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Law-Driven Innovation in Cereal Varieties: The Role of Plant Variety Protection and Seed Marketing Legislation in the European Union

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Abstract: The aim of this paper is to investigate the role of EU legislation in shaping innovation in cereal varieties. The research focuses on two fields of law and their relationship, i.e., intellectual property and agricultural law. More specifically, the normative legal investigation concerns the role played by Community plant variety protection and the EU legislation on the marketing of seed and plant propagating material in shaping innovation and stimulating plant breeding of new cereal varieties. The focus is on cereal varieties because innovation in this field has a great socio-economic impact, as well as strategic scientific and environmental implications. Breeding new cereal varieties is essential for the competitiveness of the seed and agricultural sector of the EU, and it can contribute to food security and the achievement of sustainable development goals. The study finds that it is necessary to simplify the existing legal framework by coordinating intellectual property and agricultural law, providing for legislative review and better coherence in order to effectively shape innovation and meet the changing demands of society and the sustainability challenges.

Keywords: agricultural innovation; sustainable agriculture; plant breeding; cereals; intellectual property; agricultural law; plant variety rights; seed marketing; European Union

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1. Introduction

Nowadays, the bond between agriculture and innovation is more discussed than ever [1–3]. The agriculture of the third millennium is facing new and difficult challenges, and it needs a breakthrough — innovation represents a qualitative leap in this field. Overpopulation, scarcity of natural resources, climate change, and biodiversity conservation are some of the many factors to take into consideration during the debate on the role of innovation in agriculture. In this framework, plant breeders are required to use their Promethean "creative power" to develop new plant varieties, able to improve agricultural productivity and meet the new and challenging demands of society, especially the increasing demand for sustainability in agriculture [4,5].

The purpose of this study is to investigate the relationship in the European Union between two fields of law, i.e., intellectual property and agricultural law, in shaping innovation in cereal varieties. It must be underlined that in this paper the focus is not on the innovation concerning the techniques and methods used for breeding purposes. The investigation aims to deal with innovation concerning the characteristics of the end product of the breeding activity, i.e., the plant variety. Specifically, the investigation focuses on the relationship between Community plant variety protection (hereinafter referred to as "Community PVP", also as "CPVP") and the European Union legislation on the marketing of seed and plant propagating material (hereinafter referred to as "EU seed legislation") in fostering plant breeding on varieties of cereal species.

The focus is on cereal varieties because of their relevance from a social, environmental, and economic perspective. Firstly, cereals represent the basis of the human diet: they are "staple foods" and as such they are globally eaten on a regular basis [6]. Innovation in cereal breeding can play a key role since it is crucial to feed the world's increasing

population with safe and sustainable food, while decreasing the environmental pressure of the agricultural production [7,8]. Furthermore, there is an alarming global trend towards genetic erosion of cereals, i.e., "the condition that results when a widely planted crop is uniformly susceptible to a pest, pathogen or environmental hazard as a result of its genetic constitution, thereby creating a potential for widespread crop losses" [9]. According to the FAO, at least 30 countries have reported genetic erosion of cereal crops in the last years, followed by vegetables, fruits, nuts, and legumes [9]. Furthermore, climate change and increasing temperatures will reduce global yields of some crops, including cereals [5,10]. In this context, innovation is fundamental to improving genetic diversity of plant varieties, increasing their resistance and reducing the use of plant protection products. Moreover, cereal breeding and production have a significant economic relevance, especially in the European Union. Indeed, the EU is a world leader in cereal production, especially wheat [6]. In addition, the European seed market is highly competitive, representing the third-largest seed market worldwide with more than 20% of the total global market for commercial seed [11]. Therefore, in the EU, innovation in cereal varieties is crucial for the competitiveness of the seed and agricultural sectors.

Innovation in cereal varieties is also fundamental to achieving sustainable food production systems. In this regard, the European Commission's Farm to Fork (F2F) strategy presented on 20 May 2020, cornerstone of the European Green Deal, points out that research and innovation are key drivers in accelerating the transition to sustainable, healthy, and inclusive food systems from primary production to consumption [12]. The F2F strategy will enable the transition to a healthier and more sustainable EU food system, ensuring food security, tackling climate change, protecting the environment, and preserving biodiversity. One of the most ambitious goals of the F2F strategy is to reduce the use and risk of pesticides by 50% and the use of fertilizers by 20%, by 2030. However, the strategy recognizes that climate change brings new threats to plant health. In this context, the sustainability challenge calls for innovation and seed security, ensuring access of farmers to quality seeds for plant varieties adapted to the pressures of climate change. Therefore, it is necessary to stimulate plant breeding of agricultural varieties, such as cereals, more resilient to climate change, high-yielding, and pest resistant, that can enhance agricultural productivity and food security, and safeguard the environment.

The study finds that plant breeding of certain agricultural species, such as cereals, is directly affected by the law. However, the achievement of the sustainable targets may be discouraged by the complexity and rigidity of the current (and outdated) legal framework, characterized by a lack of coordination between Community plant variety protection and the EU seed legislation.

2. Materials and Methods

This study originates from academic legal research based on normative legal investigation concerning the analysis of primary sources, jurisprudence, legal texts and doctrinal writings, in the form of a "library-based" research [13].

The focus is on the legislation of the European Union concerning, on the one hand, Community plant variety protection and, on the other, the EU legislation on marketing of seed and plant propagating material. The role of Community PVP in shaping innovation is examined vis-à-vis the EU seed legislation in light of the way the two areas of law impact the breeding of new cereal varieties. It follows that the investigation does not exclusively lie in the arena of intellectual property law but concerns its dialogue with agricultural law.

Intellectual property law and agricultural law have a complicated relationship and it has been pointed out that "despite its importance, there has been comparatively little written about intellectual property law and its intersection with agriculture" [14]. A potential pitfall is to consider plant variety protection as not connected to seed laws. On the contrary, the two areas of law share concepts and definitions and they also have mutual historical roots, since some of the first European laws on the topic both recognized a protection right for plant breeders and regulated the seed trade [15,16].

The primary sources of law employed in this study are the Council Regulation (EC) No 2100/94 of 27 July 1994 ("Basic Regulation") and the so-called EU seed legislation, which consists of 12 basic Directives covering the crops of major importance in the EU, including cereals. The Basic Regulation established the Community PVP and, unlike patents, it is considered a "technology-specific" intellectual property regime since it exclusively concerns "breeding achievements in the area of plant breeding" [17]. The seed legislation regulates the right to commercialize seeds and propagating material in the EU territory and is based on two pillars: the prior registration of the varieties in the Common Catalogues and the certification of the seed lots.

The two laws have different purposes: the rationale of Community PVP is to stimulate the breeding and development of new varieties, whereas the EU seed legislation has the purpose of ensuring the free marketing of quality seeds and propagating material throughout the EU territory.

The study focuses on the analysis of the protection and registration requirements and procedures in order to assess the points of contact and contrast between the two areas of law.

3. Results

3.1. Preliminary Remarks

It must be highlighted that a plant variety is defined according to Article 5 (2) of the Basic Regulation as "a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: 1. defined by the expression of the characteristics that results from a given genotype or combination of genotypes, 2. distinguished from any other plant grouping by the expression of at least one of the said characteristics, and 3. considered as a unit with regard to its suitability for being propagated unchanged".

Based on this definition, the notion of plant variety refers to a plant grouping defined by the "expression" of the genotype, i.e., the phenotype. It follows that two varieties with different genotypes, having similar phenotypical expression, are considered legally identical [1,18].

With regard to cereals, in 1966 the (then) European Economic Community Council adopted the Directive of 14 June 1966 on the marketing of cereal seed (66/402/EEC), last amended by Commission Implementing Directive (EU) 2020/177 of 11 February 2020. Pursuant to Article 1 thereof, this Directive shall apply to cereal seeds marketed within the EU. A legal definition of "cereals" in the seed sector is provided by Article 2 of Directive 66/402/EEC, which covers only the major cereal species. For the purposes of the Directive, cereals are defined as the plants of the following species intended for agricultural or horticultural production other than production for ornamental purposes: *Avena nuda* L.; *Avena sativa* L.; *Avena strigosa Schreb.*; *Hordeum vulgare* L. *Oryza sativa* L.; *Phalaris canariensis* L.; *Secale cereale* L.; *Sorghum bicolor* (L.) *Moench*; *Sorghum sudanense*; *xTriticosecale*; *Triticum aestivum* L.; *Triticum durum Desf.*; *Triticum spelta* L.; *Zea mays* L.

In the case of cereals, plant variety protection and seed marketing laws can significantly impact on each other's goals. The reason is that plant varieties are brought onto the market as reproductive material: in the case of cereals, as seeds. This means that the seed represents both a "commercial commodity" and a "technology carrier" [19], in which it is impossible to divide the tangible from the intangible subject matter.

This dual nature of the seed requires a dialogue between two fields of law. On the one hand, there is agricultural law, regulating seeds as agricultural products and establishing criteria for their marketing (i.e., the EU seed legislation). On the other hand, there is intellectual property law, regulating the new variety in its role as an innovative technology, creating a specific IP right for the variety resulting from the breeding activity (i.e., the Community plant variety protection).

In this context, a rule on the marketing requirements of the tangible subject matter can affect the exploitation of the exclusive rights granted to the IP holder on the intangible

subject matter. The implications of this relationship are noteworthy. A lack of coordination could jeopardize the possibility for breeders to market their variety and, consequently, to secure a return on their investment, discouraging the expenditure of additional resources in breeding programs, thus discouraging innovation.

3.2. Community Plant Variety Protection

In the European Union, the plant variety protection system is governed by the Basic Regulation on Community plant variety rights, which also established the Community Plant Variety Office (CPVO) in Angers, France. Even though the (then) European Community became party to the 1991 Act of the Convention only in 2005, the Basic Regulation is consistent with the rules set out by the 1991 Upov Convention. Indeed, its Preamble states that "[...] this Regulation takes into account existing international conventions such as the International Convention for the Protection of New Varieties of Plants (Upov Convention)".

The plant variety protection system established by the Upov Convention and the Basic Regulation is a sui generis IP system, which has been defined a "legal hybrid" between patents and copyrights [20]. This is because it does not correspond to the other existing IP regimes, especially the dominant legal paradigms which protect "inventions" on the one hand, and "artistic works" on the other [21]. The reason lies in the very nature of the protected material, which is self-replicating, thus automatically able to reproduce itself, and cannot be reduced to a disclosure in writing. Therefore, an ad hoc proprietary regime specifically designed for plant varieties was required.

Community plant variety rights have uniform effect within the territory of the European Union and are the sole and exclusive form of Community industrial property rights for plant varieties, allowing breeders to protect their innovation throughout the European Union upon a single application.

Varieties of all botanical genera and species, including hybrids between genera or species, may form the object of Community PVRs. The result is that the protectable subject matter under the Community plant variety system is not limited to a certain number of botanical genera or species.

In order to be protectable under the Community PVP system, a plant variety has to be (a) distinct; (b) uniform; (c) stable; and (d) new, according to Article 6 of the Basic Regulation. Furthermore, the variety has to be designated by a denomination, in accordance with the provisions of Article 63.

The first three technical conditions form the so-called DUS requirements dealing with the phenotypical characteristics of the plant variety and they are examined through field trials. The new variety is not required to have any commercial or cultivation value [2].

Article 7 of the Basic Regulation concerns the distinctness requirement and specifies that distinctness has to be determined "by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes". Therefore, the characteristics that distinguish a variety shall imply a certain degree of observability: they should be externally visible in the field during the technical examination. Distinctness has to be assessed in relation to other varieties whose existence is a matter of common knowledge on the date which a valid application for the grant of a PVR was received by the CPVO or by an entitled national agency.

By way of illustration, the registration into an official Catalogue or the granting of a PVR or even the application for a PVR, provided that the application has not been refused or withdrawn in the meantime, make the variety a matter of common knowledge.

The distinctness requirement has a remarkable meaning in the overall plant variety protection system since it represents the main pillar in providing the logical basis of IP protection for new plant varieties. It has been said that "when a candidate variety meets the distinctness requirement one could say that the variety has been added by the breeder to the plant kingdom or, to put it in patent terms, to the state of the art. This fact is the major justification for a possible protection of the variety with an industrial property right.

The simple copying or multiplication of a variety that has already existed as such, either in nature or in cultivated conditions, would not qualify for such a right" [16].

Article 8 of the Basic Regulation deals with the uniformity requirement. A candidate variety has to be "sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description". Compliance with this requirement does not entail that the candidate variety need be entirely uniform. The use of the word sufficiently clarifies that a certain amount of variation is tolerated and expected, especially in the case of sexually reproduced plants. Indeed, the slight variability of the offspring depends particularly on the propagation process of the variety and is related to the very nature of plants as living organisms. Consequently, the level of uniformity and the determination of off-types differ from one variety to another, depending on the method of plant propagation [22].

Article 9 of the Basic Regulation lays down the stability condition, which concerns the capability of the plant to "remain unchanged after repeated propagation". It has been highlighted that it is particularly challenging to test this requirement. Several tests have to be performed and that is the reason why a specific technical examination on stability is not carried out by the entitled official bodies across EU [16]. Undeniably, it would be quite demanding to repeatedly propagate a variety for an unlimited number of life cycles in order to check whether and to what extent the crop changed its expressed characteristics after each propagation. For this reason, it has been argued that stability tends to be more "the expression of an expectation than the reflection of a fact" [16]. Nevertheless, stability has proved to be linked with uniformity, so it can be assessed in connection with it [22]. As a result, a candidate variety is deemed to be stable when it is proved to be uniform during field tests.

Some experts suggest that the requirements of "uniformity" and "stability" should be replaced by the criterion of "identifiability" [23–25]. This criterion has been introduced for improved traditional varieties by the Malaysian Plant Variety Protection Act, in place of "uniformity" and "stability". The purpose is to facilitate plant variety protection for varieties developed by Malaysian farmers, which are not required to pass the rigorous uniformity and stability test, provided that their new variety is identified by one special characteristic [26].

More specifically, the uniformity requirement has been the subject of severe criticism because it refers exclusively to the needs of conventional agriculture, encouraging dangerous homogeneity and discouraging the conservation and sustainable use of agricultural genetic diversity [23].

The DUS requirements are tested during a technical examination of the candidate variety, aimed at assessing whether these requirements are met. This technical examination is not conducted by the CPVO itself, but rather by the competent office or offices in at least one of the Member States "entrusted with responsibility for the technical examination of varieties of the species concerned" (so-called Examination Office), in accordance with Article 55 of the Basic Regulation. The relevant Examination Office is chosen on the basis of defined principles, e.g., the climatic and environmental growing conditions of the specific variety and the preference expressed by the breeder during the application process [16].

The CPVO Technical Unit provides the Examination Offices with several technical guidelines and protocols aimed at harmonizing the determination of whether a plant variety right should be granted or not. The Examination Offices must conduct the DUS test in accordance with those guidelines, following the instructions given by the Office, as provided for in Article 56 of the Basic Regulation.

Unlike the DUS requirement, the novelty condition cannot be tested through growing trials. This requirement deals with the limited "period of grace" accorded to plant breeders, establishing for how long a candidate variety can be marketed by or with the consent of the breeder before applying for protection. After that period, the variety can no longer be protected by Community plant variety rights. Article 10 of the Basic Regulation states the principle upon which, in order to be protected by the CPVR, variety constituents or

harvested material of the candidate variety must not have been sold or otherwise disposed of to others for purposes of exploitation (rectius, commercial exploitation) by the breeder or with their consent, before the date of application for Community plant variety right. As required by Article 10, the acts jeopardizing the grant of CPVRs must not have taken place (a) earlier than one year before the date of application for Community plant variety right within the territory of the EU; (b) earlier than four years or, in the case of trees or of vines, earlier than six years before the said date, outside the territory of the EU.

As required by Article 6 of the Basic Regulation, in order to be protected, a variety must be also designated by a denomination in accordance with the provisions of Article 63 of the Basic Regulation. The variety denomination enables the identification of the variety and it is intended to be its generic designation [27].

When granting the Community PVR, the Office must examine the suitability of the variety denomination pursuant to Article 63, according to which there is an impediment to the designation of a variety denomination where: (a) its use in the territory of the EU is precluded by the prior right of a third party; (b) it may cause difficulties as regards recognition or reproduction; (c) it is identical or may be confused with a variety denomination under which another variety of the same or of a closely related species is entered in an official register of plant varieties or under which material of another variety has been marketed in a Member State or in a UPOV Member State, unless the other variety no longer remains in existence and its denomination has acquired no special significance; (d) it is identical or may be confused with other designations which are commonly used for the marketing of goods or which have to be kept free under other legislation; (e) it is liable to give offence in one of the Member States or is contrary to public policy; (f) it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder or any other party to proceedings.

Furthermore, there is another impediment where, in the case of a variety which has already been entered in an official register of plant varieties or material thereof and has been marketed there for commercial purposes: (a) in one of the Member States; or (b) in a UPOV Member State; or (c) in another State for which it has been established in an EU act that varieties are evaluated there under rules which are equivalent to those laid out in the Directives on Common Catalogues; and the proposed variety denomination differs from that which has been registered or used there, unless the latter is the object of an impediment.

3.3. EU Seed Legislation

In order to be legally and freely marketed in the EU territory, certain plant species must meet the legal requirements set out by the EU seed legislation, concerning variety registration and seed certification.

The legal framework of the European Union on the marketing of seed and plant propagating material dates back to 1966 and has been gradually amended. The seed legislation has been used as a policy instrument by favoring the release of varieties that contributed to achieving the original EU policy goals, especially food security [28].

Nowadays, the EU seed legislation consists of 12 basic Directives, covering the crops of major importance in the EU (EU listed species): one horizontal Directive regulates the Common Catalogue of varieties of agricultural plant species (i.e., Council Directive 2002/53/EC of 13 June 2002), while the other 11 vertical marketing Directives establish rules for the marketing of specific crops of major importance in the EU territory. These crops are: fodder plant seeds, cereal seed, beet seed, vegetable seed, seed potatoes, seed oil and fiber plants, material for the propagation of the vine, propagating material of ornamental plants, vegetable material other than seed, fruit propagating material and fruit plants for fruit production, forest reproductive material.

The two main elements of the EU seed legislation are: 1. the registration of the varieties in the Common Catalogues; 2. the certification of the seed lots.

According to the first pillar of the seed legislation, plant varieties of certain species should be registered in the national variety list, which the EU Member States are obliged to establish, and then in the EU Common Catalogues. The registration on the national list leads to the inclusion in the Common Catalogues, which green-lights the commercialization of the variety in the territory of all the EU Member States and ensures its free movement within the European Union.

The first Directive concerning the registrations of plant varieties and the creation of a Common Catalogue was Council Directive 70/457/EEC of 29 September 1970 on the Common Catalogue of varieties of agricultural plant species. This Directive had the significant task of setting up uniform criteria and minimum requirements for the compilation of national catalogues of agricultural plant species. However, the Directive was frequently and substantially amended and, ultimately, it was replaced by Council Directive 2002/53/EC.

There are currently two Common Catalogues in the European Union: the Common Catalogue of varieties of agricultural plant species, regulated by Council Directive 2002/53/EC, and the Common Catalogue of varieties of vegetable plant species, established by Council Directive 2002/55/EC on the marketing of vegetable seed.

As a general rule, a variety that has not been admitted in the relevant Common Catalogue cannot be commercialized in the EU. This principle has been underlined also by the Court of Justice of the European Union in the Case C–59/11, Association Kokopelli v. Graines Baumaux SAS. In that case, the Court of Justice also highlighted that the primary objective of the rules on seed registration is to improve agricultural productivity in the European Union, which is part of the objectives of the common agricultural policy as provided for in Article 39 (1) (a) TFEU.

In order to be registered on the national list, plant varieties are required to undergo the distinctness, uniformity, and stability testing (DUS requirement), according to Article 5 of Council Directive 2002/53/EC, paragraphs 1 to 3.

The content of the DUS requirement enshrined in Council Directive 2002/53/EC is equivalent to the provisions laid down in the Basic Regulation: this equivalence also concerns the DUS testing process. Therefore, the DUS requirement has the same meaning under the EU seed legislation and the Community plant variety protection.

When the breeder of a new variety accepted in the Common Catalogue applies for Community PVP within the limited period of grace, the technical report produced by the national examination authorities and concerning the DUS assessment for the variety registration is generally taken over by the CPVO, if it has been performed in conformity with specific requirements [29].

In this context, national authorities in the European Union have agreed to use CPVO technical protocols for DUS testing not only for plant variety rights grant procedures but also for the procedures concerning variety registration. Usually, the take-over of technical reports by CPVO applies only to reports produced by entrusted examination offices within the EU for a variety already benefiting from national plant variety rights or entered for national listing in an EU Member State [30].

However, the exchange of technical reports among examination authorities has not yet been regulated at the EU level, even though the CPVO, the entrusted Examination Offices, and the European Seed Association (ESA, now called "Euroseeds") have been calling for the recognition of the "one key, several doors principle" for more than fifteen years. In 2005 the CPVO launched a Strategic Discussion on the future of DUS testing in the EU territory: participating Member States and stakeholders found the "one key, several doors principle" to be a fundamental goal. The purpose was to harmonize the DUS variety testing system throughout the European Union, in order to increase efficiency and to avoid duplicated costs for both breeders and national authorities. The principle entails that a plant variety whose DUS requirements have been officially tested according to well-defined quality requirements and results in a final DUS report should not be examined a second time for DUS in the EU territory.

Furthermore, Council Directive 2002/53/EC has established that specific denomination rules must be followed to identify the varieties: Article 9 (6) thereof requires that Article 63 of the Basic Regulation shall apply. Therefore, the same denomination rules apply to both Community plant variety protection and EU seed legislation.

In addition to the DUS requirement, varieties of agricultural species, including cereals, must be of satisfactory value for cultivation and use (VCU). This is necessary in order to be admitted to the national catalogues and, consequently, to the Common Catalogue of varieties of agricultural plant species, as provided for in Article 4 of Council Directive 2002/53/EC.

VCU is tested through field trials but, unlike the DUS examination whose focus is on morphological characters of the variety, in VCU testing the emphasis is on the assessment of the agronomic traits of the plant. These traits are related to crop production and performance. The purpose of this provision is to filter only those varieties having a specific economic value for farmers. It should ensure that only the finest varieties of agricultural species are registered, thus stimulating the breeding of improved crops. Therefore, only the varieties with a significant economic value are placed on the market, and this is deemed necessary to obtain a high-quality harvest to the greatest degree possible [16].

The reason is that farmers need to know well in advance how the variety is going to perform in the field. For this purpose, the marketing of economically valuable varieties is of utmost importance. Farmers must be able to get the most suitable varieties and the most reliable information on the agronomical value for cultivation, in order to optimize the growing practices and to achieve the best yield potential [31].

It must be noted that vegetable seeds are not subject to the VCU requirement. In this case, the Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed is applied. According to Article 4 of said Directive, Member States shall ensure that a vegetable variety is accepted if it meets the DUS requirement. There is just one exception: in the case of species of industrial chicory, the varieties must be of satisfactory VCU.

The VCU requirement is not applied to vegetable varieties for different reasons. Firstly, because of "the large number of agronomic considerations and specific consumer preferences in these crops" [32]. It has also been underlined that the assessment of the VCU requirement would be complicated and costly because of the highly differentiated vegetable crop market [31].

With regard to the VCU requirement, the scope of the term "satisfactory" is determined by Article 5 (4) of Council Directive 2002/53/EC on the Common Catalogue of varieties of agricultural plant species. According to the article, a plant variety shall be regarded as of satisfactory VCU if, compared to other varieties accepted in the catalogue of the Member State in question, its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a "clear improvement" either (1) for cultivation or (2) as regards the uses which can be made of the crops or (3) the products derived therefrom.

In 2003, the Commission Directive 2003/90/EC was adopted, setting out implementing measures as regards the minimum characteristics to be covered during the examination and the minimum conditions for examining certain varieties of agricultural plant species. It also set out the conditions that the varieties have to comply with as regards the VCU requirement. These conditions, which are listed in Annex III of the Directive, are (1) yield; (2) resistance to harmful organisms; (3) behavior with respect to factors in the physical environment; (4) quality characteristics.

The broad meaning of these conditions required national authorities to specify the limits of those criteria: this led to dissimilarities in VCU assessment among Member States. Therefore, currently there is no uniform meaning for those criteria: the parameters for VCU assessment vary significantly between countries for the same variety [32].

The VCU examination involves replicated field trials and harvest tests that generally take a minimum of two years or a maximum of three years [32]. The legislation dealing with the VCU requirement seems not to consider the strong connection between the value for cultivation and use of a plant variety and the surrounding environment.

Seeds are living organisms in a living environment, where environmental factors have a substantial effect on the economically valuable characteristics of plant varieties, such as yield and quality features. More specifically, the outcomes of the VCU examination are affected by (1) the testing location and the specific climatic and soil conditions; (2) the agronomic practices; (3) the year, since the performance of the variety varies from one year to another. Therefore, the VCU of a particular variety can never be definitively established [31].

This is the reason why the role and effectiveness of the VCU testing have been questioned. It has been underlined that VCU testing does not necessarily predict the need of farmers for particular characteristics or the exact performance of the plant in a specific field: the results of the trials cannot represent a perfect assessment of the VCU of the variety. Therefore, it has been suggested that these trials should not be lengthy or complex in the pursuit of perfection [32].

Furthermore, the effect of the VCU assessment on the relevant crop sector, i.e., the agricultural sector, should be taken into consideration. The effectiveness of VCU may be questioned since "crop sectors where VCU is not compulsory and several third countries with no regulatory tests are considered as competitive as the regulated VCU crop sectors" [31]. Indeed, the productivity of the agricultural crop sector in the EU has increased not more or less than the productivity in other crop sectors where VCU is not compulsory (e.g., the vegetable sector) [31].

Another aspect related to the effectiveness of the VCU criteria concerns the burden for breeders to have their variety assessed for VCU, in particular the costs for such assessment. This could represent a limit for SMEs who want to register their varieties of agricultural crop species. Indeed, the evaluation of the value for cultivation and use does not come for free. In light of this, the International Federation of Organic Agriculture Movement (IFOAM) has suggested that VCU testing should no longer be compulsory but an optional requirement "for any species", not only for agricultural ones. According to this proposal, VCU should be used solely "as a marketing argument" by breeders and not as a compulsory requirement [33].

4. Discussion

The EU seed legislation establishes the requirements that certain plant species must meet in order to be freely marketed in the EU. In so doing, it affects the possibility for breeders to commercially exploit their IP right on the new plant variety. In fact, when a protected agricultural variety does not meet the registration requirement set out by Directive 2002/53/EC, the Community PVR holder is not able to perform the acts set out in Article 13 (2) of the Basic Regulation, e.g., offering for sale, selling or other marketing.

This restriction is provided for in Article 13 (8) of the Basic Regulation, stating that the exercise of the rights conferred by Community plant variety rights may not violate any provisions adopted on the grounds of public morality, public policy or public security, the protection of health and life of humans, animals, or plants, the protection of the environment, the protection of industrial or commercial property, or the safeguarding of competition, of trade or of agricultural production.

These interests could prevail over the breeder's right to perform the acts listed in Article 13 (2) and, thus, they could restrict the exercise of the Community plant variety right. In this case, the exercise of the Community plant variety right is restricted when the variety intended to be marketed in the EU territory does not comply with the seed legislation, which aims at safeguarding agricultural production.

As already stated, a cereal variety can be accepted in the Common Catalogue of varieties of agricultural plant species only if the variety is distinct, stable, and sufficiently uniform (DUS) and has a satisfactory value for cultivation and use (VCU), in addition to having a proper denomination.

It follows that cereal breeders that aim at protecting their new variety by Community PVP must take into consideration both the requirements for Community plant variety

protection and those set out by the EU seed legislation to commercially exploit their innovation, as shown in Table 1.

Table 1. Requirements for seed marketing and plant variety protection of new cereal varieties in the EU.

Community Plant Variety Protection	EU Seed Legislation
Novelty	
Distinctness	*Distinctness*
Uniformity	*Uniformity*
Stability	*Stability*
Variety denomination	*Variety denomination*
-	*Value for cultivation and use*

More specifically, the breeding activities on cereals and other agricultural species in the EU are conditioned by the need for breeders to develop a variety that meets the VCU requirement, in addition to the DUS requirements.

However, the VCU is lightly defined at the EU level and the specific criteria adopted at a national level for the VCU assessment differ among Member States. The lack of harmonization can lead to distortions in the internal market and fail to guarantee the competition among EU breeders on a level playing field: differences include evaluation criteria, setup, and fee amount [28].

Furthermore, it should be highlighted that the VCU trial takes place in certain testing sites of each Member State. The living environment of each testing site can deeply affect the VCU assessment, so that the variety can perform differently in different environments. In fact, the VCU requirement does not have any pan-European value [31]. However, once the variety is registered in the Common Catalogue, its commercialization is not limited to a certain area but it can be marketed throughout the European Union, even in areas where the VCU has never been assessed. This leads to a paradox: the registration of the variety in the Common Catalogue determines the marketability of the variety throughout the EU territory, even though the VCU assessment, whose negative outcome can hinder that registration, is carried out in very specific testing sites.

Another critical connection occurs during the process for the grant of Community plant variety rights and concerns the technical examination for the DUS assessment, required both for plant variety protection and variety registration. It concerns, in particular, the lack of recognition of the "one key, several doors principle". Therefore, in the case where the variety has already been officially tested for DUS and this results in an official report, the same variety should not be examined a second time for DUS in the EU territory. The official technical report should be taken over by the EU Member State or the CPVO, regardless of its positive or negative outcome. Harmonizing the DUS testing system throughout the European Union will increase efficiency and avoid uncertainty and duplicated costs, both for breeders and national authorities. Indeed, one key (the official DUS report) would open several doors (variety registration and plant variety protection in the European Union).

Moreover, even though the VCU requirement and the uniformity criterion are considered as a useful tool for conventional agriculture, they are seen as an obstacle for the selection of varieties adapted to organic farming. On the one hand, VCU trials are not able to select low-input varieties used in organic farming [31]. On the other, the uniformity requirement discourages the marketing of heterogeneous groupings of plants, not taking into account the interests of local communities [24] and the needs of organic heterogeneous material, despite the F2F target to increase the share of organic agriculture to 25% by 2030 [12].

In light of the foregoing consideration, it is not surprising that in 2013 there was a proposal by the European Commission to replace the existing seed legislation, constituted

by 12 Directives, by one single Regulation in order to update, simplify, and harmonize the current rules. The proposal had the purpose, inter alia, to extend the role of CPVO to plant variety registration in order to simplify the registration process and to allow the admission to the EU market either via registration on the national list or via direct application to the CPVO. This proposal represented a first step towards the coordination between EU seed legislation and Community plant variety protection [34].

However, the proposal was rejected in 2014 by the European Parliament. The Members of the European Parliament believed that the proposal gave too much power to the Commission and did not properly consider the different requirements of existing plant reproductive material, as highlighted in the report of the Committee on Agriculture and Rural Development and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0112/2014).

Nevertheless, a legislative revision could simplify and improve the legal framework on seed marketing, and it could also facilitate the relationship between the EU seed legislation and Community plant variety protection, thereby promoting innovation in the seed sector.

5. Conclusions

Innovation is the zeitgeist of contemporary society and, with regard to cereal varieties, it has a significant social, economic, and environmental weight. The EU breeding companies are actively engaged in cereal breeding activities and, in this context, the Community plant variety protection is supposed to stimulate the breeding and development of new varieties, and, ultimately, to foster innovation.

Although some legal practitioners initially thought that the Community plant variety protection was going to wither and die [35], Community PVP system is considered an incentive to develop new varieties, thus contributing to the achievement of the European Green Deal objectives [36]. However, the promotion of innovation in plant breeding may be discouraged by an outdated and uncoordinated legal framework.

As proposed by some authors [14], a better place for agriculture should be found in intellectual property law. Since agricultural law can affect the exercise of intellectual property rights on plant varieties, it is fundamental to update, simplify, and coordinate the existing laws.

A lack of coordination could lead to inadequate protection of the breeder's rights and, along with the obsolescence of certain legal provisions, could hinder innovation in the seed and agricultural sectors. In this context, only big firms have the capabilities required to overcome the obstacles of regulatory frameworks, whereas the developments of small companies or official institutions can be left out [1].

A peculiar aspect of the critical relationship between CPVP and EU seed legislation can be found in the requirements laid down for their specific purpose.

The two laws require that the variety must be tested for DUS, the content of which is equivalent. In light of this, the EU legislator should regulate the take-over of official DUS technical reports and recognize the "one key, several doors principle", in order to harmonize the DUS variety testing system throughout the European Union, thus increasing efficiency, avoiding uncertain outcomes and reducing costs.

However, the "one key, several doors principle" should not be perceived as a panacea that will alone guarantee the coordination between CPVP and EU seed legislation.

A legislative revision should concern also the VCU requirement and the procedure for its assessment. Even though the DUS report will be taken over, a protected cereal variety might not be allowed for marketing in the European Union if it does not meet the VCU requirement set out by the EU seed legislation, despite the fact that a Community plant variety right has been granted on it. A discussion should be initiated around the mandatory role of this requirement, considering its lack of compulsoriness for vegetable species. In addition, it is necessary to consider the dissimilarities in VCU assessment among Member States, which can affect competition on a level playing field in the internal market. It must be noticed that the EU Commission has recently published a study on the Union's options

to update the existing legislation on the production and marketing of plant reproductive material [37].

Moreover, the current legal framework is considered outdated. It should take into consideration the current sustainability challenge and the need to implement the F2F strategy and achieve its ambitious goals, by promoting the breeding of new plant varieties capable of adapting to and mitigating the impact of climate change and used in low input production systems, such as organic production. Therefore, rules on a sustainable VCU should be introduced in the EU by adopting specific requirements for the marketing of plant varieties of agricultural species, in order to meet the F2F targets.

Since plant breeding is fundamental to achieving the goals set out by the F2F strategy, the revision of the legislation should consider the possibility of adding specific sustainability characteristics to the four criteria for VCU testing established in the current legislation. In particular, the target of breeding programs should not be focused solely on yield and productivity but on the climate resilience of the major crop species that play a key role in food security, such as cereals [38].

In addition, the protection and registration requirements must take into account not only the conventional agriculture system but also the specific needs of organic farming, promoting the breeding of varieties and plant reproductive material suitable for organic production according to the objectives of the Organic Regulation (EU) 2018/848, such as organic heterogeneous material.

In conclusion, the EU legislation is certainly a policy instrument and can shape innovation in the field of plant species, by favoring the protection of varieties with specific features and establishing the criteria varieties must meet in order to be marketed throughout the European Union territory. However, the primary objective of the current laws, adopted decades ago, is to improve agricultural productivity, focusing exclusively on the needs of conventional agriculture.

Nevertheless, current challenges differ from past ones. Nowadays, the legislation must drive innovation in order to accelerate the transition to sustainable, healthy, and inclusive food systems from primary production to consumption. Therefore, intellectual property and agricultural law must be coordinated, taking into consideration the changing demands of society and the current sustainability challenges highlighted by the F2F strategy.

In light of this, the strong relationship between the EU seed legislation and Community plant variety protection should be taken into account by the EU legislator, especially with regard to agricultural species. It is necessary to update, coordinate, and simplify the existing legal framework. Even though a legislative review could carry the risk of opening Pandora's box, in a fast-changing world, the law requires constant reconsideration in order to evaluate whether it is still able to achieve the current policy goals.

There is a need to stimulate innovation in cereal varieties to face the challenges related to food and agricultural production in the third millennium, as highlighted by the F2F strategy. In light of this, the European Union will only be really able to effectively foster innovation in plant breeding when the legislator recognizes the strong link between the fields of intellectual property and agricultural law, providing for legislative review and better coordination within the existing legal framework, especially in light of the current policy goals.

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References

1. Rapela, M.A. *Fostering Innovation for Agriculture 4.0: A Comprehensive Plant Germplasm System*; Springer Nature: Cham, Switzerland, 2019. [CrossRef]
2. Blakeney, M.; Kadambot, H.M.S. (Eds.) *Local Knowledge, Intellectual Property and Agricultural Innovation*; Springer Nature: Singapore, 2020. [CrossRef]
3. Campos, H. (Ed.) *The Innovation Revolution in Agriculture*; Springer Nature: Cham, Switzerland, 2021. [CrossRef]
4. Fess, T.L.; Kotcon, J.B.; Benedito, V.A. Crop breeding for low input agriculture: A sustainable response to feed a growing world population. *Sustainability* **2011**, *3*, 1742–1772. [CrossRef]
5. Arora, N.K. Impact of climate change on agriculture production and its sustainable solutions. *Environ. Sustain.* **2019**, *2*, 95–96. [CrossRef]
6. FAO; IFAD; UNICEF; WFP; WHO. *The State of Food Security and Nutrition in the World 2019. Safeguarding Against Economic Slowdowns and Downturns*; FAO: Rome, Italy, 2019. Available online: http://www.fao.org/3/ca5162en/ca5162en.pdf (accessed on 20 May 2021).
7. FAO. *The Future of Food and Agriculture: Trends and Challenges*; FAO: Rome, Italy, 2017. Available online: http://www.fao.org/3/a-i6583e.pdf (accessed on 20 May 2021).
8. Cassman, K.G.; Dobermann, A.; Walters, D.T.; Yang, H. Meeting cereal demand while protecting natural resources and improving environmental quality. *Annu. Rev. Environ. Resour.* **2003**, *28*, 315–358. [CrossRef]
9. FAO. *The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture*; FAO: Rome, Italy, 2010. Available online: http://www.fao.org/documents/card/en/c/6ac34ffd-7a66-5d42-9573-3d09491ad39a/ (accessed on 20 May 2021).
10. Nawaz, M.A.; Chung, G. Genetic improvement of cereals and grain legumes. *Genes* **2020**, *11*, 1255. [CrossRef] [PubMed]
11. OECD. *Concentration in Seed Markets: Potential Effects and Policy Responses*; OECD Publishing: Paris, France, 2018. Available online: https://www.oecd.org/publications/concentration-in-seed-markets-9789264308367-en.htm (accessed on 20 May 2021).
12. European Commission. *A Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—A Farm to Fork Strategy for a Fair, Healthy and Environmentally-Friendly Food System*; COM/2020/381 Final; European Commission: Brussels, Belgium, 2020. Available online: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0381 (accessed on 20 May 2021).
13. Mc Conville, M.; Hong Chui, W. (Eds.) *Research Methods for Law*; Edinburgh University Press: Edinburgh, UK, 2007.
14. Chapman, S.; Sherman, B. Finding a place for agriculture in intellectual property law. *Int. Rev. Intellect. Prop. Compet. Law* **2018**, *49*, 759–762. [CrossRef]
15. UPOV. *Seminar on the Nature and Rationale for the Protection of Plant Varieties under the UPOV Convention*; UPOV/PUB/697; UPOV: Geneva, Switzerland, 1990. Available online: https://www.upov.int/edocs/pubdocs/en/upov_pub_697.pdf (accessed on 20 May 2021).
16. Würtenberger, G.; Van Der Kooij, P.; Kiewiet, B.; Ekvad, M. *European Union Plant. Variety Protection*; Oxford University Press: Oxford, UK, 2015.
17. Straus, J. Plant Variety Protection. In *The Max Planck Encyclopedia of European Private Law*; Basedow, J., Hopt, K.J., Zimmermann, R., Eds.; Oxford University Press: Oxford, UK, 2012; Volume 2.
18. Blakeney, M. Agricultural Innovation: Patenting and Plant Variety Rights Protection. In *International Food Law and Policy*; Steier, G., Patel, K., Eds.; Springer International Publishing: Cham, Switzerland, 2016.
19. Louwaars, N.P. Seed policy, legislation and law: Widening a narrow focus. *J. New Seeds* **2002**, *4*, 1–14. [CrossRef]
20. Reichman, J.H. Legal hybrids between the patent and copyright paradigms. *Columbia Law Rev.* **1994**, *94*, 2432–2558. [CrossRef]
21. UPOV. *Actes des Conférences Internationales Pour la Protection des Obtentions Végétales 1957–1961*; UPOV/PUB/316; UPOV: Geneva, Switzerland, 1972. Available online: https://www.upov.int/edocs/pubdocs/fr/upov_pub_316.pdf (accessed on 20 May 2021).
22. UPOV. *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*; TG/1/3; UPOV: Geneva, Switzerland, 2002. Available online: https://www.upov.int/export/sites/upov/publications/en/tg_rom/pdf/tg_1_3.pdf (accessed on 20 May 2021).
23. Leskien, D.; Flitner, M. *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System. Issues in Genetic Resources No. 6*; International Plant Genetic Resources Institute: Rome, Italy, 1997.
24. Seiler, A. Sui generis systems: Obligations and options for developing countries. *Biotechnol. Dev. Monit.* **1998**, *34*, 2–5.
25. Correa, C.M.; Shashikant, S.; Meienberg, F. *Plant Variety Protection in Developing Countries: A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV 1991*; Berne Declaration, Development Fund, SEARICE, Third World Network; Association for Plant Breeding for the Benefit of Society (APBREBES) and its Member Organizations: Alfter, Germany, 2015.
26. Adhikari, K.; Jefferson, D.J. (Eds.) *Intellectual Property Law and Plant. Protection: Challenges and Developments in Asia*; Routledge: Abingdon, UK, 2020.
27. UPOV. *Explanatory Notes on Variety Denominations under the UPOV Convention*; UPOV/INF/12/4; UPOV: Geneva, Switzerland, 2012. Available online: https://www.upov.int/edocs/infdocs/en/upov_inf_12_4.pdf (accessed on 20 May 2021).
28. Osman, A.M.; Bonthuis, H.; Van den Brink, L.; Struik, P.C.; Almekinders, C.J.M.; Lammerts Van Bueren, E.T. Adapting value for cultivation and use testing to stimulate the release of improved varieties for the organic sector. The case of spring wheat in The Netherlands. *Org. Agric.* **2015**, *5*, 101–111. [CrossRef]

29. Kiewiet, B. *The Community Plant Variety Protection System*; Angers, France, 2009. Article Based on a Presentation Made on 29 May 2008 in Genoa, Italy. Available online: https://cpvo.europa.eu/sites/default/files/documents/articles/2009-07-10_Article_Italy.pdf (accessed on 20 May 2021).
30. CPVO. What is a 'Take-Over' of a DUS Report? Available online: https://cpvo.europa.eu/en/help-center/faq/what-take-over-dus-report (accessed on 25 May 2021).
31. Food Chain Evaluation Consortium. *Evaluation of the Community Acquis on the Marketing of Seed and Plant Propagating Material (S&PM). Assignment 5 of the Framework Contract for Evaluation and Evaluation Related Services—Lot 3: Food Chain*; Final Report; European Commission—DG SANCO: Brussels, Belgium, 2008. Available online: https://ec.europa.eu/food/system/files/2016-10/ppm_legis_review_s_pm_evaluation_finalreport.pdf (accessed on 25 May 2021).
32. Turner, M.; Bishaw, Z. *A Review of Variety Release Procedures and Related Issues with Recommendations for Good Practice*; ICARDA Working Papers: Beirut, Lebanon, 2016.
33. IFOAM. *Position Paper. Towards More Crop Diversity—Adapting Market Rules for Future Food Security, Biodiversity, and Food Culture*; IFOAM: Brussels, Belgium, 2013.
34. European Commission. *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) 262 Final; European Commission: Brussels, Belgium, 2013. Available online: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013PC0262 (accessed on 20 May 2021).
35. Llewelyn, M.; Adcock, M. *European Plant. Intellectual Property*; Hart Publishing: Oxford, UK, 2006.
36. European Commission. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Making the Most of the EU's Innovative Potential. An Intellectual Property Action Plan to Support the EU's Recovery and Resilience*; COM(2020) 760 Final; European Commission: Brussels, Belgium, 2020. Available online: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0760 (accessed on 20 May 2021).
37. European Commission. *Commission Staff Working Document. Study on the Union's Options to Update the Existing Legislation on the Production and Marketing of Plant Reproductive Material*; SWD(2021) 90 Final; European Commission: Brussels, Belgium, 2021. Available online: https://ec.europa.eu/food/system/files/2021-04/prm_leg_future_prm-study_swd-2021-90.pdf (accessed on 25 May 2021).
38. Kahiluoto, H.; Kaseva, J.; Balek, J.; Olesen, J.E.; Ruiz-Ramos, M.; Gobin, A.; Kersebaum, K.C.; Takáč, J.; Ruget, F.; Ferrise, R.; et al. Decline in climate resilience of European wheat. *Proc. Natl. Acad. Sci. USA* **2019**, *116*, 123–128. [CrossRef] [PubMed]