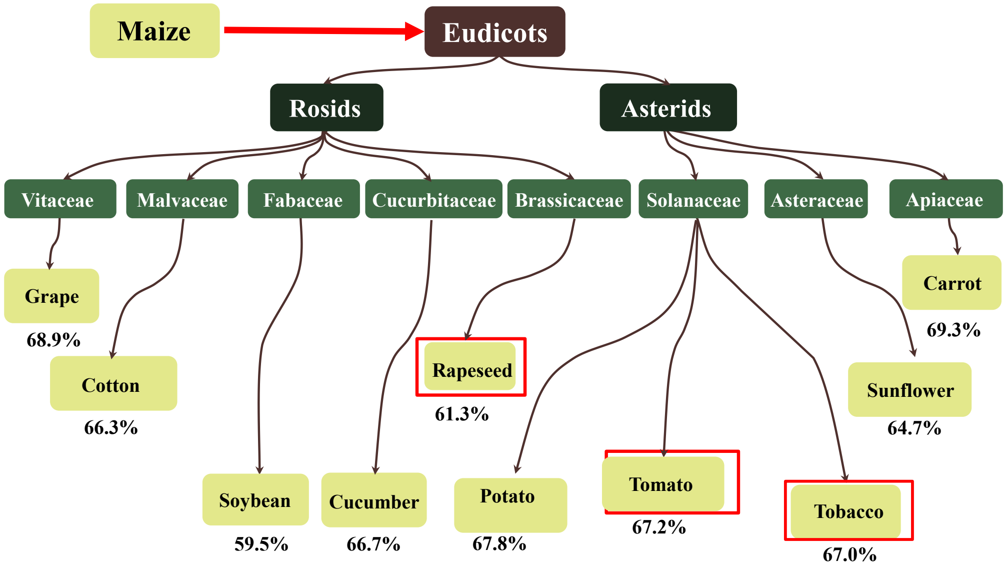
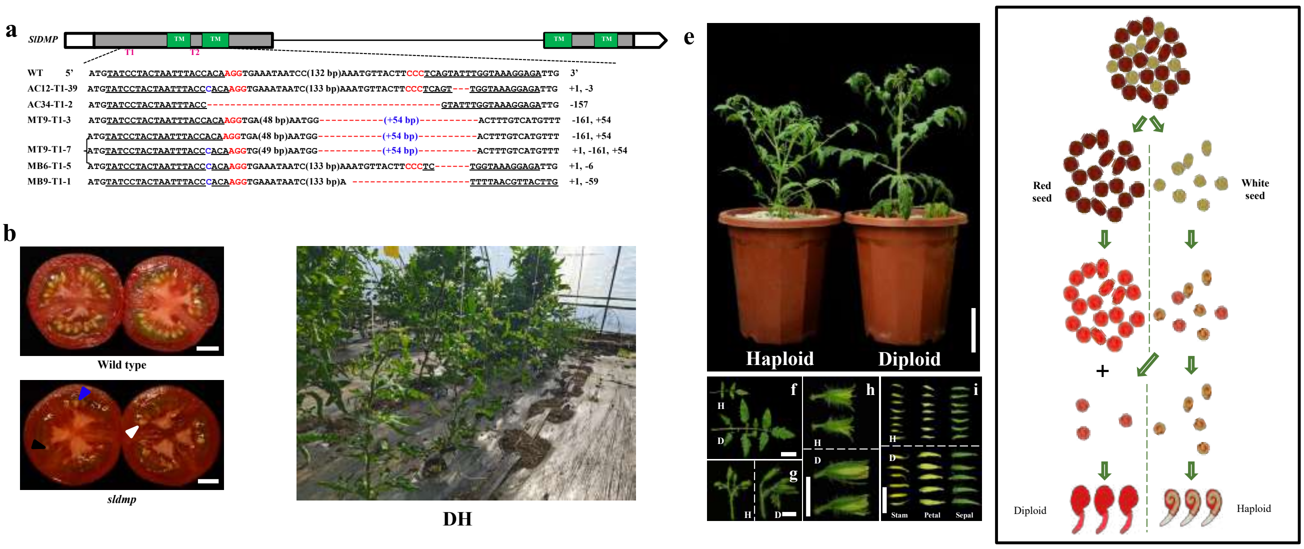
DMP-based DH system in dicot crops



Species with *DMP* gene amino acid sequence identity higher than 60%.

DMP-based DH system in tomato



Female parent	Male parent	Seed setting rate (%)	Total seeds	Haploids	HIR (%)
39 different genotypes	AC-*dmp*	24.70	29,397	509	1.94 ± 0.74

Zhong et al., 2021

DMP-based haploid induction in rapeseed and tobacco

Arabidopsis
HIR ~ 2.2%

Rapeseed
HIR ~ 2.6%

Tobacco
HIR ~ 1.1%

Zhong *et al*. 2020, 2022

Part IV Summary

1. The induction gene-based DH breeding system has obvious advantages and has been successfully used in maize.

2. The DH system has confirmed effective in multicrops and pave the way to accelerate practical breeding.

3. The high homozygosity of DH lines is beneficial for the protection of variety right.


Thank You

INTEGRATION OF NEW BREEDING TECHNOLOGIES (NBTS) INTO VARIETY BREEDING: HOW TO FIND THE RIGHT BALANCE FOR INCENTIVISING INNOVATORS?

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TRAIT INNOVATION USING NEW BREEDING TECHNOLOGIES AND BREEDING INNOVATION ARE CONVERGING

The application of New Breeding Technologies (NBTs) for crop improvement cannot be underestimated. While it has already been possible to edit genomes for more than two decades,[3] the discovery of the RNA-guided DNA endonucleases such as CRISPR-Cas9 made gene-editing orders of magnitude cheaper and easier.[4] The first gene-edited commercial agricultural products have recently reached the market[5] and have mostly been produced by a targeted knock-out of a single endogenous gene that was already known and characterized.

As of 2020, "examples of gene-edited crops at or near the end of the research pipeline [were] manifold, including fungus-resistant wheat, rice, banana, and cacao; drought-tolerant rice, maize, and soybean; bacterial-resistant rice and banana; salt-tolerant rice; and virus-resistant cassava and banana."[6]

There will be a further array of opportunities unlocked as researchers adapt the gene-editing protocols to new crops and make them germplasm independent. If properly incentivized through intellectual property rights and science-based regulation, NBTs will:

- bring trait opportunities to vegetatively propagated and/or long life-cycle crops where breeding is not possible or is unaffordable due to timelines;
- overcome issues with linkage drag encountered when introgressing beneficial traits from a wild relative;
- liberate breeding programs from the constraints of trait introgression by parallel conversion of finished (parental) lines at the end of the breeding cycle;
- allow the creation of novel allelic diversity for tuning of metabolic and developmental pathways to create breakthrough crop yield and quality improvements; and
- "democratize" breeding and improvement for orphan crops[7] or crops commercially neglected that have the potential to contribute to food security.

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[3] *Bibikova, M. et al. (2002) Targeted chromosomal cleavage and mutagenesis in* ***Drosophila*** *using zinc-finger nuclease.* ***Genetics*** *161(3):1169–1175.*

[4] *Jinek, M. et al. (2012) A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity. Science 337(6096):816–821; Gasiunas, G. et al. (2012) Cas9-crRNA ribonucleoprotein complex mediates specific DNA cleavage for adaptive immunity in bacteria.* ***Proc. Natl. Acad. Sci.*** *USA 109(39):E2579–2586.*

[5] *See, e.g., Nonaka, S. et al. (2017) Efficient increase of γ-aminobutyric acid (GABA) content in tomato fruits by targeted mutagenesis.* ***Sci Rep*** *7:7057; Pixley, K.V. et al. (2022) Genome-edited crops for improved food security of smallholder farmers.* ***Nat Genet*** *54:364–367, p. 364, where it is reported that as of 2022 there were "six genome-edited crop traits — in soybean, canola, rice, maize, mushroom and camelina — that have been approved for commercialization to date."*

[6] *Qaim, M. (2020) Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development.*

Applied Economic Perspectives and Policy *42(2):129–150, p. 142.*

[7] *See Pixley, above n 5, p. 364.*

THE UPOV CONVENTION AND NBTS

Recent proposals to revise the Explanatory Notes on Essentially Derived Varieties (EDVs) under the 1991 Act of the UPOV Convention (EDV Explanatory Notes) did not appropriately balance the risk and reward for all innovators that are investing in the development and use of NBTs. In 2021, the UPOV Working Group on Essentially Derived Varieties released a draft revision of the EDV Explanatory Notes (Draft Text).[10] A significant change to the EDV Explanatory Notes proposed in the Draft Text was to make all mono-parental varieties, and certain conventionally bred varieties, ***per se*** EDVs. The Draft Text achieved this outcome by:

- making all "[v]arieties with a single parent ('mono-parental' varieties) resulting, for example, from mutations, genetic modification or genome editing … ***per se*** predominantly derived from their initial variety";[11]
- requiring that "[d]ifferences resulting from act(s) of derivation are disregarded for the purpose of determining the EDV status of a variety";[12] and
- providing that the differences between an EDV and an initial variety "may … include essential characteristics."[13]

Putting to one side the issue of whether the EDV Explanatory Notes are an appropriate vehicle for making significant changes to the implementation of the 1991 Act of the UPOV Convention (UPOV Convention),[14] there are several issues with the Draft Text's proposed expansion of the scope of EDVs to encompass all varieties developed using NBTs ***per se***.

First, it "could deter the use of new breeding technologies on high-performing [plant. breeder's rights] varieties, slowing the overall rate of varietal improvement."[15] NBT users may be dissuaded from using elite germplasm that is protected by plant breeder's rights (PBRs) because of the knowledge that they will not benefit from the same scope of rights as varieties bred using traditional methods – principally because an "EDV declaration both limits the EDV breeder's freedom to commercialise and precludes the declaration of an EDV [derived from] that new variety."[16]

Second, the proposed approach in the Draft Text may result in control of germplasm being consolidated with incumbent PBR owners. As recently noted in a review of the Australian EDV system, the approach in the Draft Text would result in "more control to the owners of existing commercial varieties" and "benefits larger organizations, who are more likely to have established genetic material and the resources needed to develop costly long-term crossbreeding programs."[17]

Third, this approach "would significantly undermine the breeder's exemption in the case of mono-parental varieties."[18] The breeder's exemption has been described as "a cornerstone of the UPOV Convention"[19] with "access to germplasm to provide the initial source of variation in breeding programs … deemed essential from the outset."[20] However, the Draft Text clearly modifies the breeder's exemption by discouraging use of NBTs to further develop elite germplasm.

Fourth, the differential treatment of users of NBTs is inconsistent with the rest of the PBR regime, which is agnostic to the method of breeding. It is also contrary to the approach advocated in the 1991 Diplomatic Conference where it was reportedly "clearly stated that the definition of the essential derivation could not be based on the breeding method."[21]

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*[8] See Kelliher, T. et al. (2019) One step genome editing of elite crop germplasm during haploid induction. **Nature Biotechnology** 37:287–292; Maren, N.A. et al. (2022) Genotype-independent plant transformation. **Horticulture Res.** 9:uhac047.*

*[9] See Pixley, above n 5, p. 367; Menz, J. et al. (2020) Genome edited crops touch the market: A view on the global development and regulatory environment. **Front Plant Sci.** 11:586027; Jorasch, P. (2020) Potential, challenges, and threats for the application of new breeding techniques by the private plant breeding sector in the EU. **Front Plant Sci.** 11:582011.*

[10] See UPOV/WG-EDV/3/2.

[11] Ibid., p. [5].

[12] Ibid., p. [14].

[13] Ibid., p. [13].

[14] On this point see below n 30 and accompanying text.

[15] MacDonald, H., and Sherman, B. (2022) Essentially derived varieties and the Plant Breeder's Rights Act 1994 (Cth). University of Queensland, p. 16.

[16] CSIRO (2021) Comments in response to IP Australia Consultation Paper Proposed changes to Explanatory Notes on Essentially Derived Varieties under the UPOV Convention. August 2, 2021, p. [33]. Available at: https://consultation.ipaustralia.gov.au/policy/upov-edvs-2021/.

[17] MacDonald and Sherman, above n 15, p. 16.

[18] Ibid.

[19] Button, P. (2013) Opening Address at "The Development of the Provisions on Essentially Derived Varieties," Seminar on Essentially Derived Varieties. Geneva, Switzerland, October 22, 2013. UPOV Publication Nr. 358, 7.

[20] Clancy, M.S., and Moschini, G. (2017) Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture. Annual Review of Resource Economics. 9:53–74, p. 63.

Finally, the Draft Text may lead to commercial uncertainty. Indeed the key disadvantage identified in a recent Australian review of the Draft Text was that its adoption would "replace the relatively clear Australian approach to determining essential derivation with a more complex, ambiguous, and indeterminate legal regime."[22] Breeders using NBTs could only achieve commercial certainty regarding commercialization of a variety bred using NBTs by negotiating commercial arrangements with the initial variety's PBR holder prior to breeding – with a concomitant increase in the need for legal involvement and expense during breeding.[23]

Patents are often considered a viable alternative for variety protection. However, varieties obtained using NBTs cannot necessarily be protected via the patent system:

- Patents on plants are not available in many countries. For example, countries such as Argentina, Brazil, Canada, China and India do not consider plants to be within the scope of patentable subject matter.
- Patentable subject matter can change through case law or due to political or societal developments.[24]
- Further, as CSIRO has previously noted, "even where plants may be protected by patent protection, the requirements of novelty and inventiveness under the patent regime means that changes to plants (such as incremental changes) developed using genetic engineering, genome editing or induced mutagenesis might not attract patent protection."[25]
- Genome-edits typically vary slightly from line to line and are potentially variety-specific. It is yet to be seen if an efficient patent strategy can be achieved; the variety system may be not only the preferable system for protection but the only available system.
- The term of protection for varieties and the cost of patent applications may preclude the ability of breeders to genuinely consider the patent regime as a sustainable alternative.

UPOV's 2019 Seminar on the impact of policy on EDVs on breeding strategy concluded 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."[26] The Draft Text did not strike the right balance. There remains a need to review the EDV system to ensure that there are appropriate incentives for all breeders to innovate.

TOWARD FAIR AND CLEAR DECISION CRITERIA FOR EDVS

The 1991 Diplomatic Conference introduced EDVs to, among other things, ameliorate concerns that "genetic engineering and other molecular techniques had the potential to make it easier for subsequent plant breeders (i.e. competitors) to make minor or trivial adaptations to protected plant varieties."[27] The EDV concept has "the effect of reducing the impact of the breeder's exception by expanding the scope of protection granted to plant variety rights owners."[28] But the breeder's exemption remains central to the balance struck in the text of the UPOV Convention – stakeholders in the meetings leading up to the Diplomatic Conference displayed "strong support for keeping one of the milestones of the UPOV Convention: the breeder's exemption."[29]

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[21] See Guiard, J. (2013) "The Development of the Provisions on Essentially Derived Varieties," Seminar on Essentially Derived Varieties Geneva, Switzerland, October 22, 2013. UPOV Publication Nr. 358, 11. See, e.g., the comment from the delegation of Germany regarding the examples of methods that now appear in Article 14(5)(c) of the UPOV Convention: "[t]he whole formulation was defective since it rested on methods and not on the result." See Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants. Geneva, 1991, [1077].

[22] MacDonald and Sherman, above n 15, p. v.

[23] Ibid., p. 22.

[24] See Kock, M.A. (2022). Analysis of the Status Quo: Current Issues in Patents on Plants. In Intellectual Property Protection for Plant Related Innovation, Law for Professionals, Springer, Cham.

[25] CSIRO (2021) Comments on the proposed changes to the UPOV Explanatory Notes on Essentially Derived Varieties. Submission to IP Australia, May 24, 2021, p. [6].

[26] See the summary of outcomes of the 2019 UPOV Seminar on the impact of policy on essentially derived varieties (EDVs) on breeding strategy provided by the Chair of the Administrative and Legal Committee of UPOV as reported in CAJ/76/9, p. [11].

[27] Sanderson, J. (2017) Examining and Identifying Essentially Derived Varieties: The Place of Science, Law and Cooperation. In

Plants, People and Practices: The Nature and History of the UPOV Convention, Cambridge University Press, Cambridge, p. 211.

[28] Ibid., p. 215.

[29] Guiard, above n 21, p. 10.

Since the 1991 Diplomatic Conference, there have been significant developments in breeding techniques, not least NBTs. The new technologies necessitate careful consideration of whether the current approach in the UPOV Convention strikes the appropriate balance of risk and reward for all innovators developing new plant varieties. This needs to be considered under the rules of the UPOV Convention with all members afforded procedural fairness and transparency.[30] Proposals that could derogate on the right to enjoy the breeder's exemption for all users of NBTs and which shift the UPOV gauge from a phenotypic system to questions of genetic conformity should not be actioned through a document that could create significant industry uncertainty, yet is not legally binding.[31]

The meaning of the EDV provisions in the UPOV Convention is unclear[32] and there are many opinions regarding how to interpret the text and strike the balance in rewarding initial variety holders and follow-on innovators.[33] We offer the following perspective.

Predominantly derived

At its essence, predominantly derived should require a factual enquiry into whether a variety originated from the initial variety.[34] Here, breeding history is perhaps the "gold standard" evidence for proving genetic origin. However, in principle, there is no reason to mandate a particular test for determining factual derivation and, depending on where the burden of proof rests, phenotypic similarity and genotypic similarity (subject to the comments below) also represent appropriate evidence bases on which to factually determine derivation.

Essential characteristics

It is not enough that an initial variety was used in breeding – this is of course permitted under the breeder's exemption. The importance of considering "essential characteristics" is clear from the records of the 1991 Diplomatic Conference: "[t]he main [drafting] problem involved the need to express the meaning of 'essentially derived variety' in such a way that it was the ***expression*** of the essential characteristics of the initial variety and the retention of ***that expression that was important***."[35] In other words, what is critical is that there is a high level of phenotypic similarity between the initial variety and the putative EDV and such similarity is clearly carried over; that is, inherited from the initial variety by the putative EDV.

Genetic conformity

The text of the UPOV Convention does not clearly articulate what role (if any) genetic conformity is to play in the assessment of EDVs. Indeed, the 1991 Diplomatic Conference specifically amended the Basic Proposal for Article 14(2)(b)(iii) – "it conforms to the genotype or the combination of genotypes of the initial variety"[36] – to "conformity with ***the expression*** of the genotype"[37] because "when one had to define whether a variety was an essentially derived variety, one would look at the characteristics that were the expression of the genotype of the initial variety and check whether those characteristics were also expressed in the derived variety."[38]

With new technologies for genotype analysis comes opportunities to assess EDVs in qualitative and quantitative ways, and it seems to be the time for members of UPOV to debate the role of genetic conformity and reflect the consensus in the text of the UPOV Convention.

[30] A similar point is made by Ricardo López de Haro y Wood in his letter to Mr. Peter Button dated March 9, 2022. See UPOV/CIRC/E-22/048/EDV/COMMENTS/TR.

[31] Indeed, in the Australian context, "it seems unlikely" that "an Australian court would take any account of the Explanatory

Notes when interpreting the PBR Act [Plant Breeder's Rights Act 1994 (Cth)]." See Submission of the Law Council of

Australia to IP Australia's Consultation Paper concerning the proposed changes to the Explanatory Notes on Essentially Derived Varieties under the UPOV Convention, August 9, 2021, p. [7]. There was reservation, although no outright opposition, to Explanatory Notes on EDVs from the outset: see Records of the Diplomatic Conference 1991, above n 21, pp. [1118–1138].

[32] The Australian delegation "had some reservations about the definition of essentially derived varieties, which was legally imprecise and technically flawed. As it was drafted in [the Basic Proposal], it would be difficult to administer and could lead to extensive claims for infringement and litigation procedures. The definition was not based on reality in breeding practice." See Records of the Diplomatic Conference 1991, above n 21, p. [1078]. See also comment of the Delegation of

Japan: "from a technical point of view, it was rather difficult to decide what was an essentially derived variety and what was

not." Ibid., p. [1119].

[33] See, e.g., Sanderson, above n 27; CIOPORA Position on Essentially Derived Varieties (as approved by written procedure in May/June 2016). Available at: <https://www.ciopora.org/ciopora-position-papers>; Kock, M. (2021) Essentially derived varieties in view of new breeding technologies – Plant Breeders' Rights at a crossroads. GRUR Intl. 70(1):11–27; Lawson, C. (2014) Plant breeder's rights and essentially derived varieties: still searching for workable solutions. EIPR 36(8):499–517.

[34] If the UPOV Article 14(5)(b)(i) is intended to be a question of factual derivation it ought to be amended to make this clearer. In its recent review of the EDV regime in Australia, MacDonald and Sherman concluded that some of the confusion around the EDV criteria could be avoided by clarifying that "predominant derivation" is factual derivation. See MacDonald and Sherman, above n 15, p. 19.
[35] Records of the Diplomatic Conference 1991, above n 21, p. [1852.4(iii)] (emphasis added).

[36] Ibid., p. 30.

[37] Ibid., p. [1099] (emphasis added).

[38] Ibid., p. [1101].

What is clear is that genetic conformity must not be the sole or primary criterion. An assessment solely on genotype would:

- disadvantage breeders who do not have access to genetic technologies as they will be "unable to analyse their own plants with the technology that will be used to determine whether intellectual property rights exist";[39]
- disincentivize the use of modern, innovative breeding technologies that have the potential to accelerate breeding progress by only affording conventionally bred varieties the full scope of PBR protection: this is because methods such as crossing and selection are more likely to result in larger genetic changes even if those changes are not causative of the phenotypic improvement and, indeed, where those genetic changes may be associated with detrimental linkage drag; and
- create commercial and legal uncertainty particularly for species with limited genetic diversity (such as lettuce and cotton) where genetic conformity thresholds may be detrimental to incremental advances possible in crops with limited genetic diversity, and are not meaningful even when applying current methodologies.[40]

At present, there are also significant concerns regarding the reliability and reproducibility of genetic techniques noting that these "vary in their operation and interpretation and produce different measures of genetic relatedness"[41] and "[w]ithout consensus on a complete genetic testing methodology for a plant grouping, disputes are extremely difficult to resolve in a non-arbitrary way".[42] While whole genome sequence (WGS), which is becoming more cost-effective, may overcome some of the concerns regarding which genetic test to use, there are still many issues to resolve even if the use of WGS becomes widespread.[43]

Innovation and economic value

Is it enough if a variety is determined to be predominantly derived from an initial variety and it retains and expresses the essential characteristics of the initial variety? The Australian ***Plant Breeder's Rights Act 1994*** (Cth) "explicitly [adds] a qualitative layer to the test of essential derivation in so far as it uses the phrase 'important (as distinct from cosmetic) features."[44] This recognizes that a variety can use an initial variety as the starting germplasm and retain the essential characteristics of the initial variety but still not be considered an EDV on account of differentiating "features" that warrant the grant of a full PBR monopoly. This approach appears to go beyond the requirement of the UPOV Convention – while a putative EDV needs to be distinguishable from the initial variety (if not, we would be dealing with a case of infringement), the UPOV Convention does not put clear criteria around the threshold of distinguishability that delineates a new variety from an EDV. This threshold remains contentious.[45]

A possible approach is to consider whether the putative EDV is innovative and possesses characteristics with differentiating economic value. Drawing on its foundational principles, UPOV seeks to provide a regime that rewards development of ***new varieties.*** An innovation concept can be analyzed by qualitative questions when considering the differentiating "important" features that should be of "'great significance or value'."[46] By considering innovation, features that are merely "cosmetic" or known additive changes would not constitute differentiating economic value in the horticultural and agricultural sectors but could for ornamentals. On this approach, ultimately breeding progress [that benefits growers and society] is measured by phenotype – the expression of the genotype – and an examination of a variety's "performance and/or market value."[47]

The authors are grateful for the invitation to provide their views and to contribute constructively to the issues under discussion internationally. We are supportive of UPOV finding a balanced process that incentivizes innovators.

In 2021, CSIRO made submissions to IP Australia in response to the Draft Text. This paper draws on the points made in those submissions.[48]

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[39] See MacDonald and Sherman, above n 15, p. 14.

[40] A similar point is made by Sanderson, above n 27, where, having noted the high genetic similarity of cotton, it is documented: "Where this occur, it is extremely difficult to establish reliable standard thresholds from which to assess essential derivation." See pp. 220–221.

[41] See MacDonald and Sherman, above n 15, p. 14.

[42] Ibid., p. 15.

[43] Ibid.

[44] Sanderson, above n 27, p. 226. See Plant Breeder's Rights Act 1994 (Cth) section 4(c).

[45] See generally Kock, above n 33.

[46] Sanderson, above n 27, p. 226.

[47] Ibid., (citations omitted).

[48] See above nn 16 and 25.

Presentation made at the Seminar

CSIRO

CSIRO´s Plant Breeding Activities

Breeding and pre-breeding for the major Australian crops

Top-tier PBR and patent portfolio

Cotton
Originator of all Australian cotton varieties

Cereals, Canola
Trait provider to the breeding industry

Fruits & Nuts
Breeding and trait innovation

Legumes
Innovating to serve the high plant protein demand

CSIRO

New Breeding Technologies (NBTs):
A huge innovation opportunity

Opportunity	Example
Bringing trait opportunities to vegetatively propagated crops • "Breeding-by-editing" is the only effective method to achieve breeding progress	Disease resistance in grapevine, banana, potato, citrus trees, etc.
Re-wilding • Direct conversion of alleles from wild/syntenic sources into elite germplasm without linkage drag associated with large introgression fragments	Nematode resistance in cotton
Accelerating genetic gain • Liberating breeding from the constraint of trait introgression; Parallel trait conversion of all finished (parental) lines at the end of the breeding cycle	Only limited by editing system’s cost and germplasm dependency
Creating novel allelic diversity • Most crops have limited allelic diversity at important loci within their elite germplasm pool, leaving a lot of untapped improvement potential • Best allele available is not necessarily the optimal allele; Functional genomics and recent breakthroughs in protein structure/function prediction are driving allele optimisation opportunities	Optimising well-understood plant metabolic pathways, such as photosynthesis, secondary metabolites
Many other opportunities • Technology is immature	Synthetic biology in crops, site-directed recombination, trait switches, etc

4 | CSIRO Presentation | UPOV Seminar March 22, 2023

Trait innovation using NBTs and breeding innovation go hand-in-hand

- Breeders and trait innovators both need to be incentivised to use New Breeding Technologies (NBTs)
- Proposed draft text for revision of Explanatory Notes on Essentially Derived Varieties (EDVs) got the balance wrong:
  - Disincentivise the development of new plant varieties using highly innovative NBTs
  - Risk consolidating the control of NBTs with current owners of plant breeders rights and distorting the system in a manner that is at odds with the intention of the breeders' exemption
  - Lead to commercial uncertainty

➢ UPOV needs to achieve a balance of incentives agnostic to the method of breeding

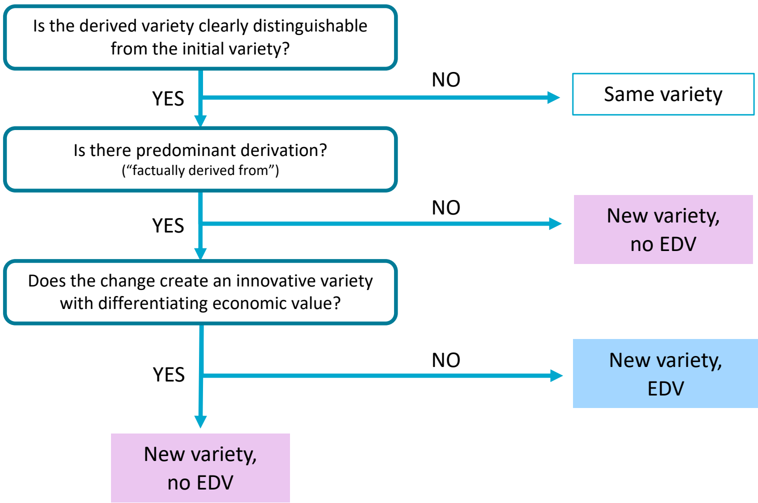
5 | CSIRO Presentation | UPOV Seminar March 22, 2023

Varieties obtained by editing should not be Essentially Derived Varieties (EDVs) by default

- Patents are not always an alternative
  - Patents on plants are not available in many countries and political views on how they should be treated are diverging
  - A key principle of the international PBR regime is to reward incremental breeding. These changes are unlikely to meet novelty and inventiveness requirements
  - Patents are much more expensive than PBR protection
- Increased geographical divergence and complexity
  - Has the potential to stifle innovation and drive industry consolidation

6 | CSIRO Presentation | UPOV Seminar March 22, 2023

Proposal for fair and clear decision criteria for EDVs



7 | CSIRO Presentation | UPOV Seminar March 22, 2023

What is the opportunity for UPOV to stimulate innovation?

- Reward innovation that creates economic value
  - Fair and clear decision criteria for EDVs needed
  - Safeguarding the breeders exemption
  - Avoiding perverse outcomes
- UPOV principle: Breeding progress is measured by phenotype
  - Veering from that principle would require a complete overhaul
  - Explanatory Notes are not the right way to change the fundamental principles of the UPOV Convention

8 | CSIRO Presentation | UPOV Seminar March 22, 2023

CSIRO

Thank you

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IMPROVEMENT OF NEW FRUIT TREE CULTIVARS AND USAGE OF GENETIC MARKERS FOR CHARACTERIZATION AND MAINTENANCE OF PLANT BREEDERS' RIGHTS

Mr. Doron Holland
Newe Yaar Research Center (Agricultural Research Organization), Ramat Yishay, Israel

Presentation made at the Seminar

New improved deciduous fruit cultivars raise the difficulty of rights protection

- ❖ Our unit at Newe Ya'ar Research Center, ARO improves new deciduous cultivars such as pomegranate, almond and apricot
- ❖ 5 new pomegranate, 6 new apricot and 5 new almond cultivars were released. Five of these are now the main cultivars grown in Israel
- ❖ All are registered for Plant Breeder's Rights in Israel and some in other countries such as USA and Europe

How can we protect these rights by molecular methods?

A glimpse at this subject complexity

Two examples are given in this lecture to demonstrate portion of the complexity of molecular usage in cultivar protection

- ❖ SNP and SSR markers for pomegranate
- ❖ Genetic mapping in almond

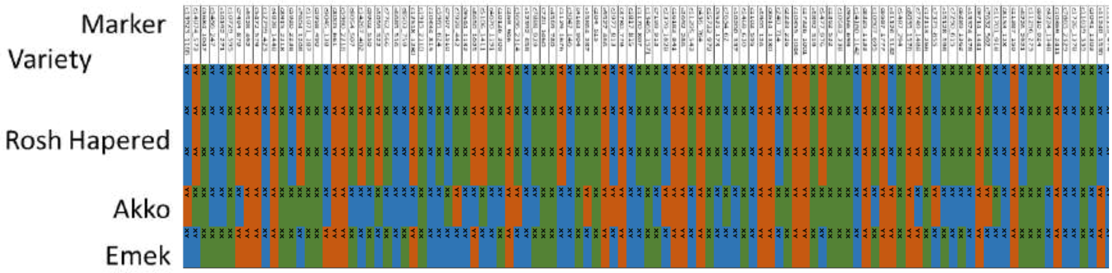
Molecular technology is used for both: -Improvement (is now a routine)

Protection - in progress and there are achievements

Pomegranate cv Emek

- In order to improve pomegranates while using local varieties, a selection was made in seedlings of the Israeli variety Akko. Male parent was unknown
- Emek cv is very early, sweet, dark red to pink, red arils, soft seeds, big, productive

350 SNP markers were established for the Newe Ya'ar pomegranate collection



The SNPs revealed that Rosh Hapered is the pollen donor

Today there are 5000 SNP markers that contribute to the accuracy of the identification of a cultivar

SSR for pomegranate identification

Variety	SC28915	SC7483	sc106926	16196
Akko	236/230	268/270	252/252	133/133
Shani-Yonay	236/236	268/270		133/133
Emek	236/236	270/270	248/252	133/139
Rosh Hapered 1	236	270	248	
Rosh Hapered 2	236	270	248	

- This varieties have many common characteristics
- Just 4 SSRs can differentiate them

more SNP markers will allow better identification

Almond cv Matan

- Using the local variety Um ElFahem and a self fertile cultivar we selected cv Matan
- Almond improvement objectives are: self fertile, large attractive kernel, good taste, high yields, balanced tree structure, suitable for hot climate
- Matan cv holds all these traits!

Self fertility *Sf* allele was used for gene assisted selection but is not enough for cultivar protection

Breeding process of cv Matan

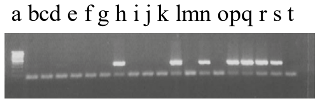
Self compatible almond cultivar (*Sf* allele) → Crossbreeding

High quality local old almond cultivar ('Um ElFahem') → Crossbreeding

Crossbreeding

↓

PCR identification of *Sf* allele in F1



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Planting only *Sf* positive seedlings

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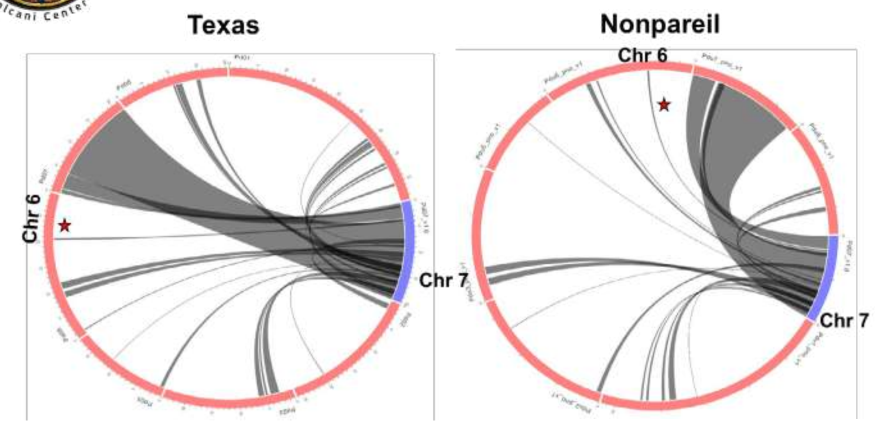
Selection for high quality cultivars

↓

Commercial usage

Major structural genomic variation between almond cultivars



Variance among cultivars is challenging the usage of genetic markers and necessitates *de novo* genomic sequencing

https://www.rosaceae.org/synview

NATURAL AND INDUCED MUTATIONS SECURED BY CLONAL PROPAGATION: IMPACT AND IMPLICATIONS

Ms. Zelda Bijzet
Research Team Manager: Crop Development, Agricultural Research Council, South Africa

Presentation made at the Seminar

PLANT BREEDING

- Plant breeding has been defined as the art and science of changing the traits of plants in order to produce desired characteristics
- This can be achieved in various ways from simply selecting plants with desirable characteristics for propagation, to more complex molecular techniques.

sapba

ARC • LNR

HOW CAN WE IMPROVE CROPS?

Conventional breeding

1. Breeding/Hybridization followed by selection
2. **Identification and selection of natural mutations**
3. **Radiation/Chemical Mutagenesis**
4. Cloning – Grafting, budding, tissue culturing

New breeding Technologies

1. Site-Directed Nucleases (SDN) (including ZFN-1/2/3 and CRISPR systems);
2. Oligonucleotide Directed Mutagenesis (ODM);
3. Cisgenesis;
4. RNA-dependent DNA methylation (RdDM);
5. Grafting (non-GM scion on GM rootstock);
6. Reverse breeding;
7. Agro-infiltration

sapba

ARC • LNR

MUTATIONS & MUTATION BREEDING

Mutation (De Vries (1901)

- A sudden, heritable change in the genetic material, which was not due to segregation or recombination.

Mutation breeding

- Mutation breeding refers to the method of using artificial mutagenesis to induce a change that would have occurred naturally to obtain new biological cultivars, mainly through chemical or radiation mutagenesis.

ROLE OF MUTATION BREEDING

- Many crops = natural bud mutations
- Supplementary to conventional breeding
- Induced mutation = breeding method for crops that never form seeds

Advantages:

- alter (improve) single characteristic
- rest of genotype unchanged
- improved traits are added,
- time required shorter than with hybridization
- benefit even higher if trait can be secured through vegetative propagation to be a commercial clone
- recessive traits

Constraints:

- Chimera formation = main problem
- Selection only from mV2 (second generation) onward

IMPORTANCE OF MUTATION BREEDING

1. Linear increase in interest from 1977 to 2018 - trend still ongoing
2. In 2018 there were 3222 mutant varieties released worldwide in over 200 crop species, as compared to 571 mutant varieties in 84 crop species in 1977.
3. These include 20 different fruit species having more than 50 cultivars
4. Mutation derived cultivars have contributed billions of dollars to the economies of many countries.
5. Main beneficiaries are developing countries, but first world countries also benefited.
6. Impact was on modified oil, protein and starch quality, enhanced uptake of specific metals, deeper rooting system, and resistance to drought, diseases and salinity as a major component of the environmentally sustainable agriculture.
7. Mutation in fruit breeding contributed mostly towards mitigating conventional breeding constraints and enhancing quality aspects
8. **ARCCIT9 – +R1.7 million trees planted in 11 years.**

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MUTATION BREEDING AND PLANT VARIETY PROTECTION

Plant Variety Protection (PVP) is a tool to **foster innovation** towards **long-term solutions** in agriculture, horticulture and forestry through a **lengthy** and **expensive** process requiring **skills** and accumulated **knowledge** that are applied in a **scientific approach.**

PVP and mutations = EDV

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ESSENTIALLY DERIVED: THE LAW

(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.

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REGISTRATION AND DISTRIBUTION OF PLANT MATERIAL

- Plant Breeders' Right obtained based on
  - **New, Distinct, Uniform, Stable**
- Fruit producers can still receive a product that is not uniform or stable
  - Breeding procedures
  - Source of bud wood
  - Crop processes (Virus cleansing etc.)
  - Overzealous commercialisation
- Questions
  - % variation allowed for changed attribute?
  - Back mutation (reversion)
  - Re-testing of original material after 5 years?
  - When is it an EDV and who should benefit from an EDV?

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OBJECTIVES THAT CAN BE ACHIEVED WITH MUTATION BREEDING

- Seedlessness/ low seediness
- Improved internal, external colour pigmentation
- Improved quality
- Change in ripening time
- Disease resistance

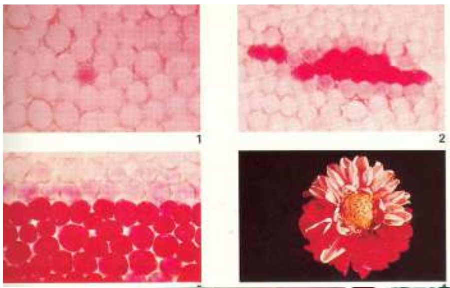
THREE LINKED STRATEGIES IN TREE CROP BREEDING

- Conventional
- Mutation
- Biotechnology

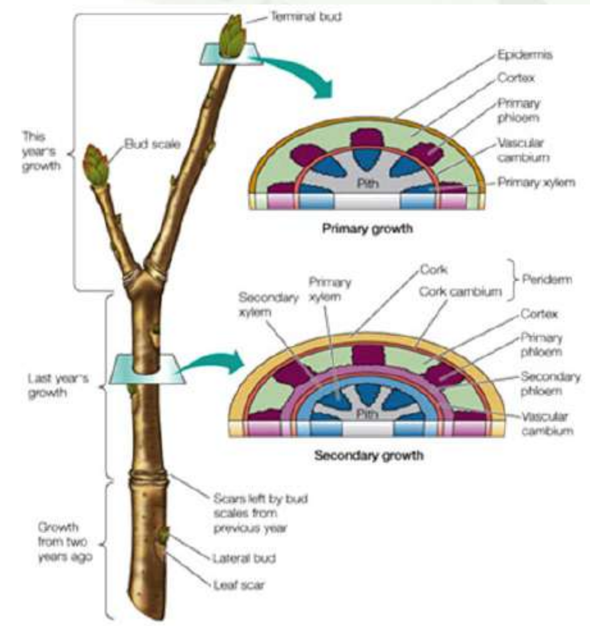
→ New improved cultivars

MUTAGEN TREATMENT AND HANDLING OF TREATED MATERIAL

- The success of a breeding project depends on the recognition of the desired genotypes and their recovery
- A mutation = one-cell event in a number of cell layers such as the epidermis and sub-epidermis with a number of meristematic cells in each layer
- Chimera formation in most cases results in mericlinal chimeras, subsequently developing in periclinal branches, shoots, tubes etc.

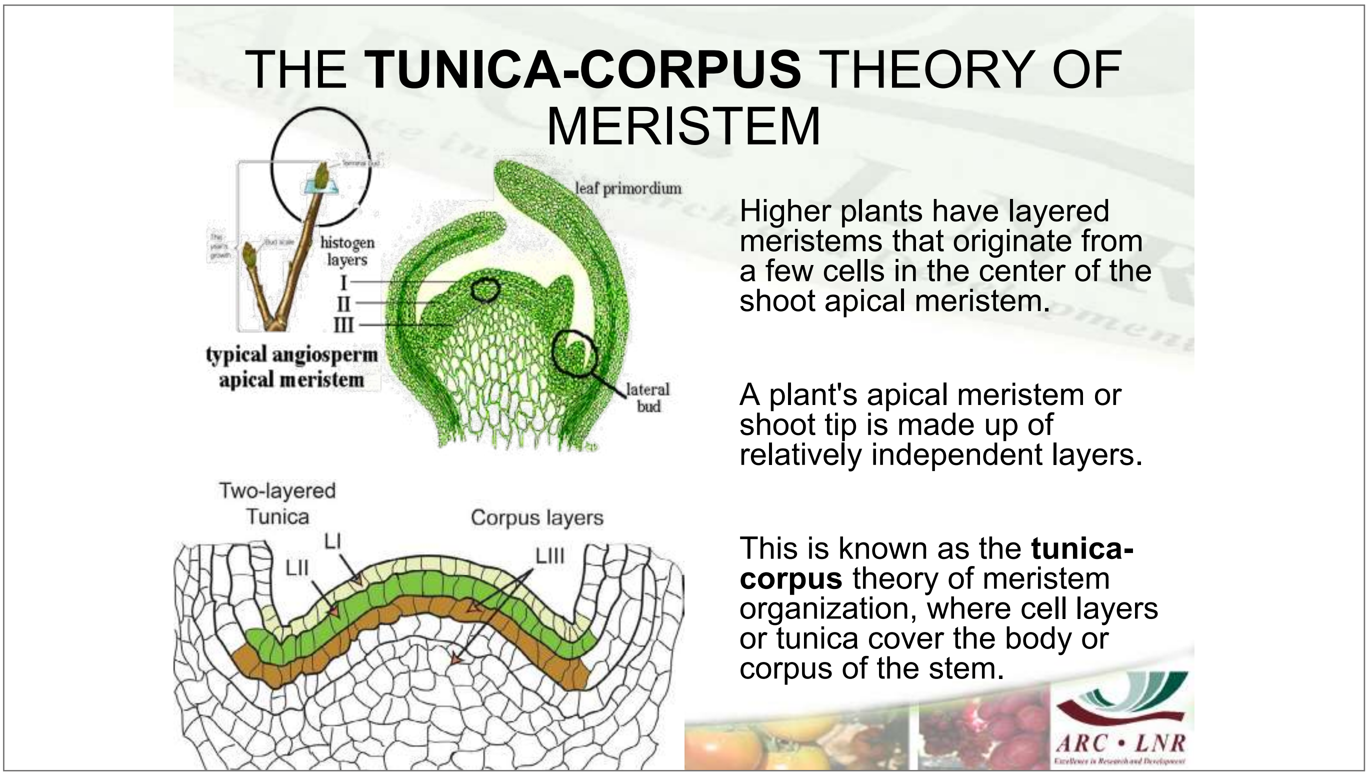


DEFINITION OF CHIMERA IN PLANTS



A chimera is a plant with two or more genetically dissimilar tissues growing side by side.

In general terms it is called "sports"


THE **TUNICA-CORPUS** THEORY OF MERISTEM
leaf primordium
histogen layers
I
II
III
typical angiosperm apical meristem
lateral bud
Higher plants have layered meristems that originate from a few cells in the center of the shoot apical meristem.
A plant's apical meristem or shoot tip is made up of relatively independent layers.
This is known as the **tunica-corpus** theory of meristem organization, where cell layers or tunica cover the body or corpus of the stem.
Two-layered Tunica
Corpus layers
LI
LII
LIII
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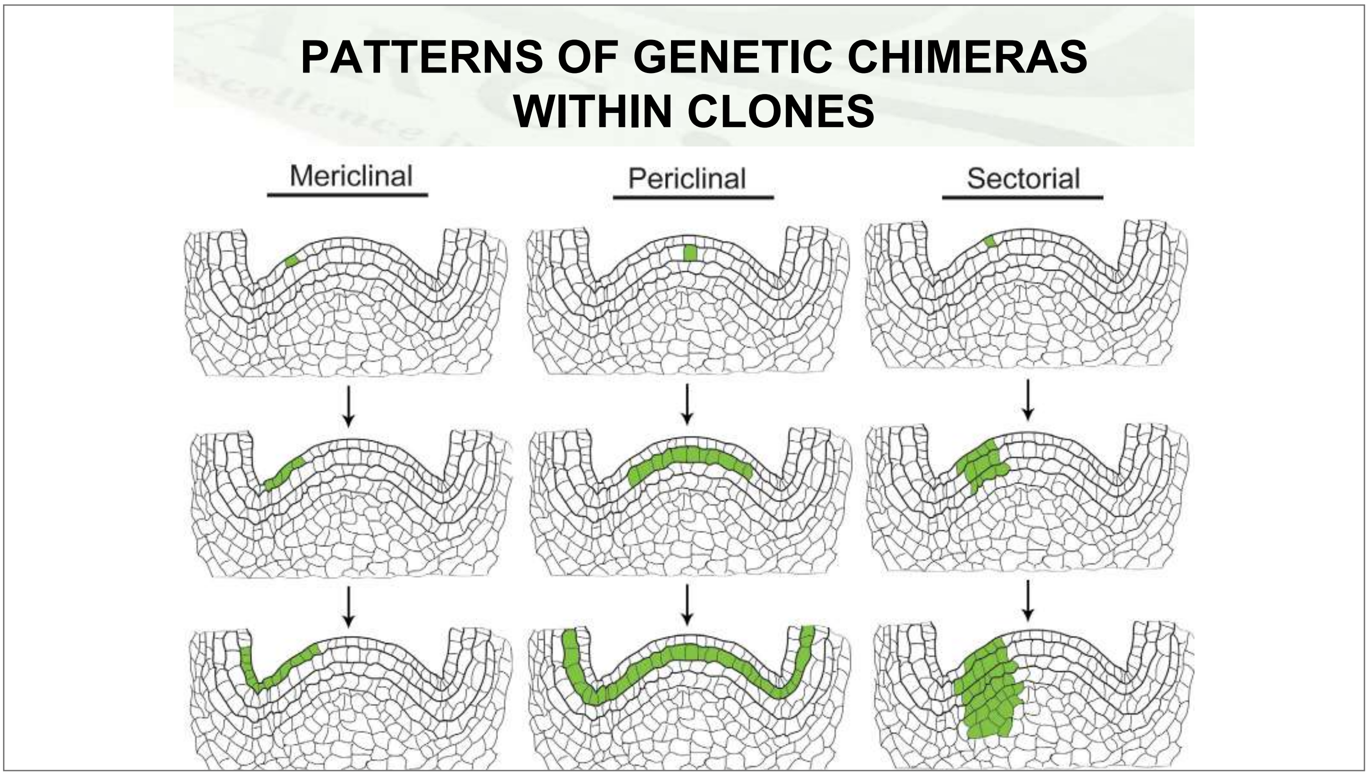
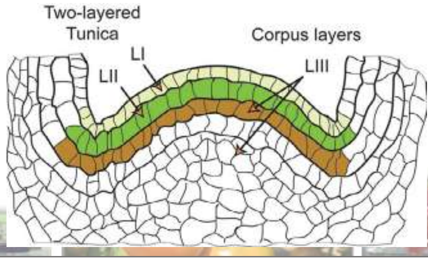

PATTERNS OF GENETIC CHIMERAS WITHIN CLONES
Mericlinal
Periclinal
Sectorial

SHOOT CHARACTERISTICS

- **All organs in plants develop from the apex.**
- **In flowering plants, the vegetative developing part consists of the L1 (dermatogen), L2 (sub-dermatogen) and L3 (corpus)**
  - **From the L1 comes the epidermis**
  - **From the L2 comes the mesophyll and gametes**
  - **From the L3 comes the vascular bundle, the roots etc.**



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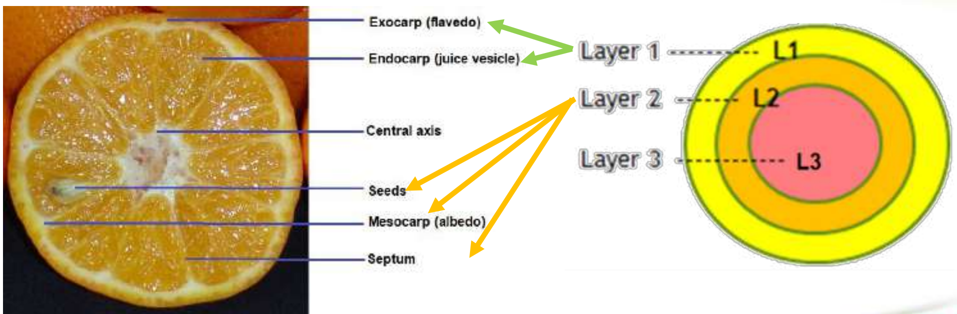
FRUIT CHARACTERISTICS

In citrus:

Layer 1 produces the juice sacs and the epidermis of the pericarp (rind)

Layer 2 produces seeds, segment walls, hypoderm and the mesocarp (albedo) of the epidermis

Layer 3 produces the vascular bundles



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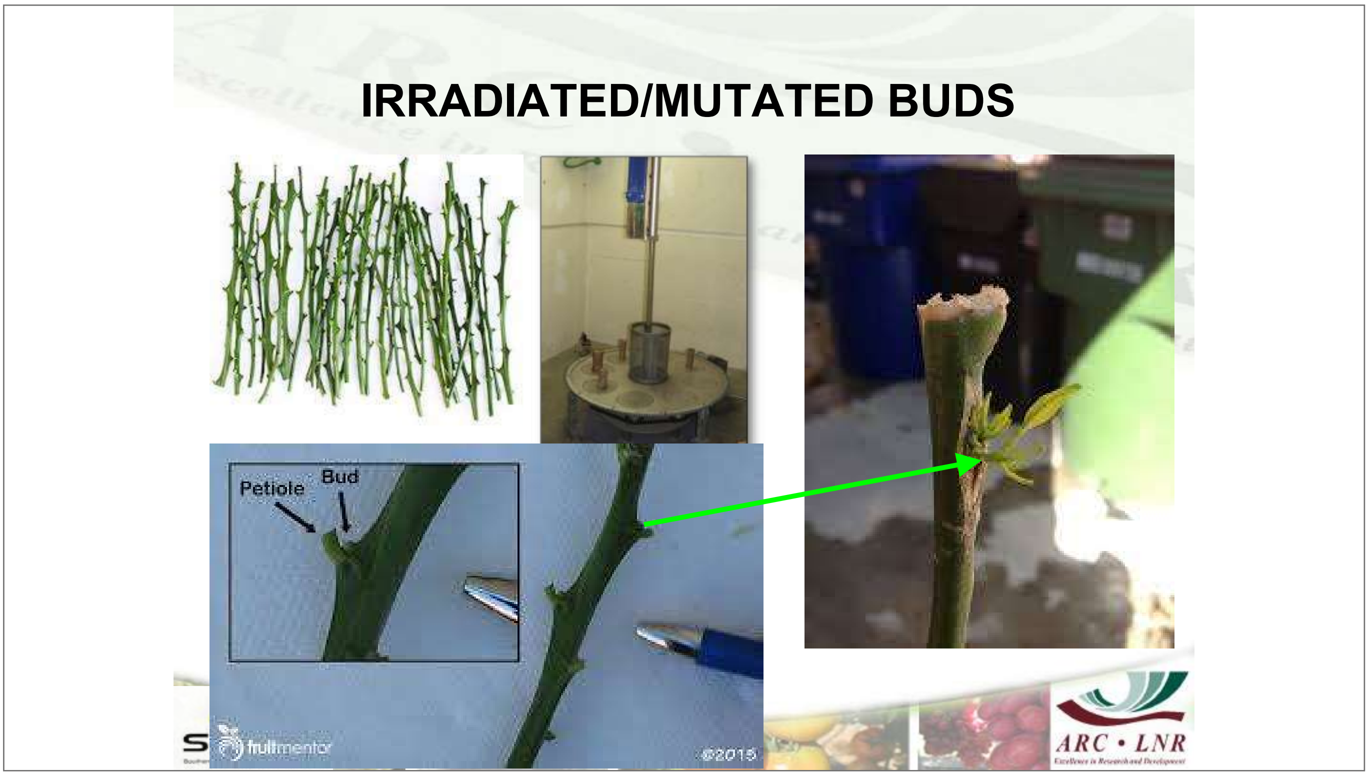
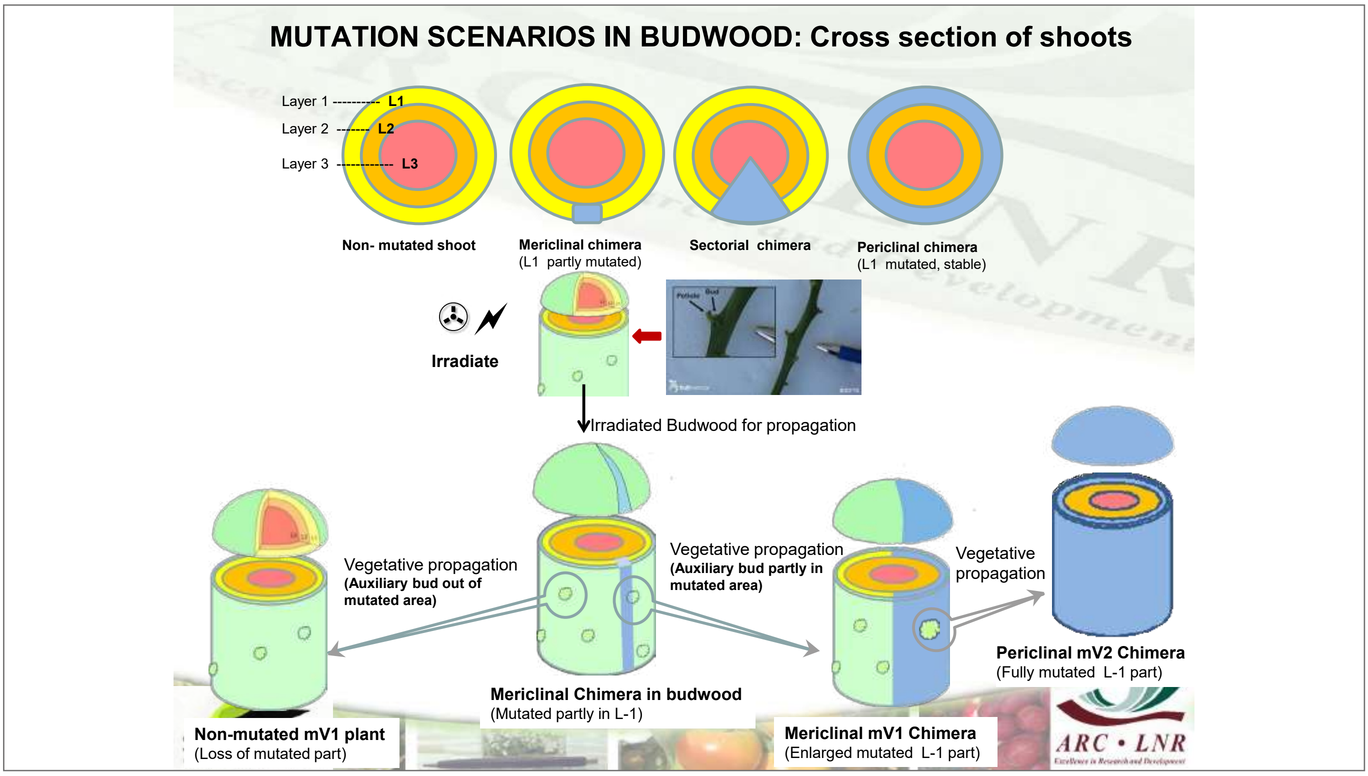

IRRADIATED/MUTATED BUDS
Petiole
Bud
fruitmentor
©2015
ARC • LNR


MUTATION SCENARIOS IN BUDWOOD: Cross section of shoots
Layer 1 L1
Layer 2 L2
Layer 3 L3
Non- mutated shoot
Mericlinal chimera
(L1 partly mutated)
Sectorial chimera
Periclinal chimera
(L1 mutated, stable)
Irradiate
Irradiated Budwood for propagation
Vegetative propagation
(Auxiliary bud out of mutated area)
Vegetative propagation
(Auxiliary bud partly in mutated area)
Vegetative propagation
Mericlinal Chimera in budwood
(Mutated partly in L-1)
Periclinal mV2 Chimera
(Fully mutated L-1 part)
Non-mutated mV1 plant
(Loss of mutated part)
Mericlinal mV1 Chimera
(Enlarged mutated L-1 part)
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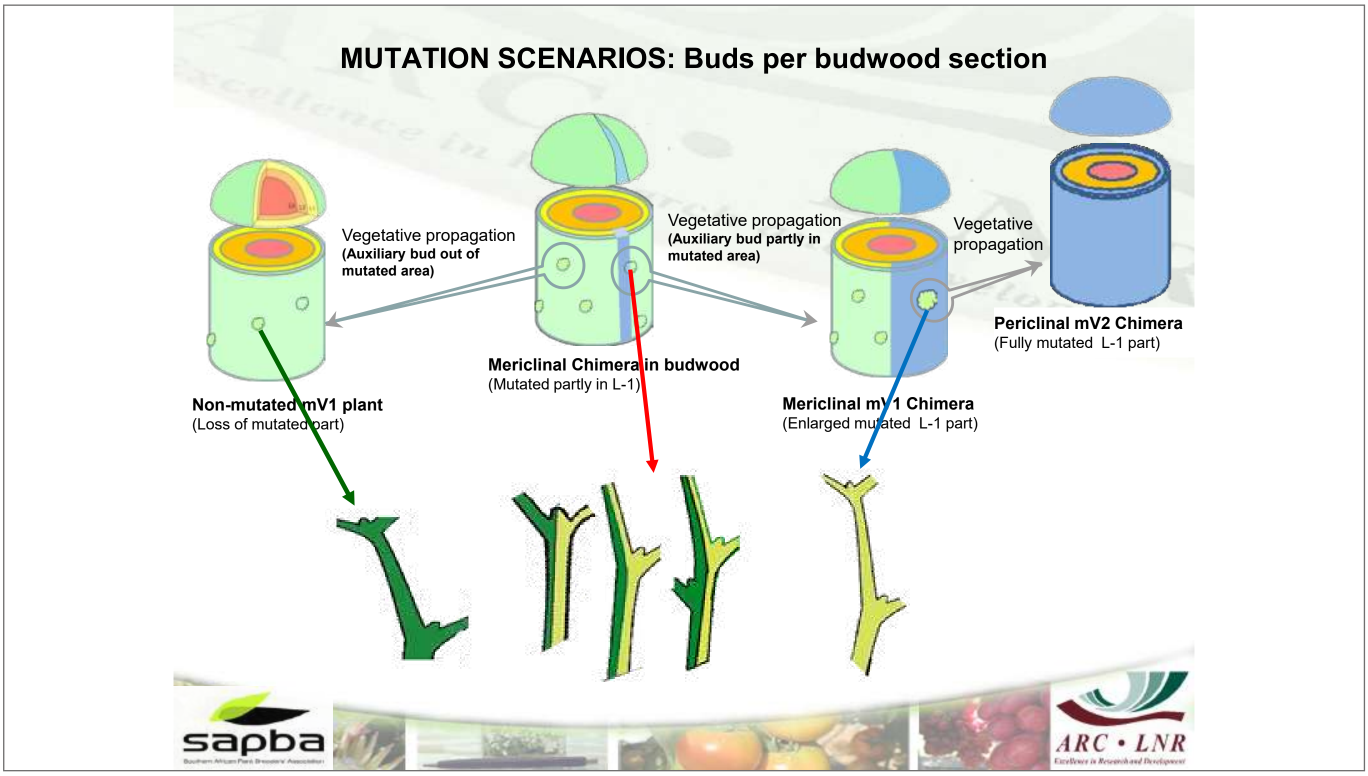
MUTATION SCENARIOS: Buds per budwood section
Vegetative propagation
(Auxiliary bud out of mutated area)
Vegetative propagation
(Auxiliary bud partly in mutated area)
Vegetative propagation
Periclinal mV2 Chimera
(Fully mutated L-1 part)
Mericlinal Chimera in budwood
(Mutated partly in L-1)
Non-mutated mV1 plant
(Loss of mutated part)
Mericlinal mV1 Chimera
(Enlarged mutated L-1 part)
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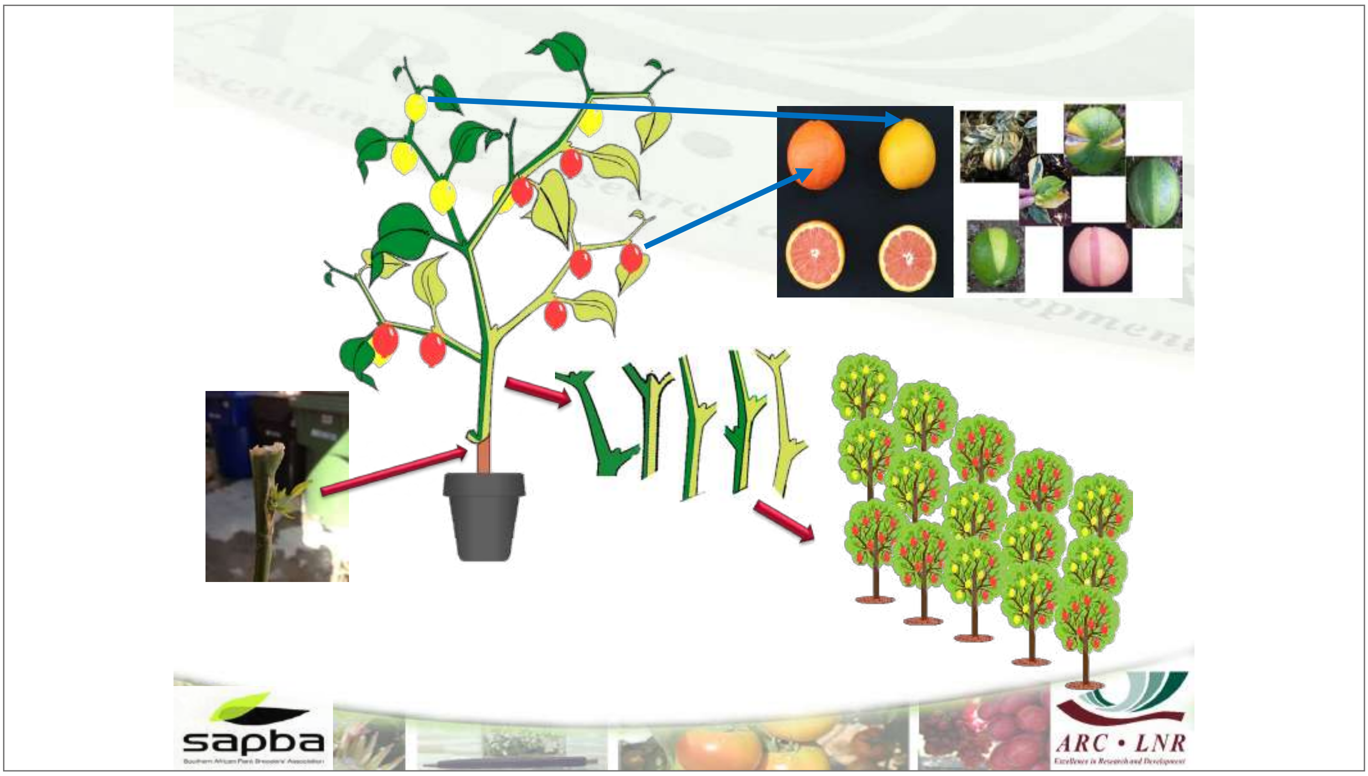
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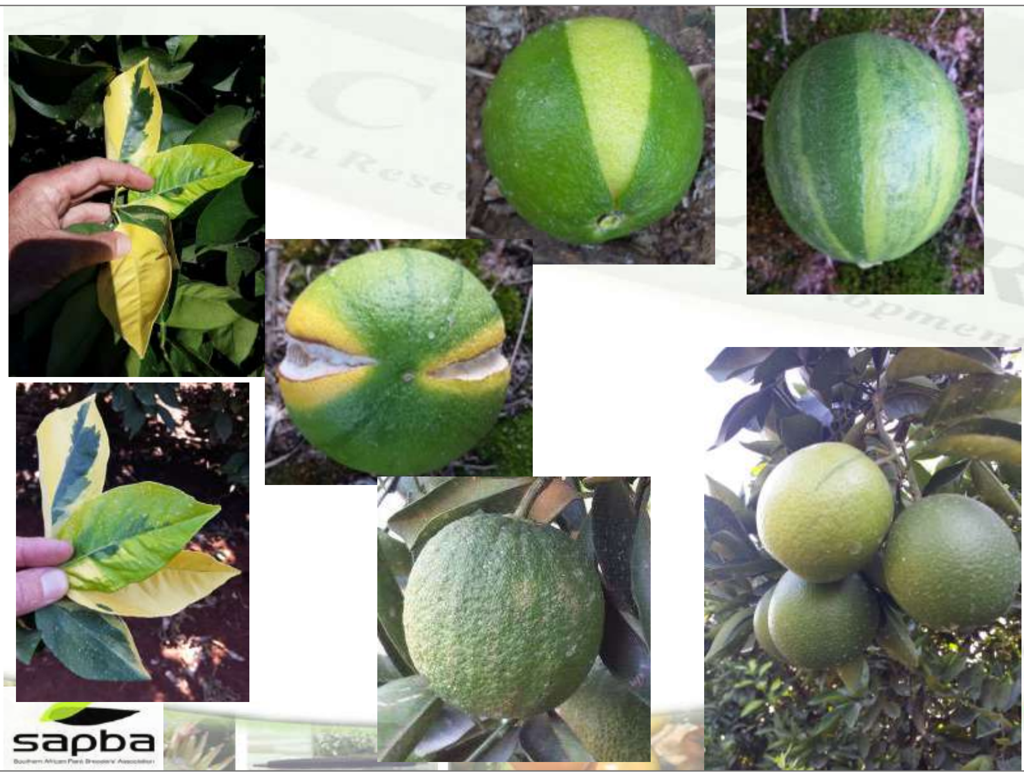
IMPLICATION OF CHIMERIC BUDWOOD BASED ON ORANGES

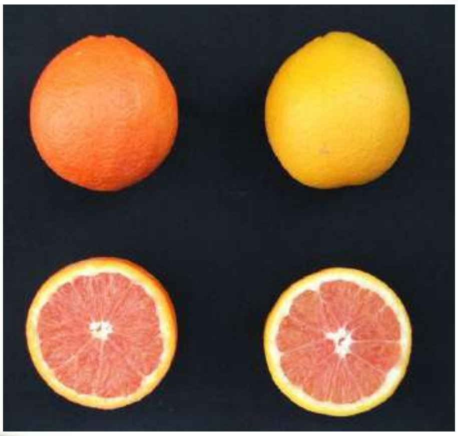
- Mutations secured by clonal propagation can be detrimental to the commercial sector in the absence of systematic phenotypic analysis

- Multiple cycles of phenotypic clonal testing is essential to test the stability of a mutation whether it is an induced or natural occurring mutation



STABLE MUTATIONS

Navels:
Dark skinned Cara Cara



Eureka! Seedless Lemon™ (ESL)

Ensuring uniform and stable cultivars from mutation breeding	
PHASES	**PROCEDURE**
Mutation phase	Induce mutations
M1 (M1V1)	Bud the mutagens treated buds onto a rootstock and plant in the field
M2 (M1V2) (Discovery of natural mutations)	Evaluate the (M1V1) plants for mutations Select mutants and take the bud directly behind the fruit that display the mutation and bud again to a rootstock and plant in the field.
M3-M8	Continuing selection, genetic confirmation, multiplication and stabilisation of field performance of mutant lines. During this phase, should there be branches that still display mutated and non-mutated fruit then the procedure of M2 is repeated on a branch where most or all the fruit is mutated.
Next generation	During this generation the material that are now deemed pure is multiplied for comparative analysis of mutant selections during different years and in different locations.
Next Phase	Application for Plant breeder's rights and subsequent release follows as soon as soon as stability and performance has been verified.

REGISTRATION AND DISTRIBUTION OF PLANT MATERIAL

- Plant Breeders' Right obtained based on
  - New, Distinct, Uniform, Stable
- Fruit producers can still receive a product that is not uniform or stable
  - Breeding procedures
  - Source of bud wood
  - Crop processes (Virus cleansing etc.)
  - Overzealous commercialisation
- Questions
  - % variation allowed?
  - Back mutation (reversion)
  - Re-testing of original material after 5 years?
  - When is it an EDV and who should benefit from an EDV?

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CONCLUSION

- Mutation breeding is important
- PBR's for EDV's are important
- UPOV depends on integrity of the applicant
  - Proof and submission of work done?
- Uniformity and stability of the trait
  - Re-evaluation after 5 years?
- What was deemed essential in the original cultivar and what % thereof is retained ?
- Change must be on an important attribute (commercial)
- Breeding vs Discovery
- Magnitude of the inputs in development of selection

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Thank You
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BREEDING AND BIOTECHNOLOGY IN ARGENTINA: A SUGARCANE GENETICS PERSPECTIVE

Mr. Germán Serino
Director, Chacra Experimental Agrícola Santa Rosa, Colonia Santa Rosa, Salta, Argentina

Sugarcane is a major crop that provides sugar, bioenergy and biomaterials. Chacra Experimental Agrícola Santa Rosa (est. 1951) develops sugarcane varieties for cultivation in Jujuy & Salta.

INTRODUCTION

Breeding sugarcane (Saccharum spp.) is a major challenge because its interspecific genome is highly polyploid, aneuploid, and heterozygous, as demonstrated by Garsmeur et al. (Nat Commun. 2018; 9: 2638) upon assembling the first mosaic monoploid reference sequence for the sugarcane genome using the commercial variety R570 as a model, demonstrating that the species ***S. officinarum*** and ***S. spontaneum*** involved in modern cultivars differ by their transposable elements and by a few large chromosomal rearrangements, explaining their distinct genome size and distinct basic chromosome numbers while also suggesting that polyploidization arose in both lineages after their divergence, and confirming that the chromosomes of current sugarcane varieties include recombinant chromosomes from both species. Sugarcane breeding also poses technical challenges. In subtropical conditions, for instance, photoperiod facilities are required to induce flowering and special measures are taken to generate fertile seeds. Fertility is also reduced because of the interspecific origin of this crop. Breeding sugarcane varieties at Chacra is a 14-year-long process.

Chacra's breeding program has developed varieties (named NA – Northern Argentina – varieties) that have been widely adopted in Argentina, Brazil and Bolivia. NA56-79, widely adopted in Brazil, is arguably the most planted sugarcane variety in history. In 2022, NA cultivars occupied nearly 60% of the sugarcane crop area in the Argentine Provinces Jujuy and Salta. Adoption of NA varieties has increased in the last seven years.

Chacra also improves sugarcane varieties through biotechnology, for which a transformation platform was established. At present, a herbicide tolerant GM variety has been developed and the regulatory dossier is being prepared to request its commercial release.

Breeding such a highly polyploid, aneuploid and heterozygous interspecific hybrid currently poses challenges. Fertility is reduced because of the interspecific origin of this crop. In sugarcane, there are currently no inbred lines, no heterotic groups have been defined and hybrid vigor remains majorly unexploited. Introgression of new traits from wild germplasm is slow and laborious, and many years of introgression work are required to introgress wild germplasm into commercial sugarcane varieties. Genetic improvement through biotechnology is challenging, as transgenes may not be transferred horizontally into commercially interesting genetic backgrounds, and therefore new "events" must be generated for each genotype (no introgression), within the corresponding regulatory time frames and costs. Furthermore, certain specific transformation recalcitrant genotypes are still practically impossible to transform, reducing the scope of gene technology applications. Within this framework, New Breeding Technologies (NBTs) that enable simpler and safer breeding alternatives are fundamental tools when seeking to leverage sugarcane breeding.

CRISPR-associated protein 9 (CRISPR/Cas9) emerged as a versatile molecular tool for genome editing in various organisms and is now the most popular method for genome editing. The Cas9 enzyme is directed by a single guide RNA (sgRNA) to a specific DNA sequence. Cas9 generates a double-strand break (DSB) 3–4 nucleotides downstream of a ~2–6 base pair sequence named protospacer adjacent motif (PAM) site (normally an NGG motif). These DSBs can be repaired by non-homologous end joining (NHEJ) and homology-directed repair (HDR) mechanisms. The main difference between these pathways is that NHEJ is an error-prone repair process and often results in the introduction of small insertions and deletions (indels). On the contrary, HDR results in a precise repair and requires recombination with a repair template with homology to the break site. Thus, gene editing allows precise and targeted genome modifications that may not be distinguished from naturally occurring genotypic variations. We are using Acetolactate synthase (ALS) herbicide tolerance as a model for gene editing in sugarcane. Acetolactate synthase, also known as acetohydroxyacid synthase (AHAS), is a key plant enzyme that catalyzes the first step in the biosynthesis of the branched-chain amino acids valine, leucine and isoleucine. ALS is also the target site for five chemical classes of herbicides: sulfonylureas, imidazolinones, triazolopyrimidines, pyrimidinyl-thiobenzoates and sulfonyl-aminocarbonyl-triazolinones. These herbicides are potent inhibitors of ALS, interfering with the synthesis of branched-chain amino acids, and therefore killing the plant. Specific mutations of the ALS gene in Ala122, Pro197, Ala205, Asp376, Trp574, Ser653 (amino acid positions correspond to the ***Arabidopsis thaliana*** ALS protein sequence) confer tolerance to ALS-inhibiting herbicides, whereas substitution of tryptophan at position 574 by leucine (Trp574Leu; W574L) confers tolerance to all families of ALS inhibitors.

RESULTS

We have selected ALS herbicide tolerance as a model for genome editing. As an initial objective to develop gene editing in sugarcane, we aim to validate the efficacy of designed sgRNAs to introduce mutations in the target sequence via CRISPR/Cas9 DSBs. To do this, we have expressed editing vectors stably integrated after biolistic co-delivery into sugarcane calli alongside a selection vector and specific ssDNA templates, seeking to: (1) validate the efficacy of designed sgRNAs to introduce mutations in the target sequence via CRISPR/Cas9 DSBs; and (2) achieve specific base modifications using a DNA template. We have designed a set of sgRNAs using specifically designed software using the sorghum genome (the closest genome sequence provided by the software) with high target specificity and low off-target activity. Homologous repair ssDNA templates (T1, T2 and T3) were also designed to attempt to functionally knock-in the ALS gene by: modifying the target (W574); eliminating a molecular diagnostic BtsCI restriction site; and eliminating a specific PAM sequence required for CRISPR to make the DSB.

sgRNAs were introduced into editing vectors including monocot codon-optimized CAS expression cassettes and delivered along template DNAs into sugarcane calli of the variety NA05-860. Geneticin resistant calli were regenerated and the 65 progeny individuals were analyzed for the presence of the NPTII selection marker, confirming the transgene was inserted in 64 events. Sixty NPTII+ events were co-transformed with the editing vector.

Putatively edited regenerants were diagnosed by PCR/Restriction Enzyme (RE) assay. Specific primers were designed to amplify a 404 bp ALS gene fragment, which was digested with BtsCI to detect elimination of the site upon its deletion or base substitution. PCR/RE positive plants displayed the target 404 bp, non-digested band when the BtsCI site was eliminated, or two, 239 and 165 bp, bands when the site remained intact. Thirteen independent events displayed editing genotypes in the PCR/RE assay, and editing was confirmed by sequencing the PCR amplified fragment. Sequencing chromatograms from RE undigested bands display overlapping bands at positions downstream of a putative editing site nearby the predicted editing site, suggesting that more than one ALS copy was edited.

CONCLUSIONS:

We show here that this initial sugarcane gene-editing development has achieved sgRNA-targeted deletion of ALS gene fragments using CRISPR/Cas9 vectors through NHEJ. This enables technology applications aimed at functional gene knockouts. Commercial applications of this technology require using specific techniques to provide insert-free DNA editing, such as biolistically delivering ribonucleoproteins into sugarcane cells, since co-delivering Cas9 into sugarcane variety NA05-860 results in foreign DNA insertion. DNA free gene editing as beyond the scope of this work.

PERSPECTIVES

We have not been able to achieve template-directed gene editing. Future perspectives that aim for functional gene knock-in will require successful implementation of this process, which will likely require stoichiometric adjustments in the DNA bombardment mixes and tests on different types of template molecules.

Sugarcane provides feedstock for sustainable agro-industrial activities. Its complex genome poses a major challenge for breeders and biotechnologists alike. Sugarcane will benefit from complementary tools that enhance cultivars by engineering specific traits into well-developed germplasm under a sensible regulatory framework to enable practical applications of NBTs.

Presentation made at the Seminar

CHACRA EXPERIMENTAL AGRICOLA SANTA ROSA

Breeding and biotechnology in Argentina: a sugarcane genetics perspective

Germán Serino
Chacra Experimental Agrícola Santa Rosa. Colonia Santa Rosa, Salta, Argentina
gserino@chacraexperimental.org

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

Sugarcane is a major crop that provides sugar, bioenergy and biomaterials

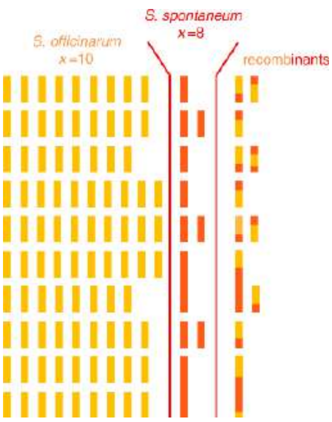
Courtesy of Ledesma SAAIC

2

Chacra Experimental Agrícola Santa Rosa (est. 1951) develops sugarcane varieties for cultivation in Jujuy & Salta

2

Breeding sugarcane (*Saccharum* spp.) is a major challenge because its interspecific genome is highly polyploid, aneuploid, and heterozygous



Garsmeur et al Nat Commun. 2018; 9: 2638.
doi: 10.1038/s41467-018-05051-5

Breeding a sugarcane variety demands years (14 at Chacra) of hard work

Sugar Tech (Jan-Feb 2022) 24(1):166–180 175

Table 8 Clonal selection stages of Chacra's Sugarcane Breeding Program

Stage (number of clones)	Plot size/trial design	Years	Sites	Selection criteria
Stage I: seedlings (250,000)	Individual seedlings/mass selection	3	1	Visual assessment (agronomic type and resistance to diseases), brix and ratooning ability
Stage II: first clonal stage (3000)	1 row, 6 m long/ unreplicated	2	1	Visual assessment (agronomic type and resistance to diseases); stalk number, stalk weight and brix (3 records between early and mid-harvest season)
Stage III: second clonal stage (250)	3 rows, 5 m long/ unreplicated	3	3	Visual assessment (agronomic type and resistance to diseases); stalk number, stalk weight and sucrose content (early, mid- and late harvest season)
Stage IV: multi-environment variety trials (20–25)	3 rows, 10 m long/ RCBD* (3 replicates)	3	10	Visual assessment (agronomic type and resistance to diseases); cane yield, sucrose content (early, mid- and late harvest season); maturity curves and ratooning ability
Stage V: macroplot (3–5)	6 rows, 70–100 m long/ RCBD (3 replicates)	3	10**	Visual assessment (resistance to diseases); cane yield; estimated sugar yield; herbicide phytotoxicity and maturity and tillering curves

**RCBD* Randomized complete block design

**Trials are not planted at every location every year

4

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EXPERIMENTAL AGRÍCOLA SANTA ROSA

Chacra´s breeding program has developed varieties that have been widely adopted in Argentina, Brazil and Bolivia

NA56-79, widely adopted in Brazil, was arguably the most planted sugarcane variety in history

5

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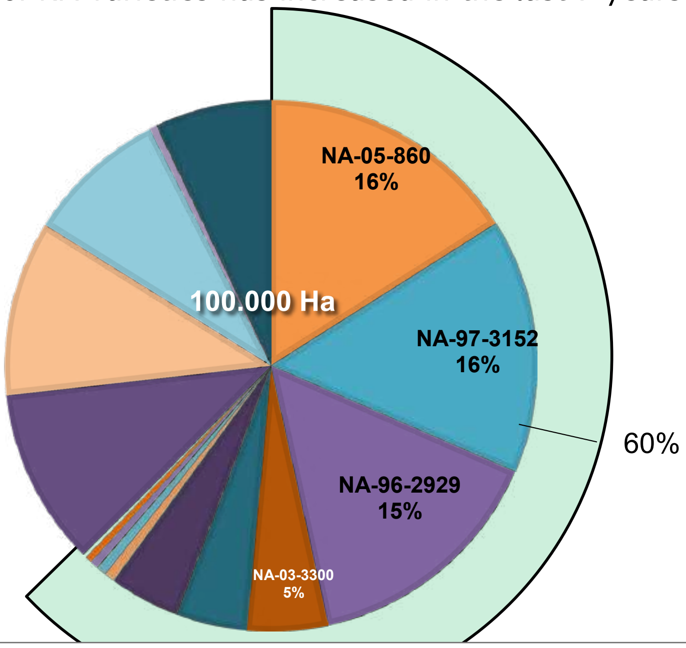
EXPERIMENTAL AGRÍCOLA SANTA ROSA

In 2022, NA cultivars occupied nearly 60% of Jujuy and Salta. Adoption of NA varieties has increased in the last 7 years



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A herbicide tolerant GM variety is in the regulatory pipeline

Field efficacy trial demonstrating herbicide tolerance in sugarcane NA varieties (2005)

7

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

Breeding a highly polyploid, aneuploid, and heterozygous interspecific hybrid currently poses challenges:

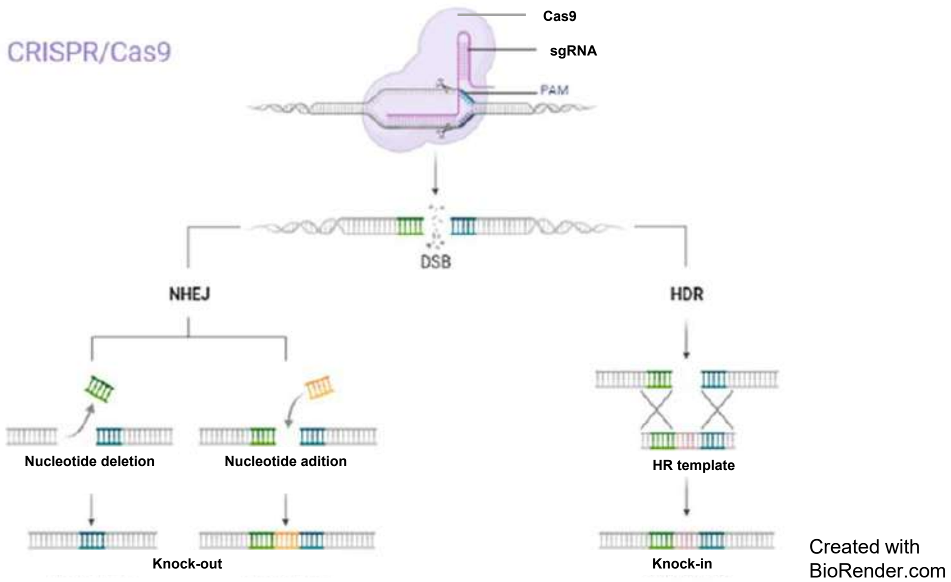
Conventional
- No inbred lines
- No heterotic groups
- Hybrid vigor unexploited
- Slow introgression of traits from wild germplasm

Genetic modification
- New "Events" must be generated for each genotype (no introgression)
- Each trait implies deregulating several events (see CTC´s Bt sugarcane)
- Impossible to transform recalcitrant genotypes

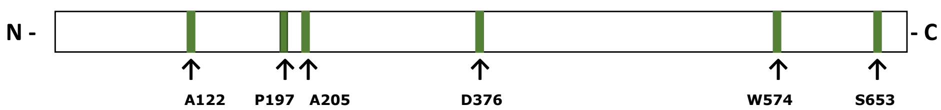
New breeding technologies that enable simpler and safer breeding alternatives are critical to leverage sugarcane breeding

8

CRISPR/Cas genome editing allows precise and targeted genome modifications that may not be distinguished from naturally occurring genotypic variations



ALS herbicide tolerance is a model for gene editing in sugarcane



Linear representation of the ALS protein. AA positions according to standardized *Arabidopsis thaliana* ALS protein sequence. (Tan *et al*. 2006; Li *et al*. 2008; Merotto *et al*. 2009)

Mutation	Tolerance
A122T	IMIs
P197S	SUs
A205V	IMIs
W574L	all families of ALS inhibitors
S653N	IMIs

Families of ALS Inhibitors
SUs: sulfonylureas;
IMIs: imidazolinones;
POBs: pyrimidinylthiobenzoates;
TPs: triazolopyrimidines, and
SCTs: sulfonylamino-carbonyltriazolinones
(Tan *et al*. 2005; Tan *et al*. 2006)

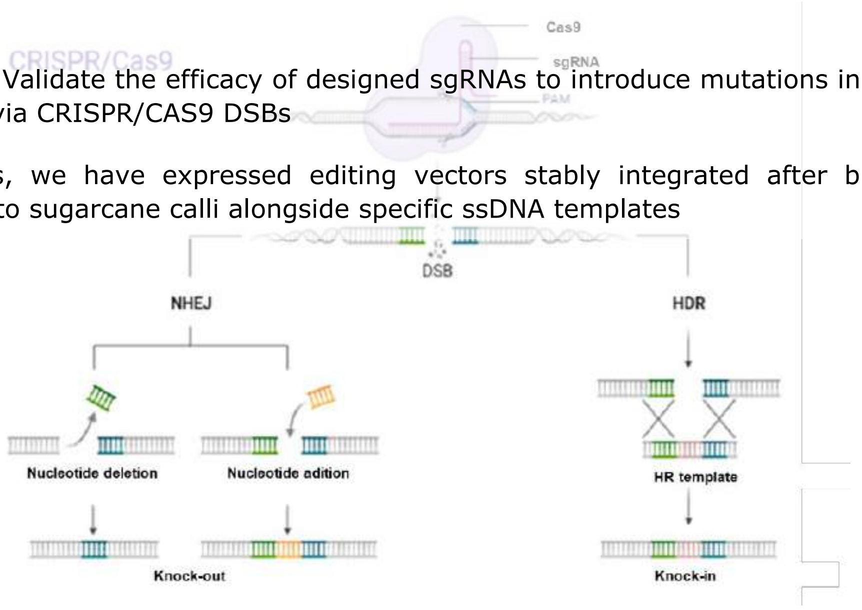
10

We selected ALS herbicide tolerance as a model for genome editing

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

Objective: Validate the efficacy of designed sgRNAs to introduce mutations in the target sequence via CRISPR/CAS9 DSBs

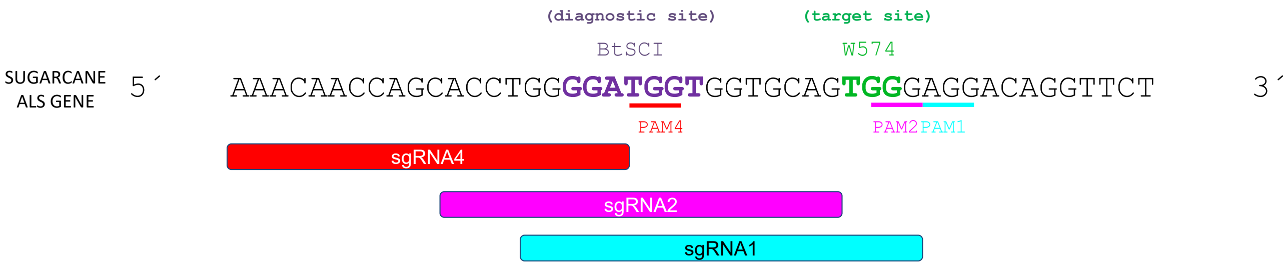
To do this, we have expressed editing vectors stably integrated after biolistic co-delivery into sugarcane calli alongside specific ssDNA templates



sgRNA

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

Software-predicted sgRNA1, sgRNA2 and sgRNA4 with high target specificity and low off-target activity



Homologous repair templates (T)

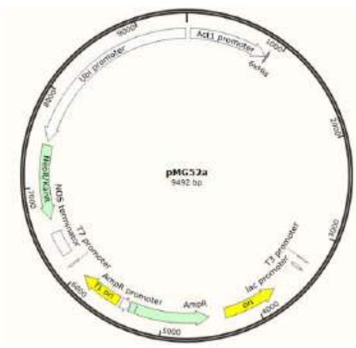
Homologous repair ssDNA templates (T1, T2 and T3) were designed to functionally knock-in the *als* gene by modifying the target (W574), eliminate a molecular diagnostic *Bts*CI restriction site, and eliminate a specific **PAM** sequence

REVERSE COMPLEMENT SUGARCANE ALS GENE 5´AGAACCTGTCCTC**CCA**CTGCACC**ACCATCC**CCAGGTGCTGGTTGTTT 3´

PAM1 PAM2 PAM4

T1	..TGTC**T**TC**GAG**CTGCACC**ACCATTC**CC..	127 nt
T2	..GGTC**T**TC**GAG**CTGCACC**ACCATGC**CCA..	92 nt
T3	..GGTCTTC**GAG**CTGCACC**AGCATGC**CCA..	92 nt

Embryogenic calli (*Saccharum* spp. Cv. NA 05-860) were transformed with editing vectors, HR templates and a selection vector through biolistic delivery



Template dsDNA
92 – 10 bp

WIPO FOR OFFICIAL USE ONLY

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EXPERIMENTAL AGRÍCOLA SANTA ROSA

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

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Transgenic calli were selected in culture media supplemented with G418

Transgenic calli regenerated in media containing with no 2,4-D

Transgenic regenerants in rooting media

Transgenic regenerants in the greenhouse

TOTAL TIME ABOUT 1 YEAR

Plants were diagnosed for the presence of the transgene

We have regenerated 65 stably independently transformed plants

Transgene integration of *nptII* and *Cas9* genes were confirmed using PCR

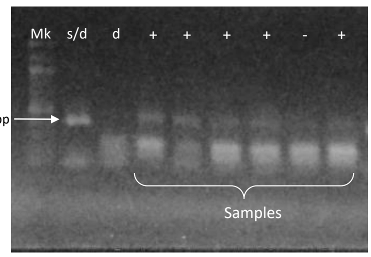
	Vector combinations	Number of Putative, in vitro selected events	*nptII* PCR	*Cas9* PCR
Stable expression	pNPTII + pEG_G1 + M1	16	16	15
	pNPTII + pEG_G1 + M2	15	15	15
	pNPTII + pEG_G2 + M1	11	11	10
	pNPTII + pEG_G2 + M2	5	5	5
	pNPTII + pEG_G4 + M3	18	17	15
		65	64	60
			98%	**92%**

Putatively edited regenerants were diagnosed by PCR/RE

Specific primers were designed to amplify a 404 bp *als* gene fragment

PCR restriction enzyme (PCR/RE) detects the elimination of the *Bts*CI recognition site near the target codon

BtsCI W574
GG**GGATGGT**GGTGCAG**TGG**GAGGACA



Putatively edited regenerants were diagnosed by PCR/RE (cont.)

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

13 independent events resulted positive for the PCR/RE assay

RE-resistant band from six plants were purified and sequenced

	Vector combinations	Number of independent events	*nptII* PCR	*Cas9* PCR	PCR/RE
	pNPTII + pEG_G1 + M1	16	16	15	5
	pNPTII + pEG_G1 + M2	15	15	15	4
Stable expression	pNPTII + pEG_G2 + M1	11	11	10	3
	pNPTII + pEG_G2 + M2	5	5	5	0
	pNPTII + pEG_G4 + M3	18	17	15	1
		65	64	60	13

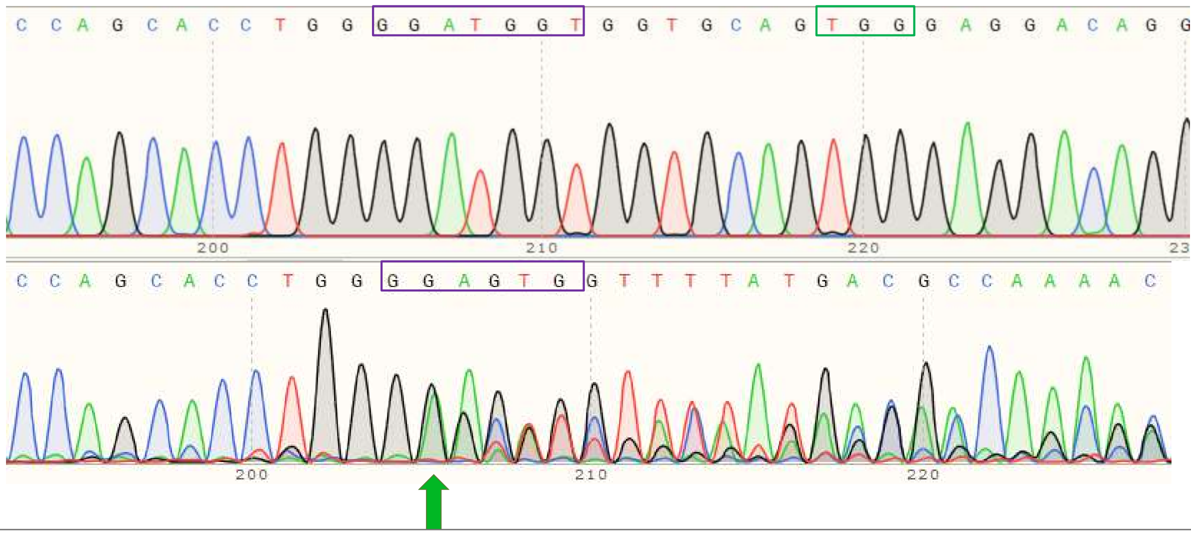
G1 → 30%
G2 → 20%
G4 → 6,6%

Editing was confirmed by DNA sequencing PCR products

CHACRA EXPERIMENTAL AGRÍCOLA SANTA ROSA

BtsCI W574

GG**GGATGGT**GGTGCAG**TGG**GAGGACA



CHACRA EXPERIMENTAL AGRICOLA SANTA ROSA

Sequencing

```
pEG1   Wt CCTGGGGATGGTGGTGCAGTGGGAGGACAGGTTCTATAAGGCCAACAGAGCACACACATA
       39 CCTGGGGAGTG-------------------GTTTTATGACGCCAAAACACACCACACATA   -19 nt
       65 CCTGGGGAGGGTGG----------------GTTCTTGGGGGCCAACAAACCGCACACATA   -16 nt
       44 CCTGGGGATGGGGGTGCTATGGGAGGACAAGTTC-------------------ACACCTA   -19 nt

pEG2   Wt TGTGCTAAACAACCAGCACCTGGGGATGGTGGTGCAGTGGGAGGACAGGTTCTATAAGGC
       46 TGTGCTAAACAACCAGCACCTGGGGA----------------GGACGGGTTCTATAAGGC   -16 nt
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CHACRA EXPERIMENTAL AGRICOLA SANTA ROSA

Summary

- We have achieved sgRNA-targeted deletion of *als* gene fragments using CRISPR/Cas9 vectors through NHEJ
- Codelivering editing vectors into sugarcane results in foreign DNA insertion

Perspectives

- We may now be able to develop functional knockout phenotypes of suitable targets
- DNA-free techniques such as biolistic delivery of ribonucleoproteins must be implemented to generate transgene-free editing
- Template DNA activity must be optimized to allow for most functional knock-ins

More generally

- Sugarcane´s complex genome poses a major challenge for breeders and biotechnologists
- Sugarcane breeding is a demanding, knowledge intensive activity
- This activity will benefit from complementary tools that enhance cultivars by engineering specific traits into well developed germplasm


Thank you!
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DISCUSSION WITH SPEAKERS OF SESSION I

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Now it is time for discussions and if there are any participants in the room or online who would like to raise questions to the above five speakers. The floor is yours.

Yes, please, if you have raised a question, please identify yourself, the name, and also the organization.

Yes, I see in the room, Ms. Judith from CIOPORA would like to take the floor.

DE ROOS-BLOKLAND Judith Maria Anneke (Ms.):

Yes, thank you. Judith De Roos from CIOPORA speaking. I have a question for Mr. Van Lookeren. I was wondering; you said that you don't want your varieties to be considered as essential derived variety (EDV) because that would be detrimental to innovation and I don't really understand why you say that, because if you have an EDV, you can ask for plant breeders' rights protection on that variety and commercialize it nonetheless. So, what is your exact argumentation for that specific conclusion? Thank you.

VAN LOOKEREN CAMPAGNE Michiel (Mr.) (speaker):

Yeah. Thank you for your question. What we think really is that if you create new innovation with your traits for new breeding technologies, you add something to that variety, and if you would be held hostage basically – you need a permission for that from the original variety originator, then that creates a dependency and the freedom to operate issue that transcends the original intent from UPOV with the breeders' exemption. So, I think that's the difficulty there.

Now, I do believe that, you know, if you would just have a variety and you add an existing trait, say you add by genome editing a waxy trait to a corn variety, that is well-known, that is not innovative, so I would say that then, yes, that would be an essentially derived variety. But if you create a completely new, a new phenotype, then that should be also a new variety without EDV. So, that is our position there because otherwise, we will drive the new breeding technologies into the hands of germplasm owners and we create a similar kind of, you know, monopoly, if you want, on the germplasm owners, which has already happened in, for example, the GM space.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Yes. I believe it's the gentleman from AIPH.

GHIJSEN Huib (Mr.) (speaker):

Huib Ghijsen from AIPH. Continuing on your answer, Mr. van Lookeren Campagne, it is in fact so that we presume that with your technology, you also can obtain a patent on that, and that we see the possibilities that both parties, so to speak, one with the germplasm and the other with the technology, do have a good position to start negotiations about, well, say, a cross license to use the technology, on the one hand, and the other to use the germplasm. Isn't that a good possibility? Thank you.

VAN LOOKEREN CAMPAGNE Michiel (Mr.) (speaker):

Yes, thank you, Huib. Nice to see you again. You know, for sure, it is a possibility to do patent protection as well, but patents on plants are not possible in all jurisdictions. There is also a hurdle for innovation. I had a special slide on that. So, we believe that that is not the solution to do that.

What we need is a balance. We do need to find a way to reward or incentivize breeders to keep breeding, but we also need to have a reward and incentivize trait providers and users and developers of new breeding technologies to be rewarded as well. And we believe that, you know, the explanatory notes, the draft explanatory notes, as developed currently, have got that balance wrong and basically flip the other way, with – it used to be that there was no, you know, the balance was fully towards the new breeding techniques (NBT) owners, and now we are flipping that the other way and we believe we need a more balanced view on that.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Thomas, the floor is yours.

LEIDEREITER Thomas (Mr.): Thank you very much. Thomas from Hamburg. A follow-up question; EDV, as you say, shouldn't be in place in that situation, but why should the new breeding technology companies be privileged compared to traditional users of mutations, for example? Why should there be a difference now? And cascade is already in place. Thank you.

VAN LOOKEREN CAMPAGNE Michiel (Mr.) (speaker):

So, I believe that the new breeding technologies are really using functional genomics in a much more directed way than mutation breeding. It is – we are able to create whole new genetic varieties that are not there, as you would do with mutation breeding, I would guess. But the functional genomic knowhow and the – the investments needed for that are really much larger than with mutation breeding. So, we believe that that should be rewarded, you know, concomitantly with the investment.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator): Yes, I see Ms. Bijzet. The floor is yours, yes.

BIJZET Zelda (Ms.) (speaker): Thank you. Yes, I just want to say what we have to look at is what is the percentage of change that has been made to the essential characteristics. So, basically, when you make your mutation or anything that you change, it must be something obviously that is of economical value to somebody out there, otherwise you wouldn't have changed it.

So, firstly, I would not want to get a PVR for something that has been changed on my project or on my cultivar that has no application economically. So, you have changed something just to call my cultivar, your cultivar. Technically, if you have changed more than a certain percentage, and with breeding, we change 50% of what you have because you have that hybridization effect. So, if I change less than that, we have to decide on how much variation of the essential characteristics is deemed to be valid to make it not an essential derived character – that variety. Because if you didn't have my original variety that I worked with, you wouldn't have to add anything to just put your single gene or something in. So, that is one of the other things we have to look at.

It is very important to know that firstly, change must be on something that is essential and economical and so that the original cultivar must declare what is essential on it, and that would be all the economical values for the – for it to be produced for money for the client or the producer, because that's what it's all about is the producer.

And then my last point is that yes, you will maybe have a problem on an EDV. We work on mutation breeding directly with some people. I will not use somebody's cultivar and not tell them but I have used it or want to use it and then try and claim it to be mine because I know that person has bred it for years and years to get to that specific cultivar, and then I only change one thing and I lie about it. That's not right.

So, I have to declare that I have used that original cultivar and what have I changed. So, that person or that breeder has is that he can only veto me on – on exporting to the same market which his cultivar is currently because it is about economical value. So, if I change a small thing and I can bump his cultivar out of the market, it's – that's exactly what EDV is there for. It's to protect the market of the original cultivar.

If that original cultivar doesn't have any market access anymore or it has fallen off exactly because of what you are changing now, then it is valid to say you have the full right to say that you bring something to that original cultivar because it's not economically viable anymore. So, those are all of the things that we have to look at is actually the end market where it is used.

And remember, you can still get the plant breeders' rights on your thing. It's still your cultivar that you bred, to EDV. The only rights that original breeder has to veto you is where he has access to markets. So, if you are going to Plant Variety Right (PVR) your cultivar where he hasn't PVR'd his cultivar, he hasn't any say on your cultivar at all.

There are things that we have to take. It's a bigger picture to look at.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Thank you. Yes, please, sir. Introduce yourself.

CUBERO SALMERON José Ignacio (Mr.): Can you hear me? I am José Cubero from Spain, Cordoba, Spain, University of Cordoba.

I think only some comments about the word mutation, because in this kind of seminar, I always hear about mutation as if it were only one event. And any text on genetics that is easily available, you can browse it and see the mutation hitting a lot of different events.

A single nucleotide, a set of nucleotides, full sections, half a chromosome, full chromosome, numbers of chromosomes, number of genomes, translocations, innovations, dilations, additions. All of these are mutations and can take to a very different way.

For example, the triticale Amarillo (ph) is the triticale that, by chance, received a chromosome of rye, observed by a worker in International Maize and Wheat Improvement Center (CIMMYT). A full chromosome changing completely the aspect of triticale, making Amarillo yielding more than wheat than the original of wheat, of course for other uses. But this is mutation also. It is not – many people think that mutation, it is irradiate or treat with a chemical, and the next step is already a variety. It is not. In the simplest case, it makes many years of observations, year after year, to eliminate Chimaeras. We have seen some presentation with Chimaeras. And eliminating all the things that were similar to the former variety. It takes many years, let's say more than twelve years. And to think that this is an EDV, to me it is really a very difficult thing to understand.

I was Professor of Genetics for more than thirty years and I think always in genetics, sorry about that, but please, when you mention mutation, mutation, it is not a single word. It is a very complicated concept hitting many, many biological facts. We need lawyers but we need biologists here too. Thank you.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Thank you. I believe your question is just a kind of a discussion and there is no specific designated person you would like to ask, right? It is just general comments, right?

CUBERO SALMERON José Ignacio (Mr.):

I said it was a comment coming from a retired professor. Sorry about that.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Okay. Thank you.

VAN LOOKEREN CAMPAGNE Michiel (Mr.) (speaker):

But it is also why the ecosystem is built around phenotype, because of that complexity.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Mr. Krieger, the floor is yours.

KRIEGER Edgar (Mr.):

Thank you very much, Mr. Chair. Edgar Krieger. I am the Secretary General of CIOPORA. I have a question for Mr. Van Lookeren.

I have two questions, in fact. You said that you would like to have a fair and balanced solution for breeders and for new breeding technology companies and both should be rewarded. How should the initial breeder be rewarded? If you exclude all these NBT varieties from the EDV concept. What is the reward for somebody who bred for ten years or twenty years, an apple variety, and then the NBT company takes it and makes it resistant, innovative? What is the reward for this breeder then?

VAN LOOKEREN CAMPAGNE Michiel (Mr.) (speaker):

Thank you for the question. I didn't say that I had a full answer in my slides. What I just wanted to state is that we both need to incentivize both the breeders that have made all of these investments and NBT providers. So, I think we just got the balance wrong with the explanatory notes now, the new draft ones, where that is driven into the germplasm providers and they are — they could become hostage of those germplasm owners.

I think there needs to be a way, like a breeders exemption. It doesn't need to be that they are not rewarded but there needs to be some freedom to operate, to create new varieties based on existing varieties that are in the market.

And I think that the conference here needs to discuss that and find a device to do that. It's just the way that it is in the explanatory notes is not – is not a way to go with the draft.

If you look at Australia's PVR Act, EDVs are defined as variety that does not exhibit any important features that differentiate it from other varieties. So, there is a sort of economic – it is already built in in some of the descriptions of the EDV system in the different jurisdictions.

KRIEGER Edgar (Mr.):

Thank you very much and my second question is a little bit more formalistic. I saw on your presentation, this proposal for fair and clear decision criteria for EDVs, and I scrolled through some of the other presentations and I saw some very similar work flow charts. I see no quotation here. Is that from you, this flow chart?

VAN LOOKEREN CAMPAGNE Michiel (Mr.) (speaker):

Yes. So, yes, that's what we developed at CSIRO. You know, obviously, we have also had discussions with people outside and things like that. So, obviously this is a topic that is, you know, debated among many, like you do, in your organization. And so, we have a hard think about how we could do that. It's not a simple question, of course.

KRIEGER Edgar (Mr.):

Thank you very much.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Yes, the gentleman in the back row. Yes. The floor is yours.

BRUINS Marcel (Mr.):

Thank you, Chairman. Marcel Bruins from – I am representing Croplife International. I hear the comment about balance a lot and that the balance is wrong, but of course, that statement is not backed up by facts at all. It is rather the opposite. And a quick analysis of the comparison between varieties on the national list and protected varieties clearly shows that the large majority of varieties on the market right now are not protected.

Such an analysis was done recently last year in the – in the CPVO report describing the contribution of plant breeders' rights to the European Union (EU). And there, it was shown that across the board, for field crops, fruits, and vegetables, a little less than 20% of all varieties on the market is protected. That means that 80% of all varieties currently on the EU market is not protected and is still fully available for further breeding, and the resulting varieties would never be an EDV. So, four out of five varieties is not protected.

And we see in the UPOV statistics that the EU is always one of the highest – the regions or countries with the highest protection level, always scores number one or number two. That means that likely in other countries, the protection level is even less than in the EU. So, the very large majority of varieties is not protected and fully, freely available. The resulting varieties would not be an EDV. Thank you.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Thank you, sir. Does anybody – oh, yes. From Green Rights, Thomas, the floor is yours.

LEIDEREITER Thomas (Mr.):

Thank you again. And to follow-up on Mr. Bruins' comment, the varieties being freely available and the discussion we're having now, to my mind, shows that there's quite some interest for the new breeding technology companies to use the protected varieties as a platform. If you want to use it as a platform and base your work on the excessive breeding efforts the classic breeders have already performed, I think taking new breeding technology varieties out of the EDV concept would be largely unfair. If you want to avoid it, like Mr. Bruins has already pointed out, there are largely – large numbers of free varieties available to do that.

The main issue I see here and the problem I see with the Australian approach is, in my mind, that if you allow varieties not to be EDV, in particular, if there is some commercial value to them, it is actually a bit of a slap in the face of the traditional breeders because they are now told well, if it's not commercially interesting, you can have it, but if it's interesting, we will take it and it's not going to be an EDV. I find that position a bit difficult from a fairness standpoint. Thank you very much.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Thank you. There are two raised hands online. The first, Lee Kwanghong from Korea. Then Michael Kock from the United States of America, I believe. Yes. Lee Kwanghong, the floor is yours.

LEE Kwanghong (Mr.):

Thank you, Mr. Chair. I would like to ask Zelda Bijzet about mutation activity. From my knowledge, it's that mutation is caused by the radiation or chemicals. In that case, the mutation randomly occurs, not intentionally. So, it has to be selected by the breeder many years or many efforts.

In that case, my point is that it is very rare about single mutation or pointed mutation in nature or by radiation or chemicals. In that case, do you think that the mutation breeding is like kind of an activation –act derivation for the difference from the initial variety, as you said, as EDV.

BIJZET Zelda (Ms.) (speaker):

Yes, thank you for the question. I hope you can hear me well. Yes, I do still think it's a considered act. For specific outcomes like on the level one or L1, L2, L3. So, we know how much grace to apply to get what outcome. It is still a lot to go and look for that variation within your new tree, like I said, [inaudible], and it can be in there or it can't be in there and it can be very hard to find with Chimaera and you have to look for it and fully get a clean and stable variation.

Yes, what we also do, we are looking now for seedless. But we don't test for all kinds of other things. If you see something by accident, you might have two outcomes from one mutation event. But like I said, we look for the essential characteristics, so it's seeded so we want it seedless, it's yellow; we want it red. So, that's what we aim at. And then, obviously, it is an EDV because you're using 99% of the original cultivar. It's still – when you go to the shop, you can still see that it's that cultivar. There is only one small attribute that changed. Although it is a lot of work and it is extremely expensive and it needs a lot of art. It's not anybody that can just be a mutation breeder because yes, it's basically an easy to make mutation but you don't find that over time it is not that easy.

So, I still think it's an EDV but what we have come to how we handle it is we go to the original owner of the cultivar, we discuss the situation, we say look, yeah, we can do this for you. Do you want to be part of it? And probably, such a person would become part of the funding devices or we can look into the amount of work and time that goes and then your base cost, what it costs to make this new cultivar, and then also to negotiate whether this new cultivar will be better for the market access than – versus the old cultivar.

And in such a negotiation or partnership, you can actually move very well if you are talking to that original cultivar owner.

Again, like I said, we had a cultivar that was barred from being – going out to the EU from South Africa, for instance, because it had a PVR, the original one had a PVR in South Africa, but it didn't have a PVR in Australia. So, if we now want to move that new EDV from Australia, the original cultivar owner didn't really have much to say about it because they didn't protect their cultivar in Australia.

So, that's the other thing that is very important to know is that you are only partially protected. You can only call your cultivar – your cultivar is only an EDV in a country where it is protected by PVR rights. So, again, if I take my cultivar to Australia, they find it to be good, and they want to move on with it, they don't have to declare that it's an EDV. They can immediately market it. But that would not be good for my partnership. So, again, it will be negotiated. But that is how it basically works.

Yes, there is a lot of work going into it. It is a concerted act. It is not really random but it is not as directed as the new breeding technologies such as like the mutation, which is totally different.

And as I said, we are in fruit breeding, very much dependent on mutations because that is the way that you can take – sometimes do things that you can't do with normal breeding. And also, in fruit, some GMOs aren't deemed or taken well by the consumer because this is a nice to have, it is not a staple food. They still prefer to buy things that they deem to be safe. They don't always understand genetics. So, they prefer something that has been naturally bred.

And for us, radiation and chemical mutagenesis, that is what nature does, it is just sped up, right, controlled pollination is sped up, it's still natural, and can go forward in that way.

LEE Kwanghong (Mr.):

Another question is that in that case, if the variety is different in many characteristics, not just several, two or three or less than five or like that, if a mutation occurs in many characteristics, more than five or ten, in that case, do you think that is also kind of such – very similar to the initial variety in genetics?

BIJZET Zelda (Ms.) (speaker):

I think one we should have a look at, whether the original cultivar was bred for, how it was bred, what apparently changed. And if you have changed – what do you call it – an amount of changes that you made is basically equal to breeding it from scratch, you've made a lot of it, it was just quick and easy maybe to do it but it's still a lot of differences, so, again, where is that cutoff point? That's what we have to decide. Do we do 10%, 20%, 50% changes to the original description of that cultivar?

So, yes, there are 10,000 yellow cultivars in the market and I changed the color. Was that originally – is it an essential characteristic? Was that now the thing that was bred for? So, that is the thing that we have to look at. So, what makes that cultivar unique? That is what you have to look at. And how do you change that uniqueness totally away from it being essential? So, it's a percentage of changes, I think, yes. In genetics, it is possibly not an EDV anymore.

LEE Kwanghong (Mr.):

I think that as professionals, you can say broadly, as in PVP opinions, it would be very difficult to say that it is very essential or the characteristics – the several differences of characteristics has occurred by just – how do you say – very – very mutation is not just occurred by some point of less mutation or like that. So, as you said, the similarity of the genomes, so to – to determine that this is EDV and this is not EDV, in case of mutation. So, I think that it has to be more discussed about this EDV and the mutation. Thank you.

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

According to the schedule, there's a coffee break, and I'm sorry for Mr. Michael Kock. You may raise the question in the next session and the same for the other participants. So, now is a coffee break.

SESSION II:
PARTNERING IN USE OF TECHNOLOGY

Moderator: Ms. María Laura Villamayor, Chair of UPOV Administrative and Legal Committee

New breeding techniques: public research institute perspective
Mr. Marcelo Daniel Labarta, Technology Transfer Office, National Institute of Agricultural Technology (INTA), Buenos Aires, Argentina

The importance of public-private collaboration to enhance application of biotechnology in plant breeding
Mr. Muath Alsheikh, Head of Research and Development, Graminor AS, Norway

How to balance PBR and patents in breeding programs: Lantmännen (farming cooperative) perspective
Mr. Bo Gertsson, Group Manager Product Development Plant breeding, Lantmännen lantbruk, Stockholm, Sweden

Discussion with speakers of Session II

NEW BREEDING TECHNIQUES: PUBLIC RESEARCH INSTITUTE PERSPECTIVE

Mr. Marcelo Labarta
Technology Transfer Office, National Institute of Agricultural Technology (INTA), Buenos Aires, Argentina

Created in 1956, the National Institute of Agricultural Technology (INTA), is an official decentralized organization at the Secretary of Agriculture, Livestock and Fisheries, with operational and financial autarchy.

INTA has its headquarters in the Autonomous City of Buenos Aires and has an institutional and operational presence in the national territory through 15 regional centers, on which 52 experimental stations, 6 research centers, 22 research institutes and 359 rural extension agencies depend.

Plant breeding at INTA has been one of the main activities carried out since its inception. When Law No. 20247 on Seeds and Phytogenetic Creations of Argentina was enacted in 1973, and later, in 1981, when activity began in the National Registry of Cultivars and in the National Registry of Property of Cultivars of Argentina, INTA had a very important role in providing documentation and information on the plant varieties that it had already developed and that were generally known in Argentina.

Currently, INTA has 1,025 varieties registered in the National Registry of Cultivars and 280 varieties with current property title Plant Breeders' Rights (PBRs) in its name (www.argentina.gob.ar/inase; www.argentina.gob.ar/inta/variedades).

At the time of writing, INTA had applied for varieties registration from 107 species (cereals, oil seed crops, forage crops, ornamentals, forest trees, fruit crops, horticultural crops, medicinal).

As already indicated, Law No. 20247, its regulations (Decree No. 2183/1991) and Law 24376 on the accession of the Argentine Republic to the UPOV Convention (1978 Act), are the legal framework for registration and intellectual property in plant varieties in Argentina. However, the entire regulatory framework related to agricultural biotechnology is carried out by the Secretariat of Agriculture, Livestock and Fisheries through the National Advisory Commission on Agricultural Biotechnology (CONABIA), with the support of control activities by INASE (National Seed Institute) and SENASA (National Agri-food Safety and Quality Service), through current regulations and procedures.

INTA has been part of the evolution and growth in scientific knowledge on plant breeding techniques. The different traditional breeding techniques were and are used by INTA researchers on various species. These techniques have been complemented over the years with new technologies that help the breeding process, such as molecular markers used to assist traditional breeding, mutagenesis induction, different DNA recombination techniques and gene editing.

The geographical distribution of INTA in the national territory implies that the different breeding programs are specialized for the geographically diverse species, using techniques that are most suitable in each case, but mainly, as a result achieving improved varieties in aspects of industrial quality, yield and adaptation to the environment and the territory in which they were developed. Another noteworthy point is the evaluation of varieties in different environments, thanks to the management of evaluation networks conducted by INTA for certain crops.

Toward the end of the 1980s and in the face of technological changes in agriculture, with greater use of an array of techniques produced and marketed by the private, technology sector, INTA gradually ventured into the development of «appropriable technologies» (private goods), such as plant varieties that it had already been developing, but also vaccines, agricultural machinery and various biological products, and also, in the transfer of know-how for the input supplier industry and agribusiness. Consequently, and considering the national legislation on science and technology, on the promotion of technological innovation, on seeds and PBRs, and on patents, trademarks and utility models, among others, INTA considered it necessary to formulate a specific institutional policy on "technological linkage" (technology transfer).

The objective of this policy was to establish an efficient mechanism for the transfer of appropriable technologies between INTA and the private sector. Since then, the strategy and models followed by the institution make a clear distinction between "non-appropriable technologies," those intended for rural producers and transferred free of charge by the extension service, and “appropriable technologies,” those transferred to the agricultural system for consideration through technological linkage agreements. In this last scheme of “appropriable technologies,” INTA focused its efforts of technology transfer on products and processes, and a significant demand for specialized technical assistance and services was consolidated.

After this background, both in terms of plant breeding and the transfer of INTA technology, it is propitious to share some examples of different situations that arose and that are related to the development of plant varieties using different available technologies.

One of these cases corresponds to the cultivation of rice, affected by different weeds at certain stages of its development and for which the INTA breeders, through mutagenesis, obtained varieties resistant to herbicides of the imidazolinones family. This mutagenic trait is owned by INTA and was incorporated to date in five registered varieties and with current PBR. Through a technology transfer agreement, INTA licensed these varieties and the technology it incorporated to a company for their production and commercialization at an international level. Also, these rice varieties were transferred to a rice foundation for production and commercialization in Argentina.

Another example corresponds to cotton varieties, on which INTA has a recognized prestige at a national and regional level for the technological characteristics of fiber and resistance to diseases. In this sense, through an agreement with the company that owns the transformation events (Genetically Modified Organisms), INTA accessed the genes that confer resistance to herbicides and lepidoptera worms to be able to incorporate them into their own varieties. Once these first three varieties of cotton had been obtained, registered and PBR granted, INTA licensed these varieties to a national company for their production and commercialization in Argentina and other countries.

An example similar to that of cotton occurred with some INTA soybean varieties, for which, through an authorization from the company that owns the transformation event (GMO), INTA was able to access said event to incorporate it into its germplasm, protect its varieties and subsequently license them to different companies for production and commercialization.

Another interesting situation has occurred with an ornamental variety obtained by INTA, of the species ***Calibrachoa***. INTA works on the improvement of ornamentals from native species of Argentina, taking into account the rights of the provinces that, as established in the Constitution of Argentina, are those who have dominion over these native resources and sharing with those provinces the benefits derived from the commercial exploitation of the varieties obtained from these resources.

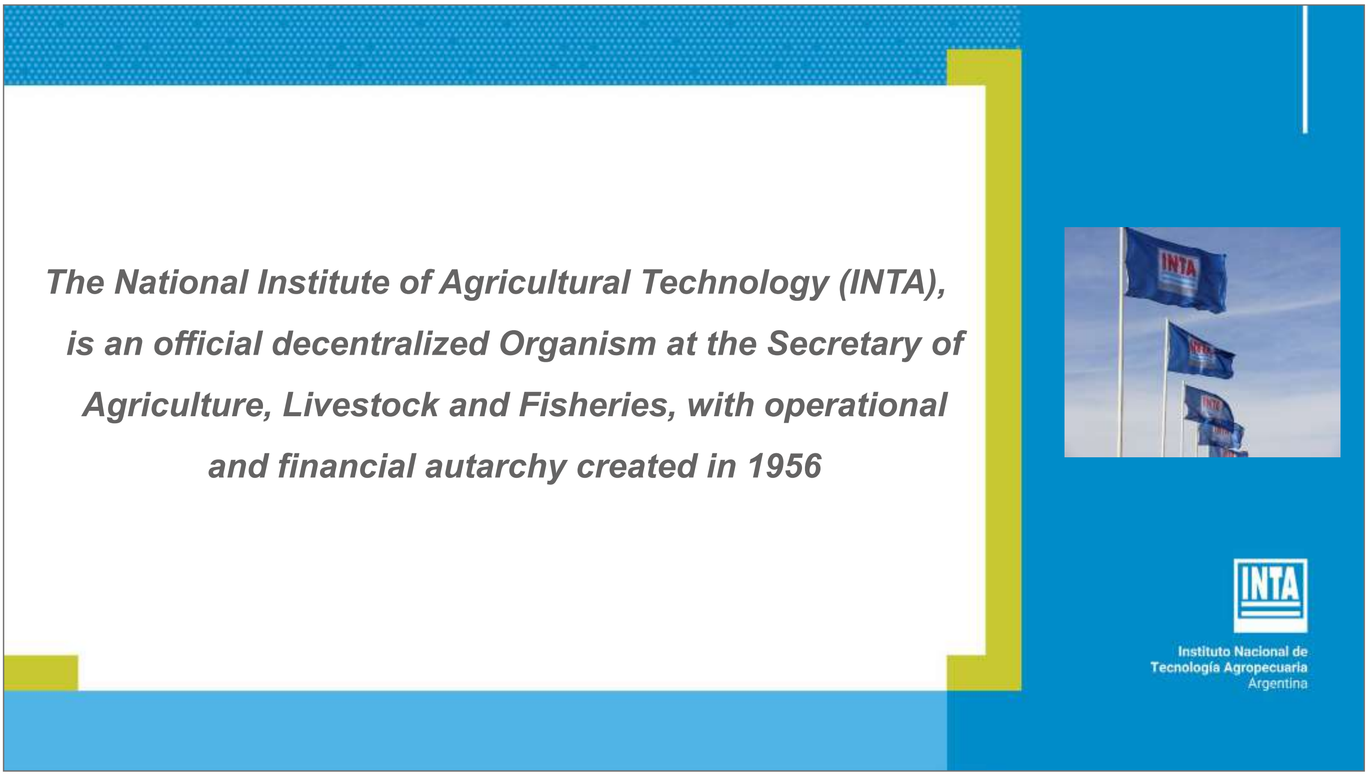
Thus, this ***Calibrachoa*** variety was obtained by traditional breeding and then licensed to a Japanese company. After a few years, the company observed that there was a plant that presented a different flower color (mutation) and as established in the license agreement, informed the INTA. Likewise, the company was interested in marketing the mutated variety and, for this, it accepted and recognized INTA’s right as owner of the initially licensed variety.

It is also good to keep in mind that INTA researchers are working on the development of different transgenes for some species, for instance: resistance to drought stress in wheat; virus resistance in potatoes; virus resistance in citrus fruits; resistance to caterpillars in cotton; characteristics of resistance to salinity and herbicides in alfalfa; and characteristics of resistance to drought stress, resistance to herbicides and tolerance to viruses in maize. All these projects and their tests are regulated by CONABIA and the corresponding control bodies. If the evaluations continue successfully and the corresponding regulatory steps are completed, these characteristics will be timely for protection and incorporation into adapted germplasm for subsequent registration, protection and consequent licensing.

As a final comment, it is considered that the objective of a public research institution in terms of the development of plant varieties should be the obtaining of better varieties and/or products adapted to productive needs and available to society as a whole. For this, the national institutions have the human/scientific capital and intellectual capacity of their researchers. They also have contractual tools that help define the terms and conditions in the relationship with a company, so that it can produce and disseminate that variety to the agricultural producer.

Consequently, it is important that the national institutions have specialized areas of management in the institution–breeder–enterprise relationship too, and for this it is necessary that they have a clearly defined, written method of managing technology transfer. Also, this management of the transfer of technology should consider the participation of breeders and researchers in obtaining the final result and the resulting benefits obtained in the future.

Presentation made at the Seminar



- Headquarters
- 15 Regional Centers
- 52 Experimental Stations
- 6 Research Centers
- 22 Research Institutes
- 359 Rural Agencies
- 2 Private Organizations

Fundación ArgenINTA InTeA

Instituto Nacional de Tecnología Agropecuaria Argentina

*About **plant varieties**, since 1981, INTA registered at INASE **1025** **varieties in the National List** and, at the moment, INTA has **280** **varieties with PBRs** in force. (registered varieties from **107** **species**)*

***Legal frame**: Law 20247 (Seeds and PVP) and Regulatory Decree 2183/1991; Law 24376 UPOV Convention 1978 Act.*

***Regulatory Agricultural Biotechnology Procedures**: National Biotechnology Commission*

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Breeding tools used:

- ***Traditional breeding***
- ***Breeding assisted by molecular markers***
- ***Mutagenesis***
- ***Gene editing***
- ***Recombinant DNA (transgenics)***

INTA Instituto Nacional de Tecnología Agropecuaria Argentina

Some examples:

Rice (imidazolinone resistance):

- ***It is a trait developed by INTA (mutagenic)***
- ***The trait is protected by Patent (INTA)***
- ***5 INTA varieties registered and protected by INTA (PBR).***
- ***License for comercial purposes to BASF Company.***

INTA Instituto Nacional de Tecnología Agropecuaria Argentina

Some examples:

***Cotton** (herbicide and lepidoptera worm resistance):*

- It is a trait developed by a Company (Monsanto)

- The trait is protected by patent (Monsanto)

- 3 INTA varieties registered and protected by INTA (PBR)

- License for seeds production and commercialization to GENSUS Company.

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Some examples:

***Soybean** (herbicide tolerance – RR1):*

- It is a trait developed by a Company (Monsanto)

- The trait is public now

- 5 INTA varieties registered and protected by INTA (PBR)

- License for seeds production and commercialization to Companies.

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Some examples:

***Calibrachoa** (Ornamental plant)*

- Varieties developed from native genetic resources.

- INTA recognize the rights of Provinces where the native resource was collected (Argentine National Constitution and legal frame)

- License to commercialization to foreign Company

- A mutant for flower color is detected by the licensee and the INTA PBR on the initial variety is recognized by licensee.

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Technology Transfer Agreements:

- Rice (BASF Company)

- Cotton (Monsanto Co.)

- Cotton (Gensus Company)

- Soybean (Monsanto Co.)

- Calibrachoa (J&H Co.)

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Other Agreements includding new technologies:

- BASF Company: to develop rice varieties herbicide resistant
- BASF Co. And Louisiana University: to test no-GMO rice varieties (mutagenics)
- MTAs to test "IMI" rice varieties in Uruguay and Brasil

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Other Agreements includding new technologies:

- CORTEVA Company: to "enter" herbicide and insects resistance trait into INTA soybean varieties.
- MONSANTO Co.: to develop cotton GMO varieties using Monsanto cotton lines as donors.
- MONSANTO Co.: to use trait RR1 for soybean in breeding INTA program.
- StelaGenomics Mexico: phosphorus metabolism technology (develop in INTA germplasm and GMO regulation process)

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Some INTA traits under evaluation *(regulatory process at CONABIA – National Agricultural Biotechnology Commission)*

- **Wheat**: Drought stress
- **Potato**: Virus resistance
- **Citrus**: Virus resistance
- **Cotton**: Coleoptera resistance
- **Lucerne**: herbicide tolerance; salinity resistance
- **Corn**: Drought stress; Virus tolerance; herbicide tolerance

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Some considerations:

- Public Research Institutions: new and better varieties and products available and for the benefit of the whole society,
- Regulatory steps must be complished with scientific rigor,
- There are different contractual tools to interact with Entities or Companies (R&D; License; MTA; Cooperation Agreement, Confidentiality Agreements, etc)
- Intellectual Property and ownership of the results: must be clearly stablished in the Agreements,
- It is important to have specific areas to manage relationships between Institution, breeders and Companies,
- It is important for the Public Research Institutions to have clear rules about technology transfer taking into account the breeders/researchers participation in the final result and future benefits.

INTA Instituto Nacional de Tecnología Agropecuaria Argentina


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INTA
Instituto Nacional de
Tecnología Agropecuaria
Argentina

THE IMPORTANCE OF PUBLIC-PRIVATE COLLABORATION TO ENHANCE APPLICATION OF BIOTECHNOLOGY IN PLANT BREEDING

Mr. Muath Alsheikh
Head of Research and Development, Graminor AS, Norway

Today, I will present the importance of public–private collaboration in enhancing the development and implementation of technology tools into plant breeding.

Figure 1 defines public–private partnership (PPP) the way I see it. The generic definition of PPP is a long- or short-term collaboration between the public sector (government) and private businesses, where here I add for #successful collaboration# that both parties share duties and responsibilities, and funds, and it is important that both parties share the interest in the outcome.

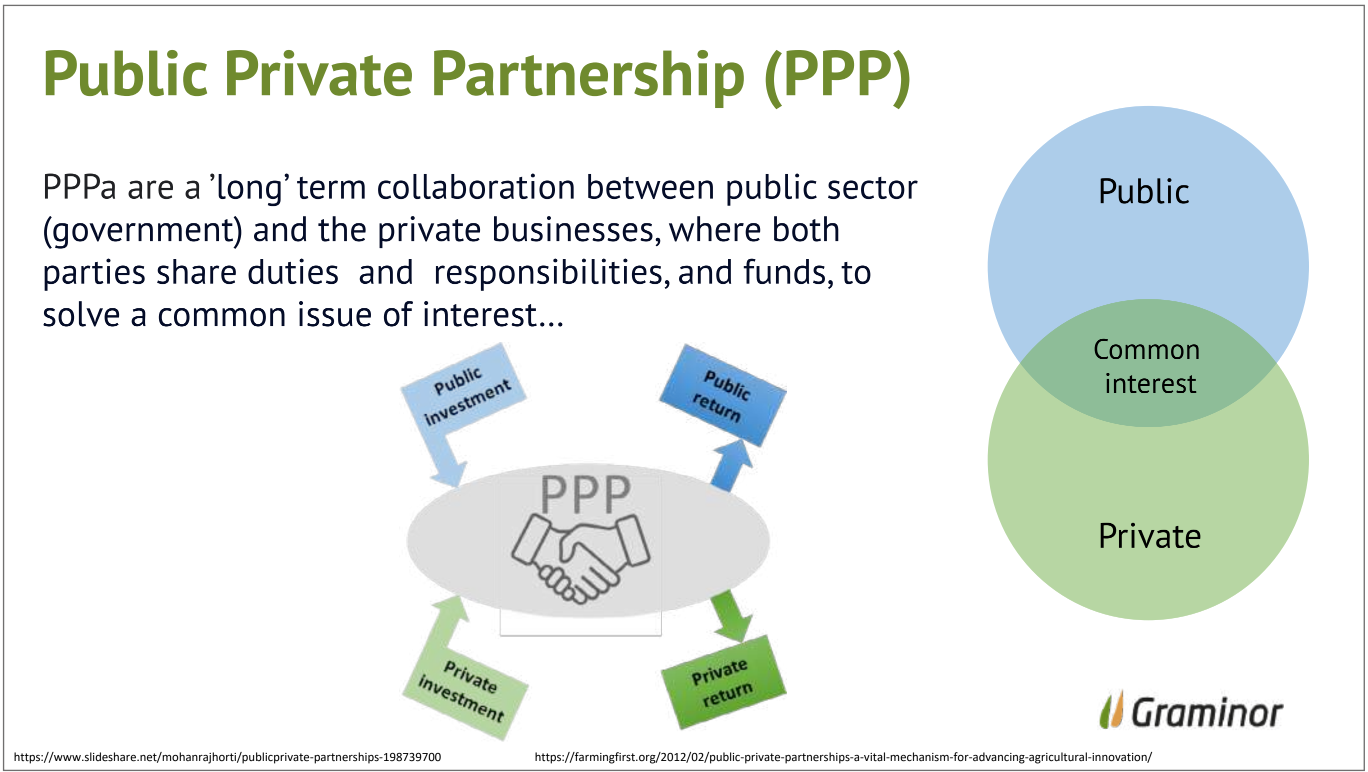

Figure 1. *Public–Private Partnership (PPP).*

The figure shows that when public and private sectors invest in a particular issue then both are expecting a return on their investments. This can add value to society or result in publications for scientists and technologies or even products for the private sector. Simply, both parties should see the value of the partnership.

We all agree that plant breeding plays a major role in sustainable food security; for example, reducing chemical usage (pesticides) through development of resistant varieties; reducing waste through production of better-quality varieties; and so on.

Nowadays plant breeding itself is becoming a more and more multidisciplinary operation, which requires different and complementary knowledge, such as genetics, statistics, digital operations, big data, etc. It is rare to see such diverse competences in one company, especially for small and medium-sized enterprises (SMEs). So, private–private collaboration (business–business) or private–public collaboration is important and vital for success.

In addition, developing a new plant variety is time-consuming, costly and a challenging operation. Therefore, plant breeders always seek methods that can increase their selection efficiency and accuracy at a low cost. And this again requires private–private collaboration (business–business) or private–public collaboration to reduce costs and increase efficiency.

Enabling technologies, especially the high throughput phenomics (HTP) technologies with, relatively, low running costs, are one of the most important developments to increase the efficiency and precision of conventional plant breeding.

Here, I show the two main HTP technologies: genomic and phenomic technologies. These technologies are the focus of many breeding programs including in the Nordic countries. Phenomic-based technologies, such as sensor technologies, and molecular-based technologies, such as molecular assistant breeding and gene editing, produce massive data. Handling and making sense of such big data is becoming more and more important for successful plant breeding programs. Development of such technologies is costly and more importantly, require different types of competencies.

- PPP collaboration is one way where expertise from different fields can come together to reach breeding innovative solutions.

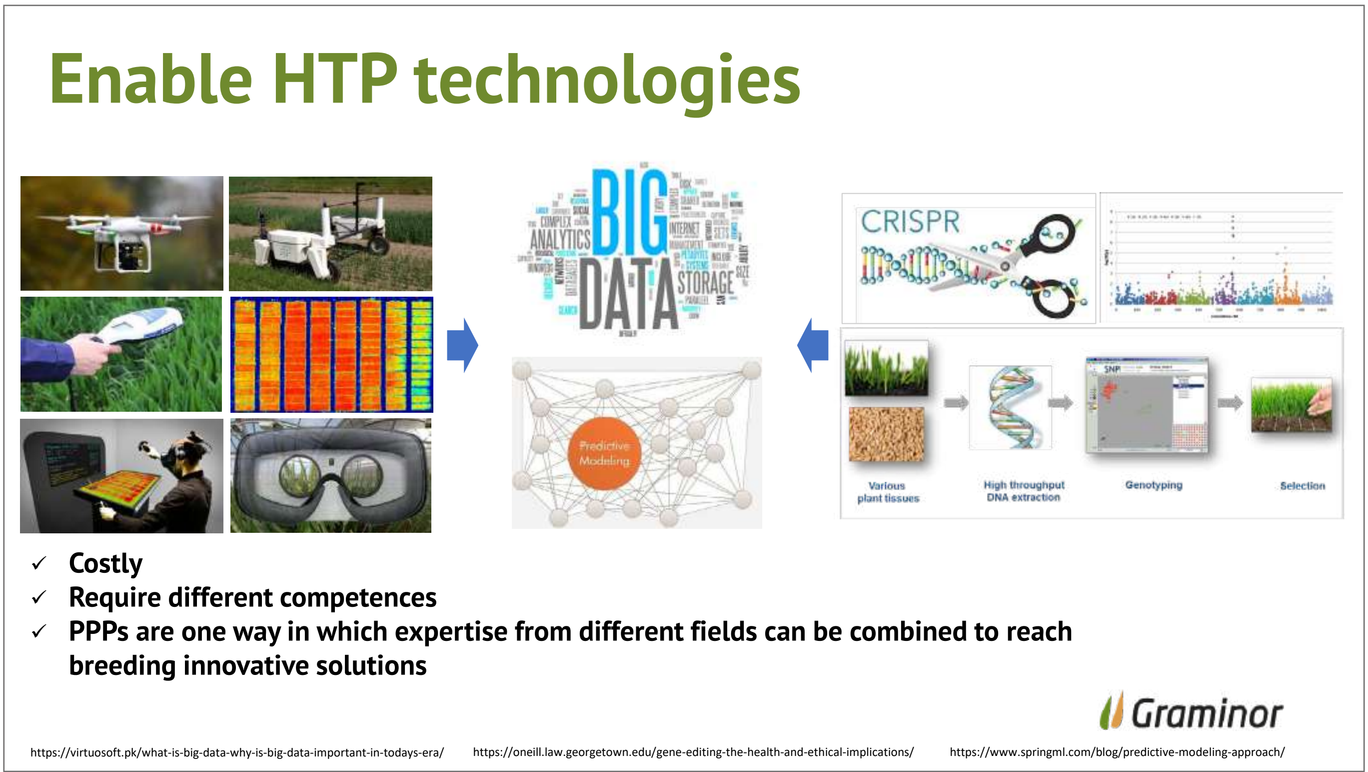

Figure 2. *Enable HTP technologies.*

I will briefly present two clusters as successful examples on the value of PPP in plant-breeding innovation:

1. the Nordic public–private partnership for pre-breeding; and
2. the Norwegian Climate Future center for research-based innovation, which focuses on the short- and long-term climate.

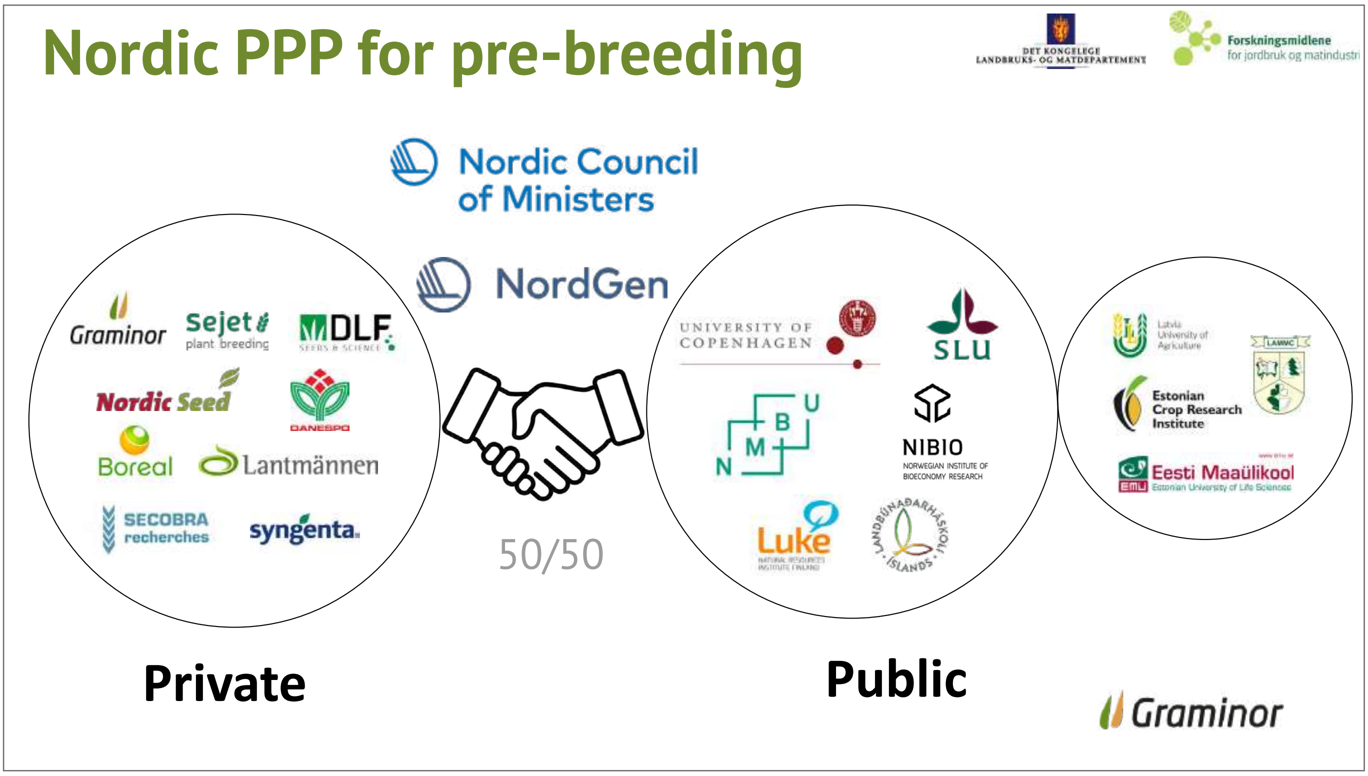

Figure 3. *Nordic PPP for pre-breeding.*

Nordic PPP collaboration for pre-breeding is a collaboration between practical plant-breeding businesses and plant-breeding related research institutions. The initiative or cluster was established in 2012, and it is still running. The cluster is funded by the Nordic countries and plant-breeding entities (50/50), and the secretariat is placed at NordGen. The main goals of this cluster are to:

- strengthen plant breeding in the Nordic countries;
- promote sustainable use of genetic resources in the Nordic region;
- introduce new traits in commercial breeding;
- develop efficient tools and methods; and
- network (pre-competitive collaboration).

Seven projects have been initiated since 2012, covering several crops. Most of these projects focus on identifying new genetic resources and HTP genomic technologies. One project focuses on developing HTP phenomics. The specific outcomes from these projects are to:

- obtain knowledge and competence;
- strengthen the network;
- develop breeding methods and tools, for instance, MAS, GS and phenomics; and
- create new breeding material, for example, new material raised from several multiparent advanced generation intercross (MAGIC) populations.

The other cluster is the national cluster addressing climate, called Climate Future. This is another example of valuable PPP. Climate Futures is a center for research-based innovation project. It is funded by the Norwegian Research Council, started in 2020 and will run for eight years, with a budget of more than 15 million euros. Thirty partners are involved in this initiative including agriculture, the oil industry, the shipment industry, and so on. They all are interested in climate.

As we know, the future climate (and even the current climate) will cause major challenges to agriculture and, therefore, could compromise our global food security. When it comes to plant breeding, the main focus of the Climate Future collaboration is to develop and integrate genotype x environment (G x E) models in current genomic models. Also, it supports plant breeding programs with current and future climate predictions to define the future market and thus breeding goals.

Figure 4. *Climate Future: breeding goals.*

The specific tasks related to plant breeding, or important predictions, are:

- short-, medium- and long-term climate prediction (G x E);
- prediction of variety performance (+offspring) in different environments (short, medium and long term) – based on current and historical information;
- to identify current locations that represent future medium- and long-term climate; and
- potential new crops for the Nordic market.

Some conclusions:

- PPPs can effectively bridge the gap between public and private sectors' competencies;
- particularly important for plant breeding is to stimulate development through innovation;
- translating research into something useful or relevant (e.g., tools);
- access to knowledge and technologies; and
- potential reduction in development costs and increased efficiency.

Presentation made at the Seminar

UPOV Seminar, Geneva
March 22, 2023

The importance of public-private collaboration to enhance application of biotechnology in plant breeding

Muath Alsheikh
Head of Research and Development/Breeder
Graminor AS, Norway
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www.graminor.no

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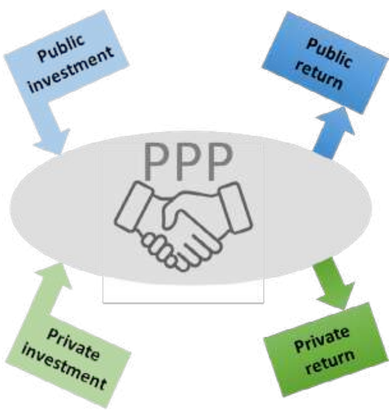
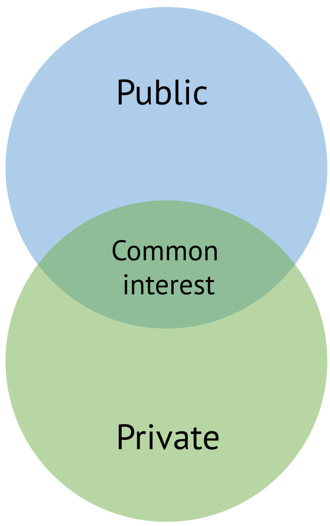
Public Private Partnership (PPP)

PPPa are a 'long' term collaboration between public sector (government) and the private businesses, where both parties share duties and responsibilities, and funds, to solve a common issue of interest…





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https://www.slideshare.net/mohanrajhorti/publicprivate-partnerships-198739700 https://farmingfirst.org/2012/02/public-private-partnerships-a-vital-mechanism-for-advancing-agricultural-innovation/

Public Private Partnership for plant breeding

- ✓ Plant breeding is one of the most sustainable way to improve food security and future challenges.
- ✓ Plant breeding is multidisciplinary and long-term operation/investment.
- ✓ Many challenges: genome complexity, multi-trait, G x E.
- ✓ Plant breeders always seek for methods that can increase their selection efficiency and accuracy at low cost.

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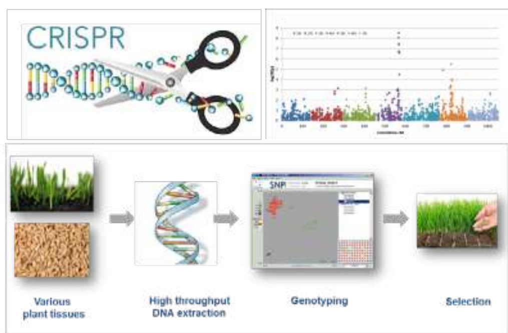
Enable HTP technologies



- ✓ **Costly**
- ✓ **Require different competences**
- ✓ **PPPs are one way in which expertise from different fields can be combined to reach breeding innovative solutions**

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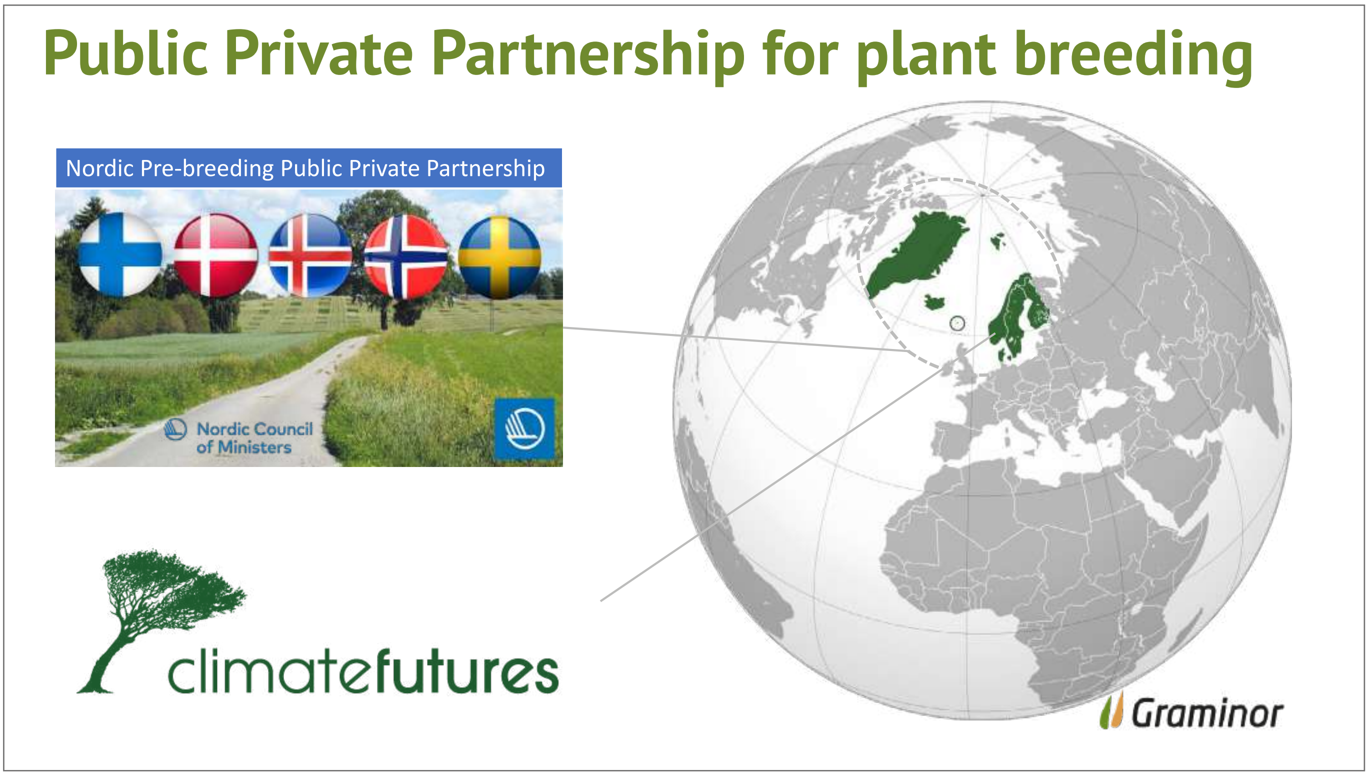
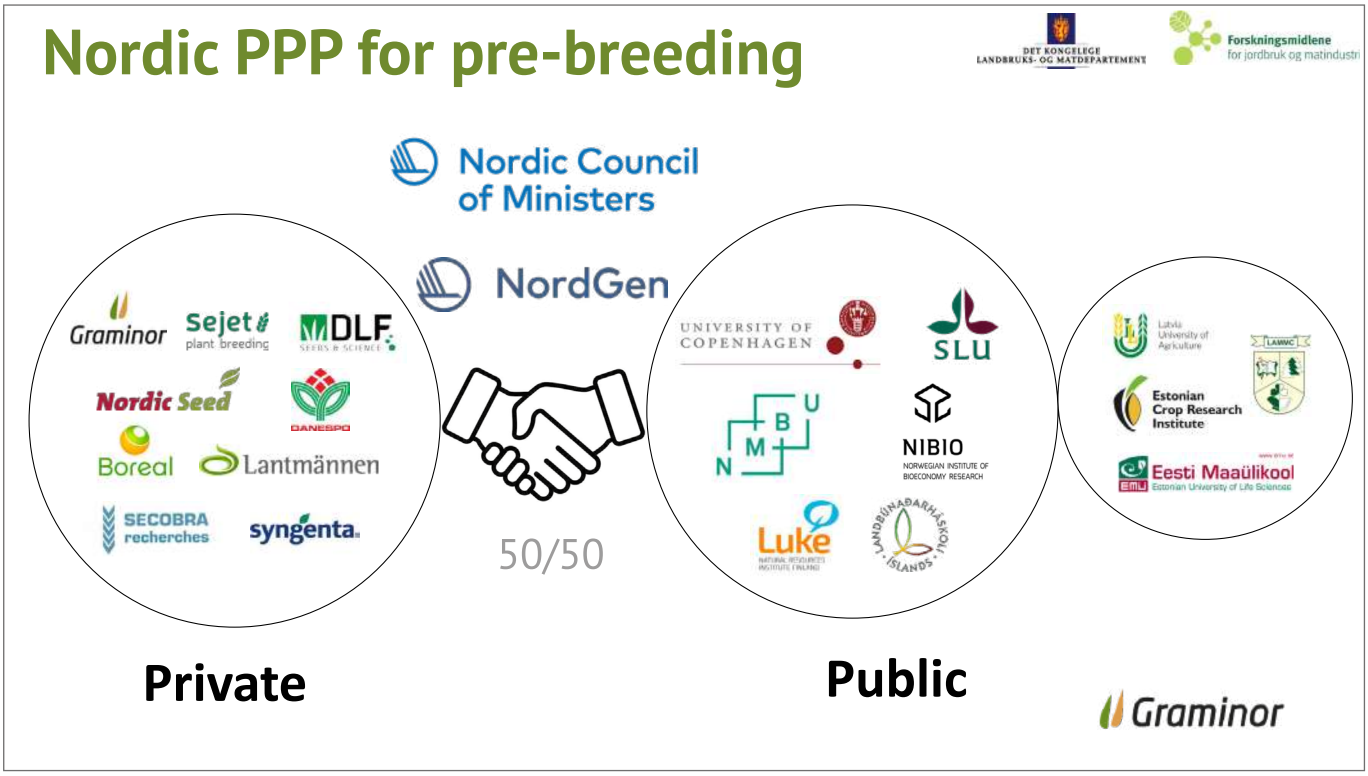
https://virtuosoft.pk/what-is-big-data-why-is-big-data-important-in-todays-era/ https://oneill.law.georgetown.edu/gene-editing-the-health-and-ethical-implications/ https://www.springml.com/blog/predictive-modeling-approach/


Public Private Partnership for plant breeding
Nordic Pre-breeding Public Private Partnership
Nordic Council of Ministers
climatefutures
Graminor


Nordic PPP for pre-breeding
DET KONGELIGE LANDBRUKS- OG MATDEPARTEMENT
Forskningsmidlene for jordbruk og matindustri
Nordic Council of Ministers
NordGen
Graminor
Sejet plant breeding
DLF
Nordic Seed
DANESPO
Boreal
Lantmännen
SECOBRA recherches
syngenta
50/50
UNIVERSITY OF COPENHAGEN
SLU
NMBU
NIBIO
NORWEGIAN INSTITUTE OF BIOECONOMY RESEARCH
Luke
LANDBÚNAÐARHÁSKÓLI ÍSLANDS
Latvia University of Agriculture
Estonian Crop Research Institute
Eesti Maaülikool
Estonian University of Life Sciences
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Nordic PPP for pre-breeding

- Strengthen plant breeding in the Nordic countries
- Promote sustainable use of genetic resources in the Nordic region
- Introduction of new traits in commercial breeding
- Development of efficient tools and methods
- *Networking (pre-competitive collaboration)*

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Nordic pre-breeding PPP: 4 phases 2012 – 2023...

PPP_Barley
2012-2020

PPP_Ryegrass
2012-2020

PPP_Apple
2012-2021

PPP_Strawberry
2018-2020

PPP_Wheat
2021-2023...

PPP_Potato
2021-2023...

PPP_Phenomics
2015-2023...

- Obtained knowledge and competence
- Strong network
- Developed breeding methods and tools; e.g., MAS, GS, phenomic....
- New breeding material; e.g., MAGIC

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sfi Centre for Research-based Innovation

NORCE

The Research Council of Norway

Forskningsmidlene for jordbruk og matindustri

climatefutures

Navigating Climate Risk

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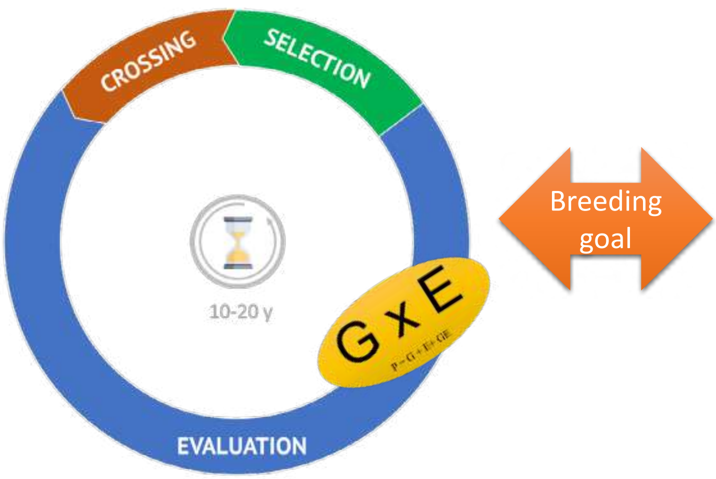
Breeding, environment and market



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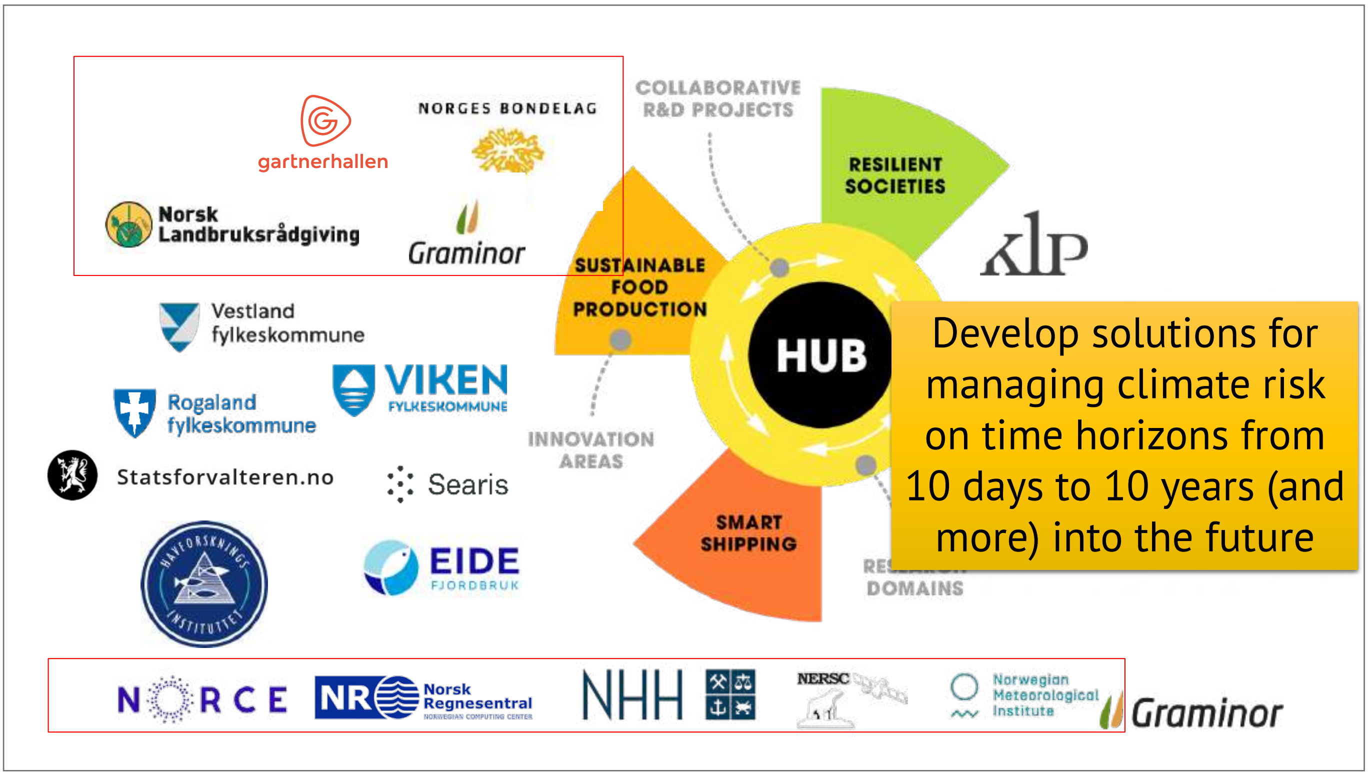
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NORGES BONDELAG
Norsk Landbruksrådgiving
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COLLABORATIVE R&D PROJECTS
RESILIENT SOCIETIES
SUSTAINABLE FOOD PRODUCTION
HUB
INNOVATION AREAS
SMART SHIPPING
DOMAINS
Develop solutions for managing climate risk on time horizons from 10 days to 10 years (and more) into the future
Vestland fylkeskommune
Rogaland fylkeskommune
VIKEN FYLKESKOMMUNE
Statsforvalteren.no
Searis
EIDE FJORDBRUK
NORCE
NR Norsk Regnesentral
NHH
NERSC
Norwegian Meteorological Institute
Graminor


Climate Future: Breeding goals
○ Short, medium and long-term climate prediction
○ Prediction of variety performance (+offspring) in different environments (short-medium-long terms) – based on current and historical information.
○ Identify current locations that represent future medium- and long-term climate
○ Potential new crops for Nordic market
G X E
P= G + E+ GE
CLIMATE FUTURES
Managing climate risk
Graminor

Some remarks

- PPPs can effectively bridge the gap between public and private sectors' competencies.
- Particularly important for plant breeding to stimulate development through innovation or/and translating research into useful and relevant tools.
- Leverage access to knowledge and technologies
- Can reduce development cost and increase efficiency

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HOW TO BALANCE PBR AND PATENTS IN BREEDING PROGRAMS

Mr. Bo Gertsson
Group Manager Product Development Plant breeding, Lantmännen lantbruk, Stockholm, Sweden

TRENDS IN INTELLECTUAL PROTECTION FROM A 40-YEAR PERSPECTIVE

The first step in setting up a breeding program is to clearly identify the goals in discussion with farmers, industry and consumers. An essential part of plant breeding is to decide on which traits are needed to reach those goals. If the necessary traits are not readily available in the primary breeding gene pool, they must be introduced through one of many technologies available to the breeder. This includes for example crosses with wild species, mutagenesis or transgenetics. Depending on the technology used the possibility for intellectual protection varies. If the process of introducing the trait is an essentially biological process, the resulting variety can be protected by Plant Breeder's Rights (PBRs), and if there is a sufficient degree of technical invention the trait is patentable.

The main demands for a patent are:

- novel
- inventiveness
- reproducible
- technical solution to a problem

The main demands for a Plant Breeder's Right are:

- novel
- distinctiveness
- uniformity
- stability
- an approved name

Using canola breeding as an example, one can find examples of traits develop by private companies and by public institutes. Some traits have been freely shared among breeders, others patented and with restricted use. Patented traits may or may not be available through licensee agreements with the patent holder. Forty years ago, the UPOV system for PBR completely dominated, but today breeders also must deal with patents, and all breeding companies need to have a patent strategy.

LANTMÄNNEN

Lantmännen covers the whole value chain, from field to fork, or if you like, from trait to consumer. Lantmännen is an agricultural cooperative and Northern Europe's leading player in agriculture, machinery, bioenergy and food. Lantmännen is owned by 18,000 farmers, has 10,000 employees, operates in some 20 countries and has an annual turnover of 5 billion Euros.

Lantmännen has breeding programs in spring barley, spring and winter wheat, triticale, oats, forages, SRC willow, potatoes, faba beans and peas. The breeding programs are targeting farmers, industries and consumers. Their main breeding station is located in Svalöv, in the south of Sweden. Two other breeding stations are in Lännäs, in mid-Sweden, and Emmeloord in the Netherlands. The plant breeding department has close to 90 members of staff, and even if it is part of the big company Lantmännen, the plant breeding activity has more in common with small and medium-sized enterprises (SME) in comparison to the big international plant breeding companies. The focus is to provide the owners of Lantmännen with the best possible varieties for their farms. Crop Tailor is a wholly owned subsidiary developing new traits in oats. A large, mutagenized population in oats has been developed using ethyl methanesulfonate (EMS).

ESSENTIALLY DERIVED VARIETIES AND PARTNERSHIPS

The concept of Essentially Derived Varieties (EDVs) is important when it comes to the use of traits in plant breeding. EDV is defined under the 1991 act of the UPOV Convention. So far there are few examples of the use of EDV in Lantmännen's breeding programs. Crop Tailor has developed the oat variety Armstrong, which is the product of a mutation in the variety Belinda. Armstrong has a higher betaglukan content than the initial variety Belinda. Since both Armstrong and Belinda are varieties owned, and protected, by Lantmännen there has not been any need to develop a license agreement for the EDV in relation to the initial variety.

However, I foresee EDVs will be more common in the future, as there currently is a lot of research in the development of new traits, with the use of novel technologies in the toolbox for plant breeders. Not least the use of New Genomic Techniques (NGTs), such as CRISPR/Cas9. This will demand more administration and legal expertise, which may become a burden to SME breeding companies.

Lantmännen has cooperation with universities and research organizations in Sweden and in other parts of Europe. Of special importance is SLU Grogrund. SLU Grogrund is a competence center at SLU that brings together academia and industry to develop skills to ensure access to plant varieties for sustainable and competitive agricultural and horticultural production throughout Sweden. SLU Grogrund is the result of the Swedish food strategy and is currently running 22 projects in cooperation with industry. Several of these projects use NGT as a tool.

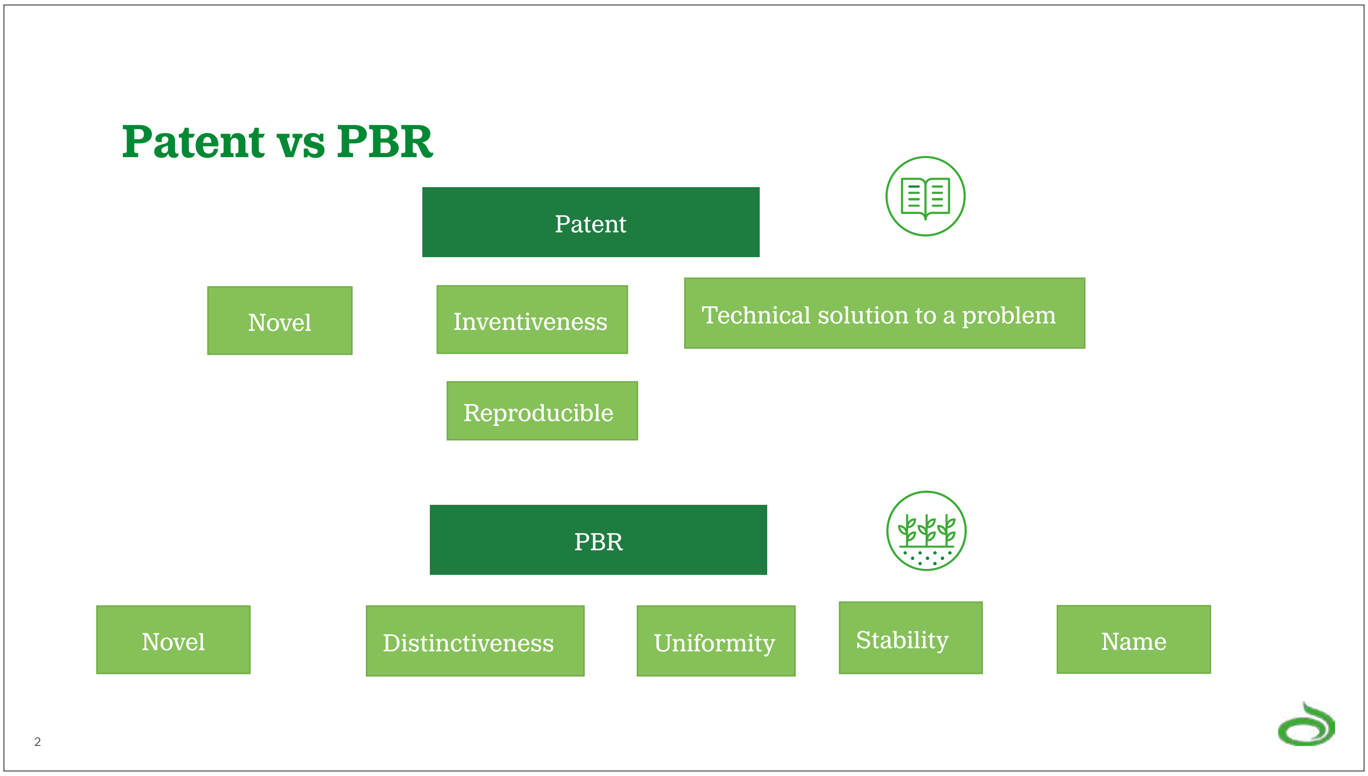
PBR, PATENTS AND TRUST FROM SOCIETY

The UPOV system is very well balanced for the interest from breeding companies, farmers, consumers and society. This has been a success story and created trust among farmers and consumers for the plant breeding industry. Since Lantmännen is a farmer's co-operative we have direct contact with the farmers, our owners, and have their full support for the plant breeding research and variety development. There is concern that this will change in the future if patents will be common in plant breeding.

TAKE HOME MESSAGES

- UPOV should be the main intellectual property system for plant varieties.
- Support from farmers, consumers and society are a prerequisite for long-term trust of the UPOV system.
- There must be a balance between breeders' exemption and the return on investment for patents and basic research.
- The limited breeding exemption in the EU's unitary patent should be incorporated into national legislation in all EU countries.
- Mutations created through random (contrary to targeted) mutagenesis should not be patentable.
- The concept of "essentially biological processes" is very important.
- Screening segregating offspring and developing markers is standard knowledge and should not be patentable.
- It is difficult for SMEs to compete with big business when they have to navigate in a patent environment.

Presentation made at the Seminar



3

Trend in more IP rights and use of patents

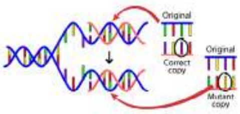
Traits in canola breeding

Trait	Source	Provider	Patent	Agreement	License fee
Low erucic acid	Cultivars Species cross	Public institute	No	No	No
Low glucs	Cultivars Species cross	Public institute	No	No	No
Hybrid restorer	Protoplastfusion Species cross	Public institute	Yes	Yes	Yes
Clearfield®	Mutation	Private company	Yes	Yes	No
Roundup Ready	GMO	Private company	Yes	Yes	No
Omega-3	GMO	Private company	Yes	No	Not available
??	CRISPR/Cas9	??	Yes	??	??

4

Lantmännen represents the whole value chain

Trait provider → Plant breeding → Seed sales → Grain trading → Product-development → Consumer products



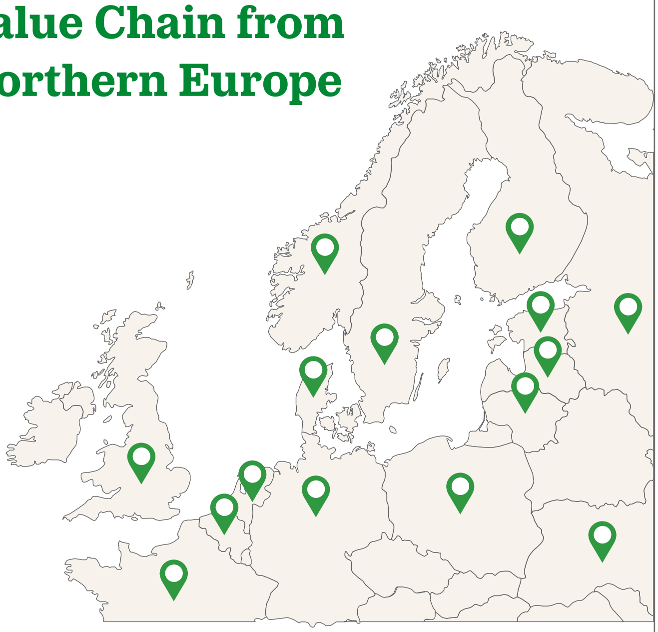
From trait... ... to consumer!

Our Base Is the Value Chain from Field to Fork in Northern Europe

- Lantmännen is an agricultural cooperative and Northern Europe's leading player in agriculture, machinery, bioenergy and food.
- We are owned by 18 000 farmers, have 10 000 employees, operations in some 20 countries, and an annual turnover of Euro 5 billion.

Chairman of the Board:
Per Lindahl

Group President and CEO:
Magnus Kagevik



6

We breed plants for farmers, industries and consumers – and for the environment

Farmers

Yield
Resistance
Agronomy
Environment

Industry

Quality
Cost of raw material
Processing qualities
Environment

Consumers

Health
Green proteins
Environment
Price

7

EDV – Essentially Derived Varieties

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

Document adopted by the Council
at its thirty-fourth extraordinary session
on April 6, 2017

- Well defined concept in theory, but more difficult in practise
- Few examples in Lantmännen
- *Armstrong*
- Likely more important in the future

Figure 1: Essentially Derived Variety "B"

Initial Variety "A"
bred by *Breeder 1*

- not essentially derived from any other variety

⇩

Essentially Derived Variety "B"

bred by *Breeder 2*

- predominantly derived from "A"
- retains expression of essential characteristics of "A"
- clearly distinguishable from "A"
- conforms to "A" in essential characteristics
(except for differences from act of derivation)

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Much of Lantmännen's Work on Innovation Is Done in an International Innovation and Research Network

SLU GROGRUND – Centre for Breeding of Food Crops

SLU Grogrund joins forces from academia and the industry to develop competence to secure access to plant varieties for a sustainable and competitive agricultural and horticultural production throughout Sweden.

- Functional genomics
- Prediction models
- Underutilized crops
- Regional adaptation of crops
- Targeted mutagenesis

How does the use of PBR vs patents affect the trust from farmers and consumers?

Take home message

- UPOV should be the main Intellectual Property system for plants
- Support from farmers, consumers and the society is a prerequisite for long term trust in the UPOV system
- There must be a balance between Breeder's exemption and the return on investment for patents and basic research
- The limited breeding exemption in the EU's unitary patent should be incorporated in the national legislation in all EU countries
- Mutations created through random (contrary to targeted) mutagenesis should not be patentable
- The concept of "essentially biological processes" is very important
- Screening segregating offspring and developing markers is standard knowledge and should not be patentable
- It is difficult for Small and Medium Enterprises to compete with Big Business when they have to navigate in a patent environment

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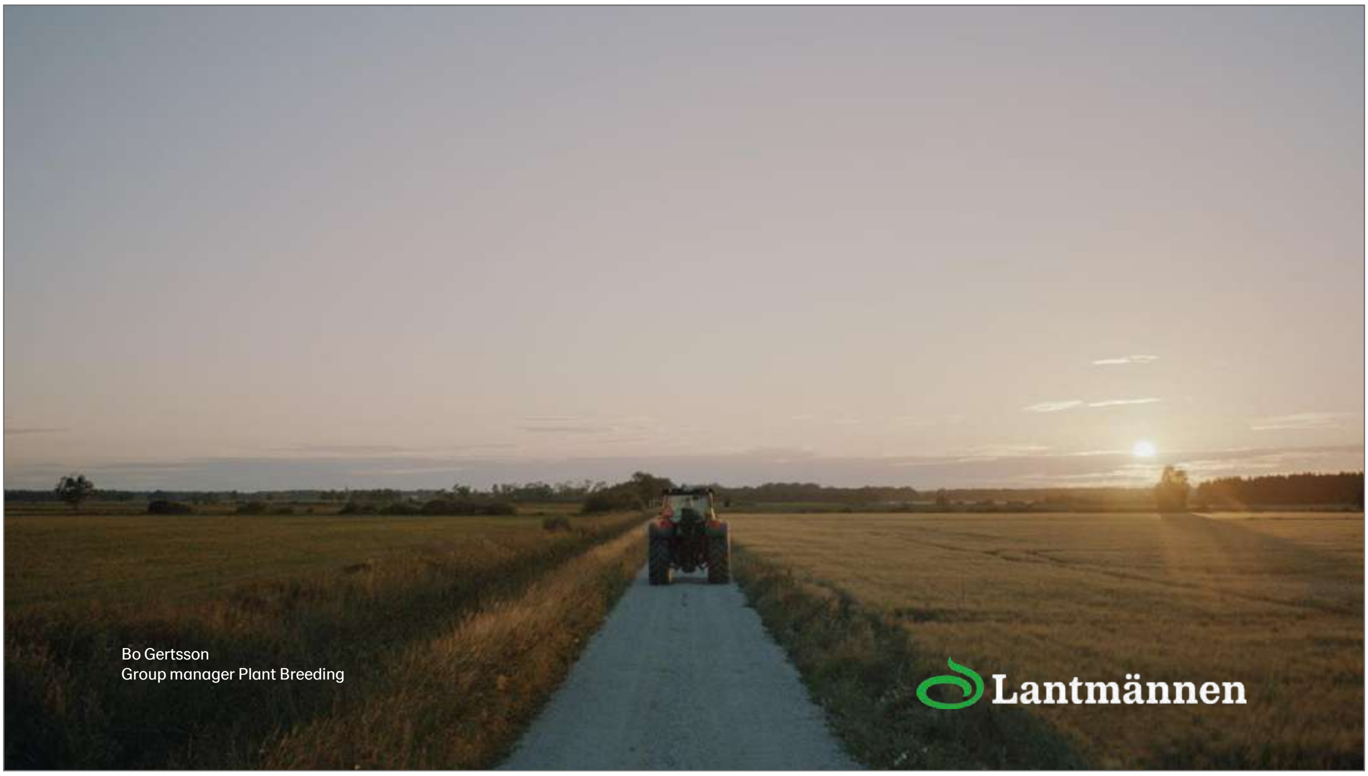

Bo Gertsson
Group manager Plant Breeding
Lantmännen

DISCUSSION WITH SPEAKERS OF SESSION II

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Now I open the floor for questions. Are there any questions?

Okay. Judith from CIOPORA, the floor is yours.

DE ROOS-BLOKLAND Judith Maria Anneke (Ms.):

Thank you. I have a question for Bo Gertsson. Can you explain to us what would be the consequence if varieties that are gene edited are no longer considered as EDVs?

GERTSSON Bo (Mr.) (speaker):

I think it's very important with this balance that I talked about and so many before me here, and that the plant breeders, they invest in developing their germplasm. And if they are not considered EDV, we are not paying attention and giving value to the work that plant breeders have been doing.

The option if – or, on the other hand, for the trait providers, to put their new traits into a nonprotected and therefore, obviously, or in most cases, older and not as developed varieties, also stops the development of the best products which we need for the farmers today.

So, I would say that that situation is not preferable either to trait providers or to the plant breeders. It has to be a well balanced value put to the products and the work done by both trait providers and plant breeders.

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Okay, with that answer? Does anybody else want to raise a hand? Okay, Gert.

WÜRTENBERGER Gert (Mr.) (speaker):

Gert Würtenberger, lawyer from Germany being engaged in plant variety issues since more than forty years.

In order to get a better feeling about what the breeding industry and it's only the interests of the breeding industry, what a fair balance might be, I have a question of Mr. Gertsson with regard to the companies who owned – own EDV Armstrong (ph), as I understood, it is a derivation of Belinda (ph). Now, leave a part the concept of EDV as it stands at the moment in the UPOV Convention 1991 and leave a part that your company is the breeder of Armstrong. Let's assume Armstrong has been developed by an independent third party. Would you regard knowing what the investments of the breeder of the EDV both, would you regard Armstrong as an unjustified or a breeding result which is exploited without giving a contribution to the breeder of Belinda? And why?

GERTSSON Bo (Mr.) (speaker):

I think that you need to look at the respective value of the genetic background, the initial variety, and the additional trait. In this case, for Armstrong, Armstrong has a higher protein content and a higher beta-glucan content compared to Belinda. And you could try to put approximate value of that, and that will actually be tested in the market and to see what the customers, the industry is willing to pay as an extra premium for those traits, and that can be used for negotiation of the value between the initial variety, Belinda, and the EDV, Armstrong.

And it has to be a case-by-case negotiation, I would think, dependent on the added value and the background. The final answer is really set by the market.

I'm not sure if that was a complete answer to your question?

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Mr. Gert?

WÜRTENBERGER Gert (Mr.) (speaker):

Not exactly, because, well, we talk about investments and the benefit out of investments. Now, what the market at the very end decided might be an aspect but which is difficult to take into consideration when a new variety is protected and about to be marketed. We have to have a clear legal situation for breeders of EDVs, whatever that means, and while trying to await what the market – how the market reaction will be is not a solution to this problem we are dealing with.

Once again, back to the investments, in order to obtain Armstrong, that the – the breeder of the initial variety, in this case, with a higher protein content, has a strong interest that every new variety arising out of Belinda, having the same property, will contribute to the commercial investments of the breed of Belinda. It is a perfect, justified expectation.

But bearing in mind that we have the breeders exemption as the essential cornerstone of the UPOV system, the question is to which extent investments of the EDV breeder justify that the breeder of the original breeder will participate in the success of the EDV.

GERTSSON Bo (Mr.) (speaker):

It is a good and difficult question and there is the problem with this, of course, that if there is a huge investment into the EDV variety and with the possibility of using breeders exemption, for other breeders to make crosses with these not patented new traits, new characteristics of the EDV, can put the developer of the EDV, in this case, Armstrong, into a problem.

The solution, I would say, is again, to look at it case-by-case and to also decide on whether it should be in a closed loop for which this case, this very specific quality is used. I think it often ends up in a closed loop just because of the reason and the problem that you are pointing out.

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Okay. Thank you. We should move on because I have another question from Chris Hannon from the United States of America.

HANNON Christian (Mr.):

Yes, thank you. As mentioned, Chris Hannon from the US Patent and Trademark Office. Bo, on your takeaway slide, you mentioned that breeding from mutagenesis should not yield patentable inventions, and I just was curious as to your rationale behind the policy of such thinking, if you could elaborate on that a little bit? Thank you.

GERTSSON Bo (Mr.) (speaker):

Yes, and I pointed out from random mutations, whereas I think that targeted mutations, new genomic technologies, there is the need for patents. But for the random mutations, that is radiation or EMS or whatever trait or method you would use, I think that the – it has, in my mind, very much to do with the expectation and the trust among also the farmers, consumers, and society. And it goes back to my experience with the transgenic, the GMs, where I think that a lot of the opposition against it came not so much only from environmental reasons but against the use of patents and the sort of power of food.

And I think to balance that trust, and I think that trust is essential to the whole business, agro business, I think we have to tread carefully in using patents. So, therefore, I draw the line between random mutations and targeted mutations in the acceptance of patents. It really goes back to the trust with consumers and society.

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Thank you so much for the response. Now I give the floor to Huib Ghijsen from AIPH.

GHIJSEN Huib (Mr.) (speaker):

Thank you, Chair. I have a question for Mr. Alsheikh. Two questions, in fact. The first is you mentioned on your slides, sustainable use of genetic resources, and then the question, are these genetic resources in danger or what is just the meaning of sustainable use?

The second question is it is very interesting that you are developing varieties for the future in relation to climate change and that you are testing varieties all over the world. Do you have any problems with, well, for instance, the ownership of new varieties or using gene technologies in other countries? How do you organize that? Thank you.

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Just a clarification. Please be brief because we don't have much time with the interpreters, so please take a short time.

ALSHEIKH Muath (Mr.) (speaker):

Thank you for the question. Just to clarify the second point, we have not really started testing anything international – outside or internationally. We're still in the research point of view.

The first question for sustainability, what I meant by it is continuous using of the gene bank material if it shows usefulness for the breeding program. That is what I meant by the word sustainable. It's the continuous. I hope I answered your question.

But I will just add for the second point of view, of course we would have a concern about genetic laws in different countries and how we will address this. Up until now, I have not really an answer for this, but for me, I will just add to what he said regarding – because this is coming to the same question, to the patenting and breeders' rights. Just a small comment that what I see personally, really, that the patenting of varieties, it will absolutely limit innovation, in my head, because now with the breeders' rights, we are allowed to cross, so that is why we have varieties. But once you lock them down, I don't know honestly what will happen with the breeders and with the patenting. I hope I answered your question just briefly.

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

Thank you so much for being brief. I have an online question that is the last question from Jean Nzeyimana.

NZEYIMANA Jean (M.):

Thank you very much. I am putting a question as a user of the outcome or the result of the research. Here in Burundi, we have a public-private partnership. This concept exists both at the national level and at the regional level. Are there – there varieties that come from the research institutes here in Burundi, in [inaudible], which is a public research institute, but also at the University of Burundi in the department or faculty which is responsible for agricultural sciences. [inaudible] So, we use, to differentiate the varieties, we use UPOV's descriptors with the molecular analysis of these varieties to determine whether this is consistent with what we have obtained from a morphological – what we have seen from a morphological point of view. However, we have another problem or issue where we were not able to find varieties that were included in the descriptors of UPOV. There are local varieties here in Burundi. We have a climate which is similar to Rwanda but also some crops that come from Asia as well here where we were not able to find the description of these varieties at UPOV. We've submitted this problem at the level of the COMISAT (ph) organization for certain crops, but we have not yet found any solution to this problem.

So, we would like to ask how we could be assisted if we were to send these different crops that we have locally which are appreciated very much by the farmers, but also some crops that come from Asia which are used as transformation products.

So, this is a problem that we have here in Burundi because our general directorate which is responsible for the certification of seeds and the monitoring of this has been doing this for about eleven years, so we have a problem and we have not yet been able to get the description. Thank you.

VILLAMAYOR María Laura (Ms.), Chair of UPOV Administrative and Legal Committee (moderator):

I'm sorry, Jean. We have to close this session and I would like you to contact directly the speaker in order that they can help you with your question because we can go forward now.

SESSION III:
ROLE OF IP RIGHTS IN SECURING INVESTMENT AND PARTNERSHIPS IN BREEDING

Moderator: Ms. Minori Hagiwara, Vice-Chair of UPOV Administrative and Legal Committee

What if your crop abundantly produces EDVs by itself
Mr. Arend van Peer, Team Leader Mushroom Research, University of Wageningen, Netherlands

Intellectual property and legal perspective on new technologies and variety development
Ms. Heidi Nebel, Managing Partner and Chair of the Chemical and Biotechnology Practice Group at McKee, Voorhees & Sease PLC, Des Moines, United States of America

Plant variety protection according to the 1991 UPOV Convention and new plant breeding technologies
Mr. Ricardo López de Haro y Wood, PBR Advisor, Madrid, Spain

Role of plant breeders rights and other forms of IP in promoting plant breeding
Mr. Michael Kock, Senior Vice President, Innovation Catalyst, Inari Agriculture Inc., Cambridge, United States of America

Origin and goal of the EDV principle in UPOV and its importance in the use of new breeding technologies
Mr. Huib Ghijsen, Juridical Counsellor Plant Breeder's Rights / Director "RechtvoorU", Middleburg, Netherlands, on behalf of AIPH

Discussion with speakers of Session III

WHAT IF YOUR CROP ABUNDANTLY PRODUCES EDVS BY ITSELF

EDVS of edible mushrooms: button mushrooms as a case study

Mr. Arend van Peer
Team Leader Mushroom Research, University of Wageningen, The Netherlands

Mushrooms represent a dynamic, growing and diversifying market. Most mushrooms are produced in South East Asia (SEA), specifically in China, South Korea and Japan. The species that dominate the SEA market are commonly known as: oyster mushroom, shiitake, enoki and wood-ear. The button mushroom, that together with the previous four species makes up the "big five" of mushroom species produced in the world, is by far the largest product in the European, North American, Canadian, Australian and Indian markets.

Currently, a number of developments are changing the traditional divides. China is strongly upscaling and modernizing button mushroom production, while in Europe an increase in production of "exotic" mushrooms (i.e., everything that is not a button mushroom) can be observed. This has important implications for mushroom breeding. Successful introduction of new mushroom species requires adaptations to local cultivation systems, climate, substrates, customer preferences and (safety) regulations. In addition, local genetic resources could become of interest, which also require breeding to develop commercial varieties.

A recent example of a successful breeding program for an "exotic" mushroom has been the development of a sporeless oyster mushroom (SPOPPO). Oyster mushrooms produce large amounts of spores that accumulate during indoor cultivation, which is common practice in Northern Europe, and are a source of contamination, can damage equipment and present serious health risks for farmers causing severe and permanent allergies. Following market introduction, the sporeless variety has significantly accelerated the development of oyster mushroom production in Europe. It is to be expected that more such efforts will become attractive with further growth of production volumes of "exotic" mushrooms.

Except for the above, recent example, breeding efforts for mushrooms have thus far remained limited in countries dominated by button mushrooms. Button mushrooms have turned out to harbor exceptional challenges for breeding. Firstly, recombination is mostly restricted to the very ends of the chromosomes. Secondly, on most basidia, where meiosis occurs, the four post meiotic nuclei are distributed over two spores where each spore receives non-sister nuclei. These spores are "fertile" and can produce mushrooms (Figure 1A). Due to the restriction of recombination at the extreme ends of chromosomes and paring of non-sister nuclei, these spores have a genetic makeup that is very similar to the parental genome (Figure 1B). As a consequence, varieties generated in this way from an initial variety are very similar in phenotype to the initial variety. Our genetic analysis of the 14 most used, present-day white varieties has shown that these are all derived from the first hybrid Horst U1 marketed in 1980 by using fertile spore cultures. They

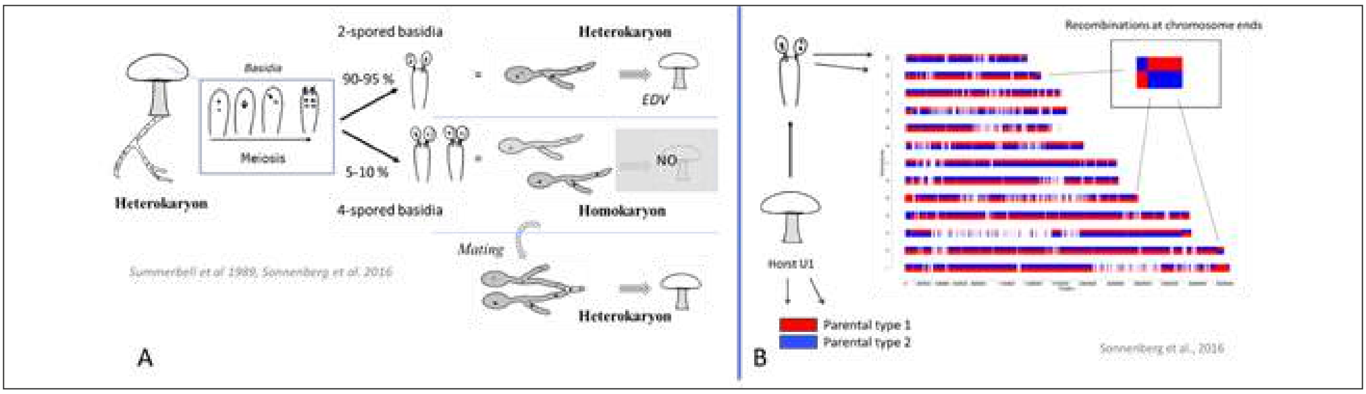


*Figure 1. **Agaricus bisporus** var. **bisporus** (commercial button mushroom) predominantly produces bi-nuclear spores that contain non-sister daughter nuclei from the meiosis (1A). Meiosis starts in special cells called basidia that form on the gills of the fruiting body. Only here karyogamy takes place, immediately followed by meiosis I and II, and distribution of the daughter nuclei over the spores. Limited recombination to chromosome ends and pairing of non-sister daughter nuclei in spores results in reconstitution of the original parental genomes in offspring almost entirely (1B). Self-sterile, uni-nuclear spores that are most suitable for breeding make up the minority.*

are either directly derived from Horst U1 or derived from derivatives. No new varieties for white button mushrooms have been developed by true outbreeding since. A real novel variety is the brown Heirloom, a commercial variety that was constructed by true breeding with U1 and a wild strain.

The difficulty of breeding button mushrooms together with the ease of obtaining single spore isolates with only slightly different characteristics has acted as a major inhibitor for breeding of new button mushroom varieties. A wild subvariety has been detected in the Sonoran Desert of California, which shows meiotic recombination more evenly distributed over the whole chromosome. This subspecies is compatible with all button mushroom varieties and is currently used to reveal the genetic base of recombination positioning. Meanwhile, a consensus has been reached to define the use of single spores or multi-spores of an initial variety to generate new varieties as generating an Essentially Derived Variety (EDV). This consensus is supported by the main breeding/spawn companies in Western countries, but there is not yet any case law on this consensus.

Most EDV's of button mushrooms produced by using single-spore cultures are phenotypically very similar to the initial variety and will not pass the DUS test, but some might have a more distinct phenotype. DUS testing of mushroom varieties is costly compared to testing plant varieties. That is due to the need of a specific inoculum (spawn), substrate, casing soil and the need to work under strict hygienic conditions. In addition, environmental factors and growers skills also can have large effects on the limited number of phenotype characteristics. A genetic threshold indicating a new variety might be generated from a single spore of an initial variety will in this respect be very useful. Above this threshold a breeder can be asked to "open his books."

As a proof of principle, 75 SNP (Single Nucleotide Polymorphisms) markers were selected to determine the genetic distance (Jaccard coefficient) between a group of traditional white varieties (from which parent 1 of Horst U1 was derived), a group of traditional off-white varieties (from which parent 2 of Horst U1 was derived), and the Horst U1 hybrid itself. Traditional white strains show little dissimilarity, as do traditional off-white strains (while both groups are genetically distinct). Meanwhile, the Horst U1 hybrid is clearly distinguishable from those groups (Figure 2), indicating that varieties generated through outbreeding can be easy distinguished. Determining a genetic threshold might thus be a sensible method to distinguish EDVs derived from spores in button mushrooms. For this, a selection of reference strains could be compiled with which new varieties can be compared for assessment of genetic distance.

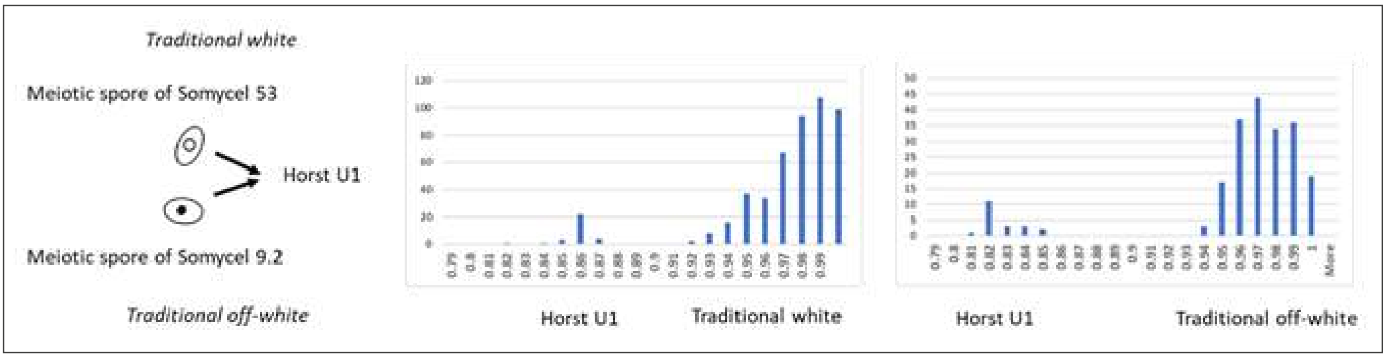


Figure 2. *Frequency distribution of Jaccard similarities between traditional white strains, traditional off-white strains and the hybrid Horst U1 calculated from 75 SNP markers.*

Similarly, genetic thresholds could serve as a valuable parameter to help formulate EDVs for other mushroom species, as well as for other button mushroom varieties not obtained from single spores but through other methods that leave the genetic makeup of the parentals of a commercial variety largely intact. These could include introgression breeding or comprise current gene technologies that also raise new discussions in plants. However, due to the particular genetics of mushroom fungi, a number of additional breeding handlings especially relevant to mushrooms could results in new strains that are largely similar to an initial variety at the genetic level.

Key to this is the property of mushroom fungi that nuclei of the parents do not fuse after a cross (Figure 3). Typically, a meiotic spore (n) germinates and develops into a mycelium (network of hyphae), that is homokaryotic (1 type of nucleus, n) and infertile. When a compatible homokaryotic network of the same species is encountered, a heterokaryon (2 types of nuclei, n + n) is established, which is fertile and can produce fruiting bodies. This characteristic allows the recovering of parental genotypes. Tissue cultures from either heterokaryotic mycelia or fruiting bodies containing both parental genotypes in separate nuclei can be treated with enzymes to degrade the cell wall, resulting in protoplasts with one or multiple nuclei. Those protoplasts can be regenerated into mycelium, and those that contain only one nucleus will generate either one of the parents. Another option to obtain parental genotypes is through collection of asexual oidiospores that, when germinated, will result in mycelia with one of the parental genotypes (Figure 3).

The possibility to recover the parental genotypes of a mushroom variety with relative ease, enables the reuse of one or both parental genotype(s) in breeding, without or in combination with meiotic products.

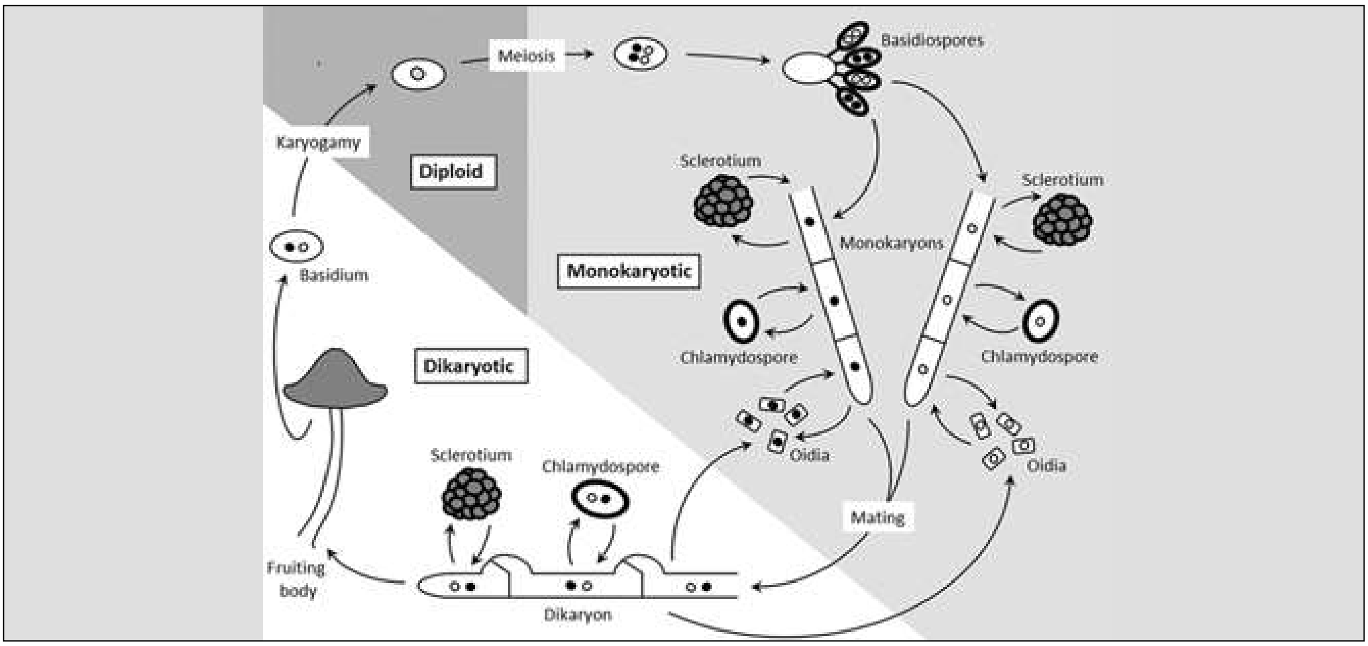


Figure 3. Life cycle of a mushroom, modified from Kües et al. (2016). Staring with a meiotic spore that germinates, a homokaryotic (rare in button mushrooms), non-fertile network of hyphae develops. Upon meeting a compatible homokaryotic network (of the same species, and with the right mating type genes), a heterokaryon can be established that is fertile and can produce mushrooms. The two parental genotypes are maintained concomitantly, and only fuse (2n) in special cells called basidia, directly followed by meiosis and distribution of four daughter nuclei over four spores.

Here we describe a couple of examples of breeding steps possible with mushroom fungi that would generate "novel" varieties with large genetic resemblance to the commercial variety from which the starting material is obtained. These examples are far from exhaustive but serve as an illustration of breeding steps leading to new varieties that might be considered EDVs.

1. ***Exchanging mitochondria***. By crossing 2 homokaryons, the newly formed heterokaryon will inherit only one type of parental mitochondrium, and often there is no preference from what parent it is inherited. A new cross between the original parents can thus generate the same heterokaryon but with a different mitochondrium than the initial variety.

1. ***Adjusting the genetic makeup of only one of the commercial parents.*** By crossing one of the commercial parents (say "A," from a heterokaryon "A" + "B") with a "third" homokaryon, meiotic offspring will contain different levels of genetic content of parent "A" and the "third" homokaryon. Selecting offspring with very high "A" levels and low percentages of the "third" genotype, followed by crossing with the "B" commercial parent, generates a heterokaryon with very high genetic similarity to the original "A" + "B" commercial variety, with only small differences in genetic content of the "A" parent.

1. ***Obtaining one of the two commercial parental genotypes through a di-mon cross.*** Instead of protoplasting or oidiopsores, one of the two parents from a commercial heterokaryon can be recovered by crossing a commercial heterokaryon with an additional homokaryon. The commercial heterokaryon can donate one or the other parental nucleus to this additional homokaryon, which will then become a heterokaryon containing its own plus one fully intact commercial parental genotype.

Clearly, most of the examples above will be hard or impossible to be identified as EDV (once agreements are in place on what are EDVs in such situations) without genetic analysis or full disclosure of the breeder on how a variety was established. We would like to propose to take the discussion on EDVs in mushrooms further, including genetic methods right from the start, to prepare a way for a healthy breeding environment for mushrooms.

Presentation made at the Seminar

What if your crop abundantly produces EDVs by itself

Mr. Arend van Peer, Team Leader Mushroom Research, University of Wageningen, Netherlands

UPOV Seminar on interaction between PVP and the use of plant breeding technologies

Geneva, 22 Mar 2023

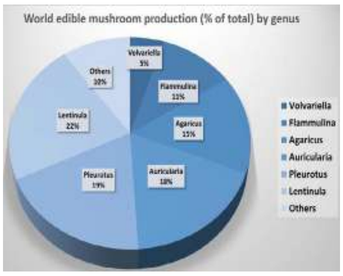
EDVs of Edible mushrooms;
Button mushrooms as a case study

A.F. van Peer, J.J.P. Baars, A.M. Sonnenberg, 03 2023

PLANT BREEDING WAGENINGEN UR

Breeding of mushrooms

- **5 dominant cultivated mushrooms world-wide**
  - Button mushroom is dominant mushroom in Europe / USA / Canada / Australia / India
- **Market share 'exotic' mushrooms keeps growing**
  - Breeding incentive increasing (e.g. SPOPPO)
  - Varieties from Asia on the European market
- **Expected: demand for new strains due to changes in production systems**
  - Limitations on fungicides/pesticides
  - Changing substrate/casing (peat, straw)
  - Automatization, different cropping regimes
- **Growing: interest in specialty button mushrooms**
  - Health (nutrition/protein)
  - Health (immune stimulation)
  - High end market (special taste/colour/texture)



Sakawhat ea 2021, DOI: 10.5772/intechopen.102694

Mushrooms and EDVs

- Mushrooms are genetically special organisms
- No clear rules exist on EDVs for edible mushrooms
- No known case laws
- Obstacles DUS testing

- Only one example of consensus for EDV:

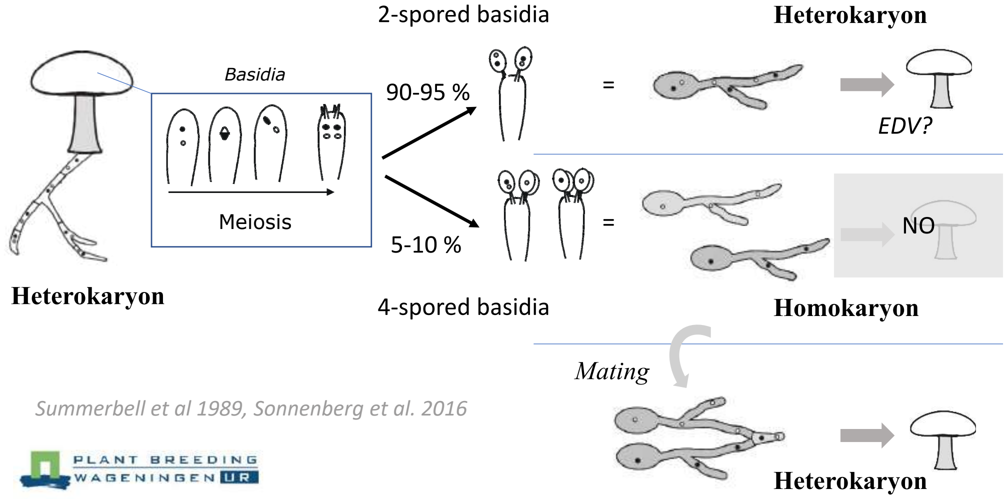
Use of single or multi spore cultures of an initial variety of button mushrooms

PLANT BREEDING WAGENINGEN UR

Button mushrooms life cycle

Button mushroom (*Agaricus bisporus*), represented mainly by 2 subspecies

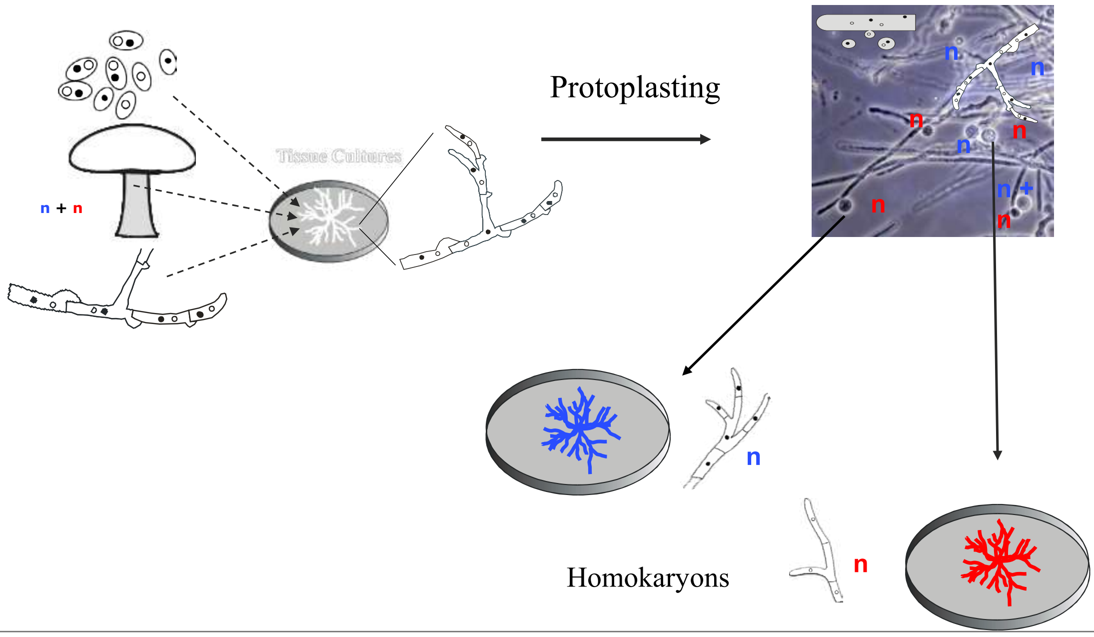
- *A. bisporus* var. *bisporus* → all commercial varieties
- *A. bisporus* var. *burnettii*



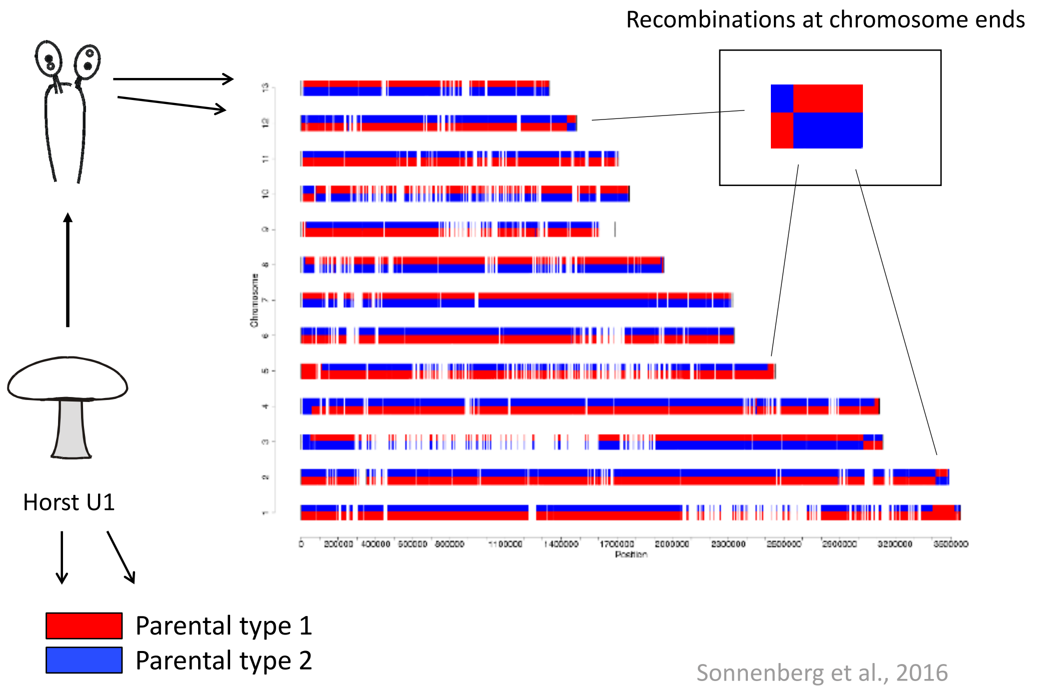
Summerbell et al 1989, Sonnenberg et al. 2016

PLANT BREEDING WAGENINGEN UR

Recovering constituent nuclei: haplotyping

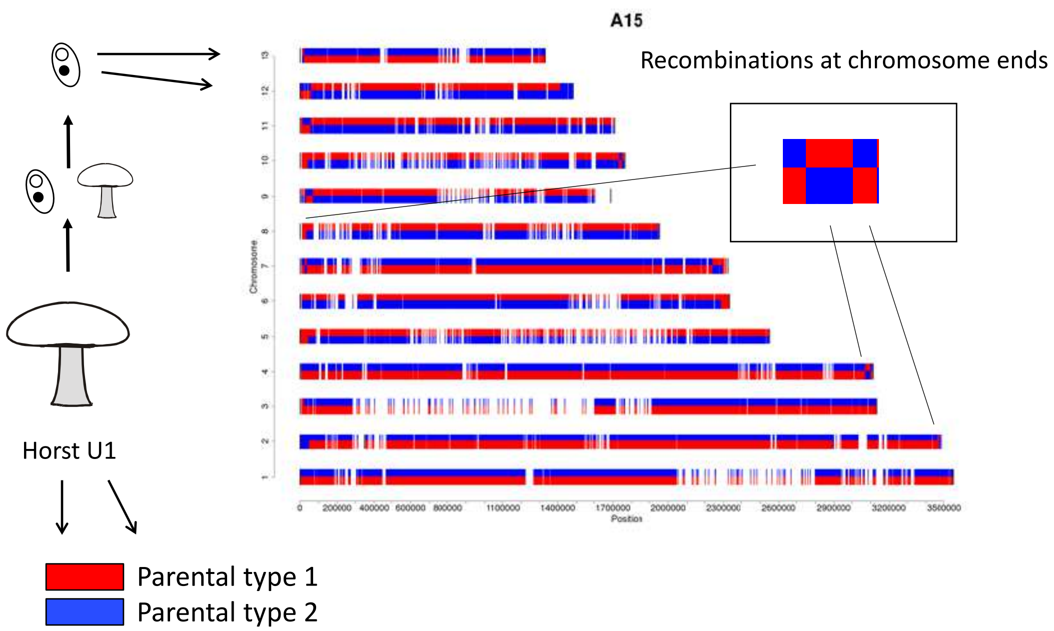


Haplotypes remain largely conserved in offspring



Sonnenberg et al., 2016

Genotype of nuclei in Sylvan A15



Obstacles in DUS testing edible mushrooms

- Low number of phenotypic traits compared to plant varieties
  - To be improved or expanded?
- Phenotype variation by environment or small genetic variation
  - Substrate quality
  - Climate (and growers skills)
  - EDVs button mushroom
- DUS tests for mushrooms are expensive (compared to plant DUS tests)
  - Special inoculum preparation (spawn)
  - Special substrate preparation
  - Strict climate and hygiene
  - No test facility at this moment for button mushroom varieties

PLANT BREEDING WAGENINGEN UR

Using a genetic distance threshold to detect EDV

- Genetic distance threshold as indication for putative EDV
  - Sequencing is easy and affordable for mushroom genomes
- If sample shows value above threshold:
  - Reverse burden of proof
  - Breeder of ‘new variety’ must open its books

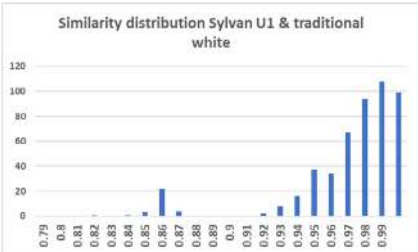
PLANT BREEDING WAGENINGEN UR

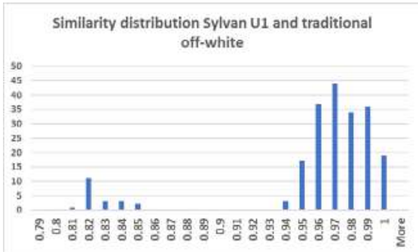
Example; genetic distance of Horst U1 and its parentals

75 SNP markers:

Traditional white | *Traditional off-white*

Meiotic spore of Somycel 53 → Horst U1 ← Meiotic spore of Somycel 9.2



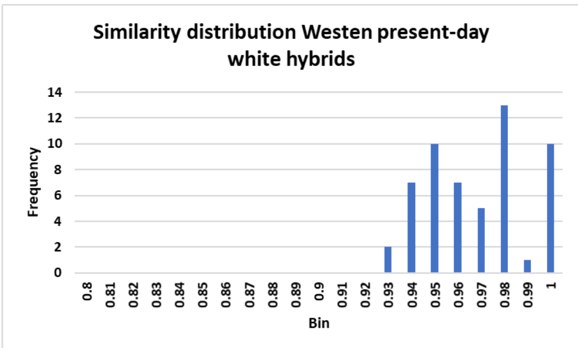


Horst U1 | Traditional white | Horst U1 | Traditional off-white

PLANT BREEDING WAGENINGEN UR

Example; genetic similarities with the present-day hybrids

75 SNP markers:



- Fertile single spore cultures of *A. bisporus* var. *bisporus* generates genetic variation in a range from ~ 0.92 to 1.0.

PLANT BREEDING WAGENINGEN UR

EDV definitions for Mushrooms

Consensus:

Use of single or multi spore cultures of an initial variety of button mushrooms = EDV

No definition or consensus: Needed to make breeding worthwhile

- **Recovering haplotypes** of a protected variety by protoplasting and:

Restoring the original variety by mating the recovered haplotypes

Restoring [...] but with a different mitochondrial type

Using an intact parental type in breeding

- **Introgression breeding**:

Repeated backcrossing to high similarity with a protected variety

What is the genetic threshold above which a variety is considered as an EDV?

PLANT BREEDING WAGENINGEN UR

Acknowledgments:

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PLANT BREEDING WAGENINGEN UR

INTELLECTUAL PROPERTY AND LEGAL PERSPECTIVE ON NEW TECHNOLOGIES AND VARIETY DEVELOPMENT

Ms. Heidi Nebel
Managing Partner and Chair of the Chemical and Biotechnology Practice Group at McKee, Voorhees & Sease PLC, Des Moines, United States of America

Long version of presentation made at the Seminar

Two Schools of Thought

Open & Available

- Germplasm should be freely available for use in more rapidly developing high yielding and resistant grain and forage plants

Protectible Investment

- Germplasm represents an investment of intellectual focus, time, and money – the investment should be legally protected to incentivize and accelerate future plant breeding

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• GOALS FOR COMPANIES FORMED AROUND BREEDING PROGRAMS

- Protect program and increase return on investment with:
- 1. Systematic, structured breeding programs
- 2. Certainty around ownership, FTO
- 3. Enforceable against competitors

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Protecting Breeding Programs

Michael T. Coe, Katherine M. Evans, Ksenija Gasic, Dorrie Main. **Plant Breeding capacity in U.S. public institutions**. *Crop Science*, 2020

- Declines in breeding programs nationwide, particularly research institutions and funded programs
- 21%+ decline in FTE for program leaders in 5 years
- 17%+ decline in FTE for technical support personnel
- Significant expertise nearing retirement (30%+ over 60 and 62% over 50)
- *Good news is that biotechnological methods (tissue culture, mutation breeding, DNA technologies, molecular breeding, gene editing) has resulted in development period decreasing to 4-11 years making plant breeding less time-consuming. Still just as expensive and expertise to do so is decreasing.*

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PROACTIVE STRATEGY TO SAFEGUARD INTELLECTUAL PROPERTY

- Codification/Acknowledgement of Rights
  - Patents
  - PVP/PBR
  - Trademark
- Interparte Agreements of Rights
  - Internal – employee agreements, assignments, IP policies, invention disclosure forms
  - External – Outlicensing –NDAs, MTAs, Bag tags, research agreements
    Inlicensing- NDAs, MTAs, Bag tags, research agreements -FTO

Trade Secrets

know how, customer lists, databases

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Asset	Intellectual Property
Breeding infrastructure, Selections, Results, Materials, Markers, Equipment, etc.	Know-How, Confidential Info, and/or Trade Secrets (and occasionally patents too)
Plants, plant parts, traits, proteins, genes (with exceptions), microorganisms, transformed cells, etc.	Patents (utility and/or plant)
Varieties, cultivars, inbreds, F_1 hybrids	Patents (utility and/or plant), PVPs, and/or Trade Secrets
Brand name for source, variety, trait, etc.; Distinctive marks, logos, and packaging	Trademark; Trade Dress

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General Forms of Legal Protection

- Patents (Utility and Plant) — 35 U.S.C. § 161-164
- Plant Variety Protection Act Certificates — 7 U.S.C. §§ 2321 et seq.
- Material Transfer Agreements/Other Contracts
- Restrictions of Use - Bag Tags/Sales Contracts
- Trade Secrets — State Law (Uniform Trade Secret Law); Defend Trade Secrets Act; •18 U.S.C. § 1836 (b)

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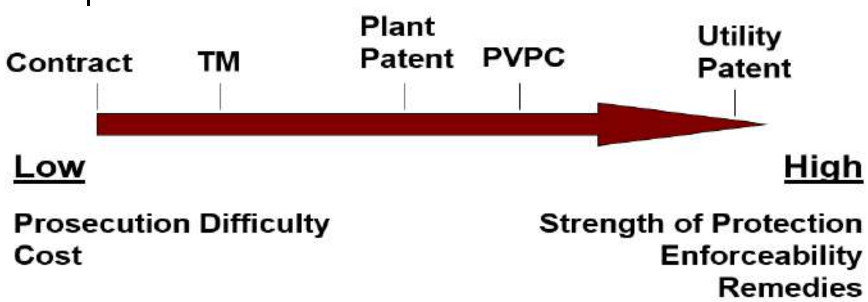
Considerations in appropriating limited resources for IP Safeguards

Strike a balance among:

- Licensing strategy
- Industry expectations/common practice
- Costs vs. benefits
- Enforceability
- Scope of Protection



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What Is a Patent Worth?

OCTOBER 16, 2019 • RESEARCH BRIEFS IN ECONOMIC POLICY NO. 185

Empirically, we find that the first patent increases a startup's chances of securing funding from venture capitalists (VCs) over the next three years by 47 percent, of securing a loan by pledging the patent as collateral by 76 percent, and of raising funding from public investors through an initial public offering by 128 percent. The VC funding effect is strongest for startups founded by inexperienced entrepreneurs and located in areas where attracting investors' attention is harder but is weakest for biochemistry startups. Mirroring the ambiguous effects of subsequent patents on the performance of startups, we find that the approval of a startup's second application appears to have no statistically significant impact on the startup's ability to raise VC funding.

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- ***IP Identifier Tool for Identifying Valuable IP***
- ***CHRISTOPHER HUSSIN* | *02.08.23***
- The US Patent and Trademark Office (USPTO) recently announced the launch of the agency's new **Intellectual Property (IP) Identifier** tool. The tool is designed for those who are less familiar with IP, and it can be used to help identify whether a user has intellectual property and how best to protect it.
- The USPTO notes that companies significantly benefit from protecting their IP:
- Companies benefit from having IP protection. When used as collateral, a company's first patent increases venture capital funding by 76 percent over three years and increases funding from an initial public offering by 128 percent.
- It can also help serve as a recruiting tool: The approval of a startup's first patent application increases its employee growth by 36 percent over the next five years.
- Further, protecting your IP can also increase your market share – a new company with a patent increases its sales by a cumulative 80 percent more than companies that do not have a patent.

Considerations in choosing the right protection

Type/background of plant material
- Seed vs. vegetatively-propagated
- Inbred line vs. hybrid
- Genetically modified vs. traditional breeding
- Primary traits
- Feasibility of obtaining data/info required

Market interest/strategy
- Specialty vs. commodity market
- Scope of license grant (exclusive vs. nonexclusive)
- Market areas
- Quality control/assurance

Patents (Utility and Plant)– granted by USPTO

Requirements:

- Novelty
  - Consider Statutory bar date – for example, barred from obtaining a patent if the plant was commercially or publicly available more than one year prior to filing the patent application.
- Nonobviousness
- Written description
- Seed deposit with an approved entity (for utility patents)

Length of Protection

- 20 years from filing date

Type of Protection

- Exclusionary Right—to exclude others from making, using, or selling your claimed invention without your permission within the U.S.

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Utility Patents

Broad protection-- Can be used to protect a new variety of plant that is reproduced either sexually (seed) or asexually (clonal) and can include coverage for varieties, plant parts, genes, traits, methods

- Benefit—Gold Standard of protection—Exclusionary right covers making, using or selling your particular cultivar and its derivatives (F1 hybrids, mutants, etc.)
- Detriment—higher cost; usually takes 2-3 years from filing to allowance; you cannot add to disclosure post filing without encountering written description issues
- Application must include— Detailed botanical description plus information to support claims regarding mutagenesis, genetic engineering, crossing, etc.

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Utility Patents Claims for varieties

Plants and seeds	1.	Hybrid maize seed designated XXXXX, representative seed having been deposited under ATCC accession number _______.
F1 progeny	2.	A maize plant, and its parts, produced by the seed of claim 1.
Plant parts	3.	Pollen of the plant of claim 2.
Transgenic conversions and production methods	4.	An ovule of the plant of claim 2.
Methods of plant breeding –new variety development (2+ generations)*	5.	A tissue culture of regenerable cells of a hybrid maize plant XXXXX, wherein the tissue regenerates plants capable of expressing all the morphological and physiological characteristics of XXXXX, representative seed having been deposited under ATCC accession number _______.
Methods of use*	6.	A tissue culture according to claim 5, the cells or protoplasts being of a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.
Harvested product	7.	A maize plant, and its parts, regenerated from the tissue culture of claim 5 and capable of expressing all the morphological and physiological characteristics of 34G81, representative seed having been deposited under ATCC accession number _______.

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- TRAITS

- Wide variety options for utility patent claims
  - Plants with trait developed by inventor
  - Methods of breeding or editing
  - Genetics
  - Producing a new product
  - How to characterize
  - Markers and selection

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EXAMPLE OF TRAIT CLAIM

U.S. Patent No. 9,173,355; “Carrots having increased lycopene content”

- 1. A carrot plant, the roots of which comprise an average lycopene content from about 110 ppm to about 250 ppm and an average brix content from about 11” brix to about 20” brix, wherein the lycopene content of the plant is at least about 110% of the average lycopene content of roots of the carrot variety Nutri-red when the plant and Nutri-red are grown under the same conditions, and wherein said carrot plant comprises the genetic source for expressing the lycopene content in a carrot variety selected from the group consisting of red carrot hybrid 0710 0325….

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Breaking the linkage

U.S. Patent No. 9,024,140; “Methods and compositions for producing plants with elevated Brix”

- 1. A tomato plant **comprising a hir4 allele** of *Lycopersicon hirsutum* conferring **elevated Brix** relative to a *Lycopersicon esculentum* plant lacking said hir4 allele, **wherein the plant lacks an allele genetically linked to the hir4 allele of *Lycopersicon hirsutum* conferring increased plant vegetative growth** relative to a *Lycopersicon esculentum* plant lacking said allele genetically linked to the hir4 allele, wherein said hir4 allele and allele genetically linked to the hir4 allele are located in a genomic region corresponding to markers TG155 and TG500, wherein the hir4 allele is located proximal to TG155 in said region relative to the allele conferring increased vegetative growth.

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Recombined Introgression Claim

U.S. Patent No. 9,072,271 "Agronomically elite lettuce with quantitative *Bremia lactuca* resistance"

- 7. A lettuce seed comprising a **chromosomal segment** that comprises a RBQ5 allele of *Lactuca saligna* conferring quantitative resistance to *Bremia lactucae* and lacking a *Lactuca saligna* allele genetically linked thereto that confers adventitious shoots, wherein a representative sample of seed comprising the chromosomal segment was deposited under ATCC Accession Number PTA-9046.

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Use of a New QTL

U.S. Patent No. 7,759,545 "Methods and compositions for production of maize lines with increased transformability

- 1. A method for producing a transformable corn line comprising **introgressing at least one chromosomal locus mapping** to bin 6.02 to 6.04 or bin 10.04 to 10.06, wherein said locus is introgressed from a more transformable corn line into a less transformable corn line.

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Claiming Use of a Newly Identified Source/Trait

- U.S. Patent No. 8,859,859 "Downy mildew resistant cucumber plants"
  - 1. A method of producing a cucumber plant having a resistance to Downy Mildew comprising the steps of: (a) **crossing a cucumber plant of accession PI197088** with a second cucumber plant having at least one desired trait; and (b) selecting at least a first progeny cucumber plant resulting from the crossing that comprises resistance to Downy Mildew and the desired trait.

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PITFALLS AFFECTING VALUE OF PATENTS

- Chain of Title
  - Patent Assignments- from inventor/ Owner to company
    - Make sure all are in place- bound and clearly set out obligations in employment contract
    - No clear policy for sharing of revenue, rights of employee or owner inventors
    - Freedom to Operate
      - Where did breeding material come from?
      - Rights of all materials used, starting materials, machines, methods (CRISPR) devices used etc.
      - Right to practice invention – patent rights are exclusionary

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IP Assignments – A Trap for the Unwary!

- To enforce a patent, one must have "standing" – a legally protected interest that is harmed by infringement
  - Only owners (including assignees) and certain exclusive licensees have a protected interest
  - Only owners (including assignees) can file suit
    - In the case of multiple owners, ordinarily *all* must consent
- Breeder-inventors must *fully and completely* assign their rights in their inventions to their employers to ensure that the patents can be enforced (often years later) without the involvement of the inventors
- Assignment language can be automatic, but it must clearly accomplish an actual transfer of ownership – not just a contractual promise to make an assignment in the future.
  - "I hereby assign" / "I hereby grant" = OK
  - "I will assign" / "I agree to assign" = NOT OK

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§ 2544. Research exemption

- The use and reproduction of a protected variety for plant breeding **or other bona fide** research shall not constitute an infringement of the protection provided under this Act.
  - Bona Fide Requirement Applies to "Use", "Reproduction" and "Research"
  - If Parental Material is Used Without Permission - Contrary to an MTA or Restrictions of Use Clause or Purloined is this Bona Fide Use?

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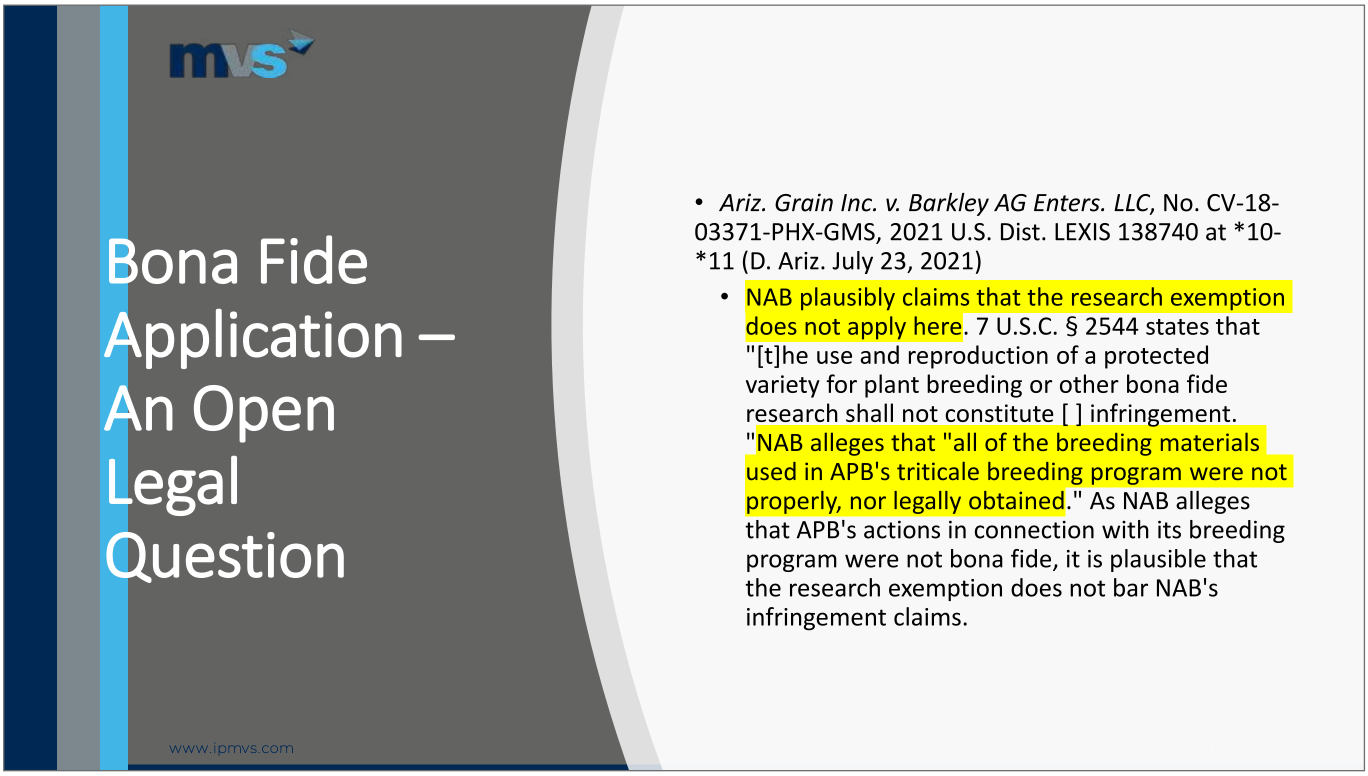
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Bona Fide Application – An Open Legal Question
• *Ariz. Grain Inc. v. Barkley AG Enters. LLC*, No. CV-18-03371-PHX-GMS, 2021 U.S. Dist. LEXIS 138740 at *10-*11 (D. Ariz. July 23, 2021)
• NAB plausibly claims that the research exemption does not apply here. 7 U.S.C. § 2544 states that "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute [ ] infringement. "NAB alleges that "all of the breeding materials used in APB's triticale breeding program were not properly, nor legally obtained." As NAB alleges that APB's actions in connection with its breeding program were not bona fide, it is plausible that the research exemption does not bar NAB's infringement claims.
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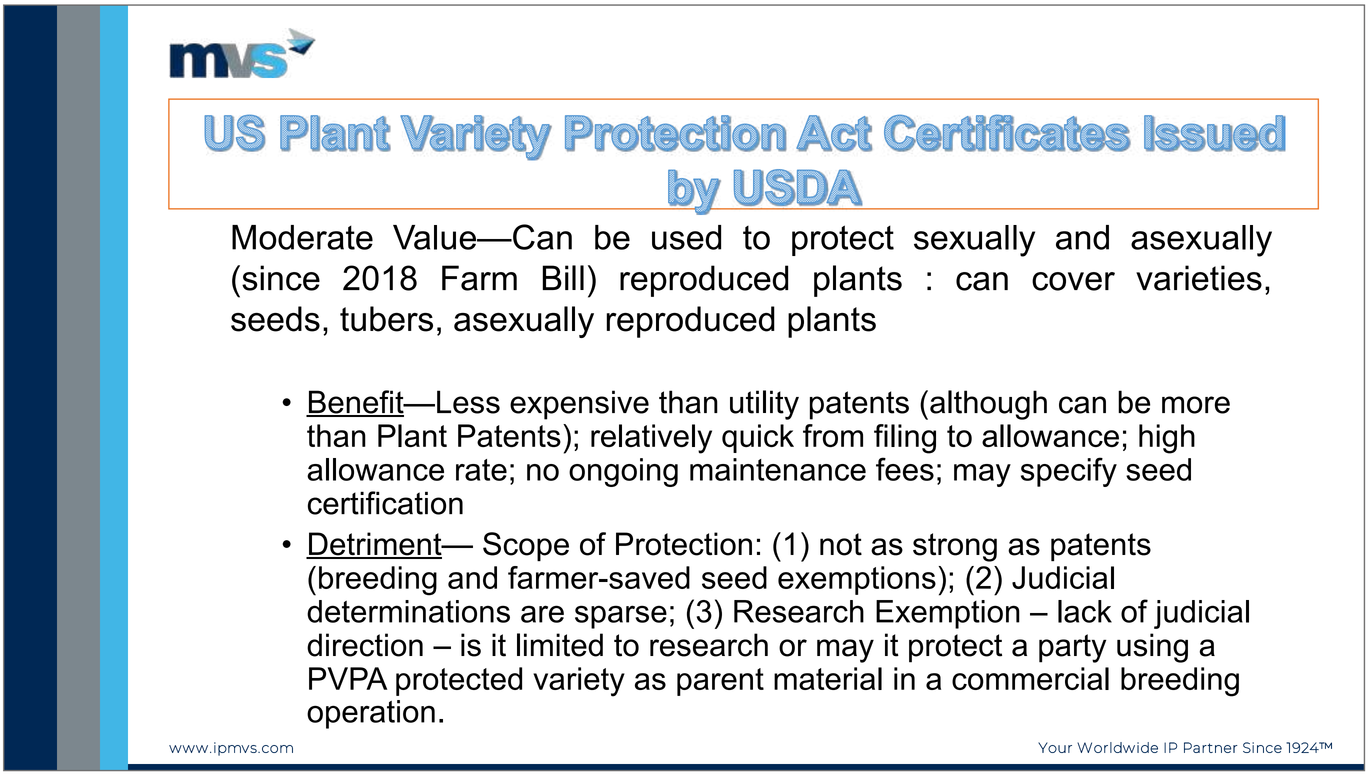
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US Plant Variety Protection Act Certificates Issued by USDA
Moderate Value—Can be used to protect sexually and asexually (since 2018 Farm Bill) reproduced plants : can cover varieties, seeds, tubers, asexually reproduced plants
• Benefit—Less expensive than utility patents (although can be more than Plant Patents); relatively quick from filing to allowance; high allowance rate; no ongoing maintenance fees; may specify seed certification
• Detriment— Scope of Protection: (1) not as strong as patents (breeding and farmer-saved seed exemptions); (2) Judicial determinations are sparse; (3) Research Exemption – lack of judicial direction – is it limited to research or may it protect a party using a PVPA protected variety as parent material in a commercial breeding operation.
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US Plant Variety Protection Act Certificates Issued by USDA

Requirements:

- Variety must be Distinct, Uniform and Stable (DUS)
- Application must include (1) breeding history; (2)selection process used to develop the variety; (3) detailed botanical description (completion of an objective description form provided by the PVPO); and Seed or tuber deposit with NLGRP
- Variety name must be designated at the time of application or prior to certificate issuance
- Consider Statutory bar date—cannot file an application one year or more after the first sale in the U.S., or 4 years (6 years for trees or vines) from the first sale elsewhere

Length of Protection

- 20 years (25 years for trees and vines) from issuance

Type of Protection

- Exclusionary right-to exclude others from marketing, selling, reproducing, importing or exporting the protected variety; includes essentially derived varieties and production of hybrids

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Plant Breeders Rights – Foreign

- Rights granted to the breeder or owner, similar to rights provided by US PVP
- Exclusionary right over the propagating material (including seed, cuttings, divisions, tissue culture) and harvested material (cut flowers, fruit, foliage) of a new variety for 20 years (25 years for trees and vines) from issuance
- A variety is:
  - New - not been commercialized for more than one year in the country of protection
    - or anywhere for 4 years or 6 years for trees or vines
  - Distinct - differs from all other known varieties by one or more important botanical characteristics
    - Most countries require growth trials by state agency to establish
  - Uniform - consistent within the variety;
  - Stable - genetically fixed
- Annual Maintenance Fees usually required

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EMPLOYMENT CONSIDERATIONS

Goal for incoming employees: buy in to protection efforts & avoid contamination with others' IP

- Education
- Assess incoming know-how/materials
- Restrictive covenants

Goal for departing employees: reminder of protections, restrict losses of IP

- Education
- Notice to new employer
- Monitoring releases from competitor


What Forms of Management
Material Transfer Agreement
Restrictions of Use – Bag Tags & Sales Contracts
Trade Secrets
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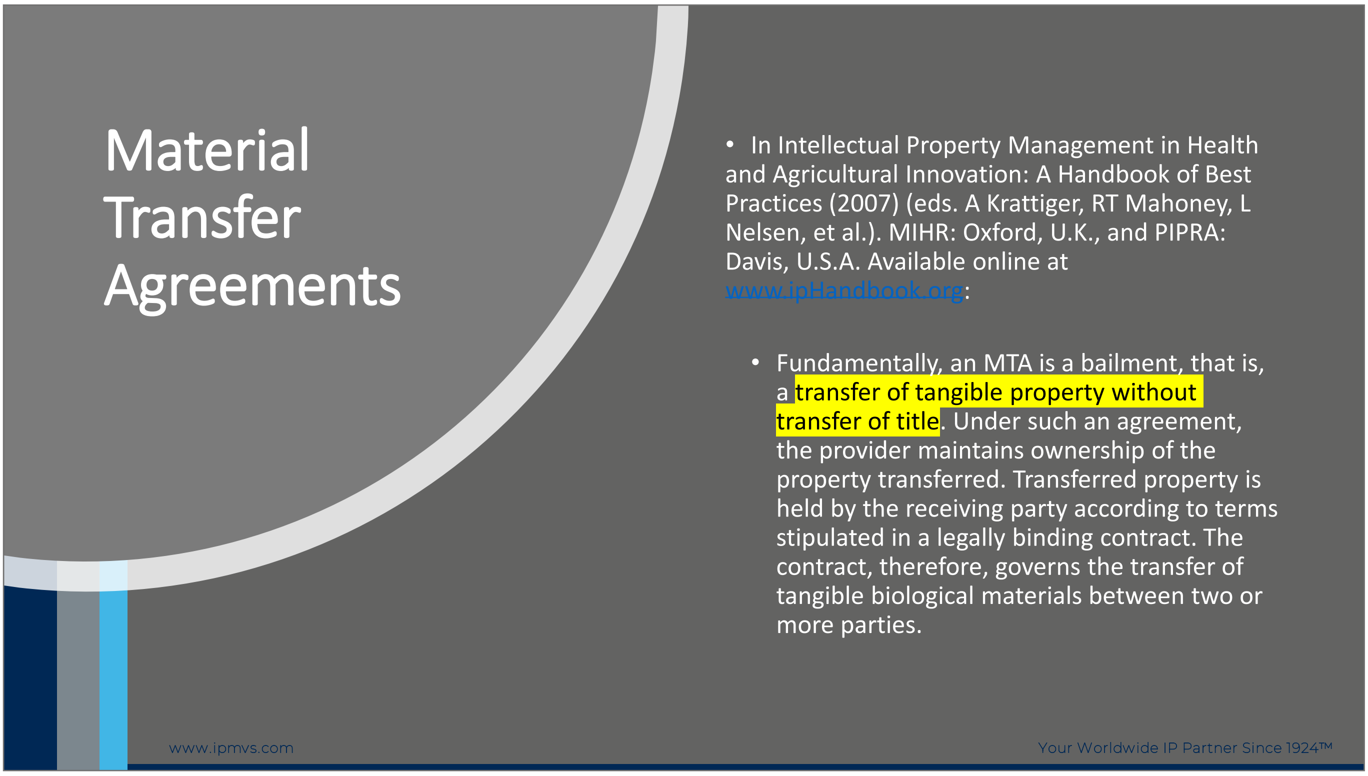
Material Transfer Agreements
• In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (2007) (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org:
• Fundamentally, an MTA is a bailment, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider maintains ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, therefore, governs the transfer of tangible biological materials between two or more parties.
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Restrictions of Use

"The soybean seed in this bag contains genetics developed, licensed or owned by Seller. All rights to make, produce or sell seed products derived from this seed reside solely with Seller. Buyer acknowledges this ownership and agrees to the following conditions: ... Buyer will not resell or supply any of this seed to any other person or entity. Furthermore, Buyer is strictly prohibited from saving or selling, for seed purposes, any gain products from this seed. Buyer further agrees not to alter, or permit the alteration of the seed ... through either genetic engineering, conventional breeding activities or other techniques."

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NOTICE TO BUYER - LIMITED SEED USE

Purchaser agrees to use this seed for the production of forage crops and not retain any propagate of such crop including but not limited to seed or other material.

PVP NOTICE

U.S. Protected Variety. Unauthorized Seed Multiplication Prohibited. Access to this seed is provided under restricted use conditions. Limited license is granted solely to produce hay or forage, with no rights to multiply, propagate or export seed. For other licenses contact Northern Agri Brands, LLC.

NOTICE: REQUIRED ARBITRATION & CONCILIATION

The seed laws of several states require arbitration, conciliation or mediation of disputes involving alleged defective seed before litigation. A complaint must be filed with the Department of Agriculture or Seed Commissioner in your state within such time to permit an inspection of seed, plants or crops. A Certified copy of the complaint must be sent by registered mail to the Seller of this seed as provided in each individual State Law. Contact Your State Seed Commission, the Department of Agriculture or the Seller of this seed for further details.

QUALITY SEED: NOTICE TO BUYER - LIMITATION OF WARRANTY

Seller warrants that the seed sold by it conforms to the descriptions on the label within tolerances established by law. THIS EXPRESS WARRANTY EXCLUDES AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING NAY WARRANTY OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE WHICH ARE HEREBY EXPRESSLY DISCLAIMED.

In any event, it is expressly agreed that Seller's liability to the Buyer or others for any loss (whether suchloss results from breach of warranty, or contact, or from negligence) shall be limited solely to the amountof the purchase price of the seed. The remedy hereby provided shall be the exclusive and sole remedy of the Buyer and all other persons for any such loss. In no event shall the Seller be liable for any consequential or incidental damages sustained by the Buyer or any other person. By acceptance of the seeds the Buyer acknowledges that the limitations and disclaimers set forth are conditions of the sale and constitute the entire agreement between the parties regarding warranty or other liabilities and the remedy therefore.

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USE RESTRICTIONS AND LIMITED LICENSES

VARIETY PROTECTION CODES
(Legend)
Protections are applicable only if product is so coded
PVP Protected
UNAUTHORIZED PROPAGATION PROHIBITED
UNAUTHORIZED SEED MULTIPLICATION AND/OR EXPORTATION PROHIBITED,
applies to varieties coded 2, 5 or 6)

2 - U.S. Protected Variety.
5 - U.S. Protected Variety – PVPA 1994.
6 - U.S. Plant Variety Protection Applied For – PVPA 1994

U.S. Varietal Patent Protection

7 - Protected under one or more U.S. Varietal Patents.
8 - U.S. Varietal Patent Pending.

If the applicable Variety Protection Code set forth is 2, 5, 6, 7, or 8 the following RESTRICTED USE LICENSE shall be binding on User:

For purposes of this section, User shall be referred to as "Licensee." This product is proprietary to Syngenta Seeds, Inc. or its licensors. The only permissible use of seed product contained in this package is for the production of a single commercial crop of forage or grain for feeding or processing. As used herein, such production shall exclude producing seed for planting unless expressly permitted under a grower level agreement with Syngenta Seeds, Inc. The seed product in this package shall not be used for research (including but not limited to agronomic comparisons and yield testing), breeding, or molecular or genetic characterization. Export, resale, or transfer of such seed product or its progeny is strictly prohibited, except that forage or grain may be exported solely for use in feeding or processing. For availability of other licenses, contact Syngenta Seeds, Inc.

The seed is protected by Plant Variety Protection (PVP) laws if so indicated on the tag attached to this package. Export of PVP protected seed or its progeny is strictly prohibited, except that forage or grain may be exported solely for use in feeding or processing unless expressly permitted under a grower level agreement with Syngenta Seeds, Inc. Licensee agrees that Syngenta Seeds, Inc. intends to only commercialize seed product for production of a single commercial crop of forage or grain for feeding or processing. Export, resale, or transfer of the seed in this package is also strictly prohibited.

The molecular and genetic makeup of the seed product contained in this package may constitute a trade secret unless expressly permitted under a grower level agreement with Syngenta Seeds, Inc. Licensee is granted a limited use license under Syngenta Seeds, Inc.'s trade secret rights only for the production of a single commercial crop of forage or grain for feeding or processing. Licensee shall not characterize the molecular or genetic makeup of the seed in this package. Licensee further agrees to keep all molecular and genetic information regarding the seed product, confidential.

This seed product is protected under one or more patents if so indicated on the tag attached to this package. To the extent that the product is covered by a patent: (a) Licensee is only granted a limited use license under such patent(s) to produce a single commercial crop of forage or grain for feeding or processing; (b) export, resale and transfer of the seed product in this package is prohibited; (c) use of this seed product for research, breeding, or molecular or genetic characterization is strictly prohibited.

No Magic Language but…. Consider Intended Result

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One or more of the parental lines used in producing this product are proprietary to Pioneer Hi-Bred International, Inc. ("Pioneer"). Parental lines are U.S. Protected Varieties and may be protected under the laws of other countries; export or transfer of possession is prohibited. Pioneer intends to supply only hybrid seed. Customer agrees that it is not acquiring any rights to use any parental line for any purpose other than production of forage or grain for feeding or processing. If the tag indicated this product is produced under one or more U.S. patents, customer is licensed thereunder only to produce forage or grain for feeding or processing. All uses outside the U.S. are prohibited to the extent they result in infringement of U.S. patents. For availability of other licenses, contact Pioneer.

. . .

By acceptance of the seed or other products the Buyer acknowledges that the foregoing terms are conditions of the sale and constitute the entire agreement between the parties regarding warranty or other liabilities and the remedy therefor.

No Magic Language but…. Consider Intended Result

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GROWER LICENSE

Grower acknowledges that technologies both owned and licensed by Syngenta are protected under U.S. patents 5,767,378; 5,994,629; 5,625,136; 6,051,760; 6,403,865; 6,075,185; 6,121,014; 6,320,100; 6,018,099; 5,466,785; 7,030,295; 5,352,605; 6,114,608; 6,566,587; 5,641,876; RE 37287 and RE 36449.

Upon receipt by Syngenta of this Agreement unaltered and executed by Grower, Syngenta grants Grower, under applicable patents owned or licensed by Syngenta, a limited use license to purchase and plant corn seed containing Syngenta Technologies ("Seed") to produce a single commercial corn crop upon the terms and conditions of this Agreement.

This license only covers the United States and does not authorize Grower to plant Seed in the United States that has been purchased / acquired in another country or plant Seed in another country that has been purchased / acquired in the United States.

GROWER RESPONSIBILITIES

Grower agrees to:

- Channel grain produced from Seed to appropriate markets as necessary to prevent movement to markets where the grain has not yet received regulatory approval for import;
- Use Seed solely for planting a single commercial corn crop;
- Not supply, transfer, license or sublicense any Seed to any other person or entity for planting or any other purpose;
- Not to save any grain produced from Seed for planting by Grower or any other person or entity;
- Not to use or allow others to use Seed, grain produced from Seed, the Syngenta Technologies or any plant material containing Syngenta Technologies for crop breeding, research (including, without limitation, generating cooperative data against corn seed containing non-Syngenta technologies), generation of registration data or Seed production (unless Grower has entered into a valid, written production agreement with a licensed seed company); and
- Abide by the terms of the Stewardship Guide.

No Magic Language but…. Consider Intended Result

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Trademarks

- Requirements:
  - Trademarks must be distinct—they cannot be generic (i.e., the cultivar/varietal name) –DO NOT USE a chosen TRADEMARK as the varietal name in a patent/PVP or in any marketing materials.
  - Trademarks cannot be confusingly similar to anyone else's trademark name – consider trademark searching before adoption
  - If the mark is highly descriptive of the characteristics/traits of the variety, it may not be protectable at least without extensive, substantially exclusive use.
- Length of Protection—Potentially forever so long as mark is used
- Type of Protection
  - Can stop third parties from using your exact trademark or a mark that is confusingly similar in sight, sound and/or meaning within the same or a related trademark class (goods/services).

And to protect your brand....Trademarks

- Trademarks protect "source identifiers" or brands not the plant - can include words, phrases, designs, logos, or even potentially colors and shapes. The level of Protection is dependent on the strength of the chosen trademark/brand.
  - Benefit—Trademark rights – based upon commercial use - can last forever and therefore can be used to protect your varieties long after any patent or PVP Certificate has expired!
  - Detriment—Trademarks require ongoing use in commerce (if you cease use for 3 or more years you risk losing your rights). This use can be by you or your licensees (consider having written trademark agreements with licensees).
  - Application must include— The name of the trademark and a list of goods/services offered under the mark - cannot be the plant variety name.

Trade Secret – Hidden In Plain Sight?

- **"Reasonable Efforts to Maintain Secrecy"**
  - Employee NDA/Confidentiality Agreements
  - Company Training on IP/Proprietary Protection
  - Restrictive Use Language in Production Agreements, Foundation Seed Agreement, Associate Agreements, MTAs
  - Restrictive Use Language on Bags/Tags/Paperwork for Bulk Seed
  - PVP/Patent Notice
    - For PVP—using "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" and after the certificate issues, such additional words as "U.S. Protected Variety
    - For Patent – using "Pat. No. X,XXX,XXX" or "Patent X,XXX,XXX" on product or "Pat. No.:www.domainname.com/patents" (and listing patent numbers next to SKU numbers or other clear designation on webpage)

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PLANT VARIETY PROTECTION UNDER THE 1991 UPOV CONVENTION AND THE NEW PLANT BREEDING TECHNOLOGIES

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I would like to thank you for inviting me to take part in this seminar, given my long-standing collaboration with UPOV and my background in plant breeding as director of the Spanish Plant Variety Office, which was in charge of plant protection, as well as in other international bodies.

I have followed the debate on the legal protection of plant varieties and on NBTs.

I personally attended and took active part in the preparation and the sessions that led to the approval of the 1991 UPOV Convention. I can clearly remember the discussions and different approaches resulting in the 1991 Convention.

The plant breeding methods available at the time were the classic ones, while molecular genetics had not made any contribution to the development of new varieties yet.

I recall that the first GM crop (Bt cotton) was not introduced in the United States of America until 1996. What is known today as "New Breeding Techniques" (NBTs), which are the main subject of my speech, did not exist.

I have been asked to give my opinion about the impact of NBTs on the Convention currently in force and on the general principles of Plant Protection as governed by the Convention.

Let me say a few preliminary words about the methods available before 1991.

These were basically ***crossing*** and ***mutation***, both including ***selection*** across several generations from sexual reproduction (crossing) and asexual reproduction (mutation). Chemical and physical procedures were used for these purposes and the output was completely random, so it could not be known whether the targeted gene had been actually affected or not. This is why so many years were needed to carry out selection by cloning, grafting, etc. Only a stroke of luck (mainly in ornamental plants) could lead to something able to be registered and protected or patented.

None of the numerous attempts undertaken to directly hit the target gene was successful: «***targeted mutation***» was an ideal.

Precisely this ideal has been achieved with NBTs. We must see whether these new methods fit into the current Convention.

I think that ***mutation*** also deserves some specific remarks. This is a word that comprises a wide variety of biological facts: changes in a nucleotide, in a DNA segment (addition or loss), in parts of a chromosome, in an entire chromosome (inversions, translocations, whether reciprocal or not), in complete or incomplete genomes (polyploids, aneuploids), etc. Each of these variants can bring about changes in the phenotype, be they purely cosmetic or truly relevant and of high value.

To talk about "mutation" as if it were a single biological reality, as I have been hearing in respect of EDVs (Essentially Derived Varieties), and to say that they are "all" EDVs, is in my opinion unbecoming of any organization in charge of protecting plant variety innovation and breeding.

The ***crossing*** method has a powerful variant—***backcrossing***, which allows us to introduce the desired gene into a valuable variety with the legitimate purpose of making it still more valuable: this is the goal of breeders, and their activity, i.e., progress in agriculture, is what the UPOV legally protects.

While it is easy to introduce a gene of great interest via backcrossing or mutation, it is just as easy to introduce a gene with zero value. The aim was to obtain a variety that was ***almost identical*** to the initial variety but ***still distinct*** thanks to the incorporation of a characteristic merely intended for registration purposes by achieving compliance with legal protection requirements. This is a sheer act of genetic piracy.

Prior to 1991, the Convention did not offer a legal basis to stop this kind of piracy. This is the reason why the concept of an "*Essentially Derived Variety*" was introduced in 1991, specifically in Article 14. The Convention thus solves this problem.

Thanks to the availability of new techniques, it is now possible to directly handle the DNA to introduce, modify and correct genes.

For instance, inserting a gene from a bacterium into a plant to make it resistant to a given disease; replacing a detrimental gene with another one; or, finally, correcting a defect in a gene just as you would correct a misspelled word in a written text using a computer program – a procedure known as gene editing which, albeit recent, is already delivering outstanding results.

The issue raised with NBTs is whether these techniques fall within the scope of plant variety protection under the 1991 UPOV Convention.

There are two aspects to consider:

1. Are NBTs to be accepted as plant breeding methods compliant with plant protection requirements?

The answer is obvious: *Of course they are*, since NBTs produce *targeted mutations and corrections of genome defects, and these are accepted breeding methods.* The varieties thus obtained must then be evaluated for compliance with the requirements of distinctness, uniformity, homogeneity and novelty to determine its eligibility for protection.

2. What types of varieties can be obtained using NBTs? Are all varieties obtained using NBTs to be considered EDVs?

NBTs are techniques that modify genes or gene sequences with great precision (finally targeted mutation!).

Such changes imply introducing traits that did not exist in a given species or were impossible to introduce via crossing, or correcting defective genetic information.

This is a topic of major importance, since if ALL plant varieties bred via NBTs are EDVs, the Convention would be rejecting and limiting scientific innovation by putting the spotlight on the tools used, not on the results obtained. In other words, if we considered ALL varieties bred via NBTs to be EDVs, we would be missing what really matters: whether the changes in the new variety add significant value, which is actually what the industry is interested in with a view to advancement and progress.

Not to mention the damage and harm this would cause to small and medium-sized research companies, which make up most of the research fabric.

Let us take a look at this along with Article 14(5). This article lays down the requirements that must be met by a new variety to be considered an EDV. These are:

(a) The Convention says *being clearly distinguishable from the initial variety.* This is obvious and even unnecessary to mention, since if the variety were identical there would be no room for protection.

Is an NBT variety clearly distinguishable from the initial variety?

Of course it is, since a different variety has been obtained. One or more important characters have been changed.

(b) The Convention says *that a variety is essentially derived if: (i) it is predominantly derived from the initial variety (...) while retaining the expressions of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. (ii) It also says that it is distinguishable from the initial variety.*

It must therefore, if it retains the essential characteristics, be distinguishable only by unimportant secondary characteristics.

(c) The Convention says *conforming to the initial variety.*

There is conformity with the initial if the essential characters of the initial are retained.

Would the NBT variety conform to the initial variety?

The concept of conformity should be construed in a manner consistent with the spirit of the UPOV Convention. Therefore, what should be assessed is whether it conforms to the initial variety in its essential characteristics, i.e., those which add value. Based on this, if the NBT variety incorporates a relevant characteristic comprised under what the Convention calls ESSENTIAL CHARACTERISTICS, the answer is: ***It does not conform to the initial variety.***

(d) The Convention says ***expressing the same essential characteristics as the initial variety.*** Everyone working with a particular crop (breeders, growers, marketers…) perfectly know which are those and ***which ones are needed.***

For example, resistance to a parasite affecting the crop, a flower color that does not exist in a particular species and therefore cannot be obtained via crossing or mutagenesis, or a rice variety able to synthesize provitamin A, etc.

These examples are real, they are ***ESSENTIAL CHARACTERISTICS*** and they can only be introduced using NBTs.

Does an NBT variety express the same essential characteristics as the initial variety?

No, because one or more essential characteristics are added or corrected (golden rice, blue flowers in roses, resistance to stalk borer in corn, etc.).

Therefore, ***THE 1991 UPOV CONVENTION IS INDEED IN A POSITION TO ENCOMPASS THE NEW BREEDING TECHNIQUES WITHIN THE GENERAL PLANT PROTECTION PRINCIPLES.***

The objective pursued by UPOV Member States in the 1991 Convention was never to restrict innovation but to prevent plagiarism.

NBTs allow breeders to obtain new varieties without plagiarism. They are unique methods as regards the introduction of traits that do not exist in a species or would be impossible to produce via crossing and selection, or the correction of defects in hereditary information, which is tantamount to introducing a new essential characteristic.

The Convention does cover NBTs. However, if the 2022 Explanatory Notes are accepted, the 1991 Convention should be reformed, as I notified the UPOV in my letter of March 9, 2022, since they involve a material modification of Article 14(5). And it would be illicit to amend the Convention via some explanatory notes. It is one thing to explain it and another to amend it.

The Convention is still open to innovation

ROLE OF PLANT BREEDERS RIGHTS AND OTHER FORMS OF IP IN PROMOTING PLANT BREEDING

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THE POTENTIAL OF NEW BREEDING TECHNOLOGIES

Agriculture is a critical enabler of food security and global well-being and a key solution to mitigate climate change. A 2018 OECD report emphasizes that ***"[g]lobal agriculture faces the triple challenge of raising productivity while ensuring sustainability and improving resilience. To achieve these goals, innovation in the form of high-performing varieties is essential."*** [2]

Studies indicate that future yield gain will primarily be contributed by improved genetics.[3] Breeders face an increasing complexity of challenges from mitigating biotic and abiotic stresses, over resource use efficiency to improved quality. They need to combine all these properties in one variety. Especially climate-change challenges such as water use efficiency or drought resistance can usually only be met by complex traits.[4] The more complex the trait, the less likely the chance to establish it by conventional breeding in a reasonable time.[5] While variety development cycles have shortened over the last decades, conventional breeding is approaching a biological barrier and will likely remain a time and resource intensive process.

New Breeding Technologies (NBTs)[6] enable a substantial acceleration of breeding. NBTs – especially CRISPR/Cas-based processes – are technologies which enable targeted genetic changes with high efficiency.[7] The initial disclosure of CRISPR/Cas9 for targeted gene editing in 2012[8] – which was honored by a Nobel Price to Jennifer Doudna and Emmanuelle Charpentier in October 2020[9] – triggered an unprecedented innovation push. The NBT toolkit constantly expands. New techniques enable genetic changes without double-strand breaks such as – for example – "base editing"[10] and "prime Editing."[11] The applications in plants extend from the exchange of "single letters" to ***"shifting entire racks of books in a library."***[12]

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[2] OECD (2018) Concentration in Seed Markets: Potential Effects and Policy Responses. OECD Publishing, Paris. doi: 10.1787/9789264308367-en. Available at: https://www.oecd-ilibrary.org/agriculture-and-food/concentration-in-seed-markets_9789264308367-en and https://seedinnovation.ca/wp-content/uploads/2019/01/OECD-Concentation-in-Seed-Markets.pdf, p. 16.

[3] Fernandez-Cornejo, J. (2004) The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development. USDA Agriculture Information Bulletin 786. Available at: https://www.ers.usda.gov/webdocs/publications/42517/13616_aib786_1_.pdf?v=41055.

[4] Moshelion, M. et al. (2015) Current challenges and future perspectives of plant and agricultural biotechnology. Trends Biotechnol. 33(6):337–342. doi: 10.1016/j.tibtech.2015.03.001. Available at: https://pubmed.ncbi.nlm.nih.gov/25842169/.

[5] In conventional breeding the transfer of a desired trait is associated with a large, often undesired genetic deviation from the initial variety that often comes with "penalties" such as yield drag. Especially for multi-allelic complex characteristics breeders have to screen thousands of off- spring with more than 95% being "waste." NBTs can specially establish the desired causative allelic variations and could crack complex breeding problems, where conventional breeding fails.

[6] The term NBT describes a diverse range of techniques for targeted changes to the endogenous DNA of a plant. For further information see New Breeding Techniques (NBT) Platform. Available at: https://www.nbtplatform.org/.

[7] Cao, H.X. et al. (2016) The Power of CRISPR-Cas9-Induced Genome Editing to Speed Up Plant Breeding. Int. J. Genomics 2016:5078796. doi: 10.1155/2016/5078796. Doudna, J.A., and Sternberg, S.H. (2017) A crack in creation: Gene editing and the unthinkable power to control evolution. Mariner Books, Houghton Miflin, New York, p. 281; Friedrichs, S. et al. (2019) Meeting report of the OECD conference on "Genome Editing: Applications in Agriculture—Implications for Health, Environment and Regulation." Transgenic Res. 28:419–463. doi: 10.1007/s11248-019-00154-1; European Academies' Science Advisory Council (EASAC) (2015) New breeding techniques. Available at: https://easac.eu/publications/details/new- breeding-techniques/. European Parliamentary Research Service (EPRS) (2019) New plant-breeding techniques: Applicability of EU GMO rules. Available at: https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/642235/EPRS_BRI(2019)642235_EN.pdf. Madre, Y. et al. (2017) New Plant-Breeding Techniques: What Are We Talking About? Farm Europe. Available at: https://www.farm-europe.eu/travaux/new-plant-breeding- techniques-what-are-we-talking-about/.

[8] Jinek, M. et al. (2012). A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity. Science 337(6096):816–821. doi: 10.1126/science.1225829.

[9] See the Royal Swedish Academy of Sciences (2020) Press release: The Nobel Prize in Chemistry 2020. Available at: https://www.nobelprize.org/prizes/chemistry/2020/press-release/.

[10] Rees, H.A., and Liu, D.R. (2018) Base editing: precision chemistry on the genome and transcriptome of living cells. Nat Rev Genet. 19(12):770–788. doi: 10.1038/s41576-018-0059-1.

[11] See https://en.wikipedia.org/wiki/Prime_editing.

[12] Capdeville, N. et al. (2020) Sophisticated CRISPR/Cas tools for fine-tuning plant performance. J. Plant Physiol. doi: 10.1016/j.jplph.2020.153332; Rönspies, M. (2020) CRISPR/Cas-mediated chromosome engineering: opening up a new avenue for plant breeding. J Experimental Botany. doi:10.1093/jxb/eraa463; Science Industry (2020) POINT Newsletter- Aktuelles zur grünen Biotechnologie. No. 222 (December 2020). Available at: https://www.scienceindustries.ch/_file/27952/point-2020-12-222-d.pdf.

NBT-made plants are not "GMO 2.0." NBTs enable complex breeding targets – such as climate resilience or water use efficiency – by facilitating "multiplexing"[13] of several target sequences in parallel in shorter time and at lower costs. For rice the editing of eight targets in parallel has been described.[14] In addition, NBTs enable efficient "breeding-by-editing" in vegetatively propagated and/or long life-cycle crops where conventional breeding is extremely cumbersome or even impossible. It also allows the creation of new allelic diversity in targeting genetic regions that are not susceptible to biological recombination. Thus, NBTs enable: (1) faster development; (2) shorter variety life-cycles; (3) lower costs; (4) expansion into more crops and regions; and (5) uncoupling of genotype-phenotype correlations. In that, NBTs can "democratize" plant biotechnology and re-invigorate competition in a field where recently only a handful of large corporations were able to play. A high adaptation rate of NBTs is likely and some NBT-derived varieties are approved for market launch15 and in some countries are already on the market.[16] As of 2020, examples include "fungus-resistant wheat, rice, banana, and cacao; drought-tolerant rice, maize, and soybean; bacterial- resistant rice and banana; salt-tolerant rice; and virus-resistant cassava and banana."[17]

THE NEED FOR BALANCED IP PROTECTION

Plant varieties are high-tech products in an easy-to-copy form[18] and require effective intellectual property protection to prevent market failure. However, more IP does not necessarily encourage more innovation.[19] It is generally undisputed that the dependency of the incentive for innovation on "IP strength» follows a bell-curve shape[20]: The broader the exclusive right for the first inventor, the stronger the incentive to make such inventions. On the other hand, the broader the exclusive right for the first inventor, the lower the incentive for follow-on inventions.[21] In other words, a weak IP system hampers initial innovations while an overly strong system stifles continuous improvement.

Plant varieties are a unique type of innovation as they are always an improvement: a new plant variety is not created in a vacuum but is always based on and/or derived from an earlier variety. While existing beneficial characteristics are retained, new characteristics are constantly added. Therefore, balancing protection and access to plant germplasm for further improvement is essential, likely more than in any other innovation area. This creates a potential dilemma for legislators: From a socioeconomic perspective, the protection of existing innovation becomes meaningless, if future innovations get stifled. Achieving this balance is a challenge and "it is extremely difficult if not impossible to determine an optimal level of protection for achieving an optimal balance of resources for inventive activities."[22] The need for such balance is explicitly recognized in the UPOV Convention by the breeder's exemption, which is deemed "a cornerstone of the UPOV Convention"[23] as "access to germplasm to provide the initial source of variation in breeding programs … deemed essential from the outset."[24] To accelerate the improvement of plant variety performance, the legislator deliberately chose to enable breeding with protected varieties and the commercialization of the resulting varieties. If breeders would have to wait until the expiration of the PBR right to utilize it for further breeding (i.e., at least 20 years), breeding progress would be substantially delayed.

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[13] *Nuccio, M.L. et al. (2021) CRISPR-Cas technology in corn: a new key to unlock genetic knowledge and create novel products. Mol Breeding 41:11. doi: 10.1007/s11032-021-01200-9.*

[14] *Wang, M.G. et al. (2017) Multiplex Gene Editing in Rice Using the CRISPR-Cpf1 System. Molecular Plant 10(7):1011–1013. doi: 10.1016/j.molp.2017.03.001. Wolter, F. et al. (2019) Plant breeding at the speed of light: the power of CRISPR/Cas to generate directed genetic diversity at multiple sites. BMC Plant Biol. 19:176. doi: 10.1186/s12870-019-1775-1. Available at: https://bmcplantbiol.biomedcentral.com/track/pdf/10.1186/s12870-019-1775-1.pdf.*

[15] *For an overview of new NBT-derived products see: https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-states-crops-food/. Gelinsky, E. (2020) Neue gentechnische Verfahren: Kommerzialisierungspipeline im Bereich Pflanzenzüchtung und Lizenzvereinbarungen. Studie im Auftrag des BAFU. Available at: https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien- berichte/endbericht-semnar-gelinsky.pdf.download.pdf/endbericht-semnar-gelinsky.pdf.*

[16] *Nonaka, S. et al. (2017) Efficient increase of γ-aminobutyric acid (GABA) content in tomato fruits by targeted mutagenesis. Sci. Rep. 7:7057; Pixley, K.V. (2022) Genome-edited crops for improved food security of smallholder farmers. Nat. Genet. 54:364–367, p. 364, reports that as of 2022, six genome-edited crop traits in soy, canola, rice, maize, mushroom and camelina have been approved for commercialization.*

[17] *Qaim, M. (2020) Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development. Applied Economic Perspectives and Policy 42(2):129–150.*

[18] *While making the first seed can be costly and laborious, the subsequent propagation is usually cheap and easy.*

[19] *Sanderson, J. (2013) Can intellectual property help feed the world? Intellectual property, the PLUMPYFIELD network and a sociological imagination. In Lawson, C., and Sanderson, J. (eds.) The intellectual property and food project: From rewarding innovation and creation to feeding the world. Ashgate, Farnham, UK.*

[20] *Tabarrok, A. (2012) Patent Policy on the Back of a Napkin. Marginal Revolution, September 18, 2012. Available at: https://marginalrevolution.com/marginalrevolution/2012/09/patent-theory-on-the-back-of-a-napkin.html.*

[21] *Shavell, S. (2004) Foundations of Economic Analysis of Law. Harvard University Press, Cambridge, MA, p. 148.*

[22] *Dutfield, G. (2017) Intellectual property rights and the life sciences industries: A twentieth century history. Routledge, London, p. 304.*

[23] *Button, P. (2013) Opening Address at "The Development of the Provisions on Essentially Derived Varieties," Seminar on Essentially Derived Varieties. Geneva, Switzerland, October 22, 2013. UPOV Publication Nr. 358, 7.*

[24] *Clancy, M.S., and Moschini, G. (2017) Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture. Annual Review of Resource Economics 9:53–74, p. 63.*

THE BREEDERS IP TOOLKIT

Breeders – both those using conventional breeding and NBTs – are essentially using three types of IP rights to protect their innovations: patents, plant breeders' rights and trade secrets. These rights have different prerequisites, different scopes and are designed to protect different types of innovation. Thus, they are less alternatives but rather complementary.

Patents provide a strong IP right with limited exemptions and are usually well enforceable. However, there are county-by-country differences, especially when it comes to the patentability of plants. The TRIPS Agreement provides substantial flexibility to countries on how to provide IP protection for plants.[25] Few countries – such as the United States of America – allow for claims on plants without limitations, others – such as the European Patent Convention – allows for claims on plants as long as the invention is not limited to a single variety. Most countries, however, deny any claim on plants.[26] In some countries that deny claims on plants, an indirect protection of certain plant-related inventions is possible through claims on "non-natural"[27] DNA sequences. Patents have a high threshold for being granted: the innovation needs to have absolute novelty, needs non-obviousness (inventiveness) and needs to meet the requirements for written description and enablement, which includes a reproducibility without undue burden. Patents have only a moderate allowance rate, which for plant related inventions is usually less than 60%. They come with lengthy examination times (for plant related inventions usually at least five years) and high costs, which could easily reach US$100,000 for one invention.

Patents are the IP tool of choice when it comes to plant innovations with a high investment and an innovation life cycle of at least ten years, such as new NBT processes; new traits defined by a specific sequence and plants comprising them; and variety-independent non-naturally occurring edits, namely, edits that can be identically created or introgressed in different varieties. Patents on traits are commonly licensed in the seed industry.

Plant Breeders' Rights (PBRs) and Plant Variety Protection (PVP) rights enjoy a larger international harmonization due to the framework established by the UPOV Convention(s).

The requirements for protection are adapted to the requirements of plant breeding and less onerous than for patents. Consequently, the allowance rate is high, costs are moderate and grants are relatively fast. On the other hand, PBR/PVPs have broader exemptions for breeders and farmers. The breeders' exemption reflects the fact that new varieties are usually derived from existing ones. Enforcement is more difficult, both against competing breeders and farmers, and especially when it comes to Essentially Derived Varieties (EDVs). The EDV provision of the UPOV 1991 Act not only suffers from a lack of clarity but also from the "coupling" of dependency and a limited scope of protection (discussed below, see "IP protection for plants obtained by multiplex editing").

PBR/PVPs are the IP tools of choice when it comes to new plant varieties including varieties that comprise complex, variety-specific edits, namely, breeding-like, multiplex edits, which cannot be identically created or introgressed into different varieties (discussed below, see "IP protection for plants obtained by multiplex editing"). PBR/PVPs are neither suitable nor designed to protect specific traits or sequences. PBR/PVPs are also licensed occasionally. Licensing to enable commercialization of EDVs is rare.

Trade secrets are also used by breeders, especially when it comes to parent lines of hybrid crops. While trade secrets could – in principle – be everlasting, they require substantial efforts to ensure secrecy and protection. In addition, trade secrets are difficult to license.

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[25] *Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPs). Available at: https://www.wto.org/english/docs_e/legal_e/27- trips.doc. The TRIPS Agreements provides a unique flexibility to members when it comes to plant related innovations. Article 27(3)(b) provides "3. Members may also exclude from patentability: ... (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."*

[26] *WIPO (2015) Intellectual property for agri-food small and medium enterprises. WIPO, Geneva, Switzerland, Chapter 3.5.6 (p. 180-194). Available at: https://www.accio.gencat.cat/web/.content/bancconeixement/documents/3b23a509.pdf*

[27] *DNA sequences of naturally occurring genes and mutations are usually excluded from patentability, either by statute (e.g., as product-of- nature) or due to lack of novelty (inherency).*

Table 1. Overview – The Breeders' IP Toolkit.

Tool	Benefits/Strengths	Costs/Weaknesses	Suitable For
Patents	Strong, enforceable right Limited exemptions Can be licensed	Country-by-country differences: plants not patentable in many countries High threshold: non-obviousness, written description/enablement (reproducibility) Moderate allowance rate Lengthy examination, high costs	New processes New traits defined by specific sequence, plants comprising them Variety-independent edits Edits that can be identically created or introgressed in different varieties USA: specific varieties
Plant Breeders Rights (PBRs)	Larger international harmonization Moderate costs, fast grant High allowance rate Can be licensed	Difficult enforcement Breeders and farmer exemption No protection for specific traits or sequences (by design) EDV provision: clarity, coupling of dependency and limited scope of protection	New varieties Complex variety-specific edits (breeding-like) Multiplex edits that cannot be identically created or introgressed in different varieties
Trade Secrets	Could be everlasting	Requires efforts for secrecy Difficult to license	Parent lines of hybrid crops

IP PROTECTION FOR PLANTS OBTAINED BY MULTIPLEX EDITING

Complex traits such as yield or water use efficiency require editing of multiple endogenous genes (multiplex editing). The innovation is in the combination. Individual target genes have usually only small contributions and are often prior art. These approaches require editing directly in each target variety as introgression of multiplex edits by crossing is practically impossible. While CRISPR/Cas systems "cut" at a specially defined DNA site, the resulting edits vary slightly by a few nucleotides. While the edited sequence for a single target gene can be replicated in another variety with reasonable probability, a combination of multiple edits will be unique in each target variety. Here patents do not provide a reliable global strategy for at least the following reasons:

1. Plants are not patentable as such in many countries.
2. DNA claims are suitable for single man-made edits but not for multiple edits that are combined in a plant cell and only in the combination provide the invention.
3. Even if plants are in principle patentable, statutory requirements – especially written description/enablement – and/or prior art will often limit the claims to the specific edited sequences. As these vary from variety to variety the claims will often be limited to single varieties. These are not only excluded from patentability in most legislations. The publication of the patent on the first edited variety may make subsequent patents on different varieties with similar edits impossible as those would be considered obvious.
4. Method claims usually only extend to the direct product but not to progenies. In consequence, in most countries the "derived composition protection" resulting from a claim on a method does not provide meaningful protection in the field of plants.

In consequence, PBR/PVP can be the only practical way to protect varieties with multiplex edits. PBR/PVP would also be effective, as crossing the edits into other lines could be quite cumbersome. In consequence, PBR/PVP are – in principle – the IPR of choice for multiplex varieties, which may revert the trend of breeders' to use more and more the patent system and re-invigorate the importance of PBR/PVP for breeders.

However, if NBT-derived varieties are always EDVs in view of their mono-parental derivation, as suggest by the Draft EXN/EDV (discussed below, see "UPOV Convention, EDV concept, and the Draft Explanatory Notes on EDVs"), they will suffer from reduced PBR protection, as there is no EDV from an EDV28: while the NBT-derived variety can be protected by PBR/PVP, every somaclonal variation would fall outside the PBR's scope (see Figure 1).

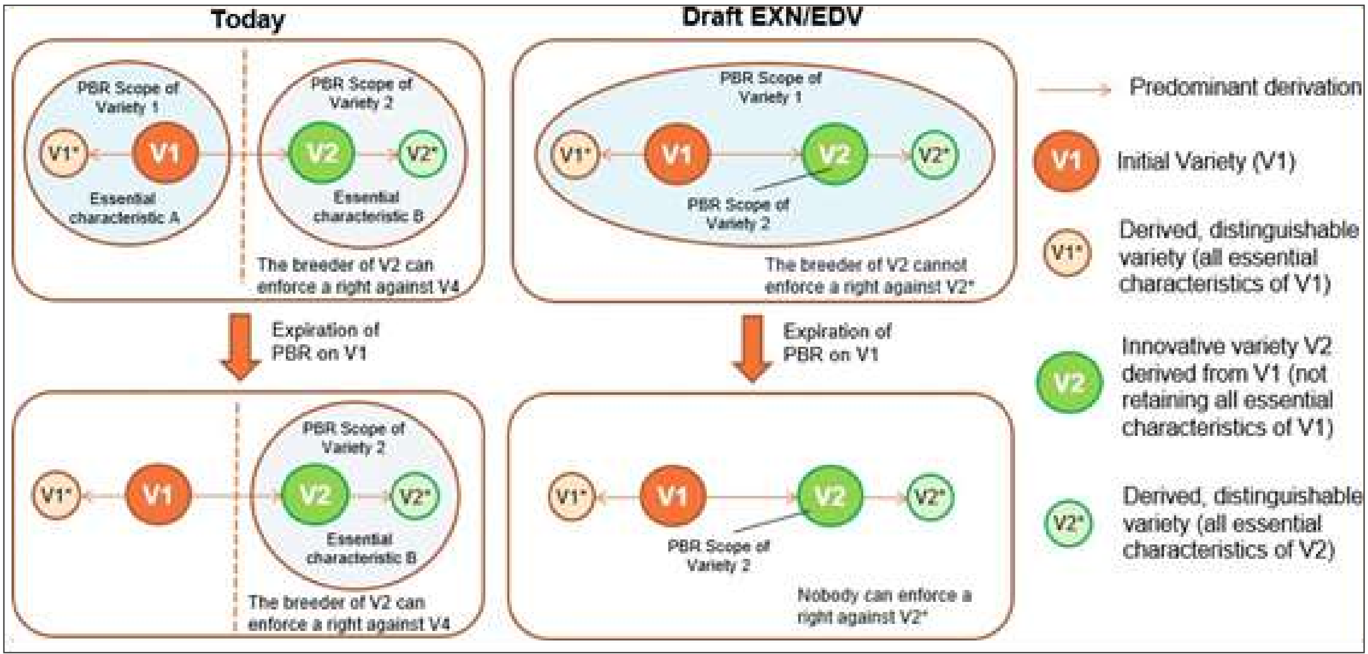

Figure 1. The consequences of a revised EDV definition.

V1 is the initial variety and V2 an innovative, clearly distinguishable variety, which is obtained by genome editing of V1 but does not retain all the essential characteristics of V1. Both V1 and V2 have further predominantly derived varieties V1 and V2*, which are also distinguishable but retain all essential characteristics of V1 or V2, respectively. The situation today is described on the left-hand side: today, V1 and V2 are considered independent varieties. Each has its own full scope of PBR. The breeder of V1 can enforce his rights against V1*. And the breeder of V2 can enforce his right against V2*. This would also be the case once the PBR for V1 expires. The change prosed in the Draft Explanatory Notes is described on the right-hand side and is quite substantial: the PBR scope of variety V1 would cover V1, V1*, V2 and V2*. The breeder of V2 cannot enforce any right against V2*. This would not change once the PBR for V2 expires. Once an EDV, always an EDV. In consequence, nobody can enforce a right against the commercial use of V2* once the protection of V1 expires. This would fundamentally undermine value capture for V2.*

Relying on the initial variety's PBR is not an alternative: it will not provide the breeder of the NBT-derived variety a right to enforce or collect a fair compensation. In addition, the protection term is still the term of the initial variety's PBR and will only cover the NBT-derived variety for a limited time. The situation would be worse, if the NBT-using breeders was forced to use genetics where the PBR has already expired: while the use of the inferior genetics would substantially reduce the benefits of the NBT-derived improvement, the diminished scope of protection does not change. An EDV does not change its status and become an original variety once the PBR of the initial variety expires. Once an EDV, always an EDV.

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[28] UPOV 1991 (below n 29), Article 15(5)(a)(i) "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[.]

UPOV CONVENTION, EDV CONCEPT, AND THE DRAFT EXPLANATORY NOTES ON EDVS

The EDV concept is laid out in Article 14(5)(a)(i), (b) and (c) ("Scope of the Breeder's Right") and Article 15(1)(iii) ("Exceptions to the Breeders' Right") of the UPOV 1991 Act.[29] It intends to balance the freedom to use protected varieties for breeding and the freedom to commercialize resulting varieties if the new variety has been changed only slightly in a few unimportant characteristics.[30] The EDV concept has a twofold effect: it is at the same time an extension of the scope of the PBR and a limitation to the breeders' exemption.

The "dependence" of a derived variety only exists if certain requirements for the initial variety (IV)[31] and the derived variety[32] are met. Debated is the requirement that the derived variety "conforms essentially to the IV in the expression of the characteristics that result from the genotype or combination of genotypes." So far, this provision has been interpreted as that the EDV must retain almost the totality of the genotype of the initial variety and be different from that IV by a very limited number – one or a very few –characteristics.[33]

NBTs raised the concern, that competing breeders may "circumvent" PBRs.[34] Therefore, UPOV opened up its explanatory note on EDV.[35] The Preliminary Draft Text for the Revision of the Explanatory Notes on Essentially Derived Varieties of September 2, 2021[36] ("Draft EXN/EDV") suggests that for mono-parental varieties "all differences are excluded from consideration of the EDV status"[37] and "[d]ifferences resulting from act(s) of derivation are disregarded for the purpose of determining the EDV status of a variety."[38] Importantly, such differences "may … include essential characteristics."[39] With that, the requirement that an EDV "retains expression of the essential characteristics" of the initial variety is simply abandoned.[40]

This would mean that Article 14(5)(b)(iii) overrules the requirement of Article 14(5)(b)(i). Further, the Draft EXN/EDV reinterprets Article14(5)(c): the clarification that the example technologies – such as mutagenesis – "may" lead to an EDV is deleted and the non-limiting character of the list of examples is emphasized and extended to genome editing.

In consequence, the Draft EXN/EDV propose a significant change to the definition of EDVs as now genetic similarity becomes the sole criteria for an EDV – at least for mono-parental varieties. Thus, an NBT-derived variety would always be an EDV irrespective of the changes to the essential characteristics and of its added value. This appears difficult to reconcile with the UPOV 1991 Act and its legislative history. The prevailing view is that the requirements (i) to (iii) of Article 14(5)(b) are cumulative, namely, one does not overrule another.[41]

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[29] International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991 (UPOV 1991). Available at: https://www.upov.int/edocs/pubdocs/en/upov_pub_221.pdf.

[30] Würtenberger, G. (2017) Protection of plant innovations. In Zech, H., and Matthews, D. (eds.) Research Handbook on Intellectual Property and the Life Sciences. Edward Elgar, Cheltenham, pp. 121, 128.

[31] An IV (a) must be protected (Article 14(5)(a)(i)) and (b) cannot itself be an EDV (Article 14(5)(a)(i)). Thus, dependence can only exist from one protected IV (Article14(5)(b)).

[32] An EDV (a) must retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the IV (Article 14(5)(b)(i)); (b) must be predominant derived from the IV (Article 14(5)(b)(i)); (c) must show clear distinctness in the sense of the UPOV Convention (Article 14(5)(b)(ii)); and (d) except for the differences, which result from the act of derivation, the EDV must show conformity to the IV in the expression of the essential characteristics that result from the genotype or combination of genotypes of the IV (Article 14(5)(b)(iii)).

[33] UPOV, Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention (UPOV/EXN/EDV/2), adopted by the Council at its 34th extraordinary session on April 6, 2017 ("EXN/EDV 2017"). Available at: https://www.upov.int/edocs/expndocs/en/upov_exn_edv.pdf, paras 10, 11.

[34] See Astée Fowers B.V. v. Danziger Flower Farm (July 13, 2005, District Court of The Hague), CPVO database on PVR case law. Available at: https://cpvoextranet.cpvo.europa.eu/PVRCaseLaw. The court held that the (morphological) differences found by the CPVO between the initial and the allegedly derived variety were so substantial in number and significance that they did not just represent one or few differences, as required for an EDV – despite a test result showing high genetic similarity.

[35] "Acknowledging that the previous guidance does not reflect the practice amongst breeders in the understanding of EDV and that the evolution of breeding techniques has created new opportunities and incentives for predominantly deriving varieties." UPOV Administrative and Legal Committee (2019) Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy. October 30, 2019. Report CAJ/76/9. Available at: https://www.upov.int/edocs/mdocs/upov/en/caj_76/caj_76_9.pdf, no. 11.

[36] UPOV Doc. UPOV/EXN/EDV/3 Draft 2 (September 3, 2021). DRAFT (Revision) – EXPLANATORY NOTES ON ESSENTIALLY DERIVED VARIETIES UNDER THE 1991 ACT Of the UPOV CONVENTION. Available at: https://www.upov.int/edocs/mdocs/upov/en/wg_edv_4/upov_exn_edv_3_draft_2.pdf.

[37] Ibid., nos. 5 and 14

[38] Ibid., no. 14.

[39] Ibid., no. 13.

[40] Ibid., especially figs. 1–5.

[41] See UPOV (1992) Sixth Meeting with International Organizations. August 17, 1992. UPOV Doc. IOM/6/2. Available at: https://www.upov.int/edocs/mdocs/upov/en/upov_iom_vi/upov_iom_vi_2.pdf, no. 12. The legislative history shows that "[t]he 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 the words of subparagraph (i). 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'. […]. The examples of essential derivation given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few."

The interaction of (i) to (iii) of Article 14(5)(b) is interpreted in that the "excepted differences" do not relate to essential characteristics but to other characteristics, namely, those which are not fundamental but rather "cosmetic."[42] According to the legislative history this also applies to mutants.[43] It is emphasized "that the fact that not every mutant automatically leads to an EDV should be more clearly expressed. The derived variety must also be within the determined thresholds."[44] In consequence, "mutations are related to the EDV concept, but not all mutants are EDVs. We should not discourage plant breeders in general or plant breeding by mutations, especially for certain species and even this might lead to innovative plant breeding."[45]

Even if one considers the Draft EXN/EDV as a "dynamic interpretation," such an interpretation cannot go against the fundamental principles of the Convention. To disregard the phenotype in the assessment of an EDV status ignores fundamental principles of breeding and would transform UPOV from an open-innovation framework to an anti-innovation copyright for plant genetics. This "would significantly undermine the breeder's exemption in the case of mono-parental varieties"[46] and thereby effect "a cornerstone of the UPOV Convention."[47]

Breeding innovation is always measured by phenotype improvement. The number of causative genetic changes (i.e., the changes which are functionally causing the phenotype change) is usually very small. All additional changes are a side-effect of the breeding process.

They are, however, not indicative for breeding progress and often undesired. Thus, using genetic distance as the predominant or sole criteria to assess dependency would also be in conflict with the legislative intent to foster breeding innovation. The text of the UPOV Convention does not assign any specific role to genetic conformity in the assessment of EDVs. To the contrary, the 1991 Diplomatic Conference specifically amended the Basic Proposal for Article 14(2)(b)(iii) from "it conforms to the genotype or the combination of genotypes of the initial variety"[48] to "conformity with the expression of the genotype."[49] It was considered that "when one had to define whether a variety was an essentially derived variety, one would look at the characteristics that were the expression of the genotype of the initial variety and check whether those characteristics were also expressed in the derived variety."50 Thus, the genotype only comes into play as the basis for the phenotype. One should "measure what you treasure": as the UPOV Convention is aimed at promoting phenotype improvement, it needs to base not only the criteria for protection on the phenotype but also the criteria for dependence (i.e., the EDV concept). The general classification of NBT-derived varieties as EDV is inconsistent with the UPOV Convention, which is agnostic to the method of breeding, and contrary to the 1991 Diplomatic Conference where it was "clearly stated that the definition of the essential derivation could not be based on the breeding method."[51]

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[42] This is in line with the requirement that an EDV must retain the essential characteristics of the IV and is further supported by the EDX/EDV 2017 interpretation of the examples provided in Article 14(5)(c): "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)." EDX/EDV 2017, above n 33, no. 10.

[43] See UPOV Doc. IOM/6/2, above n 41, Annex; Example 6. "Whether the mutation is naturally or artificially induced is irrelevant." "The complexity of the genetic change may, however, result in a mutation that no longer retains the expression of the essential characteristics that result from the genotype of variety A. In this case variety B would not be essentially derived from variety A." Example 5: "Whether a variety based upon a particular variant will be essentially derived will depend upon whether it retains the essential characteristics resulting from the genotype of variety A [...] If the selected difference is very large it will be less likely that the variant will so retain such essential characteristics. A variety based on such a variant will thus be less likely to be essentially derived from variety A."

[44] UPOV (1992) Sechste Sitzung mit Internationalen Organisationen. October 30, 1992. UPOV Doc. IOM/6/5. German original available at: https://www.upov.int/edocs/mdocs/upov/de/upov_iom_vi/upov_iom_vi_5.pdf; partial English translation in UPOV Doc. CAJ-AG/12/7/3, Annex II. Available at: https://www.upov.int/edocs/mdocs/upov/en/caj_ag_13_8/caj_ag_12_7_3_annex_ii.pdf, No. 8.

[45] Brand, R. (2013) UPOV Seminar, "The Development of the Provisions on Essentially Derived Varieties." Geneva, Switzerland, October 22, 2013. Available at: https://www.upov.int/meetings/en/details.jsp?meeting_id=29782; report available at: https://www.upov.int/edocs/pubdocs/en/upov_pub_358.pdf, p. 45

[46] MacDonald, H., and Sherman, B. (2022) Essentially derived varieties and the Plant Breeder's Rights Act 1994, pp. 15, 16. Available at: https://espace.library.uq.edu.au/view/UQ:a1d3b39/UQa1d3b39_OA.pdf.

[47] Button, P. (2013) Opening Address at UPOV Seminar "The Development of the Provisions on Essentially Derived Varieties." Geneva, Switzerland, October 22, 2013. UPOV Publication Nr. 358, 7.

[48] Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, Geneva, 1991 (Records of the Diplomatic Conference 1991), [1077]. Available at: https://www.upov.int/edocs/pubdocs/en/upov_pub_346.pdf, p. 30.

[49] Ibid., [1099], p. 344 (emphasis added).

[50] Ibid., [1101], p. 345 (emphasis added).

[51] Guiard, J. (2013) UPOV Seminar "The Development of the Provisions on Essentially Derived Varieties." Geneva, Switzerland, October 22, 2013. UPOV Publication Nr. 358, 11. See, e.g., the comment from the Delegation of Germany regarding the examples of methods that now appear in Article 14(5)(c) of the UPOV Convention: "[t]he whole formulation was defective since it rested on methods and not on the result." See Records of the Diplomatic Conference, above n 48, [1077].

NBTs enable targeted causative changes without undesired genetic deviation ("precision breeding"). If NBT-derived varieties would be EDVs irrespective of how significant the phenotype change, there would be a clear anti-innovation effect: an EDV is not simply a "dependent innovation" but is also sanctioned with limited PBR protection. There is no EDV of an EDV. This applies even if the PBR on initial variety expires. In consequence, the PBR of an NBT-derived variety would be easy to circumvent. The fact that the legislator in the UPOV 1991 Act "coupled" dependency with a reduced scope of protection shows that the EDV concept was not supposed to cover innovative varieties but only me-too varieties which were deemed not worthy of full protection. If there would have been an intent to cover true innovations, dependency and scope of protection would not have been coupled and multiple dependencies would have been enabled as is the case in the patent system for dependent improvement inventions.

As the reduced PBR protection could undermine the business case, NBT users – in contrast to conventional breeders – would be strongly dissuaded from using PBR protected elite germplasm. This would not only slow the overall rate of varietal improvement but also create a competitive disadvantage that can hardly be justified and which would remain even if the initial variety is accessed under a license agreement. To "force" breeders to build in unnecessary crossing steps to avoid an EDV status, would have an anti-innovation effect as it would delay variety development or might even be impossible for species that are strictly vegetatively propagated.

In adapting the Draft EXN/EDV, and if that would have a binding legal effect,[52] UPOV would deliberately choose to support IPR solely for breeders using conventional crossing and selection but stop providing the incentive of a fair and balanced framework to breeders using modern NBTs.

Not only is there no basis in UPOV for such discrimination,[53] it would also make UPOV a system of the past. De facto such situation would limit the benefits on NBTs to owners of large germplasm collections, specifically, large companies, who would apply NBTs to their own elite genetics. This "would result in more control to the owners of existing commercial varieties" and "benefits larger organizations, who are more likely to have established genetic material and the resources needed to develop costly long-term crossbreeding programs."[54]

One should also consider the risk of unintended consequences: if genetic conformity becomes the sole criteria for an EDV, it is difficult to argue why this should only apply to mono-parental varieties. As there is no basis in the UPOV EDV concept to distinguish between mono-parental and other varieties, it is unavoidable that also the EDV status of varieties obtained by crossing and selection will be solely determined based on their genetic conformity to the initial variety. Changes to the phenotype will be disregarded as they are eventually also the result of the act of derivation (i.e., crossing and selection). Especially for crops with a limited genetic variation (<5%) – such as cotton, lettuce or rapeseed – this would cause substantial legal uncertainty.[55]

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[52] UPOV explanatory notes explicitly do not have a legally binding effect. However, they are often used by judges as guidelines. While a judge should usually ignore an explanatory note that contradicts the wording of the UPOV Act, such explanatory notes could still create confusion and legal uncertainty, especially with judges who are less experienced with PBRs.

[53] Comments of Spain to Paragraph 14 in UPOV Doc. UPOV/EXN/EDV/3 Draft 2 (September 3, 2021). Comments from Spain to the Draft EXN "By this definition, only classic plant-breeding technologies would be taken into account. All available technologies are needed to meet the enormous challenges facing agriculture. Breeders cannot and should not be penalized for using the new technologies available to them. Let us recall the mission of UPOV, as set forth on its website: 'To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.' The system must, therefore, promote the development of new varieties to meet the challenges facing society by encouraging new plant breeders with new techniques and ensuring that they may, in turn, take advantage of the UPOV system to make their varieties available to farmers." Available at: https://www.upov.int/edocs/mdocs/upov/en/wg_edv_4/upov_exn_edv_3_draft_2.pdf.

[54] MacDonald and Sherman, above n 46, p. 16.

[55] See also Sanderson, J. (2017) Examining and Identifying Essentially Derived Varieties: The Place of Science, Law and Cooperation. In Plants, People and Practices: The Nature and History of the UPOV Convention, Cambridge University Press, Cambridge, who in the context of the high genetic similarity of cotton notes: "Where this occur, it is extremely difficult to establish reliable standard thresholds from which to assess essential derivation" (pp. 220–221).

TOWARD A BALANCED APPROACH

The critical question is: can we avoid an erosion of PBR rights for initial varieties without diminishing the scope of protection for innovative NBT-derived varieties? Such erosion is not in the interest of breeders using NBTs, as otherwise their own varieties would be vulnerable to me-too approaches. Four criteria seem to be relevant to decide whether a variety is an EDV:

1. **Clearly distinguishable:** Article 14(5)(b)(ii) requires that an EDV "is clearly distinguishable from the initial variety." If the derived variety is not distinguishable it will not be considered a separate variety and will be directly covered by the PBR on the initial variety.
2. **Predominantly derived:** Article 14(5)(b)(i) requires that an EDV "is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety." Genetic similarity is a necessary but not a sufficient indicator for predominant derivation, which requires a factual enquiry into whether a variety materially originated from the initial variety. The breeding history as evidenced by the breeder's book is usually a proper evidence to prove genetic origin. If there is no predominant derivation, there is no EDV (irrespective of the genetic similarity).
3. **Retaining the essential characteristics:** Article 14(5)(b)(i) requires that an EDV is "retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety." The emphasis on the genotype of the initial variety suggests that a change to an essential characteristic requires a change to at least one endogenous gene of the initial variety, either in quantity (i.e., the level of expression) or quality (i.e., structure and function of the gene product). In consequence, the result of a genetic transformation (e.g., with a construct expressing an insect- resistance mediating BT gene) would not change the essential characteristics of the initial variety because there is no change to the expression of an endogenous gene. The absence of a genetically determined characteristics should not be seen as an essential characteristic and, in consequence, an added characteristics should not be deemed to change the genetically determined essential characteristics of the initial variety. In contrast, if a disease resistance is achieved by modifying a disease-susceptible allele into a disease-resistant allele, an endogenous gene and thereby also an essential characteristic (disease susceptibility) is changed.
4. **Added value:** The records of the 1991 Diplomatic Conference show that "[t]he main [drafting] problem involved the need to express the meaning of 'essentially derived variety' in such a way that it was the expression of the essential characteristics of the initial variety and the retention of that expression that was important."[56] An "essential characteristics" differs from the DUS characteristics used to establish distinctness and comprises a notion of quality and value. As the Records of the 1991 Diplomatic Conference show, in the UPOV 1991 Act the adjectives "essential," "important" and "relevant" are used interchangeably and should be regarded as synonyms.[57] In the meetings with international organizations it was emphasized that "The essential characteristics are those which are 'indispensable' or 'fundamental' to the variety."[58] It is expressed, that "for determining the characteristics of a variety, which are essential" the economic purpose of the variety needs to be considered. A characteristic that is not relevant for the economic purpose should – in general – not be considered as an essential characteristic."[59] Sanderson argues that "important" is to be understood as "agronomically important" as opposed to the traditional UPOV interpretation "important to show difference."[60] Cultural and practical values are also important in examining and identifying EDVs.[61] In this context the Value for Cultivation and Use (VCU) characteristics of a variety could play an important role.[62]

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[56] Records of the Diplomatic Conference 1991, above n 48, [1852.4(iii)] (emphasis added).

[57] Records of the Diplomatic Conference 1991, above n 48, under nos. 518, 519. "there was no significant difference between 'important' and 'essential'."

[58] UPOV (1992) Sixth Meeting with International Organizations. August 17, 1992. UPOV Doc. IOM/6/2. Available at: https://www.upov.int/edocs/mdocs/upov/en/upov_iom_vi/upov_iom_vi_2.pdf, No. 9.

[59] UPOV (1992) Sechste Sitzung mit Internationalen Organisationen. October 30, 1992. UPOV Doc. IOM/6/5. German original available at: https://www.upov.int/edocs/mdocs/upov/de/upov_iom_vi/upov_iom_vi_5.pdf; partial English translation in UPOV Doc. CAJ-AG/12/7/3, Annex II. Available at: https://www.upov.int/edocs/mdocs/upov/en/caj_ag_13_8/caj_ag_12_7_3_annex_ii.pdf, no. 7.

[60] Sanderson, above n. 55, p. 215.

[61] Manno, R. (2019) White Paper of Essentially Derived Varieties. WebLegal, February 20, 2019, no. 48. Available at: https://www.weblegal.it/wp- content/uploads/2019/03/WL-white-paper-on-EDV.pdf; Sanderson, n. 55, 230.

[62] VCU characteristics are those which determine the value for cultivation and use of a verity, which is required for the market authorization of field crops in some countries, e.g., the European Union. VCU requires "a clear improvement either for cultivation in general or for the specific uses which can be made of the crops or the products derived therefrom." See Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL On the production and making available on the market of plant reproductive material (plant reproductive material law) / COM/2013/0262 final - 2013/0137 (COD) * final - 2013/0137 (COD); Article 58*

> Also, the UPOV Explanatory Notes on EDVs from 2017 ("EXN/EDV 2017")[63] explain that essential characteristics are those heritable traits that "contribute to the principal features, performance or value of the variety, are important from the perspective of the producer, seller, supplier, buyer, recipient, or user, are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics. These may or may not be phenotypic characteristics used for the examination of distinctness, uniformity and stability (DUS)."[64] The EXN/EDV 2017 further describes that also negative characteristics can be essential characteristics such as a susceptibility to disease.[65] This notion is important, as it can hardly be the intent that only varieties which have lost valuable characteristics and are inferior are outside of the EDV extension and can be marketed. To the contrary, the derived variety must show an added value to qualify as a non-EDV.

The Australian Plant Breeders Act 1994[66] determines that a derived variety is not considered an EDV if it provides an "important (as distinct from cosmetic) feature."[67] "Important" means that differences between the initial variety and the putative EDV need to be "of great significance or value," which suggests functional considerations, such as performance and/or market value.[68]

The critical point is the appropriate threshold for the added value conferred by the new characteristic of the derived variety. Defining a threshold that is neither too low nor to high is essential for a fair and balanced approach, which prevents easy workarounds but still provides full PBR protection for true breeding innovations. It appears, that a lack of alignment on the appropriate standard is the root cause of the ambiguity and the current debate. Without clarifying this point, a balanced solutions cannot be achieved.

To utilize added value as a criterium for freedom-to-operate is actually not new to the world of IP: when it comes to the right to commercialize a dependent patentable invention under a compulsory cross-license, the TRIPS Agreement in Article 31(l)(i) requires an "important technical advance of considerable economic significance." While the term needs to be interpreted for PBRs and improved varieties, it could provide a starting point for defining an appropriate threshold for added value, which should however consider not only the economic significance but also the ecological and sustainability significance. In the context of patent-related innovations Ullrich writes that the requirement for "an important technical advance" means that "the invention must constitute more than a routine elaboration on or extension of the inventive concept underlying the prior patent, and instead be a technically superior achievement that adds a new dimension to the prior patent in terms of inventiveness, technical feasibility or functionality."[69] Ullrich also emphasizes that "[t]he two criteria [i.e., considerable economic significance and technical advance] are meant to be cumulative, are categorically incommensurable and not naturally interdependent, the former relating to the economic impact, the latter to the level of inventiveness of the 'dependent' invention."[70] Thus, there needs to be a technical advance and an economic added value resulting therefrom. For plant varieties the added value should go beyond mere economic considerations and factor in ecological and sustainability elements.

Additional considerations or criteria are not suitable in the decision-making process. It should not matter whether the changed characteristic is a positive or negative trait (e.g., disease susceptibility). To require removal of positive characteristics would limit the freedom-to-operate to inferior varieties, which would not be aligned with the pro-

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[63] *EDX/EDV 2017, above n 33.*

[64] *EDX/EDV 2017, above n 33, no. 6 (i)–(iv)*

[65] *EDX/EDV 2017, above n 33, no. 6(v)*

[66] *Australia – Plant Breeder's Rights Act 1994 (No. 110, 1994) Registered March 1, 2019. Section 4 "A plant variety is an essentially derived variety of another plant variety if: (a) it is predominantly derived from that other plant variety; and (b) it retains the essential characteristics that result from the genotype or combination of genotypes of that other variety; and (c) it does not exhibit any important (as distinct from cosmetic) features that differentiate it from that other variety." Available at: https://www.legislation.gov.au/Details/C2019C00089.*

[67] *IP Australia (2016) Issues paper, A review of enforcement of plant breeder's rights. Advisory Council on Intellectual Property. 2007, updated 2016. Available at: https://www.ipaustralia.gov.au/about-us/public-consultations/archive-ip-reviews/ip-reviews/issues-enforcement-pbr. Waterhouse, D. (2013) Experience on Essentially Derived Varieties in Australia, 2. Available at: https://www.upov.int/edocs/mdocs/upov/en/upov_sem_ge_13/upov_sem_ge_13_ppt_9.pdf.*

[68] *IP Australia (2019) Essentially Derived Varieties. Available at: https://www.ipaustralia.gov.au/plant-breeders-rights/understanding-pbr/pbr- detail/essentially-derived-varieties. Expert Panel on Breeding (2002) Clarification of plant breeding issues under the Plant Breeder's Rights Act 1994, p. 21; Australia: https://www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf.*

[69] *Ullrich, H. (2023) Patent Dependency Under European and European Union Patent Law – A Regulatory Gap. Max Planck Institute for Innovation & Competition Research Paper No. 23–04. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4339426, p. 19.*

[70] *Ibid., p. 21.*

innovation concept of UPOV. It should also not matter whether the changed essential characteristic is specific to the initial variety or present in all varieties of the specie. A limitation to specific characteristics would rule out fundamentally new valuable characteristics.[71] It should not matter whether the change is "new" and "inventive" in the meaning of the patent law as there is no basis in UPOV for such a differentiation. However, certain considerations in the context of the evaluation of the "important technical advance" might be possible. Also the number or complexity of the genetic changes should not matter since simple changes can have a fundamental impact too. UPOV should reward changes to the phenotype, not the genotype, namely, the outcome not the efforts. Finally, it should not matter whether the change could have been obtained by classical breeding. The EDV evaluation has to be agnostic of the technology used.

While a UPOV working group should be able to develop criteria for the assessment of an added value, in practice a case-by-case consideration by judges or PVP offices is not only unavoidable but also appropriate. While a case-by-case evaluation would create some ambiguity, it needs to be kept in mind that a clear bright line with high legal certainty is often the opposite of a fair and balanced solution. When it comes to the interpretation of patent claims legislators deliberately avoid a bright line as it would not do justice to the reality and result in an unbalanced or unfair outcome.[72] The same should apply for the EDV concept.[73]

SUMMARY AND CONCLUSION

New Breeding Technologies are an essential tool for breeders. Breeders should be equally incentivized to use conventional breeding or NBTs and resulting varieties should enjoy full PBR protection. UPOV needs to provide a balanced protection for existing varieties and an incentive to create new varieties irrespective of the method of breeding. A phenotype-based case-by-case assessment of the economic and ecological added value of the derived variety is of critical importance to determine its EDV status. Guidelines for such assessment should be developed. To abandon the EXN/EDV 2017 and to have no explanatory notes on EDVs would increase legal uncertainty with detrimental effects on investment in breeding innovation. It would also conflict with the explicit request of the UPOV 1991 Diplomatic Conference to 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."[74]

If no agreement on guiding principle for added value can be found a revision of UPOV may be unavoidable. It would have to address at least Article 14(5)(i) and "uncouple" dependency and the limited scope of protection to enable multiple dependencies, and Article 17(i) to establish compulsory cross-licensing without public interest. The breeder's exemption has always been and must remain a central cornerstone.[75]

The author and Inari are grateful for the opportunity to contribute constructively to the discussions on EDVs. We are supportive of UPOV finding a balanced process that incentivizes all breeders.

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[71] In addition, even if the new derived variety deviates from all other varieties of the same species, it shows that a change in this characteristic is possible.

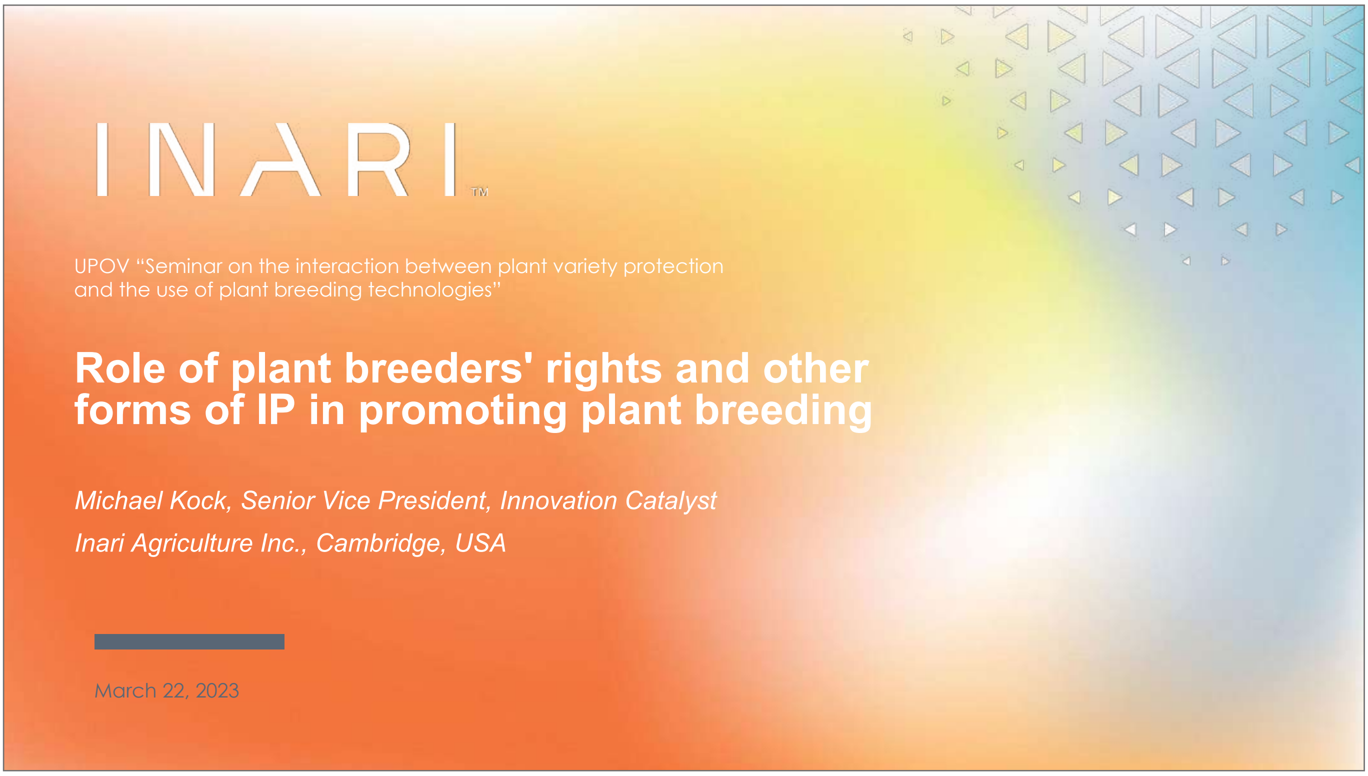
[72] For example, when it comes to the interpretation of patent claims, the Protocol on the Interpretation of Article 69 EPC clarifies that the scope of protection should neither be "defined by the strict, literal meaning of the wording used in the claims" nor should "the claims serve only as a guideline." The EPC intends "defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties." Protocol on the Interpretation of Article 69 EPC of October 5, 1973 as revised by the Act revising the EPC of November 29, 2000 – Article 1 "General principles." Available at: https://www.epo.org/law-practice/legal- texts/html/epc/2020/e/ma2a.html.

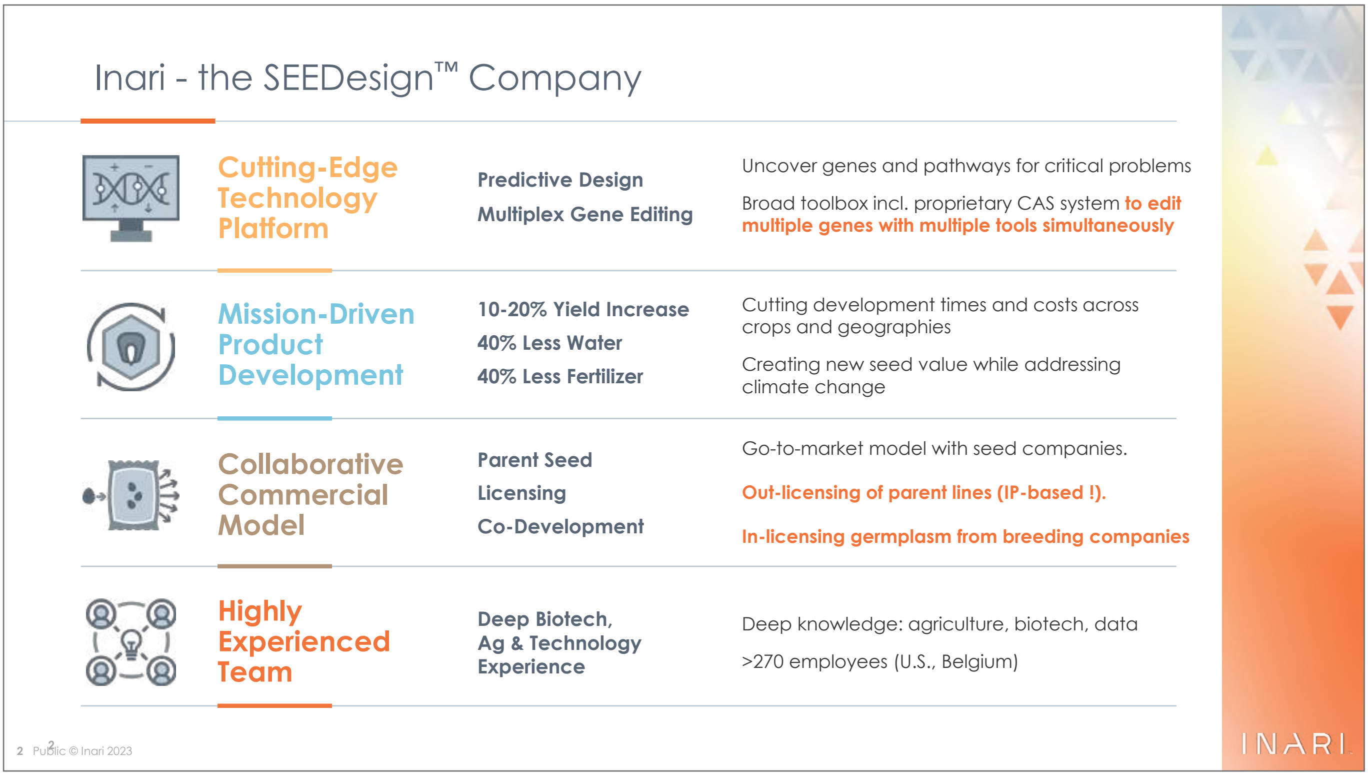
[73] Also the comments from Spain to the Draft EXN suggest that when it comes to NBTs "[p]ossible methods are included, but it should not be assumed that the end result will automatically be an EDV. Rather, results should be assessed on a case-by-case basis." Comments of Spain to Paragraph 15 in UPOV Doc. UPOV/EXN/EDV/3 Draft 2 (September 3, 2021). UPOV Doc. UPOV/EXN/EDV/3 Draft 2 (September 3, 2021). Available at: https://www.upov.int/edocs/mdocs/upov/en/wg_edv_4/upov_exn_edv_3_draft_2.pdf.

[74] Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, Publication No. 346(E) (UPOV, 1992), 349; Draft Resolution on Article 14(5), UPOV Doc. DC/DC/91/ 2 (January 14, 1991). Available at: https://www.upov.int/edocs/mdocs/upov/en/upov_dc_91/upov_dc_dc_91_2.pdf.

[75] Guiard, above n 51, p. 10.

Presentation made at the Seminar





The Potential of New Breeding Technologies

Potential	Example
Establish complex traits in accelerated time • Parallel "multiplexing" drastically reduces breeding cycles • Only efficient method to establish complex traits in multiple varieties.	• Wheat fungal resistance (6 alleles) • Yield / drought tolerance
Improvement of vegetatively propagated crops • Mutliplexing is the only effective method to achieve breeding progress in vegetatively propagating species."	• Disease resistant sugar cane
Create new genetic diversity • Certain loci are not susceptible to natural recombination. Editing can unleash new potential.	• Maize improvement

Plant varieties and seeds are high-tech products in an easy-to-copy form.
They need IP protection for a sustainable business, especially if licensing-based.

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The IP Tool Kit

Tool	Benefits Strengths	Costs Weaknesses	Good For
Patents	• Strong, enforceable right • Limited exemptions	• Country-by-country differences: Plants / plant varieties not patentable in many countries. • High threshold: Non-obviousness, written description/enablement (reproducibility) • Moderate allowance rate • Lengthy examination, high costs.	• New processes • New traits defined by specific sequence, plants comprising them • Variety-independent edits (GM-like) Edits which can be identically created or introgressed in different varieties. • US: Specific varieties
PBR Plant Breeders Rights	• Larger international harmonization • Moderate costs, fast grant • High allowance rate	• Difficult enforcement • No protection for specific traits or sequences (by design !) • EDV provision: Clarity, coupling of dependency and limited scope of protection	• New varieties • Complex variety-specific edits (breeding-like) Multiplex edits which cannot be identically created or introgressed in different varieties.
Trade Secrets	• Could be everlasting	• Requires high efforts • Difficult to license	• Parent lines of hybrid crops

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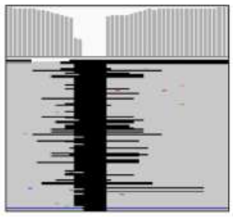
IP Protection for Multiplex Editing

- Complex traits require multiplex editing. The innovation is the combination.
- Multiplex edits are established directly in each elite variety. Introgression by crossing is practically impossible.
- Edits for a specific target gene vary slightly from variety to variety. The specific combination of edits is limited to each single variety.
- Patents do not provide a reliable global strategy:
  - Plants are not patentable in many countries.
  - DNA claims are suitable for single man-made edits but not for combinations of multiple edits.
  - The exact genetic fingerprint is not reproducible ("enablement").
  - Method claims usually only extend to the direct product but not to progenies.
- PBRs is the only practical way of protection.
- **But:** If multiplex varieties are always EDVs, they have limited PBR protection: Every variation falls outside the scope. Relying on the initial variety's PBR is no alternative.



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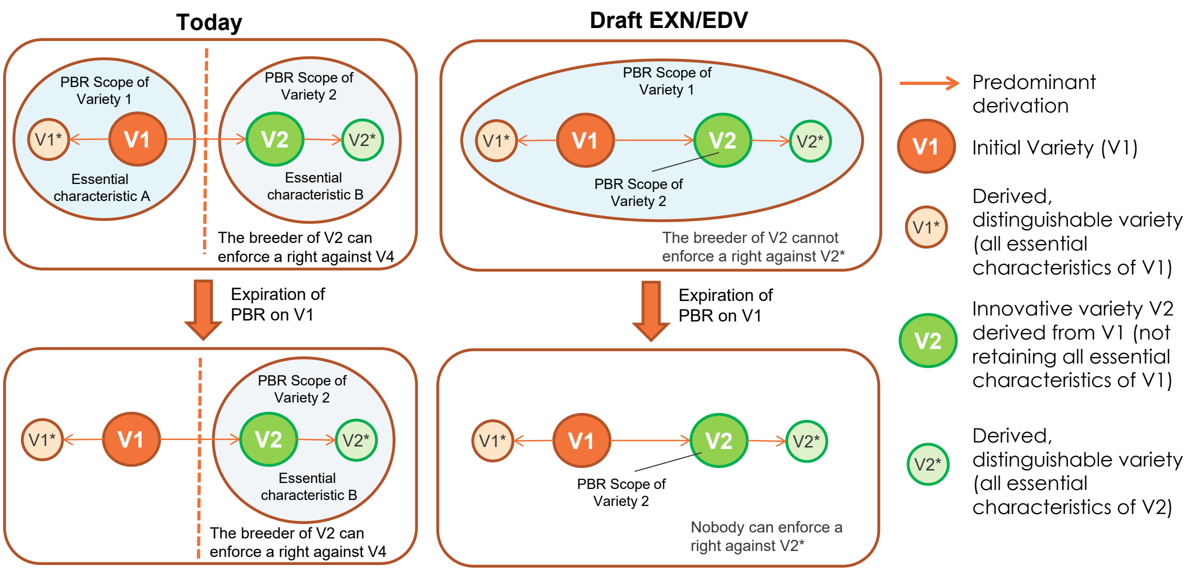
The consequences of a revised EDV definition



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UPOV & Breeding Innovation
General considerations

- Breeding innovation is measured by **phenotype improvement**.
- Causative genetic changes are limited. Additional changes are a side-effect of the breeding process, not indicative for breeding progress and undesired.
- NBTs enables targeted causative changes without undesired genetic deviation ("precision breeding").
- Breeders should be incentivized to use NBTs and enjoy full PBR protection.
- Genetic similarity as sole criteria for EDVs cannot be reconciled with the wording of the UPOV 1991 act and convert UPOV into a copyright for plant genetics.
- Legal uncertainty for crops with limited genetic diversity (cotton, lettuce).
- Breeders of NBT-derived varieties have no interest to enable "me-too" varieties.

➢ UPOV needs balance protection for existing varieties and incentive for new breeding innovation agnostic to the method of breeding.

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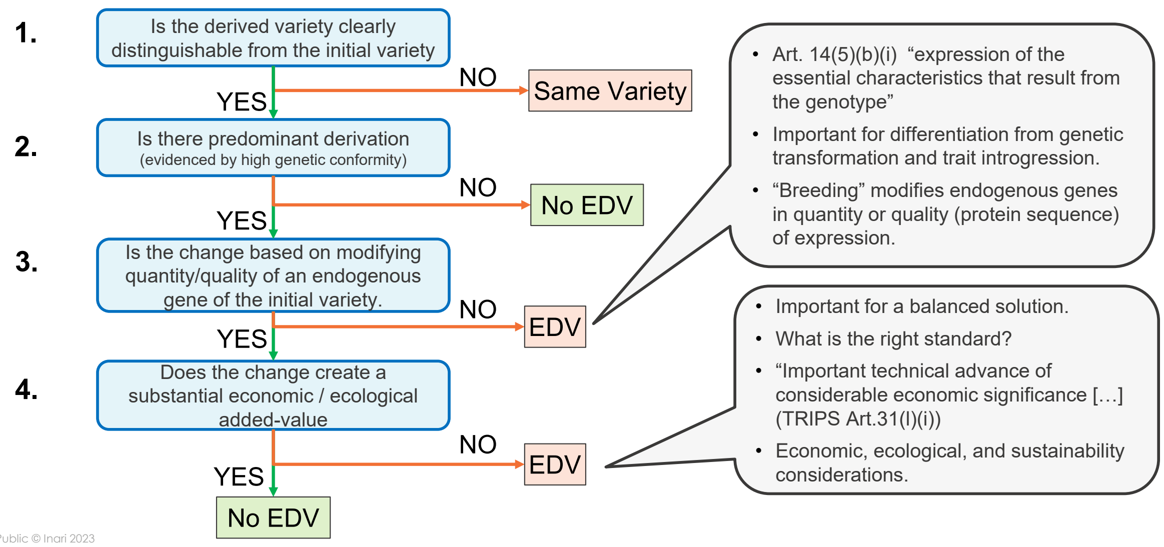
UPOV & Breeding Innovation
How to find the right balance?

Clear and fair decision criteria are required:



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Conclusions

- New breeding technologies are essential for breeders.
- UPOV must provide balanced protection agnostic to the breeding method.
- A phenotype-based assessment of the added-value is important.
- Guiding principles should be developed for case-by-case assessment.
- Abandoning the current explanatory notes is not a solution.
- If no agreement on guiding principle for added-value can be found, a revision of UPOV might be unavoidable
  - Article 14(5)(i): Uncouple dependency and limited scope of protection. → Enable multiple dependencies.
  - Article 17(i): Enable compulsory (cross-) licensing.

INARI

Thank You

INARI™

ORIGIN AND GOAL OF THE EDV PRINCIPLE IN UPOV AND ITS IMPORTANCE IN THE USE OF NEW BREEDING TECHNOLOGIES

Mr. Huib Ghijsen
Juridical Counsellor Plant Breeder's Rights / Director "RechtvoorU," Middleburg, Netherlands, on behalf of AIPH

SECURING INVESTMENT IN PLANT BREEDING

The Essentially Derived Variety (EDV) provision originates from the revision of the UPOV Convention 1978[1] to the present 1991 Convention. One of the important aims of the revision was to improve and to extend the scope of protection. According to Article 5 of the 1978 Convention, only the propagated material, and in some cases flowers that could be used as propagating material, were protected.

Start of the revision of the UPOV Convention 1978

The revision started in 1987 with the collection of comments and proposals from the 16 Member States[2] and interested non-governmental organizations: mainly breeding companies and organizations of patent holders.

The idea of dependency was proposed in the first round by the French delegation, to change paragraph 3 of Article 5 that provides for the breeder's exemption, which is an important provision, ruling the freedom to breed with protected varieties: "It would be desirable to explore the means of introducing dependence on the holder of rights in a variety which is used as the basis for a slavish modification."

This idea has resulted in a very delicate and complicated operation. But it was felt necessary by the breeding companies because of:

- much discussion about plagiarism;
- (too) small varietal distances; and
- the upcoming biotechnology providing means to add additional characteristics to conventional bred varieties.

At the same time there was concern and insecurity about how the patents on biotech inventions and traits would interfere with Plant Variety Rights (PVR), especially with regard to the breeder's exemption.

A year later, at the 22nd meeting of the Administrative and Legal Committee (CAJ-22) in April 1988, the following text was proposed to amend Article 5: "(4) The exploitation of a variety which is essentially derived from a protected variety shall give rise to payment of equitable compensation to the holder of the rights in the protected variety," with the comment that "Paragraph (4) contains a general phrase, leaving it to private negotiations, arbitration by breeders' organizations and court decisions to define the cases and, for each case, the amount of the compensation."

For this proposal the following examples were given: "easy mutations: both varieties have the same genotype, but not for a mutated characteristic. Other cases could be obtained through backcrossing or through gene transfer." In this meeting consideration was given to limit dependency to cases where only one variety was used as the basis for the creation of the new, dependent one. The provision would therefore not apply where two varieties were crossed in the initial phase of a breeding process.

In January 1986, a meeting about the implications of the upcoming biotechnology took place, as has been recorded in CAJ 16-9 and CAJ 17-10. One of the conclusions was that: "whatever genetic engineering methods may be used for breeding plants in future, their application will never exclude the grant of plant breeders' rights for the finished variety. It makes no difference whether new varieties have been obtained by processes that are already known or by processes that may become available in future. Genetic engineering, like other breeding techniques too, could only build on what already existed, i.e. on varieties from 'traditional' breeders."

---

[1] The history with all proposals, motivations and discussions concerning the revision of the UPOV Convention can be found in the documents from the 1987 to 1990 meetings and proposals of the Administrative and Legal Committee (CAJ), the meetings with the International Organizations (IOM), the papers concerning the Preparatory Meetings for the Revision (PM) and the Records of the Diplomatic Conference in March 1991.

[2] Belgium, Denmark, France, Germany, Italy, the Netherlands, South Africa, Spain, Switzerland, the United Kingdom, Israel, the United States of America, Sweden, New Zealand, Ireland and Canada.

Further development of the formulation of the text for essential derivation

In CAJ 23-4, October 1988, the following effort was made to define an essentially derived variety: "(3) If a variety is essentially based upon the material of a single protected variety [alternatively: if a variety is essentially derived from a single protected variety], the owner of the right in the protected variety may demand equitable remuneration to be paid in respect of the commercial exploitation of the new variety."

It was also concluded that under patent law dependency would only exist where the dependent invention has been granted protection itself. For PVR, dependency may cover both protected and non-protected varieties derived from a protected variety is possible. As under the breeder's exemption no infringement occurs if new varieties have been developped, no other sanction but a remuneration is possible.

In the CAJ-23 meeting the principle of dependency was generally welcomed by the committee. During the meeting it was stated that "it would be a very important addition to the Convention and it was generally supported by plant breeders. The introduction of a dependency system would mean that the breeding history of a variety would become relevant and important as this history could now be checked by the use of new technologies." It was also explained that the crossing of two protected varieties was the classic case for when the breeder's exemption should apply. Although in the case of backcrossing also two varieties are involved, the effect is that a particular characteristic can be transferred into a protected variety. Therefore dependency should also apply to varieties created by backcrossing.

In the fourth meeting with non-member International Organizations (IOM 4), October 1989, three proposed alternatives for the rights of the owner of the initial variety were discussed in the CAJ-25 meeting, which took place just after the IOM 4 meeting:

> (3) If a variety is essentially derived from a [single] protected variety, the owner of the right in the protected variety,
>
> [Alternative 1] may prevent all persons not having his consent from performing the acts described in paragraph (1[3]) above in relation to the new variety.
>
> Alternative 1 was supported by the Delegations of the Federal Republic of Germany (provided that the plant breeding methods were enumerated), the United States of America, France (first option) and Sweden. No delegation was against it.
>
> [Alternative 2] shall be entitled to equitable remuneration in respect of the commercial exploitation of the new variety.
>
> Alternative 2 was supported by the Delegation of the United Kingdom (together with Alternative 1 as amended), but rejected by that of France (because it was not balanced).
>
> [Alternative 3] may prevent all persons not having his consent from performing the acts described in paragraph (1) above in relation to the new variety. However, where the new variety shows a substantial improvement over the protected variety, the owner of the right shall only be entitled to equitable remuneration in respect of the commercial exploitation of the new variety.
>
> No delegation supported Alternative 3. It was rejected by the Delegations of France and the Netherlands. The former considered that its interpretation gave rise to many difficulties, the latter that the concept of "a substantial improvement" was foreign to the protection of new varieties of plants. It was further observed that that alternative was analogous to Article 14 of the proposal for an EC Council Directive on the Legal Protection of Biotechnological Inventions.

This decision to reject alternative 3 and agree with alternative 1, determines that the value of the added trait does not have consequences for the dependency. In other words, if the trait added is considered to contribute a substantial improvement to the derived variety, that variety will still remain essentially derived from the initial variety, or the value of the added trait does not make a difference for the dependency.

---

[3] (1) A right granted in accordance with the provisions of this Convention shall confer on its owner the right to prevent all persons not having his consent:
(i) from reproducing or propagating the variety:
(ii) from offering for sale, putting on the market, exporting or using material of the variety:
(iii) from importing or stocking material of the variety for any of the aforementioned purposes.

In the explanatory notes of the CAJ-25-2 report of October 1989, the following is stated:

At the present stage of the discussions, there seems to be general agreement on the fact that the following conditions should be met for there to be dependence:

(i) The difference between the two varieties involved must meet the requirement set out in Article 6(l)(a), that is, under the present text, be clear and relate to one or more important characteristics.

(ii) The derived variety must retain almost the totality of the genotype of the mother variety and be distinguishable from that variety by a very limited number of characteristics (typically by one).

(iii) The derived variety must have been obtained using a plant improvement method whose objective is the achievement of requirement (ii) above (mutation, gene transfer, full backcrossing scheme, selection of a variant within a variety, etc.): in other words, no varieties bred according to a classical or other scheme of crossing in which selection within the progeny is a major element would become the subject of dependence.

(iv) The mother variety must originate from true breeding work, that is, it must not itself be dependent: there should not be a "dependence pyramid". If variety C derives from variety B which derives from variety A, C would be from A rather than B, since the very objective of dependence is to give to the breeder of an original genotype an additional source of remuneration: the collecting of that remuneration through a third party, in the example the breeder of variety B, does not seem very practicable.

In the report of CAJ-25, the issue of the number of parent varieties is reflected: "Opinions were divided as to whether the word 'single' should be retained or deleted. Finally it was concluded that the derived variety had to retain most of the genotype of the parent variety, so that a variety could not possibly 'depend' on two varieties simultaneously."

In the IOM 5-2 of the October 1990 meeting the Substantive Law was discussed:

Article 12: Effects of the Breeder's Right

Subject to paragraphs (3) and (4), the acts mentioned in paragraph (l) shall also require the authorization of the breeder in relation to

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

(b) For the purposes of sub-paragraph (a)(i), a variety shall be considered 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, particularly through methods which have the effect of conserving the essential characteristics that are the expression of the genotype or of the combination of genotypes of the initial variety, such as the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant, back-crossings or transformation by genetic engineering,

(ii) it is clearly distinguishable from the initial variety in accordance with Article 7(3) and

(iii) it conforms to the genotype or the combination of genotypes of the initial variety, apart from the differences which result from the method of derivation.

This definition provides a good insight into the intention of the drafters. The text agreed will be used as the basic text for the Diplomatic Conference.

(i) The phrase "through methods which have the effect of conserving the essential characteristics that are the *expression* of the genotype or of the combination of genotypes of the initial variety" is replaced by the latter final definition:
"while retaining <u>the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety"</u>, which is in line with the language of the variety definition of article 1(vi):
"variety" means a plant grouping (...) can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes (...)

But the text in the first and third paragraph of the final text are identical while one or a few "essential" characteristics have been changed as a result of the act of derivation:

(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.*

The *italic* marked words are identical to the underlined part in the first paragraph. That leads to the discussion that, if an essential characteristic from the initial variety (e.g., flower color) is different in the derived variety (a color mutant), the derived variety has not kept the same expression in the essential characteristic "flower color" of the initial variety. Therefore, as mentioned in some debates, it could be regarded as a non-EDV, because it differs from the initial variety in the expression of an essential characteristic.

But there is no hierarchy between characteristics in the UPOV system. The adjectives "essential," "relevant" and "important" before the word "characteristic" are synonyms inconsistently used in the UPOV papers[4]. The term "essential" – or "essentielle" in French – has already been used in the first UPOV Convention of 1961.

So, the term "essential characteristics" can be replaced by "relevant" characteristics, meaning that the change of any characteristic by essential derivation will result in an EDV. For example, a color mutant variety in an ornamental crop is an EDV, although the important, essential or relevant color characteristic has been changed.

The final EDV formulation during the Diplomatic Conference, March 1991

The basic proposal of Article 14(5):

> (2) (...) in respect of essentially derived and certain other varieties) (a) Subject to Articles 15 and 16, the acts mentioned in paragraph (1) shall also require the authorization of the breeder in relation to (i), (ii), (iii), and (b) [Same as in the adopted text],
>
> (i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, particularly through methods which have the effect of conserving the essential characteristics that are the expression of the genotype or of the combination of genotypes of the initial variety, such as the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant, backcrossing's or transformation by genetic engineering,
>
> (ii) [Same as in the adopted text],
>
> (iii) it conforms to the genotype or the combination of genotypes of the initial variety, apart from the differences which result from the method of derivation.

Paragraph (i) was changed by an amendment of the United States of America, DC91/14, that is referred to the drafting committee:

> (i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, *resulting in the conservation of the essential characteristics that are the expression of the genotype or of the combination of genotypes of the initial variety*, particularly through methods [which have the effect of conserving the essential characteristics that are the expression of the genotype or of the combination of genotypes of the initial variety].

This resulted in the final text:

> (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*.

The examples have been put in paragraph "(c)."

Paragraph (iii) has been changed by a Japanese amendment DC 91/66, from: "(iii) it conforms to the genotype or the combination of genotypes of the initial variety, apart from the differences which result from the method of derivation" to "(iii) the characteristics that are the expression of the genotype or the combination of genotypes conform to those of the initial variety, apart from the differences which result from the method of derivation."

The final text has been adapted by the drafting committee by adding the word "essential" and changing the sequence of the words in the sentence: "(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."

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[4] See the UPOV technical guidelines, in particular the general introduction to DUS testing (TG/1/3) in paragraphs 2.4.4, 7.1 and 7.2. Also the discussions reflected in paragraphs 516–525 and 545–547 including the relevant proposals DC/91/56 and DC/91/57 as mentioned in the Records of the Diplomatic Conference, reveal that the adjectives ***essential, important*** *and relevant in relation to variety characteristics are to be regarded as synonyms.*

SECURING INVESTMENT AND PARTNERSHIPS

If a party has a very valuable protected variety and another party a very interesting patented characteristic, cooperation can be secured by the use of cross-licensing. This has also been advocated by UPOV.

The text of the UPOV Convention 1991 was discussed in the same period as the EU Directive 98/44/EC for patenting of biotechnological inventions.

In the case that one party is not willing to cooperate, Article 29 of EU PVR Regulation 2100/94 and Article 12 of the Biotech Directive 98/44 provide the possibility of a compulsory cross license between breeding and biotech companies. Although the requirements to obtain such a compulsory license is complicated, it may support the ultimate cooperation between the parties.

CONCLUSIONS

1. The use/modification of an existing valuable genotype has the advantage that the unique and (proven) economically interesting combination of characteristics remain unchanged, from which the EDV can profit.
2. The text of essential derivation with the definition of an essentially derived variety has been extensively and cautiously discussed during four years with all interested parties.
3. Although it has been more then 30 years ago the result can still be applied, despite its complex character.
4. The dependency is unrelated with the economic value of the resulting EDV or the added characteristic(s).
5. The term “essential characteristics” can be replaced by “relevant characteristics,” meaning that the change of any characteristic by essential derivation will result in an EDV.
6. The role of IP rights in securing investment and partnerships in breeding is important for further progress and partnerships, while parties can secure their interests and investments in breeding technologies.
7. The breeder that uses targeted breeding techniques to create an EDV can choose upfront the most suitable parent variety. Preferably one for which he is able to reach a settlement with the PVR holder.
8. The principle of cross licenses serves the purpose of facilitating the mutual dependency of the holder of the patented (biotech) trait versus the holder of the original PVR protected variety.

Presentation made at the Seminar

AIPH

Short introduction

- Educated both as lawyer (2001) and agricultural engineer (1971)
- Independent legal counselor since 2009
- Previously, IP manager for Bayer Bioscience 2000-2009
- Chairman Technical Working Party Agricultural Crops 1994-1996
- Technical Expert for the Dutch Board of Plant breeder's Rights 1991-2000
- Breeder at Barenbrug Holland 1971-1991
- Proposed by the International Association of Horticultural Producers (AIPH) as speaker on this seminar, aiming a mutual understanding within UPOV about origin and goal of the EDV principle. Urgent in the use of NBT's and growers do need security about access to new varieties. They need seed on right time, in right quantity of right quality.

AIPH

2

The revision of the UPOV 1978 Convention to 1991

- The EDV provision originates from the revision of the UPOV 1978 Convention to the present 1991 Convention.
- One of the important aims of the revision: to improve and to extend the scope of protection.
- The revision started in 1987 with the collection of comments and proposals from the 16 member states, observer states and non-governmental organizations from breeders, biotech companies and patent holders
- It took 4 years with extensive deliberations which have been recorded in the meeting papers accessible on the UPOV website and very valuable to understand the meaning and scope of the EDV provision

AIPH

3

The revision of the UPOV 1978 Convention to 1991

The concept of dependency was felt necessary because of:

- much discussion about plagiarism
- (too) small varietal distances, and
- the upcoming biotechnology providing means to add additional characteristics to conventionally bred varieties

  (Plant breeders were concerned that a new variety, taking 15 years of hard work and investment could be hijacked by inserting a new gene)

AIPH

4

The concept of essential derivation

In the October1988 CAJ meeting the following text was proposed to define an essentially derived variety:

" If a variety is essentially based upon the material of a single protected variety the owner of the right in the protected variety may demand *equitable remuneration* to be paid in respect of the commercial exploitation of the new variety."

- ✓ It was also established that the crossing of two protected varieties was the classic case for when the breeder's exemption should apply.
- ✓ Although in the case of backcrossing also two varieties are involved, the effect is that a particular characteristic can be transferred into a protected variety. Therefore dependency should also apply to varieties created by backcrossing.

AIPH

5

The concept of essential derivation

The selection from the initial variety of a:

- Mutant (natural or induced)	same
- soma clonal variant	genetic
- variant (off type)	structure
- genetic modification	as INV

----

* (repeated) back-crossing → measuring genetic similarity of EDV-INV

AIPH

6

The concept of essential derivation

After the 4th meeting with International Organizations, October 1989,
3 text alternatives for the Rights of the owner of the INV were discussed in the 25th meeting of the CAJ:

If a variety is essentially derived from a protected variety, *the owner of the right* in the protected variety,

[1] may ***exercise*** his rights on the essentially derived variety
Supported by all delegations

[2] shall be entitled to ***equitable remuneration*** in respect of the commercial exploitation of the new variety.
Supported by a few delegations only

[3] may ***exercise*** his rights on the essentially derived variety .
However, where the new variety shows a substantial improvement over the protected variety, the owner of the right shall only be entitled to equitable remuneration in respect of the commercial exploitation of the new variety.
Not supported by any of the delegations!

AIPH

7

The concept of essential derivation
Element of substantial improvement was rejected

[3] "may ***exercise*** his rights on the essentially derived variety"

"However, ***where the new variety shows a substantial improvement over the protected variety***, the owner of the right shall only be entitled to equitable remuneration in respect of the commercial exploitation of the new variety"

It was considered that its interpretation gave rise to many difficulties, and the concept of "a substantial improvement" was foreign to the protection of new varieties of plants

Not anyone of the member state delegations in 1989 supported alternative 3!

AIPH

8

The concept of essential derivation

Rejection of alternative 3 and support for alternative 1:

→ the value of the added trait(s) does not have consequences for the dependency.

→ In other words: if the trait(s) added is/are considered to contribute a substantial improvement to the derived variety, that variety will still remain essentially derived from the initial variety, or

→ the value of the added trait(s) does/do not make any difference for the dependency.

AIPH

9

The concept of essential derivation

- In CAJ October 1989 , there seems to be general agreement on the fact that the following conditions should be met for dependence:
- The derived variety must retain ***almost the totality of the genotype*** of the mother variety and be ***distinguishable*** from that variety by a very ***limited*** number of characteristics (***typically by one***).
- The derived variety must have been obtained using a plant improvement method whose ***objective*** is the achievement of the requirement above: mutation, gene transfer, full backcrossing scheme, selection of a variant within a variety, etc.:

AIPH

10

Further development of the formulation of essential derivation

Discussion on the Substantive Law in the IOM 5 October 1990 meeting

A variety shall be considered to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived, from the initial variety, (..) through methods which have ***the effect of conserving the essential characteristics*** that are the expression of the genotype (..) of the initial variety, such as the selection of a natural or induced mutant or transformation by genetic engineering etc.,

(ii) it is clearly distinguishable from the initial variety in accordance with Article 7(3) and

(iii) it conforms to the genotype (..) of the initial variety, apart from the differences which result from the method of derivation.

This is the basic text for the Diplomatic Conference where it is changed by 2 amendments and the drafting committee to the present text

(..) = "or combination of genotypes"

AIPH

11

Further development of the formulation of essential derivation

How essential is an essential characteristic?

- There is no hierarchy between characteristics in the UPOV system
- The adjectives 'essential', 'relevant' and 'important' before the word ' characteristic' are synonyms, inconsistently used in the UPOV papers
- The term 'essential' - or 'essentiels' in French' - has already been used in the first UPOV Convention of 1961
  (La varieté nouvelle doit être stable dans sa caractères essentiels)
- The characteristics must just be suitable to Describe, Define and Distinguish the varieties
- So a color mutant variety in an ornamental crop is an EDV, although the important, essential or relevant color characteristic has been changed!

AIPH

12

Securing investment and partnerships

- Text UPOV'91 Convention was discussed in the same period as the EU Directive 98/44/EC for patenting of biotechnological inventions.
- If a party has a very valuable protected variety and another party has a very interesting patented characteristic, cooperation can be secured by the use of cross-licensing. This has also been advocated by UPOV.
- In the case that one party is not willing to cooperate, article 29 of EU CPVR Regulation 2100/94/EC and article 12 of the EU Biotech directive 98/44/EC provide the possibility of a compulsory cross license between breeding - and biotech companies.
- Although the requirements to obtain such compulsory license is complicated, it might support the ultimate cooperation between the parties.

AIPH

13

Conclusions

1. The use / modification of an existing valuable genotype has the advantage that the unique and (proven) economically interesting combination of characteristics remain unchanged, from which the EDV will profit;
2. The text of essential derivation with the definition of an essentially derived variety has been extensively and cautiously discussed during 4 years with all interested parties;
3. Although it has been more then 30 years ago the result can still be applied, despite its complex character;
4. The dependency is unrelated with the economic value of the resulting EDV or the added characteristic(s);

AIPH

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Conclusions

5. The term 'essential characteristics' can be replaced by 'relevant' characteristics, meaning that the change of any characteristic by essential derivation will result in an EDV;

6. The role of IP rights in securing investment and partnerships in breeding is important for further progress and partnerships, while parties can secure their interests and investments in breeding technologies;

7. The breeder that uses targeted breeding techniques to create an EDV can choose upfront the most suitable parent variety. Preferably one for which he is able to reach a settlement with the PVR holder;

8. The principle of cross licenses serves the purpose of facilitating the mutual dependency of the holder of the patented (biotech) trait versus the holder of the original PVR protected variety.

AIPH

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<u>Thank you !</u>

Any questions ?

AIPH

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DISCUSSION WITH SPEAKERS OF SESSION III

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

For now, I would like to open the floor to questions and discussions if there's any.

I see Edgar from CIOPORA, so the floor is yours.

KRIEGER Edgar (Mr.):

Thank you very much, Madam Chair. I have a question to Mr. López De Haro. You made the impression that the EDV principle has been introduced to piracy or plagiarism. I quote what you have said. While it is easy to introduce a gene of great interest via backcrossing or mutation, it is just as easy to introduce a gene with zero value. The aim was to obtain a variety that was almost identical to the natural variety but still distinct thanks to the incorporation of a characteristic merely intended for registration purposes by achieving compliance with legal protection requirements. This is a sheer act of genetic piracy.

Prior to 1991, the Convention did not offer a legal basis. This is the reason why the concept of EDV was introduced.

You said that variety, which is the sheer act of genetic piracy, is an EDV because it is distinct. As the Director of the Spanish PVR Office, that means that you have granted PVR protection to varieties which are a sheer act of genetic piracy, so which are plagiaristic varieties. Can you please explain that?

Second question; Article 14 – I just have to open the UPOV Convention. Article 14.5, second indent, says varieties which are not clearly distinguishable in accordance with article 7 from the protected variety fall under the scope of protection of the protected variety. Don't you agree that this is the right provision to fight plagiarism and genetic piracy instead of EDV?

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Mr. López, the floor is yours.

LÓPEZ DE HARO Y WOOD Ricardo (Mr.) (speaker):

Well, when I referred to plagiarism, it was just an example. It was significantly important because it is something that could actually happen with an essentially derived variety which had a trait, a simple trait, for example, a fruit, a derived fruit, and what could this lead to is that the breeder of the variety could – the breeder of the essentially derived variety, EDV, could market the variety at a price that was significantly less or less than the price of the original variety and the two were very similar. So, this is something that was discussed at length, at length in the diplomatic conference, and it was in fact the reason why many of the aspects have come out in different places, not that it's plagiarism, but that it could be partial plagiarism.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

So, I have a hand up from the online – from Mr. Thomas from CIOPORA. So, please go ahead, please.

LEIDEREITER Thomas (Mr.):

Thank you. I have one question and two comments. One is a big thank you to Mr. Huib Ghijsen, who made probably the best presentation I heard on the documents of the UPOV Conference. I think you clearly rebutted the idea that is often spread and told that EDV was meant only for plagiarism and this was really a very good, greatly shown and brilliantly shown in your presentation. Thank you for that.

With regard to Ms. Nebel from the US, I was wondering; you said the breeding activities in the United States of America are decreasing substantially at the moment and as Mr. Kock already pointed out, Dr. Kock already pointed out, in the US, you do have utility patents for plants. So, the decrease is happening actually in the country where there is maximum protection, from your point of view, which, from my limited point of view, is a bit contradictory and rather benefiting the idea of UPOV and plant variety rights.

And just before you answer that, I do understand the position of you, Dr. Kock, to say that there should be a case-by-case discussion on what is the actual value, what is added, and how to do that, but this discussion could not be entered into by the parties, from my point of view, if there is no dependency. If you exclude the dependency from the beginning, then nobody will discuss the actual value of the added characteristic.

So, I do understand that at the moment, people are repulsed by the explanatory notes as they were, but saying we need more balance and achieving balance by excluding EDV, per se, if the added – if the added trait is variable, I think that cannot bring any solution because there will not be any discussion at the end of the day.

Thank you for listening to me for so long.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

So, Ms. Nebel, the floor is yours if you'd like to answer.

NEBEL Heidi (Ms.) (speaker):

Thank you. Great point. I think I was coming from the viewpoint of we can't afford any further decline and there is a lot of talk of what's going on in Washington D.C. right now and with the recent report published by the USDA is looking at introducing some things like breeders exemptions to utility patents.

So, I think I was viewing forward, trying to say we need to do everything we can to stop further decline. And so, that's where I was coming from.

I think a viable IP protection scheme involves all, involved PVPs, PVRs, depending on where your market is, trade secrets, all kinds of contracts, including bag tags, material transfer agreements. I think it all – we need a layering of all kinds of rights. So, I was not intending to denigrate one or the other, but under the topic of generating and securing investment, I think that where in the United States of America and Canada you can get utility patents on plant varieties that are the result of traditional breeding, we need to make sure that that continues. So, that's sort of where I was coming from. And I know that Michael wants to speak as well.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Thank you. Actually, Mr. Huib has a question in relation to that. So, after that, I will pass it on to Michael. So, yeah, in that order, please. So, the floor is yours.

GHIJSEN Huib (Mr.) (speaker):

Okay. Thank you. I have a question concerning the patenting of varieties in the United States of America because the important consequence is that there is no breeders exemption on the patented varieties. And also, I am wondering whether that has any influence on the decrease of breeding activities because when I see your presentation and also of Michael's, I really am impressed about all of the intellectual property tools that are being used in the United States of America compared to Europe. And this costs money and people and a lot of investment to protect everything and to get licenses and freedom to operate and whatever.

Don't you agree with me that possibly the strong protection systems in the United States of America may be a cause of the decrease of plant variety breeding? Thank you.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Ms. Nebel, the floor is yours.

NEBEL Heidi (Ms.) (speaker):

I would respond that patents and incentivizing development of intellectual property, whether it's drugs, anything, is proven to work. So, what the cause is of the decrease in breeding programs, I can't opine to. I merely was pointing that out to – to accentuate how important it is that we have all IP.

For example, if you look at AUTM's statistics, technology transfer in the United States of America has contributed over USD865 billion to the United States of America gross domestic product. The simple answer is that utility patents and patents and the patent system does incentivize innovation and does contribute to the gross domestic product of a country. So, to the extent that patents, utility patents are allowable, I think we need to make sure that those are always available.

And I should disclose that I was part of the litigating team that handled the J.E.M. Pioneer case at the Supreme Court, so obviously I have a bit of a bias to keep my – to keep our decision intact as far as that goes.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Thank you. Okay. I will hand over to Mr. Kock and I have two more questions from the floor, so let's wrap it up. We do have a coffee break right after this, so, thanks.

KOCK Michael (Mr.) (speaker):

Yeah, thank you. I think most experts agree that stronger IP rights does not necessarily mean more incentive for innovation, but that actually, the curve of more innovation follows a bell curve, right. And that is something that in the United States of America which is potentially part, in my view, of the root cause, why we see a decline, that there are no breeders in research exemption in the utility patent. And actually, that was, if you read the recent USDA report, also a remark which was made in saying that is something which needs to be investigated, whether the strength of the IP right has gone beyond what is healthy for a sustainable system.

But of course, in the US, if you would have utility patent, there would be an EDV of an EDV, right? So, also, the next variety, if it has the right to be marketed, would have the full right of protection and not the diminished right of protection under the UPOV Convention, which for me, by the way, is a strong argument why it was not considered to protect or to extend to innovative new plant varieties. If that would have been the extent, then I think there would have been a bifurcation of dependency and scope of protection.

So, Thomas, to your question, how to enter into discussions, of course, in the end, I don't think that you need to start with dependency as a default and define it in EDV, because this wouldn't solve the problem of scope of protection. In the end, the added value needs to be argued then in a defense, right, in a court case, right. Or if the decision is in front of the PVR Office, like in Australia, in front of the PVR Office to show that it is indeed an added value.

So, I think finally, that needs to be covered but it should not be just a side discussion because in the end, it is decisive whether something is an EDV or not.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Okay. Thank you, Kock, Mr. Kock. I will hand over to Judith if you're still open to the question.

DE ROOS-BLOKLAND Judith Maria Anneke (Ms.):

Thank you. Yes, please. I was intrigued by the presentation of Mr. Huib Ghijsen, which I have to admit that I saw previously, but that really says that all the delegates at the time of the UPOV 1991 Convention did not give their consent to the – to the estimation about value. So, I was wondering, regarding Mr. López De Haro, that means that also Spain did not approve of that approach at that time, and I think the same is true for Australia. So, I was wondering whether the delegates could maybe comment on that, please?

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Mr. López, would you like to?

CUBERO SALMERON José Ignacio (Mr.):

I'm afraid I didn't understand exactly what you were referring to. Which approach?

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Is the question whether Spain and Australia supported this idea to take out the word "substantial" improvement?

DE ROOS-BLOKLAND Judith Maria Anneke (Ms.):

Improvement. Yes.

CUBERO SALMERON José Ignacio (Mr.):

I didn't make a comment about substantial improvement but I think in any case, I assume that it refers to what could be a trait that substantially improves a variety. But I'm afraid I don't have a response there, nor did I make any comment on this substantial improvement. I didn't make a comment about that. Thank you.

DE ROOS-BLOKLAND Judith Maria Anneke (Ms.):

This was about the voting during the UPOV 1991 discussions that led to the adoption of the convention text. So, I think there, as you mentioned, Spain was one of the members, and also Australia, that made the choice at that time to not go for the value approach with the substantial improvement. But maybe this is something to discuss at another time.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

So, any other – so, are we ready to then – okay. Maybe just – sorry. Mr. Cubero, thank you for waiting. The floor is yours.

CUBERO SALMERON José Ignacio (Mr.):

I started plant breeding in 1962. And at the time, my professor of plant breeding and genetics explained the fact that because he was very close to me in the field of genomic engineering, that it was easy to steal a variety, just introducing and irrelevant gene. And it was clear but for all of the professors of genetics of plant breeding at the time.

In many meetings I attended, at the time, it was the breeders, what made the breeders worried, nobody explained never that introducing an essential characteristic, an important, let's say an important characteristic. For example, a resistant to an important disease, a different quality, [inaudible] in maize, for example, and many other things. They never explained that they were unimportant. They only explained just introducing a small and unimportant characteristic was stealing a variety. Never was the advance in a variety was forbidden. It was piracy. Never in my life did I hear that.

When I think, in respect to some of the questions, there is a difference between the conversations between the diplomatic conference and the diplomatic conference. In the conversations, it seems, by the last speaker, in the conversations before UPOV 1991 Act, the participants would think that introducing an essential, an important, very important characteristic, was nothing and all were EDVs. If this is what the delegates in the previous meeting in 1991 were thinking, they were wrong, completely wrong. It means that more biologists would be invited, not only lawyers. Not only lawyers. Sorry. My family was plenty of lawyers.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator):

Okay. Thank you, Mr. Cubero.

CUBERO SALMERON José Ignacio (Mr.):

One thing is that – one different thing, the diplomatic conference that was approving the final – the final writing, the final text.

HAGIWARA Minori (Ms.), Vice-Chair of UPOV Administrative and Legal Committee (moderator): Thank you very much, Mr. Cubero.

SESSION IV:

SUPPORTING THE DEVELOPMENT OF NEW VARIETIES THAT MAXIMIZE BENEFIT FOR SOCIETY – THE ROLE OF THE UPOV SYSTEM OF PVP

Moderator: Mr. Anthony Parker, Vice-President of the UPOV Council

Setting the scene
Ms. Yolanda Huerta, Legal Counsel and Director of Training and Assistance, UPOV

Role and importance of phenotype/genotype for the granting of PVP and EDV-status
Mr. Gert Würtenberger, Chairman of the GRUR Expert Committee on the Protection of Plant Varieties (Vorsitzender des GRUR Ausschusses für den Schutz von Pflanzenzüchtungen) and Lawyer, Meissner Bolte, Munich, Germany

Breeders' view on essentially derived varieties
Ms. Erin Wallich, Intellectual Property Manager, Summerland Varieties Corporation, Summerland, Canada, on behalf of ISF, CropLife International, CIOPORA, APSA, AFSTA, SAA and Euroseeds

Diversity of breeding technologies and impact for plant variety protection
Mr. Christian Huyghe, Scientific Director for Agriculture, National Research Institute for Agriculture, Food and the Environment (INRAE); Chair of the scientific committee of the CTPS (French committee for variety registration and seed certification), France

Discussion with speakers of Session IV

Closing remarks

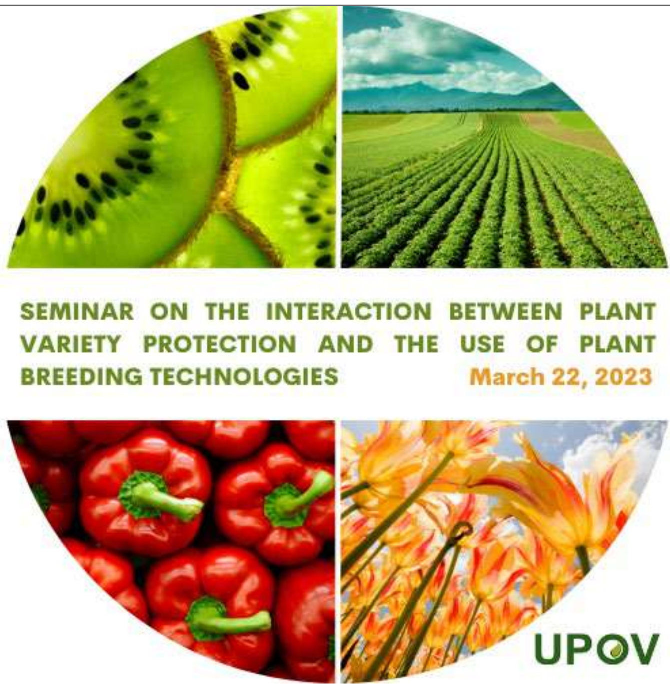
SETTING THE SCENE

Ms. Yolanda Huerta
Legal Counsel and Director of Training and Assistance, UPOV

Presentation made at the Seminar

Setting the Scene

Yolanda Huerta
Legal Counsel and
Director of Training and
Assistance

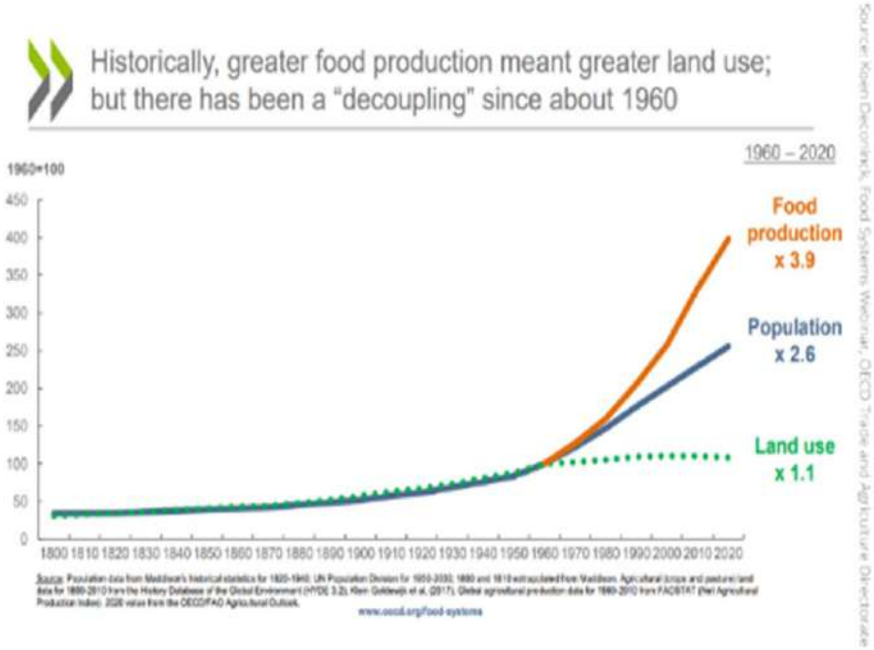


UPOV

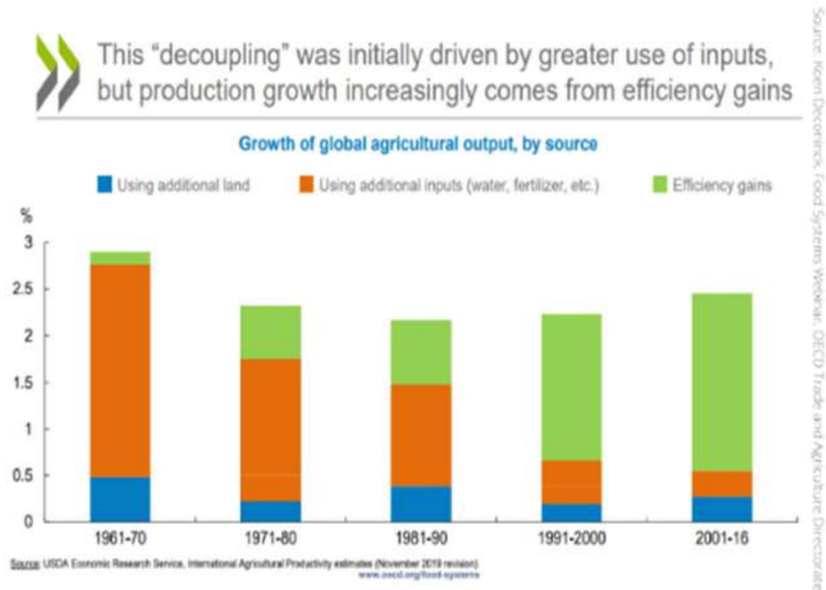
OVERVIEW

- The Context
- UPOV Convention
- UPOV guidance

The context



How to produce more and better with less



UPOV

UPOV MISSION STATEMENT

To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society

UPOV

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What are the challenges in encouraging investment in plant breeding?

- **identify** important variety characteristics
- **secure resources to breed** varieties with those characteristics
- **deliver** them to farmers and growers

UPOV's role: Creating the space for policy dialogues for harmonization, enhancing cooperation, developing guidance on the UPOV Convention and its implementation, including enforcement

- **Plant breeding is long and expensive**

BUT

- **Plant varieties can be easily and quickly reproduced**

➔Breeders need effective protection and enforcement measures to recover investment

➔Increased role of use of biochemical and molecular techniques for variety identification and breeders' rights enforcement

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OVERVIEW

- The Context
- UPOV Convention
- UPOV Guidance

EXCEPTIONS TO THE BREEDER'S RIGHT (1991 Act)

Compulsory

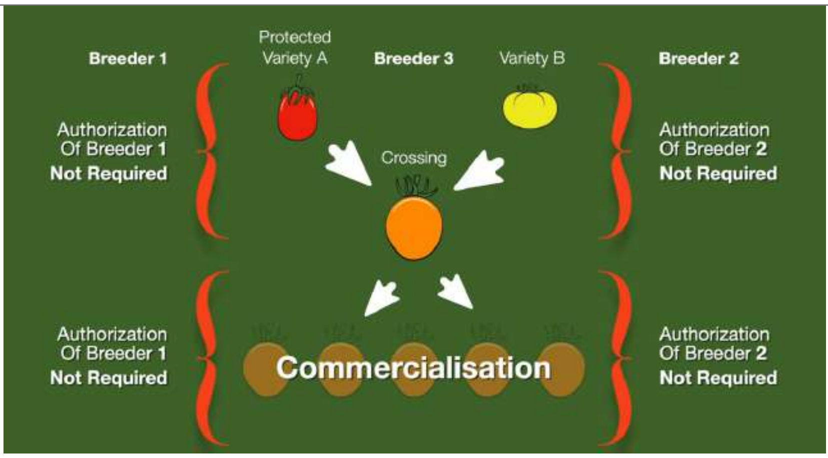
Acts done:

- privately and for non-commercial purposes
- for experimental purposes
- **breeding other varieties (breeder's exemption")**

Optional

Farm-saved seed

2



Authorization for commercialization of newly bred varieties not required except for

(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.

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Scope of the Breeder's Right (1991 Act)

Article 14

Scope of the Breeder's Right

(1) [*Acts in respect of the propagating material*]

(2) [*Acts in respect of the harvested material*]

(3) [*Acts in respect of certain products*]

(4) [*Possible additional acts*]

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

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Essentially Derived Varieties

PURPOSE:

to ensure sustainable plant breeding development by:

– providing effective protection for the breeder

and

– encouraging cooperation between breeders and developers of new technologies such as genetic modification

UPOV

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Essentially Derived Varieties

Article 14

Scope of the Breeder's Right

(5)[*Essentially derived and certain other varieties*]

(a) […]

(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.

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Essentially Derived Varieties

May be obtained for example by:

- **selection** of a natural or induced **mutant**
- **selection** of a **somaclonal variant**
- **selection** of a **variant individual** from plants of the initial variety
- **back-crossing**
- transformation by **genetic engineering**

UPOV

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OVERVIEW

- The Context
- UPOV Convention
- UPOV Guidance

Guidance on EDV

- Resolution of the 1991 Act Diplomatic Conference

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.

- EDV Explanatory Notes of 2009
- EDV Explanatory Notes of 2017
- Current Revision started in 2019

Seminar on the Impact of Policy on Essentially Derived Varieties (EDVs) on Breeding Strategy in 2019

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2019 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***.

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ROLE AND IMPORTANCE OF PHENOTYPE/GENOTYPE FOR THE GRANTING OF PVP AND EDV-STATUS

Dr. Gert Würtenberger
Chairman of the GRUR Expert Committee on the Protection of Plant Varieties (Vorsitzender des GRUR Ausschusses für den Schutz von Pflanzenzüchtungen) and Lawyer, Meissner Bolte, Munich, Germany

With every intellectual property right, the question of the specific subject matter of protection arises. The subject matter of protection is decisive not only for the justification of an exclusive right but also the determination of the scope of protection of the granted property right. Due to the interdependence of the subject matter of protection and the scope of protection a precise identification of the subject matter of protection is required.

SUBJECT MATTER OF PROTECTION

The UPOV Convention obliges the contracting parties to grant and protect breeders' rights for all plant genera and species.

The requirements for protection are summarized in Article 5 of the UPOV Convention 1991:

The breeder's right will be granted when the variety is

I. new,

II. distinct,

III. uniform and

IV. stable.

As a formal requirement, moreover, there is the variety denomination according to Article 20 of the UPOV Convention 1991. According thereto, the variety must be identified with a variety denomination as a generic name.

The granting of the breeder's right may not be dependent on other requirements, as stated in Article 5(2) of the UPOV Convention 1991.

Article 1(vi) of the UPOV Convention 1991 defines a variety as:

> [A] plant grouping within a single botanical taxon of the lowest known rank which, regardless of whether it fully meets the requirements for the granting of a breeder's right,
>
> - by means of which the characteristics resulting from a certain genotype or a certain combination of genotypes can be defined,
>
> - can at least be distinguished from any other plant grouping by the expression of one of the characteristics mentioned and
>
> - in view of their suitability to be propagated unchanged, can be seen as a grouping.

Article 5(2) of Regulation (EC) No. 2100/94 of the Council of July 27, 1994, on Community Plant Variety Protection takes up this definition.

As an interim result, it follows from these regulations that the subject of plant variety protection is plant material, which is characterized by specific external characteristics, but that can be traced back to the genotype or a combination of genotypes, namely, not determined by external factors. The expression of the characteristics must allow a clear objective differentiation between the varieties of a plant genus. Finally, such characteristics must enable the granting authority to describe the same in a clear manner.

The subject matter of protection is therefore the genetic structure as far as it expresses external characteristics that may allow users distinctness and thus a clear description.

DISTINCTNESS (UPOV CONVENTION 1991, ARTICLE 7)

The most important material requirement to obtain protection for a new breeding achievement is that 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" (UPOV Convention 1991, Article 7).

As follows from Article 1 (vi) of the UPOV Convention 1991, the requirement of distinctness is linked to "the expression of characteristics resulting from a genotype or a combination of genotypes."

Since DNA can nowadays be described, in theory, it is possible to determine the subject matter of protection of a plant variety by analyzing the genome.

However, although the DNA is the protected object, the protection is of, and must be linked to, the external characteristics, expressions of which can be traced back to the genome. These can be qualitative, quantitative and pseudo-qualitative characteristics. They are described in the variety description that is attached to the grant of the plant variety right.

The connection to external characteristics is due to the fact that the granting of an exclusive right requires an advantage over the previously known variety. In plant variety rights law, this is the case when the breeding activity leads to an enrichment of the flora. Such progress, however, does not already exist when the genetic structure has been changed in any way, but only when this change becomes apparent in an external characteristic that not only reflects a progress in breeding but also is significant enough to justify granting of an exclusive right. This is emphasized by Article 7 of the UPOV Convention 1991, as cited above.

CONCLUSIONS

Plant variety protection is granted for new breeding results if, among other things, they are clearly distinguishable from any other plant grouping in at least one decisive characteristic.

A basic prerequisite for the use of molecular biological methods in the examination of distinctness would be a reliable connection between the marker and the expression of the characteristic. In many cases, however, it has not yet been possible to establish a connection between the characteristics to be used for granting the property right and the corresponding markers in the genome.

Even if such a link could be established, the mere examination of distinctness with regard to the genome cannot serve as a justification for the granting of a property right. Exclusive rights require justification. This justification was and has always been connected with the idea of reward. Only those who create progress should be rewarded with an exclusive right of exploitation for a limited period of time. However, more or less large differences in the genetic structure of plants do not mean progress. Rather, this must have advantages over the previously known plant, because, for example, the disease resistance is significantly increased, the shelf life of fruits is improved without additional technical effort or the durability of cut flowers is significantly extended. Progress must therefore become manifest.

The idea of a reward leads to the question of which characteristics must be relevant to justify protection if there are differences between the candidate variety and the previously known varieties of the same species.

As the genetic structure as such does not indicate which properties a breeding result has, which may be a desirable advantage, it is the phenotype that is the only means which allows a decision to be made on whether a breeding result deserves an exclusive right or not. This is equally valid for determining whether a new variety should be independent of a protected initial variety or qualified as an Essentially Derived Variety (EDV). The original idea of the EDV concept was to avoid copy breeding. If a new variety shows only marginal differences in comparison to the initial variety that fulfill the distinctness requirement but have to be regarded only as minor variations of it (catchword: minimal distances) there is a justification to regard the new variety as an EDV. But to allow a judgment of whether the difference is sufficient the phenotype is the only means to determine whether a new variety deserves to be independent of the rights vested in the initial variety. As with regard to EDVs, one needs to find the right balance between the breeder's exemption and the need to protect the breeders of initial varieties to safeguard that they will be rewarded properly for having created the same. Just looking at the genetic structure of the new breeding result and granting an independent right for it as long as there is sufficient distance in the genetic structure by no means would safeguard that each breeder must be properly rewarded for his investments and intuition to find a new variety that represents a rewardable breeding progress.

BREEDERS' VIEW ON ESSENTIALLY DERIVED VARIETIES

Ms. Erin Wallich
Intellectual Property Manager, Summerland Varieties Corporation, Summerland, Canada,
on behalf of ISF, CropLife International, CIOPORA, APSA, AFSTA, SAA and Euroseeds

Good afternoon to everyone in Geneva. My name is Erin Wallich, Intellectual Property Manager for Summerland Varieties Corp. (SVC). I want to take this opportunity to thank UPOV for inviting breeders to give their views on Essentially Derived Varieties (EDVs) and the proposed changes to the 2017 explanatory note on EDVs. As indicated in the title of this talk, "Eroding the Cliff Edge," breeders are acutely aware that today's scientific and technological advancements in plant breeding, while welcome, are rapidly changing the landscape of intellectual property (IP) protection for plant varieties. Breeders recognize that we are at a critical juncture where it is up to all of us to ensure that those changes do not inadvertently undermine our hard-fought IP rights. Let me explain ...

To begin with, I want to remind everyone about UPOV's mission statement: "To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society." This ideal has resonated with countries and breeders everywhere and has resulted in 78 of the world's countries adopting the UPOV system of plant protection.

In fact, Plant Breeders' Rights (PBR) and its adoption in Canada was the impetus for creating the company for whom I work. Our company was an idea first conceived by Agriculture and Agri-Food Canada's (AAFC) Summerland Research and Development Centre who had been breeding apple and sweet cherry varieties for 100 years. When PBR was first introduced in Canada in 1990, AAFC wanted to use the system to protect their varieties, but because they were a government entity that was prohibited from engaging in business, they needed a Canadian third party who could commercialize their varieties on their behalf. AAFC worked with the British Columbia Fruit Growers' Association (BCFGA) to create SVC in 1993. Today, SVC is owned by BCFGA, a non-profit grower organization, and we primarily manage varieties that come from AAFC's public breeding program, which we commercialize for the benefit of tree fruit growers worldwide.

In addition to representing AAFC breeders, I take the floor today in the name of numerous breeder associations: the African Seed Trade Association (AFSTA), the Asia and Pacific Seed Alliance (APSA), the International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), Crop Life International, Euroseeds, the International Seed Federation (ISF) and the Seed Association of the Americas (SAA). These associations represent the interests of thousands of companies and public entities who are active in research, breeding, production and marketing of agricultural, horticultural, ornamental and fruit plant varieties. Our members file almost all PBR applications in UPOV member countries and spend millions annually for the application and maintenance of their PBR titles.

Everyone in this meeting understands that crossing and selection remains the principal means of improving most plant traits and increasing genetic diversity in breeding populations. The fact that traditional breeding is critically important to continued crop innovation is apparent even to those working in mutagenesis breeding since they, themselves, wish to use the newest and most innovative of these varieties in their programs. We must also acknowledge that most of the breeding programs in the world are heavily invested in traditional breeding and have been for decades. They have a lot at stake here. Plant improvement through crossing and selection requires extremely long time horizons with considerable investment and long-term commitment. Given the enormous upfront costs of traditional breeding, it is absolutely essential that PBR provides strong protection for those breeders so that they can recoup their investment by collecting royalties that will support the future of these programs. Likewise, the integrity of PBR is important for the variety licensees. They bankroll this entire system through their investment in protected varieties and must be able to rely on PBR to protect that investment. Thus, strong protection for traditional breeders is the promise of the UPOV system that we must carefully and diligently preserve.

New Breeding Technologies (NBT), including genetic modification, random mutagenesis and targeted mutations, provide opportunities to create predominantly derived varieties from one initial variety. Breeders see NBT as a gift because it is an opportunity for rapid crop innovation at a much lower cost relative to traditional breeding. This is especially important in this time of climate change where immediate changes to the germplasm will likely be necessary to ensure crop resilience. In fact, with UPOV's breeders' exemption, a breeder can choose a commercially successful, but PBR protected, variety as their starting point and use NBT to make significant improvements to that variety. At first glance, this appears to be a wonderful and inclusive system that promises boundless benefits to society. The reality is that traditional breeding and NBT are not on a competitively balanced playing field. NBT is relatively cheap and fast, which means that its immediate benefits will quickly overwhelm the more gradual progress of traditional breeding. In addition, the breeder who uses NBT will have access to an additional form of IP, the patent system, which shields it from the breeders' exemption and, thus, the threat of someone else doing the same to them. What we ask is that UPOV recognize that NBT is a powerful tool that needs to be used responsibly. In other words, NBTs need to be introduced into the breeder toolbox in a way that respects the time, money and effort that traditional breeders have invested into their existing germplasm.

UPOV's Breeders' Exemption was originally intended to provide for the use of protected germplasm for the development of new varieties by crossing and selection. It should not allow for the exploitation of a single protected variety without the acknowledgement of the original breeder. The EDV principle placed a limitation on the Breeders' Exemption so that breeders and innovators could continue to support their programs as originally envisioned by PBR. Breeders are concerned that this limitation has now been undermined by the Explanatory Note for EDVs 2017 (EXN 2017) because it has created a very narrow scope for defining EDVs. According to the EXN 2017, a single modification of an essential characteristic may create a new variety beyond the scope of the EDV principle. The EXN 2017 also suggests that multiple modifications of an initial variety may lead to a new variety rather than an EDV, which is clearly inconsistent with the UPOV 1991 Act, which has no such limitation. Most breeders are unaware of the EXN 2017, but when they do learn of it, they are shocked and alarmed.

The EXN 2017 has, in effect, created a work-around for the EDV principal, and with the advent of NBT, that work around is now relatively easy to achieve. The breeding community wants to be clear that should UPOV preserve the current EXN for EDVs, the likely consequences are entirely predictable. There is little doubt that the current environment will attract parties whose primary objective is to recreate existing varieties with just enough of a change to design around the existing IP. That is not innovation. That is piracy. Thus, the breeders have a right to ask UPOV who, exactly, will benefit from this scenario and why have they suddenly become more important than the traditional breeders who comprise the majority of UPOV users?

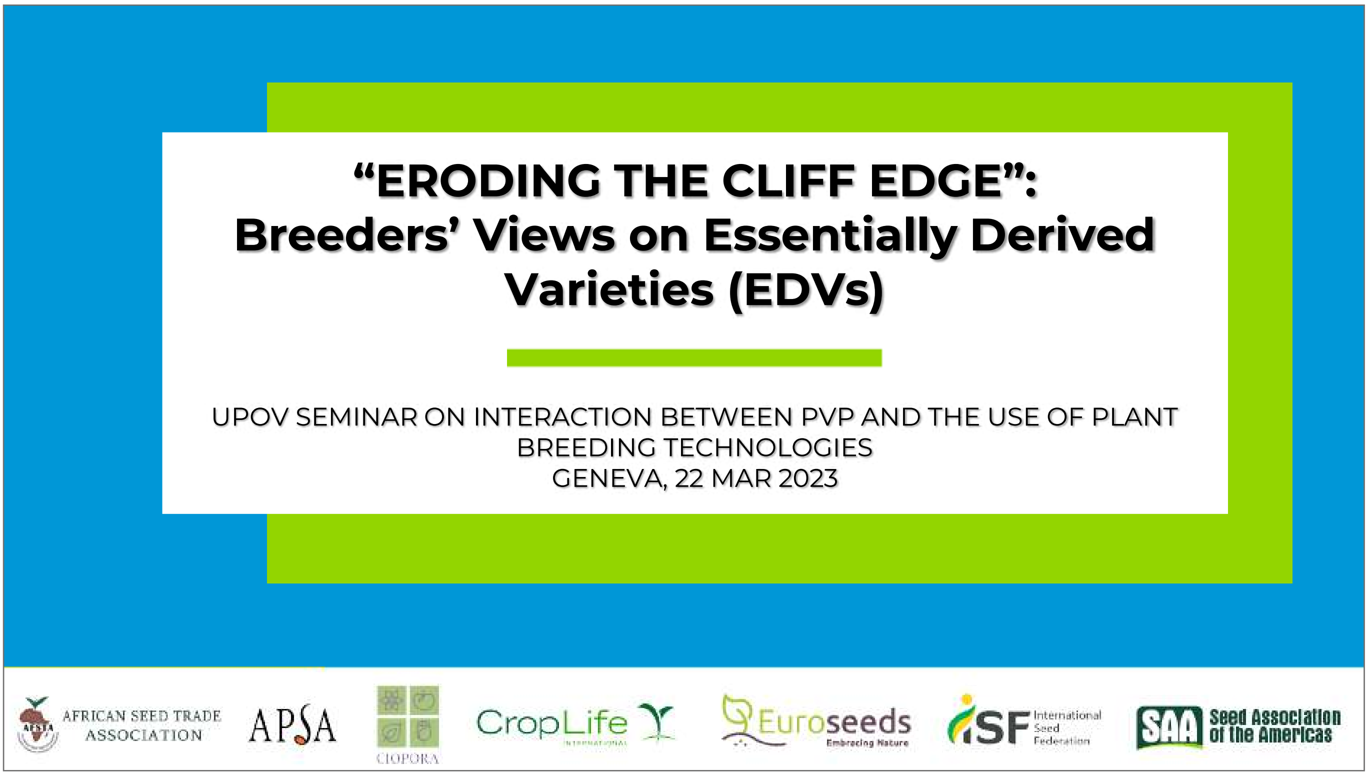
Some will defend the claim that changing an "essential characteristic" should allow for a new variety beyond the scope of EDV; however, there is no crystal-clear definition for an "essential characteristic" of a variety. A breeder or grower might define it as a trait of commercial significance. A PBR office might define it as a differentiating trait in a Distinctness, Uniformity and Stability (DUS) test. That definition could change with time if a particular trait makes a plant increasingly resilient to climate change. This vague definition is a particular problem when a traditional breeder is faced with defending their rights against another breeder who has made a single change to that traditionally bred variety. Since the court will have considerable difficulty determining whether the altered trait was truly "essential," whatever that means, both the traditional and NBT breeders will be burdened with a lengthy court proceeding with little assurance of success. The risk remains high that courts will rule against the traditional breeder, which means that the new variety, which should have been considered an EDV, now has the potential to undermine the value of the traditionally bred variety in the marketplace since the new variety was created at a fraction of the cost and time. In the face of this grossly unfair competitive environment, the traditional breeders will quickly lose the royalty streams that would otherwise keep their programs viable.

Consequently, the breeders who use the UPOV system respectfully request that Draft 3 of the EXN EDV be implemented to provide much needed clarification on EDVs. Draft 3 clearly articulates the breeders' position that predominant derivation is the key requirement for EDVs. Predominant derivation can be achieved by either genetic modification or mutagenesis (random or targeted) of a single Initial Variety (IV). Predominant derivation can also be achieved by a process such as repeated backcrossing that uses two or more parents followed by selective retention of the genome of a single IV. Draft 3 explains that an EDV may include changes to the essential characteristics of an IV, and an EDV may have one or many differences relative to the IV. Draft 3 does not hamper innovation. It provides a fair and balanced solution for breeders who use traditional breeding techniques and provides a pathway for those using NBT to work with traditional breeders to truly innovate for everyone's benefit. After all, protecting crop innovation for the benefit of society is the raison d'être for the UPOV plant protection system.

The breeders would also like to point out the inherent contradiction in UPOV's inability to reach a consensus on whether to update the EXN EDV. By failing to respond to the breeders' wishes, UPOV is making ***a clear decision that is not based on consensus*** to support NBT breeders over traditional breeders. Moreover, this decision will have predictable results. The large breeders, who have the resources to rapidly adapt, will likely incorporate NBT tools and take advantage of IP protection systems outside of PBR. However, they may also become more cautious in their licensing practices, which means that the innovative varieties that come from their traditional breeding programs will become increasingly less available to small and medium-sized growers as they consolidate their licenses with fewer, larger growers. This consolidation will be deemed necessary to ensure that traditionally bred varieties do not end up in the hands of third parties who have the interest and capacity to use the licensed varieties in their own NBT-based programs. But what about the many smaller private and public breeding programs? Weak IP protection under the PBR system means that these traditional breeders will always be the underdogs when defending their rights against a third party who has modified their most valuable commercial varieties with NBT. Since they will be undermined by changes to their own varieties, these traditional breeders will be forced to close their programs and decades of investment will be lost. Most alarmingly, without these programs, we no longer have the means to introduce and maintain biodiversity in many of our domesticated plant populations. The result will be a gradual genetic bottleneck for many of the world's crops and a society that no longer benefits from what was once an egalitarian plant protection system.

As we all know, intellectual property rights are only as strong as our ability to enforce them. The current EDV rules as contemplated under the EXN 2017 undermine the strength of PBR laws in all UPOV countries. The EXN 2017 makes the current EDV rules unclear and contradictory, which means that courts will struggle to interpret them, and breeders will be faced with expensive court cases with unpredictable results. This is not what the various countries and breeders signed up for. They signed up for strong PBR laws that create a fair IP framework, encourage investment in plant breeding and split benefits downstream. We want UPOV to share this long-term vision for PBR and we, the breeders, respectively request that you replace the EXN for EDVs 2017 with the EXN EDV Draft 3 or, at the very least, repeal it. And we ask that you do this before it's too late.

Presentation made at the Seminar



UPOV'S MANDATE IN CANADA

- Agriculture and Agri-Food Canada (AAFC) with 100 years of investment in plant breeding
- Plant Breeders' Rights (PBR) introduced in Canada in 1990
- Summerland Varieties Corp. (SVC) was created to manage AAFC's varieties
- SVC is owned by the British Columbia Fruit Growers' Association and our mandate is to protect AAFC varieties for the benefit of tree fruit growers worldwide

AFRICAN SEED TRADE ASSOCIATION · APSA · CIOPORA · CropLife International · Euroseeds Embracing Nature · ISF International Seed Federation · SAA Seed Association of the Americas

ONE OF MANY

- Representing thousands of companies and public entities who are active in research, breeding, production and marketing of agricultural, horticultural, ornamental and fruit plant varieties
- These stakeholders apply for and maintain almost all Plant Breeders' Rights under the UPOV system worldwide

AFRICAN SEED TRADE ASSOCIATION · APSA · CIOPORA · CropLife International · Euroseeds Embracing Nature · ISF International Seed Federation · SAA Seed Association of the Americas

CROSSING AND SELECTION

- Remains the principal means of improving most plant traits and increasing genetic diversity in breeding populations
- Extremely long time horizons for new variety development with considerable investment
- PBR protection is a critical tool for ensuring continued support for breeding programs and for protecting the investments of licensees

AFRICAN SEED TRADE ASSOCIATION · APSA · CIOPORA · CropLife International · Euroseeds Embracing Nature · ISF International Seed Federation · SAA Seed Association of the Americas

NEW BREEDING TECHNOLOGIES

- New breeding technologies (NBT) provide opportunities to create predominantly derived varieties from initial protected varieties
- This is possible because UPOV’s Breeders’ Exemption makes PBR an open source system
- New varieties can be created more rapidly and at a lower cost
- NBT traits can then be protected under a patent system which effectively blocks further breeding (no Breeders’ Exemption) with the new variety

AFRICAN SEED TRADE ASSOCIATION · APSA · CIOPORA · CropLife International · Euroseeds Embracing Nature · ISF International Seed Federation · SAA Seed Association of the Americas

OUR CONCERNS

- The Breeders' Exemption was meant to allow the use of protected germplasm for the development of new varieties by crossing and selection
- The Breeders' Exemption was *not* meant for the exploitation of a single protected variety without the consent of the original breeder
- The EDV principle is the necessary limitation of the Breeders' Exemption so that breeders and innovators are able to support their programs as originally envisioned by PBR

AFRICAN SEED TRADE ASSOCIATION · APSA · CIOPORA · CropLife International · Euroseeds Embracing Nature · ISF International Seed Federation · SAA Seed Association of the Americas

OUR CONCERNS

- Current EXN-EDV (2017) has a very narrow scope; i.e., one modification of an essential characteristic may create a new variety beyond the scope of the EDV principle
- EXN 2017 is not consistent with the UPOV 1991 Act, which does not restrict the number of modifications for EDVs
- EXN 2017 does not reflect the breeders' understanding of EDVs
- Creates an opportunity for breeders using NBT to design around existing protections under the UPOV system

AFRICAN SEED TRADE ASSOCIATION · APSA · CIOPORA · CropLife International · Euroseeds Embracing Nature · ISF International Seed Federation · SAA Seed Association of the Americas

OUR CONCERNS

- The current Explanatory Note allows for a situation where a new, independent variety can be created from a single modification to an "essential characteristic" of a PBR protected variety
- An "essential characteristic" is difficult to define, but does not necessarily include traits that confer commercial value
- The new variety now has the potential to undermine the value of the original variety in the marketplace because it was less costly to create

EXPLANATORY NOTE: EDV DRAFT 3

- Draft 3 provides much needed clarification on EDVs
- Predominant derivation is the *key requirement* for an EDV and the result of:
  - Genetic modification or mutagenesis (random or targeted) of a single Initial Variety
  - Use of two or more parents followed by selective retention of the genome of a single Initial Variety through processes such as repeated backcrossing
- Differences between an EDV and its Initial Variety may include essential characteristics, and they are not limited to one or a few differences
- Draft 3 does not hamper innovation and provides a fair and balanced solution for breeders using crossing and selection as well as NBTs

CONSEQUENCES OF STATUS QUO

UPOV's unwillingness to update the EXN EDV is a decision with predictable consequences

- ✓ Large breeders have the resources to rapidly adapt
- ✓ Innovative varieties will become increasingly less available to small- and medium-sized growers as breeders reduce exposure by consolidating their licenses with fewer, larger growers
- ✓ Small- and medium-sized breeders will have weak IP protection
- ✓ Private and public traditional breeding programs will close
- ✓ Crop biodiversity will gradually decline
- ✓ Societal benefits from plant breeding will erode

CONSEQUENCES OF STATUS QUO

- Intellectual property rights are only as strong as your ability to enforce them
- The current EDV rules are unclear and contradictory and effectively weaken PBR
- Breeders need strong PBR laws that create a fair IP framework, encourage investment in plant breeding, and split benefits downstream
- Thus, the 2017 EXN for EDVs must be replaced by EXN EDV Draft 3 or be repealed


THANK YOU!
AFRICAN SEED TRADE ASSOCIATION
APSA
CIOPORA
CropLife
Euroseeds
Embracing Nature
ISF International Seed Federation
SAA Seed Association of the Americas

DIVERSITY OF BREEDING TECHNOLOGIES AND IMPACT FOR PLANT VARIETY PROTECTION

Mr. Christian Huyghe
Scientific Director Agriculture,
National Research Institute for Agriculture, Food and the Environment (INRAE);
Chair of the scientific committee of the CTPS (French committee for variety registration and seed certification), France

New breeding technologies have recently emerged. The advances in molecular biology and genomic selection are increasingly being used for a range of species. They speed up the process of breeding, make it possible to better use and protect the genetic diversity available either in the breeding pools or in the genetic resources, and do not induce any change in the intellectual property regime applicable to varieties and breeding material. On the other hand, New Genomic Techniques (NGTs) sometimes referred to as NBTs (New Breeding Techniques) are creating a very different situation that will be explored in the present paper. The key message of this presentation is that the Essentially Derived Variety (EDV) issue is likely to be modified by the NGTs, their future use in breeding over a range of crops and the intellectual property regimes that are relevant in the domain.

Among the NGTs, the CRISPR/Cas method is today the dominant technology, while ten years ago, significant effort was given to two other techniques (TALEN and Zinc-Finger). Major recent progress has been recorded in technical and financial access to CrispR/Cas technology, making it a tool that is affordable to an increasing number of public and private laboratories. Among the various enzymes, Cas9 is today the nuclease with the highest number of studies and uses in fundamental and applied research.

The most significant technical progress and use of CRISPR/Cas technology recorded in recent years include:

- more variability in ***PAMs (Post Adjustment Multipliers) motives + "PAMless"*** making it possible to edit all parts of the genomes;
- ***base-editing and prime-editing*** methods to induce modification of one or more bases;
- ***multiplex modifications*** are possible to simultaneously target several DNA sequences and to modify expression of several genes of multigenic families;
- ***action on gene expression*** is now possible. In this situation, the Cas enzyme recruits effectors. It is also possible to induce an ***action on epigenome*** by modification of epigenetic marks leading to condensation/de-condensation of DNA;
- ***chromosome reorganization*** has been obtained with induction of inversion and translocation of chromosomes;
- to avoid the ***in vitro step***, which is a very limiting factor as some species are difficult to deal with cultured ***in vitro, de novo*** induction of the meristem has been implemented through "Virus-induced heritable gene editing"; and
- ***production of edited plants without intermediary phases of transgenesis*** has also been achieved, again, increasing the range of species that could be edited.

As a result of all these still ongoing technical improvements, CrispR/Cas is clearly a promising tool whose possibilities for plant breeding have not yet been fully documented. It seems to provide the possibility to speed up innovation by shortening breeding cycles, to foster agriculture sustainability with the possibility to edit more traits and to provide new variation, including for traits that are not variable in an agronomic species.

In recent years, many proofs of concept have been provided of the ability to modify agroecological traits.

In a survey run in 2022 by the Scientific Committee of the French CTPS, according to scientific literature (Web of Science), the genome-editing techniques have been successfully used for various plant breeding objectives. This includes:

- ***yield*** (such as plant architecture, number of grains, grain weight) (25% of the papers);
- ***nutritional and product quality*** (such as increasing the content of nutritious compounds, decreasing antinutritional factors) (22%);
- ***resistance to biotic stresses*** (such as bacteria, fungi, viruses, insects) (19%);
- ***industry and processing*** (including shelf-life duration, browning) (17%);
- ***resistance to abiotic stresses*** (including resistance to drought stress, cropping on polluted soils, tolerance to high temperatures) (8%);
- ***Aroma/color*** (of flowers and fruits) (6%); and
- ***tolerance to herbicides*** (3%).

However, as documented by the French Priority Research Program on Genomic Selection, these results have been recorded on a limited number of species, concentrating most efforts on rice, tomatoes, maize, soybean and oilseed rape – the top five species. This is due to the underlying market size, the need of high-quality genome sequencing and the possibility to implement efficient in vitro regeneration.

THE EVALUATION OF EDITED VARIETIES IS UNDER DISCUSSION, AT LEAST IN EUROPE

Two approaches are possible, either considering the breeding method or the final product, namely, the variety:

- An approach based upon the breeding method would lead to different considerations of: (1) the classical breeding method, including genomic selection; (2) genetically modified organisms (GMOs); and (3) NGTs. In the case of NGTs, it would then need to determine the risks associated with the method such as off-targets that are limited with the most advanced CrispR/Cas technologies and mutations occurring during the in vitro culture stage.
- An approach based upon the value of the final product would lead to consideration of two contrasting situations:

  - If the edited traits are already variable within the species and among registered varieties, the agronomic traits of varieties have been under evaluation for the variability already existing within the species, corresponding to a continuous breeding. Under the existing process of evaluation for registration, both positive services and negative ones (disservices) are observed and aggregated in the existing registration rules. The only exception of this situation would occur if the variation has been extremized to such a value that the plant physiology is altered.

  - A new variation, for traits where no variation has ever been exploited. This could generate new effects/services never observed and evaluated in classical breeding. In such a situation, evaluation of services and disservices and their explicit integration in the decision rules would be required.

NGTS RAISE NEW ISSUES FOR INTELLECTUAL PROPERTY AND EDV

Several issues have to be discussed and considered. The open access to genetic diversity is at the core of the efficiency of the breeding programs. As a consequence of NGTs' implementation, concerns may be raised regarding the accessibility to the genetic diversity, existing either in the current varieties under Plant Breeders' Rights (PBRs) or in the genetic resource. This is related to patents on edited traits.

The coexistence of the various intellectual property regimes is really at stake as NGT variety could be under PBRs and patent(s). The consequences for breeders are important. Indeed, for using, as a source of diversity, a variety carrying a patented gene/allele, the breeder should either pay a license right if the gene is preserved in the final variety or withdraw the gene and not pay a license right. The multiplicity of patented genes would create a minefield for breeders, reinforcing the need of well-documented platforms.

The EDV key features are according to B. Kiewiet (2006)[1] : (1) retaining the expression of the essential characteristics of the initial variety; (2) being conform (essentially in the Basic Regulation) to the initial variety; and (3) to be related to phenotypical characteristics and to be genetically heritable. EDV are also determined as originating from an act of derivation and being phenotypically similar to the initial varieties except for the difference due to the derivation.

How does this fit with NGTs? The genome editing may go far beyond a simple/single modification. Indeed, regulation genes could be modified, deep physiology could be affected, such as features related to photosynthesis and the multiplex possibility increasing the extent of the modifications that could be obtained. Moreover, due to the NGTs technical progress, high-throughput editing could be proposed by specialized operators, proposing thorough editions on varieties protected by a PBR previously delivered to another owner.

The integration of NGTs into breeding programs will provide part of the answer. Indeed, the technique could be used either early or late in the breeding schemes.

When the creation of new genetic diversity is used early in breeding programs, it will likely focus on traits where the induced genetic diversity may require the adaptation of many other physiological traits. This is likely to be the situation for most edited traits related to yield (phenology, resistance to abiotic stresses, architecture) and to quality. In that case, no EDV issue will be relevant.

On the other hand, if the NGTs are used to provide extra traits in optimum genetic backgrounds, EDV issues become relevant. It can be anticipated that this is likely to be the case for pest and disease resistance traits/genes, as well as resistance to herbicides.

CONCLUSIONS

NGTs are creating a new situation for plant breeding and related intellectual property issues. Indeed, NGTs offer large possibilities, thanks to their precision and the multiple targets, even if today, proofs of concept have mainly been published. Some hurdles have still to be overcome, as not all species can be edited because high-density genome sequencing is needed and ***in vitro*** regeneration must be easily performed. It is thus important to ensure technological sovereignty.

The variety evaluation has been discussed with a need to characterize services and disservices at the scale of the crops and cropping systems when new variation is made available. Traceability and transparency will be required for coexistence.

Concerns may be raised related to societal acceptance leading to the need to investigate the possible sharing of benefits, to facilitate the access to technology and to focus on traits relevant to major societal issues, such as adaptation to climate change and agroecological transition. The access to genetic resources must be guaranteed as well as diversity of cultivated species.

However, the cost and accessibility of these technologies could speed up the concentration of breeding companies. Indeed, today six international companies have 50% of variety market shares. This was reinforced by the GMO technologies. If such a concentration actually occurs, this would lead to a possible weakening of the PBR system, which shows a tremendous efficiency since 1961 to foster genetic gains in all cultivated species.

Varieties carrying edited traits could be considered as ***essentially derived varieties*** but edited traits or multiplex edition could modify expression of essential characteristics, and this would not fit anymore in the EDV rules. Moreover, high-throughput genome editing could become a reality for some economically important species.

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[1] https://cpvo.europa.eu/sites/default/files/documents/articles/EDV_presentation_PlantumNL_March_2006_BK.pdf

22 March 2023,
UPOV
Geneva

Diversity of breeding technologies and impact for plant variety protection

Christian HUYGHE, Scientific Director Agriculture, INRAE, France

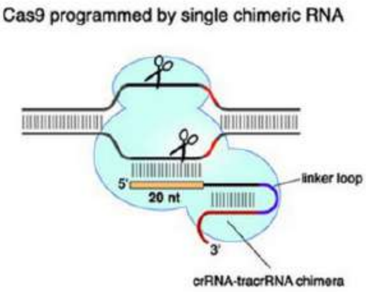
Key message

- The Essentially Derived Variety (EDV) issue is likely to be modified by the New Genomic Techniques (NGTs), their future use in breeding over a range of crops and the intellectual property regimes that are relevant in the domain

INRAE

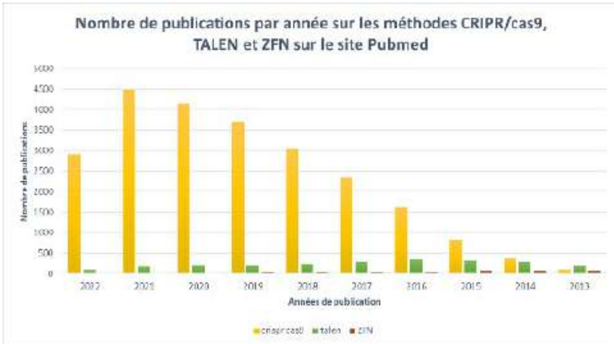
CRISPR/Cas method is today the dominant NGT technology

« Clustered Regularly Interspaced Palindromic Repeats » / « CRISPR Associated Protein 9 »



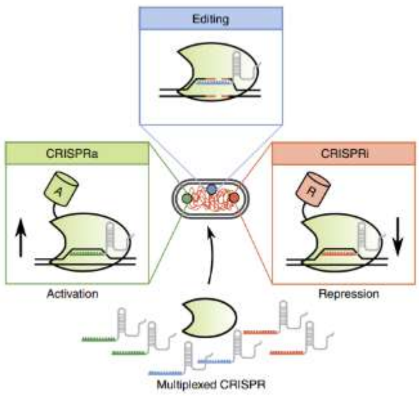
Major recent progresses
Technical and financial accessibility
Tool affordable to an increasing number of laboratories
Possibilities of multiple targets editions

Cas 9: nuclease with the highest number of studies and uses (fundamental and applied research)



INRAE

CRISPR/cas : recent technical progresses and use of this technology



(McCarty et al., 2020)

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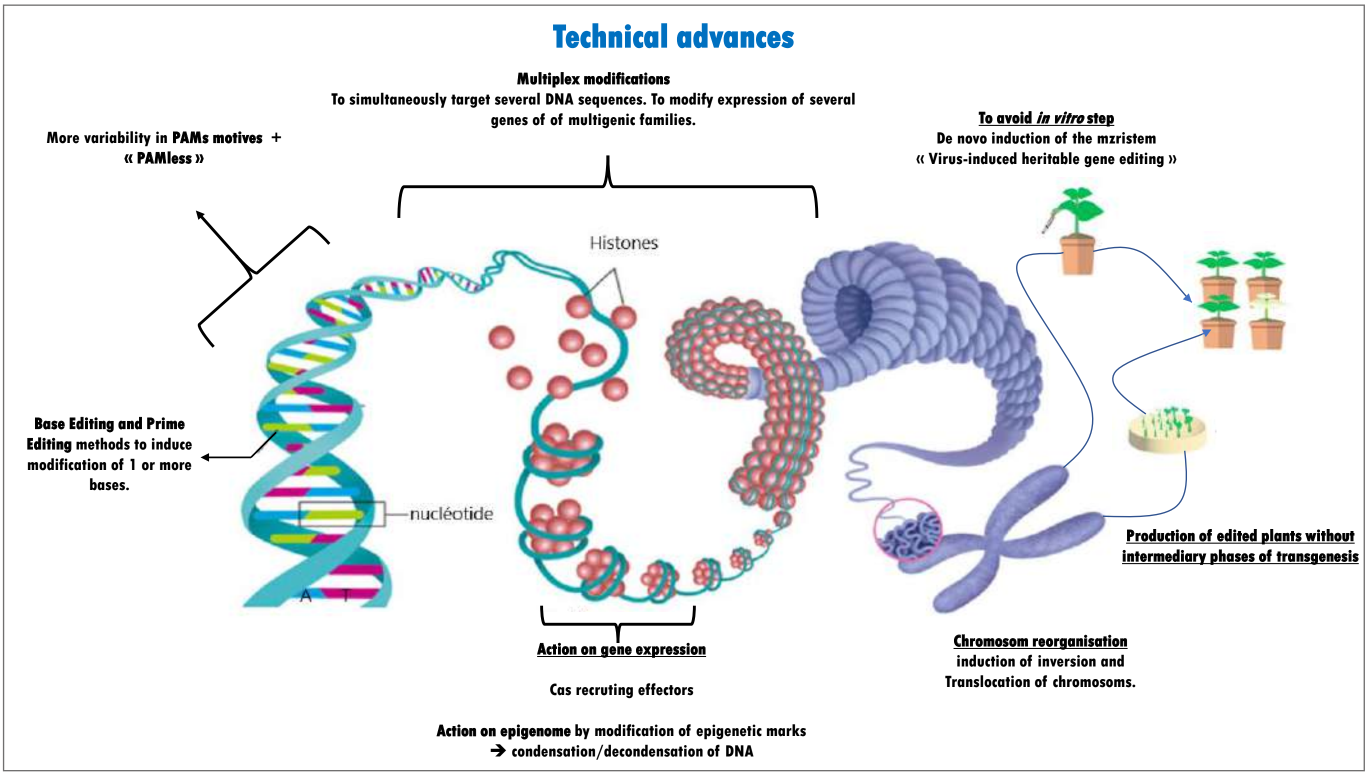


- **Promising tool whose all possibilities for plant breeding have not yet been documented**
  - **Accelerating innovation to foster agriculture sustainability**
  - **More accessible traits**
  - **New variation available**

- Many proofs of concept of the ability to modify agroecological traits

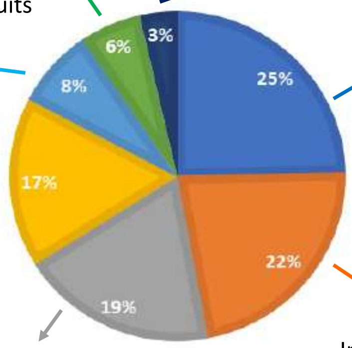
According to scientific literature (WOS): use of genome editing techniques for plant breeding objectives

Aroma / coulor
Flowers
Fruits

Tolerance to herbicides

Resistance to abiotic stresses
Resistance to drought stress
Cropping on polluted soils
Tolerance to high temperature

Yield
Plant architecture
Number of grains
Grain weight



Industry and processing
Shelf life duration
Browning

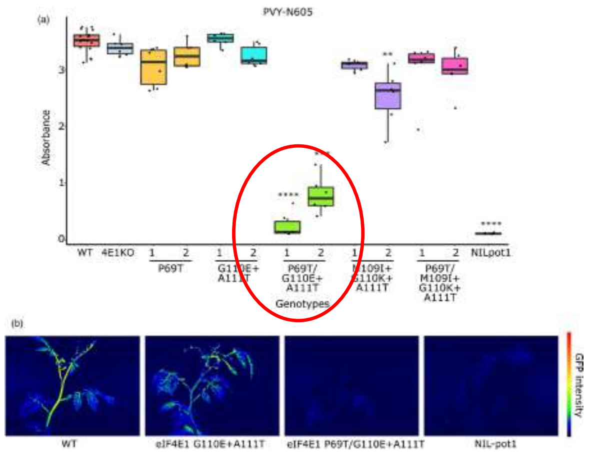
Nutritional and product quality
Increasing content of nutritious compounds
Decreasing antinutritional factors

Resistance to biotic stresses
bacteria, fungi, viruses,
insects

INRAE

Example of gene-editing of tomato, copying eiF4E1 pepper allele. Inrae Avignon, France

An iterative gene-editing strategy broadens eIF4E1 genetic diversity in Solanum lycopersicum and generates resistance to multiple potyvirus isolates

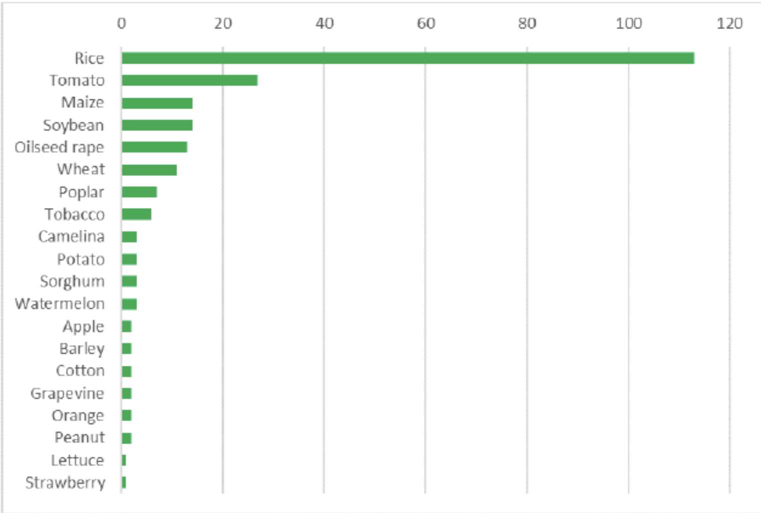


Kuroiwa K, et al, Plant Biotechnology Journal, First published: 30 January 2023, DOI: (10.1111/pbi.14003)

INRAE

A limited number of species concentrates most efforts:

- Market size
- High-quality genome sequencing required
- Efficient *in vitro* regeneration



Number of scientific publications, with proofs of concept (in 2022)

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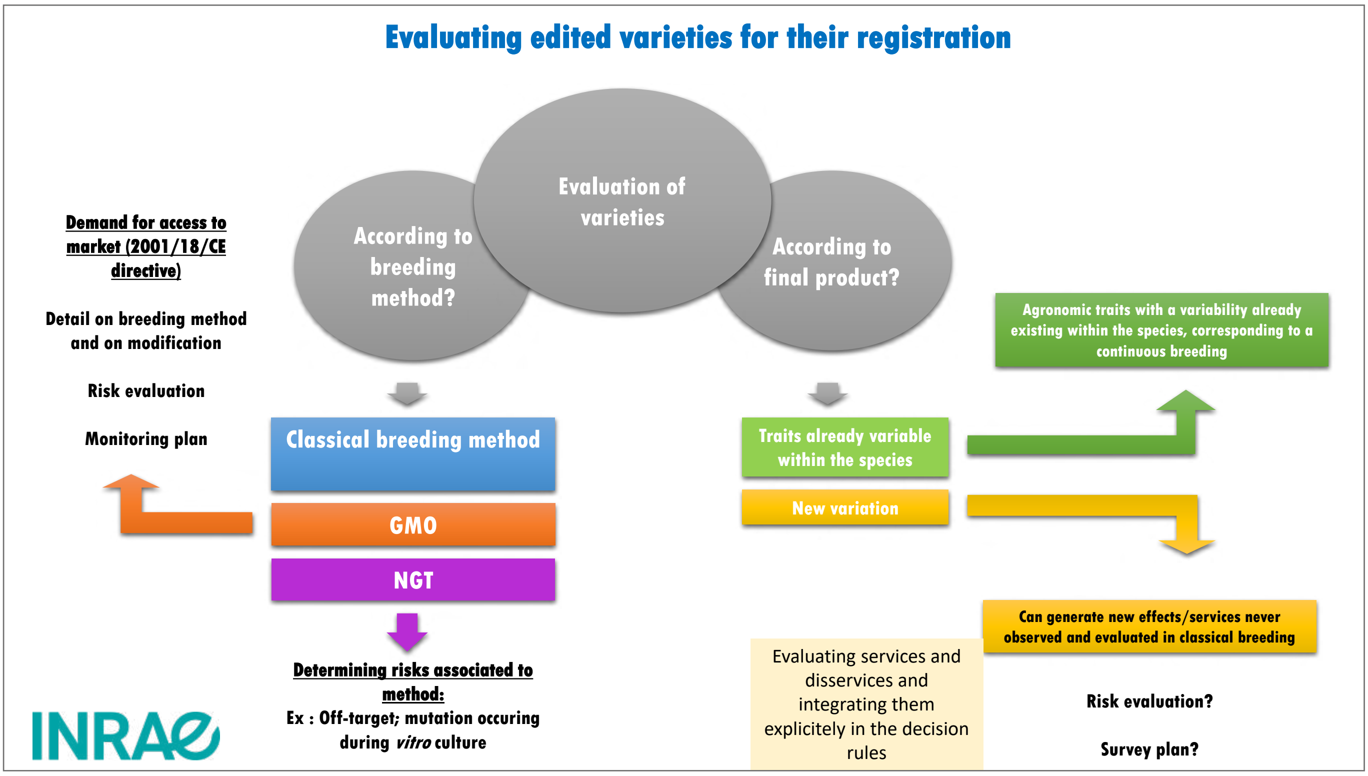
Evaluating edited varieties

INRAE



Intellectual property issues and EDV

Access to genetic diversity

- Concerns regarding the accessibility to the genetic diversity, existing either in the current varieties under Plant Breeders Rights or in the genetic resource
  - Patents on edited traits are a key issue
  - The coexistence of the various intellectual property regimes is really at stake

INRAE

Intellectual property

	Patent/technology	Patent/trait	P.B.R.
Technology	✓	✗	✗
Gene	✗	✓	✗
Variety	✗	✗	✓
Breeder exemption	✗	✓	✓
Farmer priviledge	✗	✓	✓
Crossed licence	✗	✓ ⇄	✓

NGT variety could be under P.B.R. and patent

INRAE

For breeders

For the use of a variety carrying a **patented gene/allele**, the breeder must:
- Pay a licence right if the gene is preserved in the final variety
- Withdraw the gene and not to pay a licence right

Multiplicity of patented genes would create a minefield for breeders

↓

Full transparency required on PI on varieties

↓

More challenging work for breeders

Survey of patents databases (OEB, PINTO, ACLP, ILP, …)

↓

Patents on traits could be a source of rejection by the society

Essentially Derived Varieties

- EDV key issues (according to B. Kiewiet, 2006)
  - Retaining the expression of the essential characteristics of the initial variety
  - It conforms (essentially in the Basic Regulation) to the initial variety
  - EDV must be related to phenotypical characteristics and must be genetically heritable
  - EDV are determined as
    - Originating from an act of derivation
    - Phenotypically similar to the initial varieties except for the difference due to the derivation
- How does this fit with NGT?
  - The genome editing may go far beyond a simple/single modification
    - Regulation genes
    - Deep physiology
    - Multiplex possibility
  - **With NGTs progresses → high-throughput editing by a specialized operator on a variety protected by a PBR (*delivered to another owner*).**

INRAE

- Integration of NGTs in breeding programs
  - Creating new genetic diversity to be used in breeding programs (*the induced genetic diversity may require the adaptation of many other physiological traits*). This is likely to be the situation for most edited traits (phenology, resistance to abiotic stresses, architecture).
    - In that case, the technology will be used early in the breeding programs and no EDV will be relevant
  - Providing extra traits in optimum genetic backgrounds.
    - In that case, EDV is relevant. This is likely to be the case for pest and disease resistance traits/genes

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Conclusions

- **NGT: large possibilities**
  - Precision, multiple targets
  - Today, mainly proofs of concept
  - Importance of technological sovereignty
- **NGT: some hurdles as not all species can be edited**
  - Need of high-density genome sequencing
  - In vitro regeneration
- **Variety evaluation**
  - Variable traits : no need of modification of the evaluation pathway
  - Disruptive traits : characterization of services and disservices at the scale of the crops and cropping systems
- **Traceability and transparency required for coexistence**
- **Intellectual property**
  - Different possible regimes
  - An important issue on patenting edited traits
- **Concerns**
  - Acceptability: sharing benefits, access to technology, focussing on traits of societal relevance (climate change, agroecological transition)
  - Genetic resources and diversity of cultivated species
  - Boosting effort of public research

- **Technologies (cost, accessibility) that could speed up concentration of breeding companies**
  - Today 6 companies= 50% of variety markets
- **Possible weakening of the PBR system** (which showed a tremendous efficiency since 1961 to foster genetic gains in all cultivated species)
- **Essentially Derived Varieties**
  - Varieties carrying edited traits could be EDV, but…
  - Edited traits or multiplex edition could modify expression of essential characteristics
  - High-throughput edition could become a reality for some 'important' species

DISCUSSION WITH SPEAKERS OF SESSION IV

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

We are quickly running out of time but I would like to open the floor both here in person and virtually for questions to any of our speakers that we have.

Any questions coming from the floor or any questions coming virtually?

Okay, sure. Absolutely. I don't see any questions yet but you know, let me kick one off with a difficult question for our panelists. So, we've heard from Ms. Huerta at the beginning of this session that one of the objectives of the EDV concept is to encourage cooperation between breeders and the developers of new technologies such as genetic modification. I would like to solicit from our panelists here on this idea that perhaps a broad and strong interpretation of the EDV concept actually creates a fair and balanced relationship, one of parity and good negotiation position between the breeder of the initial variety and the secondary breeder, perhaps using new breeding techniques.

Would you like to take that? Okay. Thank you, Gert.

WÜRTENBERGER Gert (Mr.) (speaker):

Well, as the concept is at the moment, it won't work. I am always in favor of negotiation but if the rights holder of the initial variety does not get what it is in her or his or its mind, then it doesn't work. You need to have a balance of weapons, so to say. And again, just allow to use the EDV and then the owner of the rights and the initial variety need to come and negotiate and if they don't come to a negotiation result, which may be the case in 20% or 10% of the cases, then you need to ask the courts for support. But the basis, of course, should be negotiations. And from the seed industry, certain crops, we know this works, the licensing platforms, but not, as I said, with the present approach.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Thank you, Gert. Maybe I will turn it over to – we'll go in order of presenters. Erin, do you have any reaction to my statement?

WALLICH Erin (Ms.) (speaker):

I think that if you are coming as someone using new breeding technologies and you're offering an innovation that's not particularly attractive to a breeder, it's not going to add to the value of their initial variety, then yeah, probably they will turn you down. However, there are competing breeders out there and what one breeder may not want, another breeder might be interested in talking about.

There is also a lot of open varieties out there that you don't need to actually use a protected variety as your starting position. But I think with disease, the increase of disease and the increased need for adapted crops, I think if an NBT breeder came to another breeder, traditional breeder, with something that was going to make their variety viable in the marketplace, then 100% they are going to be interested in that innovation.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Christian, your thoughts?

HUYGHE Christian (Mr.) (speaker):

I think that the discussion will never be balanced and it will always be – the losers are going to be the breeders for three reasons. The first is that the resources needed are not at all the same. The breeders have an awful lot of genetic resources they have to handle. While those, the providers of technology, they will have more and more access to a diversity of techniques, though the costs today they have related to the cost to the access to technology will drop down. This is the first reason.

The second is that they do not have the same long-term vision. A breeder must have a long-term vision. Otherwise, it is appears while the provider of technology could have a very opportunistic approach, changing one trait and then move to another.

And the third one, to my mind, which is the most important, is that the losers, the main loss for the society will be the loss of diversity of species.

With the plant breeders' rights, it is possible for a breeder to live on the small market because there is little competition, but he may live. But with the introduction of the new technologies, if they are not properly regulated, there will be more progress on the large species than on the small ones. And the breeders of the small ones will disappear.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Thank you for your thoughts and views. I will turn it back over to the floor if there are any questions, or online. I see first back of the room, I think CIOPORA. CIOPORA, I'm sorry.

DE ROOS-BLOKLAND Judith Maria Anneke (Ms.):

Thank you, Anthony. Well, I would also like to answer your question because I think we saw earlier, a flow chart presented with the two options that if there is no value created, that would be an EDV, but if there is a new value, then that would not be an EDV. I think if you are not adding value to a variety, why would you market it? So, in that case, I think there would be no interest in cooperation or in marketing that variety at all. The interest in marketing a new variety is of course only in the case where there is a new value. So, that indeed is the grounds for cooperation and entering into a negotiation.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Thank you very much. I think I see also our friend from Spain. Please, you have the floor.

CUBERO SALMERON José Ignacio (Mr.):

I have to answer first to the last question because yes, you have interest in trading and selling a variety with a very insignificant character because you can – you can sell it at a lower price and then it is – it was because of that – it is not a good word – it was called in very old times, piracy.

But anyway, I was not talking about that but to – for me, that the title of your talk, this breeder's view on essential derived varieties. But you know that not all the breeders share your ideas. Then I would suggest that the title would be some breeders' views on essentially derived varieties, or better, much better in my opinion, a big seed company's view on essentially derived varieties.

And it makes a big difference because a big company doesn't have – will never have the problem of EDVs because they are producing continuously, new varieties, introducing new genes, and they don't have the problem of EDVs. The EDVs, it is for small farmers or even for private farmers – sorry – for private breeders. Still, there are private breeders. For example, on ornamentals.

And then please only, you can accept my grammatical correction or not, but not all the breeders. Even in the state, you know that there are big companies but there are associations of small and medium-sized seed companies that are opposing to this concept of EDVs.

And – and then I think that perhaps you talk about many other people here in the audience, speak about traditional breeders and modern or NBT breeders. No, this is wrong. Breeders, plant breeders have accepted all time, all techniques. After 10,000 years of only selection, in the 18th century was introduced crossing. Only in the 17th century. To be enhanced in the 19th century.

At the beginning of the 20th century, the genetic ideas of Mendel were accepted after some long discussions that finished in the fourth congress of plant breeding. By the way, it was called the 4th Congress In Genetics. Plant breeding is the model of genetics. The two first congress, international congress in genetics, does not exist. They were congresses in plant breeding. They were accepting genetic ideas. Then they came mutations, then they came polyploidy, then they came handling of chromosomes. Then molecular markers. All of these techniques were accepted by plant breeders. And then NBT, and they will be accepted by the plant breeders, and in the future, they will accept any technique.

I was a traditional breeder. I went to the states for a sabbatical to learn by myself the new techniques, and I went back to Spain, I told more people. Look, forget about that. It is necessary to inform young people because our minds are not made for these kinds of techniques.

But this is the way new techniques are accepted and they will accept NBTs. Just now, they are accepted, and it is not difficult. Please don't speak about traditional –

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

I'm not sure there's a question in there. There's certainly a statement or maybe several and we certainly appreciate it, but we do have limited time and we need to open the floor to others.

Now, I think there was a statement maybe directed. Erin, did you want to respond to it or?

WALLICH Erin (Ms.) (speaker):

I feel a little bit like yes, that you are right, that breeders do accept multiple approaches to crop innovation. I don't disagree with that in the slightest. We too are very interested in new breeding technologies even though breeding tree fruits is a twenty or thirty year process. We would like to shorten it up as well.

My point was really about creating a plant protection system that continues to value long-term investment because the crossing and selection process is, at the end of the day, the way that you maintain genetic biodiversity in your domesticated plants.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Thanks, Erin. So, I think we'll move. Elmar, please, and then we're going to switch to online. We have a few questions. So, please, you have the floor.

PFÜLB Elmar (Mr.) (speaker):

Thank you very much, Anthony, and thank you very much for these really interesting discussions. I'd like to ask a question with regards to what will the breeding community look like in about five years, ten years' time? Because what we hear today is very often you know, we have the traditional breeder's and we have the ones that use NBTs. So, it's kind of, you know, two sides that kind of are competing. But how – it's related to the former remarks – will the traditional breeders adapt new breeding technologies and what will that mean then in terms of EDV? How do we design that concept with regard to dependencies? I have a feeling, that's the real question, if you're not careful enough, wouldn't we create too many dependencies and really have a breeder's exemption that is in the way? Although, that's really down the road. It's not – the situation is different today but let's think five, seven years down the road. What would that mean? Then looking at the breeding community, what are they doing? What type of tools they are using?

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

If one of our speakers would care to take that question?

HUYGHE Christian (Mr.) (speaker):

Yeah, I would like to react. I don't think it's – the question is good, but I don't think it is completely relevant. And the point is not what about the breeders' community. It is what the farming and agriculture is going to look like in fifteen or twenty years from now. And it's how we are going to address the key challenges. If we are not able to address the challenges such as losses of biodiversity, adaptation or mitigation of climate change, then we will be in a real problem.

And the question is then, what are the best organizations and the associated intellectual property which will make us able to cope with these key challenges? The common good we are facing are tremendously important, as Anthony reminded us at the beginning of this session, and this is the key point. And the breeder community must adapt to that but not thankful, per se. So, yeah, it was a good point but I react another way.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Okay. Thanks very much. Now, we don't want to be ignoring our participants online, so we have two final questions that we will take from those who have been patiently waiting online. So, Kwanghong Lee, please, you have the floor.

LEE Kwanghong (Mr.):

Okay. Thank you, Mr. Chair. Let me explain my opinion, that personally, I finally understand the purpose of this seminar is for the new technologies of breeding and EDVs. Actually, the EDV is a relation between breeders, not breeder – between breeders and sellers. So, it's kind of – what do you say – a zero-sum game, like I said. So, it seems like the – I want to ask breeders associations, presenters, about this new breeding technology, that they agree to accept the NBT as not EDV. Okay? Thank you.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Erin, I think that one was for you.

WALLICH Erin (Ms.) (speaker):

Yeah. I think at this point, the concern is about the explanatory note and the fact that it undermines the EDV concept. It is extremely narrow and at this point in the breeders' opinion, there is a lot of innovation from new breeding technologies that would create fairly minor differences from an issue of variety but would still fall outside of the scope of an EDV. So, that is a real concern because you are starting to get into an area where you're getting back to the question of – of situations that are very similar to piracy, where someone needs to use a new breeding technology to make a very rapid and inexpensive change to an initial variety and then put it out, and then they can put it into the marketplace for cheaper. It will undermine the market share for the breeder. It will undermine the market share for whoever is licensing the rights to that initial variety. Things like that do happen and they have happened to our company. So, that's what we're most anxious about avoiding.

We're also quite concerned about the fact that there needs to be – there does need to be a lot of clarity in how to describe an essentially derived variety because there is worry that if you end up in a court and you're having, as a traditional breeder or any breeder, if you end up in the court and you're having to try to define what an essentially – an essentially derived variety is and the – the means that you're using to describe that are very vague, then you're going to leave it in the hands of the court. The court is not going to understand what the differences are. And that can be very, very, very expensive for all parties that are involved. And there are plenty of examples of that going on right now. We want to avoid that.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Okay. Thank you. Thank you, Erin. Okay. Thomas Leidereiter, you have the last word on this but please, succinct, to the point, impactful, and then I think we have to close this part of the session. So, please, the floor is yours.

LEIDEREITER Thomas (Mr.):

Thank you very much. Can you hear me?

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Yes.

LEIDEREITER Thomas (Mr.):

Good. Thank you. There is one very short remark to my dear friend, Jose Cubero, who was speaking a lot today, and we have been in a working group on EDV before. EDV and intellectual property is not a botanical concept. It is just a legal concept. And I know Jose doesn't like to hear it but it's for the lawyers to determine the scope of protection.

Secondly, I would like to address the speaker from France, which I don't dare to say his name because I think I can't pronounce it. I agree totally with the three risks which you have described in your presentation with the future of classic breeders, and there is a good reason that AIPH, we're represented by Huib Ghijsen, and the breeders' group, represented by CIOPORA and all other breeders, are jointly cautious to freeing new breeding technologies from the EDV concept. And it is a risk to genetic diversity and to the farming industry in the future and by this, it is detrimental to the UPOV mission statement. It is detrimental to the whole of society and therefore a risk for UPOV as well. Thank you.

PARKER Anthony (Mr.), Vice-President of the UPOV Council (moderator):

Well, thank you. So, once again, thank you for that lively discussion. Thank you for the presentations, for – that were very enlightening and informative. I think our session is now over for the last session for the day, but I would like to invite back someone who you have met before this morning, our President of UPOV Council, Dr. Yehan Cui, for some closing remarks.

CLOSING REMARKS

CUI Yehan (Mr.), Vice-President of the UPOV Council (moderator):

Thank you, Mr. Anthony Parker. It has been a long day and dear participants in the room and also online, in the seminar, there are seventeen speakers providing a wide perspective, covering a wide range and interaction between plant variety protection and the use of plant breeding technologies. Thank you all for the hard work on your routine breeding activities, legal, and administrative work, to bring us the very interesting and the best quality of the presentations today.

Specifically, we also come across several senior speakers who give us very valuable experience and what the ’91 Convention, what happened at that time, and also what the PVP Office did dealing with the routine plant variety protection work. Also, the EDVs and some legal aspects.

So, I propose a round of applause to them and the – for the very distinctive and very valuable presentations today. Thank you.

Thank you. As Peter mentioned earlier in the opening, the purpose of the seminar is to gather information and interaction between plant variety protection and the use of plant breeding technologies to present to the consultative committee and working group on EDVs for their understanding and consultation and consideration and develop an updated version of the explanatory notes on EDVs.

As we know, plant breeding technologies have been developed rapidly in the past twenty years. New breeding technologies, together with conventional breeding methods, have created a lot of new varieties, some of them through UPOV’s PVP system to be protected and has benefitted the whole society since then.

From UPOV’s perspective, we would very much like to seek the balance between at least between the plant variety protection and plant breeding technologies being used particularly to – in new breeding technologies.

Our goal is to encourage the breeders continue to breed new varieties by using either new breeding technologies or conventional ways in the future.

Finally, many thanks for all the speakers, moderators, participants, and to come to take part in the seminar. Also, thanks to all the UPOV staff and WIPO staff to make this seminar a success. At last, many thanks to all the interpreters for your hard working. Please note the proceedings of the seminar will be published on the UPOV website.

Now, may I declare the seminar is closed. Thank you all.

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