

RESEARCH ARTICLE

How regulatory issues surrounding new breeding technologies can impact smallholder farmer breeding: A case study from the Philippines

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Societal Impact Statement

The widespread use of patents on plants and plant parts in low- and middle-income countries demonstrates the increasing privatisation of crop genetic resources and potentially limits the use of these resources in farmer breeding, increasing the dependence of smallholder farmers on the private seed sector. Use of genetically modified traits in farmer breeding poses biosafety issues. Adaptation of patent legislation to the benefit of smallholder breeding and development of alternative seed sources from the public breeding sector could contain these negative impacts on farmer-breeder efforts and ultimately on food and nutrition security.

Summary

- This paper explores the potential impact of increased use of digital sequence information (DSI) through new breeding technologies (NBTs) and its associated patent and biosafety strategies and policies on smallholder agriculture and breeding in low- and middle-income countries.
- We performed a case study in the southern Philippines, involving multiple field visits and interviews, where smallholder farmers deliberately and successfully incorporated a genetically modified, patent-protected trait into popular open-pollinated varieties (OPVs) of both yellow and white maize, resulting in the wide-spread dissemination of glyphosate-tolerant open-pollinated varieties (OPVs) called *sige-sige*.
- The particular case poses a suite of questions regarding farmer producer health, biosafety and access to plant genetic resources protected by patent rights. Considering current trends, it is predicted that the rise of NBTs such as gene editing will lead to more patents on breeding processes and on gene-edited crop plants, including in low- and middle-income countries and emerging economies. Since in many jurisdictions NBTs may be regulated as genetic engineering processes and products, biosafety regulations and related management requirements need to be considered as well.
- By recognising and supporting the breeding efforts of farmers, governments can tap into the potential for creating a wider portfolio of varieties that are better

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adjusted to the needs of smallholder farmers. If the spread of GMOs in smallholder agriculture should be contained, alternative seed sources for farmer-breeding from the public breeding sector will be highly needed.

KEYWORDS

biosafety, digital sequence information, farmer breeding, genetic modification, intellectual property rights, new breeding technologies, patents

1 | INTRODUCTION

The increasing use of digital sequence information (DSI) and new breeding technologies (NBTs) is revolutionising plant breeding and its applications in agriculture (Schmidt et al., 2020). Gene-editing technologies, in particular, the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology, provide breeders with unprecedented tools to generate variations at specific target sites in the genome of any plant. The use of gene-editing technologies is quickly spreading around the globe and so is the number of patents on these technologies (Martin-Laffon et al., 2019; Oldham & Hall, 2018). In addition, the legislation and regulation of genome-edited plants is equally evolving rapidly in many countries in order to adjust the legal realm to the new technologies (Schmidt et al., 2020). All these developments impact on the efforts of plant breeders around the world. This article aims to reflect on the likely impacts for a particular group of plant breeders, namely, farmer breeders in low- and middle-income countries.

The formal breeding sector has for a long time disregarded farmer efforts in breeding. Most plant breeders have not recognised the added value of plant breeding by farmers, in particular by smallholder farmers in low- and middle-income countries. Yet, since the development of agriculture farmer breeding has created all crops that constitute our current diets (Harlan, 1992). Farmer breeding never stopped since the emergence of professional breeding by trained specialists, but continued to provide new crop diversity in crops and for agro-ecosystems that were not addressed by the public and commercial plant breeding sectors (Salazar et al., 2007). It took different forms from selective evaluation between various varieties or lines provided by breeding institutions to improvement or restoration of traditional farmers' varieties and to crossings between local varieties and public or private sector varieties for the combination of preferred traits. Farmer breeders have continued to fulfil the request for crops and varieties adapted to local farming conditions and food cultures. Furthermore, interactions between the formal sector (public and private plant breeders) and farmer breeders do occur. Farmer breeders are anxious to use new useful diversity to which they have not been exposed before, and supportive professional breeders have visited farmers' fields in order to take note of actual performance of their breeding products and to advise farmer breeders on technical issues. These interactions have been of major importance in participatory plant breeding, an approach in which farmers join forces in local breeding efforts and seek

interaction with and support from public breeders in particular (Sperling et al., 2001).

However, mandates in public breeding in low- and middle-income countries have substantially changed over time. Privatisation has been a prominent feature of agricultural research policy in many low- and middle-income countries since the last decade of the 20th century. Structural adjustments resulted in a reduced role of the state, in liberalisation of markets and trade and also in a reduced role of the public breeding sector (Tripp & Byerlee, 2000). As a result, support for and recognition of farmer breeding have remained limited, resulting in difficulties for farmer breeders to access major new genetic diversity to use in their own breeding efforts.

Another challenge facing farmer breeders results from the recent surge in intellectual property rights (IPRs) in plant breeding, a development which can limit their Freedom to Operate, that is, the freedom to perform a specific action without infringing any enforceable intellectual property rights that are owned by others (WIPO, 2020). In order to incentivise plant breeding and to reward plant breeders for their efforts, a tailor-made IPR system was developed for the protection of new plant varieties. This plant breeders' rights system takes into account the biological nature of the protected subject matter and breeding practices. One of its main characteristics is the breeder's exemption, which allows any breeder to use a plant breeders' right-protected variety for the development and commercialisation of a new plant variety. As a consequence, plant breeders' rights do not limit or delay the availability of plant genetic resources for further breeding. Such exemption does not normally exist in the case of patents, although in some European countries, a limited breeder's exemption has been included in patent law (Prifti, 2017). With the rise of biotechnology, many countries started to allow the patenting of life forms, including plant genetic material. Since the 1980s, the number of patents on plants and plant parts such as cells or DNA sequences, as well as on breeding methods, have rapidly grown around the world (Correa et al., 2020). Because most patent laws do not include a breeder's exemption, the growing number of patents on plants will limit third party's access to breeding materials in the geographical locations, and for the time (usually 20 years), the patents on these materials are granted. This decreases the gene pool from which both farmers and breeders can source freely to use the seeds and breeding materials they need (Binenbaum et al., 2003; Correa et al., 2020). Both intellectual property systems in plant breeding impact on the marketing of seed obtained from protected plant varieties, limiting smallholder farmers to gain income

from the sales of farm-produced seed obtained from protected plant varieties (Blakeney, 2009).

Considering current trends, it is likely that the rise of NBTs such as gene editing will lead to more patents on breeding processes and resulting crop plants in the near future. In addition, since in several jurisdictions NBTs are regulated in the same way as other genetic engineering processes and products, this implies that biosafety regulations and related management requirements need to be adhered to. This paper explores which impact this may have on farmer breeding in low- and middle-income countries. We do so by extrapolating from a case study in the Southern Philippines where smallholder farmers deliberately and successfully incorporated a genetically modified (GM) trait into popular open-pollinated varieties (OPVs) of both yellow and white maize. The development and widespread dissemination of glyphosate-tolerant OPV varieties called *sige-sige* varieties described in the case study raises many critical issues related to the agency of smallholder farmers in managing their crop portfolio and accessing and using plant genetic resources.

After a brief overview of our methods, this article will first describe patenting trends in biotechnology and NBTs and then explore developments in biosafety regulations linked to the use of NBTs. We then describe how farmer breeders in the Philippines have crossed a protected GM trait into popular open-pollinated varieties of both yellow and white maize and how these varieties have spread over large parts of the country. By linking the analysis of currents trends in patenting and biosafety issues with the experiences of the creation and distribution of herbicide-tolerant farmer varieties in the Philippines, the *sige-sige* case study provides useful insights into the potential impact of NBTs on future farmer-breeding developments. The paper concludes with suggestions for policy change in order to support farmer breeders and to protect their freedom to operate.

2 | METHODS

The first two sections are based on literature reviews of both academic and legal documents, enriched with the occasional reference to media articles and web-based materials. Whereas these two sections aim to portray general trends in the use of intellectual property rights and biosafety regulations related to NBTs around the globe, they also summarise the national situation in the Philippines. The information of the case study presented in the next section is mainly based on data derived from bilateral interviews and focus group discussions with smallholder farmers during a 2-month long fact-finding trip through parts of the Visayas and Mindanao in early 2020. Some additional information was obtained from intermediaries, in particular in areas with severe peace and order problems. Villages were visited where, based on previous information, farmer-breeding activity was to be expected. A total of 18 focus groups discussions (FGDs) were held in villages in seven provinces (North Cotabato, South Cotabato, Sultan Kudarat, Bukidnon, Misamis Oriental, Zamboanga del Norte and

Negros Oriental province). Farmers of different gender, age and socio-economic status were represented, and no attempt was made to influence the composition of the individual FGDs. In addition, one regional Department of Agriculture and seven provincial Departments of Agriculture were visited, in which three to four agricultural officers were met for informal interviews. All meetings took up to 1 h for discussions and were semi-formal, in that the standardised list of questions was used. In seven FGDs with farmers, samples of cultivated *sige-sige* maize varieties were shown and phenotypes evaluated by cob size and shape as well as seed form and colour, in order to distinguish between individual *sige-sige* varieties. Names of the villages and departments have been recorded by the authors, but not included in this publication to protect the interests of the persons interviewed and to avoid their possible exposure to prosecution or legal claims.

The FGDs and the private interviews with the agricultural officers focussed on the following six major questions: (1) By whom, where and how were the first *sige-sige* varieties created? (2) When did (subsequent) *sige-sige* varieties arrive in the municipality and in the wider region or province? (3) How did the diffusion of *sige-sige* varieties take place? (4) Which percentage of maize lands were currently cultivated with *sige-sige* varieties vis-à-vis commercial hybrids and traditional farmer varieties? (5) Why were *sige-sige* varieties perceived as preferable to either commercial hybrids or traditional farmer varieties? and (6) Which categories of farmers preferred to grow *sige-sige* varieties and on which type of lands?

3 | TRENDS IN PATENTING OF NBTs AND GENE-EDITED PLANTS

The use of intellectual property rights as well as the focus on the development of hybrid varieties by the private breeding sector in an increasing number of crops has led to the ongoing privatisation of the access to and use of plant genetic diversity. Whereas the creation of hybrid varieties of maize has already taken off in the 1930s (Kutka, 2011; Troyer, 1996), later followed by hybrid development in many more crops, the patenting of plant genetic material only started in the 1980s and spread from the United States across the world (WIPO, 2019). Nowadays, more and more emerging economies and low- and middle-income countries allow for the patenting of plants and plant genetic materials. This development took place despite the fact that the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) established in 1995 allows its member countries to exclude any plant, whether wild or obtained through conventional breeding or biotechnology, from patentability (WTO, 1995, Article 27.3.b).

According to Correa et al. (2020), 60% of the 126 countries in the Global South (the regions of Latin America, Asia, Africa and Oceania, mostly low-income and often politically or culturally marginalised) allow for the patenting of plants or parts thereof. Many of these countries (43%) follow the European patent model, which excludes the patentability of plant varieties and essentially biological processes to obtain them. Since these patent laws do allow for the patenting of

genetic material and plant parts such as cells and DNA sequences, or biotechnological processes to produce plants, they practically allow the patent owner to exercise control over the further use of a whole plant, and any plant variety, that contains the patented component or was obtained by use of the patented process, for the total time of the patent protection. The Patent Act of the Philippines, our case study country, also follows this EU-based model: Section 22 on Non-Patentable Inventions holds that ‘Plant varieties or animal breeds or essentially biological processes for the production of plants or animals (...) shall be excluded from patent protection’, adding that this provision does not apply to micro-organisms and non-biological and microbiological processes (Intellectual Property Office of the Philippines, 2015). Despite the patent law excluding plant varieties from patentability, multiple patents have been granted in the Philippines on genetic material and biotechnological processes since the 1990s, as will be further discussed below.

The remaining 40% of the 126 countries have a patent law that excludes plants from patentability. An example is provided by the patent law of Brazil, which excludes from patentability ‘all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, and the natural biological processes’ (Brazil, 1996, Article 10.IX). Another example is formed by the patent law of India, which excludes from patentability ‘plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals’ (India, 1970, Article 3j). The scope of these exclusions depends, however, on the interpretation of the patent law by patent offices and courts. Whereas one would expect the patentability of isolated genes to be excluded based on a strict interpretation of the Indian law, studies (e.g., Correa et al., 2020; Ravi, 2013) show that patents on isolated genes have nevertheless been granted in that country. In Brazil, the guidelines on the examination of biotechnological patents (issued by the Instituto Nacional da Propriedade Industrial, 2015) provide that transgenic tissues or organisms are not patentable, but the methods for producing a transgenic plant are patentable if they meet further patentability requirements. This means that despite the above cited exclusions from patentability contained in the Brazilian patent law, products obtained through biotechnological processes are patentable, allowing agrobiotechnology companies effective control over the market of transgenic crop varieties.

Several studies show that across the world, the numbers of patents on plants and plant genetic material (King & Schimmelpfennig, 2005; Louwaars et al., 2009; WIPO, 2019), as well as of patents on NBTs (Oldham & Hall, 2018), are rapidly growing. Brinegar et al. (2017) showed that the number of patent applications filed in gene-editing technologies increased 15-fold since 2005, while Martin-Laffon et al. (2019) showed the steep rise in the number of patents to be related to the application of the CRISPR gene-editing technology in different parts of the world, with China and the United States being far ahead. Oldham and Hall (2018) showed that the number of countries in which patent applicants seek protection for their inventions in the field of synthetic biology is growing as well.

The main scientific breakthroughs in crop biotechnology, from the development of recombinant DNA in 1971 to the current NBTs, are made by researchers in public research institutions, after which the private sector steps in by further investments and product development (WIPO, 2019). This also applies to the field of NBTs (Friedrichs et al., 2019; Martin-Laffon et al., 2019; Oldham & Hall, 2018). It is to be expected that current developments will fit into a longer trend, in which a few multinational companies have become to hold the major share of biotechnology patents. For example, King and Schimmelpfennig (2005) showed that six multinationals controlled over 40% of private-sector agricultural biotechnology patents issued in the United States by the end of 2000, with Louwaars et al. (2009) providing similar figures for patent portfolios in Europe (2005–2006) and showing a rise towards a share of 80% in biotechnology patents in the United States in the period 2000–2004. These trends of concentration of biotechnology patents in the hands of a few actors are closely correlated with the consolidation in the plant biotechnology and plant breeding sector at large. In the last three decades, 30 independent companies in the seeds and agrochemical industries have been incorporated through mergers and acquisitions in only four—Bayer, Corteva, ChemChina (owning Syngenta) and BASF—which together hold around 60% of the current agricultural biotechnology market (WIPO, 2019).

Marco and Rausser (2008) argue that an important driver behind this consolidation is the control of patent rights necessary for producing various products, such as Roundup Ready maize: ‘the production of Roundup Ready corn relies on nine patented technologies, controlled at one point by five independent firms. Consolidations in the 1990s reduced that control to two firms’ (p. 133). In the Philippines, Bayer was granted a patent on ‘a chimeric gene for conferring to plants an increased tolerance to a herbicide’ (patent PH 1/0/031176) in March 1998, which expired on August 16, 2019 (WIPO, 2021). Further patents and patent applications that may cover the use of glyphosate-tolerant maize varieties in the Philippines are owned by Monsanto (patent PH 1/2009/500484, granted in 2014), Dow (patent PH 1/2014/501726, granted in 2019; patent PH 1/2014/501728, published in 2014) and Genective (patent PH 1/2014/500208, published in 2014).

Given the fact that nowadays national patent laws in most countries of the world allow for the patenting of NBTs and the plants and/or plant genetic materials that are developed with the use of these technologies, one should expect that the number of patents will continue to grow. As addressed above, this growing number of patents on breeding materials however impedes the freedom to operate of any breeder, be it a farmer-breeder or public or company breeder, since patents laws do not normally allow others (third parties) to use the protected material for further breeding without the consent of the right holder. A complicating factor in regard to the new gene-editing technologies is that a patentable genome-edited plant can be phenotypically and even genotypically indistinguishable from a naturally occurring mutant plant or a plant obtained by conventional plant breeding. This phenomenon has resulted in concerns amongst traditional plant breeders to become entangled in

costly patent infringement procedures in case they would develop and market a new plant variety which main traits look similar to those of a patented genome-edited plant due to congruent mutations (Dederer, 2020).

Only a small number of multinational companies can afford the necessary patent attorneys to secure both protection of their own assets and access to third-party tools and materials (e.g., through licensing, cross-licensing or acquisitions). The big majority of smaller international and national breeding companies, public breeding institutions and certainly farmer-breeders do not have access to such legal resources and are left with a few options: they can either apply for licenses and pay the necessary fees, they can try to avoid or hide the use of IP-protected materials and processes or they can simply go ahead with their traditional breeding efforts and hope for the best. Farmer-breeders will likely opt (consciously or unconsciously) for the latter.

4 | BIOSAFETY LAWS AND DISPERSAL CONTROL ISSUES

Another field of legislation that has major impacts on the use of NBTs and resulting plant products, including seeds, is formed by biosafety laws that regulate the use of genetically modified organisms (GMOs). In agriculture, GMOs are understood to be organisms that are produced 'usually by the inclusion of genes from unrelated species of organisms that code for traits that would not be obtained easily through conventional selective breeding' (Fridovich-Keil & Diaz, 2020). Most countries in the world, and the international community through the Cartagena Protocol to the Convention on Biological Diversity, have established biosafety laws in the 1990s and early 2000s in order to monitor and control the development and release of GMOs, including precautionary measures to mitigate the risk of contamination, that is, the introgression of transgenes into existing (non-transgenic) germplasm (CBD, 2021). This has proven particularly relevant in so-called centres of crop diversity and/or origin (Engels et al., 2006).

The Philippines established a National Committee on Biosafety in 1990, which published the first Philippines Biosafety Guidelines in 1991. With its biosafety regulations in place, in 2002, the Philippines was the first country in Asia to have a GM crop admitted for marketing and cultivation, a maize variety containing an insecticidal trait derived from *Bacillus thuringiensis* (Bt). Until today, the country leads the cultivation of GM crops in Southeast Asia in terms of acreage (Polinag, 2020).

Many countries in the world are currently considering whether genome-edited plants created by the use of CRISPR technology are to be considered GMOs or not. Schmidt et al. (2020) showed a growing list of countries that have exempted such plants from GMO biosafety regulations provided the resulting plant products do not contain any foreign DNA. Argentina was the first country in the world to do so in 2015, and many other American countries have followed suit since then. The European Union and New Zealand are currently the only

two jurisdictions that have placed all genome-edited crops under existing GMO biosafety regulations, both as a result of court rulings. Many other countries in Europe, Asia and Africa are still discussing how to regulate genome-edited crops. The Philippines has recently finalised this process, choosing a two-pronged approach, deregulating the cultivation of crops that have been produced with NBTs but do not contain transgenic DNA. In 2018, a team of experts advised the government to change its biosafety regulations from being process-based, that is, regulating all products derived through genetic engineering, to one being product-based (Polinag, 2020). Two years later, the National Committee on Biosafety of the Philippines issued the 'Resolution on New Plant Breeding Techniques (NBTs) or Plant Breeding Innovations (PBIs)', which states that 'only PBI-derived GM plants and plant products would be regulated under JDC1 [the biosafety regulations]. Consequently, PBI-derived non-GM plants and plant products would not be regulated under the said Circular' (NCBP, 2020). A GMO is understood to 'contain a novel combination of genetic material obtained through the use of modern biotechnology (...) that is not possible through conventional breeding', whereas 'non-GMOs or conventional products (...) do not contain a novel combination of genetic material' (NCBP, 2020).

Schmidt et al. (2020) have argued that lower regulatory burdens for genome-edited products mean a cheaper and faster path to market, 'which assures that small and medium-sized enterprises and academic research institutes can afford to clear regulatory hurdles'. They added that 'If there is no need to generate revenue to pay for costly regulatory approvals, researchers can diversify the agricultural products and pursue humanitarian goals that do not generate profits'. This latter point becomes evident when looking at the costs for deregulating (getting approval for commercial release of) a GMO crop. Bayer et al. (2010) and Falck-Zepeda and Zambrano (2011) have looked at this for several countries including the Philippines and came to the conclusion that the total cost of compliance with biosafety regulations in the Philippines would range from U.S. \$100,000 to 1.7 million for a single product over its lifetime. The lower estimate applies for technologies and products already approved in other countries, allowing the developers to use data generated elsewhere which decreased costs. Even though the costs in low- and middle-income countries are generally substantially lower than in developed countries, they are still far out of reach of most public research organisations in these countries, not to mention farmer breeders.

Apart from the above costs for deregulating a GMO crop for commercial release, breeders have been confronted with many other costs that indirectly result from the application of biosafety laws. These costs relate, for example, to the careful management and monitoring of GMOs under development in order to ensure that unapproved traits do not escape into the environment or contaminate food chains. After several disputes and resulting fines of hundreds of millions to settle legal action (see, for example, Businesswire, 2011), the biotechnology industry has set up the Excellence Through Stewardship initiative to ensure responsible management of an agricultural biotechnology product 'from its inception through to its ultimate use' (Excellence through Stewardship, 2021).

Given the high financial and reputational risk for technology owners in case an unapproved GM technology escapes, these technology owners demand full compliance with the highest biosafety standards in any license to third-parties, further restricting the opportunities for less wealthy breeders to access and use such technologies in their own breeding programmes.

From the above, it appears that the impact of biosafety legislation on smallholder agriculture is severalfold. First, strict biosafety requirements and high environmental control standards will allow only few actors in the private sector to develop and market new products, including new crop varieties featuring novel traits stemming from the use of NBT. Public and private sector institutes in most countries will have insufficient funding to apply NBT or to obtain appropriate licenses for crops, varieties and agro-ecosystems that do not offer substantial returns on investments. As a consequence, only a narrow set of crop varieties incorporating NBT traits developed for big-scale commercial agricultural systems will be offered in the market. While many new crop varieties, in particular, in commercial crops, are offered in the form of hybrids, farmers need to buy new seed every growing season if they want to maintain the same yields. Second, if those conditions inspire farmers to breed their own new varieties from whichever source material they have access to, they may include commercial varieties that are protected by patent rights, causing litigation risks, and they may also include commercial varieties that have been genetically modified, causing biosafety risks once such farmers' varieties start to spread.

In most countries in the world, such practices are considered illegal. This is equally true for the Philippines. As many countries, the Philippines has in place a *sui generis* plant variety protection system and a patent system. The Philippine Plant Variety Act (Philippines, 2002) contains the breeder's exemption which allows the use of protected varieties 'for the purpose of breeding other varieties' (Section 43.c). In addition, this Act allows for the sale of farm-saved seed of a protected variety among smallholder farmers 'provided that the small farmers may exchange or sell seeds for reproduction and replanting in their own land' (Section 43.d). These two exemptions are, however, not included in the Philippine Patent Act (Intellectual Property Office of the Philippines, 2015), which—in practice—allows for the protection of both biotechnological processes and its products as explained above. With regard to the national biosafety regulations, biosafety permits need to be acquired for field trials, for commercial propagation and for direct use of any GMO (NCBP, 2014). So, only approved GMOs (i.e., formally registered GMO crop varieties that have received all biosafety permits) can legally be produced and sold in the market, and farmers who choose to grow the deregulated GMO crops need to adhere to product specific stewardship measures such as a refuge system for insect resistance management when growing maize containing a *Bacillus thuringiensis* trait.

Despite this legal situation, the below case study shows that smallholder farmers in the Philippines have bred and are growing farmer varieties that result from crossings with patent-protected crop varieties containing genetically modified traits.

5 | FARMER VARIETIES WITH A PATENT PROTECTED GM TRAIT IN MAIZE IN THE PHILIPPINES: A CASE STUDY

Maize is a major staple crop in the Philippines. In 2018, the production volume of maize in the Philippines was estimated at approximately 7.8 million metric tons (Statista, 2021). Next to rice, maize is to be considered as the second staple crop in the Philippines. White varieties are cultivated for human consumption, in particular, in the Visayas and northern Mindanao, whereas yellow varieties are grown for the purpose of animal feed, mainly in Luzon and the southern provinces of Mindanao.

The most important constraint in maize production in the Philippines is weed management (Croplife, 2020). Due to shortage of labour and frequent monsoon rains and high temperatures during the early growth period of maize, hand weeding is often impractical, delayed or neglected. As a result, severe uncontrolled weed infestations have been identified as one of the major reasons causing low maize yields. Actual losses due to weeds in maize fields have been reported at 15–30%.

Many smallholder farmers in the Philippines grow open-pollinated varieties of maize. An important feature of OPVs is that these can easily integrate new genetic information (i.e., genes) from other varieties grown in the neighbourhood by cross-fertilisation, whereas continuous farmer's selection allows the maintenance of the overall phenotype characterised by a limited number of major traits that characterise any given OPV, as reported from the centre of origin of maize, Oaxaca in Mexico (Louette, 1999). This same phenomenon has also been observed for the Tiniqub maize variety in the Philippines: while minor variations occur, the main features of the variety have remained the same for reportedly more than 100 years, although modern OPVs and hybrids are often planted next to this traditional variety. This capacity to continuously select for a desirable phenotype forms a very important technical basis for further breeding activities by smallholder farmers. Here, we report on a class of maize OPVs managed by smallholder farmers that emerged over the last decade and that have incorporated a herbicide-tolerance trait based on genetic modification. The maize OPVs containing the herbicide-tolerance trait are called *sige-sige* varieties. They are obtained from crossings between popular OPV varieties and modern hybrid varieties. *Sige-sige* is a term that captures a major characteristic of OPVs, which is that seeds from their harvest can be replanted for the next season. It loosely translates into 'on and on' or 'continual'.¹ The ability to use seeds from the harvest for next season planting is a most desirable trait for many smallholder farmers, in particular, under riskier growing conditions associated to terrain, quality of the soil, water stress challenges, distance from roads and peace and order problems, because commercial hybrid seeds are costly while OPV seeds can be produced and selected on-farm. *Sige-sige* varieties have previously been reported in the press (Davao Today, 2015), by the breeding sector

¹To be distinguished from *ukay ukay* seed which is counterfeit seed, including fake GM seeds containing the *Bacillus thuringiensis* trait.

(Tukasin Natin, 2018) and by researchers (Lucid, 2020). The distribution of these varieties and the reasons for their popularity, as well as their origins, form a showcase for smallholder farmers' breeding capacity.

As explained above, farmers participating in the FGDs brought sample cobs, allowing us to recognise distinct *sige-sige* varieties by shape, size and colour of the cobs and the kernels. From observing these samples, at least two distinct varieties of yellow *sige-sige* and up to seven varieties of white *sige-sige* could be recognised.

Whereas hybrid maize varieties may reach yields of 8 tons per hectare (Bertomeu, 2012; Manila Bulletin, 2020; Pioneer, 2012), *sige-sige* varieties tend to peak at 5 tons per hectare. However, farmers reported that *sige-sige* varieties need only 50% of the fertilisers needed for commercial hybrids, and so the production costs of *sige-sige* varieties are much lower. Since smallholder farmers need to save on costs for seeds and fertilisers given the risks they experience under their farming conditions, they therefore prefer the OPVs, including the *sige-sige* varieties.

Anecdotal reports, FGDs and key informant interviews with staff of public breeding institutions converge on the understanding that the first *sige-sige* variety was a yellow variety that was cultivated by farmers in the southern provinces of Mindanao from around 10 to 15 years ago, and from there arrived in the Northern provinces of Mindanao at eight to 10 years ago, still later spreading in Visayas 5 to 7 years ago. In these provinces, maize is cultivated as a cash crop for the feed industry. White *sige-sige* varieties appeared only later and spread from around 5 to 8 years ago in the central provinces of Mindanao, spreading quickly from there to the northern Mindanao provinces and from there to Visayas. In these provinces, white maize is cultivated as a staple food in lieu of rice. The same farmers that cultivate white maize also cultivate yellow maize types, mainly commercial hybrids, as a cash crop for animal feed.

Currently (referring to recent growing seasons until 2020), *sige-sige* maize varieties have become widespread, occupying an estimated 35 to 50% of maize farm lands in Mindanao in the South of the Philippines and in the central island provinces of the Visayas, an estimate based on farmers' information obtained in the FGDs in each of the provinces concerned. The Visayas and Mindanao share a total of around 1.2 million hectares of maize of the total 2.5 million hectares maize farm lands in the country, implying an overall share of *sige-sige* varieties in all maize fields in the country of 20% approximately. More in particular, according to farmers' estimates, yellow *sige-sige* varieties currently occupy 35–40% of yellow maize farm lands in the Visayas and Mindanao on average. In northern Mindanao, white *sige-sige* maize varieties occupy 50% of white maize farm lands approximately, equalling 25% of the total maize farm lands in northern Mindanao. In the Visayas, farmers in the FGDs estimated that of all farm lands planted with white maize, 80% approximately are planted to OPVs, of which half are *sige-sige*, amounting to a total of 40% approximately of all white maize farm lands. Whereas these figures are farmers' estimates and may not be accurate they do point to the widespread occurrence of these varieties. Little competition exists between the commercial maize hybrids and the *sige-sige* OPVs. The production

shares have not substantially changed since the full diffusion of the *sige-sige* varieties occurred. Both hybrids and OPVs are attractive under their own circumstances, that is, *sige-sige* varieties for poorer farmers in riskier areas, and commercial hybrids for richer farmers in better endowed areas.

Understanding how *sige-sige* varieties were created and where it 'started' appeared a challenge, since farmers tended to refer to other villagers and other provinces as the source, and public sector maize breeders were also not sure. However, most references seemed to point to communities in the province of Sultan Kudarat. In our analysis, anecdotal reports, FGDs and key informant interviews converge on the understanding that the first *sige-sige* variety was a yellow variety that was cultivated by farmers in the southern provinces of Mindanao from around 10 to 15 years ago and from there arrived later in the Northern provinces of Mindanao and in Visayas. White *sige-sige* varieties appeared only later and spread from around 5 to 8 years ago in the central provinces of Mindanao, further spreading quickly from there to the northern Mindanao provinces and from there to Visayas. The total number of yellow and white *sige-sige* varieties that could be observed in farmers' fields includes two different yellow and up to seven different white *sige-sige* maize varieties, based on the accumulated analysis in FGDs. It seems that at least the white *sige-sige* varieties are derived from various distinct white maize OPVs that served as maternal parents.

From discussions with farmers, confirmed by maize plant breeders from the University of Southern Mindanao, the following approach to the creation of *sige-sige* varieties could be reconstructed, and the parental varieties could be identified. In all cases, the starting point appeared to be a popular high-yielding OPV that acted as the maternal parent, *carabeano* for the yellow *sige-sige* varieties and *tiniquib* for the white. Farmers reported that in order to perform crossings female parent plants were de-tasselled to ensure cross-pollination, a concept that was properly understood. Herbicide-tolerant commercial varieties were used as the male parent. After two seasons of selection of the progeny under herbicide sprays, all surviving plants exhibited full herbicide tolerance. The new OPVs largely exhibited the maternal parent phenotype, but with the added herbicide tolerance trait. Nowadays, *sige-sige* varieties are also used as male parents to create new *sige-sige* varieties, since these already contain the herbicide tolerance trait.

Early adopters of the first *sige-sige* variety may have been to some extent aware of patent protection and biosafety regulations and therefore did not openly announce the new variety but opted for silent dispersal. However, it appeared that the difference between plant breeders' rights and patent rights was not clear. As explained above, the Philippine Plant Variety Act allows for the use, exchange and sale of farm-saved seed of a protected variety among smallholder farmers, as well as for the use of any protected variety for breeding other varieties. Yet, these flexibilities do not exist under the Philippine Patent Act. And while policy makers have claimed that 'In the Philippines you cannot patent living organisms' (on citation in Business Mirror, 2018), GMOs are being patented in the Philippines. Diffusion of the *sige-sige* varieties took place through informal sharing

of seeds of these new varieties between farmers and by sales in local markets. Whereas early patents on the use of the glyphosate trait conferring herbicide tolerance trait have now expired worldwide (Rüdelshiem et al., 2018), it seems evident that the first sige-sige varieties were developed before the patents had expired. As far as the authors are aware, no farmers have been prosecuted for patent infringement in relation to the development and use of the sige-sige varieties in the Philippines, nor for ignoring national biosafety regulations. However, in the media, seed companies have complained about the situation and demanded stricter legislation (Business Mirror, 2018). In response, it has been argued that the Philippines lack the manpower and financial resources to implement a proper biosafety liability and redress system (Polinag, 2020).

The outstanding feature of sige-sige maize varieties is their deliberate creation paired to their wide diffusion, a phenomenon which fits the concept of stewardship rather than ownership of plant genetic diversity which is shared by many smallholder farmers and the cultures in which they operate (Andersen, 2008; Visser et al., 2019). It is only logical to think that introgression of herbicide tolerance traits into farmers' OPVs, characterised by their free movement and exchange, may have also occurred in other parts of the world.

6 | REFLECTIONS ON THE IMPACT ON FARMER BREEDING

The study described above provides major lessons to policy makers, the breeding sector and smallholder farmer organisations. Below we address some major findings.

- The herbicide tolerance trait introgressed into the (resulting) sige-sige varieties renders these varieties genetically modified organisms (GMOs). Consequently, many concerns with the introduction and widespread use of intellectual property rights-protected GMOs also regard the sige-sige varieties, be it concerns from an environmental, health or power relations nature (Bequet, 2020; Maggi et al., 2020). The dependence that patents on genetically modified crop varieties legally create (e.g., no right to use the protected plants for further breeding) and the subsequent disregard for patent rights on the glyphosate tolerance trait on the part of the sige-sige variety creators is one of those concerns. The increased use of herbicides with disputed effects on the environment and human populations exposed to large-scale application of the herbicides, and the possibility of further distribution of such traits into the plant kingdom, are two other. The appearance and wide diffusion of sige-sige varieties pose powerful challenges both to proponents of genetically modified crops and to those opposing their cultivation. For many smallholder farmers, herbicide tolerance appears a desired trait since it provides for effective weed control, and concerns associated with genetic modification and large-scale herbicide use have apparently not prevented diffusion of the sige-sige varieties. Proponents of the use of genetically modified crops

may ask themselves whether the patent system protecting innovations is socially acceptable in cases where the protected crops are needed by poor farmers who cannot afford commercial seed prices due to riskier and more difficult farming conditions. Opponents may wish to increase efforts to offer environmentally sound alternatives answering farmers' needs. The question to be asked in this context is how the public breeding sector can better answer farmers' demands without relying on patent-protected traits created by genetic modification.

- Understanding the breeding process developed by the creators of the sige-sige varieties will help to inform future work aimed at supporting farmers' management of maize genetic resources and their contributions to the development of new germplasm. From the FGDs, it appeared that the farmers who developed the sige-sige varieties made many trials and errors. In general, every community may harbour one or more farmers who enjoy the process of selection and breeding. Some of these may have been seed farm workers turned breeders whereas others may have continued with their own breeding after having joined participatory plant breeding trainings. However, only few farmer breeders can afford sustained efforts and succeed in reaching their breeding goals, given that the discipline and means needed in breeding are substantial and challenges in effectively selecting plants from a progeny population are huge. A better understanding of the breeding processes characterising farmer breeding will highlight not only technical issues but also policy and regulatory conditions that need to be addressed in supporting farmer breeding.
- The widespread use of sige-sige varieties, if not unknown to, then poorly monitored by the Philippine authorities, suggests that biosafety issues may have not been properly considered and that potentially negative consequences from the uncontrolled distribution of transgenic crops stemming from the use of genetically modified traits in farmer breeding cannot be foreseen. Only the development of alternative crop varieties for smallholder agriculture not making use of transgenic traits can stem such unwanted consequences. In that context, it is remarkable that provincial and local branches of the governmental Philippine Crop Insurance Corporation accept insurance for sige-sige planted crops, in response to the popularity of sige-sige varieties, thereby tacitly and informally adjusting both its biosafety and seed marketing regulations, which only allow insurance on formally registered crop varieties.

7 | CONCLUSIONS

The following major conclusions can be drawn. The diffusion of sige-sige varieties in the Philippines over the last 15 years has been phenomenal. This success and the underlying farmers' efforts and approaches need recognition and support as well as protection, presenting a neat example of farmer-breeding and their underlying capacity to perform breeding. The emerging varieties form a response to the prevalent agro-ecological and socio-political conditions. Moreover, the substantial number of distinct sige-sige varieties also form

proof of smallholder farmers' capacity in plant breeding, and their emergence reflect the need of farmers for a wider and better adapted portfolio of varieties. Taking this example to heart, governments should support farmer breeding to create modern OPVs and options for market registration of the resulting varieties. The public breeding sector should play a major role in such developments and help filling the gap between the private seed sector's predominant focus on large-scale commercial agricultural systems and smallholder farmers' needs, which include the cultivation and use of many minor but locally important crops. Policies and regulations on the use of patent-protected traits in breeding should better balance the interests of commercial seed companies and those of public breeders and smallholder farmers seeking their own ways forward, and the negative effects of patented breeding materials on smallholder agriculture should be more carefully considered and repaired. In providing alternative, naturally occurring traits, negative biosafety consequences stemming from the unauthorised use of genetically modified traits in smallholder agriculture can be avoided.

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AUTHOR CONTRIBUTIONS

B.d.J, R.S. and B.V. jointly wrote the manuscript. B.d.J was in particular responsible for the research and information on the legal framework regarding biosafety and IPRs. R.S. carried out the field research in the Philippines concerning the spread of new farmer maize varieties. B.V. analysed the results of the field research.

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