



Review Regulating Seeds—A Challenging Task

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Abstract: Seed is an essential start of any crop production. Seed, as both botanical seed and vegetive planting materials, is thus a very important component of agricultural livelihoods in food, ornamental, and industrial value chains, of local and global food security, and a determinant of sustainability. All farmers need good seed, irrespective of the farming system and markets that they supply. Seed qualities, in terms of germination/vigour, health, and genetic content, are a concern of all farmers. Farmers have various ways to access seeds. With time, the diversity of farmers' and formal seed systems have become increasingly refined and complex. Given the importance of seed, not just for farmers but for society at large, seeds have become subject to an increasing number of regulations that pursue different policy objectives. Some have been intentionally developed to regulate seed systems themselves, while others impact them as a side effect. Various components of different policies, regulations and outcomes, their interactions and apparent dilemmas and inconsistencies are discussed to highlight the significance of seeds and to illustrate the importance for policymakers and regulators to carefully phrase rules and be sensitive toward the possible unintended effects of their actions. This particularly relates to seed marketing regulations, intellectual property and farmers' rights, and biodiversity and biosafety rules. A general conclusion is that rules and regulations need to respond to evolving technical and socio-economic developments. Since seed systems differ widely and operate side by side, regulating a particular system may negatively impact others. The challenge for policymakers is to create policies and regulations that support both formal and farmers' seed systems where they are most effective while minimalising negative consequences for breeding, selection, and seed production in either system. Several suggestions and recommendations for how to do so are provided in this special issue.

Keywords: seed policy; variety registration; seed certification; intellectual property rights; genetic resources; plant biotechnology

1. Introduction

Seed is an essential component of any crop production. The term 'seed' is used in this article to include both the seeds and other (vegetative) planting materials. Seed quality, in terms of germination/vigour, health, genetic adaptation to ecological conditions, and preferred product qualities, is a concern of all farmers. The continuous selection of seeds by farmers over the past 10,000 years has 'domesticated' the crops that we currently live on, a process of conscious and unintentional natural selection in the evolving farming systems. These gradually removed characteristics are vital for plants in nature, such as thorns, toxins, and early seed shattering. The same processes increased traits that favour consumption qualities and yield components such as weed suppression and disease resistance under cultivation conditions that are quite different from natural growing conditions. A variety of selections, landraces, or farmers' varieties evolved and continue to be improved in this way and through increasingly refined plant breeding procedures creating diversity and increasing selection efficiency.



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Copyright: © 2021 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). Seeds also need to withstand storage, to germinate and produce strong seedlings, and seed transmitted diseases need to be suppressed. The latter is done traditionally, even in the absence of detailed knowledge about viruses, bacteria or fungi, by selecting healthy-looking plants for use as seed in the following growing season, and by handpicking discoloured seed before planting. In larger scale seed systems, consisting of breeding, seed production, conditioning and marketing, such tasks are taken over by seed cleaning machines and quality control procedures.

Farmers have various ways to access seeds. Throughout history, farmers have re-used the harvest of their crops, with or without selection, as seed for the next season. Depending on the crop, this could be true seeds, but also roots, tubers, stems, and other plant parts that can be used as vegetative starting material. For this paper and this special issue, we include all these under the term 'seed' even though that may be botanically incorrect. For crops that are not produced for their seeds, seed production is often a more specialised endeavour. In cassava, the 'seed' (stem segments) is merely a rest-product of cultivation, but many vegetables flower and set seed only after the main product is harvested.

In many communities, particular farmers became known as good seed suppliers in times of need, or subsequently as a regular source. Other farmers would be a source of knowledge about soil management, mechanisation, or other aspects of agronomy. Some local seed specialists developed into specialised seed producers and merchants. Some of these, such as Vilmorin in France (since 1743) [1] and Groot in The Netherlands (since 1800), passed on their trade to subsequent generations in their families, professionalising their seed businesses. Vilmorin and Sluis & Groot are still trade names even though these companies are part of the larger Limagrain and Syngenta companies, respectively. The World Food Prize winner 2019, Simon Groot of East West Seeds, has such family roots [2].

This professionalisation brought about specialisation in the distinctive tasks necessary to optimally produce seeds. In more advanced seed systems, breeding, seed production, conditioning, and commercialisation, are done by specialised people. The roles of the private and public sectors are also quite distinct in this respect. The private sector can be expected to cater for the needs of crops, and farmers can afford to pay for quality seeds, i.e., using formal seed sectors. The public sector should particularly focus on breeding research and the actual breeding of crops and should avoid competing with (emerging) seed enterprises in their markets [3].

2. Seed Systems

The result of the professionalisation described above is that two rather distinct seed systems emerged: the farmers' (or informal) and formal seed systems. Both systems comprise of different aspects of breeding (selection), multiplication (production), and distribution (sharing) [4]. As we will indicate below, this distinction is useful to identify opportunities to support and strengthen them. It is, at the same time, overly simplistic as there are various linkages between the two, creating intermediate forms.

2.1. Farmers' Seed Systems

The basis of farmer seed systems is the production of seeds by farmers themselves. The selection in their particular location and cropping system, and within their cultural perceptions with regard to, e.g., the colour and taste of the product, results in the genetic makeup of crops to evolve in particular directions that may be different from their neighbour's [5]. However, farmers also have a tendency to look out for 'things to try', which means that when they see a different variety with interesting characteristics, they tend to try it out in their own field. In most cultures, farmers are proud when asked for a sample of their seed and are willing to share it with anyone; however, some may do that only with people they know. This seed sharing among neighbours and relatives [6] may result in the replacement of the farmers' own variety, but more likely in the admixture (physical and almost always genetic), increasing the diversity and thus advancement of the crop. Farmers who show an interest in selection, and who become known as a reliable supplier

of good seed, commonly appreciate the status in the community that it provides but rarely become dependent on providing seeds for their livelihoods.

Farmers' seed systems are dynamic, but they also have some limitations. Firstly, the anticyclic effect of seed supply. After a good season with a healthy crop and dry harvesting conditions, most farmers in a community are likely to be able to store good quality seed. After a poor season, and notably after rains during and after harvesting, farmers may struggle to save seed and neighbours that they may normally depend on for seed will have few or no seeds to share either. Secondly, farmers' varieties that have proven to be well adapted to the local conditions may fail to adapt quickly enough to the effects of climate change and to the intensification of farming due to population pressures. Thirdly, the range of exchange is often limited to neighbours and relatives, limiting the use of the available gene pool.

2.2. Formal Seed Systems

The emergence of seed markets created a specialisation of tasks in seed production, conditioning, and marketing. The production of vegetable seeds, i.e., crops that are not produced for their seeds like cereals and pulses, create a particular challenge for farmers. Some plants have to be kept in the field in order to bolt and produce seeds, which may disturb land preparation for the next crops. For some temperate crops, such as cabbages and onions, this may mean keeping those plants for close to two years. Similarly, animal farmers are commonly not geared to producing forage seeds. This developed a demand for specialist producers of good quality seed of specific varieties.

Some botanists turned into breeders even before the laws of heredity were known in the scientific community. Pierre Andrieux, a botanist in the service of King Louis XV of France in the 18th century, and Luther Burbank in the USA in the second half of the 19th century were good examples. After 1900, when Mendel's laws of heredity became known to the scientific community, and plant breeding became a science, a "push" developed from breeders needing ways to get their varieties to farmers [3].

Both "push" and "pull" aspects in seed chains exist today, with specialised breeders, seed producers, seed conditioners, and marketeers operating in a seed system. The distribution of tasks, and the subsequent distance between the seed supplier and the customer (farmer), brought about a need for guarantees with regard to varietal identity and seed quality through regulation, thus dubbed 'formal seed systems'. Often, there is a distribution of tasks among public and private operators along the seed chain. Where plant breeding is mostly private in Europe, with some breeding research supported by the government, breeding of many crops is, on the other hand, mainly a public task in the USA, performed by the Land-Grant Universities. Public sector breeding is also common in most countries in the Global South, with the exception of commercial seeds for maize, soybean, and many vegetables.

Seed production has not been a government task in Western Europe, but in the USA, it was for a long time. The distribution of free seed by the US Department of Agriculture was abandoned only in 1924, when private seed production began. Public seed production schemes were developed in several countries in the Global South as part of the Green Revolution; these have been privatised in different ways following Structural Adjustment policies in the 1980s and 1990s [7]. Public extension agents may play an important role in several countries, both in the marketing and distribution of seeds.

Formal seed systems also face challenges. Both public and private breeders have to focus on a sufficiently large 'recommendation domain' [8] and may not be able to provide specifically adapted varieties for all farmers, notably in ecologically diverse (mountainous) regions. Logistical and planning challenges, especially in government seed production schemes, often resulted in seeds arriving at the farms in the wrong quantities and at the wrong time. Commercial seed providers are generally more efficient, but this comes at a cost. The cost of seed is less of an issue with crops that are produced for the market and crops with a high multiplication factor (low sowing rate), which explains why this sector is

particularly active in crops like maize and vegetables rather than home-consumed legumes and small grains.

2.3. Other Seed Sources

A substantial number of subsistence farmers do not—or are not able to—save their own seed or obtain it in the community. Studies indicate that up to 20–40% of farmers in West Africa purchase food grain from the local market at the time of planting [9]. They are too poor or otherwise unable to select and store seeds themselves. Such 'seed' is commonly not sold as seed, but since the grain in many cases originates from the same area, the varietal characteristics may still be fine in the local growing conditions, and type names may even be known by the merchant. Germination capacity can, however, not be assessed very well, even though smell and colour can be indicative.

Similarly, communities suffering from natural or human-made disasters may depend on unconventional sources of seed. Emergency assistance organisations may bring in seed. The organisations commonly, by choice or necessity, bring in seeds from far away, adapted to very different cropping conditions [10]. The risk can be illustrated by the distribution of sorghum seeds of a variety maturing in six months in a region where the growing season is at the most three months (first author's observations in Southern Sudan). Such disaster-struck farmers may get no yield after spending all their energy on preparing the land and caring for the crop. The administrative requirement of the aid organisation to purchase certified seed may turn out disastrous for the recipients.

2.4. Integrated Seed Sector Development (ISSD)

The existence and complementary values of these different seed systems are not always fully recognised. National seed policies in many countries concentrate on the formal seed systems only, even when for most crops, over 90% of seed that is planted by farmers come from non-formal sources. Such policies can even outlaw farmers' seed systems and make it difficult for donors and national research systems to develop ways to support them.

This observation became the basis of the formulation of the concept of integrated seed sector development, connecting formal and farmers' knowledge and materials, and supporting different seed systems to operate side by side [11], and its challenges for policy-making [12]. It is based on two concepts:

- (i.) Linking seed systems through a diversity of actions, to combine scientific and farmers' knowledge and plant materials to improve the various systems;
- (ii.) Different seed systems exist and need to be recognised in order to develop further.

Linking knowledge and materials may get the shape of participatory plant breeding where scientific and farmer-breeders cooperate in developing better varieties for local use [13] or stimulating farmers to obtain seeds of their preferred varieties from demonstration fields for further testing and multiplication in their own farms. Another possible alley is to support farmer-seed groups, with basic seed and knowledge on seed production agronomy and even business administration tools in order to provide better seed locally and open up opportunities for bottom-up seed company (or cooperative) development as opposed to opening up to foreign investors [14]. Moreover, community seed banks [15,16], seed fairs [17], provision of storage bags, or improved seed store designs, and a range of other initiatives can support farmers' seed systems [18].

With regard to the second concept, it must be recognised that farmers get seed from a variety of sources, that all have a role to play, and that there is no one-size-fits-all strategy to support and improve them. For example, a farmer may get maize seed from the national formal sector, vegetable seed from imported sources, legume seeds mainly from their own or their neighbour's production fields, virus-resistant cassava seed from a research farm, bean seed from local bean traders or grain markets, and millet seed from a community seed bank. All these sources of seed, each with values and limitations, may be recognized, and different actions may be needed to resolve them.

The concept of ISSD gives recognition to the variety of challenges that farmers face in obtaining or keeping the seed of their choice, which should open up ways to legitimately support these seed systems. It is in that latter aspect that new challenges emerge, as will be explained in the next section.

3. Regulating Seed Systems

3.1. Seed Laws

3.1.1. Rationale: Protecting Farmers through a Variety of Registration and Seed Quality Controls

Secondly, seed laws are to create a level playing field for seed producers by keeping poor quality seed from the market [19].

Seed is not only important for farmers, but also to governments in pursuing policies with respect to food security, consumer protection, and aspects of sustainable farming. Laws and rules that regulate seed marketing and use emerged with different objectives in mind.

The seed laws in the USA and Europe are particularly concerned with the protection of farmers from buying poorly performing seeds. The USA does this at the federal level by legislating that the information on seed labels be true; in Europe, minimal standards for varieties and seed quality components are regulated [20]. The latter laws, which are currently harmonised at the EU level, and similarly at the level in most former Soviet states, concentrate on a variety of registration and seed certification procedures and standards adapted to different crop groups [21]. Variety registration is, in the first instance, to affix one name to each variety, which must be identifiable (distinct), stable, and sufficiently uniform to secure stability (so-called DUS—standards). This is not a requirement for ornamentals. For major field crops, there is also a requirement that the new variety has a superior value for cultivation (the farmer) and use (the processing industry). These VCU requirements in the EU are rooted next to the farmer protection policy and in the food security policies that were important in the EU before and following the second world war. The strict regulation also creates a level playing field for seed companies to compete. Many countries in the Global South have adopted seed regulations that are similar to those in the EU [22].

Such differences in approach to variety registration and seed quality control, which affect international seed trade, led to the establishment of various international organisations that are meant to harmonise the technical implementation of the rules. The International Seed Testing Association standardises seed testing methodologies (not necessarily the standards) [23]; the Seed Schemes of the Organisation for Economic Cooperation and Development (OECD) provides harmonisation of certification procedures and label requirements, facilitating international acceptance of such quality control procedures [24]; and the International Plant Protection Convention creates clarity in phytosanitary rules and measures [25]. Often, the requirements to deal with the detailed rules that are necessary for authorities in other countries to approve such quality declarations are very detailed. Several countries do not have an accredited ISTA-laboratory within their borders, and acquiring approvals under the OECD Seed Schemes requires extensive institutional and human resource capacities. Finally, non-regulatory measures to facilitate international seed trade are the Trade and Arbitration Rules of the International Seed Federation (ISF) [26]. In order to facilitate regional seed trade, various regions have created regional variety registers, such as the European Union, SADC, ECOWAS, in southern and west Africa, respectively, and the East African Community and COMESA in the eastern parts of the continent.

3.1.2. Important Areas of Discussion

The general impression is that these rules have functioned very well in order to support the modernisation of agriculture and increasing production levels in Europe. However, these high-input farming systems are under significant scrutiny. Currently, questions are raised about the strict regulations suffocating local initiatives and, through that, insufficiently supporting farmers' choices and genetic diversity of crops in fields. In Europe, policies towards making agriculture more sustainable take prevalence over increasing yields. Batten et al. [27] discuss this.

Concerns towards these seed regulations point at the (often lack of) relevance of the conventional variety trials for the diverse farming systems in the Global South [28] and Europe [20], and concerns about the diversity of varieties allowed to the seed market (particularly new farmers' varieties) [29,30]. Batur et al. [31] and De Jonge et al. [32] review the challenges and opportunities of registering farmer varieties in Europe and the Global South, respectively. In addition, the Europe-based seed laws can also create friction with the needs of the different seed systems operating side by side. Mulesa et al. [33] discuss this in the framework of wheat and teff seed security in Ethiopia, while Kuhlmann and Dey [34] perform a global study to present a framework that evaluates how regulatory flexibility can be built into seed systems to address farmers' needs and engage stakeholders of all sizes. First of all, it appears difficult in many countries to implement field inspection and seed testing operations while maintaining the necessary facilities. Further, questions arise as to how to approach seed quality controls with emerging farmer-seed production cooperatives in remote areas where visits by field inspectors are difficult to arrange. Mastenbroek et al. [35] discuss the option to resolve such problems through the introduction of Quality Declared Seed approaches that relieve the burdens of conventional full certification rules. Questions arise whether this could lead to an uneven playing field and obstruct the emergence of local seed companies.

Furthermore, initiatives to support farmers' seed systems to sustainably secure seed availability and provide choices for farmers, and supporting the on-farm management of plant genetic resources, need policy space and should not be made illegal through clauses in national seed laws that all seed has to be certified [36]. However, definitions and rules necessary to support such initiatives should not unnecessarily create opportunities for substandard seeds in the regular seed markets, such as unnecessarily creating opportunities for substandard seeds in the regular seed markets, including low-quality grain sold as high-quality seed.

3.1.3. Challenges for Policy Makers

The diversity of seed systems requires policymakers to carefully analyse the seed situation in the country for different crops and farmers. To support these different seed systems may require specific rules and exemptions [12]. Meanwhile, there are good reasons to strive for levels of regional or global harmonisation to facilitate international seed trade.

3.2. Protection of Intellectual Property

3.2.1. Rationale: Stimulating Private Investments in Breeding and Seed Production

In Europe, where private rather than public breeders were (and still are) dominant, notably in horticulture, a call for protecting their work through intellectual property rights came up about a century ago. There was a general consensus that plant varieties do not fit the patent system, which led countries to design a separate protection system. The USA issued plant patents (which are not the same as utility patents granted to industrial inventions) for non-edible vegetatively reproduced crops, and in European countries 'soft' systems for protection emerged for all crops in the 1930s, which were harmonised in 1961 in the UPOV Convention [37]. The objective was to provide breeders with opportunities to recoup their investment while supporting and maintaining broad access to genetic resources (breeder's exemption) and maintaining possibilities for traditional seed saving (farmers' privilege). This system was amended a few times, strengthening the rights, following developments in agriculture and breeding (last in 1991). For such legal protection, the variety has to be clearly identifiable (i.e., DUS), which requires extensive testing.

Plant Breeder's Rights have greatly supported commercial plant breeding in the countries that (first) introduced such protection, and also public sector breeders gradually started to use the system in order to support the marketing of their varieties. The latter function is underrated in many discussions about breeders' rights. When all seed producers

may commercialise a new variety, which often involves significant costs of demonstration and marketing, there is a risk that no one will make such investments as others may take the market when a variety appears to generate demand. When a seed producer has an exclusive right, investments in demonstrations may be more feasible. This is the reason why Uganda gave exclusive rights to the marketing of public maize varieties and hybrids in its policy to promote investment in local seed enterprises in the 1990s (first author's observation).

3.2.2. Important Areas of Discussion

The technological developments in plant breeding influenced the plant breeder's rights in the 1980s [19]. The emergence of genetic modification could lead to conventional plant breeders losing their rights when an additional gene/trait would be introduced in an otherwise good variety. Such new varieties would be distinct from the original ones and thus protectable. By introducing a patented trait in all popular varieties, a biotechnologist could potentially gain all rights without any breeding activity [38]. The PBR system would thus lose its function towards stimulating conventional breeding. In order to curb that risk, the concept of Essential Derivation [39] was introduced in the UPOV Act of 1991. Breeders changing one or few traits in a protected variety would get a breeder's right that would only be implemented with the consent of the breeder of the original variety. This would also resolve the issue of the status of mutants, which often occur in vegetatively propagated fruits and ornamentals. This concept created several 'grey areas' in definitions and application and has led to multiple court cases, and still fuels important discussions. Smith [40] proposed a change of the UPOV Convention and different possible definitions for different crops. Bostyn [41] identifies similar challenges to the concept but focuses rather on mechanisms to share the value between the original breeder and the one creating a derived one because biotechnologists require a financial reward for their work.

With the emergence of biotechnology and through subsequent court decisions in the USA, the (utility) patent system entered the area of plant breeding [42]. Patents started to be granted on plant varieties (USA) and/or traits (in many countries) and on technological methods. The rationale was that there were no arguments to withhold such protection and that it would stimulate investment in research and development, making use of new technological developments. However, since the exemptions of the breeder's rights system are not valid in the patent system, the gradual emergence of the patent system in breeding created a lot of concerns among breeders and farmers in the early 2000s, notably because of the absence of the breeder's exemption in patent law [38]. These concerns led in Europe to regulatory changes: a 'limited' breeder's exemption in the 'unitary patent' system [43], and the decision not to grant patents on traits obtained through conventional breeding methods (e.g., those identified in nature or a genebank and crossed into elite material) [44]. Still, notably with the emergence of different forms of gene editing, the debate is still on. Kock [45] focuses on the licensing of patented subject matter on Fair, Responsible And Non-Discriminatory (FRAND) terms that can provide a business model for biotechnologists while limiting the risks of restrictive (monopolistic) behaviour of patent holders, resulting in negative effects of patenting.

Smulders et al. [46] argue that the 'reach through' aspect of patents could be turned to good use beyond commercial controls over parties along the value chain. They indicate that the power that the patent gives to its holder could also be used to make sure that sustainability aspects can be enforced upon breeders, farmers, and traders.

3.2.3. Relation with Farmers' Rights

Debates also emerged on the exclusive rights themselves. The main opposition comes from farmers whose right to re-use farm-saved seed is curtailed by breeder's rights that put restrictions on, especially, the sales of farm-saved seed of protected varieties. A major concern is that the laws could infringe on the farmers' (informal) seed systems, where seed can be freely exchanged (and sold under the radar of the seed laws). This led in the 1980s

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to debates about 'Farmers' Rights', which was finally formulated in the International Treaty on Plant Genetic Resources for Food and Agriculture, signed 2001 [47]. It is a wide-ranging concept, particularly the start of article 9c, which speaks on the rights of farmers to save, use, exchange, and sell farm-saved seed. This right is, however, curtailed with the phrase that follows, 'subject to national law and as appropriate', which was added during the negotiations by countries that had operationalised Intellectual Property laws on plants and plant parts. This formulation still calls for a wide range of heated debates, mainly by and on behalf of smallholder farmers. Adhikari et al. [48] analyse some of this debate and set out a list of possible substantive Farmers' Rights as a contribution and foundation for further consultations and negotiations on this topic. Since 2018, the concept of Farmers' Rights is also embedded in the United Nations' Declaration on the Rights of Peasants and Other People Working in Rural Areas of 2018 [49,50].

3.2.4. Challenges for Policy Makers

The main challenge for policymakers is to strike a balance between rights and obligations between the parties in the chain from biotechnology, breeding, and farming. In particular, the impact of the patent system in plant breeding and of both patents and plant breeder's rights on smallholder farmers require due attention. In some cases, the holders play an important role themselves, through their licensing strategies and (non-asset) declarations to not exercise their rights on smallholders. Ongoing debates around the concept of Farmers' Rights put these discussions in a much broader framework of Human Rights.

3.3. GMO-Regulation

3.3.1. Rationale: Protecting the Safety for Man and Environment?

The emergence of practical applications of plant biotechnology in the 1980s led to concerns about the safety of the products of genetic modification for 'humans and environment'. Particularly this latter concern led to the Cartagena Protocol on Biosafety [51,52] under the Convention on Biological Diversity, on the international movement of living modified organisms (LMO, often referred to as GMO) and requires nations to formulate national laws to implement it. Such biosafety laws commonly require pre-market notifications and safety checks. To prove safety for humans and the environment, these dossiers require extensive and costly research to convince regulators, and even then, concerns may prevail, calling upon the 'Precautionary Principle' as formulated in the Cartagena Protocol. The effect is that in several countries, GMO crops are either forbidden, or their registration is so complex and costly that the effect is the same.

3.3.2. Important Areas of Discussion

The biosafety rules, and notably the responsibility of the technology developer and provider, also led to extensive stewardship systems adopted by the companies that are marketing GMO traits and crops. These are meant to make sure that GMO crops are used 'responsibly' (e.g., with reference to refuge obligations) and transparently. Since rules and decisions on specific traits differ among countries, and because of labelling requirements, it is important to trace the use of GMO-varieties, seeds, grain, and processed products along the value chains. Stewardship rules are commonly included in license contracts.

The complex and costly biosafety rules, together with the patenting of traits and methods, led to the marketing of GMO crops almost exclusively by those companies that have the legal and financial resources to deal with them. In addition, these costs led those companies to apply the technology mainly to the globally most important and commercially interesting seed crops such as maize, soybean, and cotton, where such costs can be recovered. There are uses on papaya [53] and eggplant [54], but these have remained limited to few countries. Next to ethical concerns related to genetic modification, this economic effect of biosafety rules led to additional opposition against GMO crops. Most countries in Africa followed the example of Europe with its very cautious approach. Recent

policy changes in Africa were discussed by Komen [55], leading to the adoption of a GM cowpea in Nigeria.

The emergence of new technologies, such as cis-genesis and gene editing [56], can significantly reduce the time required for breeding. These technical developments currently create new challenges for policymakers and regulators. Are the products of these breeding methods GMO? And if (not) so, should they be regulated? Different countries come to different conclusions, which risks challenges for the international trade of agricultural products. Louwaars and Jochemsen [57] discuss the different ethical issues around these technologies and mechanisms to implement consumer choice. Van der Berg et al. [58] discuss the technologies from the point of view of safety and implementation of current GMO regulations. Important in that debate is that the new breeding methods—compared to 'traditional' genetic modification, cannot be identified through the testing of the products derived therefrom. Strict biotechnology regulations commonly create stewardship obligations by the technology developer and go hand in hand with patents on the modified traits [59]. Both can lead to restrictions on seed saving and local exchange of seeds among farmers.

3.3.3. Challenges for Policymakers

Technological developments have put biotechnology back on the agenda of policymakers. The objective of the GMO regulations was to secure safety for consumers and the environment, but ethics and power relations in breeding play an important role in the biotechnology debate. At the same time, especially now that new genetic techniques become available, challenges of food security, effects of climate change, including the emergence of 'new' pests and diseases, forced countries to re-think the roles of plant breeders and their toolbox.

3.4. Biodiversity Laws

3.4.1. Rationale: Conservation of Biodiversity

Concerns about the disappearance of plant genetic resources in agriculture that had developed in the scientific community came to the political 'surface' in the 1980s at the FAO with the conclusion of the International Undertaking on Plant Genetic Resources for Food and Agriculture (IU–PGRFA) [60]. The Green Revolution created single varieties that became popular in very large tracts of land in many countries, replacing the landraces that had evolved locally. This fuelled concerns about dwindling diversity [61] even though later research provided proof otherwise [62]; the consensus is that landraces can be an important source of potentially important alleles [63]. Louwaars [64] puts the 'modernization bottleneck' in the framework of historical trends in diversity starting from the domestication of crops.

This diversity is the very basic material for the breeders working on that revolution. There was a general consensus that the conservation of such resources is essential. Three complementary strategies were developed to secure that objective: (i) nature management important for the conservation and further evolution of crop wild relatives, (ii) on-farm management of PGRFA through the continued use of genetically diverse varieties with specific adaptation, and (iii) in genebanks, where diversity is stored, evaluated, and made available to breeders [65].

The concerns initially led to the policy declaration (in this non-binding International Undertaking) that such PGRFA are a "heritage of humankind", i.e., for nobody to own [60]. This concept was overturned a few years later by the declaration at the Convention on Biological Diversity (CBD) that genetic resources fall under the sovereignty of the nations where the resources had obtained their specific characteristics [51]. Based on the Convention, various countries developed one or several national biodiversity laws. Such laws commonly regulate the collection of biological diversity in nature and farmers' fields and establish institutional arrangements for access. The CBD aims at three objectives: conservation, sustainable use of biological diversity, and the fair and equitable sharing

of benefits arising out of their use. This created challenges for signatory states [66]: the obligation to conserve, and the need to establish institutional arrangements to regulate, monitor, and negotiate access by prospective users. This proved even more challenging regarding the large numbers of genetic resources in plant breeding moving across borders, notably through the programmes of the international research institutes of the CGIAR [67]. It took eight years (and three more for entering into force) of the International Treaty on PGRFA, formulating multilateral operation of both access and benefit-sharing for a list of important food and fodder crops rather than bilateral negotiations. This is done under the same objectives as the CBD, through conservation, sustainable use, and equitable sharing of benefits. The multilateral system includes all genetic resources of these crops that are 'under the control of the governments' that are party to the Treaty. Benefit-sharing funds are used to support farmers, particularly those involved in the conservation of PGRFA through their continued use [68].

3.4.2. Discussion Points

There is a general agreement that (agro)biodiversity is important and needs to be conserved. Yet, there is much debate on how and by whom this should best be done. Louafi et al. [69] discussed the binary division in current approaches, which often focus on either in-situ conservation of seeds by farmers or ex-situ conservation of PGRFA stored in genebanks. They propose a more holistic and inclusive framework to crop diversity management that takes into account the concerns and needs of a wide range of actors using crop diversity.

There are also discussions about what is to be considered 'sustainable use' and whether the rules should also apply to information connected to the physical resource [70,71]. Major debates are also still ongoing about how benefits may be shared, what is to be considered 'equitable', and who should benefit. All this boils down to the question of how to balance the three objectives of the CBD and IT PGRFA.

Countries find it hard to operationalise the rules for Access and Benefit Sharing at the national level; to establish the institutional and human capacities to manage the necessary negotiations on access. A major step to resolve this was taken in the Nagoya Protocol, which makes user country governments responsible for adhering to the set rules [72] but challenges for users remain.

Schebesta [73] responds to the deadlock in the international debates on Access and Benefit Sharing that has been ongoing for close to 30 years. She discusses consumer-based mechanisms as positive drivers for benefit sharing by using private labels similar to the sustainability labels in consumer markets to incentivize ABS obligation compliance, which may create benefits for companies through a consumer-facing label on products.

3.4.3. Challenges

Access to genetic resources remains important for breeders. Sharing benefits is increasingly recognised as justified, but operationalisation and agreeing on the term 'equitable' remains a major challenge. Implementing the three objectives of the Convention on Biological Diversity appears difficult in many countries.

4. Conclusions

Seeds are an essential start of crop production for all farmers in all farming systems. Availability of affordable seed of the right genetic, physiological, and sanitary quality in the right quantities and at the right time is a concern for many farmers. This requires a diversity of seed systems to effectively, reliably, and continuously develop, multiply, and provide affordable seeds that respond to the changing needs of farmers.

Various policy areas affect such seed systems that include plant breeding and research, seed multiplication, and distribution. Seed laws directly affect seed systems through variety registration and seed quality control mechanisms and standards. Other policy areas and their subsequent regulations also have important impacts on seed systems. These are, for

example, intellectual property rights, access to and benefit-sharing on biodiversity and related Farmers' Rights, and genetic modification.

There is a major challenge in all these policy areas to make sure that the rules impact the targeted seed systems in the desired way and avoid having a negative impact on others at the same time. For example, the quality guarantees that seed regulations are important for commercial seed systems but may create obstacles for less formal ways of seed supply. Similarly, Intellectual Property Rights and Farmers' Rights on seeds need to respond to policy objectives from where they stem and when operating together to balance rights and obligations in the respective farming systems.

Further, it may be clear that policies created for other policy objectives, such as biosafety and biodiversity, can have an effect on seed systems, notably on their breeding components. They are not primarily created to impact seed systems, which means that the rules and their implementation may be even more likely to bring about challenges to the diversity of seed systems that they may affect.

We conclude that the broad area of policies that affect breeding and seed systems is both important for society and complex. Seed systems are necessarily complex and diverse so that one-size-fits-all approaches rarely work, and that choices need to be made at the national level, and coherency among the different policy areas affecting seeds is badly needed.

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