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Decoding Seed Quality: A Comparative Analysis of Seed Marketing Law in the EU and the United States

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Abstract: The European Union's (EU) approach to safeguarding seed quality and ensuring agricultural productivity includes a range of regulatory measures related to seed marketing, including the restriction of market access to seed varieties that are properly certified. In order for varieties to be properly certified, they have to be registered in a Plant Variety Catalogue. EU seed laws, and their Member State implementation, have traditionally favoured uniform crop production of commercialised breeds over conservation varieties, which has been a contributing factor to crop genetic erosion. The United States' (U.S.) approach to seed marketing regulation is often presented as an alternative model to the EU's approach. In the United States, any seed can be indistinctly marketed if properly labelled. In this regulatory framework, certification and registration of seed is voluntary. In light of the continued issues regarding crop genetic erosion and the recent developments in EU seed law reform, this article examines the key elements of both regimes and considers their different approaches to market access for conservation varieties. The most important differences relate to in truth-in-labelling (U.S.) and ex ante quality control mechanisms (EU). These differences highlight that EU and U.S. seed laws must be placed in their respective broader regulatory context and that their relative comparability hinges on policy aims related to seed quality. This raises the broader question as to what the key policy aims of seed laws are and whether these oft-compared regimes are in fact analogous in terms of goals and structure.

Keywords: seed law; crop genetic erosion; conservation varieties; plant variety registration; certification; truth-in-labelling; seed quality; EU law; U.S. law; Federal Seed Act



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1. Introduction

Crop genetic diversity in the agricultural sector is a fundamental component in a resilient food production system, not only as it allows the system to recover from agricultural challenges such as environmental hazards, pests, and diseases, but the crops seeds are also a carrier for genetic information—an indispensable resource for breeders and farmers in the development of new crop varieties. “Genetic erosion” has been defined as “the loss of individual genes and the loss of particular combinations of genes (i.e., of gene complexes)” [1] (p. 115). When used in a narrow sense, genetic erosion refers to the loss of genes or alleles, while the broader use of the term refers to the loss of entire varieties [1]. In this article, it refers in particular to the loss of conservation varieties, also referred to as ‘traditional’ or ‘locally adapted varieties’, ‘farmers varieties’, or, in legal terms, ‘landraces’. In this article, we use the term ‘conservation variety’. Gradual diminution of such genetic information, as stored in conservation varieties, reduces the adaptive potential of crops to deal with external hazards, which may lead to widespread crop losses, threatening global food production [2,3].

Agricultural genetic diversity has come under pressure from the rise of modern farming systems, which favour uniform crop production and specialization, as well as other environmental factors [2,4–8] (p. 29), [9]. The Food and Agriculture Organization

(FAO) estimated that, between 1900 and 2000, nearly 75 percent of global agricultural crop diversity was lost and up to 22 percent of wild relatives of peanut, potatoes, and beans will vanish by 2055 owing to climate change [10]. Another contributing factor to genetic erosion is regulatory. Specifically, regulation of the seed market—legislation related to the sale, trade, and exchange of seed—has been critiqued as tacitly restricting market access for genetically diverse seeds [2,7,9,11].

This critique extends to European Union (EU) seed legislation, which not only regulates the expanding EU seed market, but, by extension, has also shaped EU agricultural practices, which have negatively impacted agricultural genetic diversity [6,9]. This negative relationship is based on the fact that EU seed laws are shaped around and built on the then emerging seed-breeding sector, which in turn means a prioritization of conventional agriculture and commercially bred seed varieties over conservation varieties. While these critiques are valid, agrobiodiversity loss is a multi-faceted and wicked problem. Other drivers of agrobiodiversity loss include, though are not limited to, climate change, demographic changes, urbanization, change in agricultural practices, and land use change. From a policy perspective, the use and regulation of conservation varieties is thus one of various important factors in aggravating, or limiting, further genetic erosion that must be placed in a broader regulatory context that considers all the factors mentioned here [10].

The EU has been at the centre of global biodiversity and agricultural policy [1,12,13]. The United Nations (UN) Convention on Biodiversity (CBD) of 1992 and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of 2001 have been especially influential in redesigning national and international legislation to better accommodate agrobiodiversity needs [12,13]. Both emphasise the sustainable use and conservation of all plant genetic resources (not merely domesticated or agricultural varieties) [1]. The UN Sustainable Development Goals (SDGs) also recognise the importance of genetic diversity as a means to halt biodiversity loss (SDG 15) and achieve zero hunger (SDG 2) [14–16]. Moreover, the last IPCC Report on Climate Change and Land emphasised the value of the use of local genetic diversity as a means to build resilience against extreme climate events [17] (p. 468). The EU's involvement in these international instruments has shaped its seed marketing rules, driving the EU to amend its legislation by introducing certain derogations in an attempt to limit the potential negative impact of its marketing rules on agrobiodiversity [18–20]. Despite the growing awareness of the importance of agrobiodiversity and related policy changes, the EU approach remains insufficient to comprehensively address its indirect contributions to genetic erosion. Louwaars & Burghaud (2016), Bocci (2009), Winge (2015), and Prip & Fauchald (2013), among others, have argued that the mandatory requirement to register 'novel varieties' for commercialisation on the market (the core characteristic of the EU seed marketing system) creates barriers and limitations for the access to the market for conservation varieties [2,6,9,11,21,22]. In this context, 'novel varieties' refer to any variety new to the commercial market, though not necessarily new to the agricultural landscape. This term includes commercially bred varieties as well as conservation varieties, as they would both be introduced to the commercial market. 'Novel' is a slight misnomer for conservation varieties, as per definition, they have existed traditionally in order for them to adapt to the local environment.

Within this literature, the EU's regulatory system is routinely compared to that of the United States (U.S.), in which registration and certification of seed is voluntary [6,10,20–25]. Some publications have proposed the possibility of incorporating elements of the U.S. seed marketing system into the EU regulatory framework [21,22].

Legal scholarship on EU seed law and its relationship with crop genetic erosion is comprehensive. In contrast, legal writing on the U.S. model tends to limit its analysis to the role of registration and certification, largely ignoring the broader implications of U.S. regulatory choices on, for instance, seed quality (with the notable exception of Blaustein, 2016 [26]) [6,10,20–25]. This article fills that gap by analysing and assessing the statutes and regulations that govern seed marketing in the U.S. and explicating key regulatory differences between the EU and U.S. regimes. By analysing the U.S. seed marketing regime,

we aim both to contribute to the ongoing debate on how to reform seed marketing law in relation to conservation varieties and to investigate whether or not it is in fact desirable to adopt elements of the U.S. regime, as suggested in the literature [6,10,20–25,27]. This longstanding debate is made particularly timely by the EU's renewed focus on "facilitat[ing] the registration of seed varieties, including for organic farming, and to ensure easier market access for traditional and locally-adapted varieties" in its EU Biodiversity Strategy for 2030 and the EU Farm to Fork Strategy (see p. 8 of both Strategies).

The remainder of this article is structured as follows: Sections 2 and 3 discuss the seed marketing regimes in the EU and the United States, respectively. Section 4 compares these approaches and informs the conclusions presented in Section 5.

Before moving on to this substantive analysis, a brief note on terminology. As legal terminology differs between the EU and the United States, this article adopts the following definitions:

- 'Seed' refers to any type of plant reproductive material, including but not limited to tubers, seeds, roots, cuttings, or rhizomes [23];
- 'Seed law' and 'seed marketing law' refer to non-IPR (intellectual property rights, IPR)-related legislation governing the placing on the market of agricultural and vegetable seeds;
- 'Conservation varieties' means a 'set of populations or clones of a plant species that are naturally adapted to the environmental conditions of their region' (See Art 2(c) of derogation Directive 2008/62/EC providing for certain derogations for the acceptance of agricultural landraces and varieties that are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties);
- 'Breeder' refers to the person(s) applying for registration of a plant variety;
- 'Operator' refers to the person(s) responsible for compliance with seed marketing legal requirements;
- 'Law', 'legislation', and 'rules' are used interchangeably to refer to legal provisions enacted by legislative and administrative branches in the EU and the United States. These include EU Directives, Regulations, and Decisions; EU Member States legislation; and U.S. Statutes and implementing regulations.

2. EU Seed Marketing Legislation

After WWII, the rise of industrialised agriculture in the EU necessitated the adoption of seed marketing legislation. During this period, the responsibility of seed breeding shifted from farmers to specialised seed breeders [21,22]. This resulted at the time in the rapid expansion of the seed breeding market fueled by the private sector. In an attempt to regulate this rapidly emerging seed breeding market—including the sale, trade, and exchange of seed—early national regulation in European countries focused on ensuring the quality of the marketed seed, e.g., germination rate and being free from disease, and ensuring the veracity of the variety. The aim of this regulation—apart from creating and maintaining a functioning market for seed—was to improve market transparency and protect the farmers purchasing the seed [6] (p. 191), [21].

Seed law in Europe has evolved significantly over the last century, heavily influenced by the process of EU integration, as well as by market and sector trends. In 1966, the harmonization of EU seed legislation started with the adoption of four directives related to the marketing of seed and other propagating material: seed potato, beet seed, cereal seed, and fodder plant seed specifically. Five new directives were introduced between 1967 and 1970, including the Common Catalogue for Agricultural plant species, and three more were issued in 1991 and 1992. Between 2008 and 2010, three derogations were issued with special interest preservation and registration of conservation varieties threatened by genetic erosion [21,28].

Over the years, the Directives have been subject to a myriad of amendments. This has led to a complex and fragmented patchwork, which incorporates technological standards

dating from the 1960s to the early 2000s [6]. This complicates legal interpretation and divergence in national transposition of EU seed law (see Proposal for Plant Reproductive Material Law, COM(2013)262, p. 2) [22]. At the time of writing, EU seed legislation is spread out over 11 ‘vertical’ directives, each applicable to specific genera (seed families), and one ‘horizontal’ directive (the Common Catalogue) that applies across genera. The common goal of these directives is to ensure seed quality and increased agricultural productivity (see Rec 4,5 of Directive 2002/54/EC on the marketing of beet seed; Rec 5 of Directive 2008/72/EC on the marketing of vegetable propagating and planting material, other than seed).

2.1. Seed to Market

Seed lot certification is the focal point of EU seed marketing law. The certification requirement aims to ensure, among other things, varietal purity, germination capacity, and freedom from diseases, and can thus be regarded as an *ex ante* quality control mechanism. All 11 vertical directives refer to some type of certification requirement. A typical example reads “Member States shall provide that beet seed may not be placed on the market unless it has been officially certified as ‘basic seed’ or ‘certified seed’”.

Within the 11 vertical directives, several seed categories are introduced to indicate the intent of the commercialisation of the seed. As an example, ‘basic seed’ includes, among other characteristics, “seed which has been produced under the responsibility of the breeder according to well-defined practices for the maintenance of the variety” (see Art 2(1)(c)(i) of Directive 2002/54/EC on the marketing of beet seed, p. 2) and ‘certified seed’ means “seed which is of direct descent of basic seed [and] which is intended for the production of [beet]” (see Art 2(1)(d)(i)(ii) Directive 2002/54/EC on the marketing of beet seed, p. 3). Two further categories, used in only a section of the other directives, include ‘commercial’ and ‘standard’ seed [21] (pp. 8–10).

The directives further contain rules on packaging, sealing, marking, labelling, and requirement of accreditation and registration of the supplier [22] (p. 368).

The main prerequisite for certification is acceptance of the plant variety in a National Catalogue and, for certain species also in the EU Common Catalogue.

The Common Catalogue is in essence a list of varieties of agricultural plant species, compiled solely on the basis of National Catalogues (see Art 1(2) of Directive 2002/53/EC on the Common Catalogue for Agricultural Plant Species, hereinafter the ‘Common Catalogue’). The scope of the Common Catalogue is limited to certain plant varieties, as indicated in recitals 2 to 6 of the Common Catalogue. These recitals state that the goal of the catalogue is to compile data regarding the registration carried out for 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), on the basis of the information available in national variety catalogues. Hence, this Common Catalogue does not cover seed or propagating materials from ornamental plants (1998/56/EC), forest plants (1999/105/EC), fruit plants (2008/90/EC), vegetable species (2002/55/EC and 2008/72/EC), and vine propagating material (68/193/EEC). These should be registered in either national catalogues or in their respective registrars, e.g., vegetable seeds should be registered in the Common Catalogue of varieties of vegetable species (see Art 2 of Directive 2002/55/EC) [29]. Interestingly, only Directive 1998/56/EC on the marketing of ornamental plants does not specify or make mandatory the listing of such variety in either national or Common Catalogue.

The process of accepting a plant variety in one of the catalogues is commonly referred to as the ‘registration’ of the variety (the legal term is ‘acceptance of varieties’) [6,9,21]. An example hereof is Art 3(1) of Directive 2002/55/EC on the marketing of vegetable seed: “Member States shall provide that vegetable seed may not be certified, verified as standard seed and marketed unless the variety is officially accepted in one or more Member States.” See, also, Rec 5, Art 3(2) and Art 6 of that same directive. EU harmonisation requires that, to qualify for variety registration, the variety must adhere to the criteria of ‘distinctiveness’,

‘uniformity’, and ‘stability’ (DUS-norms), as specified in, among other directives, Art 5 of the Common Catalogue. Additional testing procedures are required for agricultural plant seeds to prove the variety brings ‘progress’ in quality and/or beneficial agronomic characteristics for the agricultural sector, which is assessed through ‘value for cultivation or use’ tests or VCU-testing. This includes beet, fodder, potato, oil, and fiber plants varieties and, in Art 4(1) of Directive 2002/55/EC on the marketing of vegetable seed, industrial chicory is also specified.

The onus is on the breeder to apply and pay for the registration of the novel plant variety in the relevant catalogue—a procedure carried out by an officially accredited and independent authority at the Member State level, based on the procedure enshrined in that Member States’ transposition of EU harmonised rules. Only once the novel variety is registered, its seed lots can be examined and certified based on its registration status.

An example of what such a process would look like can be found in the Dutch implementation of EU seed law through the Dutch Zaaizaad- en plantgoedwet 2005. The law entrusts the Dutch Raad voor Plantenrassen (Board of Plant Varieties), a governmental agency, with the responsibility of maintaining the Dutch National Catalogue, called the Dutch Plant Variety Register (Nederlands Rassenregister) [30]. The board authorises the acceptance of novel varieties and publishes an annually updated plant variety list, as required by EU Law. The DUS- and VCU-tests necessary for registration are carried out by accredited authorities [31]. If these tests have been successful, the novel variety is accepted in the National Catalogue (Dutch Plant Variety Registrar). Once a novel variety is registered, the certification inspectors of the Dutch certification authority, or Nederlands Algemene Keuringsdienst (NAK), verify the quality and varietal purity of the seed during the growing season for certification [32].

2.2. EU Seed Law on Conservation Varieties

The regulatory scope of the EU seed laws extends beyond commercially bred varieties to, for instance, conservation varieties. Conservation varieties are generally genetically diverse and low yielding. They are also adapted to local ecosystems and climate, making them generally more resilient to external hazards, pests, and diseases. Modernized agricultural practices are heavily dominated by genetically uniform and high-yielding varieties. In the development of modernised agriculture, the genetically diverse conservation varieties are continuously replaced by high-yielding modern varieties, resulting in a loss of that genetic information.

EU seed laws have been historically critiqued for their inadaptability and lack of consideration of alternative agricultural systems (e.g., organic agriculture or agroecological practices) or conservation varieties, skewing the regulatory system in favour of genetically uniform and high-yielding commercial varieties [9,22,24].

The substitution and favouring of these commercially uniform and pure-bred, or pedigree, varieties is legally ingrained in the DUS- and VCU-testing criteria, which have been created with a view of supporting conventional agricultural practices. The DUS-testing procedures are constructed on Good Agricultural Practices, and based on standardized testing protocols as identified by the Community of Plant Variety Office (CPVO) [33] (p. 229). Its norms are enshrined in Art 5 of the Common Catalogue as follows: ‘Distinctiveness’ within the variety is considered when its essential characteristics are clearly distinguishable from the other registered varieties in the Common Catalogues or the National Catalogues. The ‘Uniformity’ of a variety is tested through the examination of a satisfactory number of plants and assessed whether these plants are similar or identical in characteristic and genetics [1] (p. 33). Lastly, the criterium of ‘Stability’ requires the variety, after several reproduction cycles, to maintain its original distinctive characteristics. Art 5(4) of the Common Catalogue defines the satisfactory nature of VCU in stating that the variety should express “a clear improvement” to other known varieties in the catalogue in either cultivation or the products derived from said variety.

Another factor that has led to the favouring of conventional varieties is the EU's Common Agricultural Policy, which also strongly favours the use of commercially bred seed varieties, as these conform to conventional agricultural practices [34]. The criterium of 'uniformity' within DUS-norms is particularly regarded as detrimental for genetic diversity within seeds [6] (p. 206). The testing procedures do not easily account for any measure of genetic diversity within the seeds, or when the variety is in fact not pure bred, but purposefully a mixed variety to benefit its resilience [10,20]. The DUS- and VCU-testing procedures themselves play a key role in that characteristics such as 'high-yield' are disproportionately valued in seed varieties, rather than favouring lower-yielding though locally adapted varieties. After pressure and lobbying from the organic sector in the Netherlands, the Dutch Government has now developed a VCU-testing regime to specifically consider growing without chemical fertilizers and pesticides, though in this instance, only for organic spring wheat [6,35,36] (p. 134). There is current research on how to expand VCU-testing to other types of wheat varieties in the Netherlands [37].

Moreover, VCU- and DUS-testing procedures are often conducted over several locations (so as to ensure a minimal effect on the seed by varying environmental conditions) and over two or three seasons [1] (p. 33). These testing conditions are particularly challenging for conservation varieties as they are regionally adapted to specific environmental conditions. Additionally, to bridge two to three years before placing the (low yielding) conservation variety on the market would disincentivize applicants.

To address these critiques and to facilitate the placing on the market of conservation varieties, the EU adopted several Directives between 2008 and 2010, enacting targeted derogations of harmonised rules to support the marketing of conservation varieties, specifically for agricultural plants seed, vegetable seeds, and fodder plant mixtures (see derogation Directive 2008/62/EC; derogation Directive 2009/145/EC; derogation Directive 2010/60/EC).

These Directives empower Member States to design a registration system for conservation varieties, with increased flexibility for both substantive as well as procedural requirements. The EU argues that such a registration system would facilitate the marketing of such varieties and allow for the "in situ conservation and the sustainable use of plant genetic resources" (see Rec 2 of derogation Directive 2008/62/EC). In one of the directives, the recitals emphasise the importance of crop genetic diversity and the essential role conservation varieties play in this (see derogation Directive 2008/62/EC).

The Directives also allow for derogations, which would enable Member States to adopt provisions regarding the evaluation of the distinctness, stability, and uniformity of conservation varieties; in brief, to deviate from the DUS norms under strict conditions. Moreover, under the derogations, Member States must continue to register conservation varieties in a Plant Variety Catalogue. Moreover, complete abolition of the DUS criteria is not allowed under EU rule. In particular, the derogation Directives indicate that, for the distinctness and stability criteria, domestic rules still have to adhere to minimal character traits as specified by CPVO and/or UPOV, and the uniformity criteria still need to be tested on the basis of off-types, with the application a population standard of 10% and an acceptance probability of at least 90% (see, i.e., Art 4(2) of derogation Directive 2008/62/EC).

The derogations also contain restrictions to the marketing of conservation varieties, hampering their commercialisation and further development [21]. In particular, the derogations instruct Member States to limit the marketing of conservation varieties to their region of origin and imposed quantitative restrictions on the package size and weight.

EU Plant Variety Database currently holds 374 registered agricultural and 165 registered vegetable conservation varieties across all 27 member states. This is 1.23 percent (out of 30,511 registered agricultural varieties) and 0.78 percent (out of 21,237 registered vegetable varieties), respectively, of all registered varieties in the EU. By means of comparison, in the Netherlands, five varieties, out of the 1960 (0.25 percent) registered agricultural seed varieties in the Netherlands, are registered as conservation varieties, and only one out

of 8918 (0.01 percent) registered vegetable varieties have been accepted as a conservation variety [38].

The picture that emerges is one where exceedingly little room is provided for the registration of conservation varieties, regardless of the possibilities provided by national derogations. In light of this ongoing issue, as well as the increased fragmentation of the regulatory framework, EU seed law was reviewed between 2007 and 2008. This resulted in an Action Plan in 2009, which in turn led to a proposal for a new regulation on the production and making available on the market of plant reproductive material (see Proposal for plant reproductive material law) [22,39]. One of the many objectives of the proposal, as stated in the preamble, was the strengthening of in situ conservation for improved biodiversity in seed breeding. Nevertheless, the proposal maintained its controversial strict variety testing regime. The proposal also aimed to consolidate and harmonize the 12 existing directives and the three derogations into a single regulation directly applicable in all Member States. Additionally, the proposal extended the scope of the regulation to all 'plant reproductive materials', and expanded the current role of the Community Plant Variety Office (CPVO), from granting intellectual property rights over plant varieties to being responsible for all the registration of all plant varieties for the marketing in the EU. Hereby replacing the responsibilities of authorised national authorities and bearing the responsibility for the management of the Union variety register and the registration of plant varieties via direct application procedure to the CPVO. Such a move would not only remove redundant or overlapping legal acts and align the law with technical development and innovation in the seed breeding sector, but also move the EU further forward in the harmonisation of seed marketing requirements.

In 2014, the European Parliament rejected draft regulation in a 650 to 15 vote. "Many Members emphasised that EU legislation on plant reproductive material needs to facilitate and encourage the maintenance of biodiversity in agriculture and horticulture" [40]. The harshest critiques originated from the representatives of the environmental, food sovereignty and grass-roots seed movement, and small-scale growers, which argued that the regime proposed in the draft regulation would have continued to criminalize informal seed networks, and remained overly bureaucratic and costly for the breeder [41–43].

The European Parliament called for the submission of a new proposal by 2015 [40]. Again, in 2019, the European Parliament requested a study on the Union's options to update the existing legislation (see Decision 2019/1905 requesting the Commission to submit a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material, and a proposal, if appropriate in view of the outcomes of the study). In response to this request, the Commission published the "Commission Staff Working Document—Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material" (SWD(2021) 90 final) on 29 April 2021. The study presents possible options for revising the legal framework, including the improvement of procedures and the introduction of amendments to further improve the commercialisation of conservation varieties and access to genetic resources.

The study finds that its critique and concerns of the previous evaluations remain relevant. It emphasises that the rigidity of the Directives hampers synergistic relationships with other EU policies, notably the Farm to Fork strategy as well as the Biodiversity Strategy of 2030, which both advocate for the facilitation of the registration systems for the benefit of conservation varieties. Relatedly, though technically beyond the scope of this article, which focuses on 'EU seed law' strictu sensu, Regulation 2018/848 on organic production and labeling is worth mentioning. Article 13 of this regulation allows for the adoption of special provisions for the marketing of plant reproductive material of organic heterogenous material. The use of heterogeonus materials in plant breeding has similar characteristics to conservation varieties; they are by definition genetically diverse and thus do not adhere to DUS criteria. The regulation stipulates that such plant reproductive materials do not have to meet registration and certification requirements. Even though this is specific to organic

materials, rather than conservation varieties, it is interesting to contrast and compare the statutes of this derogation for organic heterogeneous materials. Other articles such as Chable et al., 2018; Renaud et al., 2016; and Lammerts van Bueren, 2002 look specifically at seed breeding within organic crop production, but were published before the introduction of this new regulation [20,24,36].

Despite renewed efforts to propose alternatives, the existing regulatory framework in the EU continues to favour conventional breeds over conservation varieties, thereby contributing to an important factor of agrobiodiversity loss through genetic erosion. In light of the ongoing EU seed reform, this article will now consider the U.S. regulatory system related to seed marketing in order to assess the desirability of the adoption of some of its features in the revision of EU seed law.

3. U.S. Seed Marketing Legislation

The Federal Seed Act (FSA), enacted in August 1939, is the cornerstone of U.S. seed law (see federal Seed Act 7 U.S.C. 1551–161). The United States Department of Agriculture (USDA) further implemented its provisions through the Federal Seed Act Regulations. The FSA established the legal requirements for placing agricultural and vegetable seeds on the market for ‘interstate commerce’, i.e., seeds traded between the states of the United States, in keeping with the so-called ‘Commerce Clause’ contained within the U.S. Constitution. The FSA applies also to the marketing of seeds imported into the United States, but is beyond the scope of this article. Within the borders of the States, State laws govern the seed market (see U.S. Const. Art 1, §8, cl. 13 and cl. 18). This means that U.S. seed law can be found in the FSA, the Federal Seed Act Regulations, and 50 state-based statutes.

To facilitate seed operations across the United States, the Association of American Seed Control Officials regularly issues and updates its Recommended Uniform State Seed Law (RUSSEL). This document presents guidelines after which the States can model their own statutes and regulations, while being able to incorporate or alter provisions to reflect the unique situations and interests of each state [44]. Notwithstanding these divergences, all U.S. seed marketing laws are ‘truth-in-labelling’ laws, designed to ensure market transparency by requiring seeds to be sold bearing specific information, establishing rules to prevent ‘misrepresentation’—in the wording of the FSA—of seeds and creating a legal basis for the public enforcement of those requirements. As this approach is shared between all state seed regimes and the federal regime, the remainder of this section will focus on this common provision.

Historically, most of the seed industry in the United States has vehemently opposed the imposition of any requirement directly or indirectly, implying the adoption of mandatory varietal quality standards, such as the function of certification and registration in the EU regime [45]. As a result, the marketability of seed is not constricted by ex-ante control mechanisms carried out by public authorities. The rationale behind U.S. truth-in-labelling legislation is that consumers (in this case, farmers purchasing seeds) should have the freedom to choose which varieties are best suited for their operations, shifting the responsibility for (informed) quality control from the government to the consumer [20] (p. 142). The USDA supports this approach as it enables buyers to make an informed choice [46].

The basic condition for market access under U.S. seed law is the provision of a label containing a list of mandatory information—see Section 201(a) of the FSA. There is a notable exception for seed exchange between farmers, in which case labelling is only required if advertised—which is detailed in Section 3.1 below [44] (pp. 395–398). Apart from labelling, there are two additional requirements. First, the varietal purity and germination capacity of seeds must be tested no more than five months before placing on the market to determine the percentage of germination (see Section 201(c) of the FSA). Second, it is mandatory to store records of origin, treatment, germination, and purity of each seed lot for a period of three years from the moment the seed variety is placed on the market (see Section 202 SA and 7 CFR 201.7). The main purpose of these supplementary obligations is to facilitate

the enforcement of marketing rules, which require labels to include information regarding germination capacity and seed purity.

3.1. Market Access Requirements: A Labelling Game

U.S. seed law aims to ensure “honestly represented but minimally regulated new varieties” [26]. To ensure such ‘honest’ representation, truth-in-labelling legislation identifies a list of mandatory labelling particulars that must be present on the label of seeds. Mandatory requirements for agricultural seed in the FSA include the species and variety (U.S. law generally uses the word ‘kind’ to refer to ‘species’; for the sake of consistency in the article, we use the word ‘species’), lot and seller identification data, origin of the seed (or a statement declaring the origin is unknown), germination rates, and date of testing of the germination rate. The labelling of vegetable seed must adhere to similar requirements, but is additionally obligated to state the name of the variety on the label (see Section 201(b) FSA).

3.1.1. Seed Naming

The name of the species and the plant variety is a key element of seed labelling. That being said, it must be noted that some types of agricultural seeds (such as alfalfa, barley, or bean) can also be labelled with the words “Variety Not Stated” (see 7 CFR 201.10(a)). Regarding the naming of species of seeds, FSA regulations provide a list of kinds of agricultural and vegetable seeds that must be used in labelling (i.e., of a ‘kind’ is ‘artichoke’, ‘asparagus’, or ‘beet’). Names that have become synonymous through broad general usage may be used instead, provided that the particular name only applies to a singular plant species and is not misleading (see 7 CFR 201.34(b)). No such list with specificities exists regarding plant variety names. Ultimately, the proper naming of a variety is the breeder’s responsibility. As a general rule, seeds are to be marketed using the identical name when first introduced into the channels of commerce of the United States for sale to the public.

For ‘new’ varieties, the naming is at the discretion of the breeder (see Section 201.34(d)(2) of the FSA). To ensure the ‘novelty’ of the plant variety, it would be necessary to assess whether identical plant varieties are already being marketed in the United States, and the name used of said variety. This is of particular importance when intending to market a variety from a third country for the first time on the U.S. market. Such a check can be challenging, as there is no public record listing the plant varieties marketed in the United States. The sole public initiative that may aid in ascertaining the naming of plant varieties is the Variety Name List, as maintained by the USDA’s Agricultural Marketing Service, divided into two parts: one for agricultural seed and one for vegetable seed. The Variety Name List records the used or proposed varietal names “to prevent violations of the Federal Seed Act by providing lists of names that have already been used by plant breeders and others who are naming varieties” [46].

The utility of the list is limited for three reasons. First, the content of the list is merely a record of names, which lacks any other associated information. The list is thus inadequate to assess character traits pertaining to a novel or existing variety. Second, the list is incomplete, as only the names of varieties voluntarily submitted by breeders are included. Breeders often do not use the Variety Name List, and as a result, numerous varieties are not entered into the database [26]. Third, even if the USDA also carries out research activities to identify additional variety names to enlarge its database, the sources used to do so (including variety release notices, official journals, private seed catalogues, and seed trade publications, among others) are not suited to ensure accuracy and may result in names that have never been used to effectively market seed being included in the list.

Oftentimes, breeders decide to voluntarily register varieties through a scientific society to facilitate name labelling. Such registration consists of submitting a scientific article to publicise a new plant variety in journals such as the *Journal HortScience* (from the American Society for Horticultural Science) or the *Journal of Plant Registrations* (from

the Crop Science Society of America) [26] (p. 333). These ‘registration articles’ enable breeders to register commercially bred plant varieties “provided that the new variant has demonstrated uniqueness and utility” [47]. It should be emphasised that this requirement is not the same as adhering to the DUS criteria, though the peer reviewers will apply scientific methods to assess the “newness and strengths of the new variety” [26] (p. 335). Registration articles require the deposit of plant genetic material into the USDA-ARS National Plant Germplasm System prior to publication.

3.1.2. Quality Labelling

The FSA requires labels to show the percentage of germination for each species and variety of seed comprising more than 5 percent of the content of the container, and of those seed varieties identified individually on the label (see 7 CFR 201.29(a)). For vegetable seeds, percentages on germination capacity are only mandatory if the vegetable seeds are marketed in containers of more than one pound and, for seed marketed in containers of one pound or less, if the “variety which germinates less than the standard” (see 7 CFR 201.29). In the latter case, the label must include the words ‘Below Standard’ clearly shown in a conspicuous place on the label.

This means that U.S. regulation allows for the marketing of sub-standard seeds. While the FSA Regulations identify ‘minimum germination standards for vegetable seeds’, these are not legally binding (see 7 CFR 201.31). Rather, these standards are an acknowledgement of what constitutes ‘reasonable standards of germination’ to ‘best protect crop production for each kind of vegetable seed’ as ‘investigated, determined, established, and promulgated from time to time’ by public authorities (see Section 403.c FSA). The law requires operators to inform farmers that the seed variety does not meet reasonable quality standards, but they can still offer the variety for sale. Therefore, this ‘below standard’ clause illustrates that, in truth-to-labelling systems, the intervention of the government in the market favours ensuring transparency rather than quality. The assumption of a market populated by fully informed actors supports the further assumption of a market able to regulate itself in terms of quality; as there will be little to no demand for low quality seed, operators will be discouraged from bringing them to market.

3.2. Seed Lot Certification in U.S. Law

As described in Section 2.1, certification of seed lots is the main market requirement of EU seed law, whereas in the United States, seed lot certification is voluntary. There is only one exception to that rule: as a general rule, those seeds coming from plant varieties that have been granted protection by U.S. IPR law (in particular, by the Plant Variety Protection Act) cannot be marketed unless certified by an official seed certifying agency. This requirement applies to plant varieties “for which a certificate of plant variety protection under the Plant Variety Protection Act specifies sale only as a class of certified seed” (see Section 501 FSA). Despite its voluntary nature, the process of certification is regulated at both the Federal and State level, and requires seed ‘certifying agencies’ to meet specified qualification standards and comply with specific procedures to get seed lots certified, such as requiring certifying agencies to obtain specific information from certification applicants [48]. Certification regulations also define the eligibility requirements for certification of varieties, and identify the classes of certified seed. Some States additionally include mandatory minimum germination standards, moving away from the federal rule.

The premise of certification, at both Federal and State level, is that certification revolves around a specific plant variety. At this definition of plant variety, Federal and State level legislation often differ. On the one hand, the Federal Seed Act defines a plant variety as “a subdivision of a kind which is characterized by growth, plant, fruit, seed or other characters by which it can be differentiated from other sorts of the same kind”. At the same time, many State level rules include definitions that (abridged with the definition of ‘variety’ generally used in IPR law at the international and Federal level) explicitly refer to the fact that a variety is a subdivision of a kind that is clearly distinct, uniform, and stable, and

instruct certifying agencies to use the DUS criteria (see, among others, West Virginia Code R. § 61-39-5, Definitions of terms Used for Purposes of Certification Programs, Register Vol. XXXVIII, No. 24, 17 June 2021). Thus, voluntary certification of seed lots still results in the application of the DUS criteria in the United States, identical to the mandatory marketing requirement in the EU. However, as seed certification is voluntary, seed varieties that do not comply with the DUS and VCU criteria can still be legally marketed in the United States. In theory, this could benefit the trade of conservation varieties.

Whether or not DUS criteria are explicitly mentioned, all U.S. regulations require a form of certification assessing that seeds are “produced of a cultivar or named variety under a limited generation system which ensures genetic purity, identity, and a given minimum level of quality” [49] (p. 1). DUS criteria are thus considered at this voluntary certification level, potentially resulting in at least some conservation varieties not being able to be certified because of their inability to meet the required standards.

The U.S. regulatory system—centered on voluntary registration and certification in combination with truth-in-labelling—allows conservation varieties to have relatively unrestricted market access. This U.S. approach is not necessarily motivated by the protection of agrobiodiversity, but rather by the lack of distinction made between the conservation and commercially bred varieties in the FSA. The next section will compare this, and other components of the regulatory system, to the EU’s approach.

4. Comparative Analysis and Discussion

The previous sections of this article have analysed the key elements of the EU and U.S. seed marketing rules, in order to illustrate how these diverge with respect to market restrictions. In this section, the article will contrast and compare these differences in turn.

First, EU seed law regulates the sale, exchange, and trade of seeds in all 27 Member States, including import and export to third countries, as well as seeds traded between Member States. Despite divergence in transposition of these directives in national legislation, they set a common baseline for marketing rules. The FSA, on the other hand, only covers interstate commerce and imports, with transactions within the borders of States being regulated by State law. This results in a wide range of rules applying in different state markets depending on the purpose of the sale of the seed lot.

Second, the material scope of EU seed law covers agricultural plant species (e.g., potatoes, cereals, fodder, and oil crops), vegetables, and fruit, as well as reproductive materials beyond the food system, such as ornamental, forest, and fiber plant species. In the United States, the scope of seed laws is strictly limited to agricultural and vegetable species.

Third, in the EU, seeds may only access the market if derived from a certified seed lot. For certification, seeds must originate from a seed variety listed in a catalogue of official varieties (frequently referred to as “registration”). A variety may be registered owing to (i) its specific distinctiveness, uniformity, and stability traits; and, for some species, (ii) a satisfactory ‘value for cultivation and use’ (see Art 4(1) of the Common Catalogue Directive). EU rules focus on ensuring that marketed seeds adhere to a certain level of quality, such as a mandatory germination capacity and freedom of diseases. In the United States, both certification and registration is voluntary, which means that Federal and State rules make no such distinction. The sale of seed is not limited to those certified or registered nor to those able to meet DUS criteria; not even to seeds that meet a certain standard of quality. The U.S. voluntary certification rules are, however, regulated by the government and require genetic purity and identity, as well as a minimum level of quality. In this, DUS-testing acts as an *ex ante* quality control mechanism to assess the quality of the seed, similar to the EU.

Fourth, the aforementioned difference in registration and certification has great implications for the marketing of conservation varieties. In the EU, for conservation varieties, regarding the derogation Directives, Member States may implement a certain level of flexibility in their evaluation process, though registration of these varieties remains mandatory. In the United States, as the sale of seed is not limited to these certified or registered varieties,

conservation varieties have unrestricted access to the market as conservation varieties are marketed with the same rules as for commercial seed. Owing to the voluntary nature of certification and registration, it is, however, difficult to quantitatively assess the number of conservation varieties currently on the market. In the EU, in addition to mandatory certification and registration, conservation varieties have supplementary restrictive marketing requirements such as restricted quantities for sale of seed, limited maximum profit, and limited scope for sale to the region of origin.

Fifth, both regimes operate with a labelling system that has to state standard information, e.g., name of the variety and country of production. In the United States, however, the label has to include certain quality standards such as germination rate. In this, the United States aims to provide an honest representation of the quality, rather than setting a minimum quality benchmark.

The main difference that emerges from the above is the degree of public interference with respect to the promotion and assurance of seed quality. In the United States, government control of the market is set out to provide a high level of transparency to help farmers make 'informed choices' (including choosing to purchase seeds that are below a certain standard of quality), while the EU system focuses on ensuring access to 'quality' seed, pre-empting the possibility of buyers being exposed to low(er) quality seed. By extension, the EU's approach places the assessment of 'quality' in the hands of the regulator, whereas the U.S. approach allows farmers and other market participants to determine quality. This is in line with the EU's technocratic approach to regulation and its considerable regulatory capacity. That said, it also reflects a profound ideological difference as to the role of the regulator (big 'R' versus small 'r') in the EU and the United States, respectively.

5. Conclusions

Conservation varieties have historically evolved through external environmental pressures, such as climate conditions, pests, and diseases, making them highly adapted to local environments. In contrast to commercially bred varieties, conservation varieties are generally lower yielding. The value and quality characteristics of these conservation varieties stem from their ability to recover from and deal with environmental stresses and being a carrier of expansive genetic information that can be utilised for further seed breeding. Their value thus extends beyond agricultural productivity.

In the EU, farmers' use of these conservation varieties is limited by the modernisation of agricultural practices and agricultural policy, but also by the EU's seed law framework, which hinders the placing on the market of these varieties. EU seed law operates under the premise of safeguarding the quality of seed and maintaining agricultural productivity. Conservation varieties are thus compelled to adhere to a similar criteria of, among others, genetic uniformity, as commercially bred varieties to be allowed to be accepted in a National or Common Catalogue.

Despite the implemented derogations within the EU seed regime specific to market conservation varieties, it includes the setting of quantitative and substantive market restrictions for these varieties, such as regional market limitation and seed packaging weight restriction. Seed law in the EU thus complicates, if not obstructs, any meaningful commercialisation and maintenance of these varieties. A relevant comparison is EU Regulation 2018/848 on organic production and labeling and its regulation of the use of heterogenous materials in organic plant breeding. These seeds are, similar to conservation varieties, inherently genetically diverse, which means they do not adhere to the DUS criteria. Article 13(1) of the Regulation nonetheless allows for the marketing of this plant reproductive material without complying to the requirements of registration and certification. The article recommends further legal analysis of the possibilities, similarities, and differences with organic seed breeding production and conservation varieties, and whether these statutes could be similarly implemented for conservation varieties.

A comparative legal analysis indicates that the U.S. system of seed marketing does not uphold the same principles of quality control and the safeguarding of agricultural

productivity. By allowing market access to virtually any seed, regardless of compliance with DUS and VCU criteria, conservation varieties may be marketed like commercial seed. As a result, in the United States, low quality seed can be legally market if properly labelled. The rationale behind such a regulatory choice is the assumption that proper labelling and market dynamics allow farmers to be sufficiently informed to obtain the most appropriate seed for their operations. Naturally, the availability of conservation varieties on the market does not necessarily lead to the adoption of conservation species over conventional varieties. While the broader availability of these species could be a step towards reducing further agrobiodiversity loss, there are several intervening factors in farmers' choices of species, as well as further factors contributing to genetic erosion more generally.

A wholesale adoption of the U.S. truth-in-labelling approach by the EU would thus not guarantee a solution to the EU's problems regarding crop genetic erosion. Rather, the revision of EU seed laws should look to find alternative ways of decoding seed quality, in order to acknowledge the inherent value of seed from conservation varieties and their role in agricultural production in the maintenance of agrobiodiversity, and in the development and resilience of future food production.

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