CropLife Australia

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IP Australia Essentially Derived Varieties Submission



1 INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and suppliers of crop protection products (organic, synthetic and biological based pesticides) and agricultural biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, Australian and international companies. Accordingly, CropLife advocates for policy positions that deliver whole of industry and national benefit. CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally. Our focus is specifically on sustainable environmental land management and an Australian farming sector that is internationally competitive through globally leading productivity and sustainability practices. Both of these outcomes are achieved through access to the world-class technological innovation and products of the plant science sector.

The plant science industry contributes to the nation's agricultural productivity, environmental sustainability and food security through innovation in plant breeding and pesticides that protect crops against pests, weeds and disease. More than $31 billion of the value of Australia's agricultural production is directly attributable to the responsible use of crop protection products, while the plant science industry itself directly employs thousands of people across the country.[1]

CropLife Australia welcomes the opportunity to comment on IP Australia's review of the essentially derived variety (EDV) provisions in the *Plant Breeder's Rights Act 1994*.

CropLife supports a plant breeder's rights framework that encourages continued investment in plant breeding while maintaining opportunities for innovation through the breeder's exemption. As breeding technologies have evolved, particularly through the development of genome editing and other precision breeding techniques, it is suitable to review whether Australia's EDV provisions continue to appropriately balance these objectives.

Australia's current EDV provisions should be clarified and modernised to better align with the internationally accepted understanding of essential derivation under UPOV 1991.[2]

[1] Deloitte Access Economics, *Economic Contribution of Crop Protection Products in Australia* (Report, August 2023) <https://www.croplife.org.au/resources/reports/economic-contribution-of-crop-protection-products-in-australia/>.
[2] International Convention for the Protection of New Varieties of Plants, opened for signature 2 December 1961, as revised at Geneva on 19 March 1991, entered into force 24 April 1998 ('UPOV Convention 1991') art 14(5)(b).

CropLife has consistently advocated for greater alignment of Australia's EDV provisions with UPOV 1991 over several consultation processes and considers that the need for reform is now well established. The current requirement that an EDV must not exhibit any "important (as distinct from cosmetic) features" that differentiate it from the initial variety, appears to create uncertainty and may establish a higher threshold than applies in many comparable jurisdictions. Reform should focus on providing greater certainty for breeders while preserving incentives for both initial and follow-on innovation. Both patents and Plant Breeders Rights (PBRs) are essential to the ability of CropLife members to continue investing and conducting business in Australia and globally.

Key recommendations:

1. Australia's EDV framework should align with UPOV 1991 recommendations and international practice.
2. The EDV threshold should adequately protect the substantial investment made by initial breeders.
3. The framework should recognise the realities of modern breeding technologies, including genome editing and precision breeding methods.
4. Any reforms should maintain incentives for both initial breeding and follow-on innovation.
5. Greater clarity and guidance are preferable to creating new uncertainty and an unfair playing field through uniquely Australian concepts.
6. Questions of EDV status should primarily be resolved between the breeders concerned. Where disputes cannot be resolved through agreement or alternative dispute resolution, they should be determined by the courts, consistent with the approach followed in other UPOV member countries.

2 CLARITY OF EDV PROVISIONS

2.1 Important Features

The current distinction between "important features" and "essential characteristics" creates uncertainty within the Australian EDV framework. While the Plant Breeder's Rights Act includes "essential characteristics", the concept of "important features" is not separately defined and is unique to Australia. The uncertainty is compounded by the fact that what constitutes an important feature may vary between crops, markets and breeding objectives and may evolve over time. A characteristic that may be minor in one crop may have significant agronomic, commercial or technical value in another.

CropLife further considers that it remains unclear whether the "important features" requirement imposes an additional threshold beyond the requirement that a variety retain the essential characteristics of the initial variety. This uncertainty is at the centre of many stakeholder concerns regarding the scope of EDV protection in Australia. Previous industry submissions have argued that a variety should not be excluded from EDV status merely because it exhibits differences in one or more essential characteristics. Where those differences result from the act of derivation, the variety may still be considered an EDV if it remains predominantly derived from the initial variety.

Accordingly, CropLife supports reform that better aligns Australia's EDV framework with UPOV 1991 and is of the firm view that retention of the current section 4(c) will not achieve the policy objectives of the EDV principle.

2.2 Essential Characteristics

CropLife supports retaining the concept of essential characteristics as a core component of the EDV framework. However, additional guidance on the interpretation and application of the concept would be beneficial.

The UPOV Explanatory Notes recognise that essential characteristics may include morphological, physiological, agronomic, industrial and biochemical characteristics and that these characteristics contribute to the principal features, performance or value of a variety.[3]

[3] International Union for the Protection of New Varieties of Plants, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention* (UPOV/EXN/EDV/3, adopted 27 October 2023).

The Notes also recognise that essential characteristics may evolve over time as breeding objectives and market requirements change.

Incorporating the description in full from the explanatory material reflecting the UPOV description of essential characteristics would assist stakeholders in understanding how the concept should be applied in practice and promote greater consistency in the interpretation of the EDV provisions. Such guidance would be particularly valuable in the context of modern breeding technologies and increasingly complex trait development, where determining the characteristics that contribute to a variety's identity and value may be less straightforward than under traditional breeding approaches.

2.3 Cosmetic Features and Commercial Significance

CropLife considers that the phrase "as distinct from cosmetic" may create uncertainty in circumstances where a characteristic that appears aesthetic in nature also has agronomic, technical or commercial significance.

In many crops, characteristics such as colour, shape, size, appearance or other morphological traits may influence market acceptance, consumer preferences, handling characteristics, reproductive performance or other commercially relevant outcomes. As a result, it may not always be clear whether such characteristics should be regarded as cosmetic or as features relevant to the value and identity of the variety.

CropLife considers that the concern extends beyond uncertainty in interpretation. The requirement that an EDV must not exhibit any "important (as distinct from cosmetic) features" that differentiate it from the initial variety introduces an additional Australian-specific hurdle that is not found in UPOV 1991. The focus of the EDV assessment should be whether the variety is predominantly derived from the initial variety and whether the requirements of Article 14(5)(b) are satisfied. A separate inquiry into whether differences are "important" or "cosmetic" risks diverting attention from the fundamental question of derivation, and creates significant uncertainty that may discourage innovation development and commercial investment, thereby reducing benefits to Australian growers.

3 APPROPRIATE THRESHOLDS FOR ESTABLISHING EDV

3.1 Practical Experience Under the Current Framework

Stakeholders have consistently raised concerns that the current Australian framework does not adequately recognise the substantial investment in the development of elite germplasm where a new variety is predominantly derived from an initial variety protected under PBR.

The absence of publicly reported disputes should not be interpreted as evidence that the current framework is functioning effectively. As noted by industry stakeholders during previous consultations, the perceived difficulty of meeting the current Australian EDV threshold may actively discourage breeders and trait providers from pursuing EDV claims. This may be a contributing factor to the very small number of EDV applications made in Australia since the introduction of the legislation.

Advances in Plant Breeding Innovations (PBIs), including genome editing, have increased the importance of ensuring that the EDV framework continues to operate as intended.

The use of PBIs has enabled the introduction of targeted changes into commercial elite varieties while retaining the overwhelming majority of the genetic background and commercially valuable characteristics of the original variety. In these circumstances, a variety may remain predominantly derived from an initial variety despite exhibiting one or more new characteristics introduced through the act of derivation.

CropLife considers that the current Australian framework creates uncertainty regarding whether such varieties would qualify as EDVs where the introduced characteristic is considered an "important feature".

3.2 Aligning Australia's Threshold with UPOV 1991

CropLife supports an EDV threshold that remains aligned with the underlying purpose of the EDV concept under UPOV 1991: protecting the interests of breeders who invest in the development of initial varieties while preserving opportunities for continued innovation.

CropLife considers that discussion of the EDV threshold can sometimes conflate two separate issues: whether a new variety is sufficiently distinct to qualify for PBR protection in its own right, and whether that variety remains essentially derived from a protected initial variety. A variety may contain a valuable new characteristic and qualify for PBR protection, while still remaining an EDV. These are separate questions that should not be confused.

A variety should not automatically fall outside the scope of EDV protection because one or more additional characteristics have been introduced through the act of derivation. A variety may remain essentially derived where it is predominantly derived from the initial variety and continues to retain the expression of the essential characteristics of that variety, notwithstanding differences, including differences in essential characteristics, arising through the act of derivation.

Excluding a variety from EDV protection solely because it contains an important new characteristic risks excluding precisely the types of varieties that the EDV concept was intended to address. The EDV principle was introduced to recognise circumstances where a breeder has relied substantially on the breeding investment embodied in an initial variety while introducing one or more additional characteristics through the act of derivation. The introduction of those characteristics should not, by itself, negate the underlying derivational relationship.

CropLife notes that this issue is particularly relevant in the context of monoparental derived varieties, including varieties developed through mutation, genetic modification and genome editing. In such cases, the introduction of a new characteristic should not, by itself, displace the breeding contribution embodied in the genetic background of the initial variety where predominant derivation remains evident. CropLife considers that genuinely monoparental derived varieties which are clearly distinguishable from their initial variety are per se EDVs. While the 2023 UPOV Explanatory Notes expressly recognise such varieties as per se predominantly derived, a cumulative interpretation of Article 14(5)(b)(i), (ii) and (iii) supports the conclusion that differences arising from the act of derivation, including differences in essential characteristics, do not remove such varieties from the EDV concept.

Accordingly, CropLife does not consider it necessary to develop a uniquely Australian threshold where UPOV 1991 already provides the appropriate foundation. The threshold for essential derivation should be assessed using Article 14(5)(b), supported by the UPOV Explanatory Notes and internationally accepted interpretations of the EDV principle. Plant breeding is increasingly international, with breeding programs, germplasm, varieties and intellectual property portfolios frequently spanning multiple jurisdictions. Maintaining Australian-specific EDV concepts that differ from the internationally recognised UPOV framework risks creating uncertainty for breeders operating across jurisdictions and may result in different outcomes for the same variety. CropLife therefore considers that harmonisation should be a central objective of any reform.

3.3 Genetic Similarity Thresholds

CropLife does not support the incorporation of a fixed numerical genetic similarity threshold into the *Plant Breeder's Rights Act 1994*.

The determination of essential derivation should continue to be based on the requirements set out in Article 14(5)(b) of UPOV 1991, including predominant derivation, rather than a single numerical measure of genetic similarity. The significance of genetic similarity may vary between species, breeding methods and the genetic diversity of the species concerned.

CropLife considers that appropriately developed crop-specific genetic similarity thresholds may have value as a procedural or as a screening tool. Genetic information may assist in identifying circumstances where further examination of derivation is warranted and may complement other forms of evidence, including breeding records, pedigree information and phenotypic characteristics. However, exceeding such a threshold should not automatically determine that a variety is an EDV. Rather, this should be determined on a case-by-case basis, and best interpreted by a court where both parties can make their case. Any assessment must continue to consider the full circumstances of derivation, including how the variety was developed and whether it was predominantly derived from the initial variety.

Genetic similarity may therefore provide useful supporting evidence in the assessment of essential derivation, but it should not operate as a standalone or determinative legal test for EDV status.

3.4 Incentives for Innovation and Investment

The EDV framework is important in maintaining an appropriate balance between rewarding the substantial investment required to develop new plant varieties and preserving opportunities for follow-on innovation.

Since the introduction of the EDV provisions, breeding technologies have continued to evolve. Modern techniques, including genetic modification and genome editing, enable targeted changes to be made to commercial varieties. These technologies can introduce valuable new characteristics while retaining the majority of the genetic background, performance and commercial value embodied in the initial variety.

Greater clarity regarding the EDV threshold would support continued investment in plant breeding and provide confidence that substantial breeding investments will be appropriately recognised where a new variety remains predominantly derived from a protected initial variety.

At the same time, reforms must continue to support follow-on innovation and preserve the breeder's exemption, which remains a fundamental feature of the PBR framework.

Breeders must have confidence that the substantial investment embodied in an initial variety cannot simply be appropriated through predominantly deriving a new variety and introducing a characteristic that takes it outside Australia's unusually narrow EDV test.

4 ADMINISTRATIVE PROCESS

4.1 Greater transparency and certainty

CropLife supports the provision of additional information and guidance to assist breeders, rights holders and applicants in understanding the operation of the EDV framework.

Any guidance developed by IP Australia should be consistent with UPOV 1991 and the UPOV Explanatory Notes and should avoid creating additional Australian-specific tests or interpretations.

Additional guidance on concepts such as predominant derivation, essential characteristics, important features and the relationship between these concepts would assist stakeholders in understanding how the EDV provisions are intended to operate in practice.

The publication of practical guidance materials and case studies illustrating how the EDV framework may apply in different breeding scenarios would also be useful.

CropLife also supports greater transparency regarding EDV determinations. Consideration could be given to publishing de-identified summaries of EDV decisions, disputes or determinations. Any such publications/decisions should be appropriately redacted or de-identified as EDV disputes may involve commercially sensitive genetic, technical and market information. This would provide stakeholders with a greater understanding of how the legislation is interpreted and applied while maintaining appropriate confidentiality protections.

However, guidance alone will not resolve all uncertainty associated with the current framework. Where terminology within the legislation itself is unclear or capable of differing interpretations, legislative clarification is required. Guidance should therefore be viewed as complementary to, rather than a substitute for, broader reforms that improve alignment with UPOV 1991 and the intended operation of the EDV provisions.

4.2 EDV Applications and Disputes

IP Australia notes that only a small number of EDV applications have been made since the commencement of the *Plant Breeder's Rights Act 1994*. However, CropLife does not consider that the effectiveness of the EDV framework should be assessed solely on the number of formal applications, disputes or determinations.

The starting point for any EDV assessment should be whether a variety is predominantly derived from a protected initial variety, consistent with Article 14(5)(b) of UPOV 1991. The central question is not how often the EDV provisions have been invoked, but whether the framework appropriately recognises and protects the relationship between an initial variety and a subsequently derived variety.

The low number of EDV applications does not, in itself, demonstrate that the current framework is operating effectively. Equally, it does not demonstrate that the current threshold is inappropriate. The relevant question is whether Australia's EDV provisions provide a clear, predictable and internationally consistent framework for recognising varieties that are predominantly derived from protected initial varieties. CropLife considers that greater alignment with UPOV 1991 and the current UPOV Explanatory Notes would improve certainty and confidence in the operation of the EDV framework.

CropLife considers that questions of EDV status should primarily be resolved between the breeders concerned, rather than through administrative determinations by the PBR Registrar. Where disputes cannot be resolved through agreement or alternative dispute resolution, they should be determined by the courts, consistent with the approach followed in other UPOV member countries.

5 CONCLUSION

CropLife supports a Plant Breeder's Rights framework that encourages both the development of new plant varieties and continued innovation that builds upon those initial breeding achievements. The EDV provisions play an important role in maintaining this balance by recognising the substantial investment required to develop elite germplasm, while preserving opportunities for follow-on breeding through the breeder's exemption.

Australia's current EDV framework has served an important role in supporting plant breeding innovation. However, uncertainty remains regarding concepts, including "important features", "essential characteristics" and the threshold for establishing essential derivation. This uncertainty has become increasingly relevant as breeding technologies evolve, where techniques such as genome editing are able to introduce targeted changes into highly adapted commercial varieties.

Reform should focus on improving clarity, consistency and predictability while maintaining the balance between rewarding investment in initial varieties and encouraging further innovation. CropLife does not consider that Australia's current, uniquely narrow EDV framework achieves the balance intended by UPOV 1991. In particular, the continued application of section 4(c) places undue emphasis on the nature of differences between varieties rather than the fundamental question of derivation.

CropLife supports:

- an EDV threshold that recognises the realities of modern breeding technologies and contemporary breeding practices;
- continued incentives for both initial breeding and follow-on innovation;
- greater transparency and practical guidance to assist stakeholders in understanding and applying the EDV framework; and
- improved international consistency in the operation of plant breeder's rights.

A clear, predictable and internationally aligned EDV framework will help ensure Australia's plant breeding sector is an attractive destination for investment, supports the development and adoption of innovative breeding technologies, and continues to deliver improved varieties that enhance agricultural productivity, sustainability and food security.