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INNOVATION AND PLANT VARIETY PROTECTION IN THE EUROPEAN UNION: THE CASE OF CEREAL VARIETIES. AN EMPIRICAL LEGAL STUDY

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Innovation and Plant Variety Protection in the European Union: the Case of Cereal Varieties.

An Empirical Legal Study

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PREFACE

When Demeter came to our land, in her wandering after the rape of Kore, and, being moved to kindness towards our ancestors […] gave these two gifts, the greatest in the world – the fruits of the earth, which have enabled us to rise above the life of the beasts, and the holy rite, which inspires in those who partake of it sweeter hopes regarding both the end of life and all eternity.

ISOCRATES, Panegyricus

I am in this wretchedness, yoked in these constraining bonds, because I gave privileges to mortals: I hunted for, and stole, a source of fire, putting it into a fennel-stalk, and it has shown itself to be mortals' great resource and their teacher of every skill. Such is the offence for which I am paying this penalty, pinned in these bonds under the open sky.

AESCHYLUS, Prometheus Bound

Agriculture and innovation represent the cornerstone of human life as we know it.

The path of the humankind changed with the beginning of agriculture, more than 10.000 years ago, allowing men and women of the Neolithic to provide more food with less effort in a permanent place. The predictability of food availability facilitated the population increase, while the settlement enabled the creation of the world's first villages.

Agriculture represents a social and cultural turning point, as well as a scientific landmark. The existing genetic variability springs from the - ongoing - process of wild plants domestication, started by the first farming communities. This phenomenon involves the selection on a phenotypic basis of the wild crops more suitable for the need of a certain society, and the following cultivation of the selected crop, by the necessary human intervention on the plant and the surrounding environment[1].

[1] Pigna G., Morandini P., 2017, *Domestication of New Species,* in Pilu R., Gavazzi G. (eds.) More Food: Road to Survival, Bentham Science, Sharjah. The authors state that the domestication process: '*implies the stable acquisition (and therefore the inheritance by the progeny) of a suite of traits, which are collectively defined as the domestication syndrome, which mark the difference between the crop and its wild ancestors'*. It is worth mentioning that crop domestication represents a fundamental transition point in agriculture: when gatherers became farmers. Therefore, beyond its scientific value, this phenomenon has also a great historical and socio-cultural significance. As underlined by the authors: '*crops are marvelous organism on which we ultimately depend, or have depended, for most of our history, for food, feed, fiber, flower, fuel and fun (consider beverages such as wine, beer, tea or coffee, for instance)'*. Although references have been made only to agriculture, domestication is vastly applied in zootechnics as well.

In that human-managed environment, some species of cereals such as einkorn and barley were able to adapt to cultivation, so farmers started to harvest and plant their seed. Slowly, cereals became the basis of the human diet.

In light of this, it does not surprise the worship of gods by ancient religions as personifications of fertility and farming. In particular, the protection of harvests by those divinities was always associated with the cultivation of cereal crops. Indeed, the word '*cereal*' has its roots, its etymology, in the Roman Myth and it originates from the Latin word *Ceres*, which is the benevolent goddess of agriculture, fertility, and cereals, the equivalent of the Greek goddess Demeter. At that time, the category of cereals included wheat, barley, spelt, oats, and millet, but not the unknown maize, from the Americas, or rice, from Asia.

The goddess of agriculture was a central figure in ancient Greek religion and mythology: the Eleusinian Mysteries, the most legendary and secret ritual of ancient Greece, were based on the cult of Demeter and her daughter Persephone, also called Kore, who was abducted by Hades and could return from the underworld only each spring, for six months, to meet her mother. Those rites celebrated the reunion of Persephone with her mother Demeter, and symbolized the eternity of life through the emblem of the buried seeds, whereby the end of life is connected with a new beginning, in an endless circle.

Another key figure of Greek mythology is the Titan Prometheus, who was bound to a rock and sentenced to eternal suffering because he defied Zeus by stealing the fire and giving it to mankind. Prometheus is the avatar of human progress and innovation, a benefactor for humanity that as a fire-bringer allowed the civilization of society. The fire indeed is not intended in its literal meaning way but as the fire of '*creative power'*.

Those myths show how humans have always cared about agriculture and food production, as well as they cared about progress and innovation, in spite of the possible consequences.

In the current society, the bond between agriculture and innovation, symbolically between Demeter and Prometheus, is nowadays more discussed than ever. The agriculture of the third millennium is facing new and difficult challenges, and it needs a breakthrough. Innovation may represent a qualitative leap in this field. Overpopulation, scarcity of natural resources, climate changes, biodiversity conservation, and sustainability, are barely some of

the factors to take into consideration during the debate on the role of innovation in agriculture.

In this framework, cereal breeders are required to use their Promethean *'creative power'* on cereal crops in order to develop new plant varieties, able to improve agricultural productivity and meet the demands of the society.

The present research gravitates towards the role of specific laws in fostering innovation for the benefit of agriculture in the European Union, specifically innovation in the breeding of plant varieties of cereal species. Metaphorically, the research has the purpose of analyzing whether the law could chaperone Prometheus and Demeter for their journey into the third millennium.

List of Abbreviations

Basic Regulation: Council Regulation (EC) No 2100/94 of 27 July 1994

CJEU: Court of Justice of the European Union

CBT: Conventional Breeding Techniques

CPVO: Community Plant Variety Office

CPVP: Community Plant Variety Protection

CPVR: Community Plant Variety Right

DUS: Distinctness, Uniformity and Stability

EDV: Essentially Derived Variety

EPC: European Patent Convention

EPO: European Patent Office

ETGM: Established Techniques of Genetic Modification

EU: European Union

EUTM: European Union Trademark

FAO: Food and Agriculture Organization of the United Nations

FSS: Farm-saved Seed

GMO: Genetically Modified Organism

IP: Intellectual Property

IPR: Intellectual Property Right

ISF: International Seed Federation

ISTA: International Seed Testing Association

ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture

NBT: New Breeding Techniques

OECD: Organization for Economic Co-operation and Development

PBR: Plant Breeder's Right

PVP: Plant Variety Protection

PVR: Plant Variety Right

R&D: Research and Development

R&I: Research and Innovation

SMEs: Small and Medium-sized Enterprises

TFEU: Treaty on the Functioning of the European Union

TRIPs: Agreements on Trade-Related Aspects of Intellectual Property Rights

UN: United Nations

UPC: Unified Patent Court

UPOV: International Union for the Protection of New Varieties of Plants

VCU: Value for Cultivation and Use

WIPO: World Intellectual Property Organization

WTO: World Trade Organization

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INTRODUCTION

SUMMARY: 1. Purpose. - 2. Research question. - 3. Methodology. - 4. Outline.

1. Purpose

The purpose of the research is to understand whether and, if so, how Community plant variety protection is nowadays fostering innovation and stimulating plant breeding in the European Union, with regard to varieties of cereal species.

The rationale of Community plant variety protection is to incentive plant variety creation and to stimulate further innovation: this is the social goal of the relevant legislation. The current research aims at assessing whether this legislation achieves its social goal with regard to the EU cereal breeding industry.

In the European Union, innovation in cereal varieties has an enormous relevance: it has an economic and social impact, as well as a scientific and environmental one. Indeed, it is crucial for the competitiveness of the seed, agricultural, and food industry, and it is also fundamental in terms of food security, as well as biodiversity conservation and sustainability in agriculture.

Moreover, cereals represent the basis of the human diet. They are 'staple foods' and as such they are globally eaten on a regular basis and they represent the largest part of the human nutrition. Therefore, innovation in cereal breeding is crucial in order to feed the world's increasing population. Furthermore, in the EU market the main seed production is represented by cereal varieties: the European Union industry has a world-leading role in cereal production, especially wheat.

Considered the importance of the sector, breeders are interested in protecting their new varieties of cereals with intellectual property rights, in order to get a return on investment. In the European Union, a breeder may apply for an EU intellectual property right over their new plant variety on the basis of well-defined requirements: these IP rights are called *Community plant variety rights* and they are unitary intellectual property rights, not a bundle of rights.

Community plant variety protection is supposed to support the creation of new plant varieties for the benefit of society: Community plant variety rights have an alleged role in fostering innovation on plant varieties, the scope of which is going to be investigated.

In the current study, the role of Community plant variety protection in fostering innovation in cereal varieties is also examined vis-à-vis the EU seed legislation because of the impact the two legislations have on variety creation.

As a matter of fact, new plant varieties are brought onto the market as reproductive material: in the case of cereal varieties, as seeds. In this context, the seed represents both a *commercial commodity* and a *technology carrier*[2], in which it is impossible to divide the intangible and tangible subject matter. The dual-nature of the seed reflects the two legislations affecting the seed sector: broadly speaking, there are 1. rules regulating seeds as commercial commodities, establishing criteria for their marketing (i.e. *the seed legislation*), and 2. rules governing the reproductive material as a technology carrier, granting exclusive IP rights to the breeder over a newly bred plant variety (i.e. *the plant variety protection*). The two legislations are linked to one another because both of them have an impact on the seed sector and may represent an incentive for variety creation. This linkage might be particularly tight with regard to varieties of cereal species, since seed marketing laws do not apply to every plant species but only to a number of them, including cereals. In light of this, the role of Community plant variety protection may be affected by the EU seed legislation: an obstacle to the marketing of a cereal variety may jeopardize the 'reward' provided by the relevant intellectual property right, and negatively impact the creation of further varieties.

With this in mind, the purpose of this study is basically to investigate the effectiveness of Community plant variety protection in fostering innovation and stimulating plant breeding in the European Union industry with regard to cereal varieties. The effectiveness of the Community plant variety protection system is investigated both *per se* and in connection with the EU seed legislation.

It is important to underline that GMO plant varieties are not covered by the present investigation because of their very marginal role in the EU industry and agriculture.

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[2] Louwaars N., 2002, *Seed Policy, Legislation and Law: Widening a Narrow Focus,* in Journal of New Seeds, 4, 1/2, p. 2-4.

Cereal breeding companies based in the EU are the target audience of the current investigation, as representatives of the EU cereal breeding industry. For the purpose of this research, 'cereal breeding companies' refers to private companies actively engaged in activities of R&D and plant breeding of new varieties of cereal species (thereby excluding public institutions and natural persons), which operate within the Community plant variety protection regime. A large part of those companies is represented by SMEs, as defined in Article 2 of the EU Commission Recommendation of May 6th 2003 concerning the definition of micro, small and medium-sized enterprises[3]. As a matter of fact, the economic fabric of the seed companies operating within the European Union is mostly made up of SMEs: 90% of the over 7,000 companies are SMEs, operating in research, breeding, production, and commercialization activities[4]. Also, SMEs have been notably inclined toward the use of the Community plant variety protection systems, refusing the patent one[5].

The choice of this target audience also has the purpose of overcoming the popular *'clichéd view'* of the plant breeding industry, as a sector exclusively dominated by multinational enterprises. The view of the industry is sometimes marked by hostility because farmers and plant breeders are seen as contemporary *David and Goliath,* operating in the constant antagonism between peasants and multinational corporations. This approach does not take into consideration the role of SMEs in plant variety innovation and their effort to develop improved varieties for the benefits of both farmers and consumers.

In light of this, this study also wishes to show the EU breeding industry from a different point of view, taking into consideration the many SMEs engaged in cereal breeding, addressing their challenges, difficulties, and exploring the significant role of the innovations carried on by them, both for farmers and consumers.

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[3] '*Article 2. Staff headcount and financial ceilings determining enterprise categories. 1. The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. 2. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. 3. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.'*

[4] Data extracted in 2017, available at https://www.euroseeds.eu/decreasing-environmental-footprint-agriculture-without-decreasing-yield

[5] Bently L., Vaver D., 2004, *Intellectual Property in the New Millennium: Essays in Honour of Professor W.R. Cornish*, Cambridge University Press, Cambridge, p. 153-154.

2. Research question

One main research question is going to guide the categorization of the research topic. In this way, it is possible to pinpoint the so-called '*research gap'*, which is the problem not yet satisfactorily addressed by existing literature in this field.

Over the years, some attempts have been made to empirically assess the views of European plant breeders on Community plant variety rights[6]: an important study was carried out in 2001 by the European Union as part of the Fourth Framework Programme (PIP Project). The core aspect of that research has been the assessment of the two systems of intellectual property protection over plants: patents and plant variety protection. In particular, the PIP project aimed at assessing the attitudes towards plant intellectual property (as already said, both patents and Community plant variety rights) within the European plant breeding industry, and at evaluating whether the existing legal framework is both effective and appropriate. *Inter alia*, the study showed that there is general satisfaction among plant breeders with the plant variety rights system. Some concerns were expressed about the farm-saved seed provisions. The study also showed a lack of awareness of plant breeders about legal issues. It is interesting to note that 60% of the breeders who participated in the second questionnaire '*felt unable to answer any of the substantive law questions'*[7].

As regards to the empirical findings, the EU cereal breeding industry has its own peculiarities: hence, the findings obtained by the researches focused on the plant breeding industry as a whole cannot be a general indicator of the views of the cereal breeding sector on the specific intellectual property regime of Community plant variety protection. Furthermore, those studies may be partially outdated.

The legal literature on the topic has often looked at Community plant alongside patents on biotechnologies, in the framework of what may be identified as the regimes of '*intellectual property over plants*'. The interface between plant variety rights and patents, as well as advantages and disadvantages of both systems of protection have been overviewed and extensively analyzed by the relevant literature.

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[6] Those studies have been properly analyzed and summarized by Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford, pp. 397-454.
[7] Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford, p. 453.

It was not possible to find any empirical legal study specifically focused on Community plant variety protection over cereal varieties. One might assume that legal scholarship has not yet focused on the relationship between innovation in cereal varieties and Community plant variety protection in the European Union. The choice of a specific crop sector, i.e. cereal, where to investigate the effectiveness of the Community plant variety protection regime is based on the idea that each crop sector has its own peculiarities and regulations, thereby the legislation may have different impacts.

In the current study, the effectiveness of the Community plant variety protection system in not merely analyzed in the framework of 'intellectual property law', but also in its dialogue with the seed legislation affecting the marketing of seeds of cereal varieties. In light of this, the current research does not exclusively lie in the intellectual property law arena but it refers to further fields of law, in particular the agricultural law.

Therefore, the research gap that the current study wishes to address is represented by the focus on a specific crop sector in the framework of both intellectual property law and agricultural law. The research topic is considered worthy of study for the reasons illustrated in the first chapter of the current study.

Given the foregoing considerations, the main research question explored by the current study is the following one:

1. Nowadays, is Community plant variety protection fostering innovation in cereal varieties in the European Union industry?

Through this question, the research aims at evaluating the effectiveness of that system. In order to provide a complete answer, the research is going to be lead by other sub-questions:

a. What is plant breeding?
b. What is the relevance of plant breeding in cereal varieties?
c. What is plant variety protection?
d. Which is the international legal framework on plant variety protection?
e. How is plant variety protection regulated in the European Union?
f. How is seed marketing regulated in the EU?
g. In this context, how is cereal seed marketing regulated?
h. What is the relationship between Community plant variety protection and seed legislation?

i. What are the views of the EU cereal breeding companies on the effectiveness of Community plant variety protection?

j. What are the advantages and shortcomings of the current system?

Those sub-questions are both leading the investigation and designing the structure of the following chapters, in order to provide the basis for the final answer.

3. Methodology

This study originates from a combination of academic and applied research carried out at the University of Macerata, at the Max Planck Institute for Innovation and Competition, and within an Italian SME named Agroservice spa, engaged in activities of research, testing, development, multiplication and commercialization of seeds for agriculture, especially cereals.

The synergy of studying law in the books and law in action[8] deeply affected the choice of the research methodology. The approach underpinning the formation of this research project is interdisciplinary, since the normative legal investigation is coupled with empirical one, based on a qualitative method, in order to develop an '*empirical legal research'*.

Normative research is based on the analysis of primary sources, judicial precedents, textbooks, academic papers. Therefore it should be qualified as 'library-based'[9]. Whereas, empirical research[10] in law aims at studying and understanding how the law operates in a specific social context and its effects within that context: it mixes what the law says to what the law does[11] in order to provide a '*critique of the law'*.

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[8] Legal theory firstly developed in 1920 by Roscoe Pound, one of the major representatives of legal realism, in the article '*Law in Books and Law in Action'*, published in the American Law Review*,* 44, 12-3, where he underlined the importance of how the law is applied in the society.

[9] McConville M, Hong Chui W. (ed.), 2007, *Research Methods for Law,* Edinburgh University Press, pp.47.

[10] In the last 20 years the use of empirical data and empirical research methods in legal research have highly increased. See Tyler T. R., 2017, *Methodology in Legal Research,* in Utrecht Law Review*,* 13, 3 and Hutchinson T., Duncan N., 2012, *Defining and describing what we do: doctrinal legal research*, in Deakin Law Review, 17, 1. Moreover, the role of empirical research is believed fundamental because "if laws are intended to produce certain results, questions about whether they do produce the expected results, whether they produce other results, and whether the identifiable results are as consistent with the reason for law as one might have anticipated, are all important to examine". Teitelbaum L. E., 1985, *An Overview of Law and Social Research*, in Journal of Legal Education*,* 35.

[11] Baldwin J., Davis G., 2003, Empirical Research in Law, in Tushnet M. and Cane P. (ed.), *The Oxford Handbook of Legal Studies,* pp. 880-899. Baldwin and Davis said that empirical legal researchers intend to emphasize '*the disparity between textbook and everyday reality'*.

The empirical legal approach allows the researcher to use more than one research technique to study a certain context and it may be more reliable than a single-method approach[12]: the convergence of the data collected, both legally and empirically, determines the level of consistency of the regime.

Empiricists aim at describing and explaining social phenomena and, in doing that, they borrow research methods from the social sciences[13], so as to choose between qualitative and quantitative approaches[14]. The choice of a qualitative method over a quantitative one for the current study relies on its closeness to traditional legal research, since it prioritizes interpretation and meaning. It is also appropriate for lawyers with no training in quantitative research[15]. In addition, the current investigation does not depend on statistical quantification and it does not involve any measuring. Instead, it wishes to identify and understand a certain legal context in an exploratory, and not explanatory, manner: in this sense, qualitative research is more suitable for the purpose of the research.

The combination of legal and empirical findings in a single system allows to ascertain the supposed so-called '*external effectiveness'* of the law. This means analyzing whether the existing legal rules are effective in real life, if they achieve their social goals[16].

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[12] Nielsen L., 2003, *The need for Multi-method approaches in Empirical Legal Research*, in Cane P., Kritzer H., (eds.), The Oxford Handbook of Empirical Legal Research, Oxford University Press, p. 953. In order to examine the categories of legal research, see Van Hoecke M. (ed), 2011, (ed.), *Methodologies of Legal Research – Which Kind of Method for What Kind of Discipline?*, Oxford and Portland, OR: Hart Publishing.

[13] Legal scholars believe that a pure application of the social sciences empirical methods could not be suitable for legal scholarship. In social sciences, the research question embodies the causal relationship, whereas in legal arena the causal relationship is an argument for answering the research question. The legal rule is supposed to have a social purpose therefore observation of the phenomena *per se* is not enough: the legal scholar aims at postulating a different interpretation or a new rule in order to achieve that purpose. Therefore, empirical studies are crucial to identify whether there is a social problem and if normative intervention could mitigate it but, still, it is fundamental that the core of the research remains normative. See Engel C., 2017, *Empirical Methods for the Law*, in Max Planck Institute for Research on Collective Goods Preprint, Bonn, 7, available at: https://ssrn.com/abstract=2966095 or http://dx.doi.org/10.2139/ssrn.2966095

[14] Empirical content has become crucial for some legal papers. See Tyler T. R., 2017*, Methodology in Legal Research,* in Utrecht Law Review*,* 13, 3 and Hutchinson T., Duncan N., 2012, *Defining and describing what we do: doctrinal legal research*, in Deakin Law Review, 17, 1. Moreover, the role of empirical research is believed fundamental because 'if laws are intended to produce certain results, questions about whether they do produce the expected results, whether they produce other results, and whether the identifiable results are as consistent with the reason for law as one might have anticipated, are all important to examine'. Teitelbaum L. E., 1985, *An Overview of Law and Social Research*, in Journal of Legal Education*,* 35.

[15] Wulf A. J., *The Contribution of Empirical Research to Law,* in The Journal Jurisprudence, 29, 2016, 29-49.

[16] Schrama W., 2011, *How to carry out interdisciplinary legal research. Some experiences with an interdisciplinary research method*, in Utrecht Law Review, 7, 1. The author defines external effectiveness as following: it '*refers to the external consistency of the legal system with the context and culture in which it functions. […] External effectiveness evaluates the difference between the legal reality and the real reality*'.

To this end, the pure legal standards are coupled with empirical non-legal data and insights from other disciplines, i.e. socio-economics and life sciences, collected via qualitative research methods. The purpose is to outline the addressed context, to provide the legal debate with facts and arguments, and, ultimately, to answer the questions leading the current research. The interpretation of the collected data uses thematic analysis methods[17]. The raw data are not published because they include sensitive data.

The design of this interdisciplinary research is based on a unilateral method, which means that the problem lies in the legal arena, and the legal analysis is supported by empirical data[18]. As already said, the legal arena where the problem lies consist of intellectual property law and agricultural law.

4. Outline

In order to offer an answer to the research question, this study is structured in six parts.

The first introductory chapter provides an overview of the topic and its historical background. It addresses key concepts such as plant breeding and plant varieties protection, and it describes the relevance of cereal breeding in the EU.

The second chapter addresses the international legal framework on plant variety protection, i.e. the International Convention for the Protection of New Varieties of Plants (UPOV Convention), which is the first internationally recognized multilateral convention on plant variety protection. The third chapter focuses on the current Community plant variety protection system in the European Union. i.e. the applicable law. An overview of the system is provided and the most critical provisions are analyzed. Both chapters are based on a normative research approach, where the main form of information is provided by the primary sources of law along with the relevant judicial decisions and legal literature concerning the chosen field of investigation (method known as '*black letter law'*).

The same normative research approach could also be found in the fourth chapter, which deals with the EU seed legislation, i.e. the legislation regulating the marketing of seeds in the EU. The analysis of the relevant Directives is deeply related with Community

[17] For further insights, see: Braun V., Clarke V., 2006, *Using thematic analysis in psychology*, in Qualitative Research in Psychology, 3, 2, pp. 77-101.
[18] Schrama W., 2011, op. cit.

plant variety protection: points of critical connection between the two legislations are explored, in order to evaluate whether there may be an influence on the effectiveness of Community plant variety protection. Special emphasis is put on the rules governing the marketing of cereal seeds. The materials analyzed are: primary sources of law, judicial decisions, legal academic writings, and also life science literature.

The fifth chapter is empirically driven and it focuses on the data collected during the three-years of study. The chapter also explains the methodology used for data collection and data analysis. Data collection entailed three methods, used in combination, usually referred to as *triangulation*[19]*:* participant-observation[20], surveys, and semi-structured interviews. Data interpretation has been based on the method of thematic analysis[21] to identify and report patterns and prevalent themes within the collected data set, which is crucial for the interpretation of findings. Thematic categorization has not involved the use of computer-assisted analysis.

The final chapter draws the conclusion combining the legal outcomes and the empirical thematic categories developed from the data set, in order to provide an answer to the main research question.

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[19] Nielsen L., 2003, *The need for Multi-method approaches in Empirical Legal Research*, in Cane P., Kritzer H., (eds.), The Oxford Handbook of Empirical Legal Research, Oxford University Press, p. 953.
[20] The author acted as privileged observer of the chosen context because of the role played within Agroservice.
[21] Braun V., Clarke V., 2006, *Using thematic analysis in psychology*, in Qualitative Research in Psychology, 3, 2, pp. 77-101.

CHAPTER 1
Overview of the studied context

SUMMARY: 1. Preliminary remarks. - 1.1. Introduction to plant breeding. - 1.2. Definition of terms: innovation in cereal varieties. - 2. Significance of the study. - 2.1. Challenges of the third millennium. - 2.2. The 2030 Agenda for Sustainable Development. - 2.3. The EU cereals sector. - 2.4. Innovation in cereal varieties: a peek to CPVO statistics. - 3. Introduction to plant variety protection. - 3.1. Intellectual property rights over plant varieties. - 3.2. Origins of plant variety protection. - 3.3. Plant variety protection: the hybrid intellectual property regime. - 3.4. Intellectual property rights over plants: patents vs. plant variety rights. - 3.5. The role of plant variety protection in fostering innovation. - 4. Final remarks.

1. Preliminary remarks

1.1. Introduction to plant breeding

Plant domestication, as well as the development of new plant varieties, are primordial phenomena[22], based on the constant work of generations of farmers[23]. Plant breeding is a time-consuming science and it needs a large amount of economic, natural and human resources to be carried out efficiently.

Before the discovery of the Mendelian Laws by the Augustinian world-renowned monk Gregor Johann Mendel[24] during the second half of the 19th century, crop improvement was solely performed by farmers[25], in an informal and unscientific[26] manner. Thanks to the

[22] As already illustrated, the phenomenon of creation of new plant varieties started more than 10.000 years ago, during the Neolithic era, when cultivators started to domesticate wild plants.
[23] Another tool of improvement was and is time: over the millennia, a lot of invisible crop improvements have been made. UPOV, 1983, *Genetic Engineering and Plant Breeding*, Geneva, p. 10.
[24] He is unequivocally recognized as the *'father of genetics'*.
[25] Ceccarelli S., 2009, *Evolution, plant breeding and biodiversity,* in Journal of Agriculture and Environment for International Development*,* 103, 1-2, pp.131-145.
[26] The crop improvements were driven by mythology and aesthetics, not science. Also, they took place under leisure experiments, not under necessity or urgency. See: Padwa D. J., 1983, *Genetic Engineering: a new tool for plant breeders*, in Genetic Engineering and Plant Breeding, UPOV Publication N. 340(E). By way of

dissemination of Mendel's genetic laws, plant breeding became a business based on a formal and scientific approach, and it turns out to be a prerogative of the so-called '*breeders*': scientists, geneticists, and biologists whose job purpose is to bred, or discover and develop new plant varieties. Consequently, companies started to invest in research and development (R&D), in order to create crops having the desirable traits and characteristics, capable of meeting the nutritional needs of the society.

As stated by the International Union for the Protection of New Varieties of Plants, known as UPOV[27], investments for modern plant breeding are required every year. They consist of scientific manpower with great skills and knowledge, land, and specialized equipment (e.g. growth chambers and laboratories). The expenditure of work and energy must go on over the years: surely enough, it takes a long time to find and develop new plant varieties, sometimes up to fifteen years.

On top of that, the outcomes are not always positive: at the end of the testing and developing period, scientists could obtain unsatisfactory results. The reasons are several: the new plant varieties could not have the long-awaited characteristics, or the market demands could have changed during the years, making the commercialization of the new variety a failure. Either way, a negative result could certainly jeopardize the possibility of a return on investment.

At the same time, since a new variety is not an inert product and it is naturally self-replicating, other subjects could effortlessly reproduce it thus taking away the possibility, for the original breeder, to commercially exploit the achieved results. In this context, private companies carrying out plant breeding activities have to balance the profits with the expected return of those investments. As already stated, those activities are worth the time and the effort made only if the breeder can, at least, recover costs sustained for the development of those value-added innovations. Otherwise, plant breeding would be not remunerating and, therefore, no business would have pursued it.

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illustration, the author mentions the use of pumpkins: '*Let us not forget that the pumpkin was used ad a musical instrument, as a rattle, long before it was used as a foodstuff*'.

[27] UPOV, 2003, *Introduction to Plant Variety Protection under the Upov Convention,* p. 2, http://www.wipo.int/edocs/mdocs/sme/en/wipo_ip_bis_ge_03/wipo_ip_bis_ge_03_11-main1.pdf

Despite the common belief that plant breeders are modern '*sorcerers' apprentices*'[28], the society benefits from the gargantuan improvements carried out by breeders over the years, although sometimes it does not realize it.

In the case of plant varieties for agricultural purposes, those improvements mainly concern agricultural production, which is very valuable to society. In this context, the development of new cereal varieties has significant social, environmental, scientific, and economic impacts, because of their crucial role in the EU agriculture and economy.

1.2. Definition of terms: innovation in cereal varieties

Innovation is the *Zeitgeist* of contemporary society, especially in advanced economies, but it does not have any particular legal meaning. Innovation applies to ideas, processes, and products in countless businesses and it is often related to the concepts of originality and more efficiency.

Since innovation is related to a particular place and a particular time, what is deemed to be an innovation in the European Union in 2020, may not be considered the same in another country or in another period. Therefore, for the purpose of the research, the scope of this 'innovation' is limited to the contemporary context of the European Union.

Innovation in cereal variety is broadly considered the creation of new varieties of cereal species. For the purpose of the current investigation, the cereal species taken into consideration are the ones listed in Article 2 of Directive 66/402/EEC on the marketing of cereal seed, as lastly amended[29]. It is worth noting that minor cereal crops, such as *Triticum monococcum*, are not listed in Article 2.

With regard to the scope of innovation, newness does not necessarily mean 'improvement' because, in this context, varieties are deemed to be improved only when they

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[28] Reference is made to the poem '*The Sorcerer's Apprentice*' (in the original German version: '*Der Zauberlehrling*'), written by Johann Wolfgang von Goethe in 1797. The rationale behind the reference is on the widespread opinion considering plant breeders as hazardous scientists and futuristic 'wizards', playing with Mendelian Laws and genetics on biological material, incapable to properly control the 'spirits that they called' (*'Die Geister, die ich rief'*), i.e. the effects of crop improvement on the environment and human health.

[29] *Avena nuda L., Avena sativa L., Avena strigosa Schreb., Hordeum vulgare L., Oryza sativa L., Phalaris canariensis L., Secale cereale L., Sorghum bicolor (L.), Sorghum sudanense, xTriticosecale Wittm., Triticum aestivum L., Triticum durum, Triticum spelta L., Zea mays L.*

are characterized by 'improved productivity'. However, the importance of innovation in cereal varieties is not only tied to productivity and food security, as important as it is, but also related to safety, sustainability and fight against genetic vulnerability. In this framework, an innovation in cereal variety is worth of promotion when it is either productive, resistant, or adaptable to low input conditions. In terms of genetic vulnerability, innovation is worth of promotion also when a new variety is constituted, as different from the existing ones, because the existence of numerous genetic characteristics in some geographical area decreases the loss of flexibility in the plants, hence the genetic vulnerability thereof. In this sense, it does not represent an innovation the plagiaristic practice on plant varieties known as '*cosmetic breeding'*. It is worth highlighting that innovation in cereal varieties does not only concern the novelty *per se* but also the breeding methods used.

In light of this, for the purpose of this study innovation in varieties of cereal species is considered the creation of new plant varieties of cereal species, having scientific relevance (hence, it is not plagiarism) and meeting the society's needs in terms of food security, food safety, biodiversity protection, and sustainability.

2. Significance of the study

2.1. Challenges of the third millennium

Achieving food security[30] is going to be one of the biggest global challenges over the next few years, in response to the expected growth of the world's population, ergo the increase of food demand.

According to the data collected by the Food and Agriculture Organization of the United Nations (FAO)[31], by 2050 there are going to be almost 10 billion mouths to feed and there will be a rise in agricultural demand by 50 percent, compared to 2013. Therefore,

[30] The concept of 'food security' is constantly evolving. Suffice it to say, in 1974 the World Food Summit focused the definition only on the volume and stability of food supply whereas in 2001 the State of Food Insecurity emphasized the importance of food demand, safety and access for vulnerable groups. See: FAO, 2003, *Trade and Food Security: Conceptualizing the Linkages*, Rome, p. 25 et seq.
[31] FAO, 2017, *The future of food and agriculture - Trends and challenges*, Rome, p. x.

agriculture must be able to boost and improve productivity as well as high-quality harvests while facing climate change and scarcity of natural resources to be used in a sustainable manner (so-called, *'*resource efficiency*'*). Specifically, as stated by the FAO reports, the current agricultural system based on resource-intensive methods is causing massive soil consumption, deforestation, water shortages, high levels of CO^2 emissions and, yet, almost 800 million people are nowadays suffering from hunger[32].

For that reason, society needs an innovative approach to agriculture, that has to be sustainable while increasing agricultural productivity and food nourishment.

Within this context, research and innovation in the plant sector are playing a key role. In particular, one of the major research contributions lies in plant breeding. The activity of developing new plant varieties is carried out by breeders - whether natural or legal persons -, in order to respond, primarily, to the above-mentioned increase of food demand.

The aims of breeders are multiple: 1. enhancing productivity of plants; 2. obtaining better pests and diseases resistance; 3. decreasing the pressure of agricultural activities on the environment (i.e. sustainable use of soil, water, biodiversity); 4. increasing the nutritional content of the new varieties; 5. achieving a better adaptation to climatic stress. Consequently, plant breeding is crucial not only to food security, because of the larger productivity and the higher nutrition of new varieties, but also to sustainability, because of the lower use of chemical products - linked to the improved resistance - and the better resource efficiency - related to the lower impact on the surrounding environment. Low-impact farming is deemed necessary for the agriculture of the third millennium.

In addition, innovation in plant breeding is fundamental to reduce crop genetic vulnerability. This phenomenon is defined by FAO as *'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*'[33]. The gene diversity drop represents a significant threat to agricultural production. According to FAO, this event roots in the massive presence of monocultures in agriculture that leads to loss of variability and, therefore, loss of flexibility due to the great presence of only a few

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[32] Ibid., p. xi.
[33] FAO, 2010, *The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture*. Rome, p. 15.

genetic characteristics in some geographical areas. That happens because only a wide range of unique traits allows plants to face the changing conditions of the environment[34].

It goes without saying that the phenomenon of genetic vulnerability could also bring to catastrophic losses in terms of biodiversity. For that reason, the fundamental role of plant breeding is frequently stressed by scientists and researchers because, through the development of new varieties starting from existing ones, it provides value and increases genetic diversity.

As a matter of fact, breeders need biodiversity, and they require nothing but access to plant genetic diversity in order to fulfill their tasks: the more traits, the more possibilities to breed new varieties. Therefore, the breeding activity hardly follows the Schumpeterian process of '*creative destruction'* because new plant varieties cannot be created from scratch[35].

The report of FAO gives concrete examples of countries that put into practice effective measures to tackle genetic vulnerability, mainly through the promotion of breeding programs and the introduction of a broader number of plant varieties (e.g. Thailand, Cuba), underlining in this way the vital function of plant breeding against genetic erosion and, therefore, its role for biodiversity protection[36].

With this in mind, the role of plant breeding in the specific sector of cereal varieties has to be highlighted. First of all, the largest amount of global agricultural production is made up of cereals (e.g. wheat, rice, barley, corn, rye, oats, millet, etc.), which represent the foundation of the human diet. Suffice it to say, FAO estimated that just 150 of the global crops are aimed at food consumption and 80 percent of human nutrition is provided by 12 of them, with rice, wheat, corn and potato alone providing 60 percent[37]. In addition, some of the cereals made up the so-called *'flex crops'*, meaning that they could be used not only for

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[34] FAO, 2004, *Biological diversity is fundamental to agriculture and food production,* http://www.fao.org/docrep/006/y5418e/y5418e00.htm

[35] See: Kochupillai M., 2016, *Promoting Sustainable Innovations in Plant Varieties*, Springer, Berlin & Heidelberg. The author believes that innovation in plant varieties *'is a vicious cycle of innovation (creation) leading to destruction (both natural and unnatural) and calling for (even) more 'destructive creation'.'* The author believes that improved seeds, pesticides and fertilizers leads to further degradation of land/soil and the lost of old varieties and biodiversity in general.

[36] FAO, 2010, *The Second Report*, cit., p. 15.

[37] Northoff E., 2007, *International plant gene pool becomes operational,* in FAO Newsroom, http://www.fao.org/newsroom/en/news/2007/1000690/index.html

food but also for feed, fuel, fiber or industrial material[38]. As a result, the world cereals consumption has highly increased: FAO reported a rise of 1.8 percent a year in the first decade of the twenty-first century[39]. Considering this large production and consumption of cereal crops, it goes without saying that reaching a high, efficient, and sustainable production of cereals could both improve food security and increase sustainability, whereas an inadequate and unsustainable production could lead to serious problems.

Also, in relation to genetic vulnerability, the same FAO reports that there is an alarming global trend towards the genetic vulnerability of cereals: at least 30 countries have reported genetic erosion of these crops in the last years, followed by vegetables, fruits and nuts and food legumes[40]. Therefore, plant breeding in cereal varieties seems fundamental in order to maintain cereal genetic diversity and avoid losses in terms of biodiversity.

In light of this, there are no doubts regarding the central role played by plant breeding and constant innovation in the cereal seed sector for the benefits of the society and the environment, in order to achieve global food security, food safety, sustainability, and to contrast the genetic vulnerability of cereal crops.

2.2. The 2030 Agenda for Sustainable Development

Fostering innovation for agricultural purposes is strictly connected to the implementation of the 2030 Agenda for Sustainable Development[41]. The Agenda addresses the threefold economic, social, and environmental dimensions of sustainable development by setting 17 goals[42], whose implementation and success rely on countries' own policies and

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[38] See: Saturnino M., Borras Jr., Jennifer C. Franco et al., 2016, *The rise of flex crops and commodities: implications for research*, in The Journal of Peasant Studies, 43, 1.

[39] See: FAO, 2015, *Statistical Pocketbook. World food and agriculture,* Rome, p. 31; FAO, 2017, *The future of food and agriculture - Trends and challenges*, Rome, p. 35.

[40] FAO, 2010, *The Second Report*, cit., p. 16.

[41] During the 2015 UN Sustainable Development Summit, more than 150 world leaders adopted this new sustainable development agenda. It incorporates follow-up from the Rio+20 Conference on Sustainable Development. The 2030 Agenda aims to promote globally shared prosperity and well-being for all over the next 15 years. The effort should be made to tackle poverty, inequalities and climate change. Source: United Nations website, http://www.un.org/sustainabledevelopment/development-agenda/

[42] Particularly, the 2030 Agenda wishes to: 1. end poverty in all its forms everywhere; 2. end hunger, achieve food security and improved nutrition and promote sustainable agriculture; 3. ensure healthy lives and promote well-being for all at all ages; 4. ensure inclusive and equitable quality education and promote lifelong learning opportunities for all; 5. Achieve gender equality and empower all women and girls; 6. ensure availability and sustainable management of water and sanitation for all; 7. ensure access to affordable, reliable, sustainable and

programs. The Agenda is characterized by its universality: it strives for its application to all countries, at all levels of development.

Even though the Sustainable Development Goals of the 2030 Agenda are not legally binding, the European Union is making a positive contribution to achieving the 17 goals stated in the Agenda[43]. Indeed, the EU has played a leading role, not only in shaping the global 2030 Agenda[44] but also in the implementation of its ambitious goals[45]. Thus, in November 2016, the European Commission issued a communication[46] to the EU Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entitled *'Next steps for a Sustainable European Future - European action for sustainability'*. In the document, the European Commission underlines how sustainability, in its threefold dimension, represents a core value of the EU project and is consistent with its vision.

Nowadays, the European Union is facing several challenges and sustainability concerns, so it is fundamental to preserve the EU social model and social cohesion while tackling those issues. In order to do that, the EU promptly answered the 2030 Agenda call to action through two work streams: the first one is based on the full integration of the goals in the EU current policy framework; the second one on developing a long-term vision and implementation. The Commission considered that those goals should be pursued in a collective way and in order to turn them into opportunities. In particular, the Commission

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modern energy for all; 8. promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all; 9. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation; 10. reduce inequality within and among countries; 11. make cities and human settlements inclusive, safe, resilient and sustainable; 12. ensure sustainable consumption and production patterns; 13. take urgent action to combat climate change and its impacts; 14. conserve and sustainably use the oceans, seas and marine resources for sustainable development; 15. protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss; 16. promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels; 17. strengthen the means of implementation and revitalize the global partnership for sustainable development. Source: UN website, http://www.un.org/sustainabledevelopment/sustainable-development-goals/

[43] Source: European Union website, https://ec.europa.eu/europeaid/policies/european-development-policy/2030-agenda-sustainable-development_en

[44] Through public consultations, dialogue with our partners and in-depth research. Source: European Union website, https://ec.europa.eu/europeaid/policies/european-development-policy/2030-agenda-sustainable-development_en

[45] Ivi.

[46] The Communication of the European Commission is available at the following website: https://ec.europa.eu/europeaid/sites/devco/files/communication-next-steps-sustainable-europe-20161122_en.pdf

stated that '*for these challenges to become opportunities for new businesses and new jobs, a strong engagement in research and innovation is needed'*[47], enhancing the role of Research and Innovation (R&I) in order to reach sustainable development. The importance of R&I is particularly emphasized when mapping the EU main actions contributing to the implementation of the 2030 Sustainable Development Goals.

For example, with regard to the goal n. 9 posed by the Agenda and focused on fostering innovation, the Commission underlined how R&I are playing a crucial role in the EU since they are largely funded through the Horizon 2020, the EU Framework Programme for Research and Innovation.

Also, in order to achieve sustainable development, the Commission believes that innovation is not only important *per se* but also as related to the accomplishment of the goal n. 2 of the 2030 Agenda. This goal aims at putting an end to hunger, achieving food security and improved nutrition, and promoting sustainable agriculture.

With this in mind, the reformed Common Agricultural Policy (CAP) of the European Union has been complemented by FOOD 2030 - Research & Innovation for Tomorrow's Nutrition & Food Systems[48]-, an action on the role of research and innovation within the EU to future-proof the nutrition and food systems. The action addresses four priorities: nutrition, environmental sustainability, circularity and resource efficiency, and innovation. The drivers of this action are the following: research breakthroughs, innovation and investment, open science, and international cooperation. Interestingly, in this action, innovation is both a driver and a priority, as if to say that innovation generates innovation. Innovation should support agriculture and food production, in a virtuous circle of innovation.

In this context, innovation in plant varieties for agricultural purposes, especially the varieties playing a key role in food production, such as cereals, is essential to achieve the goals of the Agenda.

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[47] EU Commission, 2016, *Next steps for a Sustainable European Future. European action for sustainability - SWD (2016) 390 final,* p. 2.

[48] Within the action Food 2030, Research & Innovation for Tomorrow's Nutrition & Food Systems, a high-level event was held in Belgium, Brussels, on October 2016. It provided a platform for dialogue aimed at building a coherent research and innovation policy framework for Food and Nutrition Security. The background document sets out how the EU Research and Innovation policy contributes to the major global challenge of ensuring food and nutrition security. See: European Commission, 2016, *European Research & Innovation for Food & Nutrition Security*, Brussels, https://ec.europa.eu/info/sites/info/files/conferences/food2030_2016/food2030_conference_background.pdf

In this framework, the role of plant breeding in tackling the challenges of the 2030 Agenda has been recently addressed by the International Union for the Protection of New Varieties of Plants (UPOV), an intergovernmental organization based in Geneva, Switzerland, established by the International Convention for the Protection of New Varieties of Plants (UPOV Convention). During its fifty-first ordinary session, UPOV set out the connection between an effective system of plant variety protection, aimed at the development of new and improved varieties for the benefit of the society, and the 2030 Agenda[49]. The UPOV Council believes that the vision of the Agenda, and especially its goals n. 1, 2, 9, 12 15, 17, are strictly linked to UPOV's mission. That is because new plant varieties *'are an important means of responding to the challenges of a growing and increasingly urbanized population, climate change, parallel demands for food and energy production and evolving human needs[50]'*. When developing a new plant variety for agriculture, the purpose of plant breeders is primarily to obtain larger yields, better climatic adaptation, improved resistance to pests and diseases, decreased pressure of agricultural activities on the environment, and increased nutritional content; and these targets play a crucial role in the achievement of the 2030 Agenda goals.

In this context, only a broad range of plant varieties might tackle those imperative challenges. In this regard, the plant variety protection systems, unlike other IP systems, ensure the so-called '*breeder's exemption'* for breeding purposes, whose objective is to promote the development of improved varieties by facilitating the access to protected plant varieties.

In this way, plant breeding programs and innovation in plant varieties are encouraged in a sort of '*open science'* system. Therefore, there is a specific linkage between fostering innovation in plant varieties for agricultural purposes, such as cereal varieties, and the implementation of the UN Sustainable Development Goals set out in the 2030 Agenda.

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[49] UPOV Council, 2017, *Annex to UPOV Press Release 112,* http://www.upov.int/edocs/pressdocs/en/upov_pr_112.pdf

[50] Ibidem.

2.3. The EU cereals sector

The EU cereals sector is facing several challenges: uncertainties in the world agricultural markets due to increased volatility, use of the new breeding techniques, global demand, climatic changes, increasing competition from outside the EU.

The cereals sector in the European Union regards both the seed industry and agricultural sector because it represents the third biggest agricultural sector in terms of output value after the vegetable/horticultural plant sector and the dairy sector and all Member States produce cereals[51].

As already stated, the seed is not only a technology carrier but also a commercial commodity[52] whose market plays a decisive role worldwide and especially in developed countries. Suffice to say that, in 2014, the seed market had an estimated value of around USD 52 billion[53].

The European Union commercial seed market is highly competitive: in 2013, it represented the largest exporter with a value of EUR 4.4 billion at a global level, which is more than 60% of worldwide export[54]. After five years, in 2018, it reached the value of EUR 7.4 billion[55], involving almost 1000 seed companies, whose majority are SMEs[56]. Globally, the sector is highly concentrated, but SMEs provide an important contribution to conventional seed production and organic crop production.

In order to better understand the importance of these data, it is worth noting that the EU is the third-largest seed market worldwide after the USA and China, representing more than 20% of the total global market for commercial seed. France, Germany, Italy, Spain, and

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[51] Kelly P., 2019, *The EU cereals sector: Main features, challenges and prospects,* European Parliamentary Research Service.
[52] Louwaars N., 2002, *Seed Policy, Legislation and Law: Widening a Narrow Focus,* in Journal of New Seeds, 4, 1-2, p. 2-4.
[53] OECD, 2018, *Concentration in Seed Markets: Potential Effects and Policy Responses,* OECD Publishing, Paris, p. 25
[54] In 2013, the EU commercial seed market had a value of approximately 6.8 billion Euros. European Commission, 2013, *Executive Summary of the Impact Assessment. Accompanying the document 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),* SWD (2013) 163 final, Brussels, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0163&from=EN
[55] Source: European Seed Certification Agencies Association (ESCAA) website, http://www.escaa.org/index/action/page/id/7/title/seed-production-in-eu---2018
[56] Source: European Seed Association (ESA) website, https://www.euroseeds.eu

the Netherlands are the leading seed producers in the EU: they collectively account for two-thirds of the EU market[57].

As regards the crops produced, the main seed production in EU is represented by cereals with 1,053,200 ha (wheat is the first species produced), ahead of forage species with 505,230 ha, maize with 139,620 ha, oilseeds with 132,670 ha, and potatoes with 119,615 ha[58]: thus, in EU the value of cereal seed production outweighs all the other crops.

It is interesting to notice that the ranking above, provided by the European Seed Certification Agencies Association, divides cereal crops from maize, even though the relevant legislation otherwise provides: *Zea mays L.* lawfully belongs to the cereals sector according to Council Directive 66/402/EEC. However, it is not uncommon to find similar approaches, in particular by international organizations or seed associations: indeed, maize has an idiosyncratic position in the global seed market and, as such, it is often individually examined. Suffice to say that, of an estimated value of around USD 52 billion in 2014, almost 40% consists of maize itself[59]. Moreover, commercial maize seed is mainly represented by hybrid varieties: since the 1950s, maize plant breeding shifted from open-pollinated varieties to hybrids, which significantly boosted its productivity[60]. Consequently, maize varieties are less subject to the practice of farm-seed saving, unlike other cereals, since hybrids do not propagate unchanged. Therefore, the use of farm-saved seed could result in nonuniform yields and unprofitable crops, representing an economic loss for the farmer. Also, unlike other cereal varieties, the global maize seed production is driven by GM varieties: in 2014, 32% of hectares planted with maize are planted with a GM variety, making up almost 60 million hectares worldwide[61]. In light of this, it should not surprise that maize MON 810 is still the only GMO that has been authorized for cultivation in the EU[62]. Nevertheless, only

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[57] France itself represents almost one-third of the EU total. See, OECD, 2018, *Concentration in Seed Markets: Potential Effects and Policy Responses,* OECD Publishing, Paris, p. 27.

[58] Source: European Seed Certification Agencies Association (ESCAA) website, http://www.escaa.org/index/action/page/id/7/title/seed-production-in-eu---2018

[59] OECD, 2018, *Concentration in Seed Markets: Potential Effects and Policy Responses,* OECD Publishing, Paris, p. 27.

[60] Source: Euroseeds website, https://www.euroseeds.eu/system/files/publications/files. Last access: April 2019

[61] Ibidem, p. 28. GM maize production is led by the USA.

[62] Source: EU Register of authorized GMOs, https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm. Last access: September 2019.

when maize is considered as being a cereal crop, the data reflects the actual cereal seed production in the EU.

With regard to cereal crops, it is worth noting that the European Union is one of the world's leaders in cereal production: as highlighted by FAO in its biannual report on global food markets[63], in 2019 the statistics forecast an EU cereal production of 311.4 million tonnes (mt) of cereal, making it the third-largest global producer of cereal after China (546.6 mt) and USA (446.9 mt). According to those statistics, the EU is going to confirm its leadership in global wheat production, with a forecasted production of 149.5 million tonnes for the year 2019, followed by China (132.0 mt), India (99.6 mt) and Russian Federation (82.0)[64].

According to Eurostat[65], 57 million hectares of the 110 million hectares of arable land in the EU are dedicated to the cultivation of cereals. Also, the harvested production of cereals in the EU in 2016 was around 301 million tonnes[66], representing about 11.6 % of global cereal production[67]. Nearly 65% of the cereals produced are intended for feed and almost 32% for human consumption; the remaining part, only 3%, is allocated for biofuel[68].

Therefore, the key role played by cereal varieties in the European Union seems indisputable, especially by wheat, both for the seed industry and the agricultural sector.

2.4. Innovation in cereal varieties: a peek to CPVO statistics

The cereals sector plays a key role in the EU economy and agriculture.

In this context, one might wonder whether the high seed production and crop cultivation rate, shown in the previous paragraph, goes hand in hand with a high innovation

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[63] FAO, 2019, *Food Outlook. Biannual report on global food markets*, Rome, p. 108.
[64] Ibidem, p. 110.
[65] Data extracted in January 2017, available at http://ec.europa.eu/eurostat/statistics-explained/index.php/Main_annual_crop_statistics#Further_Eurostat_information
[66] Data extracted in November 2017, available at http://ec.europa.eu/eurostat/statistics-explained/index.php/Agricultural_production_-_crops#cite_note-1. This information is part of a set of statistical articles based on Eurostat, 2016, *The Agriculture, forestry and fishery. Statistical book*, which is an online Eurostat publication presenting a summary overview of recent European Union (EU) statistics on agriculture, forestry and fisheries.
[67] According to Eurostat, France (18.0 %), Germany (15.1 %) and Poland (9.9 %) together contributed to 43% of the EU total. Spain was the next largest cereal producer.
[68] Source: EU Agriculture and Rural development website, available at: https://ec.europa.eu/agriculture/cereals_en

rate in cereal varieties. This aspect is pivotal for two reasons: 1. innovation increases the competitiveness of the EU breeding and seed industry; 2. as abovementioned, new plant varieties are necessary to tackle the challenges of agriculture in the third millennium.

Undoubtedly, innovation may concern different aspects of cereals, such as breeding, production, and cultivation. For example, innovation may concern new breeding techniques, innovative plant protection products, more efficient methods of production, high technology farming, etc. Nevertheless, for the purpose of the current investigation, the focus is exclusively on new plant varieties of cereal species, being the subject matter of plant variety protection.

The question concerning the innovation rate in cereal variety cannot be simply answered. Indeed, there is not an official list of 'new plant varieties of cereal species' in the EU that could be analyzed. However, in order to provide a partial answer to that question, the statistics made by the Community Plant Variety Office should be taken into consideration. It is worth noting that those CPVO statistics concern the new plant varieties which have been the subject matter of an application for Community plant variety rights. Therefore, innovative cereal varieties for which an application for Community plant variety protection was not fulfilled[69] are not taken into account. Those applications have been examined because an application for Community plant variety rights entails an innovative effort made by the breeder to develop a new plant variety, showing whether the sector is innovatively active or not.

From the data, it is possible to note that innovation in cereal varieties is very active in the EU. The applications for Community plant variety rights received by the Office are divided into four crop sectors: ornamental, agricultural, vegetable, and fruit sectors. The total number of applications received from 1995 until 2018 is 65,067. The main species represented in the agricultural crop sector are cereals: the number of plant variety protection applications received by CPVO for said agricultural species since 1995 regards mainly

[69] A breeder may decide not to apply for Community plant variety protection because they believes that protection is not needed, or that only national plant vaeity protection is sufficient. The analysis of the national plant variety rights could not be carried out because of the language-related difficulties and, also, because the relevant databases are not always available online.

cereals, with maize, common wheat and barley ranking among the top five[70]. Regarding the total number of applications, in 2018, the ornamental sector is the one where applications are filled the most (35,580), followed with significant distance by agricultural (16,119), vegetable (9,088) and fruit sectors (4,280).

Despite the significant relevance of cereal crops in EU agriculture, the number of applications received by the CPVO for the agricultural sector, where cereals belong, has fluctuated over the last few years. In 2014, the applications received by the CPVO in the agricultural sector have been 1,026, whereas in 2017 they turned out to be only 818[71] : almost 20% less over three years. Those applications notably increased during 2018: they reached the amount of 1013[72].

In light of this brief analysis, innovation in cereal varieties seems actively carried on in the European Union, even though innovation in the agricultural sector does not reach the peak of ornamental varieties[73]. Also, the high number of applications shows the undeniable value of Community plant variety protection in the EU. However, those fluctuations related to the agricultural sector applications may be the symptom of lack of steadiness in the innovation activities of the cereal breeding industry. In this framework, it is essential to analyze whether the relevant legislation has a role in fostering and stimulating the breeding of new varieties of cereals, or not at all.

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[70] Until 2018, maize received the highest number of applications among all the crop sector (4,788), common wheat received 2,024 applications and barley 1,366. Source: CPVO annual statistics on 31/12/2018, updated on 13/02/2019, data available at www.cpvo.europa.eu

[71] In 2015 and 2016 there have been comparable numbers: the applications were, respectively, 933 and 939. Source: CPVO annual statistics, updated on 18/01/2018, data available at www.cpvo.europa.eu

[72] Source: CPVO annual statistics on 31/12/2018.

[73] According to Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford, p. 242: '*the difference in numbers between the ornamental applications and applications in respect of other species is not surprising given the ease with which it is possible to copy most ornamental varieties - it also shows that the textual changes contained within the Regulation (with a greater emphasis on the various aspects making up the variety as opposed to merely the grouping itself) makes the right more attractive to ornamental breeders. Also related to this was the fact that in the period from April 1995 to July 2003 the largest number of applications filed came from the Netherlands (which has the highest incidence of ornamental plant breeders) followed by Germany, France, Denmark and the UK'.*

3. Introduction to plant variety protection

3.1. Intellectual property rights over plant varieties

Intellectual property refers to the ownership of an exclusive right to intellectual creations, usually for a certain period of time. Those creations of the mind may result from any industrial, scientific, literary, or artistic production. The intellectual property system aims at balancing the public interest and the interests of creators, for the benefit of the society. Indeed, new creations of the mind are valuable for the society because they allow economic as well as intellectual development.

The rationale behind intellectual property lies in its capacity to encourage progress and further innovation in order to improve the quality of life and well-being of the society: the main social purpose of IP is to reward and encourage the creations of the mind.

According to the World Intellectual Property Organization (WIPO), intellectual property rights '*are like any other property right'* and *'allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation'*[74]. Their purpose is to '*reward creativity and human endeavor, which fuel the progress of humankind'*[75].

The first international recognition of intellectual property was provided in 1883 by the Paris Convention for the Protection of Industrial Property, and in 1886 by the Berne Convention for the Protection of Literary and Artistic Works: none of them mentioned *'plant varieties'*.

As a matter of fact, the self-replicating nature of plant reproductive material was seen as an obstacle to intellectual property: plants were not considered as 'patentable' subject matter[76]. However, in the first half of the twentieth century, the rise of innovation in plant varieties opened the door to intellectual property rights on plant varieties, by the creation of *ad hoc* legal instruments capable of securing a source of revenue for breeders.

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[74] WIPO, 2004, *What is Intellectual Property?,* WIPO Publication No. 450(E), Geneva, p. 3.
[75] Ibidem, p. 4.
[76] Vezzani S., 2013, *Le risorge fitogenetiche per l'alimentazione e l'agricoltura nel dibattito sui global commons*, in Rivista critica del diritto privato, III, pp. 433-464.

3.2. Origins of plant variety protection

During the twentieth century and after the dissemination of the Mendelian laws, the economic interest in breeders' achievements increased and it was associated with the request for effective legal protection of the biological inventions.

The massive investments made by plant breeders were not properly safeguarded by the existing legal instruments[77]: once the plant was placed on the market, the sales price fell at the fastest rate[78]. The reason for the price decrease lies in the intrinsic self-replication capacity of the plant: as a living material, the inherent aptitude for reproduction makes it possible for third parties to reproduce the biological creations for a countless number of times once they had first access to to the genetic resources.

However, in order to carry on innovation in agriculture, the research and development (R&D) outcomes had to be profitable. The sale of the new organisms obtained through plant breeding had to guarantee the return on investment and to improve the companies' competitiveness. Therefore, breeders needed to be entitled to claim for remuneration against the use of their new plant varieties. Indeed, the grant of a financial reward is a significant incentive to stimulate innovations.

Due to the increasing pressure of plant breeding companies demanding proper protection for new plant varieties, *ad hoc* legal instruments began to be implemented by some western countries, in order to protect the new biological inventions and to foster the innovation in agriculture[79]. This is the moment when the complex relationship between agriculture and intellectual property started.

The first European country to tackle the problem was France, where the French *Conseil International Scientifique Agricole* emphasized the urgency for the government to recognize remuneration claims to breeders, in case of third parties' use of their

[77] Since plant varieties were not patentable, breeders had no appropriate protection for their inventions.
[78] Vezzani S., 2013, Le risorge fitogenetiche per l'alimentazione e l'agricoltura nel dibattito sui global commons, in Rivista critica del diritto privato, III, pp. 433 – 464.
[79] Valletta M., 2005, *La disciplina delle biotecnologie alimentari. Il modello europeo nel contesto globale*, Giuffrè, Milano.

achievements[80]. Despite the attempt of legislative regulation of the matter, a proper intellectual property right for the breeder was not introduced[81].

The very first plant variety protection by way of intellectual property regimes was developed in the U.S. in 1930 through the Townsend-Purnell Plant Patent Act[82]. The system provided patent-like[83] protection to plant breeders, for the purpose of incentive innovation and stimulate research[84]. It was indeed necessary to recognize plant breeders as inventors of new plant varieties but the existing utility patent system was not suitable for products of nature such as plant genetic resources. Even though the Plant Patent Act was part of the Patents Code, the *sui generis* plant protection system differed from the utility patent regime because it recognized the peculiarities of the biological subject matter[85]. For example, the patentability of plants was limited to asexually reproduced varieties, because sexually reproduced varieties were considered to lack stability, and it excluded tuber propagated plants (i.e. potatoes) for a twofold reason: 1. the homogeneity between reproductive material and food material could lead to lack of enforceability of the plant patent; 2. the fear of monopolies, especially regarding those plant varieties which are essential for food and agriculture[86]. Also, the plant had to be distinct but a definition of this requirement was not provided by the law[87]. Furthermore, one of the requirements for a utility patent was the supply of a written form by the applicant: the form had to indicate the disclosure of the invention, which should be made through a sufficient description of the subject matter in the

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[80] Würtenberger G., 2017, *Protection of plant innovation,* in Duncan M., Herbert Z., (eds.), Research handbook on intellectual property and the life sciences, Edward Elgar Publishing, Northampton, p. 121.

[81] The first attempt was by means of "Le Décret" in 1922. Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, *European Union Plant Variety Protection,* Oxford University Press, p. 2

[82] The current U.S. plant patent system developed from the Townsend-Purnell Plant Patent Act and very few changes have been made since then. See, Janis M., Jervis H., Peet R., 2014, *Intellectual Property Law of Plants*, Oxford University Press, pp. 183-235.

[83] Considering the peculiar nature of the inventions as living organisms, plant patents could not be fitted within the utility patent scheme existing at the time.

[84] The U.S. Congress believed that, as a consequence, the agricultural sector and the public in general would benefit from the plant patent system. The legislation aimed at achieving plant varieties resistant to diseases, more productive and nutritious, with the effect of securing food supply for the entire country. See, Janis M., Jervis H., Peet R., op. cit.

[85] For those reasons, the Plant Patent Act system has been considered '*a sui generis system which anticipates in many respects the UPOV Convention*'. See, UPOV, 1991, *Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention,* Geneva, p. 20.

[86] UPOV, 1991, op. cit., p. 21

[87] Nevertheless, a definition was provided by the Senate Committee report accompanying the Act, as follows: *'in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties'.* See, Blakeney M., 2004, *Genes and Plant Breeding in an IPR-led World*, 4th International Crop Science Conference Brisbane, 26 September to 1 October 2004.

sense that it might allow a person of ordinary skills and knowledge to realize the invention. This kind of disclosure was believed to be not possible for plants and living organisms in general[88]. Therefore, the Plant Patent Act lightened the requirement of '*sufficient patent disclosure'*.

In Europe, the first country to recognize an embryonic breeder's right were the Netherlands through the 1941 Breeders Ordinance[89]. This text introduced two different kinds of exclusive breeders' rights, depending on the classification of the varieties to protect: if the varieties were subject to mandatory cataloging[90], the right concerned only the first generation of seed; in case the new variety was not subject to cataloging, an exclusive right to market the seed for 25 years was recognized to the breeder[91].

The Dutch Breeders Ordinance was followed by the German Seed Law, which partially represented the background of the UPOV Convention[92]. The law was preceded by the draft of the Seeds and Seedlings Law, which was presented to the German Parliament in 1930. Even though the draft never became law, it contained a set of definitions of legal terms and introduced new concepts that were later adopted by the UPOV Convention, such as the requirement of distinctiveness, the need for seed testing, the issues concerning the essentially derived varieties. The German Seed Law on the Protection of Varieties and the Seeds of Cultivated Plants was adopted on 27 June 1953 and its goal was to foster the innovation in plant varieties. In order to be protected, the new plant variety had to be individualized (as meaning 'distinct') and stable; also, food plants should be of agronomic value. The breeder of a new plant variety had the exclusive right to produce them for the purposes of trade, to offer them for sale and to market them. The law allowed third parties to produce and market derived seed upon payment of a remuneration to the breeder; it also permitted the use of the protected variety by third parties for the creation of new ones, anticipating the so-called

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[88] This aspect has been interestingly highlighted by Chapman S., Sherman B., 2018, *Finding a place for agriculture in intellectual property law*, in IIC International Review of Intellectual Property and Competition Law, 49, 7, pp. 759-762. The authors draw attention to the idiosyncrasy of the biological material subject to intellectual property protection. With mechanical creations, it is possible to divide the *intangible* and *tangible* form of the subject matter and that is the reason why, in case of patents, it is possible to reduce the invention to a disclosure in writing.

[89] Published on July 5, 1942.

[90] Those varieties could be market only after being tested and officially cataloged, under a registered denomination.

[91] UPOV, 1991, *Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention,* Geneva, p. 28.

[92] Ibidem, pp. 26-27.

breeder's exception. Also, the law established the compulsory use of the variety denomination in case of marketing[93].

The demand for protection of breeder's right started to gain a certain weight also at the international level in light of the growing international trade of biological material. In particular, during its congress held in Semmering, Austria, in 1956, the International Association of Plant Breeders (ASSINSEL)[94] passed a motion calling for a diplomatic conference to discuss the adoption of a plant varieties protection system. The Association highlighted the necessity of an international agreement recognizing appropriate protection for new plant varieties through a *sui generis* system, instead of adapting utility patent rights to the biological subject matter[95].

Even though the 1883 Paris Convention for the Protection of Industrial Property established that industrial property shall also apply to agricultural products[96], it was considered as to include only '*end products'*, not the plant variety from which those products derived[97]. For example, the provision is interpreted as referring to *'grain'* as the end product derived from the harvest, not as a new variety of cereals. Therefore, plant varieties did not seem included in the provision.

Also, breeders believed that the proprietary rights regime applicable to plant varieties should differ from the patent system in light of the idiosyncrasies of the innovation in question, which is biological material able to reproduce itself, unlike industrial inventions. Furthermore, there was the necessity to balance farmers' and breeders' rights. The request was accepted by the French government which, in 1957, called for an international conference on the subject. The invitations were sent to a few European countries[98], on the

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[93] Ibidem.

[94] ASSINSEL was founded in Amsterdam in 1938, to represent the request of the breeding companies for plant varieties protection. In 2002, ASSINSEL merged with the International Seed Trade Federation (FIS), forming the International Seed Federation (ISF), which combines together their two areas of expertise, i.e. plant breeding and seed trading. Source: https://www.worldseed.org, accessed February 2019.

[95] Janis M., Jervis H., Peet R., 2014, *Intellectual Property Law of Plants*, Oxford University Press, p. 70.

[96] Article 1 (3) of the Paris Convention stated that: *'Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour'.*

[97] Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford, p. 11.

[98] The following countries were invited by France: Austria, Belgium, Denmark, Finland, Federal Republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland, the UK. See, Blakeney M., 2004, *Genes and Plant Breeding in an IPR-led World*, 4th International Crop Science Conference Brisbane, 26 September to 1 October 2004.

basis that they shared the same concern as France on the topic. The first session of the conference took place in Paris, in May 1957. The discussion went on for few years and conducted to the 1961 Paris Diplomatic conference, where the *International Convention for the Protection of New Varieties of Plants* (so-called UPOV Convention) was adopted on 1 December 1961[99].

3.3. Plant variety protection: the hybrid intellectual property regime

As already said, plant varieties as the subject matter of intellectual property rights have peculiar characteristics. Unlike other protectable material, plant varieties could be easily copied because of the self-replicating nature of the relevant biological material.

This is the reason why the UPOV introduced the existing concept of plant variety protection as a *sui generis* intellectual property system. Indeed, during the Diplomatic Conference held in 1961, it was stated that '*des discussions précédentes, il ressort que le droit de l'obtenteur présente des particularités telles qu'il ne correspond exactement à aucun droit existant. […] Le Comité d'experts est d'accord pour reconnaitre que le droit porte sur un objet immatériel, résultat du travail du cerveau humain et qu'il entre par conséquent dans le domaine de la propriété intellectuelle*'[100].

The Contracting Parties agreed to create a *sui generis* system for plant variety protection because, as the Experts Committee highlighted, plant variety protection as an intellectual property regime does not correspond to any other existing intellectual property rights, especially to the dominant legal paradigms which protect 'inventions' and 'artistic works'.

Customarily, intellectual property rights encompass two categories of rights[101]: 1. *industrial property*, as the protection of inventions and distinctive signs (it includes patents for inventions, trademarks, industrial designs, and geographical indications); 2. *copyright*, which covers original artistic and literary works.

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[99] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., op. cit., p. 3. The Convention officially came into force on August 10, 1968, following the ratifications of the U.K., Germany and the Netherlands.
[100] UPOV, 1972, *Actes des Conférences Internationales pour la Protection des Obtentions Végétales 1957-1961,* UPOV/PUB/316, Geneva, p. 36.
[101] WIPO, 2004, *What is Intellectual Property?,* WIPO Publication No. 450(E), Geneva.

Briefly, patents are a form of industrial property rights that are basically granted for inventions offering a new technical solution to a problem. Patents are secured after the file of a patent application, including a detailed description of the invention. The scope of protection of the patent is assessed on the basis of that description. Conversely, copyright concerns the exclusive right of the holder to authorize or prohibit certain acts related to an artistic or literary work, such as its reproduction in all forms, i.e. the *copying*, hence the name *copyright.* Copyright is obtained automatically, without any registration or formalities. Within this framework, neither of the two traditional paradigms of intellectual property could suit plant varieties.

Plant variety protection is indeed a legal *hybrid*[102] between patents and copyrights, with its own idiosyncrasies due to the nature of the protected biological material, which is automatically able to duplicate itself.

Similarly to patents, plant variety protection refers to an invention and, similarly to copyrights, it aims at protecting the right holder against the unauthorized *copying* of the protected material. However, unlike copyrights, for plant variety protection a specific application must be filed and, unlike patents, the variety description does not allow a person of ordinary skills and knowledge to realize the invention.

As a matter of fact, the biological material cannot be reduced to a disclosure in writing: for plant varieties, the *intangible* and *tangible* forms of the subject matter cannot be divided. The intangible part of the plant variety can be replicated by having access to the tangible incorporation of the invention. Therefore, when dealing with new plant varieties, both the intangible as well as the tangible biological material play a central role in intellectual property protection[103].

The peculiar nature of plant variety description as compared to patent claims has also been highlighted by the Board of Appeal of the Community plant variety office, during the Case A 007/2007 (*Ralf Schräder v. CPVO).* In that occasion, the Board of Appeal stated that *'the unique nature of the plant variety right is reflected by the fact that the emphasis is on the physical material, the plants themselves, and not on the description of the variety. In*

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[102] Reichman J., 1994, *Legal Hybrids between the Patent and Copyright Paradigms,* in Columbia Law Review, 94, 2432.

[103] Chapman S., Sherman B., 2018, *Finding a place for agriculture in intellectual property law*, in IIC International Review of Intellectual Property and Competition Law, 49, 7, pp. 759-762.

other words, both the evaluation is to grant and also decisions relating to infringement of registered plant variety rights are also made by reference to the actual plants concerned. […] Variety descriptions of plant varieties do not have the same legal value as patent claims. Whereas the scope of protection of patents is assessed on the basis of the plant claim, the assessment of a plant variety is general conducted in a trial (technical examination and technical verifications) and not on the basis of the variety description. The variety description is nothing more than a "snapshot" of the plant variety right when that right was tested'.

In addition to the foregoing considerations, plant variety protection exclusively concerns '*breeding achievements in the area of plant breeding*', differently from patents which may be considered as '*technology-neutral*', [104]. Not even animal breeding is included in plant variety protection: plant variety protection has been designed to be '*technology-specific'*.

Furthermore, innovation in plant varieties heavily relies on access to existing germplasm. New plant varieties cannot be created from scratch. Therefore, the relevant protection systems, unlike other IP systems, was required to ensure facilitated access to biological material. This is the purpose of the so-called '*breeder's exemption'* for breeding purposes, not envisaged by the patent system.

The foregoing considerations lead to the inescapable conclusion that plant variety protection clearly represents a *sui generis* intellectual property system, a *legal hybrid* between patents and copyrights that was specifically designed for plant varieties, taking into consideration their self-replicating nature and the need to maintain a robust access to existing germplasm, in order to safeguard innovation in this field.

3.4. Intellectual property rights over plants: patents vs. plant variety rights

The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, also referred to as TRIPs Agreement, addresses the topic of intellectual property over plants. Article 27 (3) (b) thereof states that '*Members may also exclude from patentability: […] (b)*

[104] Straus J., 2012, *Plant Variety Protection*, in Jürgen Basedow et al. (ed.), The Max Planck Encyclopedia of European Private Law, vol. 2, Oxford University Press, Oxford, pp. 1281-1285.

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'.

In light of this, the Contracting States might decide to exclude, *inter alia*, plants as such from patentability; however, they shall recognize protection for plant varieties (1) either by a *sui generis* system; (2) or by a patent; (3) or by both titles. Nowadays, the most widespread *sui generis* system to protect the rights of the breeders on their new plant variety is the plant variety protection system provided for by the UPOV Convention.

In the European Union, the protection of plant varieties, as the biological creation of a new plant variety, rules out patent protection: patents cannot exist alongside plant variety protection for the same subject matter. This principle is enshrined in Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, also called 'Biotech Directive'.

Directive 98/44/EC deals with the patentability of biotechnological inventions within the EU, in particular it addresses those inventions which are (1) new, (2) involve an inventive step, and (3) are susceptible of industrial even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. The term 'biological material' indicates any material containing genetic information and capable of reproducing itself. Even biological material which is isolated from its natural environment may be patentable, no matter if it previously occurred in nature.

In this context, Article 4 of Directive 98/44/EC specifically states that plant and animal varieties, as well as essentially biological processes for the production of plants or animals, *shall not be patentable*[105]. In particular, inventions which concern plants or animals *are patentable*, provided that the application of the invention is not technically confined to a single plant or animal variety, as specified in Recital 29 of the Biotech Directive.

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[105] A similar exception is present in the European Patent Convention (EPC), whose Article 53 (b) excludes plant or animal varieties from patentability, except when they are the result of microbiological processes or the products thereof. Therefore, the EPC does not provide that plant varieties are excluded from patent protection as such.

This exception is identical to the one provided by Article 92 of the Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community plant variety rights, also referred to as Basic Regulation. According to Article 92, any variety which is the subject matter of a Community plant variety right shall not be the subject of any patent for that variety.

Therefore, a patent may concern the component to be implemented into plants of different varieties or species, whereas plant variety protection concerns only specific varieties[106]. In this sense, there may be an overlap of intellectual property rights over a certain plant: the plant variety could be protected by Community plant variety rights, while a specific component can be patented.

The possibility for those intellectual property rights to overlap has been considered by the relevant legislation. This is the reason why some significant provisions, such as the provisions on the compulsory license, have been coordinated between the Biotech Directive and the Basic Regulation.

3.5. The role of plant variety protection in fostering innovation

One may wonder why plant variety protection should have a role in fostering innovation in plant varieties. The linkage between plant variety protection and fostering innovation lies in the very nature of the plant variety rights, as intellectual property rights. As stated above, the rationale of intellectual property is to incentive the creation of new inventions and ideas: the 'reward', given in the form of public recognition and/or temporary monopoly on the protected material, is supposed to stimulate further innovation.

In this context, the connection between plant variety protection and innovation has also been officially underlined both by the International Union for the Protection of New Varieties of Plants and the Community Plant Variety Office.

The benefits for the society deriving from plant breeding activities have been internationally recognized only during the second half of the twentieth century. In 1961, the International Convention for the Protection of New Varieties of Plants (UPOV Convention) stated in its Article 1 that the purpose of the Convention is to *'recognise and to ensure to the breeder of a new plant variety, or to his successor in title, a right the content and the*

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[106] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., op. cit., p. 10.

conditions of exercise of which are defined hereinafter'. The main ambition of UPOV is to support the development of new plant varieties, for the benefit of the society, through the promotion of an effective system of plant variety protection (PVP) by granting breeders an intellectual property right, the so-called *breeder's right*. The breeder's right, which is the equivalent of the plant variety right, is an exclusive right granted to the breeder in order to protect their new plant variety. The purpose is to reward the inventor for the high investments made during the breeding activities. The breeder's right as laid down by the UPOV Convention is going to be analyzed in the second chapter.

The UPOV believes that, other than PVR, there are other tools to encourage plant breeding, like growth in public funding, facilitated access to genetic resources, and support to public-private partnerships[107]. However, the focus is on the role of breeder's right in fostering innovation because this measure is supposed to guarantee important benefits and higher economic returns, compared to other instruments.

In particular, the UPOV believes that plant variety protection is associated with:

(a) increased breeding activities,

(b) greater availability of improved varieties,

(c) increased number of new varieties,

(d) diversification of types of breeders (e.g. private breeders, researchers),

(e) increased number of foreign new varieties,

(f) encouraging the development of a new industry competitiveness on foreign markets, and

(g) improved access to foreign plant varieties and enhanced domestic breeding programs[108].

From the list made by UPOV, it clearly appears that plant variety protection is deeply linked to innovation, in the form of increased breeding activities, greater availability of improved varieties, and increased number of plant varieties.

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[107] See: UPOV website, FAQ section, '*Why is plant variety protection necessary?*', http://www.upov.int/about/en/faq.html#QG40

[108] See: UPOV website, FAQ section, 'What are the benefits of plant variety protection and UPOV membership?', http://www.upov.int/about/en/faq.html#QG40

The same association between PVP and innovation is also displayed by the Community Plant Variety Office (CPVO)[109]. The CPVO is the EU agency responsible for the management of the EU Plant Variety System established by Council Regulation (EC) No. 2100/94 of 27 July 1994, which is based on the 1991 Act of the UPOV Convention. The system, which is going to be examined in the third chapter, aims at granting plant variety rights, as unitary IP rights valid throughout the European Union, for plant varieties meeting specific requirements. The mission of CPVO is *'to deliver and promote an efficient Intellectual Property Rights system that supports the creation of new plant varieties for the benefit of Society[110]'*.

Therefore, an efficient IPRs system for new plant varieties shall promote innovation in the plant sector and support the creation of new varieties. Indeed, the exclusive right granted to the breeder facilitates a return on investments through which further breeding activities can be funded, creating a virtuous circle of innovation.

In light of the foregoing considerations, it seems that plant variety protection has a paramount role in increasing the creation of new plant varieties.

4. Final remarks

Creating a virtuous circle of innovation in cereal varieties is necessary for the benefit of farmers, consumers, and the society in general. The role of Community plant variety protection in fostering innovation in the European Union has been generously illustrated, as well as the importance of promoting innovation in cereal varieties.

The first section of the chapter provided an overview of the research, useful to state the research problem and to highlight the significance of the research; whereas the second part introduced the key concept of plant variety protection.

Interestingly, agriculture and intellectual property have always had a tricky relationship, especially with regard to seed 'privatization'. The risks connected to the privatization of seeds, as one of the most important agricultural inputs, fed the dominant narrative describing the plant breeding industry.

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[109] CPVO is taken into account for a specific reason: the chosen contest of the current research is the European Union and, specifically, the Community plant variety protection.
[110] See CPVO website, Our mission, http://cpvo.europa.eu/en/our-mission.

In particular, this narrative describes the breeding industry as exclusively governed by multinational enterprises, which monopolize the global seed market: those companies patent their seed-related innovations in order to prevent farmers from saving and re-using their seeds. This narrative is especially focused on the privatization of those crops highly used in agricultural production and customarily subject to the practice of farm-saving: in particular, cereal seeds.

This research does not aim at denying the existence of this phenomenon. However, it wishes to demonstrate that this narrative, when translated into the European Union agricultural framework, does not take into consideration the role of SMEs in the breeding industry, the need to foster their innovations in cereal varieties, the challenges those enterprises face both when innovating and when marketing their varieties, as well as the idiosyncrasies of Community plant variety protection in the intellectual property context such as the '*breeder's exemption'* and the '*farmer's privilege',* which are going to be analyzed in the third chapter.

For the benefit of the research outcomes, it is important to frame the research in ways that are not conditioned by the dominant narrative. This is the reason why, in the current study, the Community plant variety protection is not only studied '*in the books'* but also '*in action*', taking into account its dialogue with the EU seed legislation governing the marketing of plant reproductive material. This approach is supposed to represent the best fit in order to offer a response to the research question that is not affected by the dominant narrative or by the initial researcher's expectations.

CHAPTER 2
International Legal Framework of Plant Variety Protection: the UPOV Convention

SUMMARY: 1. The International Convention for the Protection of New Varieties of Plants. - 2. Definition of breeder. - 3. Definition of plant variety. - 4. Genera and species. - 5. Conditions of protection. - 5.1. The DUS requirement. - 5.2. The novelty requirement. - 5.3. The variety denomination. - 6. National treatment. - 7. Application for the grant of the breeder's right. - 8. Scope of the breeder's right. - 9. Restrictions. - 10. The breeder's exemption. - 11. The farmer's privilege. - 12. Exhaustion. - 13. Essentially derived varieties. - 14. Duration. - 15. Double protection ban. - 16. Final remarks.

1. The International Convention for the Protection of New Varieties of Plants

The 1961 International Convention for the Protection of New Varieties of Plants (so-called '*UPOV Convention'*) has been the first international agreement to introduce a legal framework for plant breeders' rights (also called plant variety rights) and to introduce and govern the *sui generis* plant breeder's protection system[111] by granting inventors of a new plant variety an intellectual property right, the so-called *breeder's right*.

Regarding the territoriality of the breeder's right, it is worth highlighting that the UPOV Convention does not recognize a pan-jurisdictional right valid throughout the UPOV members and enforceable by the UPOV Office, but rather a national right that is restricted to the country of the grant and that is enforceable only on a national basis[112].

The UPOV Convention has established an intergovernmental organization called *Union for the Protection of New Varieties of Plants*, also referred to as UPOV, with headquarters in Geneva, Switzerland, that aims at promoting an effective system of plant

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[111] Also known as plant variety right system.

[112] The only plant breeder's right having a unitary effect, which is valid and enforceable in all the relevant Member States, is the one recognized in the European Union in accordance with the Regulation (EC) No 2100/94. Indeed, the EU system was created *'on the simple idea of treating the whole Community for the purposes of plant breeders' rights as if were a single Country'*, see: Obst D., 1986, *Developments in the Field of a 'European Community Plant Breeders' Rights',* Utrecht).

variety protection. UPOV plays a central role in international policy since it is the main body that addresses the issue of protecting and developing new plant varieties. Although it has been established more than 50 years ago, UPOV is still broadly criticized; in particular, its legitimacy has been frequently questioned. Concerns have been raised regarding its lack of fairness, accountability, transparency and public debate. Also, UPOV is accused of ignoring the need of developing countries and taking into account only industrial agriculture, which is a prerogative of developed countries[113].

The Convention was revised in 1972, 1978 and, lastly, in 1991[114], as provided for in Article 27 of the 1961 text[115]. The revision of 1972 did not modify substantive provisions of the Convention and, currently, nearly all the UPOV members are party either to the 1978 or to the 1991 version of the agreement. Substantial differences shall be noticed between the 1961/1978 texts and the 1991 one, since the latter version introduced some significant changes.

The Preamble to the 1961/1978 text remarks the rationale behind the adoption of the Convention, which consists in the awareness of: 1. the importance to protect new plant varieties both for the development of agriculture and for safeguarding the breeders' interests; 2. the limitations the public interest might set to the free exercise of the breeder's right; 3. the need for uniform and clearly defined principles. However, some uniform and clear definitions were not provided until 1991.

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[113] These are the reasons why some developing countries, e.g. India and Thailand, have not become UPOV members yet, opting for a *sui generis* national protection system. See: Sanderson J., 2017, *Plant, People and Practices. The Nature and History of the UPOV Convention*, Cambridge University Press, Cambridge. The author claims the legitimacy of UPOV, also underlining the merit of the Union as follows: it recognized plant variety protection; it regularized and normalized numerous practices concerning plant varieties; it identified and defined new scientific and legal concepts such as 'Essentially Derived Varieties (EDVs)'; it created useful databases like PLUTO (that is a compilation of data supplied by 61 UPOV members and 2 intergovernmental organizations; the data collected concerns plant breeder's rights, plant patents or national listings); it provided information and guidelines about plant denomination, for a better identification of the variety, and so on.

[114] Nowadays, 75 countries are members of the of the International Union for the Protection of New Varieties of Plants. Source: https://www.upov.int, accessed February 2019.

[115] According to article 27 (1) thereof, the UPOV Convention had to be reviewed periodically in order to improve the working of the Union.

2. Definition of breeder

In accordance with Article 1 of the 1961/1978 texts, the purpose of the Convention is to *'recognise and to ensure to the breeder of a new plant variety or to his successor in title, a right*' under the conditions therein described. However, in the 1961/1978 versions, it is possible to notice the problematic absence of a fundamental notion: the texts did not provide a definition of the notion of *breeder*.

In order to understand the significance and the consequence of such lacuna, it is worth noting that the figure of the plant breeder was rapidly evolving: the traditional breeder *in the field*, selecting plant varieties outdoor, started to work alongside the modern breeder *in the laboratory*, dealing with biotechnologies. Also, the increasing events of *biopiracy*[116] called for a clarification of whom was entitled to be recognized as the breeder of a certain variety: for example, the person who *sic et simpliciter* discovered a wild variety, shall be considered the breeder of that variety? Also, shall be considered as the breeder of a variety the person who identified a variety used in a specific country and simply brought it to another country, where such crop is neither used nor known? The implications of this lack in the 1961/1978 UPOV texts were numerous, and that is why this absence was '*seen as a contributing factor*' to plant piracy[117]. Furthermore, a definition was necessary in terms of the relationship between the UPOV Convention and other legal instruments[118].

The lacuna was filled by the 1991 Convention, which stated in its Article 1 (iv) that:

'Breeder' means

- the person who bred, or discovered and developed, a variety,

- the person who is the employer of the aforementioned person or who has commissioned the latter's work, where the laws of the relevant Contracting Party so provide, or

- the successor in title of the first or second aforementioned person, as the case may be.

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[116] Biopiracy is considered as the unlawful appropriation and consequent commercial exploitation of biological materials from a certain territory, without providing a fair remuneration to the entitled subjects. For further insights on biopiracy, Shiva V., 1998, *Biopiracy: The Plunder of Nature and Knowledge*, Green Books.
[117] Sanderson J., 2017, op. cit., p. 95
[118] Ibidem, p. 96

This definition finally clarified that the mere discovery of an indigenous plant does not make the discoverer a breeder under the 1991 UPOV Convention: there should be a *development*, a human activity aimed at changing and/or improving the characteristics of the crop. Therefore, plant breeders' rights shall not be granted to an existing variety that a person merely discovered and propagated in an unaltered manner.

Notwithstanding the progress made, the definition of breeder still has a gap. Indeed, the content of the *breeding* notion is nevertheless unclear: Article 1 (iv) provides a mere tautological definition of breeder as '*the person who bred*', without specifying what the acts of breeding shall entail. The Explanatory Notes[119] simply state that there is no restriction to the methods or techniques that the breeder might use to create a new variety: therefore, the act of breeding is not limited to conventional breeding techniques. Nothing more has been said on the subject.

However, the same Explanatory Notes have the merit of clarifying that the term *person* in Article 1 refers both to physical and legal persons and that there is no restriction on who can become a breeder: it could be, *inter alia*, an agronomist, a farmer, a research center, a breeding enterprise, an amateur horticulturist, et cetera. In this way, the Notes answered the question of whether a farmer might be considered a breeder under the UPOV Convention.

3. Definition of plant variety

Differently from the notion of 'breeder', Article 2 of the 1961 UPOV Convention provided a definition of plant variety, that is '*any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies the provisions of subparagraphs (1)(c) and (d) of Article 6',* provisions that refer to the sufficient homogeneity and stability of the crop.

The definition was amended by the 1991 UPOV Convention in its Article 1 (vi), where the notion *variety* acquired a more specific meaning, such 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 breeder's right are fully met, can be:*

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[119] UPOV, 2013, *Explanatory Notes on the Definition of Breeder under the 1991 Act of the UPOV Convention,* Geneva, UPOV/EXN/BRD/1, pp. 4-5.

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,

- distinguished from any other plant grouping by the expression of at least one of the said characteristics and

- considered as a unit with regard to its suitability for being propagated unchanged'.

The amendment was necessary to clarify the issues arisen from the former definition of plant variety: for example, the 1991 UPOV text specified that neither a single plant nor a trait shall be considered a variety. As provided for by said Article, a plant grouping within a single botanical taxon of the lowest known rank forms a plant variety, where the word *taxon* identifies a taxonomic unit (i.e. a unit used in biological classification) arranged in a hierarchy to classify the plant kingdom: a certain taxon includes several taxa of lower rank (e.g. a genus includes several species, a species includes several varieties).

Furthermore, from the sentence *'irrespective of whether the conditions for the grant of a breeder's right are fully met'* should be extrapolated that the definition of plant variety provided by the 1991 Act is broader than the notion of *protectable variety*. Thereby, an ancient wheat variety, which could not be covered by a PBR because of its lack of novelty, or a new variety, after the expiration of the plant breeder's right, could be semantically put in the same 'variety' basket but not in the 'protectable variety' one.

Furthermore, even if they are not explicitly listed, the reference to the '*combination of genotypes*' may allow hybrids in the 1991 UPOV notion of variety[120]. Even if there is not an internationally recognized legal definition of hybrid, hybrids might be defined as the offspring of a crossbreeding process between genetically dissimilar parents (e.g. between plant parents of different species)[121].

A clear definition of plant variety was deemed to be necessary to easily define the scope of application of breeders' right, especially in relation to patent claims over plant genetic components. The identification of what is included and what is excluded from plant breeder's protection plays a vital role, particularly for those countries that are also Member States of the European Patent Organisation. Indeed, Article 53 (b) of the Convention on the Grant of European Patents (European Patent Convention, EPC) of 5 October 1973, deals

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[120] UPOV, 2010, *Explanatory Notes on the Definition of Variety under the 1991 Act of the UPOV Convention*, Geneva.

[121] Source: https://www.nature.com/subjects/plant-hybridization. Latest access: April 2019

with exceptions to patentability and it states the following: *'European patents shall not be granted in respect of: […] (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof'*. Consequently, it was warmly desirable to have a common definition in both fields, in order to avoid inconsistency between the UPOV system and the European patent protection. A different and inconsistent definition of plant variety could have resulted in conflicting claims over the same genetic resource, which might have been deemed patentable on the one side, and protectable with the breeder's right on the other.

That being said, the current definition of variety provided by Article 1 (vi) of the 1991 UPOV Convention literally reproduces the Rule 26 paragraph 4 of the Implementing Regulations to the Convention on the Grant of European Patents. Therefore, for the purpose of consistency, such definition is so far undisputed.

The only discrepancy concerns the interpretation of the last condition of the plant variety definition, i.e. the 'suitability for being propagated unchanged'. In particular, some have read in this condition a reason to not include hybrids in the notion of plant variety. Indeed, hybrids do not propagate unchanged and both the UPOV and the EPC definitions of variety - differently from the definition provided by the Regulation(EC) No 2100/94 in its Article 5 - do not explicitly make reference to 'hybrids'. The Technical Board of Appeal of the European Patent Office argued in its decision of 07 January 2008 (Case T-0788/07) that hybrids shall not be considered plant varieties. Consequently, they are deemed to be patentable by the European Patent Office[122].

4. Genera and species

Article 4 of the 1961 UPOV Convention allowed Member States to apply the Convention to all botanical genera and species based on the '*principle of progressive implementation*', which means that the adoption of the necessary measures by UPOV

[122] For further insights, see Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., pp. 33-34 and Kiewiet B., 2011, *Do hybrids fall within the scope of the definition of a plant variety?,* Angers, available at the following website: https://cpvo.europa.eu/sites/default/files/documents/articles/BK_Article_on_hybrids_%20final_July_2011.pdf

members could be progressive, aimed at including the largest possible number of genera and species over the years.

The Contracting States of the 1961 Convention had to apply the provisions to at least five of the thirteen genera named in the list annexed to the Convention[123] at the moment of the entry into force in its territory, and the number of protected species had to increase progressively.

Article 4 of the 1978 Act slightly differed from the previous version of the Convention: it eliminated the list of genera subject to compulsory protection.

Differently, Article 3 of the 1991 Convention has a less loose approach: according to it, the UPOV provision shall be applied to all plant genera and species at the latest by the expiration of a period of five years after the entry into force of the Convention in the territory of the Member State. This amendment was necessary because the progressive implementation principle left many breeders from numerous countries without any protection for their varieties. Indeed, such principle has been regarded from the very beginning as *'one of the basic flaws of the UPOV system'* that was perpetuating *'the existence of the so-called infringement paradise countries'*[124].

Therefore, the 1991 Act require Member States to put efforts into extending protection to all plant genera and species at an early stage, in order to effectively recognize plant breeder's rights to all crops, to harmonize the plant variety protection system and to promote seed trade among UPOV members.

5. Conditions of protection

5.1. The DUS requirement

In order to be protected with PBRs, a plant variety shall comply with the following conditions: 1. novelty; 2. distinctiveness; 3. uniformity (also referred to as homogeneity); 4.

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[123] The annex to the Convention listed the species to be protected in each of the thirteen genera enumerated: wheat; barley; oats or rice; maize; potato; peas; beans; lucerne; red clover ryegrass; lettuce; apples; roses or carnations.

[124] Statement of Mr. Royon, representing CIOPORA. See, UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, UPOV/PUB/346, pp. 221-222

stability. A suitable denomination shall also designate the variety under the conditions established by the Convention[125].

The requirements were already established in Article 6 of the 1961/1978 UPOV Convention[126], however the 1991 text offered a specification of these notions, dedicating a

[125] The need to develop a harmonized description system of new varieties is the rationale behind the numerous '*Explanatory Notes on Variety Denominations under UPOV Convention'* adopted by the Union over the years. Source: www.upov.int. The main purpose of the Notes is to ensure that the designation of protected varieties is the same in all members of the Union. Therefore, the Notes are necessary for a uniform interpretation of the provisions regarding variety denominations: they will aid national authorities and breeders during the examination and selection of a suitable denominations. Variety denominations are important because they enable the identification of the variety and they should not lead to confusion on the value or the characteristics of the crop and the identity of the breeder.

[126] Article 6 (1) of the 1961 UPOV text, entitled 'Conditions Required for Protection', provides that : *'(1) The breeder of a new variety or his successor in title shall benefit from the protection provided for in this Convention when the following conditions are satisfied: (a) Whatever may be the origin, artificial or natural, of the initial variation from which it has resulted, the new variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when protection is applied for. Common knowledge may be established by reference to various factors such as: cultivation or marketing already in progress, entry in an official register of varieties already made or in the course of being made, inclusion in a reference collection or precise description in a publication. A new variety may be defined and distinguished by morphological or physiological characteristics. In all cases, such characteristics must be capable of precise description and recognition. (b) The fact that a variety has been entered in trials, or has been submitted for registration or entered in an official register, shall not prejudice the breeder of such variety or his successor in title. At the time of the application for protection in a member State of the Union, the new variety must not have been offered for sale or marketed, with the agreement of the breeder or his successor in title, in the territory of that State, or for longer than four years in the territory of any other State. (c) The new variety must be sufficiently homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation. (d) The new variety must be stable in its essential characteristics, that is to say, it must remain true to its description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction or multiplication, at the end of each cycle. (e) The new variety shall be given a denomination in accordance with the provisions of Article 13'*. Article 6 (1) of the 1978 UPOV Convention specified the novelty criteria referred to in subparagraph (b), as follows: *'(b) At the date on which the application for protection in a member State of the Union is filed, the variety (i) must not—or, where the law of that State so provides, must not for longer than one year—have been offered for sale or marketed, with the agreement of the breeder, in the territory of that State, and (ii) not have been offered for sale or marketed, with the agreement of the breeder, in the territory of any other State for longer than six years in the case of vines, forest trees, fruit trees and ornamental trees, including, in each case, their rootstocks, or for longer than four years in the case of all other plants. Trials of the variety not involving offering for sale or marketing shall not affect the right to protection. The fact that the variety has become a matter of common knowledge in ways other than through offering for sale or marketing shall also not affect the right of the breeder to protection'*.

specific article to each of the four conditions: Article 6 for novelty[127], Article 7 for distinctness[128]; Article 8 for uniformity[129]; Article 9 for stability[130].

The last three conditions are known as *DUS requirements*, since the new variety has to be distinct (D) on a phenotypical level from other existing and known varieties, sufficiently uniform (U) in its expressed characteristics within a population, and stable (S) after repeated propagation. These three requirements form the basis of the so-called *DUS Test*, an examination carried out on the basis of Article 7 of the 1961/1978 Acts and Article 12 of the 1991 text. Those Articles state that protection for new varieties is granted only after an examination showing that the variety meets the requirements set out by the Convention. In particular, the DUS Test is based on growing trial usually conducted in the field and performed by the competent national authorities aimed at investigating whether the variety complies with the DUS requirements[131]. The outcome of the examination is a description of the variety through its relevant characteristics[132].

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[127] Article 6, Novelty: *'(1) [Criteria] The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety (i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date. (2) [Varieties of recent creation] Where a Contracting Party applies this Convention to a plant genus or species to which it did not previously apply this Convention or an earlier Act, it may consider a variety of recent creation existing at the date of such extension of protection to satisfy the condition of novelty defined in paragraph (1) even where the sale or disposal to others described in that paragraph took place earlier than the time limits defined in that paragraph. (3) ["Territory" in certain cases] For the purposes of paragraph (1), all the Contracting Parties which are member States of one and the same intergovernmental organization may act jointly, where the regulations of that organization so require, to assimilate acts done on the territories of the States members of that organization to acts done on their own territories and, should they do so, shall notify the Secretary-General accordingly'.*

[128] Article 7, Distinctness: *'The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. In particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be'.*

[129] Article 8, Uniformity: *'The variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics'.*

[130] Article 9, Stability: *'The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle'.*

[131] UPOV, 2002, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, Geneva.

[132] By way of illustration: plant height, leaf shape, time of flowering.

One of the most important documents adopted by UPOV concerning the DUS testing is the *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*[133], which identifies the principles to use in the DUS examination in order to conduct an harmonized procedure throughout the UPOV members. The purpose is to facilitate cooperation among Contracting parties and to provide effective protection for new plant varieties.

Over the years, the Union has provided more than 300 documents specifying Test Guidelines Procedures (so-called *TGP documents*)[134], associated with the General Introduction. These guidelines for the examination of the DUS criteria are prepared for each relevant species[135] and sorted by botanical name[136]. The mission of the documents is to set out the principles used in the examination of the DUS conditions. The documents are supposed to be a practical guidance for the harmonized examination of individual species or variety grouping by members of the Union.

These documents do not contain binding obligations for Members, unlike the text of the UPOV Convention, so they shall be interpreted consistently with the relevant Act of the Convention adopted by each Contracting Party.

5.2. The novelty requirement

The fourth requirement, i.e. the novelty, which could not be examined through growing test, unlike the DUS requirement, introduced a limited *period of grace* in which time a candidate variety might be marketed by or with the consent of the breeder in order to evaluate its performance before applying for a Community PVR.

The novelty requirement had an interesting evolution over the years: according to 1961 UPOV Act, a variety is deemed to be new under the Convention whether, at the date of the

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[133] UPOV, 2002, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3, Geneva.
[134] The Test Guidelines are prepared by the relevant Technical Working Party, working in the field of each specific species. The draft made by the Technical Working Party is sent to the appropriate international professional organizations for the species concerned. On the basis of the comments and observations received, the Technical Working Party finalizes the draft and presents it to the UPOV Technical Committee for the final adoption and publication.
[135] Although, in some cases, the Test Guidelines are covering a wider or narrower grouping of varieties.
[136] Source: UPOV website, www.upov.int. Last access: February 2019

application, such variety has not yet been marketed or offered for sale with the consent of the breeder in the territory of the State where the application is submitted or it has been marketed/offered for sale for no longer than four years in the territory of any other State. Then, the 1978 UPOV version allowed the market or offer for sale for no longer than one year in the State where the application is presented, at the time of the filing. In case of another State, the market or the offer for sale should have taken place for no longer than six years in the case of vines, forest trees, fruit trees and ornamental trees, or for no longer than four years in the case of the other species. Also, according to the 1978 Act, the right of the breeder is not affected where the variety has become a matter of common knowledge through means different from offering for sale or marketing.

However, these definitions left room for several misinterpretations. The problems concerned: the effect of the the disposals other than sale and offer for sale on the novelty requirement; the reference to the propagating or to the harvested material, or even to both; the relevance of the purpose of the sale (e.g. in case of breeding purposes). These doubts were put to rest by the 1991 Convention, which unambiguously articulated the novelty requirement by making explicit reference to either *propagating or harvested material* of the variety that has not been *sold or otherwise disposed to others* for *exploitation purposes*, by or with the consent of the breeder for the same period of time indicated in the 1978 Act.

In this context, 'exploitation' means 'commercial exploitation', so acts done for non-commercial purposes do not jeopardize the novelty requirement of the candidate variety.

It is worth highlighting that in plant variety protection there is a significant difference between the notion of distinctness and the notion of novelty, unlike other IP laws. As underlined by Van Der Kooij, in plant variety protection *distinctness* deals with the comparison among varieties, whereas *novelty* concerns the marketing of the variety before the date of application for plant breeders' rights. Contrarily, the notion of *new* in patent law has a meaning similar to *distinct* in plant variety protection.[137]

[137] Van Der Kooij P.,1997, *Introduction to the EC Regulation on Plant Variety Protection*, Kluwer Law International, p. 15.

5.3. The variety denomination

A condition of notable importance for the grant of plant variety protection is the appropriate denomination of the new variety for identification purposes. The variety denomination should be suitable as generic designation and should allow the identification of the variety, without misleading or causing confusion about the characteristics, value or identity of the new variety or the identity of the breeder (Article 13 of the 1961/1978 Act and Article 20 of the 1991 Act).

The denomination shall not consist solely of figures, such as a denomination containing numbers only, except where this is an established practice for designating varieties, e.g. for particular variety types - like hybrids - or for particular varieties used by a limited number of specialists.

According to the UPOV provisions, there exists an obligation to use the denomination: indeed, the use of the variety naming is mandatory for any person who markets propagating material of the protected variety, even after the expiration of the breeder's right. The UPOV Member States should ensure that the free use of the denomination in connection with the variety is not hindered by other rights, even when the protection expires.

Therefore, the plant naming submitted by the breeder should differ from others denomination used to identify existing varieties of the same or a closely related botanical species, in any of the UPOV Member States, and shall not affect prior rights of third parties.

Whether the proposed denomination does not satisfy such requirements, the national authority for the protection of new varieties of plants shall refuse to grant the right and shall require the breeder to propose another suitable denomination within a given period of time. It is important to underline that, when applying for protection of a specific variety in different Member States of the Union, the breeder shall use the same denomination in all Contracting Parties. Moreover, the denomination shall be registered at the same time when the breeder's right is granted.

The last paragraph of Article 13 in the 1978 Act and Article 20 of the 1991 Act concern the relationship between variety denomination and trademark: according to it, it is allowed *'to associate a trademark, a trade name or other similar indication with a registered variety denomination'*. With reference to the use of trademarks, it is extremely interesting to observe

what Van Der Kooij noticed[138]: in some plant catalogues is it possible to find the trademark symbol after variety denominations. However, this symbol is often wrongly used. Some companies mistakenly add the trademark symbol after the plant naming not to indicate that such plant name has been registered as trademark, but to imply that the relevant plant variety is protected by a breeder's right. In light of this, the author suggested that a specific symbol for PBRs shall be introduced at the international level, in order to easily indicate whether a variety is protected by plant breeder's right or not[139].

The importance of giving a suitable variety denomination has been emphasized by UPOV, especially through its Explanatory Notes aimed at ensuring uniform interpretation and application by all Member States of the *'broadly worded provisions'*[140] set up in the Convention, an explanation that could assist both national authorities and breeders during the naming process and in their choice of variety denominations[141]. Indeed, UPOV normalized relevant concepts and established an effective system of plant naming at the international level, embraced by scientists, lawyers, and plant breeders[142].

The implementation of such system has been also supported by the creation of databases by UPOV, e.g. the PLUTO database. This plant variety database, whose name stands for *PLant varieties in the Upov system: The Omnibus*, collects the data supplied by the competent national authorities of the Members of the Union and by the intergovernmental Organization for Economic Cooperation and Development (OECD) regarding plant breeder's rights, plant patents and national listing[143]. As regards variety denomination, one of the main aspects of the PLUTO database is to provide information on plant naming denominations, to analyze variety denomination and to permit denomination search for similarity.

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[138] Van Der Kooij P., 2002, *Defending PBR: P, B, or R?,* in European Intellectual Property Review, 24, 1.
[139] The author suggests the adoption of the letter B notice.
[140] UPOV, 2012, *Explanatory Notes on Variety Denominations under the UPOV Convention*, Geneva, UPOV/INF/12/4, p. 2.
[141] Sets of rules aimed at governing at an international level the denomination of plants have also been provided by groups of botanists and taxonomists, e.g. through the *International Code of Botanical Nomenclature* in 1867 and the *International Code of Nomenclature for Cultivated Plants* in 1953. However, this Codes are not legally binding and they have been open to *'disregard and misuse by plant breeders, traders and marketers'.* See, Sanderson J., 2017, *Plant, People and Practices. The Nature and History of the UPOV Convention*, Cambridge University Press, Cambridge, p. 72.
[142] Sanderson J., 2017, *Plant, People and Practices. The Nature and History of the UPOV Convention*, Cambridge University Press, Cambridge, p. 73.
[143] According to the UPOV website, nowadays data from over 800,000 documents is available in the PLUTO search system. Source: https://www.upov.int/pluto/data/current.pdf

In conclusion, it goes without saying that the effort of the UPOV on such aspect clearly underlines the importance of an appropriate variety denomination for plant variety protection and, therefore, this requirement shall not be overlooked by breeders during the application process, since the lack of this requirement might lead national authorities to decline the registration of the relevant plant variety.

6. National treatment

The UPOV Convention, in whichever version considered, explicitly recognizes the principle of national treatment, respectively in Article 3 of the 1961/1978 Acts and Article 4 of the 1991 version. National Treatment is considered to be a basic principle of the UPOV system, whereby nationals and residents of a Member of the Union shall get the same treatment accorded to the nationals of all other Members of the Union[144]. Therefore, the Union Contracting Parties are required to draft a provision on national treatment in their laws in accordance with the UPOV Convention. However, a specific national treatment provision is not necessary when the national law does not restrict the protection for new varieties on the basis of the nationality[145] of the applicant[146].

7. Application for the grant of the breeder's right

Pursuant to Article 11 (1) of the 1961 UPOV Convention, the breeder has the right to freely choose the UPOV Member State where to file the first application for the protection of their new variety. The second paragraph of the Article stipulates that, in order to apply in other Contracting Parties of the Union for subsequent applications, the breeder may not wait for the grant of PBR by the State where they made the first application. This provision is

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[144] Specifically, according to the 1991 UPOV Convention: '*nationals of a Contracting Party as well as natural and legal persons resident and legal entities having their registered offices within the territory of a Contracting Party shall, insofar as the grant and protection of breeders' rights are concerned, enjoy within the territory of each other Contracting Party the same treatment as is accorded or may hereafter be accorded by the laws of each such other Contracting Party to its own nationals, provided that the said nationals, natural persons or legal entities comply with the conditions and formalities imposed on the nationals of the said other Contracting Party*'.

[145] Also interpreted as place of residence of natural persons or place of registered offices for legal entities.

[146] UPOV, 2009, *Explanatory Notes on National Treatment under the 1991 Act of the UPOV Convention,* Geneva.

connected to the *principle of independence of protection*, laid down in the last paragraph of Article 11, according to which the protection granted in the different UPOV Member States shall be independent of the protection obtained for the same variety in other countries, whether such countries are UPOV members or not. It follows that a Member State shall not refuse or limit protection for a new plant variety on the basis that another State has not granted a PBR for the same variety or the title has therein expired. The same provisions might be found in Article 10[147] of the 1991 Act of the UPOV Convention, entitled *Filing of Application.*

The moment when an application is filed is significant for the exercise of the *right of priority* recognized to the applicant. Indeed, according to Article 12 (1) of the 1961 UPOV Convention and Article 11 (1) of the 1991 UPOV Convention, from the date of filing the first application in one of the UPOV Member States, the breeder enjoys a right of priority for a period of twelve months for the purposes of filing in the other Contracting parties of the Union. The Article makes reference to the act of *duly* filing, therefore it might be assumed that the period shall run from the date when a *valid* application has been filed.

The 1991 Act included a specific provision regulating the examination of the application, i.e. Article 12, which stipulates that the breeder may be required to provide all the necessary documents or material and that, during the examination for compliance with the conditions of protection, the relevant authority might grow the variety or carry out other text or also take into account the results of other trials already performed.

8. Scope of the breeder's right

Regarding the scope of protection of the breeder's right, the UPOV texts had a noteworthy evolution over the years. Under the 1961/1978 Act, the acts that shall require the prior authorization of the breeder were the following: 1. production for purposes of

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[147] The cited Article states the following: *'(1) [Place of first application] The breeder may choose the Contracting Party with whose authority he wishes to file his first application for a breeder's right. (2) [Time of subsequent applications] The breeder may apply to the authorities of other Contracting Parties for the grant of breeders' rights without waiting for the grant to him of a breeder's right by the authority of the Contracting Party with which the first application was filed. (3) [Independence of protection] No Contracting Party shall refuse to grant a breeder's right or limit its duration on the ground that protection for the same variety has not been applied for, has been refused or has expired in any other State or intergovernmental organization'.*

commercial marketing, 2. offering for sale, and 3. marketing of the reproductive or vegetative propagating material.

Under the 1991 Act, the list of acts requiring the prior authorization of the breeder was extended and, also, a specification was made regarding the category of material concerned: according to Article 14, for propagating material of the protected variety the prior authorization was required for the following acts: 1. production or reproduction (multiplication); 2. conditioning for the purpose of propagation; 3. offering for sale; 4. selling or other marketing; 5. exporting; 6. importing; 7. stocking for any of the purposes abovementioned[148]. For harvested material, the said acts shall require the authorization of the breeder only when such material was obtained by means of *unauthorized use* of propagating material of the protected variety and unless the breeder had a *reasonable opportunity*[149] to exercise their right in relation to the said propagating material. Unlike the 1961 Act, the 1991 Convention does not limit the scope of protection to propagating material and to commercial marketing, thereby granting broader protection to the plant varieties rights holder.

The extension of the scope of protection beyond the propagating material of the new plant variety is known as *cascade principle*[150]. However, this principle does not have an absolute extent since it is limited by the *reasonable opportunity* to exercise the breeder's right at an earlier stage, over the propagating material, by the owner of the protected variety. Therefore, in case the breeder had the chance to exercise their right over the propagating material but they decided not to, they is no longer entitled to it on the relevant harvested material.

Nevertheless, the 1991 Convention does not provide a definition of harvested material: a clue could be extrapolated by Article 14 of the 1991 Act when stating '*[..] harvested*

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[148] Without prejudice to the possibility for each Contracting Party to include additional acts, as provided for in Article 14 (4) of the 1991 Act.

[149] Concerns have been raised regarding the interpretation of "'*reasonable opportunity*', since no definition is provided by the UPOV Convention. The concerns regard the degree of uncertainty of this legal concept, which could increase the number of legal disputes. For further insights on the notion of 'reasonable opportunity', see: Sanderson J., 2017, op. cit., pp. 183 - 204. The author cited the 'Melanie' case and the relevant German Federal Supreme Court decision (14.2.2006, X ZR 93/04) which addressed the interpretation of 'reasonable opportunity'. The case concerned a plant variety, protected in Germany, which was unlawfully reproduced in a third country where the same plant variety protection was not recognized. Later, the variety was brought back to Germany as harvested material. The German Supreme Court stated that in this case the breeder did not have a reasonable opportunity to exercise their right at an earlier stage, over the reproductive material.

[150] Sanderson J., 2017, op. cit., p. 193. The cascading principle was opposed by the U.S.

material, including entire plants and parts of plants' thereby denoting that the definition of harvested material is embracing both entire plants and parts of plants, meaning that at least some forms of harvested material could be potentially used for propagating purposes[151].

When harvested material is used for propagating purposes, a question arises on how it should it be considered. In order to avoid an overlapping of notions between harvested material and propagating material, the emphasis should be on the purpose, the destination underlying the use and commercialization of the material: when reproductive purposes are not concerned, it shall be considered harvested material. Therefore, its use and commercialization shall not require the authorization of the breeder when it has been lawfully obtained from propagating material of the protected variety.

According to the cascade principle, the 1991 Act also recognized the possibility for Contracting Parties to extend the scope of protection of the breeder's right to products made directly from harvested material of the protected variety, through the unauthorized use of the said harvested material, unless the breeder has had reasonable opportunity to exercise their right in relation at an earlier stage, i.e. to the said harvested material. Such possible extension has been questioned during the Diplomatic Conference for the revision of the UPOV Convention[152]: concerns have been raised about the excessive broadening of the breeder's right and the extreme complexity to exercise this right in practice.

Reference is made to the burden of proof and the related difficulties to bring evidence that a protected variety formed the basis of the product concerned. In particular, the Polish delegation highlighted that the identification of the material would be likely impossible since most of the varietal differences tend to disappear during the industrial processing[153]. Differently, the Dutch delegation believed that such provision was necessary for complete protection for the breeder's right, even if evidence could be brought only in a limited number of cases. For the Swedish delegation, there was also a defining issue about the notion of *products made directly from harvested material* had a certain degree of uncertainty[154]. In light of those concerns, the Conference decided to adopt a facultative provision.

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[151] UPOV, 2013, *Explanatory Notes on Acts in respect of Harvested Material under the 1991 Act of the UPOV Convention,* Geneva.
[152] UPOV, 1992, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants,* UPOV Publication No. 346 (E), Geneva.
[153] Ibidem, p. 406.
[154] Ibidem, p. 407.

9. Restrictions

A limitation to the exercise of the breeder's right is set up by the UPOV Convention and it concerns the emblematic *public interest* restriction, according to which the public interest is the only interest that could prevail over the breeder's right to enjoy the exclusivity of the plant variety protection.

Pursuant to Article 9 of the 1961/1978 Acts and Article 17 of the 1991 Act, the exercise of the right of the owner of the protected plant variety could be restricted by Contracting Parties only for reasons of public interest. A definition of 'public interest' is not provided by the Convention, ergo it is possible that each member of the Union would give the criterion a different meaning.

In this case, a third party is authorized by means of a compulsory license to perform those acts for which the owner's authorization is required. However, according to paragraph 2 of the abovementioned Articles, the compulsory license shall not be granted for free: an equitable remuneration shall be ensured to the right holder by the Contracting party.

10. The breeder's exemption

In addition to securing the breeder's right, the UPOV Convention emphasized the importance of stimulating innovation in breeding through unrestricted access to protected varieties for the development of new ones. This provision is known as *breeder's exemption* or as *principle of independence*[155], and it is considered to be a cornerstone in the plant variety protection system[156], representing one of the main divergences between PBRs and patents. The principle of independence contrasts with the patent rights system *principle of dependence*, according to which a patent is dependent to another patent where the latter has been used for the development of the former. In the case of plant varieties, the UPOV Members unanimously decided to opt for the 'independent status' of new plant varieties,

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[155] Van Der Kooij P.,1997, *Introduction to the EC Regulation on Plant Variety Protection*, Kluwer Law International, p. 39.

[156] International Seed Federation, 2012, *ISF View on Intellectual Property*, Rio de Janeiro, available at https://www.worldseed.org/wp-content/uploads/2015/10/View_on_Intellectual_Property_2012.pdf

meaning that a new variety is not considered dependent from all the varieties used during the breeding activities. This principle relies on the intrinsic nature of breeding: new plant varieties cannot be created from scratch, they are the product of recombination of genes from existing varieties[157]. The different scope of these rights is one of the reasons why patents rights are perceived as stronger and less flexible than breeders' rights[158].

The relevance of the breeder's exemption for the plant variety protection system shall be extrapolated by the circumstance that it was already established by the 1961 Act. Pursuant to Article 5 of the 1961 Convention, the authorization by the breeder was not needed either for the '*utilization of the new variety as an initial source of variation for the purpose of creating other new varieties or for the marketing of such varieties*'. In the 1991 Act, the exceptions to breeder's rights are laid down in Article 15. In particular, the breeder's exception is specified in Article 15 (1) (iii) which provides an exemption for '*acts done for the purpose of breeding other varieties*' and for the commercialization of the new varieties obtained, except where the provisions of Article 14 (5) apply, i.e. to essentially derived varieties (EDVs).

In addition to the breeder's exemption, Article 15 (1) established that the breeder's right shall not extend as well to *'(i) acts done privately and for non-commercial purposes'* and *'(ii) acts done for experimental purposes'.* Therefore, the production or reproduction of propagating or harvested material of the protected variety for, e.g., (i) private gardening and (ii) scientific research led by a university, are considered non-infringing activities.

In conclusion, the highly remarkable value of the breeder's exemption has to be underlined: it represents a fundamental and distinctive aspect of the UPOV system and the plant variety protection system in general, neglected by the patent system, which explicitly recognizes the need for breeders to rely on the latest crop improvements and the importance of access to new varieties for the development therefrom and for carrying on innovation in the breeding sector, for the benefit of the society.

Some years ago, a seed association has argued that the current scope of the breeder's exemption is too liberal: an initial predetermined period of exclusivity, where the exemption is not available, should be recognized to plant variety owners in order to permit a return on

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[157] Ibidem.
[158] Prifti V., 2015, *The Breeder's Exception to Patent Rights. Analysis of Compliance with Article 30 of the TRIPs Agreement*, Springer International Publishing, p. 63.

investment[159]. However, such suggestion has not gained relevant support so far: perhaps, the unrestricted access to protected plant varieties by other breeders is perceived by plant variety owners neither as a threat to their breeder's right nor an obstacle to further innovation.

11. The farmer's privilege

Although the 1961/1978 Acts of the UPOV Convention recognized the breeder's exemption, they did not explicitly state anything regarding the possibility to exclude the act of seed saving from the scope of the breeder's right: only the 1991 Act took into consideration the traditional farmers' practice of saving harvested material for further propagation (farm-saved seed or FSS).

An optional exception has been provided by Article 15 (2) of the 1991 UPOV Convention, which allows Contracting Parties to *'restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety'*. This provision laid down the so-called *farmer's privilege.* The reference is explicitly made to the use for 'propagating purposes' and 'on their own holdings', meaning that the members of the Union shall not extend this provision neither to the act of seed saving for commercial purposes nor the act of transferring the saved seeds to other farmers[160]. Indeed, the States have the duty to reasonably limit the farmer's privilege and to safeguard the legitimate interests of the breeders.

In light of this, it is not surprising that the Diplomatic Conference indicated that such provision should be optional: this exemption has never been regarded as a fundamental aspect of the UPOV system[161]. Specifically, during the Diplomatic Conference that led to the 1991 Act, while discussing about the farmer's privilege, the Dutch Delegation underlined that *'the main goal of the revision of the UPOV Convention was to strengthen the position of the breeder in relation to varieties developed by him and protected under the plant*

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[159] Janis M., Jervis H., Peet R., 2014, *Intellectual Property Law of Plants,* Oxford University Press, p. 86. The authors cited the position paper of the American Seed Trade Association on Intellectual Property Rights for the Seed Industry.
[160] World Intellectual Property Organization, 2017, *Introduction to Intellectual Property. Theory and Practice. Second Edition*, Kluwer Law International, pp. 261-262.
[161] Janis M., Jervis H., Peet R., 2014, op. cit., p. 86.

breeders' rights system'[162]. Nevertheless, such delegation also highlighted that the farmer's privilege had been already recognized in numerous States and this process was *'probably not reversible'*[163]*:* the inescapable consequence had to be the coexistence between the practice of farm-saving seeds and the breeders' rights.

A limitation to the FSS practice was deemed necessary because farmers are the first buyers and users of protected plant varieties and an excessive extension of the farmer's privilege could lead to inadequate protection of the breeder's right. The solution proposed relies on the payment to the breeder of an equitable remuneration by the farmer using such privilege. However, this aspect represented a vexed question that could not reach the consensus among the Member States: therefore, the Diplomatic Conference chose to leave the decision on the equitable remuneration on each Member of the Union. Thus, each State has the possibility to decide whether a payment is due to the breeder by the farmer who is saving and reusing the harvested material of a protected variety, according to the obligation to safeguard the legitimate interests of the breeder, pursuant to Article 15 (2).

Furthermore, for the purpose of this research, it is interesting to notice that, according to the Dutch and French Delegations, this exception should be limited to those crops that have been traditionally subjected to such practice, meaning self-pollinating plants i.e. cereals and especially small-grained cereals. However, the Diplomatic Conference faced some difficulties in specifying a *numerus clausus* list of species in an international Convention[164], so it left the choice to the Contracting Parties.

12. Exhaustion

The principle of exhaustion of intellectual property rights was first developed in German patent law around the beginning of the XX century[165]. According to the exhaustion doctrine (also called *first sale doctrine*), when a protected good is marketed for the first time

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[162] UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, p. 352.
[163] Ibidem.
[164] Issue underlined by the UK Delegation. See, UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, p. 353.
[165] The relevant theory of the *Zusammenhang der Benutzungsarten*"was formulated by Joesph Kohler. See, Schovsbo J., 2012, *Exhaustion of Rights and Common Principles of European Intellectual Property Law*, in Ohly A., Common Principles of European Intellectual Property Law, Mohr Siebeck, Tübingen, pp. 169-188.

by the right owner or with their consent, they loses the right to control the subsequent circulation of the relevant good. That means that the holder of the IP right loses the resale right on that specific item: *ergo,* their rights are exhausted.

The rationale of the exhaustion principle lies in the necessity to limit the distribution right of the IPR holder and to avoid that an unending control over the distribution of the protected goods might affect commercial relations and free movement of goods. The exclusive right of the IPR owner concerns the exploitation of the intangible good, not the physical item incorporating it, which could be re-marketed after the legitimate first sale.

The principle of exhaustion is common to intellectual property law and it applies also to breeders' rights. In this case, the purpose of the rule of exhaustion is to ensure that the breeder's right holder can exercise their right and be remunerated in the first propagation stage. Also, exhaustion in plant variety protection aims at guaranteeing the right of the breeder to forbid further or unauthorized propagation of the protected variety[166].

The right to prohibit further propagation required for an adaptation of the principle of exhaustion from the patent law paradigm to the plant variety protection one. Indeed, exhaustion doctrine in patent law *'protects the purchaser from interference in the use of the purchased patented item and in its disposition or sale'*[167]*,* whereas in plant variety protection it is necessary to take into consideration that the protected organisms are automatically able to duplicate themselves, so a limited interference might be allowed in order to protect the right holder.

In light of the above, the 1991 Act provided for a specific provision concerning the exhaustion of the breeder's right, i.e. Article 16 (1) and (2) which states that:

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[166] The role of the exhaustion doctrine in avoiding the further and unauthorized propagation of protected plant material has been addressed by the Supreme Court of the United States in the well-known *Monsanto v. Bowman* judgment. In this patent infringement case, occurred in 2013 and filed by Monsanto against Bowman, the Court stated that a purchaser of a patented crop might resell the patented material, consume it himself or use it to feed their animals, but there is a limit. The Supreme Court held that: *'the exhaustion doctrine does not enable Bowman to make additional patented soybeans without Monsanto's permission'.* In other words, even if the patented material is naturally able to replicate itself, the purchaser does not have the right to use such copies. In case an unauthorized replication occurs, the right of the holder is deemed to be not exhausted. For further insights see: Blakeney M., 2016, *Agricultural Innovation: Patenting and Plant Variety Rights Protection,* in Steier G. and Patel K. (eds.), International Food Law and Policy, Springer International Publishing, pp. 149-150. See also: Lai J., 2014, *The Exhaustion Doctrine and Genetic Use Restriction Technologies: A Look at Bowman v Monsanto*, in The Journal of World Intellectual Property, 17, 5-6.

[167] Chamber S., 1995, *Exhaustion Doctrine in Biotechnology*, in IDEA: The Journal of Law and Technology, 35.

'(1) [Exhaustion of right] The breeder's right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 14(5), which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned, or any material derived from the said material, unless such acts (i) involve further propagation of the variety in question or (ii) involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes.

(2) [Meaning of 'material'] For the purposes of paragraph (1), 'material' means, in relation to a variety, (i) propagating material of any kind, (ii) harvested material, including entire plants and parts of plants, and (iii) any product made directly from the harvested material'.

The wording of the Article 6 (1) (i) clarifies that the use of any material of the protected variety, put on the market by the breeder or with their consent and subject to further propagating activities, do not exhaust the exercise of their right.

It is interesting to underline that Article 16 (2) put semantically in the same basket propagating material, harvester material and products made directly from the last one. Therefore, no matter in what form the protected variety was set on the market: the use of any material involving further propagation, does not exhaust the breeder's right.

By way of illustration, when a farmer buys seeds of a protected variety and those seeds produce harvest which is further propagated to produce new seed, the breeder's right is not exhausted. According to Article 14 (1), the farmer needs the authorization of the breeder, that could be subject to conditions and limitations, such as receiving an adequate remuneration (i.e. royalties), for the further propagation of the protected cereal variety performed by the farmer. Also, this provision applies in case seeds of a protected variety, which are sold as groceries, are used for propagating purposes: in this event, the breeder's right does not exhaust as well. Consequently, it seems clear that the breeders' rights shall not apply to acts performed for consumption purposes.

The reference to the further propagation is made necessary by the very nature of plant varieties, which are self-replicating and could effortlessly be reproduced, contrary to other material covered by intellectual property rights: therefore, exhaustion should be limited to acts that do not involve a further production of seed. Indeed, the acts of 'production or

reproduction' of new seed of a protected variety, when they are not covered by Article 15 on the exceptions to the breeder's right, fall under Article 14 (1) (a) and shall require the authorization of the breeder.

13. Essentially derived varieties

Another key concept introduced by the 1991 Act concerns the limited protection accorded for the so-called *essentially derived varieties* (EDVs). The urgency to address such issue was related to the complaints advanced about *cosmetic* breeding activities[168], i.e. the creation of a plant variety derived from a protected one, characterized by small and insignificant differences therefrom.

The marketing of such altered variety, in competition with the protected one, could be carried on without the possibility for the breeder of the protected variety to claim for liability. The problem arose because in the 1961/1978 UPOV Acts there was a loophole that allowed cosmetic breeding activities, whereas it allowed the initial use of the protected variety for breeding purposes and, at the same time, it limited the protection for infringing acts exclusively to the specific protected variety. Therefore, the development and marketing of a trivially different variety were not explicitly forbidden.

However, the UPOV system is supposed to stimulate breeders to seek protection for varieties that are not a trivial accomplishment in light of the existing protected ones[169]. That is rooted in the very nature of intellectual property rights because *'if the goal of intellectual property law is to encourage costly innovation that might not otherwise occur, its scope should be limited to inventions that require some significant effort'*[170].

In light of this, it was necessary to strengthen the scope of protection of the breeder's right to discourage the production of those varieties that are only slightly altered from protected ones. This issue had an impact also on the general principle of independence,

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[168] The notion of 'cosmetic plant breedin'g deals with plagiaristic practices aimed at marketing plant varieties that do not constitute proper innovations since they are characterized by irrelevant changes from the protected variety. For further insights, Leskien D., Flitner M., 1997, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, in International Plant Genetic Resources Institute, Issues in Genetic Resources, 6, Rome, p. 60.
[169] Janis M., Jervis H., Peet R., 2014, op. cit., p. 71.
[170] Alexander G., Peñalver E., 2012, *An Introduction to Property Theory*, Cambridge University Press, p. 186.

typical of the plant variety protection system: an exception to such principle for essentially derived varieties was introduced. So, in the 1991 Act a principle of *limited dependence* was introduced for EDVs and exclusively for them. This principle was applied to establish a relationship among initial varieties and derived ones, for the purpose of discouraging plagiarism[171].

Even though there was who believed that the EDVs concept was related to exceptions to the breeder's exemption, the notion of essentially derived variety was included in Article 14, dealing with the scope of the rights granted to the breeder. The reason of this choice lies in the what has been considered the cornerstone of the UPOV Convention, i.e. the free access to genetic variability: the concept of EDVs was primarily contemplated as an underpinning to the breeder's right, not as a limit to such access[172].

Consequently, pursuant to Article 14 (5) (a) of the 1991 Act, the provisions of Article 14, paragraphs (1) to (4) shall apply as well in relation to: *'(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety; (ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and (iii) varieties whose production requires the repeated use of the protected variety'*. This provision establishes the abovementioned principle of limited dependence for essentially derived varieties, which only exists whenever the breeder's right has been granted on the initial variety and the initial variety is not itself an essentially derived variety. Basically, dependence can only exist from a protected initial variety.[173]

During the Diplomatic Conference, the Japanese delegation underlined the importance to lay down, alongside the dependence principle, some common criteria to identify the essentially derived varieties: it was utterly necessary to set a demarcation line between what had to be considered an EDV and what was not, by means of internationally harmonized

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[171] See, International Seed Federation, 2012, *ISF View on Intellectual Property*, Rio de Janeiro, where the ISF stated that the introduction of the EDVs concept has drastically reduced plagiarism in plant breeding *'because all plagiaristic varieties fall under the EDV principle'*.

[172] UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, p. 339. Also, the International Seed Federation stated in its 2012 View on Intellectual Property that the EDVs concept does not restrict the breeders' exception.

[173] International Seed Federation, 2012, op. cit., p. 22.

rules[174]. Paragraph (b) of Article 14 (5) addressed this concern, specifying that: '*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'.*

Basically, in relation to an initial variety, the EDV is described by the following three technical aspects: 1. predominant derivation from an initial variety; 2. distinctness and 3. conformity in the expression of the essential characteristics resulting from the genotype. The requirement of *predominant derivation* denotes that there should not be more than *one* initial variety. Instead, while distinctness measures the existence of the difference, conformity measures the extent of such difference[175]. The UPOV Convention does not specify, in case of dispute, who should prove the predominant derivation of the EDV. However, it surely is more challenging for the breeder of the initial variety to be able to demonstrate such a requirement. Therefore, the International Seed Federation suggested that the burden of proof regarding the predominant derivation should be reversed and placed upon the breeder of the alleged essentially derived variety: the owner of the initial variety shall only prove that the distinctness and conformity requirements are fulfilled[176].

It is worth highlighting that the conformity requirement shall not be related to the genotype itself but to the *expression of the essential characteristics*[177] of it. The problem of

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[174] UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, pp. 346-347.
[175] Janis M., Jervis H., Peet R., 2014, op. cit., p. 83.
[176] International Seed Federation, 2012, op. cit., p. 22. Also, ISF developed guidelines to facilitate EDV dispute procedures. They are available at the following website: www.worldseed.org.
[177] In its Explanatory Note, the UPOV provided some examples of what might be considered the notion of 'essential characteristics': *'(i) essential characteristics, in relation to a plant variety, means heritable traits that are determined by the expression of one or more genes, or other heritable determinants, that contribute to the principal features, performance or value of the variety; (ii) characteristics that are important from the perspective of the producer, seller, supplier, buyer, recipient, or user; (iii) characteristics that are essential for the variety as a whole, including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics; (iv) essential characteristics may or may not be phenotypic characteristics used for the examination of distinctness, uniformity and stability (DUS); (v) essential characteristics are not restricted to those characteristics that relate only to high performance or value (for instance, disease resistance*

how checking the conformity with the genotype was brought to the attention of the Diplomatic Conference[178]: the Member States decided that the comparison among genotypes was not practical and, therefore, the resemblance among the varieties had to address its expressed characteristics.

A clarification is due: when it has been determined that a variety is an EDV, in accordance to Article 14 (5), such variety stays an essentially derived variety, even when the protection for the initial variety expires. The reason why once a variety has been proven to be an EDV it remains an EDV, lies in the fact that essential derivation is a technical question. Differently, limited dependence concerns the legal aspect and the legal consequences of the essential derivation in plant breeding. Indeed, Article 14 (5) deals separately with the two notions: subparagraph (a) refers to the legal aspect of limited dependence, whereas subparagraph (b) concerns the technical features of essential derivation.

It is worth mentioning that Article 14 (5) (c) of the 1991 Act provides some examples of breeding methods that might be used to obtain EDVs. However, the wording of the provision make it clear that those processes may not necessarily result in an EDV and that essentially derived variety could be obtained in other ways[179].

14. Duration

When intellectual property rights are created, the law restricts their use by granting protection only for a fixed and limited period of time. In the case of plant breeders' rights, this period of time has been modified over the years. Also, different duration of the protection has been provided for some specific varieties.

Pursuant to Article 8 of the 1961/1978 Acts, the breeder's right shall have a duration of a minimum fifteen years from the date of the issue of the title of protection. In the case of vines, forest trees, fruit trees and ornamental trees, including their rootstocks, the period

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may be considered as an essential characteristic when the variety has susceptibility to disease); (vi) essential characteristics may be different in different crops/species'. See, UPOV, 2017, *Explanatory Notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention*, Geneva, UPOV/EXN/EDV/2.

[178] UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, p. 344.

[179] Article 14 (5) (c) of the 1991 UPOV Convention: *'(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering'.*

shall be not less than eighteen years. Obviously, Contracting Parties might guarantee longer periods of protection and they might also differentiate the duration for some classes of plants.

However, breeders argued that such minimum period of protection was inadequately short: they claimed to take into consideration the long time needed for both breeding activities and seed production processes, and also the length of the commercial life of their crops.

So, in the 1991 UPOV Convention a longer minimum period of protection for breeder's rights was formulated: according to Article 19, the protection shall be granted for at least twenty years from the date of the grant of the breeder's right. In the case of trees and vines, such period shall be not less than twenty-five years. The special term for trees and vines is justified by the longer time required to develop these varieties before they begin to produce fruits.

15. Double protection ban

The 1961/1978 Acts of the UPOV Convention enshrined in their Article 2 (1) the so-called *double protection ban*. According to it, each UPOV member shall adopt a form of protection of the breeder's right established in the Convention by granting either a special title of protection or a patent. In the event that national laws recognized a form of protection under both a *sui generis* title and a patent, the Member State is required to provide only one of them for one and the same botanical genus or species. Therefore, cumulative protection under both forms was not permitted.

This aspect was intensely discussed after the adoption of the Convention and especially during the Diplomatic Conference that led to the 1991 Convention: some UPOV members argued that the wording of Article 2 (1) would affect patent law and the prerogative of each State to decide which forms of protection shall be afforded to a variety; also, the risk of discouraging new members from joining the UPOV was emphasized. In particular, some UPOV members like Germany, Australia, the United Kingdom and the USA highlighted that the deletion of such provision would permit Contracting parties to decide for themselves

how they want to protect plant breeders' rights[180]. Also, in case a Member State wants to introduce a double protection ban, it could do it at a national level. Hence, a double or cumulative protection ban should not be admitted any longer.

This request, shared by all the UPOV Members with the exception of Denmark and Sweden, led to the elimination of the double protection ban in the 1991 Act, whose Article 2 merely states that '*each Contracting Party shall grant and protect breeders' rights'*. This wording leaves to Member States the choice of which intellectual system should be used and whether cumulative protection shall be granted, without affecting the possibility of concurrent patentability of plant varieties. Therefore, according to 1991 Act, the national law of the member State might provide for either only one or both forms of protection, leaving the breeder the decision to choose between the two of them or even permitting concurrent protection by both rights.

The new version of Article 2 (1) provided by the 1991 Convention meaningfully complies with Article 27 (3) (b) of the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPs Agreement, which states that '*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*'. So, according to such provision, Member States might decide to exclude, *inter alia*, plants as such from patentability but they shall recognize protection for plant varieties, either by a *sui generis* title, by a patent, or by both titles. It is important to remind that nowadays the most widespread *sui generis* system used for the protection of breeders' rights is the plant variety protection system established by the UPOV Convention.

16. Final remarks

The UPOV Convention has been the first international agreement to provide a legal framework for the protection of plant varieties through a *sui generis* system. It has

[180] UPOV, 1991, *Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants*, Geneva, UPOV/PUB/346, pp. 213-218.

introduced and normalized several concepts concerning plant varieties, while leaving a certain degree of freedom to Member States to adapt such provisions to their national environment.

The UPOV Convention has not been revised after 1991. Surely, some provisions could be clarified and improved but the difficulties to face in order to reach a new agreement on such elements might not be overcome: the interests at stake of the members of the Union are very different and sometimes potentially conflicting. As it has been said, *'a review could have the character of opening the Pandora's box'*[181].

Hence, one could meaningfully assume that, without a review, the responsibility to carry on the harmonization and the implementation of the UPOV system might fall on jurisprudence. Of course, the impact of case law is indissolubly limited to the jurisdiction of the Courts. However, Member States might take into account the interpretation of vague concepts and provisions provided for by the judges of another Contracting Party when addressing the same questions. Indeed, the cooperation among UPOV membership, both on a legal and a technical level, is fundamental for a better implementation of the plant variety protection system and many countries became aware of the benefits of such cooperation.

In this context, it is not surprising that the membership of the Union has experienced a significant evolution over the years: from thirteen States representing only industrialized European countries to seventy-five members, including developing countries and international organizations, such as the African Intellectual Property Organization and the European Union.

It is indeed the implementation by the European Union of this *sui generis* plant variety protection system to be analyzed and discussed in the following paragraphs.

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[181] Statement of the pro tempore President of the CPVO, Bart Kiewiet. See: Kiewiet B., 2004, *Evolution of the Legal Environment of Plant Breeders' Rights,* Angers, p. 2, available at the following website: https://cpvo.europa.eu/sites/default/files/documents/articles/ISFBerlin2004EN.pdf

CHAPTER 3

The Community plant variety protection in the European Union

SUMMARY: 1. The Community plant variety protection. - 2. Degree of harmonization. - 3. Alternativeness of the system. - 4. Independence of the system. - 5. Definition of breeder and entitlement to Community plant variety rights. - 6. Definition of plant variety. - 7. Genera and species. - 8. Conditions of protection. - 8.1. The DUS requirement. - 8.2. The novelty requirement. - 8.3. The variety denomination. - 9. Application for the grant of the Community PVR. - 10. Appeals against the decisions of the Office. - 11. Scope of the Community plant variety right. - 12. Restrictions. - 13. Essentially derived varieties. - 14. The farmer's privilege. - 15. The breeder's exemption. - 16. Exhaustion. - 17. Contractual exploitation rights. - 18. Compulsory exploitation rights. - 19. Duration. - 20. Infringement. - 21. Enforcement - 22. Final remarks.

1. The Community plant variety protection

The European Union joined the membership of UPOV on 29 July 2005 and became party to the 1991 Act of the Convention. However, even before being a UPOV Member, the European Union modeled its legislation on the rules set out by the UPOV Convention[182]. Specifically, in 1990 there was a first attempt to regulate plant variety rights within the then European Communities through the draft of a Council Regulation published on 28 September 1990.

During the same period, the UPOV Diplomatic Conference aimed at amending the 1978 Act of the Convention was taking place, so the consultations on the Regulation draft were suspended in order to await the outcomes of the UPOV Conference and modify the draft accordingly[183]. This draft led to the adoption of Council Regulation (EC) No 2100/94

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[182] In particular, the Regulation (EC) No 2100/94 states in its Preamble that '*[...] this Regulation takes into account existing international conventions such as the International Convention for the Protection of New Varieties of Plants (UPOV Convention), [...]'.*

[183] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, *European Union Plant Variety Protection,* Oxford University Press, Oxford, p. 4.

of 27 July 1994 on Community plant variety rights, hereinafter referred to as 'the Basic Regulation'.

It has been noticed that only scarce background documentation exists about the proposal for the Regulation. Three possible reasons have been formulated regarding the absence of such documentation[184]: 1. the UPOV revision was taking place at the same time as the European Community discussion, which was shaped accordingly, so the European talk did not catch a significant attention; 2. the plant variety right system in the European Union is *'uncontroversial and of interest to only a specialist few'*; 3. patent lawyers, especially the ones who favored patents over plant variety rights, expected that the Community plant variety system was going to 'wither and die' in comparison with patent protection, consequently they did not show much interest in the discussion thereof.

The Basic Regulation, which is consistent with the 1991 UPOV Convention and determines all the relevant substantial and procedural rules for plant variety protection, created an autonomous protection system allowing for the grant of a unitary IP right on new plant varieties throughout the European Union, upon a single application and under specific conditions: the right granted is called Community plant variety right (CPVR or Community PVR). Article 1 thereof formally states that the system of Community plant variety rights is the '*sole and exclusive form of Community industrial property rights'* for plant varieties.

The Community plant variety right has uniform effect within the territory of the European Union, which means that its grant, transfer, and termination shall be on a uniform basis throughout the abovementioned territory, according to Article 2 of the Basic Regulation. The Community regime[185] recognizes an exclusive right to the owner of a certain variety having the characteristics required by the Basic Regulation. This system is alternative and independent from national ones.

It is clear from the Preamble that the purpose of the Basic Regulation is to stimulate the breeding and development of new varieties, given the importance of safeguarding

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[184] Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford, pp. 201-202.

[185] By means of the Lisbon Treaty, the European Union took the place of the European Community and became its legal successor. Despite this, the regime created by the Regulation (EC) No 2100/94 is still named '*Community plant variety rights'* system and its implementation and application is still carried out by the '*Community Plant Variety Office'*. In the present contribution the wording 'European Union plant variety rights and 'Community plant variety rights' are going to be indifferently used to indicate the IP regime for plant varieties established by the Regulation (EC) No 2100/94.

agricultural production and the need to supply the EU market with products offering specific features.

In order to implement the rules set out in the text, Article 4 of the Basic Regulation established the Community Plant Variety Office (CPVO), an EU agency governed by European public law, with its own legal personality and its own financial independence. The CPVO is based in Angers, France, and it is managed by its President who is aided by a Vice-President. The tasks of the CPVO includes, *inter alia*, the examination of the applications, the approval of variety denominations, the grant, and the cancellation of Community plant variety rights. All the decisions of the CPVO are taken under the authority of the President, except those made by its Board of Appeal[186]. The Board of Appeal has been established according to Article 45 of the Basic Regulation and it decides on appeals filed against the decisions of the Office. In each case, the Board is made up of three members, technically and legally qualified: a chairman and two other members. The Board of Appeal of the CPVO represents a *'quasi-judicial body'*, as defined by the General Court in the Case T-133/08 (*Ralf Schräder v. CPVO*), resembling the procedures and powers of a court[187].

Pursuant to Article 114 of the Basic Regulation, detailed implementing rules have been adopted for the purpose of applying the Basic Regulation through the Commission Regulation (EC) No 1239/95 of 31 May 1995, subsequently recast by the Commission Regulation (EC) No 874/2009 of 17 September 2009, hereinafter referred to as 'Implementing Rules'. They have been recently amended by the Commission Implementing Regulation (EU) No 2016/1448 of 1 September 2016.

2. Degree of harmonization

The choice of a Regulation lies in the necessity to create a unitary IP right valid throughout European Union, within a distinct system, independent and alternative from national ones. The Community regime co-exists with Member States systems governed by national laws, the content of which is not uniform. The reason for the heterogeneity of

[186] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 19.
[187] Ekvad M., 2018, *The Functioning of the Community Plant Variety Office Board of Appeal,* in Geiger C., Nard C., Seuba X., (eds.), 2018, Intellectual Property and the Judiciary, EIPIN series, Vol. 4, Edward Elgar Publishing.

national laws on IP protection of plant varieties lies in the lack of harmonization at the EU level, differently from other fields of IP rights such as, *inter alia*, trademarks, designs or copyrights.

Nonetheless, substantial dissimilarities have not been noticed in the DUS technical procedures aimed at granting national or EU plant variety rights, at least among EU Member States which are UPOV members as well[188]. By way of illustration, the requirements for the protection of a new plant variety are analogous on both national and the EU levels. According to Article 55 of the Basic Regulation, within the CPVO system the technical examination for a new plant variety application is carried out by national offices designated by the CPVO Administrative Council, which shall follow the CPVO guidelines based on the UPOV standards. Therefore, the result is that the national authorities end up following the same test protocol, i.e. the DUS protocol[189], both for national applications and CPVO ones.

Almost all the EU Member States are UPOV Contracting Parties, thereby the UPOV Convention is being applied by national laws[190], except for Malta, Greece, Luxemburg, and Cyprus, which either do not have a specific law protecting new plant varieties or their laws do not conform with the UPOV standards. Therefore, a question springs up: should the EU harmonize the laws of the Member States on plant variety protection? The issue concerning the lack of a Directive about plant breeder's rights at the national level has been addressed by Van Der Kooij[191]. The author underlines that national laws are not entirely homogeneous among Member States even among Contracting parties of the 1991 UPOV Convention, due to the several optional provisions in the last version of the Convention, e.g. the ones concerning the farmer's privilege[192] and the duration of the protection[193].

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[188] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., pp. 6-7.
[189] The DUS protocol, provided by UPOV, aims at setting out the principles which are used in the examination the distinctiveness, uniformity and stability - ergo, DUS - of new plant varieties.
[190] However, not all the Member States are bound by the same UPOV Convention: some of them follow the 1961 or the 1978 text, other ones the 1991 version.
[191] Van Der Kooij P., 2008, *Towards an EC directive on plant breeder's rights?,* in Journal of Intellectual Property Law and Practice, 3, 2.
[192] See Article 15, paragraph 2 of the 1991 UPOV Convention. Some national laws, e.g. Italian laws, do not recognize the farmer's privilege; while in other countries it refers only to some specific varieties, e.g. in Germany, or sometimes even to all varieties, like in Austria.
[193] See Article 19, paragraph 2 of the 1991 UPOV Convention. The article only establishes minimum terms of duration of the plant variety protection. It follows that some countries apply longer term of protection, for some varieties or for all of them. The consequence is a disadvantageous competitive position for the EU breeders who benefit of a shorter period of protection within the internal market.

A different approach to the optional provisions may result in disparities among national laws which *'may lead to a distortion of competition'*[194] within the internal market, especially because national plant variety rights have not been replaced by Community rights so far: the entry into force of the Basic Regulation in 1995 has not led towards a considerable decrease of the national applications. Hence, the author believes that harmonization is needed and the adoption of a Directive *'would not be superfluous'* in view of the possible distortion of the competition that the current national systems are potentially implementing in the EU internal market[195].

3. Alternativeness of the system

A significant characteristic of Community plant variety protection lies in its alternativeness from Member States national systems since *'it neither substitutes nor harmonizes such national system, but is thought to be an alternative to them*[196]*'*. However, two intellectual property rights on the same plant variety - i.e. the national one and the EU one - could not overlap: a simultaneous claim is not possible according to Article 92 paragraph 1 of the Basic Regulation which states that cumulative protection is prohibited and any cumulative right shall be deemed as ineffective.

National PVRs have not been replaced by Community PVRs: national rights are still granted on new plant variety rights because of the territoriality of some varieties, which can be exploited only in specific countries or even in well-defined areas of a specific country. In such a case, it would be useless to apply for a European Union-wide right for a variety that could be commercially exploited only in a particular country.

In some authors' opinion, *'national rights may be maintained as 'dormant' rights for the time of existence of the Community right, and can be 'revived' once the Community right is no longer effective*'[197]. In other words, national rights have been seen as a further opportunity for the breeder to protect their innovation after the EU plant variety right has expired. However, it is hard to agree with such a point of view.

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[194] Van Der Kooij P., 2008, op. cit.
[195] Ibidem.
[196] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 4.
[197] Ibidem.

Starting from an obvious consideration, the novelty requirement is needed for the grant of the plant variety right, according to Article 6 paragraph 1 of the 1991 UPOV Convention, which has been transposed into the Article 10 paragraph 1 of the Basic Regulation as well as into national laws of UPOV Member States[198]. A variety is deemed as new if, when filing of the application for a plant variety right, the propagating or harvested material of said variety has not been sold or otherwise exploited *'(i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date'*[199]. Considering that the duration of the EU plant variety rights is twenty-five years for varieties that are not vine and tree species, according to Article 19 (1) of the Basic Regulation, it seems unlikely that the variety was not commercially exploited for the whole period and that the variety could be still considered 'new' when the Community right is no longer effective. So, a brand new national right shall not be granted.

In a different scenario, the national right could have been granted before the EU right, with the consequence that the holder is unable to invoke the rights conferred by the national protection for as long as the Community plant variety right remains effective, according to Article 92 paragraph 2 of the Basic Regulation. However, it seems unlikely that after the termination of the Community right, the national law is able to provide the breeder any further year of protection. Indeed, in most of the EU countries that are also UPOV Contracting Parties, e.g. the Netherlands, UK, France, Germany and Denmark, the duration of the protection is twenty-five years[200], as for the CPVO system, and sometimes the duration is even shorter[201]. That means that when the EU breeder's right is no longer effective, there

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[198] For example, Article 6 of the 1991 UPOV Convention has been transposed into Article 103 of the Italian Code of Industrial Property - Decreto Legislativo 10 February 2005, n. 30 - as follows: *'Art. 103. Novità. 1. La varietà si reputa nuova quando, alla data di deposito della domanda di costitutore, il materiale di riproduzione o di moltiplicazione vegetativa o un prodotto di raccolta della varietà non è stato venduto, né altrimenti ceduto a terzi, dal costitutore o con il suo consenso, ai fini dello sfruttamento della varietà: a) sul territorio italiano da oltre un anno dalla data di deposito della domanda; b) in qualsiasi altro Stato da oltre quattro anni o, nel caso di alberi e viti, da oltre sei anni'*.

[199] Article 6 paragraph 1 of the 1991 UPOV Convention.

[200] In case of vine and tree species, the duration is longer, up to 30 years, and in some countries, like Germany, Denmark the Netherlands and UK, the same duration applies to other species, e.g. potatoes.

[201] In light of Article 109, paragraph 1 of the Italian Code of Industrial Property, the duration of the protection is twenty years: *'Art. 109. Durata della protezione. 1. Il diritto di costitutore, concesso a norma di questo codice, dura venti anni a decorrere dalla data della sua concessione. Per gli alberi e le viti tale diritto dura trent'anni dalla data della sua concessione'*, according to Article 19 of the 1991 UPOV Convention which

will be no 'dormant' national right to 'revive'. Therefore, one could meaningfully argue that the national right is *sic et simpliciter* an alternative to the EU breeder's right and it could hardly act as a 'dormant' right.

4. Independence of the system

It is essential to underline that the independence of the Community plant variety protection system does not entail self-sufficiency of said system: indeed, the enforcement of plant variety rights is tied to national systems. In case of infringement of a unitary plant variety rights throughout the European Union, the enforcement is dealt on a national basis, where disputes are litigated before national courts acting as EU courts.

In such a context, the enforcement of Community plant variety rights might be characterized by fragmentation and legal uncertainty, in the sense that there exists the possibility of having opposite rulings in similar cases by different national courts. Also, there is the certainty of not having a harmonized case law in the European Union, not to mention the issues related to the dissimilarity of national judicial procedures and the variability of duration and costs of litigation from one Member State to another. It is worth underlining that only effective enforcement could increase deterrence against plant variety rights infringement.

In this context, the absence of a supranational specialized court may pave the way to expensive and time-consuming parallel lawsuits, it may instigate forum shopping and affect legal certainty, and these factors could undermine the effectiveness of plant variety protection in the European Union. In the field of patent law, these concerns inspired the foundation of the soon-to-be-established Unified Patent Court (UPC)[202], a court common to

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states that *'1. The breeder's right shall be granted for a fixed period. 2. The said period shall not be shorter than 20 years from the date of the grant of the breeder's right. For trees and vines, the said period shall not be shorter than 25 years from the said date'.*

[202] For a more in-depth analysis, see: Marongiu Buonaiuti F., 2016, *The Agreement Establishing a Unified Patent Court and its Impact on the Brussels I Recast Regulation. The new rules introduced under Regulation (EU) No 542/2014 in respect of the Unified Patent Court and the Benelux Court of Justice,* in Cuadernos de Derecho Transnacional; 8, 1; Renghini C., 2018, *Il sistema di tutela brevettuale nell'Unione Europea: il brevetto europeo con effetto unitario e il tribunale unificato dei brevetti,* Doctoral thesis, University of Macerata.

the Contracting Member States which will have exclusive competence about claims on European patents and European patents with unitary effect.

In order to briefly illustrate its functioning, suffice to say that, when hearing a case in accordance with Article 24 of the Agreement, the Court will base its decisions on (a) Union law, including Regulation (EU) No 1257/2012 and Regulation (EU) No 1260/20121; (b) the UPC Agreement; (c) the European Patent Convention; (d) other international agreements applicable to patents and binding on all the Contracting Member States; and (e) national law. The UPC rulings will have effect in the territory of the Contracting Member States which ratified the Unified Patent Court Agreement and the enforcement procedures of the decision, as stated in article 82 of the Agreement, will be governed by the law of the Contracting Member State where the enforcement takes place.

As highlighted in the premises of UPC Agreement, the Court aims at improving the enforcement of patents and it wishes to enhance legal certainty for litigation about the infringement and validity of patents.

The Agreement recognized that innovation is disadvantaged by the different national court systems and, in such context, the most affected subjects are the SMEs because they are the ones facing bigger difficulties to enforce their patents. The solution to this problem may be found in the establishment of a supranational and specialized court that will take into consideration the demand of proportionality and flexibility of the parties and that will guarantee quick and high-quality decisions. For the purpose of the current research, the considerations found in the UPC Agreement must be borne in mind since they explicitly connect IP enforcement through a supranational court with promotion of innovation, especially for SMEs.

In conclusion, the Community plant variety protection system, in spite of its independence, has a vital string attached to national systems that might affect its effectiveness.

5. Definition of breeder and entitlement to Community plant variety rights

The definition of breeder, as the person entitled to Community plant variety rights, is enshrined in Article 11 paragraph 1 of the Basic Regulation and it follows the content of Article 1 (iv) of the 1991 UPOV Convention, stating that '*The person who bred, or*

discovered and developed the variety, or his successor in title, both - the person and his successor - referred to hereinafter as 'the breeder', shall be entitled to the Community plant variety right'.

Like its precursor, Article 11 paragraph 1 does not define the content of the *breeding* notion. However, this wording has been interpreted in Case A 017/2002 by the Board of Appeal of the CPVO as a concept that '*does not necessarily imply inventing something totally new but includes the planting, selection and growing on of pre-existing material and its development into a finished variety'.* Certainly, the use of pre-existing material is intrinsic to plant breeding, which can create new genetic variability only from existent one: again, new plant varieties cannot be created from scratch.

This interpretation paves the way to further unanswered questions: what is then the difference between 'breeding' and 'development'?

The interpretation provided by the CPVO Board of Appeal seems to suggest that the concept of 'development' identifies the final stage of the overall breeding procedure. Also, what does 'finished variety' mean? One might say that 'finished variety' is a synonym of distinct, uniform, and stable variety. However, since the Board of Appeal did not use this wording, the two concepts might not overlap. Again: to what extent does the selection need to be carried out?

The investigation concerning the notion of 'breeding' led some authors[203] to seek a solution in the CPVO technical questionnaire. They implied that the CPVO gave meaning to the notion of breeding through the technical questionnaire linked to the CPVR application form. When filling the questionnaire, the plant variety right applicant is required to provide mandatory *'information on the breeding scheme and propagation of the variety*'. The required information by each questionnaire, which differs from one another depending on the variety involved, might concern the breeding techniques, the parent varieties, the location and time of the discovery, the developing methods, the origin of the variety, the method of propagation et cetera.

However, it does not seem possible to extrapolate a proper definition of breeding on the basis of the questionnaire. After analyzing it, one might meaningfully assume that the key characteristic of the breeding notion is the use of a systematic method in the creative

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[203] See, Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 28.

process: in order to provide the information required by the technical questionnaire, the breeding procedure is supposed to be marked by thoroughness, organization, observation, trials and potentially repeatability.

Having said that, one might wonder what differentiates the 'breeding' process from the 'discovering and developing' one. Indeed, according to the wording of the Articles, there is supposed to be a difference between 'breeding' and 'discover and development' of a new variety. The CPVO Board of Appeal in Case A 001/2004 stated that '*discover means that somebody comes across a variety either by search or by chance, being conscious of the fact that it is a new variety, which was unknown to him before and which in his opinion is unknown to other persons as well*'.

Although a definition of discover has been determined, an interpretation on the concept of 'development' has not been provided by the Board of Appeal so far. Nonetheless, some legal scholars have provided some interesting yet conflicting exegesis. On one side, some authors[204] consider that developing a variety *'could mean simply doing that which is necessary to bring the discovered variety to the European market'.* The rationale behind this interpretation rests on what is believed to be the main objective of the Regulation, i.e. promoting the development of new varieties to be commercially exploited within the internal market. Starting from this analysis, the authors draw the conclusion that the Community plant variety system is *'more monopolistic and commerce-driven than the patent system'* because it does not require an absolute novelty of the new plant variety.

However, this analysis is not acceptable for a twofold reason: 1. it outweighs the 'discover' activity at the expense of the 'development' one: the wording of Article 11 makes it clear that a 'developing' endeavor has to be involved and since there is no progress, no improvement, no modification of the discovered variety, it follows that there is no development; 2. if this was so, the right on such discovered variety shall not be considered an IP right. Suffice to say that intellectual property concern products that are the result of intellectual input. A pre-existing discovered variety is simply not a product of intellectual input, it is not the result of creative endeavor, consequently it shall not receive IP-like protection.

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[204] Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford, pp. 239-241.

On the other side, some authors[205] believe that *'the notion of 'develop' comes quite close to that of 'breeding' in its pure sense*'. Yet, such a statement might make both the definition of 'breeding' and 'development' look redundant and tautological. One might argue, conforming to the interpretation of the CPVO Board of Appeal in Case A 017/2002, that the concept of development of a new variety is not similar to the concept of breeding, but it represents a stage of the breeding procedure. The development of a new variety might be considered the second phase of the overall breeding process, a stage that entails field trials, selection, evaluation, and multiplication of the variety; while the notion of 'breeding' in its broad sense concerns the entire process of creation of a new variety, from A to Z, starting from germplasm collection and parental selection.

From this interpretation, it might be argued that the distinction between 'breeding' and 'discovering and developing' a new variety relies on the different premises of the two scientific procedures.

Aside from the definition of 'breeder' and 'breeding', Article 11 of the Basic Regulation deals with the entitlement of Community plant variety rights. As stated in the abovementioned paragraph 1, it is entitled to CPVRs the person who bred, or discovered and developed the variety or their successor in title. However, plant breeding is often not a one-person-job but the result of teamwork. This situation was taken into account in paragraphs 2 and 3 of Article 11, which establish a joint entitlement of the CPVR in the following cases: *'2. If two or more persons bred, or discovered and developed the variety jointly, entitlement shall be vested jointly in them or their respective successors in title. This provision shall also apply to two or more persons in cases where one or more of them discovered the variety and the other or the others developed it. 3. Entitlement shall also be invested jointly in the breeder and any other person or persons, if the breeder and the other person or persons have agreed to joint entitlement by written declaration'.* Therefore, in such a scenario, more than one person will be entitled to the Community plant variety right.

Article 11 differentiates itself from Article 1 (iv) of the 1991 UPOV Convention regarding the entitlement to the plant breeder's right on a new plant variety bred or discovered and developed by the employee of the person who has commissioned the work. According to Article 1 (iv) of the 1991 Act of the UPOV Convention, the employer of the

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[205] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 30.

person who bred, or discovered and developed, the new variety or who has commissioned the latter's work, is the breeder of the variety, where the laws of the relevant Contracting party so provide. Differently, Article 11 (4) of the Basic Regulation states that '*If the breeder is an employee, the entitlement to the Community plant variety right shall be determined in accordance with the national law applicable to the employment relationship in the context of which the variety was bred, or discovered and developed'*. The provision provides that the national law[206] applicable to the employment relationship shall define the subject entitled to the CPVR on the new plant variety[207]. In so doing, it sets an exception to the rule stated in Article 11 paragraph 1, which establishes that only the breeder is entitled to CPVR.

6. Definition of plant variety

The definition of variety set out in Article 5 (2) of the Basic Regulation literally reproduces the wording of Article 1 (vi) of the 1991 Act of the UPOV Convention, the meaning thereof is so far undisputed and also consistent with the definition provided by the European Patent Convention (Rule 26 paragraph 4 of the Implementing Regulations to the Convention on the Grant of European Patents), as already mentioned above.

Unlike the 1991 UPOV definition of plant variety, Article 5 (1) of the Basic Regulation explicitly refers to 'hybrids' as the object of Community plant variety rights, even though it does not provide a legal definition of 'hybrid'. Therefore, hybrid varieties fall within the scope of the definition of a plant variety under the Regulation (EC) No 2100/94.

Moreover, the Basic Regulation defines the notion of 'plant grouping' in its Article 5 (3), stating that *'a plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred to hereinafter as 'variety*

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[206] For example, Article 111 of the Italian Industrial Code deals with property rights of new plant varieties and its paragraph 2 states that *'If the new plant variety is created in the context of employment relationship, Article 64 shall apply'*. Suffice to say that the referred-to Article 64 affirms in its paragraph 1 that *'1. When an industrial invention is made in the performance or fulfillment of a contract or work or employment relationship, in which the inventive activity is contemplated by the contract or relationship and is remunerated for that purpose, the rights deriving from the invention belong to the employer, without prejudice to the right for the inventor to be acknowledged as the author'*.

[207] It is worth mentioning that the last paragraph of Article 11 states that *'5. Where entitlement to a Community plant variety right is vested jointly in two or more persons pursuant to paragraphs 2 to 4, one or more of them may empower the others by written declaration to such effect to claim entitlement thereto'*. It has been affirmed that this provision might be superfluous (Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 30) since entitlement is considered to be as transferable as any other good.

constituents'. This provision clearly illustrates that even a grouping of plant cells, capable of producing entire plants, could represent a 'variety' for the purpose of the Basic Regulation.

As it might be easily noticed, the paragraph introduced a new expression: i.e. 'variety constituents'. Even though the wording is new, the concept thereof is familiar: 'variety constituents' is used as a synonym for the 'propagating material', which is used in the Basic Regulation as well (e.g. in Article 14 paragraph 1)[208].

7. Genera and species

As illustrated in Article 5 (1) of the Basic Regulation, *'varieties of all botanical genera and species, including, inter alia, hybrids between genera or species'* may form the object of Community PVRs[209]. 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[210].

The extensive protection provided by this paragraph of the Basic Regulation is consistent with the goal of the 1991 Act of the UPOV Convention, which required Contracting parties to recognize plant breeders' rights (i.e. plant variety rights) on all botanical genera and species in order to promote the harmonization among UPOV Member States and to prevent PBR infringements.

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[208] Van Der Kooij P.,1997, *Introduction to the EC Regulation on Plant Variety Protection*, Kluwer Law International, p. 13.

[209] Even if most hybrids result from crossing processes within the same taxon (e.g. maize), the Regulation underlines that even hybrids that are the offspring of breeding between different genera or species are protectable subject matter. For further insights, see Van Der Kooij P.,1997, *Introduction to the EC Regulation on Plant Variety Protection*, Kluwer Law International, p. 12. The author underlines that also *"varieties of mushroom and other fungi can be protected, although such varieties are not considered to be plant varieties within the usual meaning"*.

[210] It is worth mentioning that the Regulation does not provide a definition of 'botanical genera and species'.

8. Conditions of protection

8.1. The DUS requirement

In order to be protectable under the Community plant variety protection 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 denomination in accordance with the provisions of Article 63'*.

As shown in the previous paragraphs, the same conditions are listed in the 1991 UPOV Convention. The first three technical conditions form the so-called DUS requirement, which deals with the phenotypical characteristics of the plant variety resulting from a certain genotype. As a general rule, the Basic Regulation does not require any commercial or cultivation value of the new plant variety (i.e. value for cultivation and use or VCU). The duration of the DUS technical examination for the grant of Community PVRs varies from one year for most ornamental species to six years for certain fruit tree varieties[211].

Article 7 of the Basic Regulation concerns the distinctness requirement and it slightly differs from the wording of the 1991 UPOV Convention by adding that the distinctness has to be determined *'by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes'*[212]. The provision clarifies that the distinctness requirement has to be assessed through a phenotypic evaluation of the variety. Therefore, the characteristics that distinguish a variety are supposed to imply a certain degree of observability, *ergo* they should be externally visible in the field during the technical examination carried on by one of the entrusted examination offices of the CPVO network.

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[211] Source: CPVO website https://cpvo.europa.eu/en/applications-and-examinations. Last access: May 2019

[212] Article 7 of the Regulation (EC) No 2100/94, Distinctness: *'1. A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application determined pursuant to Article 51. 2. The existence of another variety shall in particular be deemed to be a matter of common knowledge if on the date of application determined pursuant to Article 51: (a) it was the object of a plant variety right or entered in an official register of plant varieties, in the Community or any State, or in any intergovernmental organization with relevant competence; (b) an application for the granting of a plant variety right in its respect or for its entering in such an official register was filed, provided the application has led to the granting or entering in the meantime. The implementing rules pursuant to Article 114 may specify further cases as examples which shall be deemed to be a matter of common knowledge'*.

Those characteristics might be externally observable even only under specific circumstances, in a certain period of time or in a well-defined environment.

As in the 1991 UPOV Convention, Article 7 (2) of the Basic Regulation affirms that the new plant variety has to be distinct from other varieties whose existence is *a matter of common knowledge* on the date which a valid application for the grant of a PVR has been received by the CPVO or by an entitled national agency. 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. Moreover, in its decision of 3 June 2002 (Case 023/2002, *Comtesse Louise Erdody*), the CPVO Board of Appeal expanded the criteria of *common knowledge* taking into account the aspects considered in one of the UPOV Test Guidelines Procedures. This document states that, in order to establish common knowledge of a plant variety, the commercialization of propagating material and the existence of living plant material in publicly accessible plant collections have to be considered. Therefore, a variety that has been offered to sale and maintained in a botanical garden open to the public shall be considered to be of common knowledge. This interpretation extends the notion of common knowledge beyond the literal wording of the provision under analysis.

Even the Court of Justice of the European Union had the chance to answer a question regarding the meaning of common knowledge in plant variety protection. In its decision of 15 April 2010 (Case C-38/09, *Schräder v. CPVO*), the Court confirmed the interpretation provided by the UPOV, in particular by the point 5.2.2.1 '*Common Knowledge'* of the UPOV Document TG/1/3 of 19.04.2002, which reads as follows: *'the publication of a detailed description is, inter alia, one of the aspects which should be taken into consideration in order to establish common knowledge'*.

The debate connected to a balanced application of the distinctness requirement is strictly related to the remarkable meaning of such a requirement in the overall plant variety protection system: distinctness represents the main pillar providing the logical basis of IP protection for new plant varieties. Indeed, using the words of Würtenberger, Van Der Kooij, Kiewiet, Ekvad, '*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'[213].

Article 8 of the Basic Regulation deals with the uniformity condition of protectable varieties. This provision is similar to the one concerning uniformity in the UPOV Convention; the only difference concerns the clarification added in its final part[214]. Instead of stating that the new crop has to be *'sufficiently uniform in its relevant characteristics'* as laid down in Article 8 of the UPOV Convention, it says that 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'*. This added part does not seem to deviate from the UPOV text: it appears that the legislator wanted to emphasize the role of the expressed characteristics of the candidate variety when assessing its uniformity.

Compliance with this requirement does not entail that the candidate variety shall be entirely uniform. The use of the word 'sufficiently' makes it clear that limited variation is expected and tolerated: it is rooted in the nature of plants as living organisms and connected to the propagation of the variety. Consequently, the level of uniformity and the determination of off-types differ from one variety to another, depending on the method of plant propagation in question[215] and whether the candidate crops are hybrids or not[216].

Article 9 of the Basic Regulation laid down the stability condition for CPVP[217] and, like for the uniformity requirement, the sentence '*expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description'* took the place of the UPOV wording *'relevant characteristics'*. Therefore, no

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[213] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 39.

[214] Article 8 of the Regulation (EC) No 2100/94, Uniformity: '*A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is 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'*.

[215] Briefly, plant reproduction may be accomplished sexually or asexually. Sexual reproduction in plants relies on the key role of pollination, which might be either self-pollination or cross-pollination. Unless mutation occurs, the offspring produced by means of asexual pollination are genetically identical to the parent plant, unlike sexually reproduced plants which differ from the parent plant (or plants).

[216] The UPOV General Introduction and DUS Test Guidelines, already mentioned in the previous paragraph, are the benchmarks against which the level of uniformity is usually measured.

[217] Article 9 of the Regulation (EC) No 2100/94, Stability: *'A variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle'*.

substantial dissimilarity shall be noticed between the two provisions. As illustrated by Article 9, stability concerns the capability of the plant to '*remain unchanged after repeated propagation*'. It has been highlighted that this requirement is particularly hard to test (the wording 'remain unchanged' implies that 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[218]. 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 such reason, it has been argued that stability tends to be more *'the expression of an expectation than the reflection of a fact*'[219].

Nevertheless, stability has proved to be linked with uniformity so it can be assessed in connection with it. As stated in the already-mentioned UPOV General Introduction: *'7.3.1.1 In practice, it is not usual to perform tests of stability that produce results as certain as those of the testing of distinctness and uniformity. However, experience has demonstrated that, for many types of variety, when a variety has been shown to be uniform, it can also be considered to be stable. Furthermore, if the variety is not stable, material produced will not conform to the characteristics of the variety, and where the breeder is unable to provide material conforming to the characteristics of the variety, the breeder's right may be cancelled. 7.3.1.2 Where appropriate, or in cases of doubt, stability may be tested, either by growing a further generation, or by testing a new seed or plant stock to ensure that it exhibits the same characteristics as those shown by the previous material supplied. Further guidance on the examination of stability is considered in document TGP/11, 'Examining Stability'*[220]. As a result, a candidate variety is deemed to be stable when it is proved to be uniform during the field test.

When it is established that a protected variety no longer meets the requirements set in Article 8 or 9 of the Basic Regulation, the CPVO will cancel the CPVR on that variety *with effect in futurum*, according to Article 21 of the Basic Regulation.

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[218] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p.46.
[219] Ibidem.
[220] UPOV, 2002, *General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants*, TG/1/3, Geneva.

It has been argued that, when it is established that a variety is no longer stable, this variety has not been stable from the beginning: it follows that the CPVR shall be declared null and void instead of being canceled[221]. This interpretation seems utterly valid and it is strictly connected to the intrinsic nature of the stability requirement which concerns the condition of the variety to remain unchanged in its expressed characteristics from one generation to the next one. The Basic Regulation does not refer to a particular window, therefore one might assume that this requirement has to be maintained over time. In conclusion: either a variety has been stable *ab initio,* or it never was.

As already mentioned, distinctness, uniformity, and stability are tested during a technical examination of the candidate variety aimed to assess whether these requirements are met. This technical examination is not conducted by the CPVO itself, which does not have a technical infrastructure. Instead, the examination is carried out 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[222]. 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[223].

The CPVO Technical Unit provides the Examination Offices with several technical guidelines and protocols aimed at harmonizing the determination of whether a CPVR shall

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[221] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 47.

[222] Article 55 of the Regulation (EC) No 2100/94, Technical examination*: '1. Where the Office has not discovered any impediment to the grant of a Community plant variety right on the basis of the examination pursuant to Articles 53 and 54, it shall arrange for the technical examination relating to compliance with the conditions laid down in Articles 7, 8 and 9 to be carried out 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 by the Administrative Council, hereafter referred to as the 'Examination Office or Offices'. 2. Where no Examination Office is available, the Office may, with the consent of the Administrative Council, entrust other appropriate agencies with responsibility therefore or establish its own sub-offices for the same purposes. For the purpose of the provisions of this Chapter, such agencies or sub-offices shall be considered as Examination Offices. They may avail themselves of facilities made available by the applicant. 3. The Office shall forward to the Examination Offices copies of the application as required under the implementing rules pursuant to Article 114. 4. The Office shall determine, through general rules or through requests in individual cases, when, where and in what quantities and qualities the material for the technical examination and reference samples are to be submitted. 5. Where the applicant makes a claim for priority pursuant to Article 52 (2) or (4), he shall submit the necessary material and any further documents required within two years of the date of application pursuant to Article 51. If the earlier application is withdrawn or refused before the expiry of two years, the Office may require the applicant to submit the material or any further documents within a specified time limit'.*

[223] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., op. cit., p. 76.

be granted or not. The Examination Offices shall conduct the DUS test in accordance with those guidelines and following the instructions given by the Office, as provided for in Article 56 of the Basic Regulation[224]. Detailed protocols adopted by the CPVO Administrative Council exist in each of the four crop sectors, i.e. 1) agricultural; 2) vegetable; 3) ornamental and forestry; 4) fruit. Every protocol refers to a specific botanical taxon in each crop sector and it describes the technical procedures to be followed during the technical examination. The list of protocols is updated on a regular basis by the CPVO, with additions of new protocols and revisions to existing ones: currently, there are 194 protocols[225].

The CPVO technical documents used in the DUS testing rest upon the UPOV guidelines. These guidelines recommend the characteristics to take into consideration during the DUS evaluation with regard to all botanical genera and species. The UPOV protocols are not directly translatable into the Community plant variety protection system because of their optional provisions[226]. It is important to highlight that the CPVO guidelines, even when they are based on the UPOV protocols, are independent of those of other jurisdictions and the CPVO is not obliged to accept their findings, although they are all UPOV-based. The CPVO Board of Appeal has remarked this aspect in Case A 003/2003 (*Prophyl Pty Ltd and Swane Bros Pty Ltd vs CPVO*), whose decision reads as follows: *'the fact that a plant variety right has been granted for Probril in other UPOV-member states did not oblige the Office to take over their test reports or their decisions. The Community system is independent –*

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[224] Article 56 of the Regulation (EC) No 2100/94, The conduct of technical examinations: *'1. Unless a different manner of technical examination relating to compliance with the conditions laid down in Articles 7 to 9 has been arranged, the Examination Offices shall, for the purposes of the technical examination, grow the variety or undertake any other investigations required. 2. The conduct of any technical examinations shall be in accordance with test guidelines issued by the Administrative Council and any instructions given by the Office. 3. For the purposes of the technical examination, the Examination Offices may, with the approval of the Office, avail themselves of the services of other technically qualified bodies and take into account the available findings of such bodies. 4. Each Examination Office shall begin the technical examination, unless the Office has otherwise provided, no later than on the date on which a technical examination would have begun on the basis of an application for a national property right filed on the date on which the application sent by the Office was received by the Examination Office. 5. In the case of Article 55 (5), each Examination Office shall begin the technical examination, unless the Office has otherwise provided, no later than on the date on which an examination would have begun on the basis of an application for a national property right, provided the necessary material and any further documents required were submitted at that date. 6. The Administrative Council may determine that the technical examination for varieties of vine and tree species may begin at a later date'*.

[225] Source: https://cpvo.europa.eu/en/applications-and-examinations/technical-examinations/technical-protocols?t=&field_crop_sector_tid=All&order=field_crop_sector&sort=asc. Last access: April 2018.

[226] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., pp. 36-37.

and different – from their systems. The Office has to examine the application in accordance with the provisions of the Council Regulation'.

The President of the CPVO has the power to add further characteristics to be tested during the technical examination for the DUS assessment of a candidate variety. In particular, in its judgment of 08.06.2017 (Case C-625/15, *Schniga GmbH v. CPVO*), the Court of Justice of the European Union stated that: '*the CPVO's task is characterised by the scientific and technical complexity of the conditions governing the examination of applications for Community plant variety rights and, accordingly, the CPVO must be accorded a broad discretion in carrying out its functions (see, to that effect, judgment of 19 December 2012, Brookfield New Zealand and Elaris v CPVO and Schniga, C-534/10 P, EU:C:2012:813, paragraph 50). […] In those circumstances, only the flexibility that allows the recognised power of the President of the CPVO, under Article 23(1) of the implementing regulation, to insert additional characteristics in respect of a variety is also capable of ensuring the objectivity of the procedure for granting Community plant variety rights'.* Therefore, in the view of the Court of Justice, the President of the CPVO has the power to add a new characteristic in the technical examination of a variety, even if that characteristic was not mentioned to in either the technical questionnaire or in the test guidelines/protocols.

Upon conclusion of the DUS examination, the Examination Office has to send an examination report to the CPVO when requested by the CPVO itself or if the Examination Office considers the results of the test adequate to evaluate the variety, as laid down in Article 57 of the Basic Regulation[227]. Where the Examination Office deems that the DUS conditions are met, it shall send a description of the variety to the CPVO as well. Subsequently, the CPVO has to communicate the results of the technical examinations and the description of the variety to the applicant, who has the opportunity to comment thereon.

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[227] Article 57 of the Regulation (EC) No 2100/94, Examination reports: *'1. The Examination Office shall, at the request of the Office or if it deems the results of the technical examination to be adequate to evaluate the variety, send the Office an examination report, and, where it considers that the conditions laid down in Articles 7 to 9 are complied with, a description of the variety. 2. The Office shall communicate the results of the technical examinations and the variety description to the applicant and shall give him an opportunity to comment thereon. 3. Where the Office does not consider the examination report to constitute a sufficient basis for decision, it may provide of its own motion, after consultation of the applicant, or on request of the applicant for complementary examination. For the purposes of assessment of the results, any complementary examination carried out until a decision taken pursuant to Articles 61 and 62 becomes final shall be considered to be part of the examination referred to in Article 56 (1). 4. The results of the technical examination shall be subject to the exclusive rights of disposal of the Office and may only otherwise be used by the Examination Offices in so far as this is approved by the Office'.*

The applicant has the responsibility to provide suitable plant material for the DUS testing purposes on the date of the application for a Community PVR, as individuated in Article 51 of the Basic Regulation[228]. As stated by the CPVO Board of Appeal in the abovementioned Case A 003/2003: *'the variety applied for must fulfil the conditions for the grant of a community plant variety right at the date of application. This date is relevant for the period of grace (cp. Art. 10 CR). The space of time between the date of application and the testing is not meant to permit further breeding activities for the elimination of any lack of DUS criteria. The original plant material is not replaceable by further developed material'*. Therefore, an applicant cannot conduct, after the date of application, further breeding activities aimed at improving the candidate variety with the purpose of resubmitting the plant material: the main rule is that the candidate variety shall meet the DUS requirement on the date of application, at the latest.

8.2. The novelty requirement

The analysis segues from the DUS requirement to the novelty one, which cannot be tested through field trials, unlike distinctness, uniformity, and stability. As above mentioned, it is important to underline one more time that 'novelty' and 'distinctness' in plant variety protection are two different concepts, unlike patent law[229].

The novelty requirement is laid down in Article 10 of the Basic Regulation[230] and its first paragraph contains the main rule, which follows the content of Article 6 of the 1991

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[228] Article 51 of the Regulation (EC) No 2100/94, Date of application: *'The date of application for a Community plant variety right shall be the date on which a valid application was received by the Office pursuant to Article 49 (1) (a) or by a sub-office or national agency pursuant to Article 49 (1) (b), provided it complies with Article 50 (1) and subject to payment of the fees due pursuant to Article 83 within a time limit specified by the Office'.*

[229] Van Der Kooij P.,1997, *Introduction to the EC Regulation on Plant Variety Protection*, Kluwer Law International, p. 15.

[230] Article 10 of the Regulation (EC) No 2100/94, Novelty: '*1. A variety shall be deemed to be new if, at the date of application determined pursuant to Article 51, variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with the consent of the breeder within the meaning of Article 11, for purposes of exploitation of the variety: (a) earlier than one year before the abovementioned date, within the territory of the Community; (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 Community. 2. The disposal of variety constituents to an official body for statutory purposes, or to others on the basis of a contractual or other legal relationship solely for production, reproduction, multiplication, conditioning or storage, shall not be deemed to be a disposal to others within the meaning of paragraph 1, provided that the breeder preserves the exclusive right of disposal of these and other variety constituents, and no further disposal is made. However, such disposal of variety constituents shall be deemed to be a disposal in terms of paragraph 1 if these constituents*

Act of the UPOV Convention[231]. The paragraph states the principle upon which, in order to be protected with CPVR, variety constituents or harvested material of the candidate variety shall 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 shall not have taken place (a) earlier than one year before 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.

In order to establish the time limit for novelty, Article 51 of the Basic Regulation has to be taken into account. The Article specifies that 'date of application' for Community PVR means the date on which a *valid* application was received by the CPVO or by a sub-office or national agency, provided that the conditions governing applications set out in Article 50 are met[232] and the fees are paid within a time limit indicated by the Office.

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are repeatedly used in the production of a hybrid variety and if there is disposal of variety constituents or harvested material of the hybrid variety. Likewise, the disposal of variety constituents by one company or firm within the meaning of the second paragraph of Article 58 of the Treaty to another of such companies or firms shall not be deemed to be a disposal to others, if one of them belongs entirely to the other or if both belong entirely to a third such company or firm, provided no further disposal is made. This provision shall not apply in respect of cooperative societies. 3. The disposal of variety constituents or harvested material of the variety, which have been produced from plants grown for the purposes specified in Article 15 (b) and (c) and which are not used for further reproduction or multiplication, shall not be deemed to be exploitation of the variety, unless reference is made to the variety for purposes of that disposal. Likewise, no account shall be taken of any disposal to others, if it either was due to, or in consequence of the fact that the breeder had displayed the variety at an official or officially recognized exhibition within the meaning of the Convention on International Exhibitions, or at an exhibition in a Member State which was officially recognized as equivalent by that Member State'.

[231] The only difference concerns the use of the wording 'variety constituents' instead of 'propagating material' which have a comparable meaning, as said above.

[232] Article 50 of Regulation (EC) No 2100/94, Conditions governing applications: *'1. The application for a Community plant variety right must contain at least the following: (a) a request for the grant of a Community plant variety right; (b) identification of the botanical taxon; (c) information identifying the applicant or, where appropriate, the joint applicants; (d) the name of the breeder and an assurance that, to the best of the applicants knowledge, no further persons have been involved in the breeding, or discovery and development, of the variety; if the applicant is not the breeder, or not the only breeder, he shall provide the relevant documentary evidence as to how the entitlement to the Community plant variety right came into his possession; (e) a provisional designation for the variety; (f) a technical description of the variety; (g) the geographic origin of the variety; (h) the credentials of any procedural representative; (i) details of any previous commercialization of the variety; (j) details of any other application made in respect of the variety. 2. Details of the conditions referred to in paragraph 1, including the provision of further information, may be laid down in the implementing rules pursuant to Article 114'.*
3. An application shall propose a variety denomination which may accompany the application.

The importance of establishing the exact date of application is strictly connected with the right of priority in accordance with Article 52 of the Basic Regulation: the right of priority is determined by the date when the application is received and, in case the date is the same, by the order in which they were received. Also, according to paragraph 2 of Article 52, in case the breeder has already applied for a PVR in a EU Member State or in a UPOV Member State, and the date of application for a Community PVR is within 12 months of the filing of the earlier application, the applicant enjoys a right of priority for the earlier application in regard to the application for the Community PVR, only if the earlier application still exists on the date of application. The right of priority has the effect to consider as the date of application for Community PVR the date when the earlier application was filed.

Paragraphs 2 and 3 of Article 10 of the Basic Regulation further explicate, respectively, the limit of the notions of 'disposal to others' and 'exploitation of the variety' within the meaning of paragraph 1.

Article 10 (2) clarifies the content of paragraph 1 indicating that the disposal of variety constituents to an official body or to others, for the purposes therein listed, is not a prejudice to novelty *'provided that the breeder preserves the exclusive right of disposal of these and other variety constituents, and no further disposal is made'*. Consequently, as long as the breeder maintains their right of disposal, novelty is not affected. However, paragraph 2 establishes a further clarification: when variety constituents are repeatedly used in the production of a hybrid variety (so-called *parental lines*) and there is a disposal of variety constituents or harvested material of such hybrid variety, the novelty of the parental lines of these hybrids is prejudiced. In other words, parental lines lose their novelty via the commercial exploitation of the hybrid variety.

Article 10 (3) contains a further specification of the main novelty rule enshrined in paragraph 1, stating that the disposal of variety constituents or harvested material for acts done for experimental purposes (Article 15, b) and acts done for the purpose of breeding or discovering and developing other varieties (Article 15, c) shall not be considered 'exploitation' within the meaning of paragraph 1, where such material is not used for further reproduction or multiplication and unless reference is made to the variety for purposes of that disposal. The same principle applies if the variety is displayed at an official exhibition

within the meaning of the Convention on International Exhibitions (Paris, 22 November 1928).

8.3. The variety denomination

As required by Article 6 of the Basic Regulation, in order to be protected a variety must be designated by a denomination in accordance with the provisions of Article 63, which is consistent with Article 20 of the 1991 UPOV Convention. The variety denomination enables the identification of the variety and it is intended to be its generic designation.

When applying for a Community PVR, the applicant must propose a denomination for the variety in question which may accompany the application (Article 50 (3) of the Basic Regulation). Pursuant to Article 28 (1) of the Regulation (EC) No 874/2009 of 17 September 2009 (so-called 'Implementing Rules') said proposal should be signed and filed at the Office.

The Office shall immediately communicate to the applicant when the denomination proposal does not accompany the application or when a proposed denomination cannot be approved, requiring him to submit a new proposal and indicating the consequences of failure to do so (Article 29 (1) of the Implementing Rules). In case the applicant has not corrected the deficiencies or submitted any proposal for a variety denomination at the time of receipt of the results of the DUS technical examination by the CPVO, the Office shall without delay refuse the application for a Community PVR.

When granting the Community PVR, the Office shall examine the suitability of the variety denomination in accordance with Article 63: a variety denomination is suitable if there is no impediment pursuant to paragraphs 3 or 4 of said Article. Basically, the impediments are consistent with the provisions set out in Article 20 of the 1991 UPOV Convention.

Pursuant to Article 63 (3) of the Basic Regulation, 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.

As determined by Article 63 (4) of the Basic Regulation, there is another impediment where, in the case of a variety which has already been entered: (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 down in the Directives on Common Catalogues; in an official register of plant varieties or material thereof and has been marketed there for commercial purposes, and the proposed variety denomination differs from that which has been registered or used there, unless the latter one is the object of an impediment pursuant to paragraph 3.

In accordance with Article 30 of the Implementing Rules, the Administrative Council adopted guidelines in order to establish uniform and definitive criteria for determining impediments to the generic designation of a variety denomination referred to in Article 63 (3) and (4) of the Basic Regulation[233].

According to Article 17 (1) of the Basic Regulation, if a trademark, trade name or similar indication is associated with the designated denomination, this denomination must be easily recognizable as such. Indeed, such a trademark should not be confused with the variety denomination.

As already said, the variety denomination as such is destined to be the generic name for the variety to be used for all the relevant crops and reproductive material of that variety. In light of this, the variety denomination as such cannot be trademarked in the EU for the same plant variety because it is devoid of any distinctive character and it designates the kind and quality of the goods, in contrast to the relevant legislation on the EU trademark.

This principle has been formally introduced by Regulation (EU) No. 2015/2424, amending Regulation (EC) No. 207/2009 on the Community trademark, replaced by

[233] These guidelines on Article 63 are available on the CPVO website. See the following webpage: https://cpvo.europa.eu/sites/default/files/documents/lex/guidelines/VD_Guidelines_explanatory_note_EN.pdf. Last access May 2019.

Regulation (EU) No. 2017/1001 on the European Union trademark (also referred to as the 'EUTM Regulation'). According to Article 7(1)(m) thereof, trademarks in conflict with earlier registered variety denominations cannot be registered, representing an absolute ground for refusal. In particular, refusal is provided for trademarks which consist of, or reproduce in their essential elements, an earlier plant variety denomination registered in accordance with Union legislation or national law, or international agreements to which the Union or the Member State concerned is a party, providing for protection of plant variety rights, and which are in respect of plant varieties of the same or closely related species.

Therefore, four requirements provide for the EU trademark refusal with regard to variety denomination of protected varieties: 1. the existence of a registered variety denomination on a protected variety, even if its protection has expired or been surrendered or terminated, at the national or EU level, including UPOV Member States; 2. the variety denomination was registered before the application for the EU trademark; 3. the EU trademark consist of or reproduces in its essential elements such variety denomination; 4. in the EU trademark application, the specification of the goods includes plant varieties of the same species as those protected by the registered plant variety denomination, or of a species closely related to[234].

Consequently, a certain plant variety covered by CPVRs can be associated to a trademark but the variety denomination as such cannot be trademarked in the EU for the same species or for closely related ones.

Article 7(1)(m) of the EUTM Regulation exclusively refers to variety denominations of plant varieties covered by Community plant variety right or national right. However, the same principle should extend to the denomination of plant varieties listed in the Common Catalogues and marketed in the EU, according to the EU seed legislation[235], even if a PVR on the relevant variety has not been granted.

In this context, a trademark for a specific plant variety which consists of, or reproduces in its essential elements, an earlier variety denomination for the same variety marketed throughout the EU and listed in the Common Catalogues, does not meet the specific EU trademark requirements for the following reasons: it may be devoid of distinctive character

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[234] EUIPO, 2017, *Guidelines for Examination of European Union Trade Marks. Absolute Grounds for Refusal - Trade Marks in conflict with earlier Plant Variety Denominations*, Version 1.0, Alicante, p. 4.
[235] The EU seed legislation is going to be addressed in Chapter four of the current investigation.

(Article 7(1)(b) of the EUTM Regulation); it may designate the kind and quality of the goods (Article 7(1)(c) of the EUTM Regulation) and it may become customary (Article 7(1)(d) of the EUTM Regulation). These three elements represent grounds for the refusal of the trademark application.

Therefore, even though Article 7(1)(m) does not refer to variety denomination of plant varieties listed in the Common Catalogues, their variety denominations cannot be trademarked for the same variety, according to Article 7(1)(b) or (c) or (d) of the EUTM Regulation, unless they have acquired distinctiveness under the conditions set out in Article 7 of the EUTM Regulation[236].

9. Application for the grant of the Community PVR

This paragraph will briefly examine the procedure before the CPVO when applying for a Community plant variety right. It is important to bear in mind that the examination of an application is threefold: formal, substantive, and technical. The aspects related to the technical examination of the DUS criteria have been already analyzed in the relevant paragraph.

As provided for in Article 12 paragraph 1 of the Basic Regulation, an application for the grant of the Community PVR may be filed by any natural or legal person provided that they are *'(a) nationals of one of the Member States or nationals of a member of the Union for the Protection of New Varieties of Plants within the meaning of Article 1 (xi) of the Act of 1991 of the International Convention for the Protection of New Varieties of Plants, or are domiciled or have their seat or an establishment in such a State; (b) nationals of any other State who do not meet the requirements laid down in (a) in respect of domicile, seat or establishment, in so far as the Commission, after obtaining the opinion of the Administrative Council referred to in Article 36, has so decided. Such a decision may be made dependent on the other State affording protection for varieties of the same botanical taxon to nationals of all the Member States, which corresponds to the protection afforded pursuant to this Regulation; the Commission shall establish whether this condition is met'*. In other words,

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[236] Article 7 (3) of the EUTM Regulation: *'Paragraph 1(b), (c) and (d) shall not apply if the trade mark has become distinctive in relation to the goods or services for which registration is required as a consequence of the use which has been made of it'.*

the main rule is that the right to apply for a CPVR in the European Union is limited to individuals that are either nationals of one of the Member States or nationals of UPOV Member State, or to companies that are domiciled or have their seat or an establishment therein. Exceptions for nationals of any other State might be decided by the EU Commission. As stated in Article 82 of the Basic Regulation, persons who are not domiciled or do not have a seat or an establishment within the territory of the European Union may apply for Community PVR only if they have designated a procedural representative who is domiciled or has their seat or an establishment within the EU territory. Article 12 (2) of the Basic Regulation also states that a CPVR application might be filed jointly by two or more of such persons.

According to Article 49 (1) of the Basic Regulation, the application for CPVR can be made directly to the CPVO or to one of the sub-offices or national agencies, established or entrusted, in a Member State, which will forward the application and a confirmation of receipt to the CPVO. As set out in Article 16 (1) of the Implementing Rules, the application made at the CPVO may be filed in paper format or by electronic means.

For the purposes of filing an application, the CPVO provides an application form, a technical questionnaire, and a form for forwarding such information, indicating the consequences of any failure of the forwarding, pursuant to Article 16 (3) of the Implementing Rules. The forms are free of charge and they have to be filled out and signed by the applicant[237].

As laid down in Article 34 (2) of the Regulation, the application, the documents required to process said application, and all other papers submitted shall be filed in one of the official languages of the European Union, which are currently 24.

The application must contain the information listed in Article 50 of the Basic Regulation, which includes: a request for the grant of a Community PVR; identification of the botanical taxon; applicant's information; name of the breeder and a declaration that 'to the best of the applicants knowledge' no further persons have been involved in the breeding or discovery and development of the candidate variety; an interim variety designation; technical description of the variety; geographic origin of the variety; information about any procedural

[237] According to Article 57 (3) of the Implementing Rules, in case a document is submitted to the CPVO by electronic means, it shall contain an electronic signature.

representative; details of any previous commercialization of the variety[238]; details of any other application made for PVR on the variety[239]. Also, the application shall contain the details listed in Article 19 paragraph 2 of the Implementing Rules, as amended in 2016[240]. In addition, in case the variety concerned represents a genetically modified organism within the meaning of Article 2 paragraph 2 of Directive 2001/18/EC, the CPVO might require the applicant to forward the written attestation of the responsible authorities stating that a technical examination of the variety does not pose risks to the environment and the human health.

Upon receiving the application, the CPVO shall issue a receipt to the applicant including the file number, the number of documents received, the date of receipt at the CPVO

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[238] I.e. date and country of any first disposal within the meaning of Article 10 of the Regulation, or if, in the absence of such disposal a declaration is made that no such disposal has occurred, as required by Article 18 paragraph 2 of the Implementing Rules.

[239] I.e. date and the country indicated in respect of: - an application for a property right in respect of the variety, and - an application for official acceptance of the variety for certification and marketing where official acceptance includes an official description of the variety; in a Member State or as a Member of the UPOV, in accordance with Article 18 paragraph 3 of the Implementing Rules.

[240] Article 19 (2) of Regulation (EU) 2016/1448 of 1 September 2016 amending Regulation (EC) No 874/2009 *'2. The applicant shall provide the following information in the application form or in the technical questionnaire referred to in Article 16(3)(a), where relevant: (a) the identity and the contact details of the applicant, his designation as a party to proceedings referred to in Article 2 and, where appropriate, the name and address of the procedural representative; (b) where the applicant is not the breeder, the name and address of the breeder and his entitlement to apply for the Community plant variety right; (c) the scientific name of the genus, species or subspecies to which the variety belongs, and the common name; (d) the variety denomination or, in the absence thereof, the provisional designation; (e) the location in which the variety was bred or discovered and developed, and the maintenance and the propagation of the variety, including information on the characteristics, the cultivation of any other variety or varieties the material of which has to be used repeatedly for the production of the variety. For material to be used repeatedly for the production of the variety, the applicant may provide the information concerning such material, if he requests so, in the form provided by the Office pursuant to Article 86; (f) the characteristics of the variety, including the state of expression for certain characteristics based on the technical questionnaire referred to in Article 16(3)(a); (g) where appropriate, similar varieties and differences from those varieties, which, in the applicant's opinion, are relevant for the technical examination; (h) additional information that may help distinguishing the variety, including representative colour photos of the variety and other information on the plant material to be examined during the technical examination; (i) where appropriate, characteristics that have been genetically modified, where the variety concerned represents a genetically modified organism within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council; (j) the date of any sale or first disposal to others, of varietal constituents or harvested material of the variety, to exploit the variety within the territory of the European Union or in one or more third countries, or to assess whether a variety is new as referred to in Article 10 of the basic Regulation, or a declaration that such sale or first disposal has not yet occurred; (k) the designation of the authority applied to and the file number of the applications referred to in Article 18(3) of this Regulation; (l) existing national or regional plant variety rights that have been granted to the variety; (m) whether an application for the variety concerned has been submitted for listing or registration or a decision has been taken pursuant to Article 5 of Council Directive 68/193/EEC, Article 10 of Council Directive 2002/53/EC, Article 10 of Council Directive 2002/55/EC and Article 5 of Commission Implementing Directive 2014/97/EU'.*

and the date of application within the meaning of Article 51 of the Basic Regulation, as required by Article 17 of the Implementing Rules. Then, as set out in Article 53 of the Basic Regulation, the CPVO proceeds to the formal examination of the application, aimed at establishing the application meets the formal requirements laid down in the Basic Regulation and in the Implementing Rules.

The CPVO has to notify the applicant in case the application does not comply with the conditions set out in Article 50 and what deficiencies have been found (Article 18 (1) of the Implementing Rules), requiring the applicant to remedy within a time limit, at the cost of rejecting the application (Article 19 (1) of the Implementing Rules).

In case the application is found valid and complete, the CPVO moves from the formal examination to the substantive examination, pursuant to Article 54 of the Basic Regulation. The Office has to assess whether the variety may be the object of a Community PVR, whether the variety is novel according to Article 10 of the Basic Regulation, whether the applicant is entitled to file an application, and whether the proposed variety denomination is suitable.

In case there are no impediments at this stage to the grant of a Community PVR, the CPVO shall arrange the technical examination for the DUS assessment, conducted by entrusted bodies on the basis of the principles already mentioned.

At the end of the examination, the CPVO adopts a decision: a valid application and successful examination lead to the grant of a Community plant variety right, according to Article 62 of the Basic Regulation. The CPVO issues a certificate attesting the grant of the CPVR, in addition a detailed description of the protected variety. The CPVO shall refuse the application when there are impediments pursuant to Article 61[241].

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[241] Article 61 of the Regulation (EC) No 2100/94, Refusal: *'1. The Office shall refuse applications for a Community plant variety right if and as soon as it establishes that the applicant: (a) has not remedied any deficiencies within the meaning of Article 53 which he was given an opportunity to correct within the time limit notified to him; (b) has not complied with a rule or request pursuant to Article 55 (4) or (5) within the time limit laid down, unless the Office has consented to non-submission; or (c) has not proposed a variety denomination which is suitable pursuant to Article 63. 2. The Office shall also refuse applications for a Community plant variety right if: (a) it establishes that the conditions it is required to verify pursuant to Article 54 have not been fulfilled; or (b) it reaches the opinion on the basis of the examination reports pursuant to Article 57, that the conditions laid down in Articles 7, 8 and 9 have not been fulfilled'.*

10. Appeals against the decisions of the Office

The decisions adopted by the CPVO may be appealed to the CPVO Board of Appeal pursuant to Article 67 (1) of the Basic Regulation[242]. The Board of Appeal has been established according to Article 45 of the Basic Regulation, which is *'responsible for deciding on appeals from the decisions referred to in Article 67'*. So far, only one Board of Appeal has been established. However, if it is deemed necessary by the Office, the Administrative Council might establish other Boards of Appeal (Article 11 (1) of the Implementing Rules).

The Board of Appeal is constituted by a Chairman, who shall be a legally qualified member, and two other members, whose qualification might be technical and legal (Article 46 of the Basic Regulation and Article 11 (2) of the Implementing Rules). All the members of the Board shall be independent and shall not perform any other duties in the CPVO: indeed, the Board of Appeal shall act independently from other bodies of the CPVO. Pursuant to Article 46 (2) of the Basic Regulation, for each case the Chairman has the duty to select the other members and their respective alternates; when required by the nature of the appeal, the Chairman may call up to two further members. The appointment of the Chairman and the members shall be made from a list of qualified members established according to Article 47 of the Basic Regulation[243], depending on the case under examination.

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[242] Article 67 (1) of the Regulation (EC) No 2100/94, Decisions subject to appeal: *'1. An appeal shall lie from decisions of the Office which have been taken pursuant to Articles 20, 21, 59, 61, 62, 63 and 66, as well as on decisions related to fees pursuant to Article 83, to costs pursuant to Article 85, to the entering or deletion of information in the Register pursuant to Article 87 and to the public inspection pursuant to Article 88'.*

[243] Article 47 of the Regulation(EC) No 2100/94, Independence of the members of the Boards of Appeal: *'1. The Chairmen of the Boards of Appeal and their respective alternates shall be appointed by the Council from a list of candidates for each chairman and each alternate which shall be proposed by the Commission after obtaining the opinion of the Administrative Council. The term of office shall be five years. It shall be renewable. 2. The other members of the Boards of Appeal shall be those selected pursuant to Article 46 (2), from a list of qualified members established on a proposal from the Office, for a term of five years, by the Administrative Council. The list shall be established for a term of five years. This shall be renewable for whole or part of the list. 3. The members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions. 4. The members of the Boards of Appeal may not be members of the Committees referred to in Article 35 nor perform any other duties in the Office. The function of the members of the Boards of Appeal may be a part-time function. 5. The members of the Boards of Appeal may not be removed from office nor from the list respectively, during the respective term, unless there are serious grounds for such removal and the Court of Justice of the European Communities, on application by the Commission after obtaining the opinion of the Administrative Council takes a decision to this effect'.*

The Chairman of the Board of Appeal shall select one of its members to be the *rapporteur* of the appeal, who has the duty to summarize the case before the hearing and draft the final decision. The rapporteur might be also assigned by the Chairman to the taking of evidence. The majority rule applies to the decision-making process of the Board of Appeal.

The decisions that might be appealed in accordance with Article 67 of the Basic Regulation include: nullification and cancellation of a Community PVR, objections to grant of right, refusal and grant of Community PVRs, amendment of the variety denomination, fees. As a general rule, the appeal brought in front of the CPVO Board of Appeal has suspensory effect (Article 67 (2) of the Basic Regulation).

Any natural or legal person is entitled to appeal: 1. against a decision addressed to that person; 2. against a decision which is of direct and individual concern to the former, even though it is addressed to another person (Article 68 of the Basic Regulation). The notice of appeal shall be filed in writing at the Office.

The time limit for the notice of appeal is two months: 1. from the service of the decision, where addressed to the appealing person; 2. from the publication of the decision, in the absence of a service. After the service or the publication, the appealing person had to file a written statement specifying the grounds of the appeal, according to Article 69 of the Basic Regulation.

According to Article 70 of the Basic Regulation, in case the Office considers the appeal admissible and well-founded, it shall rectify the contested decision. When the appellant is opposed by another party, the decision could not be rectified. If one month has passed after receiving the written statement and the decision has not been rectified, the CPVO shall immediately remit the appeal to the Board of Appeal and decide whether the appeal shall not suspend the effects of the appealed decision.

If the appeal is admissible, the Board proceeds to the examination of the appeal, investigating whether the appeal is well-founded, as required by Article 71 of the Basic Regulation. The rapporteur will draft an opinion about it. According to Article 50 of the Implementing Rules, the chairman shall, without delay, summon the parties to oral proceedings, which shall in principle be held in one hearing along with the taking of evidence. Only in the event of circumstances which have undergone change during or after the hearing, a request for further hearings shall be deemed admissible. The parties to the

appeal are entitled to make oral representations and to file observations within a specified time limit. As a general rule, oral proceedings are public except where the Board of Appeal decides that this might cause serious disadvantages for the parties to the proceeding (Article 77 (3) of the Basic Regulation).

Pursuant to Article 72, the decision is taken by the Board on the basis of the conducted examination. The Board might exercise any power within the competence of the CPVO or it might decide to remit the case for action to the competent body of the CPVO, which will be bound by the verdict of the Board.

As required by Article 52 of the Implementing Rules, the decision is signed by the Chairman and the designated rapporteur, and it must contain: '*(a) a statement that the decision is delivered by the Board of Appeal; (b) the date when the decision was taken; (c) the names of the chairman and of the other members of the Board of Appeal having taken part in the appeal proceedings; (d) the names of the parties to the appeal proceedings and their procedural representatives; (e) a statement of the issues to be decided; (f) a summary of the facts; (g) the grounds on which the decision is based; (h) the order of the Board of Appeal, including, where necessary, a decision as to the award of costs or the refund of fee'*.

The signed decision is delivered and forwarded in writing to the parties within three months after the closure of the oral proceedings. The decision is supplemented by a statement informing that the decisions of the Board of Appeal are open for further appeal before the Court of Justice of the European Union. The action shall be brought within two months after the date of service of the decision.

As laid down in Article 73 of the Basic Regulation, the decision of the Board may be appealed to the Court of Justice only on grounds of law, i.e. lack of competence, infringement of an essential procedural requirement, infringement of the Treaty, of the Regulation (EC) No 2100/94, or of any rule of law relating to their application or misuse of power. The subjects entitled to the further appeal are the unsuccessful party, the Commission, and the CPVO.

The CJEU may annul or alter the appealed decision and the CPVO is bound to comply with the judgment of the Court of Justice. In case the Court remits the case for action to the Board of Appeal, the latter is bound by its decision. As a general rule, actions brought before the Court of Justice do not have a suspensory effect, unlike actions before the Board of Appeal.

11. Scope of the Community plant variety right

The scope of the right of the holder of the Community plant variety right is laid down in Article 13 of the Basic Regulation[244], whose content is substantially identical to Article 14 of the 1991 UPOV Convention. The structure is also the same: Article 13 lists the acts the holder of the right is entitled to perform, then the following Articles (such as Articles 14, 15 and 16) provide a limitation to the right.

Paragraph 2 of Article 13 lists the acts in respect of the 'material' of the variety, i.e. variety constituents or harvested material, that only the 'holder' of the right, defined in paragraph 1 of Article 13 as the person to whom a Community PVR has been granted, is

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[244] Article 13 of Regulation (EC) No 2100/94, Rights of the holder of a Community plant variety right and prohibited acts: *'1. A Community plant variety right shall have the effect that the holder or holders of the Community plant variety right, hereinafter referred to as 'the holder', shall be entitled to effect the acts set out in paragraph 2. 2. Without prejudice to the provisions of Articles 15 and 16, the following acts in respect of variety constituents, or harvested material of the protected variety, both referred to hereinafter as 'material', shall require the authorization of the holder: (a) production or reproduction (multiplication); (b) conditioning for the purpose of propagation; (c) offering for sale; (d) selling or other marketing; (e) exporting from the Community; (f) importing to the Community; (g) stocking for any of the purposes mentioned in (a) to (f). The holder may make his authorization subject to conditions and limitations. 3. The provisions of paragraph 2 shall apply in respect of harvested material only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents. 4. In the implementing rules pursuant to Article 114, it may be provided that in specific cases the provisions of paragraph 2 of this Article shall also apply in respect of products obtained directly from material of the protected variety. They may apply only if such products were obtained through the unauthorized use of material of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said material. To the extent that the provisions of paragraph 2 apply to products directly obtained, they shall also be considered to be 'material'. 5. The provisions of paragraphs 1 to 4 shall also apply in relation to: (a) varieties which are essentially derived from the variety in respect of which the Community plant variety right has been granted, where this variety is not itself an essentially derived variety; (b) varieties which are not distinct in accordance with the provisions of Article 7 from the protected variety; and (c) varieties whose production requires the repeated use of the protected variety. 6. For the purposes of paragraph 5 (a), a variety shall be deemed to be essentially derived from another variety, referred to hereinafter as 'the initial variety' when: (a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety; (b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and (c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety. 7. The implementing rules pursuant to Article 114 may specify possible acts of derivation which come at least under the provisions of paragraph 6. 8. Without prejudice to Article 14 and 29, 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'.*

entitled to perform: 1. production or reproduction (multiplication)[245]; 2. conditioning for the purpose of propagation[246]; 3. offering for sale[247]; 4. selling or other marketing[248]; 5. exporting from the EU[249]; 6. importing to the EU[250]; 7. stocking for any of the purposes above mentioned. The performance of any of these acts requires the authorization of the right holder, who might subject it to conditions and limitations, and it shall not prejudice the provisions of Article 15 and 16, which are going to be examined below.

With reference to the scope of protection of the Community plant variety rights, the Preamble to the Regulation reads as follows: *'whereas the scope of protection should be extended, compared with most national systems, to certain material of the variety to take account of trade via countries outside the Community without protection'*. In other words, Article 13 is not applicable only to acts performed within the European Union territory, but it might be extended to cases where material of a protected variety is subject to multiplication in a third country and then brought back to the EU.

As in the 1991 UPOV Convention, Article 13 (3) specifies that the authorization of the holder for such acts in respect of the harvested material, i.e. all products of the harvest, is required only 1. if this was obtained through the unauthorized use of variety constituents of the protected variety, and 2. unless the holder has had reasonable opportunity to exercise their right to the said variety constituents. Otherwise, the authorization is not needed. As highlighted by Van Der Kooij, *the reasonable opportunity to exercise his right* shall be decided by the Courts on the basis of all the relevant circumstances[251].

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[245] This is considered to be by Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 128, *'the holder's most important right, because it is almost never affected by the exhaustion rule laid down in Article 16'*. Indeed, the importance of this act in respect of the protected variety is strictly connected to the intrinsic nature of the object of Community PVR, which it is naturally self-replicating and it could be effortlessly reproduced by third parties. Therefore, this right has to be limited as little as possible in order to provide an effective protection of the relevant variety.

[246] By way of illustration, this might include seed cleaning or coating.

[247] The offering for sale may take place in marketplaces, on websites, in catalogues etc.

[248] The question springs up whether, e.g., the display of the protected material is covered by the 'other marketing' acts referred to in this provision. According to Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 129, any disposal for commercial purposes should require the holder's authorization.

[249] This includes the territory of all the EU Member States. It is also supposed to include the associated overseas non-European countries and territories referred to in Article 198 of the Treaty on the Functioning of the European Union.

[250] Ibidem.

[251] Van Der Kooij P., 1997, op. cit., p. 32.

Despite the uncertainty over the extent of the 'reasonable opportunity' condition, paragraph 3 clarifies that, in respect of acts effected on harvested material, the holder of a Community PVR shall exercise their rights at first over the variety constituents of the protected variety. In case they had the chance to exercise their right in respect of the variety constituents but they did not pursue it, the holder will not be any longer able to prevent these acts from being undertaken without authorization. Therefore, the extension of the scope of protection over the harvested material, known as *cascade principle*, does not have an absolute extend but is limited by the circumstances referred to in paragraph 3.

Paragraph 4 of Article 13 affirms that the protection might be extended in respect of products obtained directly from material[252] of the protected variety (e.g. pasta made from protected varieties of wheat) under the same conditions of paragraph 3, i.e. the unauthorized use of material of the protected variety and the reasonable opportunity for the holder to exercise their right. This extension might be provided in the Implementing Rules pursuant to Article 114. Nowadays, the Implementation Rules have not provided this extension of protection yet. Nonetheless, some countries have implemented this provision in their national laws, such as Germany and the Netherlands[253].

12. Restrictions

Article 13 (8) of the Basic Regulation provides for restrictions on the exercise of the rights conferred by Community PVP. The Article states that the exercise of CPVRs should not violate any provisions adopted on the grounds of public morality, public polity or 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. This Article explicated the provision laid down in Article 17 (1) of the 1991 UPOV Convention, which concisely reads as follows: *'except where expressly provided in this Convention, no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of public interest'*.

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[252] As noted by Van Der Kooij P., 1997, op. cit., the broad reference to *material* might be considered inaccurate. The provision should have referred to products obtained directly from *harvested* material of the protected variety, as in Article 14 paragraph 3 of the 1991 UPOV Convention.
[253] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 133.

This provision reflects the conditions laid down in Article 36 TFUE[254] (ex Article 30 of the EC Treaty), under which Member States may prohibit or restrict the free movements of goods. Interesting to notice that, differently from patent law and especially from Article 53 (a) of the European Patent Convention[255], public morality is not an obstacle to the grant of a Community plant variety right but it may impede the exercise of such right after its grant.

13. Essentially derived varieties

Paragraphs 5 and 6 of Article 13 deal with a characterizing aspect of plant variety protection, providing an exception to the principle of independence that represents one of the most important differences between plant variety protection system and the patent system. Indeed, these provisions introduce a *limited dependency* among varieties.

Article 13 (5) of the Basic Regulation basically complies with Article 14 (5) (a) of the 1991 UPOV Convention, stating that the provisions of paragraphs 1 to 4, examined in the previous paragraph, shall be extended to the varieties which are essentially derived from the variety in respect of which the Community PVR has been granted, where this variety is not itself an essentially derived variety (EDV)[256]. In other words, the breeder of an essentially derived variety cannot exploit their achievement, unless the holder of the PVR on the initial variety has authorized them to perform the acts listed in Article 13 of the Basic Regulation. This provision aims at preventing cosmetic breeding activities and plagiarism in plant breeding.

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[254] Article 36 of the Treaty on the Functioning of the European Union, (ex Article 30 TEC): '*The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.*

[255] Article 53 (a) of EPC, Exceptions to patentability: *'European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'.*

[256] As affirmed by Würtenberger, the notion of EDV *'lies in the area of conflict between sufficient scope of protection for a new breeding result and the principle of independence',* Würtenberger G., 2013, *Legal perspectives on Essentially Derived Varieties,* in Revista Eletrônica do IBPI, 8.

With regard to Article 13 (6), its content is substantially similar to Article 14 (5) (b) of the 1991 UPOV Convention. The provision reiterates the principle under which a change in the genotype of a variety, predominantly derived from an initial variety and which conforms essentially to the phenotype (i.e. the expression of the characteristics) of such initial variety, does not give rise to a new and distinct variety. Only the genetically inheritable characteristics should be taken into consideration, and such characteristics vary from species to species and from variety to variety. Concerns have risen about trivial changes, like color mutation, that might have the effect to allow an EDV to *'fall outside the provision'*[257].

On such a specific issue, an answer might be found in a recent judgment of an Italian Court about a Community PVR infringement case (Case 3519/2015, before the Tribunale di Torino, *Almo vs. SA.PI.SE.*). The dispute is between the holder of a Community PVR on a sought-after rice variety, called Gladio, and the holder of a Community PVR on another rice variety, Sirio CL, allegedly essentially derived therefrom. The existence of the requirements laid down in Article 13 (6) (a) and (b) was undisputed. Indeed, Sirio CL was obtained by crossing Gladio with another variety, so there was predominantly derivation from such initial variety. Also, it was deemed to be distinct, since a Community PVR was granted on said variety and the Court shall treat the Community PVR as valid, pursuant to Article 105 of the Basic Regulation. Thus, the dispute concerned the requirement set out in Article 13 (6) (c). The plaintiff argued that Sirio CL conforms essentially to the initial variety in the expression of the characteristics that results from its genotype: indeed, the morphophysiological characteristics were exactly the same and the only changes on Sirio CL were limited to the color of the stigma and the color of the lemma. Contrarily, the defendant claimed that it does not conform essentially to such characteristics because Sirio CL had phenotypic differences from Gladio.

The Court found that any differences that may exist between the initial and the derived variety are irrelevant when the derived variety predominantly conforms to the initial variety through the essential characteristics resulting from the genotype of the initial variety. Using the words of the UPOV document on EDV (IUM/6/2 of 30 October 1992), the Court

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[257] Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford. p. 226.

highlighted that *essential characteristics* are *indispensable or fundamental* to the variety. These characteristics, as already mentioned, vary from species to species and from variety to variety. However, only characteristics that are heritable genetically should be taken into account, unlike descriptive features which represent environmental effects and therefore should be ignored[258].

In light of this, the Court established that Sirio CL reproduced the essential genotype characteristics of Gladio, which it did not get from the other initial parent. Consequently, the court decided that Sirio is an essentially derived variety from Gladio. From this judgment, it is possible to conclude that the variation in the color of the stigma and the lemma in a rice variety is not sufficient *per se* to regard said variety as a non-essentially derived, especially when the essential characteristics of the initial variety are predominantly reproduced by it. This decision might compensate the concerns shown above about the possibility that minimal changes in the color of a variety can prevent said variety to be regarded as an EDV, at least in the case of agricultural crops.

In conclusion, unlike Article 14 (5) (c) of the 1991 UPOV Convention, Article 13 does not provide examples of breeding methods and techniques that might be used to obtain EDVs. Indeed, paragraph 7 states that possible acts of derivation might be specified in the Implementing Rules, but that has not happened yet. The result is that the interpreter shall avoid the association between the use of a specific breeding technique and essential derivation in a certain variety.

14. The farmer's privilege

As already said above, Article 15 (2) of the 1991 UPOV Convention provides an optional exception regarding the so-called *farmer's privilege* or *agricultural exemption*. The Regulation (EC) No 2100/94 applied such a derogation.

The rationale behind this choice may be found the Preamble to the Basic Regulation, which states the following: *'whereas, the exercise of Community plant variety rights must be subjected to restrictions laid down in provisions adopted in the public interest; whereas*

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[258] The Court underlined that the UPOV document used two different words to describe the two different concepts: *characteristics* and *features* of the variety.

this includes safeguarding agricultural production; whereas that purpose requires an authorization for farmers to use the product of the harvest for propagation under certain conditions'. Therefore, it shall be extrapolated that the recognition of the farmer's privilege concerns public interest, specifically the safeguard of agricultural production.

Nevertheless, this privilege shall be balanced and permitted within certain limits in order to not jeopardize the scope of plant variety rights and the main purpose of the Basic Regulation, i.e. fostering the breeding and development of new varieties, which may also seriously affect agricultural production. This is the reason why Article 14 of the Basic Regulation[259] limits the privilege to certain acts, certain species, certain conditions. Where

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[259] Article 14 of Regulation (EC) No 2100/94, Derogation from Community plant variety right: *'1. Notwithstanding Article 13 (2), and for the purposes of safeguarding agricultural production, farmers are authorized to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right. 2. The provisions of paragraph 1 shall only apply to agricultural plant species of: (a) Fodder plants: Cicer arietinum L. - Chickpea milkvetch; Lupinus luteus L. - Yellow lupin: Medicago sativa L. - Lucerne; Pisum sativum L. (partim) - Field pea; Trifolium alexandrinum L. - Berseem/Egyptian clover; Trifolium resupinatum L. - Persian clover; Vicia faba - Field bean; Vicia sativa L. - Common vetch; and, in the case of Portugal, Lolium multiflorum lam - Italian rye-grass; (b) Cereals: Avena sativa - Oats; Hordeum vulgare L. - Barley; Oryza sativa L. - Rice; Phalaris canariensis L. - Canary grass; Secale cereale L. - Rye; X Triticosecale Wittm. - Triticale; Triticium aestivum L. emend. Fiori et Paol. - Wheat; Triticum durum Desf. - Durum wheat; Triticum spelta L. - Spelt wheat; (c) Potatoes: Solanum tuberosum - Potatoes; (d) Oil and fibre plants: Brassica napus L. (partim) - Swede rape; Brassica rapa L. (partim) - Turnip rape; Linum usitatissimum - linseed with the exclusion of flax. 3. Conditions to give effect to the derogation provided for in paragraph 1 and to safeguard the legitimate interests of the breeder and of the farmer, shall be established, before the entry into force of this Regulation, in implementing rules pursuant to Article 114, on the basis of the following criteria: - there shall be no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding, - the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organization of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing, - small farmers shall not be required to pay any remuneration to the holder; small farmers shall be considered to be: - in the case of those of the plant species referred to in paragraph 2 of this Article to which Council Regulation (EEC) No 1765/92 of 30 June 1992 establishing a support system for producers of certain arable crops (4) applies, farmers who do not grow plants on an area bigger than the area which would be needed to produce 92 tonnes of cereals; for the calculation of the area, Article 8 (2) of the aforesaid Regulation shall apply, - in the case of other plant species referred to in paragraph 2 of this Article, farmers who meet comparable appropriate criteria, - other farmers shall be required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; the actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned, - monitoring compliance with the provisions of this Article or the provisions adopted pursuant to this Article shall be a matter of exclusive responsibility of holders; in organizing that monitoring, they may not provide for assistance from official bodies, - relevant information shall be provided to the holders on their request, by farmers and by suppliers of processing services; relevant information may equally be provided by official bodies involved in the monitoring of agricultural production, if such information has been obtained through ordinary performance of their tasks, without additional burden or costs. These provisions are without*

these criteria are met, the Community PVRs shall not extend to said acts, according to Article 15 (e) of the Basic Regulation.

Article 14 (1) of the Basic Regulation states that the farmer's privilege concerns the use for propagating purposes of the harvested material obtained by planting propagating material (i.e. variety constituents) of a variety covered by Community PVR, except for hybrids or synthetic varieties[260]. This use shall be made by farmers, in the field. Both the planting of propagating material and the propagation of harvested material shall take place on the farmer's own holdings. In other words, a farmer is not allowed to transfer its harvest to another farmer to sow it on the latter holding.

Article 14 (2) further limits the exemption, allowing it only in respect of the listed *agricultural* plant species, mainly fodder plants and cereals. This represents a closed number and exhaustive list, which means that varieties of the species not set out in paragraph 2 are not subject to the farmer's privilege, e.g. ornamental species.

The restriction to some varieties of agricultural species is consistent with the opinions expressed during the 1991 UPOV Diplomatic Conference, during which some delegations underlined that the farmer's privilege should be limited to those species traditionally subject to the FSS practice like, *inter alia*, cereals.

Article 14 (3) sets out additional conditions in order to give effect to the farmer's privilege and, at the same time, to safeguard the legitimate interests of the breeder and the farmer. These conditions have been thoroughly established by the Commission Regulation (EC) No 1768/95 of 24 July 1995, hereinafter referred to as 'the Agricultural Exemption Regulation', on the basis of the criteria specified in Article 14 (3) of the Basic Regulation.

This Article specifies the following criteria: the level of the farmer's holding shall not be quantitatively restricted; the product of the harvest may be processed, without prejudice to the restriction aimed at ensuring identity of the product entered for processing with the one resulting from it; the holders have the exclusive responsibility on monitoring the compliance with the provision of Article 14; the farmers shall supply all the relevant information when requested by the Community PVR holder; small farmers shall not pay any

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prejudice, in respect of personal data, to Community and national legislation on the protection of individuals with regard to the processing and free movement of personal data'.

[260] A synthetic variety has been defined by Allard as a variety *'maintained under open pollination following synthesis by hybridization in all combinations among a number of selected genotypes'.* Allard R.W., 1960, *Principles of plant breeding*, John Wiley & Sons Inc., New York.

remuneration to the Community PVR holder, unlike other farmers who shall pay an equitable remuneration.

The last condition has utmost importance since it clearly establishes that small farmers are exempted to pay any further royalty to the plant variety right holder. The notion of small farmers is laid down in Article 14 (3) third indent and covers the farmers who do not grow plants on an area bigger than the area needed to produce 92 tonnes of cereals. In the case of other species, the notion refers to farmers who meet comparable criteria.

If a farmer does not meet this requirement, they shall pay an *equitable remuneration* to the plant variety right holder and this remuneration, which might change over time, shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area.

Seguing into the analysis of the main provisions of the Agricultural Exemption Regulation, it shall be noticed that Article 2 reaffirms a key principle on the farmer's privilege: the legitimate interests of the holder and the farmer need to maintain a balance in order to be properly safeguarded.

As provided for in Article 3 of the Agricultural Exemption Regulation, the rights and obligations of the holder which derive from the provisions of Article 14 may not be the object of a transfer to others. The rights of the holder may be invoked either by individual holders, collectively by several holders, or by an organization of holders established in the EU, which can act only for its members who have given the relevant mandate in writing to the organization. As held by the Court of Justice of the European Union in the Case C-182/01 (*Saatgut-Treuhandverwaltungsgesellschaft mbH 'STV'*[261] *vs. Werner Jäger*), for the purpose of that Article a limited company is capable of constituting an 'organization of holders' of CPVRs and it may invoke the rights of holders who are members of another organization where the other organization is itself a member of the first organization. However, the organization of holders may not invoke the rights of holders who, although not members of the first organization or of another organization which is a member, have appointed it to safeguard their interests in return for a consideration.

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[261] STV is an association of plant variety right holders that are protected under Regulation (EC) No 2100/94. Each year STV asks farmers, without specifying a particular variety, to provide information on any planting of protected plant varieties for which STV administers the rights, sending to them planting declaration forms for that purpose, together with a guide listing all the protected varieties for which it administers the rights in the relevant marketing year and the corresponding right holders and persons enjoying rights of exploitation.

In a specular manner, neither the farmer's authorization and obligations may be the object of a transfer to others, pursuant to Article 3 of the Agricultural Exemption Regulation, unless a transfer of the holding of the farmer is concerned. That Article also provides a definition of 'own holding', referred to in Article 14 (1) of the Basic Regulation, as *'any holding or part thereof which the farmer actually exploits for plant growing, whether as his property or otherwise managed under his own responsibility and on his own account, in particular in the case of leaseholds. The disposal of a holding or part thereof for the purpose of exploitation by others shall be regarded as transfer'*. That means that the farmer shall be the one exploiting the holdings in order to make use of the privilege.

Article 5 of the Agricultural Exemption Regulation deals with the level of the equitable remuneration. As a general rule, it states that the level of remuneration may form the object of a contract between the holder and the farmer concerned. In case that contract has not been concluded, the level of remuneration shall be sensibly lower than the amount charged for *'the licensing production of propagating material of the lowest category qualified for official certification, of the same variety in the same area'*[262]. This provision has been amended by the Commission Regulation (EC) No 2605/98 of 3 December 1998 by adding four paragraphs. The amendment was made on the basis that agreements between breeders' and farmers' organizations concerning the level of remuneration had been concluded and, therefore, this aspect had to be taken into account. The paragraph laid down the principle upon which, in areas and for species where these agreements do not apply, the level of remuneration will be, as a general rule, 50 percent of the amounts charged for the licensed production of propagating material, regulated by a scale established in respect of the relevant national PVRs.

Pursuant to Article 6, the obligation of the farmer to pay the equitable remuneration shall come to existence when they actually make use of the product under the conditions provided for in Article 14 (1) of the Basic Regulation. The holder has the right to determine

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[262] In case there is not a licensed production in the area where the holding of the farmer is located and in case there isn't a uniform level of the abovementioned amount throughout the EU, Article 5 (2) of the Agricultural Exemption Regulation specifies the following *'the level of remuneration shall be sensibly lower than the amount which is normally included, for the above purpose, in the price at which propagating material of the lowest category qualified for official certification, of that variety is sold in that area, provided that it is not higher than the aforesaid amount charged in the area in which that propagating material has been produced'*.

the date and the manner of the payment, that shall not precede the date on which the obligation came to existence. As held by the Court of Justice of the European Union in Case C-242/14 (*SaatgutTreuhandverwaltungs GmbH vs. Gerhard und Jürgen Vogel GbR et al.*), in case a farmer who has taken advantage of the farmer's privilege without having concluded a contract for so doing with the holder, said farmer is *'required to pay the equitable remuneration by way of derogation within the period that expires at the end of the marketing year during which that planting took place, that is, no later than 30 June following the date of reseeding'*.

Regarding the notion of small farmers, Article 7 (3) sets out the rules in case of species other than cereals: indent (a) states that in case of fodder plants, those should not be grown for a duration of *'not more than five years on an area bigger than the area which would be needed to produce 92 tonnes of cereals per harvest'*; indent (b) states that in case of potatoes, they should not be grown on an area *'bigger than the area which would be needed to produce 185 tonnes of potatoes per harvest'*. In case of dispute, the person who claims to be a 'small farmer' has the burden of proof about their status; thus they have to prove that the relevant requirements are met.

With reference to the information to be provided by the farmer to the holder, the details of the relevant information may form the subject of a contract between the holder and the farmer concerned, according to Article 8 of the Agricultural Exemption Regulation. In case a contract has not been concluded, the farmer is required to provide information on request of the holder. In their request, that has to be made directly to the farmer concerned, the holder shall specify their name and address, the variety or varieties in respect of which information are required, and the relevant Community PVR. When the request is not made directly to the farmer, it may be made through an organization of farmers or cooperatives, processors or suppliers of licensed propagating material. The farmer may require a request made in writing and evidence for holdership.

The information that the farmer has to provide are the following: (a) their name and the place of their domicile and the address of their holding; (b) the variety or varieties of the holder that they reproduced and sow to make use of their privilege; (c) the amount of the product of the harvest that has been used; (d) the name and address of the person who have supplied a service of processing; (e) if the information obtained under (b), (c) or (d) cannot be confirmed, the amount of propagating material of the varieties concerned used as well as

the name and address of the supplier or suppliers thereof; (f) in the case of a farmer invoking the provisions of Article 116 (4) second indent of the Basic Regulation[263], whether they has already used the variety concerned without payment of remuneration, and if so, since when. Moreover, the holder may ask for information to the processor and to official bodies, within the limits specified in the Agricultural Exemption Regulation.

However, the Court of Justice in the abovementioned Case C-182/01 (*Saatgut-Treuhandverwaltungsgesellschaft mbH 'STV' vs. Werner Jäger*), held that the holder of a Community plant variety right can require a farmer to provide the information specified in those provisions only where there is an *'indication that the farmer has used or will use, for propagating purposes in the field, on his own holding, the product of the harvest obtained by planting, on his own holding, propagating material of a variety other than a hybrid or synthetic variety which is covered by that right and belongs to one of the agricultural plant species listed in Article 14(2) of Regulation No 2100/94'.* The decision has been taken in the same terms as in Case C-305/00 (*Christian Schulin v Saatgut-Treuhandverwaltungsgesellschaft mbH)* where the Court held that in this case the term 'farmer' refers only to the farmers taking advantage of the derogation in Article 14 of the Basic Regulation, therefore not every farmer has to provide all the relevant information on request: there has to be some sort of indication.

As a general rule, the holder of the Community PVR has to provide the farmer the information regarding the amount charged for the licensed production of propagating material of the lowest category qualified for official certification, of the same variety in the area in which the holding of the farmer is located, unless such licensed production has not taken place in the area in which the holding of the farmer is located, and unless there is no uniform level of the aforesaid amount throughout the EU. In this case, the holder shall provide the information regarding the amount which is normally included in the price at which propagating material of the lowest category qualified for official certification, of that

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[263] Article 116 (4) second indent of Regulation (EC) No 2100/94, Derogations: '*Article 14 (3), fourth indent shall not apply to farmers who continue to use an established variety in accordance with the authorization of Article 14 (1) if, before the entry into force of this Regulation, they have already used the variety for the purposes described in Article 14 (1) without payment of a remuneration; this provision shall apply until 30 June of the seventh year following that of the entry into force of this Regulation. Before that date the Commission shall submit a report on the situation of the established varieties dealing with each variety individually'.*

variety is sold in that area, as well as the aforesaid amount charged in the area in which that propagating material has been produced.

According to Article 14 and 16 of the Agricultural Exemption Regulation, the holder is also responsible for carrying out the monitoring compliance with provisions of Article 14 of the Basic Regulation, i.e. the fulfillment of the farmer's obligations. They may be assisted by organizations of farmers, processors, and cooperatives. On request of the holder, the farmer shall provide evidence supporting their statements of information and make available or accessible the proof concerning the qualification of 'small farmer' and their 'own holdings'. The farmer shall conserve the documents of, at least, the three preceding marketing years. As held by the Court of Justice in Case C-509/10 (*Josef Geistbeck and Thomas Geistbeck vs. Saatgut-Treuhandverwaltungs GmbH),* the payment of compensation for costs incurred for monitoring compliance with the rights of the plant variety holder cannot be included in the calculation of the 'reasonable compensation' provided for under Article 94 (1) of Regulation (EC) No 2100/94, which states that whosoever effects one of the acts set out in Article 13 (2) without being entitled to do so in respect of a variety for which a Community PVR has been granted *'may be sued by the holder to enjoin such infringement or to pay reasonable compensation or both'.*

In light of what it has been said so far, it seems clear that the farmer's privilege represents an issue of broad and current interest, forming the subject matter of extensive discussion. For this reason, it is not surprising that the Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, the so-called Biotech Directive, laid down in its Article 11 (1) the following provision: *'By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94'.* In other words, the farmer's privilege also applies to plant propagating material containing a patented gene and, since this provision is set out by a Directive aiming at harmonized protection throughout the Member States, a corresponding provision should be found in national patent laws of EU Member States. This results in a paradox: since there are Member States not implementing the farmer's privilege in respect

of national plant variety rights[264] - like Italy -, farmers might benefit from this exemption only for national biotech patents and not for national plant variety rights, even though this provision was primarily contemplated for PVRs.

15. The breeder's exemption

Article 15 of the Basic Regulation meticulously follows the content of the corresponding Article in the 1991 UPOV Convention, which sets out the exceptions to the plant variety right for the purpose of promoting innovation through the maintenance of free access to those varieties covered by a plant breeder's right. Consequently, in order to achieve said goal, Community PVRs shall not extend to: (a) acts done privately and for non-commercial purposes; (b) acts done for experimental purposes; (c) acts done for the purpose of breeding, or discovering and developing other varieties (the so-called *breeder's exemption* or *principle of independence*); (d) acts referred to in Article (2) to (4) in respect of the other varieties mentioned in letter (c); (e) acts whose prohibition would violate the provisions laid down in Articles 13 (8), 14 or 29.

As it may be noted, the letters from (a) to (c) correspond to Article 15 (1) of the 1991 UPOV Convention, to which reference should be made.

Article 15 (d), instead, stipulates that the Community PVRs shall not cover the acts done pursuant to Article 13 (2) to (4) of the Basic Regulation, in respect of variety constituents or harvested material of the *other varieties,* bred or discovered and developed from an initial source of variation covered by PVR, according to letter (c). Four conditions are provided for these acts in order to be performed without the authorization of the holder of the initial CPVR: the variety shall not be an EDV from the initial protected variety; the variety has to be distinct from the initial protected variety; the production of said variety should not require the repeated use of the initial protected variety; the variety or the material of this variety shall not come under the protection of a property right which does not contain a comparable provision (e.g. a national patent). Therefore, the holder of the Community PVR on the initial source of variation cannot oppose the commercialization of the variety resulting from the exploitation of the breeder's exemption on their genetic resources.

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[264] It is important to recall that the farmer's privilege provision is optional in the 1991 UPOV Convention.

In conclusion, in accordance with Article 15 (e) of the Basic Regulation, the effects of a Community PVR shall be limited in respect of: 1. the acts whose prohibition would violate any provision 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 (Article 13 (8)); 2. the acts done while taking advantage of the farmer's privilege or agricultural exemption (Article 14); 3. the acts effected when a compulsory exploitation right has been granted by the CPVO (Article 29).

16. Exhaustion

As mentioned during the analysis of Article 16 of the 1991 UPOV Convention, the principle of exhaustion plays a crucial role in intellectual property law and its introduction, using the words of the Preamble to the Basic Regulation, *'must ensure that the protection is not excessive'*. The exhaustion of rights in the EU law has been conceptualized following the German patent law approach, which is based on exact principles of the IPR legislation and does not leave to the parties the right to define their positions, unlike the 'contract approach' in U.K. law[265].

In the Basic Regulation, the exhaustion of Community plant variety rights is enshrined in Article 16[266] which corresponds to the provisions laid down in Article 16 of the 1991 UPOV Convention. According to it, a Community PVR is exhausted when the relevant material of the protected variety, or of a variety covered by the provisions of Article 13 (5) of the Basic Regulation[267] or any material derived from the said material, 1. has been disposed of to others; 2. by the holder or with their consent (e.g. by a person enjoying the

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[265] Schovsbo J., 2012, *Exhaustion of Rights and Common Principles of European Intellectual Property Law*, in Ohly A., Common Principles of European Intellectual Property Law, Mohr Siebeck, Tübingen, pp. 169-188.
[266] Article 16 of Regulation (EC) No 2100/94, Exhaustion of Community plant variety rights: *'The Community plant variety right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 13 (5), which has been disposed of to others by the holder or with his consent, in any part of the Community, or any material derived from the said material, unless such acts: (a) involve further propagation of the variety in question, except where such propagation was intended when the material was disposed of; or (b) involve an export of variety constituents into a third country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported materials is for final consumption purposes'*.
[267] Reference is made to varieties: (a) which are essentially derived from the protected variety; (b)which are not distinct from the protected variety; (c) whose production required the repeated use of the protected varieties.

right of exploitation on the basis of a licensing contract concluded with the right holder); 3. in any part of the European Union. Therefore, whether the variety constituents or the harvested material of the protected variety are put on the EU market in a legal manner (i.e. by the Community PVR holder or with their consent), the rights of the holder on said material are exhausted and they cannot forbid the purchaser to effect the acts set out in Article 13 (2) of the Regulation.

Regarding the notion of 'holder's consent', the Court of Justice held in the Case C-140/10 (*Greenstar-Kanzi Europe NV v. Jean Hustin, Jo Goossens*), that *'the holder or the person enjoying the right of exploitation may bring an action for infringement against a third party which has obtained material through another person enjoying the right of exploitation who has contravened the conditions or limitations set out in the licensing contract that that other person concluded at an earlier stage with the holder to the extent that the conditions or limitations in question relate directly to the essential features of the Community plant variety right concerned'*. This judgment clarifies that the disposal of protected material by a person enjoying the right of exploitation, made against the limitations set out in the licensing contract with the PVR holder, shall be deemed to be effected without the holder's consent. The result is that the Community PVR is not exhausted. It is worth noting that the limitations should be related to the essential features of the PVR. However, the Court did not determine what is the content of said essential features.

Moreover, concerning the holder's consent, it has been argued that a person enjoying a compulsory exploitation right on the variety, could be deemed to act without the consent of the right holder[268].

The second part of that Article determines the exceptions to the exhausting principle, such as: (a) acts involving further propagation of the relevant variety, except where such propagation was intended when the material was disposed of; o (b) involve an export of variety constituents into a third country which does not protect the relevant variety, except where the exported materials is for final consumption purposes.

Pursuant to letter (a), the holder's right is not exhausted when the variety in question is further propagated, unless - and here there is an exception to the exception - such

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[268] Van Der Kooij P.,1997, *Introduction to the EC Regulation on Plant Variety Protection*, Kluwer Law International, London, p. 40.

propagating act was intended at the time of disposal of the material. Consequently, when seeds for further propagation purposes are sold by the holder, the holder's right is exhausted.

By way of illustration, harvested material of the protected variety obtained through the legitimate use of variety constituents can potentially be used for propagating purpose. In order to understand whether the holder's right on the harvested material is exhausted or not, reference shall be made to what was intended when the variety constituents of the protected variety were disposed of: in case further propagation was intended, the CPVR holder cannot prohibit the use of the harvested material for propagating purposes, since their right is exhausted. Differently, in the event further propagation was not indented, the holder can forbid this act because their PVR right on the protected material is not exhausted[269].

Differently, letter (b) aims at not exhausting plant variety rights in those countries where protection for the relevant plant variety does not exist: it follows that such a provision does not apply to countries that provide for that protection. Also, in this case, an exception to the exception is made: there is exhaustion of the Community PVR in said third countries in case of exportation for final consumption purposes, meaning that further propagation of the variety is not involved.

17. Contractual exploitation rights

Some provisions of the Basic Regulation deal with the Community PVR as an object of property. According to the general rule laid down in Article 22 (1) of the Basic Regulation, the Community plant variety right as an object of property shall be assimilated to no more than one national regime and the laws thereof shall be applied in case of conflicting national rules[270]. Indeed, the Article clearly states that Community PVR as an object of property shall be regarded in all respects and for the entire territory of the European Union as a corresponding property right in the relevant Member State, individuated on the basis of a hierarchy of conditions: *'(a) according to the entry in the Register of Community Plant Variety Rights, the holder was domiciled or had his seat or an establishment on the relevant date; or (b) if the conditions laid down in subparagraph (a) are not fulfilled, the first-*

[269] Morri F., 2011, *La Privativa Varietale Comunitaria,* in Rivista di diritto industriale, 1.
[270] Van Der Kooij P.,1997, op. cit., p. 49

mentioned procedural representative of the holder, as indicated in the said Register, was domiciled or had his seat or an establishment on the date of registration'[271]. Pursuant to paragraph 2, in the case said conditions are not fulfilled, the Member States shall be the one in which the seat of the CPVO is located, i.e. France.

As an object of property, the Community PVR might be transferred to one or more successors in title under the conditions specified in Article 23[272] and might be also levied in execution according to Article 24[273]. Moreover, it may form the subject of contractually granted or compulsory exploitation rights. The main difference among contractual and compulsory exploitation relies on the voluntarily grant by the CPVR holder in the first case, and the compulsory grant by the CPVO in the second case.

Article 27 deals with contractual exploitation rights, stating the following: '*1. Community plant variety rights may form in full or in part the subject of contractually granted exploitation rights. Exploitation rights may be exclusive or non-exclusive. 2. The holder may invoke the rights conferred by the Community plant variety right against a person enjoying the right of exploitation who contravenes any of the conditions or limitations attached to his exploitation right pursuant to paragraph 1'.* Therefore, the exploitation of CPVRs might be granted by the holder - typically with a license agreement - fully or partially, exclusively or non-exclusively. Unlike the transfer, in case of contractual exploitation, the holder of Community PVR is going to be the same person, who could also apply the rights conferred by the CPVR against the contravention of the conditions provided in the agreement by the person enjoying the right of exploitation.

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[271] Article 22 (1) of the Basic Regulation.

[272] Article 23 of Regulation (EC) No 2100/94, Transfer: '*1. A Community plant variety right may be the object of a transfer to one or more successors in title. 2. Transfer of a Community plant variety right by assignment can be made only to successors who comply with the conditions laid down in Article 12 and 82. It shall be made in writing and shall require the signature of the parties to the contract, except when it is a result of a judgement or of any other acts terminating court proceedings. Otherwise it shall be void. 3. Save as otherwise provided in Article 100, a transfer shall have no bearing on the rights acquired by third parties before the date of transfer. 4. A transfer shall not take effect for the Office and may not be cited vis-à-vis third parties unless documentary evidence thereof as provided for in the implementing rules is provided and until it has been entered in the Register of Community Plant Variety Rights. A transfer that has not yet been entered in the Register may, however, be cited vis-à-vis third parties who have acquired rights after the date of transfer but who knew of the transfer at the date on which they acquired those rights*'.

[273] Article 24 of Regulation (EC) No 2100/94, Levy of execution: '*A Community plant variety right may be levied in execution and be the subject of provisional, including protective, measures within the meaning of Article 24 of the Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters, signed in Lugano on 16 September 1988, hereinafter referred to as the 'Lugano Convention''.*

Upon authorization from the right holder granting contractual exploitation rights, the person enjoying the right of exploitation on the Community PVR can perform one or more acts listed in Article 13 (2) of the Basic Regulation. The authorization of the holder might be subject to conditions and limitation, as stated in Article 13 (2), and these conditions and limitations may concern several contractual aspects of the agreement, such as duration of the agreement, territory in which the authorization applies, termination, royalty payments, EDVs, dispute settlement, et cetera. On request, any contractual exclusive exploitation right, including the name and address of the person enjoying the right of exploitation, shall be entered in the Register of the Community PVR kept by the Office according to Article 87 (2) (f) of the Basic Regulation. The same provision applies to compulsory exploitation rights.

Pursuant to Article 13 (8), 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.

In particular, agreements in the field of plant variety protection affecting the safeguard of competition have been brought to the attention of the Commission and the Court of Justice of the European Union because some of their provisions have been considered as deleterious for the competition within the internal market. It has been noticed that '*in general, objection might be taken to terms which are perceived to be an attempt to extend the IP right holder's monopoly power beyond the protection afforded to it by the law and/or which might be considered to be oppressive to a person in a weak bargaining position*'[274].

Such agreements are incompatible with the internal market because they may affect trade among Member States and have as their object or effect the prevention, restriction or distortion of competition within the internal market. Therefore, these agreements shall be prohibited and shall be deemed as automatically void, according to Article 101 TFUE[275] (ex Article 81 TEC).

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[274] Ekvad M., 2008, *Legal Framework in selected UPOV Members: relevant laws and jurisprudence – European Community*, in UPOV, Symposium on Contracts in relation to Plant Breeders' Rights, Geneva, UPOV/SYM/GE/08/4.

[275] Article 101 TFUE, (ex Article 81 TEC): '*1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect*

By way of illustration, in *Nungesser v. Commission* (Case C-258/78), a case concerning a license agreement among a breeding institute and a supplied of seeds, the Court of Justice distinguished among an *open exclusive license,* whereby the licensor does not grant other license in the licensee's territory and does not compete with him, and an *exclusive license*, whereby the parties agree to eliminate the competition from third parties. The latter is incompatible with Article 101 TFUE because affects the position of third parties and competition within the internal market.

In *Louis Erauw-Jacquery Sprl v. La Hesbignonne* (Case C-27/87), the Court of Justice held that a license agreement term prohibiting the export of basic seeds does not represent an improper exercise of the Community PVR and it does not infringe Article 101 TFUE. The reason is that basic seeds are intended for the purpose of propagation and the breeder is entitled to control the destination of the relevant basic seeds to approved institutions. Also, the breeder is entitled to require the licensee to resell the reproductive seeds on minimum pricing: unless the provision is capable to affect trade among Member States to an appreciable degree, there is no restriction of competition.

In the Commission Decision of 14 December 1998, also called *Sicasov decision*[276] (IV/35.280), the Commission assessed the standard agreements of Sicasov covering the production and sale of the seeds. The Commission decided that provisions limiting the export or import of basic seeds or limiting the entrust of basic seeds to a third party do not restrict competition within the internal market. The same principle applies to provisions prohibiting

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the prevention, restriction or distortion of competition within the internal market, and in particular those which: (a) directly or indirectly fix purchase or selling prices or any other trading conditions; (b) limit or control production, markets, technical development, or investment; (c) share markets or sources of supply; (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts. 2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void. 3. The provisions of paragraph may, however, be declared inapplicable in the case of: - any agreement or category of agreements between undertakings, - any decision or category of decisions by associations of undertakings, - any concerted practice or category of concerted practices, which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question'.

[276] Sicasov (*Société coopérative d'intérêt collectif agricole anonyme à capital variable*) is a French cooperative of breeders of protected plant varieties.

the export of first or second generation certified seeds if those seeds do not represent the lowest level of protection (i.e. *technical seeds*).

In the Commission Decision of 13 December 1985, so called *Roses decision* (IV/30.017), the Commission decided that the following three provision of a licensing agreement concerning protected varieties of rose bushes constitute an infringement of Article 101 TFUE: 1. the obligation of the licensee to surrender all mutation discovered by him to the licensor on rose bushes, so that the CPVR holder might decide unilaterally about the commercial exploitation of the mutations; 2. the obligation, imposed after the amendment, under which the CPVR holder might impose said unilateral decision within a period of three years from the date of surrender; 3. the *no-challenge* clause, not allowing the licensee to challenge the validity of the Community PVR.

18. Compulsory exploitation rights

As already anticipated above, compulsory exploitation rights may be granted in respect of a Community PVR by the Office on grounds of public interest, as provided for in Article 29 (1) of the Basic Regulation, which fundamentally corresponds to Article 17 of the 1991 UPOV Convention. The rationale behind the grant of a compulsory exploitation right lies in the reasoning that, in exceptional circumstances, public interest outweighs the interests of the holder of the Community PVR in enjoying the exclusive exploitation of their crop improvement, thus a restriction of the relevant intellectual property right is allowed.

It is important to underline that only the CPVO is entitled to grant compulsory exploitation rights for plant varieties which are protected by Community plant variety rights: according to Article 29 (7), Member States are not allowed to grant said rights in respect of Community PVRs. Basically, the provisions dealing with compulsory exploitation rights are provided for in Article 29 of the Basic Regulation and in the Implementing Rules, which specify the examples of public interest and lay down details for the implementation of Article 29.

With regard to applicants and persons enjoying compulsory exploitation rights, the Basic Regulation stipulates that there are basically two different categories of applications. Specifically, compulsory exploitation rights may be granted: 1. to one or more persons on application by said persons, after consulting the Administrative Council of the CPVO

(Article 29 (1) of the Basic Regulation); 2. to a category of persons satisfying specific requirements or to anyone in one or more Member States or throughout the EU, on application by a Member State, by the Commission or by an organization set up at the EU level and registered by the Commission (Article 29 (2) of the Basic Regulation).

According to paragraph 3 of Article 29, when granting the compulsory exploitation rights, the CPVO shall *'stipulate the type of acts covered and specify the reasonable conditions pertaining thereto'*, as well as the specific requirements to be satisfied by the category of persons referred above. When specifying the reasonable conditions, which may concern duration, royalty payments as equitable remuneration to the holder, holder's obligation, the Office shall take into consideration the interests of any CPVR holder affected by the grant of the compulsory exploitation rights. The fulfillment of the reasonable conditions specified by the Office is necessary to make use of the compulsory exploitation right.

Article 29 (4) states that on the expiry of each one-year period after the grant, any of the parties to proceedings may request to cancel or amend the decision, on the grounds that the circumstances determining the decision taken by the Office have changed in the meantime.

According to Article 29 (5), a compulsory exploitation right shall be granted on application to the holder of a plant variety right in respect of an EDV, only on the grounds of public interest and upon payment of an appropriate royalty as equitable remuneration to the holder of the initial variety.

Council Regulation (EC) No 873/2004 of 29 April 2004 amended the Basic Regulation replacing its Article 29. The amendment was necessary to ensure transparency and coherence of the EU system of compulsory cross-licensing after the adoption of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Article 12 of Directive 98/ 44/EC[277] establishes

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[277] Article 12 of Directive 98/44/EC, Compulsory cross-licensing: *'1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety. 2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member*

rules for the grant of non-exclusive compulsory licenses where protected plant varieties incorporate patent inventions and vice versa.

Therefore, Article 29 of the Basic Regulation was amended accordingly by modification of its title from *Compulsory exploitation right* to *Compulsory licensing*, although this term shall have the same meaning and content of the previous one as specified in the Preamble to Regulation (EC) No 873/2004, and by insertion of paragraph 5a[278], which makes express reference to compulsory licenses provided for in Article 12 of Directive 98/44/EC. This paragraph states that the holder of a patent for a biotechnological invention may obtain on application a compulsory license for the non-exclusive use of a protected plant variety pursuant to Article 12 (2) of Directive 98/44/EC. The paragraph specifies that the person enjoying the compulsory exploitation right shall pay of an appropriate royalty as equitable remuneration.

The grant of the compulsory license is subject to two conditions: (i) the demonstration that the holder of the patent has applied unsuccessfully to the holder of the plant variety right to obtain a contractual license; and (ii) the demonstration that the invention constitutes significant technical progress of considerable economic interest compared with the protected plant variety.

In case the holder of a Community PVR has been granted a compulsory license in accordance with Article 12 (1) of Directive 98/44/EC for the non-exclusive use of a patented

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States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention. 3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that: (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence; (b)the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety. 4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply'.

[278] Article 29 (5) (a) of Regulation (EC) No 2100/94, Compulsory licensing *'5a. On application, a compulsory licence for the non- exclusive use of a protected plant variety pursuant to Article 12(2) of Directive 98/44/EC shall be granted to the holder of a patent for a biotechnological invention, subject to payment of an appropriate royalty as equitable remuneration, provided that the patent holder demonstrates that: (i) he/she has applied unsuccessfully to the holder of the plant variety right to obtain a contractual licence; and (ii) the invention constitutes significant technical progress of considerable economic interest compared with the protected plant variety. Where, in order to enable him/her to acquire or exploit his/her plant variety right, a holder has been granted a compulsory licence in accordance with Article 12(1) of Directive 98/44/EC for the non-exclusive use of a patented invention, a non-exclusive cross-licence on reasonable terms to exploit the variety shall be granted, on application, to the holder of the patent for that invention. The territorial scope of the licence or cross-licence referred to in this paragraph shall be limited to the part or parts of the Community covered by the patent'.*

invention in order to enable him to acquire or exploit their plant variety right, a non-exclusive cross-license on reasonable terms to exploit the variety shall be granted to the holder of the patent, on application. However, the wording of this provision does not clarify whether the compulsory cross-license shall be granted under the same conditions laid down above for the original compulsory license, i.e. the unsuccessful application to the right holder and the existence of significant technical progress of considerable economic interest.

A clarification is provided by the Implementing Rules, especially in Article 37 (3), which states that the application for this compulsory cross-license shall contain: (a) the designation of the applicant holding a patent right and the opposing holder of the variety concerned as parties to proceedings; (b) the variety denomination and the plant species of the variety or varieties concerned; (c) a certified copy of the patent certificate showing the number and claims of the patent for a biotechnological invention and the granting authority of the patent; (d) an official document showing that a compulsory license for a patented biotechnological invention has been granted to the holder of the plant variety right; (e) a proposal for the type of acts to be covered by the cross-license; (f) a proposal for an equitable remuneration and the basis for calculating the remuneration; (g) a proposal for the territorial scope of the cross-license, which may not exceed the territorial scope of the patent referred to in point (c).

Consequently, the compulsory cross-license shall not be granted under the same conditions laid down for the original compulsory license: for the patent owner is it sufficient to prove that a compulsory license for a biotechnology patent has been granted to the PVR holder. The cross-license seems to be basically a matter of reciprocity than a fulfillment of the conditions above mentioned.

With reference to the territorial scope, the last subparagraph of Article 29 (5a) states that the license and the cross-license are limited to the same parts of the European Union covered by the patent.

Although the content of paragraph 5a is similar to Article 12 of Directive 98/44/EC, the *public interest* is not mentioned in Article 12: the grant of a compulsory license on a biotechnology patent is connected only to technical progress and economic justification.

In light of this, one might inquire whether the public interest imperative laid down in Article 29 (1) of the Basic Regulation, according to which '*Compulsory exploitation rights shall be granted […] only on the grounds of public interest'*, is playing any role in the event

of a compulsory license on a protected plant variety granted to the holder of a biotechnology patent. It might be argued that this access to the protected plant variety by the patent holder shall be granted *on the grounds of public interest* because the insertion of the new paragraph 5a should not change the basis of the provision set out in paragraph 1. In this scenario, the demonstration of *significant technical progress of considerable economic interest* should not be deemed sufficient itself: there should be an underlying public interest going beyond the mere economic factors for the grant of the compulsory license.

This issue has been clarified by the Implementing Rules, as amended by Commission Regulation (EC) No 1002/2005 of 30 June 2005 regarding the grant of compulsory licenses: Article 37 clearly states that the application for a compulsory license pursuant to Article 29 (1), (2) and (5) of the Basic Regulation shall contain, *inter alia, '(d) a statement setting out the public interest concerned, including details of facts, items of evidence and arguments presented in support of the public interest claimed'*. Differently, the application for a compulsory license referred to in Article 29 (5a) of the Regulation shall contain *'(f) a statement setting out why the biotechnological invention constitutes significant technical progress of considerable economic interest compared with the protected variety, including details of facts, items of evidence and arguments in support of the claim'*. In the latter case there is not a need for the applicant to demonstrate that the public interest is concerned.

However, this provision might conflict with Article 17 of the 1991 UPOV Convention, according to which the exercise of the right of the owner of the protected plant variety can be restricted *only* for reasons of public interest. A solution to this possible divergence has been provided by the former CPVO President, Mr. Bart Kiewiet, who stated that: *'in the working group of the Council, where the proposal is discussed, an exchange of views has taken place about the compatibility of the 'public interest' criterion used in the UPOV Convention with the 'significant technical progress of considerable economic interest' requirement to be introduced in the Community system for the cross compulsory licenses. Some Member States have expressed the fear that introducing this requirement in its PBR legislation would disqualify the European Community as a member of UPOV. Others have*

defended the position that the Directive criterion could be considered as forming part of a wide 'public interest' notion. I am inclined to defend that line'[279].

After analyzing Article 41 of the Implementing Rules, one might agree with such statement. Article 41 (2) establishes that the following grounds may constitute public interest: (a) the protection of life or health of humans, animals or plants; (b) the need to supply the market with material offering specific features; (c) the need to maintain the incentive for continued breeding of improved varieties. The provisions of letters (b) and (c) literally replicate the content of the Preamble of the Regulation, which reads as follows: *'whereas compulsory licensing should also be provided for under certain circumstances in the public interest, which may include the need to supply the market with material offering specified features, or to maintain the incentive for continued breeding of improved varieties'*.

Article 41 (3) of the Implementing Rules states that the following grounds may, in particular, constitute reasons why the invention constitutes significant technical progress of considerable economic interest compared to the protected plant variety[280]: (a) improvement of cultural techniques; (b) improvement of the environment; (c) improvement of techniques to facilitate the use of genetic biodiversity; (d) improvement of quality; (e) improvement of yield; (f) improvement of resistance; (g) improvement of adaptation to specific climatological and/or environmental conditions.

On a closer inspection, these grounds could be considered as forming part of the public interest notion: for example, the improvement of the environment represents an aspect of the protection of life or health of humans, animals or plants; the improvement of quality denotes the need to supply the market with material offering specific features; the improvement of techniques to facilitate the use of genetic biodiversity indicates the need to maintain the incentive for continued breeding of improved varieties, and so on.

In addition, it shall be highlighted that Recital 36 of Directive 98/44/EC makes reference to the TRIPs Agreement, which provides for the possibility that members of the WTO *'may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including*

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[279] Kiewiet B., 2004, *Principles, procedures and recent developments in respect of the Community Plant Variety Protection system,* Frankfurt, p. 10. Available at https://cpvo.europa.eu/

[280] The list provided by Article 41, both paragraphs (2) and (3), shall not be considered exhaustive ('the following grounds *may* constitute […]').

to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'. Indeed, Article 12 of Directive 98/44/EC complies with Article 31 (l) (i) of the TRIPs Agreement, where the notion of *significant technical progress of considerable economic interest* can be found[281]. This Article does not make an expressed reference to public interest grounds, however Article 7 of the TRIPs Agreement states that intellectual property rights should be exploited *'in a manner conducive to social and economic welfare'*. From this provision, it can be extrapolated that the grant of compulsory licenses by the TRIPs Member States can be made solely on public interest grounds. Indeed, compulsory license in patent law is *'deeply rooted in the promotion of public interest'*[282] and therefore the notions of *'significant technical progress of considerable economic interest'* and '*public interest'* shall not be deemed to be conflicting.

In light of this, the line defended by Mr. Kiewiet seems utterly persuasive: the inescapable conclusion of this analysis would be that *'significant technical progress of considerable economic interest'* may be interpreted as forming part of the '*public interest'* notion in the event of compulsory licensing of Community plant variety rights.

The role of public interest for the grant of a compulsory exploitation right has recently formed the subject matter of consideration by the CPVO: on 16 March 2017, the very first request for a compulsory license pursuant to Article 29 of the Basic Regulation in respect of a blackcurrant variety named 'Ben Starav' has been received by the CPVO. After hearing the opinion of the Administrative Council, according to Article 29 (1) of the Basic Regulation, on 28 March 2018 the CPVO decided to deny the grant of a compulsory exploitation right because the applicant had not furnished sufficient evidence of the public interest ground concerned in support of its application and such evidence shall not be proved *ex officio*. The Office underlined that the burden of proof regarding the public interest

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[281] Article 31 (l) (i) of the TRIPs Agreement: '*Where the law of a Member allows for other use7 of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: […] (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply: (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; […]'*.

[282] Hilty R., Kung-Chung L., 2015, *Compulsory Licensing: Practical Experiences and Ways Forward*, in IIC, 46, 5.

criterion lies on the applicant: in this case, the CPVO held that the application for the compulsory license was solely based on the commercial interests of the applicant. The applicant stated that the public interest ground concerned the need to supply the market with material offering specific features, in particular with the unique characteristics of the relevant protected variety, characteristics that the CPVO deemed to be present in other varieties on the market: the applicant failed to give the evidence that other varieties do not have similar features[283]. Therefore, the CPVO held that the application did not fulfill the requirements established by Article 41(2) (b) of the Implementing Rules. This case shows that the compulsory license in the CPVR system represents an ultimate measure, the *extrema ratio,* and that it shall be granted by the Office only on exceptional circumstances, as provided for in Article 29 of the Basic Regulation.

19. Duration

Article 19 of the Basic Regulation deals with the duration of the Community PVR, stating that the term shall run until the end of the twenty-fifth calendar year following the year of grant. In the case of varieties of vine and tree species, said period is extended until the end of the thirtieth calendar year.

Pursuant to paragraph 2, the Council, acting by qualified majority on proposal from the Commission, may provide an extension of these terms up to a further five years. Council Regulation (EC) No 2470/96 of 17 December 1996 has provided such extension by a further five years for potatoes[284], because these varieties require time-consuming breeding processes and begin to make a profit after a very long time[285].

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[283] Würtenberger G., 2018, *Public Interest and Compulsory Licences,* München, available at: http://ipplant.eu/public-interest-and-compulsory-licences#_ftn1

[284] Even if the duration of Community PVR for potatoes is 30 years, in 2015 the European Seed Association - Potato Section (ESA SPO) - has published a position paper on the need to further extend said term up to 35 years. According to ESA SPO, this extension is necessary in order to maintain and further develop the leading role of private potato breeding companies in Europe. The arguments to justify such extension are the following: 1. the relative low multiplication rate in potato; 2. the significant decrease in potato production in Europe in the past decade; 3. the increased segmentation of the potato market requiring increased investment for adapted varieties of each of these markets and with that; 4. the increased costs and complexity in plant breeding; 5. the slow acceptance of new varieties; 6. to safeguard the contribution to biodiversity of the micro sized private potato breeding companies in Europe; 7. to maintain the leading position of micro sized private potato breeding companies in Europe. Source: ESA SPO, 2015, *Position on the need to extend the duration of Community Plant Variety Rights for Potatoes,* Brussels, ESA_13.0543.5.

[285] Van Der Kooij P.,1997, op. cit., p. 45.

The Community PVRs are granted for a longer term than the minimum period provided for in Article 19 of the UPOV Convention, which is twenty years and, in case of trees and vines, twenty-five years. This period is even longer than the term of a European patent: Article 63 (1) of the European Patent Convention states that the term of the European patent shall be twenty years from the date of filing of the application.

It might be noticed that in the case of a Community plant variety right, the term follows the grant of the right; whereas in case of a European patent, the term follows the date of application. Therefore, the time for the grant procedure is not included in the period of protection of a plant variety right.

Article 19 (3) of the Basic Regulation deals with the surrender of the Community PVR: said right shall lapse before the expiry of the terms above mentioned, if the holder surrenders it by sending a written declaration to the Office, with effect from the day following the day on which the declaration is received by the Office. The effect of the surrender may be compared with the cancellation of the right pursuant to Article 21 of the Basic Regulation: it follows that the surrender will have *in futurum* effects on the CPVR, unlike nullity which is made effective as from the outset (effects *ex tunc*), according to Article 20 of the Basic Regulation.

20. Infringement

Article 94 of the Basic Regulation determines the acts one may perform to infringe the Community plant variety rights, establishing a principle of objective and full compensation for the victim of the infringement. Paragraph 1 (a) deals with the infringement of the rights set out in Article 13 (2). These acts are reserved to the CPVR holder and infringement occurs when they are performed by a person not entitled to do so in respect of a variety for which a Community PVR has been granted. In other words, the relevant plant variety right shall be granted and valid[286] when the infringement occurs. The infringer may be sued by the holder to stop the infringement or to pay reasonable compensation or both. However, according to Article 95, the holder may also require reasonable compensation for the infringing acts

[286] According to Article 105 of the Basic Regulation, a national court or other body hearing an action relating to a Community PVR shall not decide on its validity. The Community PVR shall be treated as valid.

occurred before the grant of the Community plant variety right, in the time between the publication of the application for CPVR and the grant thereof.

Paragraphs 1 (b) and (c) determines the conditions under which an infringement concerning the plant variety denominations occurs: (b) when a person omits the correct usage of the variety denomination as referred to in Article 17 (1) or the relevant information as referred to in Article 17 (2); (c) in case a person uses the denomination of a protected variety or a designation that may be confused with it in connection with another variety of the same botanical species or a species regarded as related, pursuant to Article 18 (3).

The infringement may lead to a twofold action by the right holder: 1. an injunction claim, in order to impede a first potential infringing act, to cease the unauthorized acts, or to prevent future infringements (in this case a reasonable compensation may be paid by the infringer); 2. a damage claim, in order to compensate the holder for the damage resulting from the unauthorized act, only when the infringer's conduct is intentional or negligent (in this case a compensation for damage is due)[287].

In the second case, the risk of committing an infringing act for the first time cannot represent the basis for a damage claim, unlike injunction claims: a committed infringement on a valid CPVR is required in order to claim damages. According to Article 94 (2), in case of slight negligence, the damage claims may be reduced according to the degree of such slight negligence. However, the claim shall not be less than the advantage derived from the infringing acts by the person who committed them: this shall be the minimum of the damage claim.

It is interesting to note that a provision setting out the calculation criteria of the compensation payable under Article 94 cannot be found in the Basic Regulation. However, the Court of Justice of the European Union has recently dealt with the ascertainment of the principles governing said calculation concerning both the '*reasonable compensation'* referred to in Article 94 (1) and the '*compensation for damages*' referred to in Article 94 (2), in its judgment of 9 June 2016 (Case C-481/14, *Jørn Hansson v Jungpflanzen Grünewald GmbH*).

Regarding the reasonable compensation calculation, the Court noted that, according to Article 94 (1), the financial compensation should correspond to the benefit gained by the

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[287] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 191.

infringer and the amount thereof shall be equivalent to the license fee which that person failed to pay[288]. The amount of the fee payable for licensed production as referred to in Article 14 (3) of the Basic Regulation can constitute an appropriate basis for calculation. However, the referring court can increase the amount of that fee, observing the principle of objective and full compensation resulting from Article 94, but such financial compensation cannot exceed the loss connected to the failure to pay that compensation which may include, *inter alia*, payment of default interest[289].

Differently, the compensation for damages concerns the loss for which an infringer must compensate the holder of a Community PVR in case of intentional or negligent conduct. The CPVR holder has to produce evidence proving that their damage goes beyond the loss covered by the reasonable compensation. Therefore, the compensation established in the Basic Regulation rests on an objective basis, covering only the actual and certain damages suffered by the PVR holder because of the infringement. A lump-sum method may be used if those matters are not quantifiable.

The result is that Article 94 cannot be interpreted as providing a legal basis to require the infringer to pay punitive damages. Analogously, the provision does not allow a restitution claim of the gains and profits made by the infringer: both the reasonable compensation and the compensation for damages are calculated on the basis of the loss suffered by CPVR holder, victim of infringement, and not on the profit made by the infringer.

According to Article 96 of the Basic Regulation, the prescription for the claims pursuant to Article 94 and 95 is three years from the time at which the Community PVR has finally been granted and the holder has knowledge of the act and of the identity of the party liable or, in the absence of such knowledge, after 30 years from the termination of the act concerned. The meaning of the provision is not completely clear: one might wonder what will happen in case the infringing acts occur more than three years after the grant of the CPVR. According to eminent scholars, such provision shall be interpreted to mean that '*the three-year term commences with the knowledge of the infringing acts by the infringer,*

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[288] Reference is made to judgment of 5 July 2012 in *Geistbeck*, C-509/10, EU:C:2012:416, paragraph 40.
[289] Thereby it excludes from the amount of the compensation the costs incurred for monitoring compliance with the rights of the plant variety holder (reference is made to CJEU judgment of 5 July 2012 in *Geistbeck*, C-509/10, EU:C:2012:416, paragraphs 50 and 51).

regardless of when he obtained the same after grant, with a maximum term of thirty years'[290]. This broad interpretation is persuasive: a different explanation would jeopardize the protection of the interests of the CPVR holder.

Lately, a case concerning a similar inquiry landed before the Court of Justice of the European Union. A request for a preliminary ruling from the Spanish Tribunal Supremo has been made to the CJEU on 9 March 2018 (Case C-186/18, *José Cánovas Pardo, S.L. v Club de Variedades Vegetales Protegidas*) concerning the interpretation of Article 96 of the Basic Regulation. The Tribunal Supremo submitted the following questions to the Court of Justice: 1. is an interpretation according to which, provided that the period of three years has elapsed, since the holder, once Community protection of the plant variety right was granted, became aware of the infringing act and the identity of the infringer, the actions provided for under Articles 94 and 95 of the Regulation would be time-barred, although the infringing acts were continuing until the time the action was brought, contrary to Article 96 of Regulation (EC) No 2100/94?; 2. if the first question is answered in the negative, is it to be considered that, in accordance with Article 96 of Regulation (EC) No 2100/94, the limitation period operates only in respect of infringing acts committed outside the three-year period, but not in respect of those taking place within the last three years?; 3. if the answer to the second question is in the affirmative, in such a situation could the action for an injunction and also for damages succeed only in relation to those latter acts taking place within the last three years? These questions are of utmost importance because prescription has a crucial role for enforcement of rights, and a restrict interpretation might undoubtedly shake the effectiveness of the Community plant variety protection system.

21. Enforcement

Plant variety rights are supposed to promote innovation and investment in the breeding sector. However, this effect *'is not only dependent on an effective grant procedure, but also, to an equal extent, on effective enforcement mechanisms'*[291]. It is essential to ensure that

[290] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 197.
[291] Ibidem, p. 202.

substantive law is applied effectively because when there is a lack of effective means of enforcing intellectual property rights, innovation is undermined and investment decreased.

Even though Community plant variety rights have uniform effect within the territory of the European Union (Article 2 of the Basic Regulation), *'this uniform effect is not entirely guaranteed'*[292] since CPVR enforcement depends on the applicable national law. As stated above, the enforcement of Community plant variety right is tied to Member States national laws as determined by Article 103 of the Basic Regulation, and civil law claims shall be brought before the competent national courts in accordance with Article 101 of the Basic Regulation[293]. Indeed, the Basic Regulation does not deal with enforcement of CPVRs.

It is a common understanding that differences in national laws and disparities in the enforcement of intellectual property rights among EU Member States are prejudicial to the proper functioning of the internal market and may lead to unequal protection and subsequent distortions of competition. It is because of these growing concerns that the European legislator adopted of Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights, which concerns the measures, procedures and remedies

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[292] Ibidem, p. 184.

[293] Article 101 of Regulation (EC) No 2100/94, Jurisdiction and procedure in legal actions relating to civil law claims '*1. The Lugano Convention as well as the complementary provisions of this Article and of Articles 102 to 106 of this Regulation shall apply to proceedings relating to actions in respect of the claims referred to in Articles 94 to 100. 2. Proceedings of the type referred to in paragraph 1 shall be brought in the courts: (a) of the Member State or another Contracting Party to the Lugano Convention in which the defendant is domiciled or has his seat or, in the absence of such, has an establishment; or (b) if this condition is not met in any of the Member States or Contracting Parties, of the Member State in which the plaintiff is domiciled or has his seat or, in the absence of such, has an establishment; or (c) if this condition is also not met in any of the Member States, of the Member States in which the seat of the Office is located. The competent courts shall have jurisdiction in respect of infringements alleged to have been committed in any of the Member States. 3. Proceedings relating to actions in respect of claims for infringement may also be brought in the courts for the place where the harmful event occurred. In such cases, the court shall have jurisdiction only in respect of infringements alleged to have been committed in the territory of the Member State to which it belongs. 4. The legal processes and the competent courts shall be those that operate under the laws of the State determined pursuant to paragraphs 2 or 3'.* Therefore, in case of infringement, there is a choice of forum: the CPVR holder may sue the defendant either before the court of the defendant's domicile or before the courts for the place where the harmful event occurred. This is an exception to the general principle of *actor sequitur forum rei.* The concept of 'harmful event' and its analogousness with the notion of 'act of infringement' in the enforcement of unitary IP rights has been investigated in Kur A., 2015, *Enforcement of unitary intellectual property rights: international jurisdiction and applicable law*, in Journal of Intellectual Property Law & Practice, 10, 6. The author analyses whether the two notions are dissimilar and whether the location of 'act' and 'effect' in different countries could make sense in intellectual property law. The conclusion is that there is a plausible equation between 'harmful event' and 'act of infringement' set out in Art. 101(3) of the Basic Regulation: the author believes that, in intellectual property law, an act of infringement can be qualified as such if it produces an effect in the territory in which it is committed.

necessary to ensure the enforcement of intellectual property rights, including Community PVRs.

This Directive shall apply to any infringement of IP rights as provided for by EU law and/or by the national law of the Member State concerned, pursuant to its Article 2. As laid down in Recital 10 of the Preamble, this Directive has the objective to approximate legislative systems so as to ensure a high, equivalent and homogeneous level of protection in the internal market. The provisions of the Directive deal with rules of evidence, right of information, provisional and precautionary measures, measures resulting from a decision on the merits of the case, damages and legal costs, publicity measures, and sanctions. Nevertheless, a unified legal practice has not been reached yet. Differences in the enforcement of Community PVRs still exists among EU Member States, because of the different national civil procedure laws and variability of costs and duration of litigation, thereby perpetuating national disparities and impacting the value of CPVRs[294].

22. Final remarks

The adoption of Council Regulation (EC) 2100/94 of 27 July 1994 on Community plant variety rights has been welcomed by plant breeders and intellectual property law practitioners because it provided for a unitary intellectual property right on new plant varieties, valid throughout the European Union. The Community plant variety regime allows breeders of new plant varieties to protect their invention and to obtain a return on their investment in the form of a royalty payment. The uniform effect of the Community plant variety rights has simplified the application procedure, thereby facilitating breeders, to the advantage of competitiveness in the internal market

The Community plant variety protection regime has also recognized the peculiarities of the plant breeding sector. By way of illustration, it implemented a longer duration of CPVRs, compared with the 1991 UPOV Convention, recognizing the time-consuming nature of breeding activities and the need for a longer period of protection in order to obtain a sufficient return on investment. Furthermore, the Community plant variety protection

[294] Cf. Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 185, and Llewelyn M., Adcock M, 2006, op. cit., p. 244.

system has taken into account the public interest overtones concerning intellectual property rights on plant varieties, for example by means of its provisions on breeder's exemption, compulsory exploitation rights, and farmer's privilege. It is indeed the farmer's privilege to represent a field of intense legal debate: a balance between the protection of Community plant variety rights and the implementation of the FSS practice seems difficult to achieve.

In addition, another ongoing debate concern the interpretation of Article 96 of the Basic Regulation, dealing with the prescription for the claims pursuant to Article 94 and 95. The decision of the Court of Justice in the Case C-186/18, *José Cánovas Pardo, S.L. v Club de Variedades Vegetales Protegidas* will clarify the scope of the provision.

However, and despite its merits, there are some concerns about the Community plant variety protection. In particular, the lack of harmonization with national legislations may lead to contradictions within the internal market: its crucial ties to national laws may critically impact on the effective enforcement of CPVRs.

In this sense, the most affected subjects are SMEs because they are supposed to be the ones facing the most significant difficulties to enforce IPRs. This concern has a meaningful relevance because of the great role SMEs play in plant variety innovation throughout the European Union.

CHAPTER 4
The Seed Legislation: Marketing Seeds in the EU

SUMMARY: 1. The EU commercial seed market. - 2. The concept of seed quality and its importance. - 3. Origin of seed marketing laws in Europe. - 4. The two pillars of the EU seed legislation. - 5. Registration of the varieties. - 5.1. Requirements for registration. - 5.2. The VCU requirement for varieties of agricultural species. - 5.3. One key, several doors principle: a perspective de iure condendo. - 5.4. Admission to the EU Common Catalogues. - 6. Certification of the seed lots. - 6.1. The generation system. - 6.2. The paradigm of uncertified farm-saved seed. - 6.3. Derogations for conservation varieties. - 6.4. An overview on cereal seed: Council Directive 66/402/EEC. - 7. Final remarks.

1. The EU seed market

As stated in the first chapter of the present contribution, the seed sector has a remarkable importance in the European Union, and within this context cereal seeds have a weighty position. In this framework, the EU seed legislation has been valuable for the achievement of specific goals, such as ensuring the free marketing of the material in the EU territory, providing quality seeds, and increasing agricultural productivity[295]. Hence, this legislation has a high impact on the EU seed market and, consequently, on the competitiveness of the seed sector.

The current chapter is going to provide an overview of the EU seed legislation, before the inauguration of the empirical section of the research. This is utterly necessary to understand whether this legislation has any role in promoting competitiveness and innovation in the seed sector in the European Union. The focus in on 'whether' and 'how' this role may have an impact on the effectiveness of Community plant variety protection on cereal varieties in the EU industry: after all, both legislations concern the plant reproductive

[295] European Commission, 2013, *Executive Summary of the Impact Assessment. Accompanying the document 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),* SWD (2013) 163 final, Brussels, p. 3.

material, which cannot be divided between *intangible* and *tangible* form of the subject matter. Therefore, the laws affecting the 'tangible' form may also have an impact on the 'intangible' one.

As already stated at the beginning of this contribution, GMOs are not covered by the present investigation because of their very marginal role in the EU seed market and EU agricultural production.

2. The concept of seed quality and its importance

Seed, as both a technology carrier and a commercial commodity[296], represents the infrastructure of the agricultural crop sector, contributing to food security and food safety. Seeds represent a decisive input in crop production and they decisively affect yield potentials. In particular, seed has a crucial influence on productivity, resistance, and health of crops and, consequently, on achieving a safe food production. Moreover, seed may positively affect the environmental impact of agricultural activities, for example, by reducing the use of pesticides, and the sustainable use of natural resources.

In light of this, the agriculture of the third millennium must rely on high-quality seeds, capable of positively influencing the farming activities, safeguarding production, and tackling agricultural challenges.

The use of quality seeds is necessary to address the current challenges of population growth, climate change, and water scarcity: the use of seeds ensuring excellent productivity, high yields, and reducing the environmental impact of agricultural activities is essential for the agriculture of the third millennium and for the future of food production. It is also a precondition for competitive and sustainable production of fuel, fibres and further plant-based products for industrial, medical, or other uses[297].

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[296] Louwaars N., 2002, *Seed Policy, Legislation and Law: Widening a Narrow Focus,* in Journal of New Seeds, 4, 1/2, p. 2-4. The author states that the seed policies shall combine in its objectives the two main functions of seeds: the technology transfer function and the ability to be a commercial commodity. Therefore, objectives to increase agricultural production and objectives to use quality seed have to be equally merged in seed policy blueprint. Furthermore, the author believes that a third function of seeds has risen as the carrier of valuable genetic resources to be conserved for future generations. This function further complicates the objectives of seed policies, adding yet another element that has to be taken into consideration by policy actors.

[297] Source: European Seed Association (ESA) website, https://www.euroseeds.eu

The critical impact of seed quality on food security and food safety may be understood by way of illustration. Worldwide there is a great concern about a devastating cereal disease called *Fusarium*, a fungal pathogen that represents a major agricultural problem and a threat to food security and safety. The use of quality seeds of cereal varieties resistant to *Fusarium* prevents the loss of crop yield and grain quality, and protects against the fungal production of toxic mycotoxins, particularly deoxynivalenol (DON) that makes the cereals toxic both for livestock and humans[298]. Consequently, seed quality is fundamental for optimal food and feed production[299].

In addition to the improvement of the performance of agricultural production, seed quality is meant to protect consumers and to secure competition at a level playing field for the seed industry. Moreover, the quality evaluation of the seeds has the purpose of permitting a realistic prediction of performance in the field: the knowledge of the seed characteristics will facilitate farmers, allowing them to adopt targeted management decisions in the production process. The cultivation of high-quality seed results in higher crop yields, minimizing the crop failure and the use of extra herbicides or pesticides while improving the nutrient and water-use efficiency, the nutritional value and the tolerance to environmental factors of the plants.

However, the quality of the seed can hardly be assessed at first glance by the buyer, i.e. the farmer. For example, seeds may not germinate or there may be a lack of vigor; they may be the vehicle of pathogens, the hosts for plant pests and diseases; also, seed lots[300] may contain a high percentage of noxious weed seeds, inert material or other crops. In any case, a simple look to the seed lots is not sufficient to evaluate the quality of said commodity.

For that reason, the marketing of plant reproductive material is subject to legislative regulation in order to ensure that certain quality standards are fulfilled and that agricultural

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[298] *Fusarium* is a serious plant disease and that is the reason why the EU established by Commission Regulation (EC) N. 1881/2006 maximum limits for *Fusarium* toxins in cereals and cereal-based products. For further information about *Fusarium* and its toxins, see: SCF, *Opinion on Fusarium Toxins,* SCF/CS/CNTM/MYC/19; EFSA (European Food Safety Authority), 2014, *Scientific Opinion on the risks for human and animal health related to the presence of modified forms of certain mycotoxins in food and feed,* in EFSA Journal, 12, 12; Sobrova P., Adam V., Vasatkova A., Beklova M., Zeman L., Kizek R., *Deoxynivalenol and its toxicity,* in Interdisciplinary Toxicology, 2010, 3, 3, pp. 94-99.

[299] DG SANCO, 2011, *Options and Analysis of Possible Scenarios for the Review of the EU Legislation on the Marketing of Seed and Plant Propagating Material,* Brussels, p. 3.

[300] A seed lot is defined by FAO as an *'identifiable quantity of seed of one variety, of known origin and history, and recorded under a single reference number'.* Source: FAO, 2018, *Seed Toolkit. Module 3: Seed Quality Assurance*, Rome, p. 3.

production is not put at risk. Indeed, ensuring an adequate supply availability of high-quality seed is crucial for the competitiveness and productivity of the agricultural sector and that is the reason why domestic and foreign markets require a consistent checking of quality.

In light of this, one might wonder how the concept of *seed quality* might be defined.

The notion of *quality* is quite indeterminate: quality pertains to an abstract category and its meaning depends on the context, time, and place of its use.

For the purpose of the present investigation, the meaning of *quality* in the seed sector is strictly connected to the current EU legislative regulations on seed marketing and the requirements seed lots must fulfill to be legally marketed in the territory. In particular, the focus is on the minimum requirements for the marketing of seed, which are typically set by national laws and according to international documents.

Even though there is not a treaty providing clarification of such a concept at the international level, there seems to be a consensus among international seed-related organizations about the scope of said term.

According to the Food and Agriculture Organization of the United Nations (FAO), the concept of seed quality *'expresses the extent to which a given seed lot meets the standards set for certain attributes determining the quality status of seeds'*[301]. Therefore, seed quality is the sum of those attributes.

According to FAO, the attributes determining the quality of seeds are the following:

- Genetic purity - strictly related to the genetic characteristics of the variety, refers to the nature of the seeds and the compliance with the declared variety. The evaluation aims to verify the origin of the seeds and whether they come from a distinct variety. Genetic purity influences the uniformity of crop production;
- Physical purity - the physical condition of the seed lot in terms of cleanliness. The evaluation aims to determine the pure seed component, assessing the presence of inert matter, noxious weed seeds and other crop seeds;
- Germination capacity - related to physiological seed performance in the fields. The evaluation aims to indicate the proportion of live seeds capable of germinating, i.e. of producing normal seedlings, under proper conditions over

[301] FAO, 2018, *Seed Toolkit. Module 3: Seed Quality Assurance*, Rome, pp. 3-10.

a given period. The combination of physical purity and germination capacity defines the percentage of pure live seeds, determining the '*planting value of the seed'* which influences the production of a high yield;

- Moisture content - referring to the amount of water in the seed: a crucial parameter because of its impact on the germination and viability of the seeds during storage. The evaluation aims to confirm whether there is safe moisture content, ensuring the storability of the lots without affecting the crop productivity;
- Seed vigor - related to the performance of the physiological functions of the seed under a range of field conditions and the potential for the development of normal seedlings. The International Seed Testing Association (ISTA) defined seed vigor as *'the sum total of those properties of the seed which determine the level of activity and performance of the seed or seed lot during germination and seedling emergence'*[302]*;*
- Seed health - concerning the production of sufficiently healthy seed, free from diseases, molds and pests, in accordance with sanitary and phytosanitary regulations[303]. Plant health affects both crop productivity and market quality.

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[302] ISTA, 1995, *Handbook of vigour test methods (3rd ed.),* in Hampton J., TeKrony D., ISTA Vigour Test Committee (eds), Bassersdorf, p. 117.

[303] Sanitary and phytosanitary regulations set out the basic rules for food safety and animal and plant health standards. The purpose is to ensure human and animal (sanitary) and plant (phytosanitary) life/health protection, ensuring food safety and preventing the spread of diseases or pests among animals and plants. Consequentially, restriction in trade may follow from the adoption of sanitary and phytosanitary measures, such as laws, decrees or ordinances which are applicable generally. In order to avoid the use of unjustified sanitary and phytosanitary measures for the purpose of trade protection, the Agreement on the Application of Sanitary and Phytosanitary Measures (the 'SPS Agreement') was signed during the Uruguay Round in 1994 held in Marrakesh. The SPS Agreement and others agreements on specific issues (e.g. TRIPs Agreement on Trade-Related Aspects of Intellectual Property Rights), in addition to the General Agreement on Tariffs and Trade (GATT 1994), are part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations, establishing the World Trade Organization (WTO). The purpose of the SPS Agreement is to ensure that the government's sovereign right to provide the appropriate sanitary and phytosanitary protection is not misused for protectionist purposes. The sanitary and phytosanitary measures adopted by the Member States shall not represent an unnecessary barrier to international trade: they should be applied solely to ensure human, animal and plant health and should be based on the analysis and assessment of available, accurate and objective scientific data. A scientific justification is required to determine that international standards are not sufficient to achieve an appropriate level of sanitary and phytosanitary protection. The States are encouraged by the SPS Agreement to harmonize their national measures on international standard, which are often more stringent than national ones. Those standards are made up by guidelines and recommendations developed by WTO member governments in other international organizations: for food safety, FAO/WHO Codex Alimentarius Commission; for animal health, the Office International des Epizooties; and for plant health, the FAO International Plant Protection Convention.

The International Seed Testing Association (ISTA) has an analogous view on the scope of the definition of seed quality. ISTA is an independent international organization founded in 1924 which has the purpose of developing and publishing standard procedures in the field of seed testing and the aim of realizing uniformity in seed quality evaluation worldwide[304]. This goal has been achieved through *The International Rules for Seed Testing* (so-called ISTA Rules)[305], internationally agreed rules for seed sampling and testing produced by the association. The methods set by the ISTA Rules are meant to measure the seed quality parameters: their use facilitates seed trading and contributes to food security[306].

About the concept of seed quality, the ISTA Rules provide standardized methods for testing seed lot quality, and those methods consist of: the analytical purity analysis, the germination test, the seed health test, the species and variety test, the moisture content determination, the seed vigor test. Notwithstanding the different wording, the parameters taken into account by the ISTA Rules on seed testing have the same content of the standards listed by FAO. For example, the analytical purity analysis concerns the presence of inert matter, weed seeds and other crop seeds in the evaluated seed lot; whereas the species and variety test is intended for the testing of the genetic purity, as the identity of the sample to the required species or variety and the varietal purity.

The same approach has been used by the Organization for Economic Co-operation and Development (OECD). In 1958, driven by the rise of seed breeding and international seed trade, the OECD established the *Seed Schemes,* which provide an international framework for the varietal certification or controlling of seed traded internationally. The OECD Seed Schemes, whose membership is voluntary and open to OECD, UN, and WTO countries (currently there are 61) have the purpose of encouraging the *'production and use of high quality seed'*[307].

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[304] ISTA's membership is a collaboration of laboratories and scientists engaged in the testing of seeds in over 70 countries worldwide.

[305] The latest volume has been published in 2019 and it is available at the following website: https://www.ingentaconnect.com/content/ista/rules/2019/00002019/00000001.

[306] Source: ISTA website, https://www.seedtest.org/en/home.html. Last access: August 2019

[307] Source: OECD website, http://www.oecd.org/agriculture/seeds/. Last access: August 2019

At present, there are eight Seed Schemes, defined according to a group of species of cultivated plants[308], currently covering 204 agricultural and vegetable species. The standards and technical requirements contained in the Schemes have been developed in close co-operation with other international seed-related organizations, such as FAO, ISF, ISTA, and UPOV: seed testing laboratories analyze those criteria, which differ depending on the group of species[309].

The OECD Seed Schemes are founded on two basic parameters: 1. varietal identity, which is *'the identity of a variety is defined by the official description of its characteristics, resulting from a given genotype or combination of genotypes',* and 2. varietal purity, which is *'the proportion of plants or seeds within the population that conforms to the official description of the variety. Plants or seeds are considered as varietal impurities (off-types) when they are obviously different from the variety'*[310].

The underlying principles of the OECD Seed Schemes include: 1. the submission only of those varieties which are officially recognized as distinct and which have an acceptable value in at least one participating country; 2. the relationship between Certified seed and authentic Basic seed of the relevant variety, which shall be characterized by varietal purity, and the presence of satisfactory conditions for the production and processing of Basic and Certified Seed, which shall be ensured and verified by field inspection and post-control tests; 3. fulfilment of post-control tests to be conducted to ascertain that the OECD Seed Schemes are operating satisfactorily, by determining whether the characters of varieties have remained unchanged in the process of multiplication[311].

In order to ensure compliance with those principles, the Schemes identify different seed categories, related to an identified generation number and equipped with its specific colored label: Pre-Basic Seed, Basic Seed, and Certified Seed. The seed shall maintain its varietal identity throughout consecutive multiplications and it shall preserve its varietal

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[308] Grasses and Legumes, Crucifers and other Oil or Fibre species, Cereals, Maize, Sorghum, Sugar and Fodder Beet, Subterranean clover and similar species, Vegetables.
[309] Source: OECD website, http://www.oecd.org/agriculture/seeds/. Last access: August 2019
[310] Paragraph 4, Annex I to the Decision - Basic Principles -, 2019 OECD Seed Schemes - Rules and Regulation -.
[311] Paragraph 5, Annex I to the Decision - Basic Principles -, 2019 OECD Seed Schemes - Rules and Regulation -.

purity, without contamination by seed of other varieties or other materials. Those standards are checked through field inspections and randomly verified during post-control tests. Afterwards, the OECD-certified seed lots are tested by an official laboratory for analytical purity, germination, moisture content, vigor, seed health, using the abovementioned ISTA sampling and testing methods[312].

The investigation leads to the conclusion that, on the international scene, a uniform definition of seed quality has not been provided yet. However, the concept of seed quality individually developed by international seed-related organizations, such as FAO, ISTA, and OECD, is substantially comparable.

Those organizations *de facto* agree on the scope of the definition of seed quality, albeit with some terminological dissimilarities: seed quality may be described as the sum of different characteristics, the most significant of which are varietal identity and varietal purity (i.e. genetic and physical purity), followed by vigor, high germination percentage, seed health and a proper moisture content[313]. According to this definition, a seed respecting those criteria should be deemed as a quality seed.

3. Origin of seed marketing laws in Europe

Seeds represent a key input for the productivity, the diversity, and the quality of both plants and food, which play a pivotal role in the national economy: the contribution of quality seed to high domestic agricultural production is undeniable.

The importance of this role has been reflected in national legislations since the 20th century: numerous States set up specific laws in order to regulate seed marketing. Those

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[312] Ryan M., 2009, *The role of international certification in facilitating trade and market developments*, in UPOV, 2009, Proceedings of the second World Seed Conference. Responding to the challenges of a changing world: the role of New Plant Varieties and High Quality Seed in Agriculture, UPOV Publication No. 354 (E), Geneva.

[313] A similar definition of quality may be found in Ferguson J.M., Keys R.D., McLaughlin F.W., Warren, J.M., 1991, *Seed and Seed Quality*, in NC State Extension Publications, available at https://content.ces.ncsu.edu/seed-and-seed-quality. The authors state that seed quality should be defined as the description of *'the potential performance of a seed lot. Trueness to variety* (i.e. genetic purity)*; the presence of inert matter, seed of other crops, or weed seed; germination percentage; vigor; appearance; and freedom from disease are important aspects of seed quality'*. Similarly, see also: Powell A., 2009, *What is Seed Quality and how to measure it?*, in FAO, 2009, Proceedings of the second World Seed Conference. Responding to the challenges of a changing world: the role of New Plant Varieties and High Quality Seed in Agriculture, Rome.

legislations had the goal to promote the domestic agricultural sector through the evaluation of seed quality before its commercialization.

Those seed laws followed the development of the formal seed production and the growing concerns about seed quality[314]: those laws had the function to provide for well-defined marketing requirements that seeds and propagating material had to meet in order to be legally marketed in the national territory.

Rudimentary examples of seed legislations may be found during the 1920s and 30s, when some European States began to introduce laws on seed certification and national registration systems.

In this context, Czechoslovakia was the forerunner as the first European country to provide a legal framework for seed marketing. With its Law No. 128 of 17 March 1921 on the Recognition of the Originality of Types, Seeds and Seedlings, and the Testing of Horticultural Types, Czechoslovakia established a national register for plant material and the entitlement of the applicant to commercialize that material under the registered indications, including the chosen variety denomination[315].

In Germany, a draft of the Seeds and Seedlings Law was submitted to the German Parliament in 1930. Even though it never became a law, this draft anticipated pivotal concepts of seed-related laws, such as distinctness and essential derivation[316].

In 1932, the Netherlands established the General Department for the Control of Agricultural Seed and Potato Seedlings; nine years later, the first Dutch seed law was adopted. The Breeders Ordinance of 1941 addressed both seed trade regulation and breeder's rights: it introduced registration and testing (i.e. certification) systems that were limited to certain plant species. A key aspect was the mandatory use of the registered denominations for the marketing of seeds and seedlings[317].

In other countries, the first attempts at legislative regulation initially focused on the institution of wheat varieties registers, where the cultivars showing particular quality characteristics were listed. The attention on wheat varieties arose from the crucial

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[314] Louwaars N., 2000, *Seed Regulations and Local Seed Systems*, in Biotechnology and Development Monitor, 42, pp. 12-14.
[315] UPOV, 1990, *Seminar on the Nature and Rationale for the Protection of Plant Varieties under the UPOV Convention - Budapest, Hungary, September 19 to 21, 1990,* Geneva, UPOV/PUB/697, p. 25-28.
[316] Ibidem.
[317] Ibidem.

importance of those crops for the national agricultural production, and because of their role as the cornerstone of food availability.

For example, in 1938, Italy established the National Registry of Selected Varieties of Wheat (*Registro Nazionale delle Varietà Elette di Frumento*) by Law No. 546/1938, where only selected, i.e. distinct, varieties of wheat were listed. Many of those varieties were developed by the Italian geneticist Nazareno Strampelli, who also supported the establishment of the Registry.

More than a decade before Italy, France introduced the Registry of Selected Plants by decree of 1922 (*Registre Des Plantes Selectionnees De Grande Culture*), which was initially intended only for varieties of wheat. Afterwards, France broadened the scope of that register by introducing the Official Catalogue of Cultivated Plant Species and Varieties (*Catalogue Officiel des Espèces et Variétés cultivées)* by *Décret du 16 novembre 1932*, which was extended to additional crops, other than wheat varieties. The decree stated that only plant species and varieties entered into the Catalogue could be marketed in the French territory.

It must be added that, long before the adoption of said laws, the agricultural sector set up specific arrangements to test seed quality on a private or semi-official basis. At that time, certification was not legally regulated and there were not official seed testing schemes or methods. Despite this, some unregulated initiatives in seed quality assessment were undertaken and, in the late nineteenth century, seed testing stations began to be founded all over Europe, especially in some of the northern countries: in Germany in 1869, in Austria in 1881, in Denmark in 1971, and in Sweden in 1876.

4. The two pillars of the EU seed legislation

The EU legislation on the marketing of seed and plant propagating material[318] dates back to 1966. At the time when it was initially introduced, the goal of the legislation was to boost agricultural productivity, in order to guarantee food security in the EU, and to increase competitiveness of the agricultural sector through the harmonization of the relevant national

[318] It is important to remind that, in the context of EU seed legislation, the term 'propagating material' has a different meaning compared to UPOV Convention.

legislations. This legislation answered the needs for agricultural modernization and for the use of modern plant varieties in agriculture.

The legislation gradually developed: the different times of its development led to a significant fragmentation and complexity. Nowadays, the EU seed legislation consists of 12 basic Directives, based on international standards and covering the crops of major importance in EU (EU listed species)[319]: 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. Those crops are: fodder plant seeds[320], cereal seed[321], beet seed[322], vegetable seed[323], seed of potatoes[324], seed of oil and fibre plants[325], material for the propagation of the vine[326], propagating material of ornamental plants[327], vegetable material other than seed[328], fruit propagating material and fruit plants for fruit production[329], forest reproductive material[330].

As already said, the EU legislation does not concern all plant varieties. It covers only those crops of major importance in the EU territory: for example, einkorn (*Triticum monococcum*) and lentil (*Lens culinaris*) are not taken into account by the relevant Directives because they have a minor role in the EU seed market. Therefore, the marketing of those crops is regulated by the relevant national laws.

The EU Directives determine the conditions under which seeds and propagating material can be legally marketed in the EU territory. The underlying principle is that seeds and propagating material meeting those requirements shall be freely marketed within the

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[319] In case a crop is not covered by the EU legislation, the national rules apply.
[320] Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed.
[321] Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed.
[322] Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed.
[323] Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed. This Directive also established the Common Catalogue of varieties of vegetable plant species.
[324] Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes.
[325] Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants.
[326] Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine.
[327] Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants.
[328] Council Directive 92/33/EEC of 28 April 1992 on the marketing of vegetable propagating and planting material, other than seed.
[329] Council Directive 92/34/EEC of 28 April 1992 on the marketing of fruit plant propagating material and fruit plants intended for fruit production.
[330] Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material.

European Union, allowing the free movement of quality seed for the benefit of the EU agriculture and economy.

Two pillars represent the backbone of the EU seed legislation:

1. the registration of the varieties;
2. the certification of the seed lots;

which are going to be investigated in the next two paragraphs.

It is worth underlining that the EU seed legislation regulates the marketing of seeds and propagating material. The 12 basic Directives determine the conditions under which seeds are allowed to be marketed *but not produced* throughout the European Union: varieties registered in the Common Catalogue may be freely marketed in the EU territory, but the production of certified seeds requires for the variety to be entered in the national catalogue of the Member State where production will begin[331]. Indeed, Member States have the right to adopt additional or stricter measures regarding the domestic production of seeds.

Under certain conditions, EU Member States may be wholly or partially exempted from the obligation to apply those Directives in respect of certain seeds and propagating material, which are generally not reproduced or marketed on the territory of the relevant Member States[332].

In this regard, Commission Decision (EU) 2010/680, which was replaced by Commission Implementing Decision (EU) 2017/478 of 16 March 2017, released certain Member States from the obligation to apply to certain species the Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC and 2002/57/EC on the marketing of fodder plant seed, cereal seed, material for the vegetative propagation of the vine, forest reproductive material, beet seed, vegetable seed and seed of oil and fibre plants respectively. The exemptions are granted on the basis of applications made by the EU Member States.

A brief investigation on the regulation of the seed produced in third countries is necessary. The seed harvested outside the EU territory shall offer the same guarantees as the EU seeds in order to be marketed in the EU territory: it shall be considered as *equivalent*.

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[331] Commission Decision of 14 December 1998 relating to a proceeding under Article 85 of the EC Treaty (IV/35.280 — Sicasov), notified under document number C (1998) 3452, (1999/6/EC), paragraph 30.
[332] For example, the growing of vines is of minimal economic importance in several EU countries, as well as the marketing of certain tree species, which are not important for forestry purposes in the other Member States.

The seed produced in third countries is considered equivalent to the seed produced within the EU only if it affords the same assurance thereof, as required by Council Decision 2003/17/EC of 16 December 2002.

According to Council Decision 2003/17/EC, the seed produced in third countries is considered as equivalent if 1. it concerns the species specified in Annex I to the Decision (fodder plant seed, cereal seed, beet seed, seed of oil and fibre plants, vegetable seed); 2. it has been produced in those third countries listed in that Annex and officially certified by the authorities listed therein.

Also, the seed shall satisfy the conditions set out by the EU rules other than those related to varietal identity and varietal purity, as laid down in the relevant Directives. The seed lots shall be accompanied by the certificates required under the relevant OECD Schemes and their packages shall be officially closed. The examination shall be carried out officially or under official supervision, in accordance with the ISTA Rules. The same principle applies for sampling: samples of the lots shall be taken officially or under official supervision, in accordance with the ISTA Rules. Furthermore, specific package marking rules shall be followed.

Should this occur, the seed shall be considered as equivalent to the seed complying with Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC and, therefore, it could be marketed in the EU internal market.

A final aspect shall be stressed: the seed marketing legislation concerns the public right to market quality seeds after official examinations. Differently, PVRs are intellectual property rights, granted for a set period and having private property connotations. Even if requirements may be considered similar, the seed marketing laws do not recognize any entitlement over the variety.

This aspect has been addressed in the Case n. 8745/2015 (*BASF Italia spa vs Società Agricola Magnani Caterina e Magnani Lorenza)* held in 2015 before the Tribunale di Milano - Sezione specializzata in materia di impresa, in Italy, concerning the alleged infringement of the claimant's exclusive rights on the rice variety named 'Polluce' by the defendant. In that case, the Court decided in favor of the defendant because the claimant did not prove its entitlement over the variety: the claimant only demonstrated that the variety was listed in the Common Catalogue, in accordance with Directive 2002/53/EC. Even though the requirements for registration partially overlap with requirements for Community

PVR, the Court stated that the effects of the two measures cannot be compared. In conclusion, the registration in the Common Catalogue does not recognize any intellectual property right over the plant variety.

5. Registration of the varieties

According to the first pillar of the seed legislation, plant varieties should be registered in a national list, which the EU Member States are obliged to establish, and then in the EU Common Catalogues.

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 by Member States 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 for reasons of clarity and rationality.

Currently, there are 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.

Pursuant to its Article 1, Council Directive 2002/53/EC concerns the acceptance for inclusion in the Common Catalogue of varieties of agricultural plant species of those varieties of beet, fodder plant, cereal, potato and oil and fibre plant the seed of which may be marketed under provisions of the Directives concerning respectively the marketing of beet seed (2002/54/EC), fodder plant seed (66/401/EEC), cereal seed (66/402/EEC), seed potatoes (2002/56/EC) and seed of oil and fibre plants (2002/57/EC).

While, according to its Article 2 (b), Council Directive 2002/55/EC deals with plants of the vegetable species intended for agricultural or horticultural production, but not for ornamental uses. By way of illustration, it includes species of onion, celery, asparagus, spinach beet, cauliflower, industrial chicory, watermelon, cucumber, carrot, fennel, lettuce, tomato, parsley, pea, eggplant.

Both the EU Common Catalogues are vitally linked to national lists because they can be compiled only on the basis of a national registration.

5.1. Requirements for registration

Before the registration, the varieties are required to undergo the Distinctness, Uniformity, and Stability testing (DUS requirement) in order to be listed. The scope of the DUS requirement has been set out in Article 5 of Council Directive 2002/53/EC, paragraphs 1 to 3.

According to Article 5 (1) thereof, a variety shall be regarded as distinct if it is clearly distinguishable on one or more important characteristics from any other variety known in the European Union, in spite of the artificial or natural origin of the initial variation from which it has resulted. Specifically, this definition contains two key concepts: *important characteristics,* which means that those characteristics must be capable of specific recognition and exact definition, and *any other variety known in the European Union*, which entails that when the application is duly made the variety shall be distinct from any other variety known in the EU which is either listed in the Common Catalogue of varieties of agricultural plant species or the Catalogue of varieties of vegetable species, or, without being listed in one of those catalogues, has been accepted or submitted for acceptance in the Member State in question or in another Member State, either for certification and marketing, or for certification for other countries[333].

The provision postulates that the characteristics that distinguish a variety must be recognizable, thus visible and observable. It follows that the distinctness requirement has to be evaluated on a phenotypic basis, in compliance with the distinctness assessment carried out for Community plant variety protection and set out in Article 7 of the Basic Regulation.

In accordance with Article 9 of the Basic Regulation, Article 5 (2) of Council Directive 2002/53/EC defines the stability requirement, according to which a variety shall be regarded as stable if it remains true to the description of its essential characteristics, after successive propagation or multiplications or at the end of each cycle of propagation or multiplications.

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[333] Unless the conditions are no longer fulfilled in all the Member States concerned before the decision on the application for acceptance of the variety to be assessed is taken.

Moreover, as provided for in Article 5 (3) of Council Directive 2002/53/EC, a variety shall be regarded as sufficiently uniform if, apart from a very few aberrations, the crops are similar or genetically identical as regards the characteristics, taken as a whole, considered for this purpose. Therefore, the characteristics evaluated are the ones used for the variety description. The distinctive features of the reproductive systems of the plants are taken into account during such examination. This description is comparable to the one provided for in Article 9 of the Basic Regulation on Community plant variety protection.

As a matter of fact, the DUS requirements enshrined in Council Directive 2002/53/EC are analogous to those laid down in Council Regulation (EC) No 2100/94 and this similarity affects the DUS testing process for Community PVRs. Generally, the DUS requirement of agricultural and vegetable varieties is assessed for national registration by examination authorities before an application for Community PVRs is submitted. Logically speaking, a breeder might want to be sure that their variety could be legally marketed in the EU territory before starting the Community PVR application process.

In addition to the DUS requirement, Council Directive 2002/53/EC established that specific denomination rules shall be followed for the purpose of identify the varieties. For the suitability of variety denominations, Article 9 (6) thereof requires that Article 63 of Council Regulation (EC) No 2100/94 shall apply. Therefore, the same denomination rules concern both Community plant variety protection and variety registration. Detailed implementing rules as to the suitability of denominations of varieties have been adopted by Commission Regulation (EC) No 637/2009 of 22 July 2009 with regard to agricultural plant species and vegetable species.

5.2. The VCU requirement for varieties of agricultural species

In addition to the abovementioned requirements, varieties of agricultural species (cereals included) shall be of satisfactory Value for Cultivation and Use (VCU requirement) 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 on the Common Catalogue of varieties of agricultural plant species, Member States shall ensure that a variety

is accepted only if it is distinct, stable and sufficiently uniform (DUS) and if it is of satisfactory value for cultivation and use (VCU).

However, the examination of the VUC is not required: (a) for the acceptance of varieties of grasses if the breeder declares that the seed of their variety is not intended for the production of fodder plants; (b) for the acceptance of varieties whose seed is to be marketed in another Member State which has already accepted the varieties, having regard to their value for cultivation and use; (c) for the acceptance of varieties (inbred lines, hybrids) which are intended solely as components for hybrid varieties satisfying the DUS and VCU requirements.

The purpose of this provision is to filter only those variety having a specific economic value for farmers: it should ensure that only the finest varieties of agricultural species are registered, stimulating the breeding of improved crops. Therefore, only the varieties having a significant economic value are placed on the market, and this is necessary to obtain a high-quality harvest to the greatest degree possible[334].

Farmers need to know how the variety is going to perform and the income they are going to get. Therefore, the marketing of economically valuable varieties is of utmost importance: farmers shall be able to get the most adapted varieties to be grown 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[335].

Vegetable seeds are not subject to the VCU requirement: the Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed is applicable. According to Article 4 of said Directive, Member States shall ensure that a vegetable variety is accepted only if it meets the DUS requirement. There is just one exception: in the case of industrial chicory, the variety must be of satisfactory Value for Cultivation and Use.

The VCU requirement is not applied to vegetable crop varieties for different reasons: firstly, because of *'the large number of agronomic considerations and specific consumer preferences in these crops'*[336]. Also, it has been underlined that the VCU requirement would

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[334] Würtenberger G., Van Der Kooij P., Kiewiet B., Ekvad M., 2015, op. cit., p. 7.
[335] DG SANCO, 2008, *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM),* Brussels, pp. 88-91.
[336] Turner M., Bishaw Z., 2016, *A Review of Variety Release Procedures and Related Issues with Recommendations for Good Practice*, ICARDA Working Papers, Beirut, p. 29.

be complicated and costly for the highly differentiated vegetable crop market[337]. This is the reason why the EU vegetable seed industry is against a change to its system by the introduction of any form of VCU requirement for vegetable varieties[338].

Therefore, in the current context, the registration of vegetable crops is based solely on the DUS criteria assessment, while agricultural species shall additionally undergo the VCU testing before their registration.

Differently from 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, which are related to crop production and performance. In order to be listed in the Catalogues, the assessment of VCU shall be regarded as satisfactory.

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 it, 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.

However, said Directive did not establish the characteristics for the examination of the VCU; it did not determine which parameters the national authorities shall take into account when assessing the satisfactoriness of the value for cultivation or use.

In 2003, the Commission Directive 2003/90/EC was adopted, which set 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 shall comply with as regards the VCU requirement. Those 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.

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[337] Indeed, for certain vegetable species yield is not the leading criterion to be considered. Vegetable seed companies have established their own systems of variety trials, where new varieties are assessed in cooperation with users in different areas.

[338] Outcomes of the qualitative survey conducted by DG SANCO.

However, it could be noted that these conditions are of basic and broad definition. For example, there is no explanation of what the term 'quality characteristics' should entail and which characteristics define the quality of a plant variety.

Therefore, national authorities have to shape the connotation of those criteria, even though it may lead to dissimilarities in VCU assessment among Member States. Currently, there is not a homogeneous designation of those criteria: the parameters for VCU assessment significantly vary between countries for the same variety[339].

The VCU examination involves replicated field trials and harvest tests that generally take a minimum of two years or a maximum of three years[340]. During those trials, the candidate varieties shall show a *clear improvement* in one or more aspects over the existing varieties.

Since seeds are living organisms, the VCU assessment fluctuates because of the environment where the trial is carried out. The legislation dealing with VCU seems to overlook the deep connection between the value for cultivation and use of a plant variety and the surrounding environment: indeed, environmental factors have a substantial effect on the economically valuable characteristics of plant varieties, such as yield and quality characteristics. This aspect may critically affect the outcomes of the VCU examination.

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 the other. Therefore, the VCU of a particular variety cannot be definitively established[341].

In light of this, national authorities have pointed out the directions towards which the breeding efforts should be made. Along with the operators in the relevant sectors, national authorities have developed and organized their own information and data for the assessment of the VCU (so-called '*chain of knowledge'*), which mainly depends on the economic importance of the crop for the national territory[342]. This has led to a large variability in the national valuation of the VCU.

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[339] Turner M., Bishaw Z., 2016, op. cit., p. 2.
[340] Ibidem,
[341] DG SANCO, 2008, op. cit., pp. 88-91.
[342] VCU assessment for some crops include certain use characteristics, such as cooking time of legumes and baking quality of wheat. Source: Louwaars N., 2000, *Seed Regulations and Local Seed Systems*, in Biotechnology and Development Monitor, 42, pp. 12-14.

Also, the role and effectiveness of the VCU testing have been questioned.

It has been underlined that the 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 those trials should not be lengthy or complex in the pursuit of 'perfection'[343].

Furthermore, the effect of the VCU assessment on the relevant crop sector, i.e. the agricultural one, should be taken into consideration. In this context, the report made by DG SANCO in 2008 analyzed the effectiveness of VCU on the competitiveness of the EU agricultural crop sectors. Even though the results of the survey indicate that the respondents consider the VCU provision as useful and they do not wish to remove it from the EU seed legislation, the report shows that 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'*[344]. 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 one)[345]. Thus, one might wonder whether the revocation of the VCU requirement would influence the competitiveness and the productivity of the agricultural crop sector.

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 small breeders 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, IFOAM[346] has suggested that VCU testing should not be compulsory anymore but an optional requirement '*for any species'* not only for agricultural species. According to such a proposal, VCU shall be solely used '*as a marketing argument'* by breeders and not as a compulsory requirement[347].

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[343] Turner M., Bishaw Z., 2016, op. cit. , p. 2.
[344] DG SANCO, 2008, op. cit., p. 5.
[345] Ibidem, p. 96.
[346] The International Federation of Organic Agriculture Movement.
[347] IFOAM, 2013, *Position Paper. Towards more crop diversity - adapting market rules for future food security, biodiversity, and food culture,* Brussels, pp. 8-9.

In light of the foregoing considerations, it clearly emerges why the effectiveness of the VCU testing is still nowadays criticized by some associations and breeders of agricultural varieties: not only because of its costs and length but because it profoundly affects the innovation of the seed industry. In order to sell their seed, the agricultural crop breeders are constantly pushed to improve their varieties to pursue a satisfactory VCU, even though they know that the examination cannot definitively establish the VCU of a crop.

Also, one might wonder why vegetable seed breeders oppose the introduction of a compulsory VCU. Maybe this requirement influences the competitiveness of the breeding companies and could affect their capability to innovate.

On top of that, national authorities apply different criteria to establish a satisfactory VCU, leading to inconsistencies between Member States for the testing of the same species. Currently, there is a substantial lack of harmonization between VCU protocols of the different Member States.

In conclusion, even though economically valuable characteristics of plant varieties are the primary goal of plant breeding activities, the varieties exclusively characterized by satisfactory VCU cannot be protected with Community PVRs because satisfactory VCU does not guarantee DUS (e.g., morphological distinctness), required for plant variety protection[348].

5.3. One key, several doors principle: a perspective de iure condendo

The technical report produced by the national examination authorities and concerning the DUS assessment is generally taken over by the CPVO, since the Office itself does not carry out technical examination but relies on national authorities. However, the DUS test shall be performed in conformity with specific requirements in order to be taken over by the CPVO[349].

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[348] Kock M., Porzig S., Willnegger E., 2006, *The legal protection of plant biotechnological inventions and plant varieties in light of the EC Biopatent Directive*, in IIC, 37, 2, pp. 135-156.

[349] Kiewiet B., 2009, *The Community Plant Variety Protection System,* Angers, available at: https://cpvo.europa.eu/sites/default/files/documents/articles/2009-07-10_Article_Italy.pdf, p. 2.

In this context, national authorities in the EU have agreed to use CPVO technical protocols for DUS testing not only for PVR grant procedures but also for official variety registration procedures.

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.[350]

However, there has not been official harmonization of the DUS testing process in the different variety technical examinations, i.e. national listing, national and Community plant variety protection. The exchange of technical reports among examination authorities has not been regulated at the EU level yet, even though the CPVO, 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 almost fifteen years.

In particular, in 2005, the CPVO launched a Strategic Discussion on the future of DUS testing in the EU territory and participating Member States and stakeholders found the *one key, several doors* principle a fundamental goal. The principle entails that a plant variety whose DUS requirements have been officially tested and results in a final DUS report should not be examined a second time for DUS in the EU territory. This principle applies only when the variety has been examined according to well-defined quality requirements: in this case, the technical report should be the keystone of any following decision to be adopted by an EU Member State or the CPVO, regardless of its positive or negative outcome.

Therefore, the official DUS report should represent the one key needed to open subsequent doors: national listing, national plant variety protection, and Community PVR. The goal of the *one key, several doors* principle is 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.

5.4. Admission to the EU Common Catalogues

After being technically examined, the varieties meeting DUS, denomination, and VCU requirements are registered in the official national list of the relevant EU Member State. In

[350] Source: https://cpvo.europa.eu/en/help-center/getting-started/take-over-technical-reports

order to be admitted to the EU Common Catalogues, the registration is notified to the Commission by the Member State. As this is received, it is published in the Official Journal of the European Union (previously, the Official Journal of the European Communities), based on the information supplied by the Member State. The registration on a 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.

On the basis of the foregoing considerations, 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 by the Court of Justice of the European Union in the Case C-59/11, *Association Kokopelli v. Graines Baumaux SAS*. The case concerned the sale on the national market of vegetable seeds not included in the official Common Catalogue of varieties of vegetable species. In that ruling, the Court confirmed the validity of Council Directive 2002/55/EC, which excludes the marketing of vegetable seed not listed in the relevant EU Common Catalogue[351].

In the registration framework, maintenance of the relevant variety is an essential step and each Member State should ensure it: indeed, the varieties accepted in the Common Catalogues must be maintained according to accepted practices. In particular, a person or several persons responsible for the variety shall be appointed and the responsible person or persons shall keep proper records in order to check maintenance at any time. The responsible person may also be requested to provide samples of the variety. Said records shall as well report the production of all generations prior to basic seed or propagating material. The purpose of the maintenance obligation is to preserve the variety during the registration period, which does not last forever.

In particular, there is a period of time during which acceptance of a variety remains valid.

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[351] In that case, the CJEU highlighted that the primary objective of the rules on seed registration is to improve 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. The establishment of a Common Catalogue on the basis of national catalogues is capable of ensuring the achievement of that objective: requiring seed to be distinct, stable and uniform, facilitate the use of appropriate seed and allow agricultural productivity to be increased, thanks to the reliability of the seed.

Pursuant to Article 12 of Council Directive 2002/53/EC and Article 12 of Council Directive 2002/55/EC, the acceptance of a variety in the Common Catalogues shall be valid until the end of the tenth calendar year following acceptance. Afterwards, it may be renewed at given intervals if it is still cultivated on such a scale as to justify this, or should be retained in the interest of conserving plant genetic resources, and providing that the requirements for registration are still satisfied.

Given the foregoing considerations, the registration of the variety surely represents a crucial step for the marketing of the relevant crops, especially because it is a precondition for the certification of seed lots, which represents the second pillar of seed marketing legislation.

6. Certification of the seed lots

According to the second pillar of the legislation on the marketing of seeds, seed lots of plant varieties covered by the EU Directives are subject to a certification process before their marketing, whether they come from inside or outside the EU.

The basic principle is that, in the EU, marketed seed of such varieties shall be certified seed: thus, certification is compulsory for the species covered by the EU Directives.

The certification procedure consists of an official examination and assessment of seed material and it is generally performed on the basis of official testing rules, e.g. ISTA Rules. Its purpose is to guarantee the quality of seeds before their marketing. Unlike the registration process, which concerns the variety itself and it is valid for ten years, certification involves each seed lot, *ergo* it shall be performed on a regular basis. Seed certification requires for the variety to be unambiguously identified: the certificate on the seed lots ensures that the seeds conform to the variety name on the label.

The Directives establish a unified certification scheme for the EU territory to be carried out by national authorities of EU countries or under their supervision. Seeds cannot be marketed in the European Union unless they have been officially certified.

As above mentioned, eleven vertical marketing Directives have been adopted for the marketing of seeds of the majority of plant species. They determine the conditions seeds must satisfy in order to be marketed in the EU territory. They also establish that seeds shall be marketed in homogenous and appropriately labelled lots, so that they are identified for

traceability purposes. Furthermore, rules concerning field inspections, packaging, sealing, labelling, and documentation have been laid down.

As a compulsory system, certification is usually officially carried out by national authorities. Nevertheless, seed company technicians may get proper training from the national certification authority to obtain a license to carry out seed certification activities in the related company. Once the license is granted, the certification authority has the task of carrying out auditing inspections to ensure that the system is enforced[352].

The EU legislation recognizes different classes of certified seed and each one of them corresponds to a different marketing category. The certification scheme is based on a *generation system*: it allows to categorize classes of seeds on the basis of their development from an earlier type. The classification of different generations of seeds ensures the buyer (i.e. the farmer) that the marketed seed derives from an identified source.

The certifiable classes, *ergo* the generations, of seeds are not unlimited: usually, the law limits the number of seed categories because many multiplications increase the possibility of variability and contamination.

6.1. The generation system

The choice of the technical terms used by the EU legislator is based on the existing international terminology, especially on the certification schemes provided by OECD.

Those OECD Schemes provide for three classes of seeds:

1. *Pre-basic*: the early generation seed, i.e. the source material (also known as *nucleus seed*) produced by the breeder;
2. *Basic*: seed derived from pre-basic seed, intended for the production of certified seed and produced by the breeder or under their responsibility;
3. *Certified*: the generation developed from basic seed and produced under the supervision of a seed enterprise; it can originate further generations of certified seed according to the national regulation. (e.g. certified 1 or certified 2)[353] .

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[352] FAO, 2016, *Seed Toolkit. Module 3: Seed Quality Control and Certification*, Rome, p. 93.

[353] FAO, 2016, op. cit., p. 65. For further insights, see OECD, 2019, *OECD Seed Schemes. Rules and Regulations*, Paris, available at http://www.oecd.org/agriculture/seeds/documents/oecd-seed-schemes-rules-and-regulations.pdf

The EU seed legislation mainly distinguishes between the categories of *basic seed* and *certified seed*.

As already anticipated, the generation of basic seed is produced under the responsibility of the breeder, which operates as the maintainer of the variety according to precise practices. Basic seed is intended for the production of certified seed. Each Directive laid down the conditions assessed during the official examination that the seed has to satisfy.

It is worth mentioning that basic seed is not usually sold to farmers: by way of clarification, it is legally allowed to sell basic seeds to farmers and to use them for sowing. However, since basic seed has the exclusive role of producing seeds of a subsequent generation, i.e. the certified seed, this generation is very valuable and therefore the marketing for sowing purposes would be unprofitable.

Differently from basic seed, certified seed is intended for purposes other than the production of seed and it is produced directly from basic seed. Certified seed shall satisfy the well-defined conditions laid down by each Directive and those conditions shall be assessed during an official examination.

Should the Directive so provide, upon the breeder request, certified seed may be produced from seed of a generation prior to basic seed, i.e. pre-basic seed, which has been found by official examination to satisfy the conditions laid down in the relevant legislation.

Generally, certified seed is used for sowing and sold to farmers, and it cannot lawfully be intended for the production of seed of a later generation. That is the reason why certified seed is also known as *commercial seed.*

Nonetheless, for certain species, such as wheat and barley, the production of *first-generation certified seed* and *second-generation certified seed* is allowed by the relevant Directives. According to those Directives, first-generation seeds derive directly from basic seeds and they can be used for two purposes: 1. either for the production of second-generation certified seed or 2. for purposes other than seed production. The breeder has the right to decide which purpose the first-generation seed will serve. Contrarily, second-generation seeds are produced from first-generation certified seeds and they are intended for purposes other than seed production.

The EU Member States are not obliged by the Directives to make provision in their legislation for first and second generations of certified seed: as a result, there are some Member States which authorize only the first generation, whereas others authorize both first

and second generations. The first-generation of seeds exported in an EU country that allows the production of a second-generation is usually designated as *technical seed*[354].

In respect of some plant species (beet, oil and fibre plant, cereal fodder plant, fruit plant), the pre-basic seed category is also established by the relevant Directives: they determine the specific conditions under which the bred seed of generations prior to basic seed may be placed on the EU internal market.

6.2. The paradigm of uncertified farm-saved seed

Awareness should be raised about the use of uncertified seed by some farmers, who choose to use their own farm-saved seed, and about the implications of not using certified seed in agriculture.

It is important to remind that there are two sources of seeds farmers can use: farm-saved seed (FSS, also referred to as *bin-run seed*), which has represented the customary source of seeds for farmers, or purchased seed, either from public breeding or from the private sector[355].

As already said, the farm-saved seed is the product of the previous harvest, which is going to be propagated by the same farmer in the same holding. Farm-saved seed cannot be marketed, purchased, sold, or transferred for propagating purposes from one farmer to another or from one holding to another: as already illustrated, just certified seed lots of registered varieties, meeting specific criteria, can be marketed in the EU. Only a few minor varieties are exempted from those requirements.

According to Article 14 of the Basic Regulation, the use of farm saved-seed of plant varieties protected with Community PVRs is not allowed for all crops but only for some agricultural plant species, mainly fodder plants, cereals, and potatoes. In the case of plant

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[354] Commission Decision of 14 December 1998 relating to a proceeding under Article 85 of the EC Treaty (IV/35.280 — Sicasov), notified under document number C (1998) 3452, (1999/6/EC), paragraph 27. The reference to 'technical seed' originates from trade practices. Indeed, this name cannot be found in EU directives.

[355] Heisey P., Fuglie K., 2011, *Private Research and Development for Crop Genetic Improvement,* in Research Investments and Market Structure in the Food Processing Agricultural Input, and Biofuel Industries Worldwide*,* United States Department of Agriculture, Economic Research Service.

varieties not protected under the Community PVR regime, this limit does not apply. For the purpose of this paragraph, reference is made to plant varieties not protected by PVRs.

In general, the practice of using the product of the harvest for propagation purposes does not concern all plant varieties: the share of FSS varies among different crops, and for some crops, mainly cereals, farm-saved seed still plays an important role even in high-income countries. By way of illustration, on the global seed market, the rate of FSS varies to more than 60% for wheat, barley, and rice to less than 20% for maize[356].

The percentage of farm-saved seed is not the same in all the countries. According to OECD[357], the estimated share of FSS in Europe is almost 25%, less than Asia and Africa, but more than North America.

The use of farm-saved seed, which is the product of the previous harvest, may carry significant risks because it does not have the guarantees and benefits that certified seed ensures. In the case of farm-saving seed, the seed quality is not ensured by the certification process: neither varietal purity nor germination is guaranteed, as well as the phytosanitary status of the seeds. Unlike certified seed lots, FSS is not traceable, it may not be weed-free and disease-free and it may not produce profitable crops. Therefore, one may wonder why a farmer should decide not to use certified seed and opt for farm-saved seed.

The main reason relies on the inferior cost of those seeds. In the case of farm-saved seed, the farmer does not need to bear the initial costs connected to the purchase of new seeds, while they can count on the farm-saved seed to re-sow. Also, seed saving represents a traditional practice: some farmers believe that the quality of FSS can be as good as certified seed. This conviction is still widespread, especially among cereals producers and, in particular, wheat producers. They rely on the *we-have-always-done-it-that-way* approach, which may hinder innovation and agricultural productivity.

Regarding the inferior initial costs of farm-saved seed, a recent study led by researchers from the University of Nebraska[358] and focused on certified wheat varieties, has

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[356] OECD, 2018, *Concentration in Seed Markets: Potential Effects and Policy Responses,* OECD Publishing, Paris, p. 25. For potatoes, the estimated rate of farm-saved seed is more than 70%, while for sugar beet such rate is almost zero.
[357] OECD, 2018, op. cit., p. 24-25.
[358] Creech C., Werlw R., 2017, *Making the Case for Certified Wheat Seed*, Institute of Agriculture and Natural Resources, University of Nebraska–Lincoln, available at: https://cropwatch.unl.edu/2017/making-case-certified-wheat-seed

shown that the price difference between FSS and certified seed is not as much as the farmer expects. The use of certified seed is connected to higher yields, *ergo* higher returns, and there are additional benefits related to the high quality of the seed, including fewer disease and weed issues, which reduce the costs for herbicides and plant protection products. As a related aspect, the use of FSS is not entirely free. Indeed, farm-saved seed is supposed to be cleaned and treated before planting, even if it is not tested. Both cleaning and treating come at a price: i.e., the costs of processing and the expenditure on specific products. However, and despite these costs, the measures adopted by farmers do not resemble the professional procedures performed by seed enterprises. Farmers do not usually have the needed technology and the industrial equipment of professional seed producers. Therefore, sometimes the seed is poorly treated or inadequately cleaned, despite the price paid for the specific products. It seems that the quality of farm-saved seed is not as good as certified seed and that the initial gains do not offset the subsequent losses.

This has been demonstrated by Assosementi, the Italian Seed Association: despite the common belief of saving a significant amount of money, in Italy the price spread between certified seed and farm-saved seed for wheat varieties[359] has been of EUR 18 per hectare for *Triticum aestivum* and of EUR 25 per hectare for *Triticum durum* in 2017. The cost gap is balanced by the higher quality and the additional benefits of certified seed.

From the overview provided, without any claim of exhaustiveness, one may suppose the possible existence of a misperception about FSS. The belief that farm-saved seed represents a lower cost option and that its quality can be as good as certified seed may not be correct.

Notwithstanding the hypothetical cost savings, farm-saved seed represents a traditional practice with significant cultural and social value, as well as economical. Over the centuries, the practice of seed saving was performed across the globe by farmers and it contributed to the conservation of crop biodiversity and, also, to the development of plant varieties. In particular, farmers carried out the selection of the most suitable plants of the harvest, in the field, and the following propagation of the relevant seeds, generating new biological diversity.

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[359] Source: Assosementi website, http://www.sementi.it/articoli/532/seme-certificato-5-ragioni-per-sceglierlo-campagna-2019. Last access: September 2019.

The importance of such practice has been internationally recognized, especially by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) entered into force in 2004. Article 9 thereof states that the Contracting Parties shall recognize the enormous contribution that indigenous communities and farmers from all regions of the world, particularly those in the centers of origin of crop diversity, have made and will continue to make for the conservation and development of plant genetic resources, which constitute the basis of food and agriculture production throughout the world. In particular, Article 9 (3) thereof recognizes the importance of the seed saving practice and it specifically establishes the right for farmers to save, use, exchange, and sell farm-saved seed/propagating material, subject to national law and as appropriate.

The European Union, as a Contracting Party, is bound by the ITPGRFA. In light of this, one may wonder whether, in the light of the commitments arising from the ITPGRFA and, in particular, its Article 9 (3), the EU seed marketing legislation shall be considered valid since it does not allow farmers to exchange and sell farm-saved seed.

The question has been answered by the Court of Justice of the European Union in the abovementioned Case C-59/11, *Association Kokopelli v. Graines Baumaux SAS*. The Court stated that Article 9 (3) of the ITPGRFA, on which Association Kokopelli relies, *'provides that nothing in that article is to be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate*'.

However, the same article does not contain an obligation that, as regards its content, is sufficiently unconditional and precise to challenge the validity of the EU seed legislation. Therefore, the Court ruled that the seed marketing Directives comply with the provisions of the ITPGRFA: the measures to be adopted are left to the discretion of each Contracting Party since the Treaty is not directly applicable.

In light of this judgment, even though it does not challenge the validity of the EU legislation, ITPGRFA does not appear to be consistent with the EU seed legislation, which does not recognize the right of the farmers to *exchange and sell* farm-saved seed. Since the absence of contradiction between the EU policies shall be ensured, in light of the consistency requirement among the EU laws set out in Article 7 of the Treaty on the Functioning of the

European Union (TFEU)[360], the EU legislator should provide for a specific regulation on the FSS practice.

Even though specific rules on FSS have not been established yet, the EU legislator recognized the existence of a public interest connected to the performance of said practice. Indeed, the farmer's privilege set out in Article 14 of the Basic Regulation is rooted in this historical practice and it involves well-defined agricultural species, that have traditionally been subject to FSS. The Basic Regulation clearly states that such a derogation to Community PVRs has been adopted in the public interest, especially in the public interest of safeguarding agricultural production, as provided for in the Preamble of said Regulation[361].

It follows that, in the EU, it exists a public interest of safeguarding agricultural production and FSS embodies this specific public interest: it could be assumed that the EU legislator aims to preserve the role of FSS in agricultural production.

In light of this, one might wonder if, in an environment dominated by industrial agriculture, the public interest of safeguarding agricultural production through the practice of seed saving is consistent with the rationale behind the EU seed legislation, whose purpose is fostering agricultural production by providing quality seed.

This is the reason why seed producers are requested to comply with specific registration and certification requirements, which are also costs and time-consuming, in order to market their products. Seeds are a decisive input in agricultural production and they dramatically affect yield potentials. This is the reason why the relevant legislation requires the breeders to ensure improved commodities with excellent characteristics.

The implications connected to the use of uncertified seed go beyond the potential economic loss of the farmers: they concern farming sustainability as well as the quantity and quality of agricultural production, *ergo* food security and food safety.

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[360] For further insights on the consistency requirement in EU law, see: Herlin-Karnell E., Konstadinides T., 2013*, The Rise and Expressions of Consistency in EU Law: Legal and Strategic Implications for European Integration*, in Cambridge Yearbook of European Legal Studies (2012-2013), pp. 139-167; Sauter W., Langer J., 2017, *The consistency requirement in EU law,* in Columbia Journal of European Law, 20, 3.

[361] The Preamble of the Basic Regulation states the following: '*Whereas, the exercise of Community plant variety rights must be subjected to restrictions laid down in provisions adopted in the public interest; whereas this includes safeguarding agricultural production'.*

However, nowadays, there is not an obligation for farmers, especially for *industrial farmers*[362], to use certified seed, even if the use of saved seed may result in the lowering of seed quality standards. Reference is made in particular to industrial farmers because they are supposed to embrace modern farming practices and to reject the adoption of traditional methods, and farm-saved seed represents one of the most relevant traditional farming practice. Industrial farmers operate in an industrial agriculture environment and, yet, they are allowed to use the product of the previous harvest for propagating purposes. This approach may appear contradictory.

In conclusion, in the current EU seed sector a paradoxical situation is occurring: there is an obligation to market quality seeds but there is not a corresponding obligation to use those quality seeds in agriculture. It seems that for the EU legislator the optimal agricultural production is not related to the use of certified seed but only to its marketing: this paradox originates from the absence of consistency within the EU legislation.

6.3. Derogations for conservation varieties

The EU seed legislation is based on the formal seed system. It answered the need for agricultural modernization and the increased use of modern plant varieties, widely adaptable and mainly developed within formal breeding programs[363].

As already illustrated, according to said legislation, only varieties listed in the Common Catalogues meeting the DUS requirement, and certified seed of those varieties fulfilling certain quality standards could be commercialized in the internal market. However, those legislations may be inappropriate with regard to informal seed systems and low-input agriculture[364].

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[362] The term *industrial farmer* refers to the professional who operates within an industrial agriculture system, characterized by the use of technology, included genetic and chemical technology, modern farming techniques, and sophisticated machines. This agriculture is based on maximizing economic returns and rejects traditional agriculture and its methods of farming.

[363] Veteläinen M., Negri V., Maxted N., 2009, *European landraces on- farm conservation, management and use*, Bioversity International, Rome, Italy, p. 271.

[364] Louwaars N., 2000, *Seed Regulations and Local Seed Systems*, in Biotechnology and Development Monitor, 42, pp. 12-14.

In particular, one might wonder what is the destiny, in this context, of all those plant varieties, especially ancient and local varieties, used in traditional agriculture and cultivated in well-identified areas. Reference is made to those varieties that have not been obtained by formal breeding activities, which have not a wide adaptation and could not meet the requirements for registration and certification (e.g. because of their lack of stability or because of their low rate of varietal purity): could they be marketed in the internal market or not?

Until 1988, informal, local, and small-scale seed systems, focused on the traditional use of landraces[365] in agriculture, have been greatly marginalized by the European legislator, as well as the question of biodiversity and the sustainable use of local genetic resources. The marketing of ancient and local varieties stayed unregulated for decades. The need to set out rules for the marketing of landraces and local varieties threated by genetic erosion, in order to ensure their conservation *in situ* and their sustainable use, was indeed not taken into consideration by the then European Community until the '80s.

However, in 1988, the concerns raised worldwide regarding the crescendo of threats to the biological diversity and the growing commitment to conservation *in situ* and sustainable use of genetic resources have been addressed by the European legislator[366].

For the first time, Council Directive 98/95/EC[367] introduced the term *conservation variety* in the European Community, which identifies the landraces and varieties (1) naturally adapted to local and regional conditions and (2) threaten by genetic erosion.

Directive 98/95/EC recognized the significance of those genetic resources and the need to regulate their marketing, even if they do not comply with the general requirements established by the seed legislation: the importance of their conservation *in situ* and

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[365] This term usually identifies local cultivars, which often do not meet the DUS criteria or the VCU requirement.

[366] On the international level, the most significant example of the growing recognition of biological diversity is represented by the Convention on Biological Diversity (CBD), which was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio 'Earth Summit') and entered into force on 29 December 1993. The CBD has 3 main objectives: 1. the conservation of biological diversity; 2. the sustainable use of the components of biological diversity; 3. the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

[367] Council Directive 98/95/EC of 14 December 1998 amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species.

sustainable use justifies the derogation as regards the requirements for registration and certification.

Recognizing the peculiar nature of those *cultivars*, the Directive stated that specific conditions shall be established for conservation varieties in order to be accepted in the official Common Catalogues.

In particular, those specific conditions shall include the possibility, during the acceptance procedure, to take into consideration the results of unofficial tests and knowledge gained from practical experience during cultivation, reproduction and use and the detailed descriptions of the varieties and their relevant denominations, as notified to the Member State concerned. If the information so obtained is deemed to be sufficient, the variety shall be exempted from the requirements set out for official examinations and it shall be referred to in the Common Catalogue as a *conservation variety*.

After ten years, Commission Directive 2008/62/EC of 20 June 2008, providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for the marketing of seed and seed potatoes of those landraces and varieties, was adopted.

Directive 2008/62/EC regulates the agricultural species of conservation varieties: it lays down certain derogations in relation to the conservation *in situ* and the sustainable use of plant genetic resources through growing and marketing (a) for the acceptance in the national catalogues of conservation varieties of agricultural plant species; (b) for the marketing of seed of such landraces and varieties.

Article 2 thereof defined critical concepts in this field, such as:

(a) conservation *in situ*, which is the conservation of genetic material in its natural surroundings and, in the case of cultivated plant species, in the farmed environment where they have developed their distinctive properties;

(b) genetic erosion, which is the loss of genetic diversity between and within populations or varieties of the same species over time, or reduction of the genetic basis of a species due to human intervention or environmental change;

(c) *landrace*, which is a set of populations or clones of a plant species which are naturally adapted to the environmental conditions of their region.

That Directive provides that Member States may accept in the national catalogues of varieties of agricultural plant species the landraces and varieties which are naturally adapted

to the local and regional conditions and threatened by genetic erosion. They shall be referred to in the Common Catalogue of varieties of agricultural plant species as *conservation varieties*.

The substantive requirements of those landraces and varieties for being accepted as conservation varieties are set out in Article 4 of Directive 2008/62/EC: it states that these varieties shall present an *interest for the conservation* and that Member States may adopt their own provisions as regards the DUS requirement for conservation varieties.

Moreover, acknowledging the idiosyncratic nature of conservation varieties, no official examination shall be required if the following information is sufficient for the decision on their acceptance: (a) the description of the conservation variety and its denomination; (b) the results of unofficial tests; (c) knowledge gained from practical experience during cultivation, reproduction and use, as notified by the applicant to the Member State concerned; (d) other information, in particular from the plant genetic resource authorities or from organizations recognized for this purpose by the Member States.

When accepting a conservation variety, it is fundamental for Member States to identify the region or regions in which the variety has historically been grown and to which it is naturally adapted, hereinafter referred to as *region of origin,* and it shall notify it to the Commission. In case the region of origin is located in more than one Member States, it shall be identified by all the Member States concerned by common agreement.

The identification of the region of origin is important because the Member States shall ensure that seeds of a conservation variety may only be produced in that region of origin, *in situ*. Due to a specific environmental problem, Member States may approve additional regions for seed production. However, the seed produced in those additional regions may be used exclusively in the regions of origin.

The rationale behind this provision rests on the importance to ensure that the link between the conservation variety and the region of origin is preserved and that the marketing of seed takes place in the context of the conservation of plant genetic resources: it shall be reminded that the conservation varieties are supposed to be naturally adapted to local and regional conditions.

Those requirements represent specific marketing criteria: indeed, the conservation variety may only be marketed if it has been produced in its region of origin, or in the

approved region referred above, and if the marketing takes place in its region of origin, or in a comparable region as regards the natural and semi-natural habitats of that variety.

Also, a derogation from official certification shall be provided for: Member States may provide that seed of a conservation variety may be placed on the market if (a) the seed descends from seed produced according to well-defined practices for maintenance of the variety; (b) the seed complies with the requirements for seed certification with the exception of the requirements in respect of minimum varietal purity and the requirements concerning official examination or examination under official supervision[368]; (c) the seed has *sufficient* varietal purity.

The seed of conservation varieties may be marketed only in closed packages or containers bearing a sealing device and those seed packages and containers shall be properly labeled with the supplier's label. The supplier shall seal the packages and containers in such a manner that they cannot be opened without damaging the sealing system or leaving evidence of tampering on the supplier's label or on the package or container.

In addition to the foregoing requirements, Directive 2008/62/EC establishes quantitative restrictions to the Member States: they shall ensure that, for each conservation variety, the quantity of seed marketed does not exceed 0,5 % of the seed of the same species used in that Member State in one growing season, or a quantity necessary to sow 100 ha, whichever is the greater quantity[369].

Those quantities are fixed in order to not jeopardize the conservation of the varieties and their sustainable use: it shall be reminded that the conservation varieties are supposed to be threatened by genetic erosion.

Interesting to notice that, pursuant to Article 6 of said Directive, a conservation variety is not accepted for inclusion in the national catalogues of varieties if (a) it is already listed in the Common Catalogue of varieties of agricultural plant species as a variety other than a conservation variety, or (b) it is protected by a Community plant variety right as provided

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[368] There are two exceptions: (1) in the case of *Oryza sativa,* seed shall comply with the requirements for certification of 'certified seed, second generation' provided for in Directive 66/402/EEC, with the exception of the requirements in respect of minimum varietal purity and the requirements concerning official examination or examination under official supervision; (2) as regards seed potatoes, Member States may provide that Article 10 of Directive 2002/56/EC concerning the size shall not apply.

[369] For the species *Pisum sativum, Triticum spp., Hordeum vulgare, Zea mays, Solanum tuberosum, Brassica napus* and *Helianthus annuus*, that percentage shall not exceed 0,3 %, or a quantity necessary to sow 100 ha, whichever is the greater quantity.

for in Council Regulation (EC) No 2100/94 (1), or by a national plant variety right, or an application for such a right is pending. Article 6 clarifies that the acceptance as conservation variety is irreconcilable with the registration in the Common Catalogue as 'non-conservation' variety, as well as with the Community PVP regime. The rationale behind the first incompatibility is quite clear: a certain variety either has the characteristics of a conservation variety, or it does not. Therefore, it can be listed either as a conservation variety or as not.

The second discordancy rests on the requirements for Community PVP, especially the novelty condition for protection. Indeed, a local variety could not be novel: since it has been *naturally adapted* to the local and regional conditions, it follows that said variety has been sold or otherwise disposed of to others for a long time. Indeed, the natural adaptation to specific conditions requires time, and it cannot be achieved overnight.

Also, whereas a conservation variety has to be threatened by genetic erosion, the relevant variety cannot be novel: it should have been cultivated for a significant time, otherwise there would have been nothing to erode, i.e. to gradually destroy. Indeed, as provided for in Article 2 of Directive 2008/62/EC, genetic erosion means the loss of genetic diversity *over time*. Therefore, there is a conflict with Community plant variety protection: a conservation variety could not be protected under Community PVR, primarily because of its lack of novelty.

Even though the legislation on conservation varieties was initially limited to agricultural species, thanks to Commission Directive 2009/145/EC and Commission Directive 2010/60/EU, similar derogations have been provided, respectively, (a) for accepting vegetable landraces and varieties traditionally grown in certain regions, threatened by genetic erosion and varieties with no intrinsic value for commercial production but developed growing under particular conditions and (b) for marketing fodder plant seed mixtures for use in preservation of the environment.

In conclusion, the derogations for conservation varieties from the EU seed legislation relies on the different role played by them in relation to non-conservation varieties. Modern varieties have been regulated to guarantee high quality and improved inputs to the industrialized agriculture, in order to boost the agricultural productivity in the EU and to stimulate the free marketing of seeds within the internal market.

Differently, conservation varieties have been regulated to safeguard their conservation *in situ* and their sustainable use, in order to avoid the loss of valuable genetic diversity in the EU territory.

This is the reason why conservation varieties could not have been put in the same basket as modern varieties, since the relevant regulation lays on different premises: the EU seed legislation deals with seeds as commercial commodity, while the conservation variety legislation addresses the seed as the carrier of valuable genetic resources to be conserved for future generations[370].

6.4. An overview on cereal seed: Council Directive 66/402/EEC

The cereal seed sector has always had crucial importance for the agriculture in the EU since the beginning of the 20th century, especially with reference to wheat varieties[371]. As already highlighted at the beginning of the current research, nowadays the European Union is one of the world's leader in cereal production and cereal varieties are the most popular crops grown in the EU: therefore, it is fundamental to explore how the marketing of cereal seeds is regulated in the internal market.

Starting from the beginning of the 20th century, some European States set up specific laws in order to regulate seed marketing. Following their lead, in 1966, the then European Economic Community Council adopted the Directive of 14 June 1966 (66/402/EEC) on the marketing of cereal seed, lastly amended by Commission Implementing Directive (EU) 2018/1027 of 19 July 2018[372].

That Directive recognizes the important place occupied by cereal production in the EU and underlines that such place depends to a great degree on the use of appropriate and quality seed in cereal cultivation.

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[370] The role of seed as the carrier of valuable genetic resources to be conserved for future generations has been highlighted by Louwaars N., 2002, *Seed Policy, Legislation and Law: Widening a Narrow Focus,* in Journal of New Seeds, 4, 1/2, p. 2-4.

[371] For example, at the beginning of the 20th century, the Italian geneticist Nazareno Strampelli started the so-called 'wheat battle': with his work on plant breeding, the Italian wheat production almost doubled. The scientist stressed the importance of using quality seeds of selected varieties in order to boost agricultural productivity. The varieties developed by Strampelli are still used in international breeding programs. Salvi S., Porfiri O., Ceccarelli S., 2013, *Nazareno Strampelli, the 'Prophet' of the green revolution,* in The Journal of Agricultural Sciences, 151, 1.

[372] Reference is made to the latest consolidated version of said Directive: 01/01/2019.

As a general rule, cereal seeds should be allowed to be marketed in the internal market only if they have been officially examined and certified, in accordance with the seed legislation concerned. The focus has been on achieving a greater productivity and on permitting the free marketing of cereal seeds in the internal market, as stated in the Preamble of Directive 66/402/EEC.

In order to achieve such goals, Directive 66/402/EEC established a uniform certification system for cereal seeds[373]. Pursuant to Article 1 thereof, this Directive shall apply to cereal seeds marketed within the EU. Therefore, as laid down in the Preamble, cereal seeds that are not placed on the market should not be subject to those rules because of their minor economic importance. The same applies to cereal seed intended for the export to third countries.

With this in mind, it is important to define what is the legal definition of *cereal* in the seed sector. According to Article 2 of the 1966 version of that Directive, the definition of cereal was associated only to major cereal species: it was linked to a list of plants without mentioning the purpose of their production. Therefore, cereals were initially defined as the *'plants of the following species: Avena sativa L. (oats); Hordeum distichum L. (2-row barley); Hordeum polystichum L. (6-row barley); Oryza sativa L. (rice); Secale cereale L. (rye); Triticum aestivum L. (common wheat); Triticum durum L. (durum wheat); Triticum spelta L. (spelt wheat); Zea mays L. (maize)'*.

This basic approach gradually evolved and the definition of cereal was enriched. In the last consolidated version of the said Directive, cereals are defined as those plants '*intended for agricultural or horticultural production other than production for ornamental purposes'* and more species showing increased importance have been added to that list: *Avena nuda L.* (small naked oat, hulles oat); *Avena strigosa Schreb.* (black oat, bristle oat); *Phalaris canariensis L.* (canary grass); *Sorghum bicolor Moench* (sorghum); *Triticosecale Wittm. ex A. Camus* (hybrids resulting from the crossing of a species of the genus Triticum and a species of the genus Secale). *Hordeum vulgare L.* (barley) replaced *Hordeum distichum L.* and *Hordeum polystichum L.*

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[373] The legislation gradually evolved and it was often amended. One of those amendments is related to the entry into force of Directive 2002/53/EC on the Common Catalogue. In 1966 the Common Catalogue was not established yet so, until then, according to Directive 66/402/EEC, Member States had the right to restrict the marketing of certified seed to those varieties which were of value for cropping and use in their own territory. This is not possible anymore.

This is the legal definition of cereal for the purpose of Directive 66/402/EEC, which does not necessarily correspond to the scientific definition of cereal, where reference is made to the biological characteristics of the cereal crops, thereby other species are included in the classification (e.g. *Triticum monoccocum*).

Also, the definition of '*marketing'* of seeds, which was absent in the 1966 version, was later added. According to Article 1a of the last consolidated version of that Directive, marketing means *'the sale, holding with a view to sale, offer for sale and any disposal, supply or transfer aimed at commercial exploitation of seed to third parties, whether or not for consideration'*. Therefore, trade not aimed at commercial exploitation of the variety shall not be regarded as marketing[374]. This definition is very important because it sets a demarcation line among what should be subject to certification rules and what is exempted.

Within this context, pursuant to Article 3, Member States shall provide that cereal seed may not be placed on the market unless it has been officially certified as *basic seed, certified seed, certified seed of first generation*, or *certified seed of second generation.* However, Member States may restrict the certification of seed of oats, barley, rice and wheat to that of certified seed of first generation.

Notwithstanding this rule, Member States may authorize producers in their own territory to place on the market (a) small quantities of seed for scientific purposes or selection work; (b) appropriate quantities of seed for other test or trial purposes, provided that it belongs to varieties for which an application for entry in the catalogue has been submitted in the Member State in question. Member States may also provide that bred seed of generations prior to basic seed may be placed on the market.

Cereal seed shall undergo official examinations in order to be certified, by means of field inspection, seed testing carried out by seed analyst in laboratories, and post-control checks.

Article 7 of Directive 66/402/EEC regulates the sampling conditions of the examination: those examinations should be carried out officially or under official supervision[375], in accordance with current international methods, insofar as such methods

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[374] E.g. the supply of seed to official testing and inspection bodies, or the supply of seed to providers of services for processing or packaging, provided the provider of services does not acquire title to seed thus supplied.
[375] Unlike cereal seeds, some plant species do not allow the certification under official supervision, e.g. potatoes.

exist. Official sampling and sampling under official supervision shall be compared by Member States. Samples shall be drawn from homogeneous lots, respecting rules on the maximum weight of lots and minimum weight of samples given in Annex III.

In case the seed sampling is carried out under official supervision, the samplers: (1) shall be authorized for that purpose by the seed certification authorities of the relevant Member States; (2) shall have the necessary technical qualifications got in official training course and confirmed by official examinations; (3) shall be an independent natural person, or persons, employed by natural or legal persons whose activities do or do not involve seed production, seed growing, seed processing, or seed trade.

When the seed sampler is employed by a seed company, they may carry out seed sampling only on seed lots produced on behalf of their employer, unless it has otherwise agreed between their employer, the applicant, and seed certification authority.

In addition, the seed sampler activities shall be subject to appropriate supervision by the certification authority and, for the purpose of supervision, a proportion of at least 5% of seed lots shall be checked-sampled by official seed samplers. Penalties shall be laid down by Member States for infringements of the rules governing examination under official supervision.

Regarding the packaging of cereal seed lots, specific rules are provided by that Directive. As provided for in Article 8, the basic seed and certified seed of all kinds shall be marketed in the EU territory only in sufficiently homogeneous lots and in sealed, packages bearing a sealing device and markings. Such packages shall be sealed officially or under official supervision by a label od by an official seal, in such a manner that they cannot be opened without damaging the sealing system or without leaving evidence. However, derogations may be provided for the marketing of small quantities to the final consumers.

In addition, packages of basic seed and certified seed of all kinds shall be labelled on the outside with an official label, not previously used, satisfying the conditions set out in Annex IV. The information shall be given in one of the official languages of the EU. Also, well-defined color rules for the labels are set, since a specific color corresponds to a different category of seed: white for basic seed, blue for certified seed and for certified seed of first generation, red for certified seed of second generation.

The package shall also contain an official document, in the same color as the label, giving the information required under Annex IV. However, this document is not necessary when the information is printed indelibly on the package.

Within this context, the Member States have the right to set derogations for the marketing of seeds to the final consumers and to require an additional supplier's label to be bear by the seed lots, with the supplier's information. On the official label or on the supplier's label, and on the package shall also report the chemical treatment used on the basic seed and certified seed of all categories.

The legislation also requires Member States to permit the marketing of specific mixtures of seeds of various cereal varieties, provided that (1) those mixtures are particularly effective against the propagation of certain harmful organisms and provided that (2) the components of the mixture comply, before mixing, with the marketing rules applicable to them. Blend of cereal species is also authorized, provided that the components of the blend complied with the applicable marketing rules before blending.

Seed lots placed on the market according to those provisions may not be subject to any marketing restrictions as regards its characteristics, examination requirements, marking and sealing other than those laid down in that or any other Directive.

With reference to seed from third countries, on the one hand, cereal seed multiplied in another country from basic seed certified in a Member State should be recognized as equivalent to seed multiplied in that Member State; on the other hand, the marketing of cereal seed harvested in third countries is allowed only if such seed affords the same assurances as seed officially certified in the EU and comply with the relevant rules.

Regarding the abovementioned Annexes to the Directives, Annex I establishes the conditions to be satisfied by the crop. Indeed, the crop shall conform to specific standards, for example, as regards minimum distance from neighboring sources of pollen, in order to avoid undesirable foreign pollination. Also, crop shall have sufficient varietal identity and varietal purity: specific rules are set for each species.

Annex II sets out the conditions to be satisfied by the seed, i.e. varietal identity and varietal purity. In particular, each category of seed of the relevant species shall satisfy minimum rates. Also, for each species minimum germination and analytical purity rates are set, as well as the maximum content of seed of other plants by number of seeds.

As far as the conditions laid down in Annexes I and II are concerned, Member States may impose additional or more stringent requirements for the certification of seed produced in their own territory.

Annex III determines the rules for lot and sample weights for each species: maximum weight of a lot, expressed in tonnes, and minimum weight of a sample to be drawn from a lot, expressed in grams. Annex IV specifies the required information on the label for each category of seeds and for seed mixtures. For example, for certified seeds (non-hybrids, nor inbred lines) the following information are required:

- EC rules and standards;
- Certification authority and Member State or their initials;
- Officially assigned serial number. Reference number of lot.
- Month and year of sealing expressed thus: ‘sealed ...’ (month and year), or month and year of the last official sampling for the purposes of certification expressed thus: ‘sampled ...’ (month and year);
- Species, indicated at least under its botanical name, which may be given in abridged form and without the authorities' names, in roman characters;
- Variety, indicated at least in roman characters;
- Category;
- Country of production;
- Declared net or gross weight or declared number of seeds;
- Where weight is indicated and granulated pesticides, pelleting substances, or other solid additives are used the nature of the additive and also the approximate ratio between the weight of pure seeds and the total weight.

Finally, Annex V establishes rules for labels and documents provided in the case of seeds not finally certified and harvested in another Member State.

In conclusion, Directive 66/402/EEC sets out rules for seed marketing of the major cereal species: conditions to be satisfied by crops and seeds and concerning testing, packaging, labeling, weight and size of the lots. The legislation concerns the overall seed production, from field to package.

However, it could be noted that those rules may be subject to significant derogations by Member States. For example, EU countries may impose additional or more stringent requirements for the certification of cereal seeds produced in their own territory; may set

derogations for the marketing of cereal seeds to the final consumers; may require an additional supplier's label to be bear by the seed lots.

This approach leaves ample room for national legislators, which can decide on important aspects of the seed legislation. The risk is that a fragmented and un-harmonized EU seed certification system may derive therefrom. The problem is that seed companies from different EU countries, which bear the cost - economically and time-wise - of seed certification, may be required to follow different conditions for the same cereal species and, therefore, may not compete on a level playing field in the internal market.

7. Final remarks

The foregoing considerations lead to the conclusion that EU legislation on the marketing of seed is undoubtedly marked by significant complexity, outmost fragmentation, non-harmonized implementation, and lack of coordination with other EU policies and legislation, such as Community plant variety protection. This environment may lead to distortions in the internal market and it may not provide legal security for consumers and professional operators, which may not fairly compete within the EU territory.

In this context, the cereal seed sector is highly affected because it also has to bear the burden of the VCU requirement and the FSS practice, which may hinder innovation.

Ample room is left for Member States as regards the seed legislation: for example, in implementing the standards for the achievement of a satisfactory VCU, or in imposing additional or more stringent requirements for seed certification, or the regulation of plant varieties not listed in the seed legislation.

This lack of harmonization may lead to distortions in the internal market and may become a burden for seed companies, potentially affecting their power to create innovative varieties. Professional operators ask for efficient implementation, reduction of costs and administrative burdens, and supports to innovation.

In this context, the weak coordination with other EU legislations and the existing uncertainties and discrepancies in the implementation of the seed legislation between Member States require clarity and transparency.

These are the reasons why, in 2013, there has been a 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), in order to replace the existing legislation.

The purpose was to replace the 12 Directives by one single Regulation, which had the role to update, simplify, and harmonize the current rules. The draft Regulation was adopted by the Commission on 6 May 2013. Such a proposal blossomed from the results of the evaluation of the EU seed legislation carried out in 2007/2008 by the Food Chain Evaluation Consortium (FCEC) and from broad surveys of interested parties (*inter alia,* competent national authorities, private sectors representatives, the CPVO).

The proposal reports that, even though there is a certain degree of satisfaction with the principles underlying the existing legislation, stakeholders expressed the need for a legislative change. In particular, the amendments should address the purposes of legal simplification, cost reduction, deregulation, increased flexibility for professional operators, the level of harmonization among Member States, the access for SMEs to public services, the role of niche and emerging markets, the rigor in health and quality requirements, and the conservation of the agro-biodiversity[376].

Following those recommendations, the proposal aimed to review the legislation in an efficient, effective, and coherent way. The main changes proposed by the Regulation are the following:

- all types of plant reproductive material shall be covered by the Regulation;

- the introduction of a unique term to cover all the plant reproductive material, both seeds and other kinds of plant propagating material;

- the introduction of basic obligations for professional operators concerning the identification of the plant reproductive material, keeping of records, facilitation of controls and maintenance of the material;

- more flexibility during the certification process;

- the possibility for professional operators to be authorized by the competent authority to carry out the certification and produce the official labels under official supervision;

- production of operator's label;

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[376] European Commission, 2013, *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),* Brussels, COM (2013) 262 final, p. 3-4.

- predefined categories of plant reproductive material, which should reflect different quality levels and production stages, named: pre-basic, basic, certified and standard;

- derogations for niche market varieties;

- the extension of the mission of CPVO (which should be named 'European Agency on Plant Varieties', EAPV) to the area of variety registration;

- the admission to the common market either via registration in the national catalogue or via direct application to the CPVO;

- the dependence of the VCU requirement on quality and agronomic characteristics of the variety, including yields, and its suitability for cultivation in resilience and low input production systems, including for organic agricultural production;

- the application of the VCU criteria to genera and species of vital importance (1) for food and feed security; (2) for food processing, feed processing or industrial processing; (3) for resilience and low-input agriculture, including organic agricultural production;

- rules on the sustainable value for cultivation.

For the purpose of the current investigation, it is interesting to notice the widening role of CPVO, extending its function to plant variety registration. The combination of those tasks aims at simplifying the registration process: pursuant to those rules, if a variety has been granted a CPVR, for the purpose of variety registration that variety should be deemed to be distinct, uniform and stable, and to have a suitable denomination, recognizing the *one key, several doors* principle. Undeniably, this approach represents the first step to fix the lack of coordination between seed legislation and Community plant variety protection.

However, the proposal was rejected by the European Parliament on 11 March 2014 and, on 16 December 2014, the Commission withdrew the proposal from its work program[377]. So, the seed legislation has not been simplified nor harmonized, and it is not clear whether legislative changes in this field will be pursued.

[377] Source: Council of the European Union website, https://www.consilium.europa.eu/en/policies/animal-plant-health-package/plant-reproductive-material/. Last access: September 2019

CHAPTER 5

Law in action: the views of EU cereal breeding companies

SUMMARY: 1. Methodological remarks. - 2. Data generation and collection. - 2.1. Data collected via participant observation. - 2.2. Data collected via electronic qualitative survey. - 2.3. Data collected via individual semi structured interviews. - 3. Data analysis and interpretation. - 3.1. Overview of the analysis. - 3.2. Prevalent themes developed from the data set. - 3.2.1. Innovation in cereal varieties. - 3.2.2. Plant variety protection of cereal varieties. - 3.2.3. Level of awareness of plant variety protection. - 3.2.4. Satisfaction with the Community plant variety protection. - 3.2.5. Shortcomings in the Community plant variety protection. - 3.2.6. Ideal legislation. - 4. Final remarks.

1. Methodological remarks

Unlike the previous chapters driven by a traditional legal research methodology, the current chapter is based on an empirical approach and, in particular, on a qualitative research method. The approach is interpretivist and exploratory.

The purpose of qualitative research it to *verstehen,* to genuinely understand the studied context, as intended by the German sociologist Max Weber[378]. Therefore, the investigation has been conducted in its natural context by playing an active part in the process. As stated in the first chapter, the purpose of the research is to investigate whether Community plant variety protection is fostering innovation in cereal varieties in the European Union industry. In order to achieve this purpose, a 'snapshot' of the views of EU cereal breeding companies towards Community plant variety protection was taken.

Data collection entailed three methods, used in combination, usually referred to as *triangulation*[379]*:* participant observation within an Italian cereal seed company combined with supplementary interviews; electronic qualitative survey on EU cereal breeding companies; and individual semi-structured interviews with experts. The raw data are not published.

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[378] Weber M., 1949, *The Methodology of the Social Sciences*, Free Press, New York.
[379] Nielsen L., 2003, *The need for Multi-method approaches in Empirical Legal Research*, in Cane P., Kritzer H., (eds.), The Oxford Handbook of Empirical Legal Research, Oxford University Press, p. 953.

Participant observation preceded the other data collection methods: this procedure facilitated the identification of information to pursue through the survey and semi-structured interviews. Also, during the observation period research hypotheses were generated, which have been tentatively proposed during the process of data collection.

In this case, qualitative data collection methods provided access to the participants' experiences, understandings, and perceptions, in particular their perception of the law.

The sampling scheme of the data is non-random, and unlike quantitative research, it relies on a smaller number of 'data sources': in the chosen context, an abundance of data might have been overwhelming and unnecessary. Therefore, the sample size is represented by representative expert opinions, which are considered data-rich and worthy of in-depth investigation. The 'data sources' may not be statistically representative: in fact, the findings of the study aim to be dependable and valid, not generalizable to an entire situation. As qualitative findings, they *'rarely provide a measure of frequency of occurrence'*[380], whereas their purpose is to offer an insight into the chosen context.

The method for data analysis is thematic analysis, that is '*a method for identifying, analyzing and reporting patterns within data'*[381]. In the current study, data analysis is associated with inductive reasoning because general themes or patterns are going to be developed from the data collected in a '*bottom-up approach'*. The project developed over time and the studied context challenged fundamental assumptions. This approach is typical of qualitative methods: differently, the archetype of quantitative research is deductive reasoning, where general hypotheses are posed before data collection[382]. The method of data analysis involves thematic categorization of the collected data set. By using this method, patterns and themes are identified within the qualitative data for the drawing of conclusions.

The first part of the current chapter is dedicated to the data generation and collection methods, whereas the second part deals with data analysis and interpretation.

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[380] Webley L., 2010, *Qualitative approaches to Empirical Legal Research*, in Cane P., Kritzer H., (eds.), The Oxford Handbook of Empirical Legal Research, Oxford University Press, p. 932.
[381] Braun V., Clarke V., 2006, *Using thematic analysis in psychology*, in Qualitative Research in Psychology, 3, 2, pp. 77-101.
[382] Webley L., 2010, op. cit., p. 928.

2. Data generation and collection

2.1. Data collected via participant observation

Reading (document analysis), talking (interviews), and watching (observation) represent the archetypal methods of generating qualitative data[383]. In this framework, observation does not merely mean hanging out with legal actors: observation requires commitment and planning. Observation is also fraught with significant difficulties, unlike the other two methods: (1) it is a time-consuming activity; (2) access to certain contexts is not easy to obtain; and, because of the time required, (3) it limits the number of 'data sources'. In light of this, observation requires a significant commitment, and this is one of the reasons why researchers often prefer to collect data through interviews[384].

Notwithstanding these difficulties, observation is a powerful data collection method. Specifically, it allows the researcher to pick up aspects that could not be otherwise acquired. Also, when the observation precedes the interviews, it is possible to clearly know the type of information to pursue and to anticipate the patterns to design the interview questions.

During the observation, the researcher has the possibility to keep away expectations or bias, as well as the consensus view in the scientific literature. Indeed, the lack of observation of the specific context may lead to questions designed in ways to solicit responses consistent with the researcher's preconceptions or with that literature[385]. Observation allows the researcher to 'empty' their mind, as a *tabula rasa,* and to discover more than expected.

In the current research, observation has been carried out in the form of *participant observation* since the beginning of the research project: the researcher has not only observed, but there was also active engagement in the activities of the research participants. There has been full interaction with participants, who consider the researcher more like a colleague, even if they know the purpose of the researchers' activities. Thanks to such an approach, it

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[383] Kritzer H., 2002*, Stories from the Field: Collecting Data Outside Over There*, in Starr J., Goodale M., (eds.), 2002, Legal Ethnography: New Dialogues, Enduring Methods, Palgrave Macraillan, New York, p. 143.
[384] Ibidem, pp. 143-144.
[385] Ibidem, pp. 154-155. The author quotes Dingwall, who said that '*interviewers construct data, observers find it"*.

has been possible to talk with stakeholders, attend conferences and meetings, participate in specific activities as a participant, and gather a relevant quantity of data and information.

The access to the specific context was possible thanks to Agroservice spa, an Italian seed company based in San Severino Marche, Italy, which allowed the researcher to spend almost three years in its facilities. Agroservice is an Italian SME based in San Severino Marche that carries out activities of production and commercialization of seed for agriculture, especially cereal seed. The commercialization concerns eighty-four varieties. Agroservice also controls the subsidiary company ISEA srl engaged in plant breeding activities. Agroservice has a more than twenty-year experience in the field of cereal seed production and commercialization, it exports in over forty countries worldwide. Along with ISEA, Agroservice manages more than ten experimental fields for their plant varieties.

The observation was carried out from November 2016 until October 2019, both within ISEA and Agroservice, two days per week, on average. During the years at Agroservice, participant observation was carried out smoothly and the supervisor acted as a facilitator in the company's environment.

The observation mainly took place in Agroservice's headquarters. It was also possible to visit ISEA's facilities and experimental fields, and to interact with other SMEs engaged in breeding activities during conferences, meetings, and events, and to visit the headquarters of Assosementi, the Italian Seed Association, in Bologna, (Italy).

Observation activities implicated full interaction with the company's administration, R&D, commercial, and production offices. Considered the significant amount of time spent within the chosen context, it was possible to interact with the personnel as a colleague. During the three years of participant observation at Agroservice spa, the researcher actively engaged in the company activities, especially in legal-related matters.

The field notes made by the researcher cannot be fully disclosed because they contain know-hows, confidential information and trade secrets, which cannot be disseminated: confidentiality is paramount in order not to jeopardize the company secrecy of Agroservice and ISEA.

The data based on participant observation, recorded through field notes, have been supplemented by semi-structured interviews with the Head of Cereal Breeding of ISEA srl, Dr. Daria Scarano, and with the Managing Director of Agroservice spa and ISEA srl, Mr. Eugenio Tassinari. The purpose of those interviews is to bring out the expression of

motivations, i.e. the personal views, thoughts, and perceptions that a researcher may not 'observe' in the surrounding environment. Interviews allow an in-depth conversation about the studied topic. Since interviews followed participant observation, it was possible to design specific questions, without falling into the abovementioned *'clichéd vision'* of the seed industry, and to understand the answers of the respondents in a better way.

The researcher informed beforehand the respondents about the content and purpose of the interviews. These interviews have been conducted within the ISEA's and Agroservice's facilities in June 2019 in the native language of the respondents, i.e. Italian. The respondents agreed to be recorded, and their interviews to be translated by the researcher.

2.2. Data collected via electronic qualitative survey

Surveys allow the researcher to collect information from a targeted group of respondents. Unlike observation, surveys do not limit the number of 'data sources': indeed, through surveys it is possible to reach a broader number of participants.

In particular, electronic surveys have significant advantages. For example, they permit a reduction in cost and time: indeed, through electronic surveys, it is possible to send questionnaires anywhere in the world, in a rapid and cheap manner. In addition, questions can be formulated in a complete way and the respondent can take all the needed time to reflect on the queries and write the answers. Another benefit of electronic surveys includes their ease of analysis[386].

However, electronic surveys have also some disadvantages. They may get low response rates compared to traditional surveys. There is also a significant risk of losing data (e.g. emails can get lost or can land in the spam folder). The last issue concerns the respondent's reluctance to click on a link sent from unknown people because of the risk of receiving a virus in return[387].

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[386] McPeake J., Bateson M., O'Neill A., 2014, *Electronic surveys: how to maximise success*, in Nursing Research, 21, 3.
[387] Boyer K., Olson J., Jackson E., 2001, *Electronic surveys: Advantages and disadvantages over traditional print surveys*, in Decision Line, 32, 4.

Notwithstanding those inconveniences, electronic surveys seemed the best choice for the current research, when considering the target group and the content of the questionnaire. In particular, respondents live in different EU Member States and it would have been time-consuming and expensive to carry out in-person surveys. Postal surveys are not suitable because they require a longer time to be received and to be forwarded. Also, respondents are more difficult to solicit. Telephone surveys have not been an option because of the use of specific and legal terminology: respondents speak different native languages, so English has been used as *lingua franca*. During a telephone survey, the mispronunciation of some terms by non-English native speakers may have led to misunderstandings capable of affecting the research findings.

The electronic qualitative survey chosen by the researcher consisted of an electronic questionnaire with both open-ended questions and closed-ended questions, sent via email to the targeted group. Surveys have been sent out in June and July 2019, and the respondents submitted their answers until August 2019. The survey aimed at collecting the opinions of EU cereal breeders on the efficiency of Community plant variety protection.

Initially, an email inviting the recipients to complete the questionnaire for research purposes was sent. In a few weeks, a second email was forwarded as a reminder to those recipients who did not answer the questionnaire. The invitation email contained information about the researcher's profile, the reason why the respondent was targeted, the purpose of the survey and an easily accessible link to the survey. The invitation email also warned the respondents about the language of the survey, i.e. English.

In order to facilitate the understanding of the text and to improve participation, some invitation emails have been written in national languages. For those respondents based in France, the invitation email has been written both in French and English. For those respondents based in Austria and Germany, the invitation email has been written both in German and English. For those respondents based in Italy, the invitation email has been written both in Italian and English. Differently. For the respondents based in other EU countries, the invitation email has been written only in English.

This choice is partly due to cost and time reasons and connected to the language skills of the researcher, and partly to the high concentration of breeding companies in those countries. Indeed, the majority of surveyed EU cereal breeding companies are based in France, Germany, and Italy.

Once the link was clicked on, the recipients were redirected to the title page of the survey. That page informed that the answers were going to be published anonymously and that the survey was going to take a maximum of 15 minutes. In addition, it provided detailed information about the study. Respondents were also invited to contact the researcher via email for any clarification about the survey. As already anticipated, the questionnaire was written in English, combining both open-ended questions and closed-ended questions. Both types of questions have been used in order to maximize the amount of useful information provided without negatively affecting the participation rate.

Indeed, open-ended questions provide better information but require more time and effort, and could be perceived as a burden by the respondents, which may decide not to complete the questionnaire. Inversely, closed-ended questions are less time consuming and involve minimal effort, but provide less information. Therefore, yes-or-no questions have been often followed by open-ended questions to give the respondents the chance to specify the reason underneath their answers.

The questionnaire was composed of seven sections, on the following topics: (1) company information; (2) plant breeding activities of the company; (3) plant variety protection; (4) infringement of PVRs; (5) enforcement of PVRs; (6) seed legislation; (7) conclusive remarks.

In the first section, the questions regarded the company's name and seat. In the second section, the participants were asked to provide information about the company's breeding activities: in which crop sector they mainly operate; the cereal species mostly involved in their breeding activities; other crops involved in their plant breeding programs; the expected results and purposes; costs and time required to develop a new cereal variety; breeding techniques used; cooperation with other companies or institutions. In the third section, participants provided information about plant variety protection: the total number of granted Community PVRs; national protection of new varieties; other forms of protection for plant-related inventions; return on investment; suggested amendments. The fourth paragraph addressed the infringement of Community PVRs: whether CPVRs infringement has ever been experienced; difficulties in proving infringement; opinion about the degree of protection of the relevant legislation; advice to decrease infringement. The fifth section addressed the enforcement of Community PVRs. Participants have been asked to provide their opinion about enforcement, about costs of litigation, and to share their experience in

enforcing Community PVRs. The sixth section concerned the seed legislation, and their opinion about it was solicited. In the last section, participants have been asked about their satisfaction with the Community PVP system and to provide a conclusive statement. As anticipated above, the observation period generated research hypotheses that have been tentatively proposed during the survey.

Regarding the target audience, the questionnaires have been sent out to EU cereal breeding companies protecting their new varieties by Community PVRs.

Therefore, the target audience is represented by:

1. *companies*, excluding public institutions and natural persons;
2. engaged in *breeding* activities; meaning that they are carrying out activities on plant material in order to produce new varieties with desired characteristics;
3. on *cereal* varieties; therefore, on varieties of the following species: *Avena nuda; Avena sativa; Hordeum volgare; Oryza Sativa; Phalaris canariensis; Secale; Sorghum; Triticum aestivum; Triticum durum; Triticum spelta; Zea mays*, as defined by Directive 66/402/EEC as lastly amended;
4. currently based in the *EU* territory;
5. protecting their new varieties by *Community PVRs*; since the researcher believes that only those operating within the Community PVR regime are able to give an informed opinion about its efficiency.

Given the foregoing characteristics, the target audience has been identified through the CPVO database of applications and titles in force, available at the following website: https://cpvoextranet.cpvo.europa.eu/mypvr/#!/en/publicsearch. This method seemed the best choice to target the correct and thereby interested group.

The research concerned the applications and title in force for varieties of the abovementioned cereal species, from 2014 (January) until 2019 (June). For each one of those varieties, the name of the Community PVRs applicant was collected. Then, the relevant email address was searched via internet. Public institutions, natural persons and companies not based in the EU were excluded from the list of participants.

At the end of the research on the CPVO database, 81 companies from 13 EU countries were listed. However, it was possible to collect the valid email addresses of only 68 of them, to whom the invitation email was sent.

The reason why it was not possible to get all the email addresses is threefold. In many cases, the company does not have a website or an official page on social media; in other cases, the company ceased to exist because of a merger or an acquisition; lastly, it happened that two email addresses were not valid and the invitation emails returned to the sender.

Feedback to the invitation email was given by 17 recipients: 15 completed the questionnaire, while 2 of them replied to the invitation email without completing the survey.

In one case, the recipient replied to the invitation email but there was not a follow-up to the researcher's subsequent email. In the other case, the recipient said they was not going to open the link because they suspected it could be a malware. The researcher replied reassuring the recipient about the nature of the link and attaching a simple .pdf document, containing all the questions. However, the recipient still did not complete the questionnaire.

With this in mind, it is necessary to choose the denominator that is going to define the response rate. The response rate may be defined as the total number of completed surveys divided by the total number of participants with whom contact was made (or the number of all possible interviews)[388]. Since the total number of questionnaires sent is 68, and the total number of questionnaires received is 15, the response rate is 22%.

This return rate may seem low, however some studies have shown that low response rate does not equate to low study validity: those researches have been able to produce more accurate results than studies with higher response rate[389]. In fact, one might assume that, probably, those who participated in the survey are the ones having an interest in the subject. Furthermore, as resulted from the PIP project[390] mentioned in the introduction of the current research, there might be a lack of awareness of plant breeders about legal issues, hence the invitation to complete the survey might have been turned down because the breeder found it irrelevant and not worthy of the effort.

It should also be stressed that the current survey is of *qualitative* nature, and it took place in 13 EU countries, speaking different native languages, and the questionnaire was only in English. All of those factors entail a lower response rate than a survey carried out in a small number of countries by using the native language of the respondents.

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[388] Morton S., Bandara D., Robinson E., Carr P., 2012, *In the 21st Century, what is an acceptable response rate?,* In Austrialian and New Zealand Journal of Public Health, 36, 2.
[389] Ibidem, p. 107.
[390] Llewelyn M., Adcock M, 2006, *European Plant Intellectual Property,* Hart Publishing, Oxford.

A further consideration: the questionnaire returns were not anonymous, although the report of the answers is. The answers provided by the respondents are going to be disclosed anonymously.

With regard to the company information, the majority of respondents are SMEs, while a minority is represented by large or multinational enterprises, as illustrated in Table 1.1.

Table 1.1

Type of company	*Total*	*Percentage*
SME	11	73%
Large enterprise	2	13%
Multinational	1	7%
Other	1	7%

Regarding the EU Member States of establishment, Table 1.2 shows that respondents are mainly based in France, Germany, and Italy.

Table 1.2

Establishment	*Total*	*Percentage*
Austria	1	6,33%
France	4	27%
Germany	4	27%
Italy	4	27%
United Kingdom	1	6,33%
Sweden	1	6,33%

It is worth mentioning that 100% of the respondent companies developed a new cereal variety in the last three years, therefore they are very active in cereal breeding activities.

2.3. Data collected via individual semi-structured interviews

Interviews are one of the three archetypal methods of generating data: they rely on '*talking*' methods and are commonly used in qualitative research. In particular, individual interviews are frequently used in empirical legal research.

A great deal of qualitative research relies on interviews because they represent an efficient method to collect data. Specifically, interviews are a valuable tool of data collection because it is possible to gain insight into the interviewee's perceptions, understandings and experiences on a specific topic.

In this context, individual interviews are more personal and intensive than questionnaires, allowing them to collect rich and detailed information.

Interviews may be conducted face-to-face or remotely. The current study opted for the remote method, via email, because it is useful to those who are geographically far apart and allows the interviewee to take the needed time to reflect on the issues raised. The remote method involved email exchanges between the interviewer and the interviewee over a certain period of time. Since the subject is very specific and technical terminology is used, the purpose was to not rush the answers of the respondents in order to provide a considered response.

Through interviews, it is possible to collect the kind of data the researcher is seeking: the researcher solicits the information through the questions. In this context, the use of open-ended questions consents the collection of in-depth information: the purpose is to let the respondents to tell their opinion on a certain subject spontaneously.

Undoubtedly, the initial preconceptions of the researcher and the literature on the topic may impact the design of the questions. In order to circumscribe this inconvenience, interviews have been carried out after the observation period to limit the influence of initial expectations. Furthermore, the observation period generated research hypotheses that have been tentatively proposed during the interviews.

The interviews have been carried out from July to September 2019 and they have been conducted individually in order to allow participants to explain in detail their opinion on the subject. The first email sent to the participants basically asked for their consent to conduct an email interview for research purposes: it provided an introduction of the researcher, detailed information about the study and explained the purposes of the interview. After the

respondents gave their consent to conduct the interview, a subsequent email provided the interview questions. The questions were open-ended in order to allow unbounded answers from respondents.

As already stated, qualitative research tends to rely on a smaller number of 'data sources', which are considered to be data-rich and allow the researcher to *'go beyond description in order to find meaning'*[391]. For the observation and survey, the research sample included EU cereal breeding companies. However, in order to capture a broader range of views, the interviews sampled experts from different but strictly related key categories.

The most suitable interviewees have been identified after a significant period of research and observation of the chosen context. During that time, it was possible to comprehend who could have relevant expertise on the effectiveness of Community PVP and knowledge of the EU cereal breeding sector.

The research led to the identification of two subjects:

1. Ms. Szonja Csörgő, Director Intellectual Property & Legal Affairs of Euroseeds, the European association representing the seed sector[392];
2. Mr. Stefano Barbieri, the person in charge of Sicasov in Italy, which is a cooperative company whose mission is to manage the plant variety rights held by plant breeders[393].

The reason beneath the choice of those two respondents relies on their expertise in the chosen context, although they belong to different key categories. The interviewees have many years of experience in the relevant fields and both of them have an in-depth knowledge of the EU breeding sector. They regularly interact with EU breeding companies dealing with PVP, including cereal breeders. Therefore, they have a high awareness about the external effectiveness of the Community plant variety protection system.

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[391] Webley L., 2010, *Qualitative approaches to Empirical Legal Research*, in Cane P., Kritzer H., (eds.), The Oxford Handbook of Empirical Legal Research, Oxford University Press, p. 932.

[392] Ms. Szonja Csörgő has the task to oversee the developments in IP law that relate to plants and seeds on the international and European level, and to represent the interests of the European seed industry in all relevant discussions.

[393] Mr. Stefano Barbieri represents Sicasov in Italy. Sicasov has been created in 1947 in France by plant breeders. Nowadays, it directly operates both in France and Italy and it cooperates with breeders and seed companies based in other States.

In light of this, the purpose of their interviews is to capture their expert opinions as representative of key categories related to EU cereal breeding companies.

Both of them were contacted via email, and both of them agreed to be interviewed.

The interview with Ms. Csörgő was held in English, while the interview with Mr. Barbieri was held in Italian and then translated into English by the researcher.

The interviews are going to be summarized below, focusing on the crucial issues discussed.

3. Data analysis and interpretation

3.1. Overview of the analysis

The current section aims at analyzing and interpreting the data collected during the empirical research, their convergence and divergence on specific issues, in order to assess the views of the EU cereal breeding companies. The most relevant findings are going to be developed into thematic categories by using the thematic analysis method.

As already stated above, the findings of the study aim to be dependable and valid, not generalizable to an entire situation. The purpose is to offer a 'snapshot' of the chosen context.

Caution should be applied in using these findings as a general indicator of the EU cereal breeding industry as a whole. By way of illustration, data have been collected neither from any breeder of rice varieties (*Oryza sativa L.),* nor from breeders based in certain EU countries, e.g. Spain and Poland. The semi-structured interviews with the two experts from related key categories try to overcome the lack of information.

The process of data analysis identified themes at an 'interpretative level'[394] and it involved four stages: at first, initial codes have been generated from a. observation notes and supplementary interviews, b. survey answers, and c. interview transcripts. Then, general themes have been developed therefrom in order to form a thematic map (those themes often contained sub-themes); subsequently, during the third phase, the network between those themes have been examined in order to identify prevalent themes (also called 'thematic

[394] As opposed to a thematic identification at a 'sematic level'. See: Braun V., Clarke V., 2006, *Using thematic analysis in psychology*, in Qualitative Research in Psychology, 3, 2, pp. 77-101.

categories') from the data set; in the final stage, a conclusion is developed from those categories for the purpose of answering the research question.

In the current chapter, a report of the prevalent themes is presented, while in the next final chapter, the conclusion is going to be drawn.

The thematic categories under which the data collected during the empirical research are going to be analyzed and discussed are:

- Innovation in cereal varieties;
- Plant variety protection of cereal varieties;
- Level of awareness of plant variety protection;
- Satisfaction with the Community plant variety protection;
- Shortcomings in the Community plant variety protection;
- Ideal legislation.

3.2. Prevalent themes developed from the data set

3.2.1. Innovation in cereal varieties

All the breeding companies involved in the empirical study, as cereal breeders, operate in the agricultural crop sector.

As regards the data collected via observation, the plant breeding activities of ISEA primarily concern plant varieties of cereals and pulses. The main cereal species involved in the company R&D activities are *Triticum durum, Triticum aestivum, Avena sativa, Hordeum vulgare, Triticosecale, Triticum spelta,* and *Triticum monococcum.*

With regard to the outcomes of the survey, only one company also operates in other crop sectors. In addition to cereals, more than 40% of the respondents are also engaged in breeding activities on oil an fibre crops (e.g. sunflower, rape seed, cotton, hemp). On a smaller scale, breeding activities also concern other agricultural crops, e.g. potatoes, peas, field beans. The cereal species mainly involved in the breeding activities of the survey respondents are *Triticum aestivum* (87% of the respondents), *Hordeum vulgare* (80% of the respondents), *Avena sativa* (60% of the respondents), and *Zea mays* (50% of the respondents). Other cereal species are involved in R&D with a percentage of less than 30%: *Secale, Triticum durum, Triticum monococcum, Triticum spelta, Triticosecale.*

Among those, only the species of *Triticum monococcum,* as a minor cereal crop, is not regulated by Directive 66/402/EEC on the marketing of cereal seed.

As already anticipated, data have not been collected from any breeder of varieties of *Oryza sativa L.* It is worth mentioning that almost 90% of the rice breeding companies from the target audience are based in Italy, whose rice production is the largest in the the European Union, especially in its northern regions, e.g. Piemonte and Lombardia, followed at a great distance by Spain, Portugal, Greece, and France[395]. In Italy, rice is differently regulated from other cereals: its marketing was initially regulated by law n. 325/1958, then by the legislative decree n. 131/2017. The legislation laid down specific rules concerning the commercialization of rice, in particular it 1. set out criteria for rice denominations and labelling; 2. established a specific register with the Italian national rice agency (*Ente Nazionale Risi*); 3. guaranteed traceability along the Italian rice supply chain in relation to specific rice varieties, from raw rice to packaging material. Those rules affect both rice breeders and rice producers, differently from other cereal breeders. In virtue of this, rice varieties represent an idiosyncrasy within the cereal species, at least in Italy, which is the country leading the EU rice research and production, as already said. In light of this peculiarity and the lack of answers from rice breeders, the empirical findings of the current study should not be referred to the rice breeding industry in the European Union.

According to the outcomes of the empirical data, the driving forces behind innovation in cereal varieties are the wish to meet the demands of farmers, consumers, and agro-food processing industry. In fact, cereal crops undergo several processing stages after their harvest and before their consumption. The cereal processes are necessary to treat and prepare the crops for different purposes, such as human food, animal feed, or industrial use. Therefore, cereal breeders do not only need to meet the needs of farmers, and the trends and tastes of consumers, but also the changing requests of the industry operating in cereal processing. Basically, innovation in cereal varieties aims at the following goals: more productivity, better pest and disease resistance, nutritional content increase, better adaptation to climatic stress, quality for food production (such as quality for baking, malting, flaking, etc.), and increased sustainability.

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[395] Data extracted from the website of *Ente Nazionale Risi*, the Italian national rice agency: https://www.enterisi.it/servizi/notizie/notizie_homepage.aspx

More than half of respondents believe that breeding cereal crops is more demanding than other crops due to different reasons. The main factor is represented by the VCU and the performance criteria: respondents believe that the requirement of *satisfactory value for cultivation and use* imposes another hurdle to be overcome for those breeders subject to the VCU requirement, such as cereal ones.

Even though the VCU does not directly concern the Community plant variety protection system, it is strictly linked to it: a breeding company, as a legal entity that aims at earning a profit, is usually going to apply for a Community PVR only after being sure that the relevant variety can be marketed. This means that the rules concerning seed marketing to a certain extent affect plant variety protection.

Furthermore, cereals are 'staple foods' and for some breeders this is one of the reasons why breeding cereal varieties is more complicated than others. Innovation in cereal varieties is strictly related to food production and food availability, and breeding activities need to meet all the requests for quantity, quality, and safety of the crops. In addition to the mentioned elements, very few breeders believe that other difficulties lie in the high expectations of the farmers as users of the new cereal varieties, in the stronger competition in the cereals sector, and in the complexity of the genome of some cereal varieties.

ISEA has raised similar concerns. The company employs scientists, agronomists, and geneticists who pursue innovation in plant varieties to meet the needs of consumers, farmers, and the processing industry, as well as for the environment. Innovation entails the development of high-quality varieties, productive, resistant, and adaptable to low-input conditions. For example, in the last years they developed a lodging resistant variety of oat and varieties of *Triticum aestivum* resistant to Fusarium. Undoubtedly, '*plant breeding is a great challenge for every crops sector*'[396] however, the breeding of cereal varieties has a peculiar role since cereals are staple foods, routinely eaten worldwide and throughout the year. Therefore, the company believes that cereal breeders have even a greater challenge because they are required to develop varieties able to feed the growing world's population, which will reach a peak in 2050. In this context, climate change should be taken into account, since it deeply affects agricultural production. This means that, going forward, there will be the need to produce more with less: less water, fewer inputs, less cultivable and arable land.

[396] Verbatim quotation from Dr. Daria Scarano (ISEA).

Also, plant diseases are constantly evolving: '*in thirty years we will not be able to cultivate the same crops we cultivate today with the same results. The challenge in cereal breeding is enormous because we also need to produce in a sustainable way. The problem is to have a real sustainable agriculture, using less pesticides, less fertilizer, using varieties that do not deplete soil nutrients*'[397]. In this context, the Head of cereal breeding at ISEA, Dr. Scarano, believes that Triticum monococcum may represent a paradigm of sustainability for two reasons: it is very disease resistant, and it does not deplete the soil. The outcomes of the observation within ISEA are also consistent with the results of the survey regarding the role of VCU during the breeding activities.

Breeding cereal varieties might be more complicated than other crops because of the satisfactory value for cultivation and use (VCU) required for some plant varieties in order to be marketed in the EU territory. VCU affects the plant breeding activities of the crops subject to these criteria because it adds a further requirement to be met during R&D, in order to commercialize the variety. This element certainly influences the 'applied research' on cereal varieties, *ergo* the cereal breeding industry, since their breeding activities aim at developing '*marketable varieties'* and at guaranteeing a return on the investments made. Usually, the registration in the national catalogue precedes the application for CPVP: the company has to be sure that the variety can be marketed, ensuring a return on investments, before applying for intellectual property rights.

Also, a paradox emerges from the VCU assessment: in order to be registered in the national catalogue, and consequently listed in the Common Catalogue and marketed within the EU market, a cereal variety shall undergo the VCU trial that takes place in certain testing sites of each EU Member State. By way of illustration, *'in Italy durum wheat varieties are tested in central and southern Italy, whose environmental conditions surely affect the VCU of the variety. However, that variety may be intended for marketing in northern European countries'*[398]. It follows that the registration for a variety, which does not display a satisfactory VCU in the testing site where the trial is conducted, may be denied. However, the same variety could perform well in the region of origin or even in other EU Member States, where it would show a satisfactory VCU. In fact, the VCU trials assess *agronomic*

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[397] Ibidem.
[398] Verbatim quotation of Mr. Tassinari (ISEA - Agroservice).

traits related to crop production and performance, which are greatly affected by the surrounding environment and growing conditions, unlike the *morphological characters* assessed during the DUS testing. In light of this, VCU determines the marketability of the variety in the entire EU territory, even though it is tested in limited areas and testing sites thereof.

In this context, a lack of satisfactory VCU would jeopardize the commerciality of the relevant variety. Therefore, cereal breeding companies are supposed to develop new varieties that are going to comply with the VCU parameters set in the EU Member State where the application for variety registration is to be made.

It should be recalled that each EU Member States individually establishes theVCU parameters. However, they often come down to 'increased productivity': when productivity is not increased, problems may arise during the VCU assessment, even if the variety is characterized by great resistance to plant diseases. Consequently, 'increased productivity' has to be taken into consideration when developing a new cereal variety.

In conclusion, the VCU requirement affects and, to a certain extent, conditions innovation in cereal varieties.

Another difficulty faced by cereal breeders concerns the 'communication' of the innovation to the consumers. In fact, it is difficult for consumers to 'perceive' the innovation in cereal varieties and it is even harder to evaluate the quality of the cereal variety *per se.* For example, '*when a new variety of orchids is bred and commercialized, the consumer 'perceives' the variety. When the consumer sees the variety, its colors and its characteristics, the consumer also sees the quality (or some of the qualities) of the orchids. Therefore, consumers can evaluate such qualities. In the case of cereal, the consumers cannot directly perceive the quality of cereal varieties: they usually appreciate the final products, such as pasta, bread, beer, or cookies, and appraise the quality of those products. However, since they cannot see the cereal, they cannot evaluate its quality. Often they ascribe the product quality to the skills of the last producer, e.g. in the case of bread to the baker'*[399]. Consumers might not ascribe the quality of the goods to the characteristics of the cereal variety. So, the problem relies on the 'lack' of perception of the innovation, which leads to difficulties in

[399] Verbatim quotation by Mr. Tassinari (ISEA - Agroservice).

communicating the innovation and raising awareness about the importance of developing new cereal varieties.

In the matter of breeding techniques, ISEA develops new plant varieties primarily through '*conventional breeding techniques*'[400], i.e. crossing and selection. Varieties with different characteristics are crossed in order to produce a genetic *ideotype*, which is a crop having the desired traits of both varieties. For example, a variety characterized by disease resistance but low productivity is crossed with a variety having high productivity but low resistance. The goal is to obtain an *ideotype* that is both productive and disease resistant. Afterward, the best crops are selected in the fields. In almost six or seven years, the crop line is stable so the observation and the agronomic trials start. Their purpose is to compare the performance of the new variety with other varieties. The critical aspect of conventional plant breeding concerns the long time required for developing a new plant variety: plant breeding is indeed a time-consuming activity, which can take up to ten years for developing a variety with the desirable traits. On top of that, an additional two years are necessary to test the DUS requirements for registration purposes.

The cooperation with research centers allowed ISEA to perform '*molecular marker-assisted breeding'*. The purpose is to identify a particular sequence of DNA of the plant: it works as a sort of '*magnifying glass'* able to show whether the plant DNA has or not the desirable crop trait. The cooperation with research centers and universities permits the transfer of 'basic research' into 'applied research'.

In addition, ISEA recently began to perform the so-called '*speed breeding'* through its own growth chambers. Those chambers allow ISEA to accelerate the breeding activities (hence, the name '*speed breeding'*) and to complete a full-plant life cycle in three months: after three months, it is possible to get new seeds. Therefore, it is possible to have four full life cycles in one year. With the growth chamber, it is possible to get a significant turnover

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[400] Conventional breeding techniques (CBT) include a wide range of techniques, such as simple selection, sexual crosses, mutation breeding. The products of CBT result in a combination of traits from sexually compatible species. Those traits pre-exist in the genetic potential of the parent organisms. The use of CBT precedes the use of the so-called '*established techniques of genetic modification'* (ETGM) which developed towards the end of the 1970 and enabled the insertion of genetic information into an organism regardless of sexual compatibility (transgenesis is an example of ETGM, whose products are commonly referred to as '*transgenic organisms'*). See: High Level Group of the Commission's Scientific Advice Mechanism (SAM), 2017, *New techniques in Agricultural Biotechnology. Explanatory Note*, European Commission, Brussels, pp. 29-49.

of crops per cycle. However, this does not mean getting the same amount of varieties. It only means '*increasing the possibilities to select the desired crop, having the desired traits*'[401]. Thanks to speed breeding, it is possible to decrease the amount time required to obtain a stable line: from six or seven years to one year and a half. In this manner, both time and costs are significantly reduced.

The majority of survey respondents relies on the use of '*conventional breeding techniques'*, commonly known as 'crossing and selection', in order to produce crops with desirable traits. There is also some use made of the so-called '*new breeding techniques*'[402] by almost half of respondents. In its recent judgment in Case C-528/16 of 25 July 2018, the CJEU stated that organisms obtained by NBT are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive (Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms). The Court considered that the risks related to the use of these NBT might prove to be similar to those that result from the production and release of a GMO through transgenesis. This ruling has been largely opposed by scientists and breeders, who believe that the GMO Directive is outdated because it does not take into consideration the technical progress after 2001 and the most recent scientific state of the art. Therefore, they strongly ask for legislative revision. However, *rebus sic stantibus*, the use of NBT may rapidly decrease among breeders in the EU so as not to be subject to the obligations laid down by the GMO Directive.

According to the empirical findings, the breeding techniques adopted by the EU companies are often assisted by accelerated breeding methods in order to reduce the time required to develop a new plant variety, hence its cost. In fact, all the respondents believe that the time required to develop a new cereal variety is long/very long, as well as the costs of cereal breeding which are perceived as high/very high. Very few breeders also use molecular assisted breeding to identify the plant DNA sequences.

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[401] Verbatim quotation from Dr. Daria Scarano (ISEA).

[402] New breeding techniques (NBT) refer to a new generation of techniques, including genome editing. Some NBT represent an improvement of CBT, inserting genetic material from sexually compatible species, while some NBT are used in combination with ETGM. See: High Level Group of the Commission's Scientific Advice Mechanism (SAM), 2017, *New techniques in Agricultural Biotechnology. Explanatory Note*, European Commission, Brussels, pp. 56-70.

3.2.2. Plant variety protection of cereal varieties

The plant variety protection system is highly supported by breeding companies from the EU cereals sector and, in particular, the Community PVP system is broadly used.

In the case of ISEA, all the new cereal varieties developed by the company are covered by Community plant variety rights. Indeed, as soon as the variety is listed in the national register, hence it can be marketed, ISEA immediately applies for Community PVR. Usually, cereal varieties are not covered with national PVRs and/or with other forms of IPRs. This choice relies on the benefits of Community plant variety protection as compared to national rights, especially with regard to its unitary effect throughout the European Union territory and the legal protection for the material concerned.

According to the survey outcomes, this approach is common to the majority of EU cereal breeding companies. Indeed, the large majority of respondents primarily use the Community plant variety protection system to protect their innovation in cereal varieties, although some of the respondents also seek protection on a national level through national plant variety rights. Other forms of IPRs to protect plant-related inventions are not commonly used by respondents: less than half of them occasionally use patents, primarily in non-EU countries, trade secrets and trademarks on their varieties. The majority of respondents holds more than fifteen CPVRs and, among them, one fourth holds more than fifty CPVRs. The size of the company affects the number of CPVRs held: generally, large enterprises hold more rights than SMEs.

More than half of the respondents systematically use CPVRs on every new variety of cereal species. However, it does not mean that national PVRs should be considered obsolete: even though one-fourth of respondents does not use national protection on cereal varieties, more than half of respondents occasionally apply for national plant variety rights, whereas few respondents always apply for national plant variety protection on every new variety of cereal species.

The application for national PVP could be built on different factors, as evidenced by the outcomes of the semi-structured interviews. There are breeding companies not protecting their varieties with Community PVRs, no matter the size of the enterprise: they may opt for national protection or even no protection at all. This is a business decision and the reasons behind this choice may be economic or it may be related to the occurrence of infringements.

The geographic location of the company is also an element to be considered. Indeed, companies based in Central and Eastern EU Member States are less likely to use the Community PVP system: '*in case of small companies especially in Central and Eastern Europe the reason is more that often they don't sell EU-wide but breed varieties mainly for their own market and maybe the markets in neighboring countries. In case, applying for national protection only in one or two Member States might be economically a better decision*'[403].

In addition, some breeders may not be interested in protecting new cereal varieties with plant variety rights for the following reasons: 1. because the relevant varieties are hybrids (since hybrids do not propagate unchanged, *copying* the material is not easily achievable); 2. because the company does not fear infringing activities; 3. because the variety 'turnover' is quite fast (meaning that the variety have a short 'commercial life'); 4. because the company believes that the costs for protection are too high compared to the benefit received[404].

3.2.3. Level of awareness of plant variety protection

The level of awareness about plant variety protection in the studied context is high.

Within ISEA and Agroservice, there is full awareness of the substance of the Community plant variety rights system, as well as the national protection system. The survey respondents also showed a significant level of awareness about plant variety protection, and Community PVP in particular. As confirmed by the outcomes of the interviews, the largest part of plant breeders is fully aware of the importance of plant variety protection, both at EU and national level, however this '*does not mean that breeders are protecting their new varieties systematically*'[405], as already discussed in the previous paragraph.

Nonetheless, it was possible to report some miscomprehensions about plant variety protection. During the observation period, the field of observation broadened beyond the company's offices and it addressed conferences and meetings on seed-related issues. In those gatherings, a number of inaccuracies about plant variety protection were identified.

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[403] Verbatim quotation by Ms. Csörgő (Euroseeds).
[404] Opinion of Mr. Barbieri (Sicasov).
[405] Verbatim quotation by Ms. Csörgő (Euroseeds).

Basically, those inaccuracies were determined by confusion between seed marketing laws and plant variety protection.

Certainly, the level of awareness among cereal breeders, and plant breeders in general, is far higher than the level of confusion about the relationship between plant variety protection and seed marketing laws. However, this miscomprehension needs to be reported.

By way of illustration, attendants have occasionally confused variety registration in official catalogues with plant variety protection. As stated in the previous chapter, seed marketing law concerns the public right to market plant reproductive material after official examinations, whereas plant variety rights are intellectual property rights. However, some believed that variety registration recognizes a sort of intellectual property right over the listed variety.

A related matter concerns the misuse of the word '*patent'*. In some occasions, reference has been made to '*patented varieties'*[406]*:* this oxymoron has been used to indicate either varieties protected by CPVRs, or varieties registered in the Common Catalogues. Another inaccuracy concerns the concept of PVRs infringement, which it happened to be mistaken with the production of uncertified seed by farmers, in relation to the FSS practice. Furthermore, 'supply contracts' of genetic material were incorrectly referred to as 'license agreements', and vice versa.

Indeed, the likelihood of confusion has also been highlighted in the survey. It has been stated that there is a need for clarification about the protection of those varieties of cereal species (e.g. *Triticum monococcum*) which are not subject to seed marketing laws. Although Article 5 of the Basic Regulation establishes that varieties of all botanical genera and species may form the object of Community plant variety rights, it is deemed necessary to make clear that also those varieties might be protected under the CPVR system.

The extent of this confusion between seed marketing laws and plant variety protection is corroborated by the referred-to Case n. 8745/2015 (*BASF Italia spa vs Società Agricola Magnani Caterina e Magnani Lorenza)* held in 2015 before the Tribunale di Milano - Sezione specializzata in materia di impresa, in Italy[407].

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[406] As stated in the first chapter, plant varieties are not patentable in the EU.
[407] The case has been illustrated in paragraph 4 of the previous chapter.

It should be noted that the improper equation between registration in the Common Catalogue and the granting of Community PVRs affects all crop sectors, not only the agricultural one. The existence of this misunderstanding has been confirmed by Ms. Csörgő (Euroseeds), who stated that *'it is an issue that I very quickly faced when I started working in Euroseeds back in 2009. We have done a lot of work, brochures and trainings for members to clarify this misunderstanding and by now I think most understand that they have to clearly make the difference between variety registration and plant variety protection'*.

3.2.4. Satisfaction with the Community plant variety protection

Overall, great satisfaction with the Community plant variety protection system has been displayed. The CPVR system '*has always been very much appreciated*'[408] by EU breeders. According to the outcomes of the interviews, the system is considered robust and balanced, having a professional office behind. This is the reason why '*the system as it is, is an important tool in fostering innovation in plant breeding in the EU'*[409]. In addition, the Community plant variety rights regime is believed to guarantee an important return on investment in R&D and to protect the right holder against the illegal use of the protected material[410].

During the years of observation, a significant satisfaction with the Community PVP system was noted, both from ISEA/Agroservice and the representatives of other SMEs met during meetings and conferences. In particular, ISEA and Agroservice deeply believe in the pivotal role played by Community plant variety protection in the European Union, especially for SMEs engaged in cereal breeding: the protection of new plant varieties by Community PVRs is deemed to be *'fundamental and necessary'*[411] in order to foster innovation in this sector, thereby increasing the competitiveness of the industry.

The survey shows that almost 90% of the respondents is satisfied with the Community PVP system for the cereal varieties, and more than 60% of them believes that the CPVP system is fostering innovation in the cereals sector and that it stimulates the breeding and

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[408] Verbatim quotation by Ms. Csörgő (Euroseeds).
[409] Ibidem.
[410] Opinion of Mr. Barbieri (Sicasov).
[411] Verbatim quotation by Mr. Tassinari (ISEA - Agroservice).

development of new varieties. In addition, the CPVP system is deemed to guarantee a return on investment for a great number of respondents, more than 70%.

According to respondents, the success of Community PVP for cereal varieties relies on several aspects: primarily, the protection accorded to the breeder, especially through the royalty payments to be made to the right holder; the unitary effect of CPVRs throughout the EU; the rules on EDV; the breeder's exemption; and the support provided by the CPVO staff.

Also, the CPVP system is deemed to be less expensive as compared to other forms of IPRs in Europe. By way of illustration, the application fee for a CPVR is EUR 450 (for online applications, in case of paper applications the cost is EUR 650) and the examination fee for cereal species (agricultural group) is EUR 1530[412]. Differently, the cost for a patent under the EPC is roughly estimated at an average of EUR 5620, from the online patent application until the grant stage[413]. The lower fees make the Community plant variety protection more accessible, especially for small and medium-sized enterprises.

3.2.5. Shortcomings in the Community plant variety protection

Despite the high level of satisfaction reported, the empirical data pointed out the shortcomings of the system that may challenge the effectiveness of Community plant variety protection.

During the years of observation, there were two ever-present topics of major concern among cereal breeders: infringement and weak enforcement of CPVRs. Concerns have been raised about the infringement of CPVRs and its connection with the FSS practice and the *abuse* of the farmer's privilege on protected cereal varieties, as defined in Regulation (EC) No 2100/94 on Community PVP. In case of infringement, the right holders struggle to enforce their CPVRs in case of FSS, in particular because of the difficulties related to the access to the information about the propagation of seeds of protected varieties.

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[412] Source: CPVO website, https://cpvo.europa.eu/en/applications-and-examinations/fees-and-payments. Last access: October 2019.

[413] Source: EPO website, https://www.epo.org/service-support/faq/own-file.html#faq-199. Last access: October 2019.

It is worth stressing that the farmer's privilege and the FSS practice do not concern all plant varieties but only a limited number: *inter alia*, cereal varieties. According to the empirical outcomes, in some EU Member States the infringement rates are not high, whereas in some Italian Regions, as well as in other EU countries, the illegal reproduction of cereal seeds of protected varieties is severely common. Participants believe that infringement may be decreased by reducing the illegal use of FSS and by ensuring access to information about FSS.

As already anticipated, in the context of FSS, Community PVRs are difficult to enforce, especially for SMEs. In particular, it is reported a scarcity of official control in relation to FSS and a lack of effective royalty collection in some EU Member States.

Significant difficulties arise for right holders with regard to access to information about FSS, in order to check whether protected varieties are involved. Those difficulties are strictly connected to the interpretation of the CJEU given in Cases C-305/00 and C-182/01, where the Court specified that the holder of a Community plant variety right could require a farmer to provide that information only where there is an *indication* about farm-saved seed. This means that not every farmer has to provide the information on request. This interpretation resulted in difficulties for breeders to enforce their rights on the use of FSS since it is not easy to gather such 'indications' and to collect evidence. By way of illustration, securing evidence may be problematic because the right holder needs to be aware of the supposed infringing activity, then they need to enter the premises of the supposed infringer and to obtain a sufficient quantity of the alleged infringing material in order to test its varietal identity. Also, the material must be obtained in a specific period of time, since the growing period occurs once a year and the infringing activity may be proved only during the final growth stage. Furthermore, the nature of the protected material raises one-of-a-kind issues of evidence in CPVRs enforcement as compared to other IPRs because, as living organisms, it hardly produces *identical* crops: for example, due to environmental conditions, the same variety could produce dissimilar plants. This aspect may affect prima facie evidence[414].

Cereal breeders are struggling to monitor the market and the use of FSS throughout the EU territory. As a matter of fact, it is difficult - mostly for SMEs - to be aware of the real

[414] For an in-depth analysis of the problems encountered in German plant variety infringement cases, see: Würtenberger G., 2006, *Questions on the law of evidence in plant variety infringement proceedings*, in Journal of Intellectual Property Law and Practice, 1, 7.

dimension of infringing activities. This has been confirmed by the survey: almost half of the respondents stated that their CPVRs *may* have been infringed, whereas 40% of them has definitely experienced infringement.

The enforcement of Community PVRs in some EU countries is also challenged by other elements: bureaucracy, high cost of litigation, slow judicial systems. Difficulties have been reported in enforcing CPVRs in third EU Member States. Indeed, different national court systems are believed to make the enforcement of a CPVR remarkably hard and disparities among Member States may arise.

In this context, different sensitivity and level of interest among the EU Member States about CPVP and plant variety protection in general may be noted. In some Member States, especially the ones where the breeding sector has great economic weight (e.g. France, Germany, the Netherlands, UK), significant importance is given to plant variety rights and their enforcement, whereas in other States a lower sensitivity exists.

These differences may have further consequences. Even though the legislation is largely defined at the EU level, national laws based on a higher sensitivity may give competitive advantages to some breeders, to the detriment of others[415]. Therefore, the harmonization of national legislations might be deemed necessary.

In addition, Courts in those States with a higher level of interest on PVP may have better expertise on plant variety protection and they may be well aware of the difficulties related to collect evidence, due to the nature of the protected material. In those cases, breeding companies may be more inclined to start a court proceeding. Differently, the lack of expertise may represent an obstacle for the right holders as they may be afraid to embark on long and costly litigation, the outcome of which is uncertain. The rules governing plant variety protection and seed marketing are very sector-based and some breeders have experienced difficulties in finding expert lawyers or legal consultants in this field.

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[415] An example is provided by Ms. Csörgő (Euroseeds): '*To give an example from the field of IP law, in some countries in the EU there is a so-called "limited breeder's exemption" in national patent laws which allows breeders to use the patented biological material for further breeding (similar to what we have in PVP). Whereas in other countries such specific exemption does not exist. Due to the territorial effect of patent law, this different approach results in a situation where some breeders in the EU can use certain varieties for further breeding (because they are doing their breeding activities in a Member State where such exemption exists in national patent law) and others cannot'.*

The easiness to illegally reproduce protected cereal varieties, especially non-hybrids, is connected to the very nature of seeds, as organisms that are automatically able to duplicate themselves. However, since the law has not found a solution to PVRs infringement yet, breeders rely upon science to avoid the illegal reproduction of cereal seed. Indeed, cereal breeders from across the world are working on the development of hybrids varieties of wheat. The reason is threefold: first of all, hybrids as such have superior performances and higher yields in comparison to lines; they also are less likely to be illegally reproduced since they do not replicate unchanged; lastly, the farmer's privilege does not extend to the harvested material obtained by propagating material of a hybrid variety covered by Community PVR, according to Article 14 of the Basic Regulation. Nowadays, hybrid varieties of wheat occupy a niche market but they may soon replace the other wheat varieties[416].

Apart from the weak enforcement of CPVRs, other two aspects are deemed as shortcomings of the system. The first one concerns the protection of the so-called *multiline cultivars* or *multiline varieties*, which are mixtures composed of different genetic lines or even different species. Because of their genetic diversity, those multiline cultivars are characterized by higher resistance and minimum yield losses compared to homozygous cultivars. Multiline cultivars have been developed for a number of cereal species, such as barley, wheat, oats[417], however their use is limited because they do not comply with the DUS standards required for plant variety protection. By way of illustration, in the Netherlands a multiline wheat variety named Tumult, resistant to yellow rust, was developed in the seventies but plant variety rights could not be granted because of its lack of uniformity due to genetic diversity[418]. Nowadays, the marketing of multiline cultivars is prevented in the EU by the seed marketing laws because they lack of uniformity and stability[419], however there are those who believe that more attention should be paid to those varieties by the CPVP system on account of their advantages in terms of resistance and productivity.

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[416] For further insights on hybrid breeding in wheat varieties, see: Mette M., Gils M., Longin C., Reif J., 2015, *Hybrid Breeding in Wheat*, in Ogihara Y., Takumi S., Handa H. (eds), *Advances in Wheat Genetics: From Genome to Field*, Springer, Tokyo, pp. 225-232.
[417] Brown J., Caligari P., 2008, *An introduction to plant breeding*, Blackwell Publishing, Chapter 4.
[418] Halewood M., 2016, *Farmer's crop varieties and farmer's rights: challenges in taxonomy and law*, Routledge, pp. 206-207.
[419] Louwaars N., Le Coent P., Osborn, T., 2011, *Seed systems and plant genetic resources for food and agriculture,* FAO, Rome, p. 9.

The last shortcoming does not concern the CPVP system *per se* but its relationship with the seed marketing laws. In particular, some cereal breeders believe that the take-over of technical reports by CPVO for a variety already entered in the Common Catalogue should be clearly regulated at the EU level.

3.2.6. Ideal legislation

The previous paragraphs have shown that the current system of Community plant variety protection is highly appreciated by cereal breeders; however, some weaknesses have been identified. In light of this, amendments to the current legislation have been suggested in order to address those shortcomings.

According to the collected data, the enforcement of CPVRs should be improved, in particular in case of FSS. As a matter of fact, effective enforcement mechanisms are necessary to ensure that the legislation is successfully applied: weak enforcement may indeed undermine innovation and decrease investments in R&D. The ideal system of Community plant variety protection for cereal varieties should facilitate the enforcement of CPVRs through a better and easier access to information about FSS from right holders, as well as proper and effective rules for the collection of royalties on the use of FSS. Those provisions may also lead to a decrease in the illegal use of protected material. The illegal reproduction of protected seed jeopardizes the possibility for the breeder to have a return on the investments. Consequently, infringement impacts the company's capability to innovate. This has been confirmed by the outcomes of the interviews. The weak enforcement possibilities on FSS may affect the CPVP goal to stimulate innovation *'since allowing the use of FSS and not having proper and strong legal provisions for enforcement (i.e. for collecting the remuneration due on the use of FSS) may be detrimental to innovation in plant breeding'*[420].

Furthermore, the ideal legislation on Community plant variety protection should be coordinated with the EU seed legislation, which also is deemed to need a deep harmonization at the EU level. It is worth mentioning that the EU seed legislation is deemed to be '*outdated'*, '*too demanding'* and '*time-consuming'* by some cereal breeders.

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[420] Verbatim quotation by Ms. Csörgő (Euroseeds).

Even though the two legislations deal with different aspects related to plant genetic material, Community plant variety protection and EU seed marketing laws are profoundly linked to one another. The former refers to reproductive material as a *technology carrier*, whereas the latter as a *commercial commodity* but, ultimately, they both deal with innovation in plant reproductive material and, as such, they have an impact on variety creation.

By way of illustration, the ideal legislation should be coordinated with regard to the DUS assessment, required both for CPVP and variety registration. In case the DUS trial for national listing complies with the CPVO technical protocols, there are those who believe that the resulting reports should be taken over by CPVO for the granting of Community PVRs. In this way, the breeders would no longer be required to send the genetic material two times: initially, to the national authority and, then, to the CPVO. Indeed, breeders often apply for CPVR as soon as the variety is listed in the national register. This is the case with ISEA: '*in such a short time, genetic drift cannot happen: therefore, a second DUS examination should not be deemed necessary*'[421]. As a matter of fact, one of the requirements for Community PVP is novelty: within the EU territory, the new variety should not have been sold or disposed of for exploitation purposes earlier than one year before the date of application for Community PVR. So, the CPVO grants protection on '*newborn'* varieties. In case the variety has been brought onto the market immediately after the variety registration, where DUS have been assessed, the CPVO is required to repeat the DUS test on the same variety only one year later. In this case, it would be easier and faster if variety registration reports were automatically taken over by CPVO for the granting of Community PVRs.

In addition, there are those who believe that the ideal legislation should pay more attention to multiline varieties, finding a place for them in the plant variety protection system.

According to the empirical outcomes, a focus should also be placed on *education* and proper *communication* about the role of plant variety protection and innovation on cereal varieties. Plant variety rights are not the most well-known IPRs: the knowledge of plant variety rights can be superficial and incomplete both within the sector, by enforcement bodies and by the farmers, who may unintentionally infringe CPVRs because of their lack of knowledge about the scope of protection of plant variety rights. Communication is also

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[421] Verbatim quotation by Dr. Scarano (ISEA).

fundamental to raise awareness about the prominence of innovation on cereal varieties and the consequences of infringing activities. Effective communication on the importance of innovation is also necessary to defeat the reluctance of farmers to pay the price charged for the seeds of new cereal varieties. Therefore, education and communication have a pivotal role as the gateway to decrease infringement on protected varieties.

During the observation period, two hypotheses were generated about the ideal legislation on the basis of the data collected. Those hypotheses have been tentatively proposed during the other processes of data collection. Both of them dealt with infringement decrease and enforcement strengthening. In particular, participants have been asked to express their opinion about 1. traceability *'from seed to plate'* throughout the supply chain, whether it may decrease infringement on Community PVRs; 2. the establishment of a supranational specialized Court in order to facilitate CPVR enforcement.

Although one-third of the participants believes that infringement may not be reduced, almost half of the survey respondents believe that traceability 'from seed to plate' may have a role in decreasing CPVR infringement. Traceability will allow the identification of the varieties throughout the chain and it will ensure efficient control. In this way, consumers will have better information about the food they are buying and they will be made aware of the origin and the quality standards of the ingredients. In traceability schemes, the food industry has a key-role in fighting infringement because it should demand the use of traceable and certified seed, which guarantees that certain quality standards are met. Nowadays, there is no legal obligation to follow traceability schemes *'from seed to plate'* but the design of traceability schemes may be spontaneously and jointly carried out by seed companies, food industry and retailers: the synergy between those actors may ensure that illegally reproduced material will no longer enter the food chain.

The hypothesis of the establishment of a supranational specialized Court has been warmly welcomed by the cereal breeding companies: there have been no negative feedback and only a few respondents did not have an opinion about it. The vast majority of the participants believe that a supranational specialized Court, having exclusive competence about claims on Community plant variety rights, would facilitate CPVR enforcement. The litigation of disputes before a single Court in the EU territory, instead of national courts acting as EU courts, would overcome the risks of fragmentation, forum shopping and legal uncertainty. Furthermore, the problems related to the different national court system would

be solved, as well as the disparities among the EU Member States based on different expertise of the national Courts on plant variety protection. In this framework, a supranational enforcement of CPVRs would facilitate breeding companies to compete on a level playing field in the internal market. However, for the moment the establishment of said Court is just a hypothesis and it not up for discussion at the EU level. This means that, in the meanwhile, the CPVRs enforcement might be improved by '*having specialized PVP courts in every Member State or having at least a specialized PVP chamber at every IP court*'[422].

In conclusion, it is clear from the results of the empirical data that the ideal legislation should guarantee better and more effective enforcement mechanisms, in particular through easier access to information about FSS and by providing for effective rules for the collection of royalties on the use of FSS. Enforcement may also be facilitated with the establishment of a supranational specialized Court having exclusive competence about claims on Community plant variety rights. The ideal legislation should also be coordinated with the EU seed legislation, in order to be less time and cost-consuming, thereby more efficient. Furthermore, a place for education and communication about plant variety rights, as well as for traceability schemes to decrease infringement on CPVRs, should be found in the Community plant variety protection system. Those amendments are supposed to definitely increase the already-high level of satisfaction shown by EU cereal breeders and to better stimulate innovation in the relevant breeding industry.

4. Final remarks

Empirical legal research allows the researcher to see the '*real reality'* and to grasp the differences with the '*legal reality'*.

Observing and talking with stakeholders and experts permitted to dive in the chosen context of investigation and to detach from the preconceptions on the research topic, in order to elicit valuable and dependable findings. In any empirical research, the collection of data represents a fundamental step: for example, it is essential to determine the methodology, the context to observe, the participants to be surveyed, and the data source necessary to capture an accurate phenomenon in a trustworthy manner.

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[422] Verbatim quotation by Ms. Csörgő (Euroseeds).

In this case, the collection of experience and opinions of stakeholders and experts had a pivotal role in answering the research question. The perceptions and opinions of EU cereal breeding companies and experts have been essential for the purpose of the research. The empirical data displayed the main concerns of the industry, the shortcomings of the system, the level of awareness and satisfaction with the Community plant variety protection, as well as the amendments hoped-for. These outcomes are valuable because they open a window to the 'real reality' of the industry and indicated the issues to be addressed.

The various data sources outlined that there is a general and high satisfaction with the Community plant variety protection among cereal breeding companies, although there are concerns over the weak enforcement of the CPVRs, mostly in relation to FSS. The illegal use of protected varieties is a major issue among breeders, which calls for an improvement of the system and better access to information. Attention is also paid to the connection between plant variety protection and seed legislation in the EU as legislations having both an impact on variety creation. Those recommendations may be useful for prospective legislative changes.

Even though the number of 'data sources' has been relatively small, the collection methods generated an interesting volume of empirical data. Those data provided several insights into the field of investigation, from different points of view. They captured the perceptions of the legislation, which are indispensable to ascertain the external effectiveness of the law.

The choice of triangulation allowed the gathering of different kinds of data: this is deemed to be more dependable than a single collection method. Multiple methods of data generation have been employed for '*observing and understanding*'[423] and, in this framework, one method served as the 'check' against data gathered through another method[424]. In particular, surveys and semi-structured interviews have 'checked' the data collected through the three years of participant observation.

The development of thematic categories from all the data set facilitated the analysis and interpretation of the collected data in a combined and unified manner. Those thematic

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[423] Nielsen L., 2003, *The need for Multi-method approaches in Empirical Legal Research*, in Cane P., Kritzer H., (eds.), The Oxford Handbook of Empirical Legal Research, Oxford University Press, p. 953.
[424] Starr J., Goodale M., (eds.), 2002, *Legal Ethnography: New Dialogues, Enduring Methods*, Palgrave Macraillan, New York, p. 6.

categories aimed to provide an overview of the empirical outcomes from all the data sources. The findings of the empirical research indicate that there are a number of legal issues that need to be examined from the perspective of the cereal breeding companies. In the next concluding chapter, those empirical findings are going to be combined with the outcomes of the normative research in order to provide a final answer to the main research question leading the current investigation.

CONCLUSION

SUMMARY: 1. Preamble. - 2. The combination of legal and empirical outcomes. - 2.1. The scope of innovation in cereal varieties. - 2.2. The coexistence of Community and national plant variety protection. - 2.3. FSS and the farmer's privilege. - 2.3. The relationship between Community plant variety protection and seed legislation in the EU. - 3. Recommendations and concluding statements.

1. Summary

The legislation on Community plant variety rights is supposed to foster innovation: the purpose of the Basic Regulation is to stimulate the breeding and development of new varieties. The relationship between variety creation and IPRs is indeed the foundation of the plant variety protection systems, at the international and EU level.

The linkage between innovation and Community plant variety rights is particularly important with reference to cereal varieties, because of their fundamental role in the global food chain, as well as in the EU agriculture and economy.

The choice of a specific crop sector, upon which the effectiveness of Community plant variety protection is investigated, lies on the idea that each crop sector has its own peculiarities and the protection regime may not foster innovation equally in each crop sector.

In the case of cereal varieties, further legislation needed to be analyzed because of its impact on cereal innovation, such as the seed legislation. As already stated, innovation affects the seed as both a technology carrier and a commercial commodity and, because of this, the seed is subject to different rules depending on which aspect is being regulated. Those rules are tied together: therefore, when assessing the impact of one of them on variety innovation, the effects of the other one on the same aspect have to be taken into account.

For the purpose of the current investigation, an empirical legal methodology has been adopted. The empirical data collected during the three years of research have been indispensable to examine the characteristics of the chosen crop sector and the effectiveness of the Community plant variety protection regime upon it: the views of cereal breeding companies have

been indeed necessary to understand whether the legislation achieves its purpose of fostering innovation.

The previous chapters of the current study outlined the substantive provisions of the UPOV Convention, the Community plant variety protection regime and the seed marketing legislation in the EU, and analyzed the empirical findings. The current concluding chapter is going to draw together the research outcomes from the analysis of law in the books and the law in action, in order to answer the question leading the research, i.e. '*Nowadays, is Community plant variety protection fostering innovation in cereal varieties in the European Union industry*?'.

In drawing those findings, areas where further legislative activity might be required are going to be pointed out. As stated in the introductive chapter, the combination of legal and empirical findings could develop into a '*critique of the law'*, which is necessary to ascertain the supposed '*external effectiveness'* of the law, whether it achieves its social goals[425]. The legislation is indeed supposed to meet the changing needs of the society, and this requirement may represent the justification for legislative changes.

2. Combination of legal and empirical outcomes

In the current research, the normative analysis of the law started from an overview of the UPOV system, segued into the investigation of the Community plant variety protection, and then moved to the EU seed legislation. The empirical research, instead, allowed the collection and analysis of data from three methods: primarily by participant observation, then via electronic survey and individual semi-structured interviews.

The combination of legal and empirical findings, resulting from the analysis of the *'law in the books'* and the *'law in action',* is provided below and it is deemed necessary to offer an answer to the research question, that aims not to be affected by expectations or bias and to take into considerations the peculiarities of the chosen crop sector.

[425] Schrama W., 2011, *How to carry out interdisciplinary legal research. Some experiences with an interdisciplinary research method*, in Utrecht Law Review, 7, 1.

2.1. The scope of innovation in cereal varieties

First and foremost, it is important to analyze what practically is '*innovation in cereal varieties'* according to the empirical findings. As already said, innovation is the *Zeitgeist* of contemporary society and, for the purpose of this research, innovation in varieties of cereal species is considered as such when it has scientific relevance and it meets the society's needs.

The empirical findings show that innovation in cereal varieties is certainly a challenge: breeding new varieties of cereal is complicated, costly and time-consuming. With regard to cereal, innovation mainly involves the following species: *Triticum aestivum, Hordeum vulgare, Avena sativa, Secale, Triticum durum, Triticum spelta, Triticosecale, Triticum monococcum, Zea mays.* Among those, only the species of *Triticum monococcum*, as a minor cereal crop, is not regulated by Directive 66/402/EEC on the marketing of cereal seed. Since innovation in cereal varieties does not only concern the novelty created, but also the breeding methods and techniques, it is worth mentioning that new cereal varieties in the EU are primarily developed through conventional breeding techniques and, to a limited extent, through new breeding techniques. The breeding activity is often assisted by accelerated breeding methods, in order to speed up the breeding process, thereby decreasing the amount of time and the cost required to develop a new plant variety. The driving forces behind said innovation are the wish to meet the demands of farmers, consumers, and the agro-food processing industry. The following goals are pursued when innovating cereal varieties: more productivity, better pest and disease resistance, nutritional content increase, better adaptation to climatic stress, quality for food production, and increased sustainability. Those findings display that innovation in the EU cereal breeding industry aims at meeting the changing needs of the society, in particular in terms of increased and better food productivity, low-input agriculture and environmental protection.

In light of the scope of innovation in cereal varieties, the combination of legal and empirical findings is going to explain whether Community plant variety protection is fostering this kind of innovation in the European Union industry.

2.2. The coexistence of Community and national plant variety protection

The normative analysis of the law indicated that the UPOV Convention has been the first international agreement to provide a legal framework for the protection of plant varieties through a *sui generis* system: it introduced important key concepts and it still represents the cornerstone of plant variety protection at the international level. The latest version of the UPOV Convention dates back to 1991 and, although some improvements might be needed, it has been said that *'a review could have the character of opening the Pandora's box'*[426]. In this context, it is the responsibility of the Contracting Parties to carry on effective implementation of the UPOV plant variety protection system and to provide for the needed interpretation of its legal provisions.

The European Union is a Contracting Party to the 1991 Act of the UPOV Convention and, therefore, the rules set out in this Convention modeled its legislation on plant variety protection. The Community plant variety protection system of the European Union has its cornerstone on the so-called 'Basic Regulation': Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights. The Basic Regulation created a unitary IP right valid throughout the European Union which is the '*sole and exclusive form of Community industrial property rights'* for plant varieties, pursuant to Article 1 of the Basic Regulation. This protection system is independent and alternative from national ones: indeed, the Community PVP regime co-exists with national systems governed by national laws, the content of which is not uniform. As a matter of fact, not all the EU Member States are bound by the 1991 UPOV Convention and, even when they are, national authorities may have established different rules due to the optional provisions set out in the last version of the Convention (e.g. the farmer's privilege and the duration of the protection). The heterogeneity among national laws on plant variety protection is caused by a lack of harmonization at the EU level: so, currently in the EU national plant variety rights are differently regulated.

In this regard, the empirical findings have shown that, in the case of cereal varieties, national plant variety rights should not be deemed obsolete because there are several

[426] Statement of the pro tempore President of the CPVO, Bart Kiewiet. See: Kiewiet B., 2004, *Evolution of the Legal Environment of Plant Breeders' Rights,* Angers, p. 2, available at the following website: https://cpvo.europa.eu/sites/default/files/documents/articles/ISFBerlin2004EN.pdf

companies in the EU that, for different reasons, are protecting their new cereal variety with national PVRs, either occasionally or on a regular basis. In this context, a harmonization at the EU level of the national plant variety protection is deemed necessary because it could lead to a distortion of competition in the EU breeding industry[427] since national plant variety rights are still significantly used by breeders.

The lack of harmonization may have further consequences, especially with regard to CPVRs enforcement: problems may arise not only because of the different regulation on plant variety protection at the national level, but also due on the different 'education' and level of interest on this topic among the Member States. Member States where the cereal breeding sector has great economic weight are deemed to give great importance to plant variety rights and their enforcement, and their Court have a better expertise on plant variety protection and specialized PVP chamber; whereas other States are considered to have a lower interest on plant variety protection and a consequently inferior expertise on it. This different approach gives competitive advantages to some breeders, to the detriment of others, and it affects the enforceability of plant variety rights at the national level. For example, the lack of expertise may represent an obstacle for the right holders as they may be afraid to embark on a long and costly litigation the outcome of which is uncertain. Therefore, an enforcement strengthening has been welcomed by the cereal breeders, according to the empirical findings, even through the establishment of a supranational specialized Court in order to facilitate CPVR enforcement.

2.3. FSS and the farmer's privilege

Since its adoption, the Community plant variety protection regime has always been appreciated by EU breeders: the system is considered robust and balanced (see: the 'breeder's exemption' established by Article 15 of the Basic Regulation which sets out the exceptions to the breeder's right for the purpose of promoting innovation through the maintenance of free access to those varieties covered by a plant variety right; and the

[427] Van Der Kooij P., 2008, *Towards an EC directive on plant breeder's rights?,* in Journal of Intellectual Property Law and Practice, 3, 2.

provisions on EVDs which introduced a principled of limited dependence for the purpose of discouraging plagiarism).

Also, its unitary effect benefited the internal market and simplified the PVR granting procedure. According to the empirical data, the vast majority of the cereal breeders is satisfied with the Community plant variety protection, in particular because it guarantees a return on investment through the royalty payments and protects the right holder against the illegal use of the protected material by third parties. In light of this, it should not surprise that Community plant variety rights are regularly used on new varieties of cereal species by a great number of cereal breeders in the EU.

The Community plant variety protection system strengthened the IP right granted to plant breeders, nonetheless taking into account the public interest overtones related to plant variety rights by adoption specific provisions on compulsory exploitation rights and about the farmer's privilege (also called, agricultural exemption). And it appears that it is exactly the farmer's privilege to be the crucial issue for cereal breeders.

It is worth recalling that, according to Article 13 of the Basic Regulation, a Community plant variety right has the effect that only the right holder is entitled to effect a number of specific acts in respect of propagating material or harvested material of the protected variety (*inter alia,* multiplication, offering for sale, selling or other marketing). The performance of any of the acts listed in Article 13 by a third person requires the authorization of the right holder, who might subject it to conditions and limitations.

Unlike other IPRs, the Community plant variety rights are not simply exhausted when the protected material is marketed for the first time but it also necessary that further propagation of the relevant variety is not involved, except where such propagation was intended when the material was disposed of. Therefore, as a general rule, the use of the material for further propagation does not exhaust the Community plant variety right. This rule takes into consideration that, in plant variety protection, the protected material is automatically able to duplicate itself, unlike other goods protected with IPRs.

Therefore, when a farmer buys and cultivates seeds of a protected variety and the harvest deriving therefrom is further propagated to produce new seed, as a general rule the Community plant variety right is not exhausted. In order to use the harvest of the protected variety for further propagation, the farmer needs the authorization of the breeder that could

be subject to conditions and limitations such as receiving an adequate remuneration, i.e. royalty payments.

However, there are limitations to the scope of the Community plant variety right and one of them is set out in Article 14 of the Basic Regulation, regarding the so-called farmer's privilege or agricultural exemption. The farmer's privilege has its roots in the traditional practice of farm-saving seed, which is still common among farmers especially with regard to cereal seeds. It is worth recalling that, on the global seed market, the rate of FSS is more than 60% for wheat, barley, and rice.

The farmer's privilege enshrined in the Basic Regulation is limited to certain acts, certain conditions, certain plant species: when the requirements set out in Article 14 are met, farmers are authorized to use for propagating purposes the harvest of a protected variety. In such case, the Community PVR does not extend to said practice, thereby those farmers do not need the right holder authorization. In particular, the farmer's privilege, which cannot be transferred, concerns the use of the harvested material obtained by propagating material of a variety covered by Community PVR, except for hybrids or synthetic varieties.

This practice shall concern only the use for propagating purposes in the field, that needs to take place exclusively on the farmer's own holdings. Also, the farmer's privilege applies only in respect of the plant species listed in Article 14 (2) of the Basic Regulation, mainly fodder plants, cereals and potatoes. In this framework, it is worth recalling that small farmers shall not pay any remuneration to the right holder, unlike other farmers who have to pay an equitable remuneration in the form of a royalty payment, sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area (usually, it amounts to 50 percent of the price charged for the licensed production of propagating material).

Therefore, when the conditions set out for the farmer's privilege are met, the farmer shall not require the authorization of the right holder to use the protected material for propagating purposes. In this context, the right holders have to monitor the compliance by farmers with the provisions of the Article, as stated in Article 14 (3) of the Basic Regulation.

However, the monitoring activity is greatly challenged by the difficulties in accessing the relevant information by right holders. Indeed, the same Article 14 (3) of the Basic Regulation establishes that farmers, supplies of processing services, and official bodies shall provide the relevant information on request of the right holders. Nevertheless, the Court of

Justice in the Cases C-305/00 and C-182/01 held that the holder of a Community plant variety right can require a farmer to provide the information specified in those provisions only where there is an *'indication'* that the farmer has used or will use, for propagating purposes in the field, on their own holding, the product of the harvest obtained by the protected material.

In light of this, it seems clear that the farmer's privilege represents a crucial issue: right holders are put in a tricky position since they are supposed to monitor the compliance with Article 14 but they cannot easily access the information required to carry on the monitoring activities effectively.

The empirical findings show that the infringement of Community plant variety rights during the FSS practice is of great concern among cereal breeders: the right holders struggle to enforce their CPVRs on FSS, in particular because of the difficulties related to the access to the relevant information. Since farmers are not obliged to provide the information on request, it is not easy to gather such 'indications' and to collect evidence (e.g. the right holder needs to obtain a sufficient quantity of the alleged infringing material in order to test the varietal identity). In this framework, the cereal breeding industry is really struggling to monitor the compliance with Article 14 by farmers within the EU market and to collect the owed royalty payments. These complications affect especially SMEs which can hardly perform the same monitoring activities as compared to multinational enterprises.

The scope of the monitoring is also important in relation to the prescription for the civil claims for CPVR infringement. According to Article 96 of the Basic Regulation, the prescription is *three years* from the time at which the Community PVR has finally been granted and the holder has knowledge of the act and of the identity of the party liable or, in the absence of such knowledge, after 30 years from the termination of the act concerned. As already stated, the content of the provision is not completely clear and this is the reason why scholars believe that such provision shall be interpreted to mean that the three-year term commences with the knowledge of the infringing acts by the infringer, regardless of when they obtained the same after grant, with a maximum term of thirty years.

The CJEU is going to decide about the suitability of such a broad interpretation in Case C-186/18, concerning the interpretation of Article 96 of the Basic Regulation. The decision of the Court is going to be of utmost importance since prescription has a crucial role for

rights enforcement, and a restrict interpretation might undoubtedly shake the effectiveness of the Community plant variety protection system.

As shown by the empirical findings, for EU cereal breeding companies is almost impossible to be completely aware of the real dimension of infringing activities: a significant number of cereal breeding companies is not even sure whether their protected varieties are infringed or not. This is the reason why the ideal Community plant variety protection should facilitate access to information about FSS and it should establish more effective rules for the collection of royalties on the use of FSS. Indeed, the weak enforcement possibilities in the case of FSS hinder a return on investment through royalty payments, discouraging innovation.

Those provisions may also lead to a decrease in the illegal use of protected material. Indeed, the spread of an uncontrolled FSS practice does not only jeopardize the possibility for the breeding company to have a return on investments for the protected variety, thereby discouraging innovation and the development of new varieties, but it also carries significant risks related to the lack of the guarantees as in the case of certified seeds. It is worth recalling that the quality of farm-saved seed is not ensured by the certification process: neither varietal purity nor germination is guaranteed, as well as the phytosanitary status of the seeds. Also, FSS is not traceable, unlike certified seed lots.

The rationale behind the farmer's privilege as a limitation to the scope of the Community plant variety right is found in the public interest for the purpose of safeguarding agricultural production, as stated in the Preamble as well in Article 14 of the Basic Regulation. It follows that FSS has a significant role in safeguarding agricultural production in the EU.

However, one might wonder whether the FSS practice, when it is carried on by 'industrial farmers' and it does not concern conservation varieties, is consistent with the rationale behind the EU seed legislation, whose purpose is fostering agricultural production by providing quality seed. Seed is a decisive input that dramatically affects agricultural production and this is why seed producers are required to comply with specific registration and certification requirements. The spread of an uncontrolled FSS practice go beyond the economic loss of the farmers: they concern farming sustainability and the quantity and quality of feed and food production.

With this in mind, it is not surprising that traceability 'from seed to plate' is believed to have a role in decreasing CPVR infringement, as showed by the empirical findings.

Traceability schemes allow the identification of the varieties throughout the food chain and they ensure efficient control. In this context, illegally reproduced seeds would not enter the food chain because of its lack of traceability. In this way, infringements on CPVRs would be decreased and certain quality standards would be met, for the benefit of both right holders and consumers.

In addition to voluntary traceability schemes, infringement of CPVR and the illegal use of uncertified seed in the food chain could also be addressed through an extension of the scope of Community plant variety rights: Article 13 (4) of the Basic Regulation states that plant variety protection *might* be extended in respect of products obtained directly from material of the protected variety, as in the case of pasta made from protected varieties of wheat, under the same conditions of paragraph 3, i.e. the unauthorized use of material of the protected variety and the reasonable opportunity for the holder to exercise their right.

Even though doubts have been raised in the past about the difficulty of identifying the material through the food chain[428], technology could assist the effective implementation of such a provision, which can complete the protection framework for the new plant varieties.

This extension has not been provided by the Implementation Rules yet. However, the perspective of an IP infringement may encourage the agro-food processing industry to require only traceable material, thereby decreasing CPVR infringement.

2.4. The relationship between Community plant variety protection and seed legislation in the EU

Innovation in cereal varieties is conditioned by the EU legislation on the marketing of seeds. The seed legislation has a relevant impact on innovation because it establishes the requirements a variety shall meet in order to be marketed in the EU and, in doing so, it influences the effectiveness of the Community plant variety protection. The Community plant variety protection regime relies on the idea that an intellectual property right over a

[428] Doubts have been raised since 1991, during the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants. See Chapter 2.

new plant variety entitles the breeder to claim for remuneration against the use of their new material: in this sense, the grant of a financial reward is a great incentive to stimulate further innovation. However, in order to obtain this financial reward, the protected material has to be marketed: this is when seed legislation ties its provisions with Community plant variety protection. It is indeed the seed legislation to regulate the marketing of reproductive material in the EU, therefore the requirements set out by the seed legislation impact the Community plant variety protection effectiveness. Consequently, it should be understood what the extent of such an impact is.

With regard to cereal varieties, the impact of the seed legislation on CPVP is threefold: 1. during the innovation process; 2. during the application for Community plant variety rights; 3. on the farm-saved seed practice, 4. on the level of awareness of plant variety rights.

First of all, during the innovation process, the breeding activity is influenced - and somehow burdened - by the VCU requirement. Article 4 of Council Directive 2002/53/EC on the Common Catalogue of varieties of agricultural plant species states that Member States shall ensure that a variety is accepted only if it is distinct, stable and sufficiently uniform (DUS) and if it is of satisfactory value for cultivation and use (VCU).

As showed by the empirical findings, the requirement of satisfactory value for cultivation and use for the marketing of cereal varieties imposes another hurdle to breeders. The breeding of cereal varieties has a peculiar role in the plant breeding landscape: cereals are staple foods, routinely eaten worldwide and throughout the year. The challenge for cereal breeders is enormous: they are required to develop cereal varieties able to feed the growing population of the world taking into account the ongoing climate changes. The new cereal varieties are required to produce high yield, to be resistant and to be suitable for a low-impact and sustainable agriculture.

In this context, VCU adds a further requirement to be met during the breeding activities, in order to permit the marketing of the variety. This element certainly influences cereal breeding. However, the VCU is not defined at the EU level: VCU parameters are established by each EU Member State and the lack of harmonization may lead to distortions in the internal market and favor the breeding companies located in Member States with looser legislation.

Furthermore, the VCU trial that takes place in certain testing sites of each EU Member State, whose environmental conditions surely affect the VCU of the variety. However, the

variety may be marketed throughout the European Union. This is a paradox: the VCU assessment determines the marketability of the variety in the entire EU territory, even though the test is carried out in restricted testing sites. VCU makes the creation of cereal varieties more demanding and it can slow down the breeding activities on cereal varieties. In this way, the VCU requirement set out by the seed legislation conditions innovation in cereal varieties and it impacts the Community plant variety protection: less innovation means fewer new varieties, thereby fewer applications for CPVRs.

The second impact of the seed legislation occurs during the CPVR application with regard to the DUS assessment, required both for CPVP and variety registration. In particular, it concerns the lack of recognition of the *one key, several doors* principle. When the new variety has been registered in the national catalogue and, in case the DUS trial for national listing complies with the CPVO technical protocols, the resulting reports should be taken over by CPVO.

As a matter of fact, the DUS criteria of plant variety protection has been generated from DUS requirement established in seed marketing laws, therefore one might wonder why the DUS assessment of the two procedures has not been harmonized yet. According to the 'one key, several doors principle', breeders should not be required to send the genetic material along with the CPVR application, especially when breeders apply for CPVR as soon as the variety is listed in the national register since genetic drift cannot occur in such a short time. In this way, the taking over of reports for variety registration by CPVO would facilitate and accelerate the granting process of Community plant variety rights: *one key* (the report) would indeed open *several doors* (variety registration and plant variety protection).

The third impact concern the farm-saved seed practice. The seed legislation requires seed producers to comply with specific registration and certification requirements in order to market their material. However, farmers are not obliged to use certified seed, even if the use of farm-saved seed may result in a decrease of quality standards. Therefore, there is an obligation to market quality seeds but there is not a corresponding obligation to use those quality seeds in agriculture. The consequence of this situation is the spread of an uncontrolled FSS practice, which can discourage innovation in cereal varieties based on the motivations mentioned in the previous paragraph.

Lastly, the empirical findings show that the seed legislation also affects the level of awareness of plant variety protection by breeders. Even though the level of awareness about

plant variety protection in the studied context is high, it was possible to report some miscomprehensions about plant variety protection determined by the confusion between about seed marketing laws and plant variety rights. It happens that occasionally the general FSS practice is *sic et simpliciter* equated with CPVRs infringement, and variety registration is supposed to grant of an intellectual property right on the new plant variety, as displayed by the Case n. 8745/2015 (*BASF Italia spa vs Società Agricola Magnani Caterina e Magnani Lorenza)* held in 2015 before the Tribunale di Milano - Sezione specializzata in materia di impresa, in Italy. The extent of this confusion is modest but it is symptomatic of the impact the seed legislation has on Community plant variety protection: if the variety registration is deemed to recognize some sort of IPR on the new plant variety, the breeder will hardly apply for Community plant variety protection.

In light of the foregoing consideration, it is not surprising that in 2013 there has been a proposal to replace the existing seed legislation, constituted by twelve Directives, by one single Regulation in order to update, simplify, and harmonize the current rules. The proposal had the purpose, *inter alia*, to widen the legislation to all types of plant reproductive material and to extend the role of CPVO to plant variety registration in order to simplify the registration process: this represented a first step towards the coordination between seed legislation and Community plant variety protection.

However, the proposal was rejected in 2014 and it is not clear whether a legislative revision in this field will be pursued. A legislative revision could definitely simplify and improve the relevant legal framework on seed marketing, and it could also facilitate the relationship between the seed legislation and Community plant variety protection, thereby promoting innovation in the relevant varieties.

3. Recommendation and concluding statements

Since 1995, the year when the Regulation (EC) 2100/94 entered into force, the Community plant variety protection regime allowed breeders from all over the European Union (then European Community) for the grant of a unitary intellectual property right on new plant varieties, upon a single application. Although the Community plant variety protection was initially thought to wither and die by some legal practitioners, the total number of applications for Community plant variety rights has steadily grown over the years.

The Community plant variety rights are the sole and exclusive form of industrial property rights for plant varieties having uniform effect throughout the European Union territory, and it has the purpose to stimulate the breeding and development of new varieties. The purpose of the current research has been to ascertain the supposed effectiveness of Community plant variety protection in fostering innovation, with regard to varieties of cereal species in consideration of their vital role in food production.

Data have shown that innovation in cereal varieties is very active in the EU and said innovation has a great social and economic weight. Breeding companies are actively engaged in cereal breeding activities and most of them regularly protect their new varieties with CPVRs. With regard to the application for CPVRs of cereal varieties, maize, common wheat, and barley are among the top five most applied agricultural species.

In this context, the Community plant variety protection is deemed to guarantee a return on investment, to stimulate the breeding and development of new varieties, and, ultimately, to foster innovation in cereal varieties. Indeed, great satisfaction has been shown by cereal breeders: overall, the Community plant variety protection regime is greatly appreciated and it is considered robust and balanced, to some extent even necessary to foster innovation in cereal varieties.

In spite of this high level of satisfaction, the legislation on Community plant variety protection may hinder innovation in cereal varieties due to the following reasons: 1. lack of harmonization with the national laws on plant variety protection; 2. weak enforcement possibilities of Community plant variety rights, especially when FSS is concerned; 3. lack of coordination with the EU seed legislation, which also needs a deep harmonization at the EU level.

In light of this, it would be recommendable to consider the adoption of Directive on plant variety rights, as suggested by Van Der Kooij[429] more than a decade ago, in order to harmonize the national laws on plant variety protection and to guarantee the competition among EU breeders on a level playing field. The harmonization could also have the side effect of improving the education and expertise of some Member States on plant variety protection.

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[429] Van Der Kooij P., 2008, *Towards an EC directive on plant breeder's rights?,* in Journal of Intellectual Property Law and Practice, 3, 2.

Furthermore, the enforceability of Community plant variety rights should be improved. With regard to farm-saved seed, access to information by right holders should be simplified, traceability schemes should be promoted, and more effective royalty collection systems should be established. Strong enforcement also depends on effective judicial proceedings: having specialized PVP courts in every Member State or at least a specialized PVP chamber at every IP court is necessary to facilitate the settlement of ongoing disputes in this little-known field of law. In this sense, a debate could be open about the establishment of a supranational specialized court on CPVRs, along the same lines as the soon-to-be-established Unified Patent Court.

Lastly, attention should be given to the seed legislation. As proposed by Chapman and Sherman[430], a better place for agriculture should be found in intellectual property law, which should be expanded in order to include in its remit other fields of law that are not conventionally considered as being part of IP law, such as seed certification laws, registration systems and food laws.

A common pitfall is to consider IP on plant varieties as uninvolved with the seed legislation. Instead, Community plant variety protection should recognize the central role that the seed legislation plays in variety innovation, the categories they share in common and their mutual historical roots, i.e. the German draft of the Seeds and Seedlings Law of 1930.

Therefore, the linkage between the Community plant variety protection and seed legislation should be taken into account by the EU legislator in order to simplify the legal framework and to improve the relationship between these fields of laws.

In conclusion, even though a legislative review of Community plant variety protection could have the effect of opening the Pandora's box, in a fast-changing world the law requires a constant reconsideration in order to evaluate whether it is still able to meet the evolving challenges of the society and, ultimately, to remain useful. Therefore, a legislative review on the abovementioned three aspects is recommendable.

The research has come to an end, thereby is time to answer in plain terms the question leading the study: nowadays, is Community plant variety protection fostering innovation in

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[430] Chapman S., Sherman B., 2018, *Finding a place for agriculture in intellectual property law,* in IIC, 49, 7.

cereal varieties in the European Union industry? In view of the legal outcomes and empirical findings, the answer is a ‘qualified yes’: this means that the Community plant variety protection has a significant role in fostering innovation in cereal varieties, however this role should be strengthened by the EU legislator in accordance with the aforesaid recommendations.

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