4

The contribution of the seed sector to the triple challenge

The seed sector makes an important contribution to meeting the triple challenge facing food systems by supporting food security and nutrition, livelihoods, and sustainable resource use and climate change mitigation. But contentious issues related to plant breeding arise in debates around food systems. These include the role of private-sector investment in plant breeding; issues around access, benefit sharing and conservation of genetic resources for plant breeding; and the role of new plant breeding technologies. Building on the framework developed in this overall report, this chapter argues that many of the contentious issues derive from the interplay of disagreements over facts, interests, and values.

Key messages

- The seed sector will play an important role in both maintaining and increasing yields to feed a growing global population, while adapting to climate change and environmental pressures.
- However, the seed sector is struggling to navigate a number of contentious issues related to plant breeding that are based on scientific facts, the interests of specific groups and personal values.
- Whether an issue is based on facts, interests or values will affect how it is addressed by policy makers.
- Implications for policy makers include the need for a better targeting of policies, greater support for competition and development of strategies to support collaboration and coexistence between different approaches to plant breeding.
- In addition, to build trust and improve the uptake of new technologies, better communication tools are needed increase access to accurate information.

4.1. Introduction

As a key agricultural input, seeds play a fundamental role in meeting the triple challenge of improving food security and nutrition, supporting the livelihoods of farmers and rural communities, and contributing to sustainable resource use and climate change adaptation and mitigation. Efficiency gains and innovation are essential to improve the productivity, sustainability and resilience of food and agricultural production (OECD, 2019[1]), and innovations in plant breeding can play a particularly powerful role in addressing the triple challenge.[1]

Since the beginning of agriculture, farmers and breeders have been selectively saving seed that performs well to enhance breeding results, enabling gradual changes in agricultural crops to strengthen desirable traits such as yield, disease resistance, storage aptitude and other processing qualities (e.g. fibre length, oil content, flour quality) (Kingsbury, 2009[2]) (Rhode and Olmstead, 2008[3]) (Kloppenburg, 1988[4]).[2] Plant breeding has also enabled certain crops to adapt to broader climatic and geographic zones, expanding their cultivation and increasing their importance in food systems. The advent of modern plant breeding has dramatically accelerated the breeding process and enabled strong yield growth. High yielding varieties formed part of the new technologies developed and adopted by farmers during the Green Revolution beginning in the 1960s (Evenson and Golin, 2003[5]).[3] In recent decades, plant breeding has enabled agricultural crops to rapidly adapt to climate change, the evolution of pests and diseases and market preferences. This potential for adaptation and genetic improvement, driven by plant breeding, can help meet the triple challenge.

Progress in plant breeding, however, has not been entirely uncontested. Contentious issues include the perceived dominance of a handful of agribusiness firms; questions about access to and benefits from genetic resources; and the appropriate regulatory approaches to genetic engineering. Some stakeholders consider that the increasing privatisation of plant breeding, the development of intellectual property protection on plant varieties, and the high prices of modern varieties have negatively affected farmer livelihoods. Others have voiced concerns about the potential environmental effects of intensive farming practices (such as irrigation, crop protection chemicals and fertilisers) required by some of the high yielding varieties introduced during the Green Revolution, as well as about the potential biosafety of transgenic organisms. At the same time, many believe that the accessibility of high-quality seed is vital to support the livelihoods and resilience of farmers, and therefore advocate for government policies that enable the availability of a diversity of crops and varieties for growers, including those developed using the latest technologies.[4] Proponents of new plant breeding techniques such as gene editing also argue that these tools could play a key role in reducing carbon emissions and the use of agro-chemicals, thus supporting more sustainable agriculture. And while some emphasise the importance of developing formal seed markets, others have pointed out that informal farmer seed networks continue to play an important role in the developing world.[5]

Over the past few decades, disagreements over these contentious issues have been playing out in science, the media, and politics. There is no clear resolution to many of these disagreements, posing challenges for the seed sector to help meet the triple challenge. Sections 4.2 to 4.4 discuss in more detail how plant breeding and the seed sector more broadly can help food systems meet this challenge. Section 4.5 then discusses a number of contentious policy issues. Section 4.6 provides an interpretation of why seed policy questions are often contentious and explores potential policy approaches.

4.2. Food security and nutrition

The seed sector directly influences three dimensions of food security and nutrition: food availability, access, and stability. The seed sector contributes to food security and nutrition through productivity growth, improved resilience and quality improvement, allowing a greater availability of nutritious food at lower prices.

Historically, improvements in varieties have underpinned large gains in agricultural productivity and food availability around the world (Huang, Pray and Rozelle, 2002[6]). Experts estimate that between 1981 and 2000, improved varieties were responsible for 40% of the growth in crop production in developing countries (Evenson and Golin, 2003[5]) while in the United States, improved maize varieties were responsible for more than half of the sevenfold increase in yield between the 1930s and the present (Fernandez-Cornejo, 2004[7]). In the United Kingdom, increases in cereal yields since 1982 were mostly due to better varieties (Mackay, 2011[8]). Recent findings suggest that there is still considerable scope to increase crop yields through genetic improvement.[6]

In addition to the availability of calories, nutrition also depends on various micronutrients (FAO, 2019[9]). Increased yields due to plant breeding have contributed to the increased affordability of many nutritious crops, including fruits and vegetables. However, despite considerable advances in plant breeding and increases in yields, malnutrition remains a problem for poor communities in both developing and developed countries. One way plant breeding could help combat this is through biofortification (Osendarp et al., 2018[10]), a process that increases the density of vitamins and minerals (e.g. zinc, iron, and vitamin A) in a crop using either conventional breeding methods or genetic engineering. Current biofortification programmes target foods widely consumed by low-income families globally (such as beans, rice, maize, sorghum, sweet potato, cassava) (WHO, 2020[11]), including those in Africa, Asia, and Latin America. More than 15 million people in developing countries now grow and consume biofortified crops (Saltzman et al., 2017[12]). Future efforts in the area of biofortification are focused on strengthening the supply of, and the demand for, biofortified staple food crops and facilitating targeted investment to those crop–country combinations that have the highest potential nutritional impact (Saltzman et al., 2017[12]).[7]

Crops are vulnerable to various stresses, such as fungi, insects, or adverse weather conditions. Pests and diseases in particular are problematic, as these evolve over time to develop resistance to the natural defences of crop varieties. Spielman and Smale (2017[13]) argue that consistent varietal turnover rates are needed to sustain and stabilise yields over time by protecting crops from changing biotic and abiotic stresses.[8] As such, even where yields remain relatively constant, plant breeders play a crucial role in preventing yield decline caused by pests and disease and climate shocks. Rhode and Olmstead (2008[3]) have shown the historical importance of breeding in preventing a decline in wheat yields in the United States in the 19th century; they estimate that without the breeding of new pest and disease resistant varieties, wheat yields would have been 46% lower in the second half of the 19th century due to increasing pest pressures. Plant breeding and varietal turnover to protect against crop pests and diseases will only become more important in the future, given predicted changes in climate and the increasingly globalised trade in agricultural products. While trade makes an important contribution to food security, it also means that crop pests and diseases can readily cross international borders and multiply quickly (FAO, 2018[14]).

Plant breeding will also play a critical role in climate adaptation strategies (Rosegrant et al., 2014[15]). Changes in weather patterns are already affecting growing seasons and crop production, particularly in tropical regions (Access to Seeds Index, 2019[16]). These problems are expected to worsen as temperatures and extreme weather events increase (Challinor et al., 2016[17]). In addition, as the impacts of climate change become more severe and further threaten food security, it is likely that the poorest populations will suffer the most. For these communities, plant breeding that can create crop varieties with a greater resilience to extreme weather conditions will be particularly important.

Plant breeding innovations are only the first step in a long journey to the farm and finally to the fork. New characteristics need to be available to farmers in high performing varieties that are generally well adapted to the agro-ecological region where they will be grown. This requires not only breeding facilities, but also multiplication and distribution infrastructure for registered varieties. It also requires the provision of authentic, high-quality seed typically ensured through variety registration, seed certification (Box 4.1), and phytosanitary measures. Moreover, while plant breeding is an essential component of agricultural productivity growth in the developing world, complementary actions are required to ensure productivity growth, including improvements in fertilisers and pesticides, improved agronomic and livestock practices (in relation to crops used for feed), and major public investments in irrigation, roads, marketing systems, and land reforms (Hazell, 2009[18]).

Box 4.1. The OECD Seed Schemes

Since the 1960s, the OECD Seed Schemes has been certifying the varietal identity and purity of seed lots destined for international trade. As of 2020, 61 countries (both developed and developing) participate in the OECD Seed Schemes.

The Schemes facilitate the movement of high quality agricultural seeds across borders by harmonising certification standards and procedures. This harmonisation helps to improve domestic production, develop export markets, and provides farmers, plant breeders and authorities with reassurance as new markets open up. As such, many participating countries have now adopted OECD rules and regulations as part of their national laws.

The ultimate goal of the seed schemes is to ensure that farmers can trust the seed they are buying. In 2016-17, the OECD Seed Schemes certified 1.2 billion kg of seed, roughly a third (28%) of the total global exports of field crops (pulses, cereals, industrial crops and forages). Currently, over 60 000 varieties of agricultural crops are registered under the OECD Seed Schemes.

The OECD Seed Schemes form a key part of the international regulatory framework governing the seed sector and works in close co-operation with other international seed-related organisations.

Expanding farmers' access to breeding innovations remains a challenge. It is estimated that the 13 leading global seed companies together reach no more than 10% of the world's 500 million small farms (Access to Seeds Index, 2019[16]). Therefore, despite their potential, innovations may not immediately translate into increased farm productivity unless accompanied by policies that improve access, such as a better infrastructure in rural areas and a supportive environment for innovation and business (World Bank., 2019[19]). There is also a growing trend of participatory approaches to ensure that the improved varieties are meeting the needs of farmers (Westengen and Winge, 2020[20]).

4.3. Livelihoods

Numerous studies have shown that increases in the incomes of smallholder farmers can have an important impact on extreme poverty and that improvements in agricultural productivity therefore not only improve food security and nutrition, but also socio-economic development (Qaim, 2016[21]).

Under suitable production conditions, improved varieties can help increase farm income as the gains from greater production (or lower costs for other inputs) offset the cost of the seed itself. Access to new varieties of food staple crops is a well-documented method for increasing individual agricultural productivity, improving the quality of crops and ensuring resilience to pests and disease, thereby improving rural livelihoods (Spielman and Smale, 2017[13]). Some varieties, bred using genetic engineering or new plant breeding techniques, have the potential to also reduce the need for agricultural inputs such as fertilisers and pesticides, and to reduce harvesting costs by controlling plant height and ripening times, which affect the amount of labour/mechanisation used per hectare (Heisey and Fuglie, 2018[22]). Breeding can also have an important impact on the demand for agricultural products and prices paid to farmers: if new varieties are able to produce agricultural crops that meet certain quality standards (size, taste, colour), they can provide farmers with access to new markets and hence additional income.

Plant breeding can also help to increase resilience to environmental stress. Varieties with greater drought tolerance in particular can help farmers adapt to changes in water availability. Drought-tolerant sugarcane cultivars are being developed in several countries, including Brazil, India, and Indonesia. The Water Efficient Maize for Africa (WEMA) project is developing drought-tolerant varieties with the intention to make these available royalty-free to smallholder farmers through African seed companies (Oikeh et al., 2014[23]). However, it is worth noting that increased resilience to adverse growing conditions may come at the cost of lower yields under good growing conditions.

Despite the potential benefits, the world's poorest farmers may be reluctant to adopt new varieties as the costs of modern varieties and complementary inputs (e.g. irrigation, pesticides and fertilisers) may be significantly higher than their previous production practices and agricultural inputs, and as they may be concerned about risks (e.g. crop failure).

It is also worth noting that widespread agricultural productivity growth does not necessarily boost aggregate farm incomes, as higher productivity also tends to lower prices. Due to global productivity growth outstripping global demand growth, there has been a long-run decline in real cereal prices since at least the early 20th century, albeit interrupted by occasional periods of volatility (OECD/FAO, 2019[24]). Historically, the main beneficiaries of productivity growth in agriculture have therefore been consumers, who enjoy lower food prices due to the decline in commodity prices. The overall impact on farmers is more ambiguous, as declining commodity prices present a challenge for farmers who fail to achieve productivity growth (Alston, 2018[25]). On the other hand, as economic development reduces the number of people working in agriculture, remaining farmers who manage to increase productivity may see gains. Moreover, in poor countries farmers and others working in agriculture may often be net buyers of food, and may hence benefit from lower food prices.

In summary, plant breeding can deliver important gains for farmers, boosting productivity and improving resilience to climate shocks, pests and disease. However, the effect on farmers' livelihoods is more ambiguous: productivity growth reduces prices, putting pressure on farmers who do not achieve productivity gains.

4.4. Environmental sustainability

As discussed in Chapter 1, crop production can be increased in three main ways: through greater land use, through greater use of agricultural inputs, or through improved agricultural productivity. Agricultural expansion onto new lands and the increased use of agricultural inputs can have considerable, negative environmental consequences depending on the land, inputs and context. Plant breeding is one of the main tools available to the agricultural sector to achieve greater agricultural productivity, and hence deliver positive outcomes for sustainable resources use and climate change mitigation.

By helping farmers achieve greater yields, plant breeding may help reduce the expansion of agricultural land, thereby reducing land use change (LUC) and the resulting greenhouse gas emissions and preserving natural biodiversity. This is particularly important in regions where the expansion of agricultural land involves the conversion of carbon rich and biodiverse landscapes (IPCC, 2019[26]). Plant breeding and genetic modification of grazing crops also has the potential to improve the quality of pasture and feed and the feed conversion efficiency of ruminant livestock. This leads to a decrease in methane emissions while reducing the need for more land use for the production of animal protein (Herrero, M. et al., 2016[27]).

Studies have shown that increases in productivity attributed to the Green Revolution were land saving at the global level, helping to protect millions of hectares of natural habitat (Villoria, 2019[28]). However, yield growth is necessary but not sufficient for land saving. For example, yield growth in lower-yielding countries may stimulate extra investment in agriculture, perhaps leading to a partial relocation of production from relatively higher-yielding parts of the world to those lower yielding countries. This may paradoxically result in increased deforestation and environmental damage if the right environmental safeguards, such as capping or regulating land use and training in Good Agricultural Practices (GAP), are not put in place (Hertel, Ramankutty and Baldos, 2014[29]).

The high yielding varieties of the Green Revolution work best with well-irrigated and fertilised soils. Some of the varieties developed during the Green Revolution were also more susceptible to pests and diseases, and farmers used additional pesticides to ensure maximum yield (Foley et al., 2011[30]). The intensive use of these inputs in some regions led to biodiversity loss as well as soil and water pollution (Khoury et al., 2014[31]) (Pingali, 2015[32]).[9] However, when suitable incentives exist, new plant breeding offers important opportunities for reducing water, fertiliser and pesticide use by improving input efficiency (Voss-Fels et al, 2019[33]).[10]

The seed sector also has an important role to play in the conservation of plant genetic resources (Euroseeds, 2020[34]). Genetic diversity is an important element for populations to adapt to changing environments, such as climate change (López-Noriega et al., 2012[35]) (FAO, 2015[36]).[11] These conservation issues are discussed in more detail in Section 4.4.

Although COVID-19 is currently creating disruptions in the sector (Box 4.2), the seed sector has an important role to play in meeting the triple challenge. The FAO Commission on Genetic Resources for Food and Agriculture recommends strengthening both formal and informal seed systems to improve the availability of and access to quality seeds of a diverse range of adapted crop varieties to achieve food and livelihood security, especially in developing countries. The role of the seed sector will differ by region or country, depending on differences in level of development, regulatory frameworks, infrastructure, and access to markets. Developing countries are increasingly involved in the global seed industry as both producers and users of new varieties.

Box 4.2. The impact of COVID-19 on the seed sector

A seed lot can be expected to travel through several countries for multiplication, production, processing, and packaging before it reaches a farmer. It is also time sensitive, with defined periods for sowing and harvesting different crops. As such, the necessary restrictions on movement and transport put in place by governments to protect their people from COVID-19 have the potential to seriously affect the production, certification, distribution and cost of seed. This presents a problem for all countries, but is likely to have a greater impact in developing countries, which may be particularly hard hit by the economic down-turn and relatively more reliant on agriculture.

The classification of the agriculture sector as “essential” in all countries is important in order for the continued production and movement of seed, and avoiding changes to regulatory frameworks is critical at a time when relevant authorities are short staffed and under pressure (OECD, 2020[37]). In order to successfully support the seed sector through this unprecedented crisis, policy makers need greater visibility over seed breeding, production, certification and trade.

OECD’s Trade and Agriculture Directorate, in collaboration with the Japanese government, is in the process of analysing the resilience of the international seed market during the COVID-19 pandemic, including a case study of the Asian seed market. In addition, following in the footsteps of the Agricultural Market Information System (AMIS) developed in response to the global food price hikes in 2007/08 and 2010, OECD will work to develop a digital seed information system that provides countries with greater visibility over seed production, certification, and potentially flows.

4.5. What are the contentious issues?

As highlighted in the previous section, plant breeding plays a critical role in meeting the triple challenge. However, the seed sector is struggling with a number of contentious issues. These issues are closely interconnected, but for the purpose of this case study, they will be explored under the following headings:

- Sources of investment in plant breeding
- Access, benefit sharing and conservation of genetic resources for plant breeding
- Modern plant breeding technologies.

As discussed in Chapters 1 and 2, in designing coherent policies for the global food system, one challenge lies in mediating trade-offs. In the case of the seed sector, an additional challenge is that there is debate over whether some issues pose a trade-off or not. For example, certain stakeholders perceive that genetic engineering of plants creates risks to human and environmental health, as well as increasing corporate control over the food chain (Bonny, 2017[38]). From this perspective, the use of transgenic crops comes with important (and to some, unacceptable) trade-offs. This perspective is far from universally shared, however. Contentious issues in the seed sector thus illustrate that there is not necessarily a consensus on what constitutes a trade-off in the global food system. Whether an issue is seen as a real trade-off or not will in turn affect how it is addressed by policy makers.

Much of the information in this section was provided by the National Designated Authorities to the OECD and observer organisations to the OECD Seed Schemes.[12] Stakeholders were invited to provide feedback on an OECD questionnaire.

Sources of investment in plant breeding

Historically, the public sector played a dominant role in plant breeding, but considerable shifts in funding have taken place over the past 60 years. Despite significant and demonstrated benefits to society, actual public sector spending on agricultural research is decreasing, particularly in developed countries (OECD, 2019[39]) (Heisey and Fuglie, 2018[22]) (Clancy, Fuglie and Heisey, 2016[40]). At the same time, intellectual property rights protections and other incentives put in place by governments have stimulated private sector R&D in plant breeding (OECD, 2019[39]) and research in high-income countries is increasingly undertaken by companies (Heisey and Fuglie, 2018[22]).[13] A review of agricultural innovation systems undertaken by the OECD in 2019 found that funding mechanisms for agricultural research have also changed, with processes for obtaining public funding becoming more competitive and with an increased emphasis on public-private collaboration (OECD, 2019[39]).[14]

As an illustration of the relative importance of private and public investments, in 2017, Monsanto's annual research budget was USD 1.6 billion (Monsanto, 2017[41]), while the CGIAR (formerly the Consultative Group on International Agricultural Research), one of the main intergovernmental initiatives to support agricultural innovation and breeding for developing countries, had an annual budget of USD 849 million (CGIAR, 2017[42]).[15]

A potential trade-off associated with this shift from publicly to privately financed R&D is that private-sector investments are likely to be skewed towards crops with larger commercial markets; to traits preferred by manufacturers, retailers and consumers; and to qualities that are conducive to intellectual property protection such as hybridisation. Investment in crops with larger markets potentially comes at the expense of investments in crops with smaller markets, or traits that are useful but more difficult to monetise. A different concern is the legal uncertainty associated with the regulatory frameworks to stimulate private-sector innovation, such as Plant Variety Protection (PVP) and seed marketing regulations. Any uncertainty around the application of PVP may affect farmers' ability to save seed, particularly in developing countries where farmers may rely on saved seed to reduce input costs and because of limited access to formal seed markets (FAO, 2018[14]). [16]

OECD country reviews of innovation, agricultural productivity and sustainability systems have identified a number of intellectual property mechanisms that support private sector investments in innovation, including PVP, patents, trade secrets, trademarks, and geographical indications (OECD, 2019[39]). This case study will look specifically at the benefits and challenges presented by PVP and patents.

The direction of plant breeding

The public and private sector dominate in different regions and crops (Areal and Riesgo, 2014[43]) (Gustafson, 2016[44]). For example, while maize breeding is usually led by the private sector, many grains with small markets are the domain of the public sector. The public sector increasingly focuses on fundamental research, or on crops for which little private sector interest exists (Heisey and Fuglie, 2018[22]). For example, the Swiss market is small and fairly specific due to the country's size and topography, limiting private sector investments in plant breeding tailored to the needs of Swiss farmers. In response, the government developed a new strategy for plant breeding to support information and technology exchange and breeding of key crops (Federal Office for Agriculture, 2015[45]).

As governments have put in place PVP frameworks to incentivise the private sector to assume a greater proportion of breeding, private research efforts have naturally shifted to those crops that deliver the greatest profits at the expense of those crops that do not.

Larger commercial markets tend to attract more investment and are hence likely to witness faster innovation. Analysis of European seed markets found that a 10% increase in total market size (as measured in revenues) was associated with an increase of 4-5% in the number of new varieties introduced per year (OECD, 2018[46]).[17] For example, if the market for barley seed in Germany grew by 10%, this would on average be expected to raise by 4-5% the number of new barley varieties introduced each year in the market. This finding also implies that if the commercial market for a crop is smaller, it will receive less R&D and hence see less innovation over time.

Crops with smaller markets may not receive much private investment or plant-breeding effort, despite their importance in terms of genetic diversity and their potential in terms of food security or livelihoods in some parts of the world. Such crops have been labelled “underutilised,” “neglected,” “minor” or “orphan” crops. For example, root, tuber and banana crops have received limited attention from researchers, extension service providers and policy makers, but are important staple crops in some of the world’s poorest regions. Strengthening research in such neglected and underutilised crops could thus have a significant impact on malnutrition. In some cases, the commercial potential of such crops goes unrealised because of a lack of scientific knowledge or recognition of the potential benefits of the crop downstream (e.g. food security and nutrition), a lack of knowledge of how to adapt the crop to consumer markets, or market imperfections and failures (Gruère, Giuliani and Smale, 2006[47]).

The same is true for investments in developing specific traits. For example, a surprisingly large share of agricultural R&D is undertaken by consumer goods manufacturers such as PepsiCo, Kraft Heinz and Nestlé.[18] Such firms made up 44% of the total developed-country private agricultural R&D in 2011. Pardey et al. (2016[48]) and Gopinath et al. (1996[49]) suggest that these companies are keen to invest in agriculture because abundant, low cost raw materials deliver productivity growth in food processing. R&D funded by these firms is thus likely to focus on the development of varieties that feed into their processed food supply chains. By contrast, private-sector investment is less likely for traits with hard-to-monetise benefits, such as those that would improve environmental sustainability of farm production.

Moreover, even in otherwise profitable markets some geographic or agronomic niches may be too small for profitable private-sector involvement. For example, even though the US maize market is the largest seed market in the world and attracts considerable commercial investment, there are several niches that receive little attention. This is the case for silage maize in New York, Pennsylvania or Wisconsin and for white kernel maize in Texas.[19]

A particularly pressing concern is that current levels of private-sector investment may not be sufficient to provide the innovation needed for crops in developing countries. Knowledge spill overs from developed countries to developing countries are limited due to variations in agro-environmental conditions: breeding for temperate climates will have fewer applications in tropical climates, and vice versa. In addition, the kind of production constraints experienced by farmers in developing countries are very different from those in developed countries (Heisey and Fuglie, 2018[22]).

Smaller, national or regional companies in developing countries may be better placed in terms of breeding of crops to meet the needs of local farmers due to better knowledge of local conditions and crops and closer relationships with local and regional research and development organisations (Gustafson, 2016[44]).

The Access to Seeds Index highlights the relative absence of seed company activity in certain countries, attributing this absence to poor infrastructure and a weak enabling environment for businesses (Access to Seeds Index, 2019[16]).[20] However, some of the leading multinationals are increasingly active in the emerging commercial seed markets in Africa, in particular through purchasing and investing in local companies (African Centre for Biodiversity, 2015[50]). In recent years the seed industry also seems to have demonstrated a more responsive approach toward smallholder farmers (Access to Seeds Index, 2019[16]). In India, the commercial seed sector is growing at more than 10% per year (Spielman, D. et al., 2014[51]). Despite this growing interest, large multinationals may fail to cater to developing country needs and local markets, limiting themselves to certain crops (e.g. maize) and breeding strategies (e.g. hybridisation) that offer greater profits and biological means to protect intellectual property.[21] In India, private-sector investment has focused on cotton, maize, pearl millet, sorghum, and vegetable crops where hybrids are possible (Spielman, D. et al., 2014[51]).

Even though investment in agricultural R&D is still highest in developed countries, this trend is shifting. World Bank figures show that public and private expenditures on agricultural R&D in high-income countries fell from 69% of the global total in 1980 to 55% in 2011. Meanwhile, middle-income countries (including the Peoples Republic of China – hereafter "China", Brazil and India) were responsible for 43% of global spending on agricultural R&D; up from a share of only 29% in 1980 (Pardey et al., 2016[48]). Heisey and Fuglie (2018[22]) argue the world may become more dependent on the public sector research of countries like China, India, and Brazil when it comes to the innovation needed to address food and environment challenges, and plant breeding in these emerging economies may enable greater spill overs to developing countries that have similar climatic zones.

One risk associated with underinvesting in plant breeding for certain varieties and climatic zones is vulnerability to pests and diseases. An example is the emergence of new virulent strains of wheat stem rust in Uganda in the late 1990s, and their subsequent spread throughout Kenya, Ethiopia, South Africa and elsewhere in Africa. Years of previous success in keeping the disease at bay meant that research funding was no longer targeted at the disease, leaving only a few researchers left to tackle the crisis (Pardey et al., 2016[48]).

A number of mechanisms have been put in place across OECD countries to capitalise on the benefits of both private and public sector funding and ensure more equitable benefits from innovation (OECD, 2019[39]). The central challenge is that while PVP and patenting may incentivise private funding of plant breeding, broad and easy access to the innovation is subsequently limited by higher prices. On the other hand, if R&D is financed by the public sector, the innovation could be made available more cheaply, but this requires the use of public funds and raises the question of whether innovation will be demand-driven. Public-private partnerships (PPPs) can under the right circumstances combine the best of both approaches. Moreddu (2016[52]) finds that PPPs are essential to increase the efficiency with which public funds are used, and improve the adaptation of innovation to demand, leading to wider diffusion. Intellectual Property Rights (IPRs), governance and implementation issues need to be carefully considered to ensure success. Areal and Riesgo (2014[43]) found that in Europe, PPPs mainly focus on strategic crops for the European market and on strategic traits (e.g. climate change adaptation, food security and biofuels). That said, PPPs also tend to focus on foundational technologies and pre-breeding and do not follow through to the development of new varieties. They may also pay limited attention to minor crops. For Canada, Phillips, Boland and Ryan (2013[53]) found that PPPs in plant breeding often required extended public sector funding, as it takes about 15 years to generate an independent cash flow (e.g. through royalties).

Heisey and Fuglie (2018[22]) explored the potential role of private sector levies in better addressing the needs of farmers. In Canada, the Saskatchewan Pulse Growers (SPG) scheme includes over 18 000 pulse producers. The scheme imposes a mandatory 1% levy on the value of the gross sale of all pulse crops and uses revenues to fund various research projects, provide royalty-free seed and carry out agronomic research. The SPG has been very successful at working with both academic and private plant breeding institutions. As such, pulse yields have increased by 40% in two decades and the internal rate of return on SPG investments has been estimated at 20% per year. Levy-funded research holds some important benefits compared to completely private or completely public R&D, including encouraging adoption by farmers. The levy is based on farmers' total output (regardless of the varieties used). In the case of new varieties, the levy may be zero, to encourage farmers to experiment and adopt new, improved varieties more quickly and at a lower cost than with the private system. As farmer associations direct the work, farmers have a greater voice in the process, which helps ensure they will benefit. While this may ensure that research responds to farmer needs, it may assign a lower priority to innovations which mainly benefit consumers or the environment.

Access and use of seeds for farmers and breeders

Farmers

Ensuring access to improved varieties in developing countries often proves difficult for a range of reasons, including poor infrastructure and distribution channels; weak regulatory frameworks for seed companies; low private and public investment (as discussed above); lack of harmonised legislation to facilitate the movement of seeds between countries; a lack of complementary inputs (e.g. fertiliser); or a lack of capacity to make use of agricultural technologies (Access to Seeds Index, 2019[16]). A persistent concern is whether the privatisation of plant breeding limits agricultural innovations from reaching the world's poorest farmers.

Many farmers in the developing and developed world rely on informal systems of seed exchange among farmers, rather than the formal seed sector (i.e. public and private plant breeding and seed production) (van Etten, 2017[54]). The use of improved varieties (mostly channelled by the formal seed sector) is closely linked to the development of the agriculture sector as a whole, including adoption of modern agronomic practices by farmers. A number of developing countries have undertaken policy and regulatory reforms to strengthen the formal seed market, and such efforts have been supported by the private sector, developed country governments and aid organisations. These reforms encourage investment by plant breeding companies and can improve farmers' access to new varieties in developing countries.

However, in the context of the triple challenge, policy and regulatory reforms may, at least initially, be a poor fit for domestic smallholder agriculture and be better adapted to large-scale, export-oriented sectors. In this case, immediate benefits may be seen at the national level with regard to trade and export earnings but improved productivity from new high-yielding and disease-resistant varieties may be slower to materialise for the majority of domestic farmers who continue to use informal seed systems. It takes time for the benefits to trickle down to local farmers and this raises questions regarding how policy reforms can be better tailored to maximise their impact for those most in need.

Some stakeholders have voiced concerns that IPR frameworks designed to increase private sector investment in plant breeding limit farmers' access to seed through restrictions on farm-saved seed (FAO, 2018[14]). IPR protection for new plant varieties has emerged gradually. Historically, plants were not covered by any form of patent and were considered products of nature. However, developing a new variety is a costly and time-consuming process: a common rule of thumb in the industry is that it takes more than ten years to develop a new field crop variety, with even longer processes for tree crops. In the absence of government subsidies or grants, plant breeders need an effective intellectual property protection system to enable them to capture the financial benefits from their investments. Over time, this has led to the emergence of a system of IPR protection for plant varieties. The system of IPRs for new plant varieties is mostly *sui generis*, that is, a system distinct from the patent system governing most other innovative industries. As with other IP systems, PVP presents a trade-off between providing incentives for innovation (which would suggest allowing the inventor to charge users) and stimulating adoption (which would suggest making the invention available as cheaply as possible).[22]

An international PVP system was established by the International Union for the Protection of New Varieties of Plants (UPOV) through successive revisions of its International Convention for the Protection of New Varieties of Plants, or UPOV Convention. 23 The original convention (adopted in 1961) was revised in 1972, 1978 and 1991. There are currently 76 members of UPOV, mostly in the developed world, but the differentiated implementation of the various UPOV Acts by countries can create confusion. The first UPOV Convention (the 1961 Act) and the 1978 Act allowed governments to permit farmers to save seeds of varieties covered by Plant Breeders' Rights (PBR), as long as it was not done for the production of seed for marketing. The 1991 Act of the UPOV Convention further clarified permission through two exemptions. The first allows for private and non-commercial use of seeds by subsistence farmers (who only produce enough food for their own consumption) and hobby gardeners, whose activities are considered private and non-commercial. The second exemption allows countries adhering to the UPOV Convention to permit seed saving by farmers "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder" (FAO, 2018[14]) (ISF, 2012[55]). In the United Kingdom, for example, farm-saved seed is allowed, but an industry-wide system exists for the collection of royalty payments on farm-saved seed. Royalty levels for farm-saved seed are lower than royalty rates on certified ("new") seed. The system applies only to newer varieties (BSPB, 2014[56]).

Despite the private and non-commercial use exemption in the UPOV convention, NGOs have voiced their concern that plant breeders' rights modelled after the UPOV Acts may be preventing the world's poorest farmers from having access to new varieties. A related concern is that, without further clarification of the private and non-commercial use exception, such legislation may prevent farmers from saving, using, exchanging and selling farm-saved seeds. Such concerns were for instance expressed by Oxfam during an FAO symposium (FAO, 2018[14]). Oxfam also expressed concern that the UPOV Convention prevents its adherents from aligning their PVP law with other international obligations under the Convention for Biodiversity and the International Treaty for Plant Genetic Resources for Food and Agriculture.[24] Oxfam called on UPOV to "establish a proper and explicit balance between Farmers' Rights and Plant Breeders' Rights in order not to obstruct the practice of seed exchange and trade amongst smallholder farmers", for example by "providing a clear interpretation of the private and non-commercial use exemption… to assist (prospective) member states to include such interpretation in their national legislation" (FAO, 2018[14]). Following the symposium, Oxfam, Plantum and Euroseeds developed a flowchart to help users understand whether or not an activity using self-produced seed is covered by the exception (Oxfam, Plantum and Euroseeds, 2019[57]).[25]

While the TRIPS Agreement requires WTO members to implement a *sui generis* plant variety protection system, there is no obligation to adopt the UPOV convention or to adopt the most recent (1991) Act. Alternative PVP systems have emerged in some countries, including India, Ethiopia, Thailand and Malaysia, while Norway decided to remain an adherent to the 1978 Act of the UPOV Convention (rather than updating to the 1991 Act) as it was considered to be more supportive of Farmers' Rights (Government of Norway, 2018[58]), while in India, PVP and Farmers' Rights are addressed in the same Act (Ramanna, 2006[59]). Alternative systems may also include a requirement for the disclosure of information on the geographical origin of genetic resources as a way to fulfil policy objectives linked to monitoring the utilisation of genetic resources.

Notwithstanding the concerns of some NGOs, an impact study carried out by UPOV identified a number of positive changes that took place following adoption of PVP across a range of countries (Argentina, China, Kenya, Poland and Korea). These changes included availability of new foreign plant varieties; diversification of agriculture and horticulture systems; stimulation of commercial breeding activities in domestic public research institutes and domestic seed companies, leading to an increase in the number of domestic breeders; an increase in domestic breeding and domestically bred varieties; and rapid adoption of new protected varieties by farmers. The study also noted an increase in collaboration between national research institutes and foreign seed companies and more public / private partnerships for plant breeding (UPOV, 2005[60]).

Plant breeders

Intellectual property rights enable firms to recover their investment by preventing competitors from making use of an innovation for a limited period of time. The challenge however is to provide incentives for private investment in innovation, without compromising the sharing of knowledge and further innovation. In most countries, there are two main types of IPRs used in plant breeding: patents for genetic traits and PVP. The UPOV system of PVPs addresses the issue of innovation through the "breeder's right". It gives the developer of a new variety the right to exclude others from commercialisation, but allows researchers to use the variety for further breeding research. Genetic traits such as herbicide resistance, however, are subject to patents, which generally provide less opportunities for further research.

Patents on genes, genetic processes, and genetically engineered plant varieties have been concentrated among a handful of large multinational companies (Clancy and Moschini, 2017[61]). Markets for genetically engineered traits are considerably more concentrated than the underlying seed markets (OECD, 2018[46]) (Deconinck, 2020[62]). This raises concerns about the impact of market concentration on innovation as well as market power and unequal benefit distribution (Stone, 2010[63]). It has also led to broader worries about the influence of a relatively small group of companies on food supply chains and public sector processes, such as risk assessments (Fernandez-Cornejo and Just, 2007[64]).

There is relatively little evidence available on the impact of market concentration on innovation in the seed industry (OECD, 2018[46]). This presents a barrier to overcoming public concern, as an informed policy debate requires detailed information. OECD (2018[65]) emphasises the importance of having precise data when discussing issues of market concentration and power, noting that publicly available data is often highly aggregated and may present a misleading picture in view of important variations by crop and by country. However, detailed data on market shares in different countries and market segments are typically not available in the public domain.

IPRs, combined with the large amount of knowledge and expertise required to set up a breeding company and the long development period for new varieties, creates a barrier for new companies to enter the plant-breeding sector. However, new plant breeding techniques (discussed in more detail below) may enable smaller companies to enter the market because of their speed and lower costs. For example, there are an increasing number of CRISPR biotechnology companies emerging from academic institutions (Brinegar et al., 2017[66]). Institutional innovations can also help facilitate access to intellectual property in the sector. For example, a number of vegetable breeding companies founded the International Licencing Platform (ILP), under which they grant each other access to patents to encourage innovation (ILP, 2020[67])

Access, benefit sharing and conservation of genetic resources for plant breeding

Maintaining crop genetic diversity is important both as an input into plant breeding (to ensure there is sufficient genetic material from which to select) and as an output (to ensure crop adaptation potential in the face of climate change, pests and diseases). Most countries now grow food crops which originated in other countries or continents (Khoury, C. et al, 2016[68]). Wild ancestral relatives or landraces which could be useful in plant breeding are therefore likely to be located outside of national borders (ISF, 2012[55]) (BSPB, 2014[56]). This raises questions about how to ensure access to genetic resources, how to stimulate the preservation and sustainable use of genetic diversity, and how to organise benefit-sharing arising from the use of genetic resources, some of which may be the result of centuries of cultivation efforts by farmers.

Bioprospecting is the process of searching for and discovering biological resources such as plants, animals or fungi that can then be used to develop valuable commercial products, such as new plant varieties or medicines. However, this may also be referred to as biopiracy when it is felt that researchers and companies have made use of biological resources without official agreement or sufficient compensation, particularly from developing countries and rural communities that have been conserving them. To ensure fair access and benefit sharing from plant genetic resources, a number of international policies and regulations governing the conservation, exchange and use of genetic resources have emerged over the past 70 years. These have created a complex regulatory landscape. The two main international agreements are the Convention on Biodiversity (CBD) (and its supplementary agreement, the Nagoya Protocol) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

The CBD entered into force in 1993 and recognises sovereign rights over genetic resources and the authority of national governments to determine access to those resources, as well as tasking governments with the responsibility of preserving that genetic diversity.

The Nagoya Protocol is a supplementary agreement to the CBD, which entered into force in 2014 and establishes a framework for "fair and equitable sharing of benefits arising out of the utilization of genetic resources”. Those countries that have adopted the Nagoya Protocol commit to setting up a transparent, non-arbitrary process for access to genetic resources and sharing benefits domestically. The Nagoya Protocol also sets up an “Access and Benefit Sharing Clearing-House” to share information on topics such as domestic regulatory ABS requirements.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) entered into force in 2004. This treaty focuses on setting up a system of access and benefit sharing for a specific list of 64 crops (known as “Annex I” crops) used in food and agriculture. These 64 crops include the major food crops (e.g. rice, maize, wheat, potatoes) but exclude some other major agricultural commodities, notably soybeans.

In terms of access, countries ratifying the ITPGRFA agree to make available their genetic diversity as well as information about the crops stored in gene banks. Under the ITPGRFA, material in local, national and international gene banks, including the collections of the CGIAR, are put in a Multilateral System for Access and Benefit-Sharing. Genetic material is made available to users (e.g. plant breeders) under terms and conditions of a Standard Material Transfer Agreement (SMTA). This is a private contract with standard terms and conditions that ensures that the relevant provisions of the International Treaty are followed.

Both the Nagoya Protocol and the ITPGRFA target conservation and sustainable use of plant genetic resources as well as the equitable sharing of benefits arising from their use. The ITPGRFA is recognised as a specialised instrument in the Nagoya Protocol and is limited in scope to the specific list of crops mentioned earlier, while the Nagoya Protocol extends to all other plant genetic resources for food and agriculture.

Article 9 of the ITPGRFA specifically recognises the contribution that farmers have made towards the conservation and development of plant genetic resources. An Ad hoc Technical Expert Group on Farmers’ Rights, established by the governing body of the ITPGRFA, has produced an inventory of examples on how to strengthen the implementation of Farmers' Rights and is currently developing options for encouraging, guiding and promoting the realisation of Farmers’ Rights.

Access and benefit sharing

Given that access to genetic resources is key to plant breeding, both civil society and industry groups have expressed concern that the different legal frameworks are not working in harmony. While PVP and plant breeders’ rights have been integrated into national laws and international trade, there is concern that aspects of the ITPGRFA (and in particular the concept of farmers’ rights) have not.

During the period from 2013 to 2019, the Contracting Parties of the ITPGRFA discussed options to enhance the multilateral system of Access and Benefit Sharing. They considered proposals, among others, to make all use of material from the system conditional on mandatory monetary benefit sharing, and to expand the coverage of the system. The International Seed Federation (2012[55]) in particular has suggested delegating the Access and Benefit Sharing responsibilities for all genetic resources for plant breeding to the authority managing genetic resources under the ITPGRFA, arguing that it makes the process more user-friendly. One possibility could be to expand the list of crops in Annex I to cover all crops where breeding occurs, as well as other genetic resources used in breeding these crops (ISF, 2012[55]). However, no consensus was reached at the last session of the Governing Body.[26]

Since its introduction, the ITPGRFA has enabled 4.2 million exchanges of genetic material through almost 60 000 Standard Material Transfer Agreements. The largest share of genetic resources (2.1 million accessions) are from Latin America and the Caribbean, and most of the genetic resources have gone to Asia (1.3 million accessions) (FAO, 2017[69]).[27] All regions are both recipients and sources of germplasm, illustrating the interdependence among countries in terms of genetic resources.

The CBD and ITPGRFA are designed to protect biodiversity and communities, and ensure fair access and benefit sharing. However, the complex interactions between the different treaties and conventions are difficult to navigate and may be particularly burdensome for farmers, breeders and regulators in developing countries. This may jeopardise the international exchange of plant genetic resources.[28]

Another challenge comes from technological developments. While current governance of genetic resources is based on access to physical material, the treaties do not cover genetic information. For example, digital sequence information (DSI) uses computational models to predict and identify when certain genes are expressed. This can significantly improve the efficiency of selection, and can also be used to explore the presence of beneficial genes in underexploited gene banks. However, these new technologies present new challenges to policy makers. The terms and conditions for access to genetic resources and benefit-sharing mechanisms under existing frameworks do not apply to DSI, when DSI is not associated with a physical resource. (Halewood, M. et al., 2018[70]) (Welch, E. et al, 2017[71]). The application of these existing legal access and benefit-sharing frameworks to DSI could create significant costs for plant breeders, and act as barriers to much needed research (Marden, 2018[72]).

Conservation

There is additional concern that, as farmers around the world transition from local varieties to bred varieties with improved productivity and resilience, varietal diversity for certain crops will decrease. This in turn could impact the genepool available for future breeding (Access to Seeds Index, 2019[16]). Although there is limited evidence that genetic diversity of cultivated plants has consistently decreased, genetic uniformity on the field may increase as farmers cultivate the same varieties over large areas (Bonnin et al., 2014[73]) while "genetic erosion" may threaten those crops for which there is limited breeder interest (van de Wouw, M. et al., 2010[74]).

Globally, a significant amount of genetic diversity exists in farms and gardens where crops are cultivated and even more in natural landscapes where wild crop relatives occur. This diversity conserved *in situ*, as well as genetic resources conserved *ex situ* in gene banks, is of inestimable value for humankind. It is challenging to identify, characterise and give value to this diversity as the benefit of these genetic resources may only be revealed in the distant future (Smale, 2005[75]; Gepts, 2006[76]).

At a global level, the gene banks of the CGIAR Research Centres in particular play a significant role in conserving and providing access to the world's genetic resources. As a subset of the ITPGRFA resources, these gene banks contain at present 750 000 accessions[29], about 12% of all plant genetic resources conserved in gene banks. Between 2012 and 2016, the different gene banks of CGIAR distributed almost 600 000 samples of their accessions. Given the overwhelming benefits of these initiatives, continued funding should be an important priority for policy makers (Koo, Pardey and Wright, 2003[77]). The FAO Commission on Genetic Resources for Food and Agriculture also plays an important part in the conservation and sustainable use of genetic resources and the fair and equitable sharing of benefits derived from their use.[30]

Maintaining or increasing diversity conserved on farms and in agricultural systems (*in situ*) is more complex but none the less important. However, the varieties that are planted are often based on demand for the final product, as well as variables such as seed prices, the genetic attributes and physical quality of the seed, costs of other inputs (for example fertiliser), and farmers' expectations and preferences for specific traits and varieties (Spielman and Smale, 2017[13]). Initiatives such as European GenRes Bridge are seeking to strengthen the conservation and sustainable use of genetic resources both *in situ* and *ex situ* across plant, forest and animal domains (GenRes Bridge, 2020[78])

Marketing legislation of seed can also influence the degree of *in situ* genetic diversity in agricultural systems. For example, EU legislation requires that only officially certified seed of agricultural crops (registered varieties) can be marketed to farmers. Current procedures and regulations for variety registration require Distinctness, Uniformity and Stability (DUS) and discourage the registration of heterogeneous plant material.[31] In several jurisdictions, variety registration is seen as a critical component of the seed quality assurance system and was originally introduced to prevent fraudulent claims. However, variety registration systems could indirectly influence the conservation of genetic diversity by limiting the diversity of seed legally available to farmers (Louwaars and Burgaud, 2016[79]). In 2013, it was proposed to develop a new plant reproductive material law in the EU which would create more flexibility, e.g. by making it easier for farmers to use traditional varieties or heterogeneous plant material, which do not fulfil the DUS criteria (EU, 2013[80]). Although this proposal did not move forward, discussions are ongoing regarding what role the variety registration system could take in supporting the conservation of genetic diversity *in situ*.[32]

Modern plant breeding technologies

For centuries, breeders have sought to enhance the genetic make-up of crops though traditional breeding techniques, such as crossing. In more recent times, chemical or radiation-induced mutagenesis has also been used to create genetic variation from which to select sought-after traits. These methods have been successful in changing the genetic make-up of crops but do not deliver predictable outcomes and often result in unwanted mutations. The trial and error involved in these techniques is part of the reason why bringing a new variety to market takes so long. It takes many crosses before a breeder can deliver a variety with the desired combination of genes and the necessary uniformity and stability features needed for agricultural use (EC, 2017[81]). On average, it takes more than ten years from the first cross before a new product gets to market (KWS, 2017[82]).

Among the many technological innovations introduced in plant breeding over the centuries, two in particular are relevant for current policy debates: genetic engineering and the so-called new plant breeding techniques (NPBTs).

Genetic engineering

The discovery of recombinant DNA techniques in the 1980s made it possible to create more specific changes and avoid some of the unwanted mutations that were produced using traditional crossing and hybridisation, leading to the emergence of genetic engineering (GE) technology (see Box 4.3 for a discussion on terminology). This transfer of genetic material can be done using natural vectors such as bacteria or viral components, or by a number of other genetic engineering techniques. In principle, the genetic material transferred could be from the same species (*cisgenic*) or from a different species (*transgenic*). As most of the early applications were transgenic, in practice genetic engineering is often interpreted as meaning “transgenic”.

GE techniques can be used to enhance input traits (e.g. resistance to droughts or herbicides); to improve output traits (e.g. crops with more micronutrients such as Vitamin A); or to create crops for non-traditional uses (e.g. for pharmaceuticals or bio-fuels) (Fernandez-Cornejo, 2004[7]). However, in practice, the most common GE crops are those with enhanced input traits, mainly herbicide tolerance, insect resistance, or the two features combined. The main GE crops produced globally are soybeans (95.9 million hectares in 2018), maize (58.9 million hectares, 2018), cotton (24.9 million hectares 2018) and canola (10.1 million hectares in 2018) (ISAAA, 2020[83]).

The first GE plant was developed in 1982, and the first commercialisation of GE plants took place in 1994 (the Flavr Savr tomato). Since then, GE seeds have had a dramatic impact on the structure and evolution of seed and biotechnology markets (Deconinck, 2020[62]) (OECD, 2018[46]). In 2017, the countries with the largest GE area were the United States (75 million hectares, or 40% of the global total), Brazil (50 million hectares, 26%) and Argentina (24 million hectares, 12%). Developing countries accounted for 53% of the global total of GE crops, and this figure is expected to grow further (ISAAA, 2020[83]).

Box 4.3. Terminology related to genetically engineered organisms

Genetic engineering is a process by which genes are inserted into the genome of an organism. A genetically engineered organism is an organism into which genes coding for desirable traits have been inserted through the process of genetic engineering.

The inserted genes could be from the same species (cisgenic) or a different species (transgenic). Strictly speaking, the inclusion of foreign genetic material is thus not a pre-requisite for genetic engineering. However, many of the first genetically engineered organisms were transgenic, and most of the genetically engineered crops currently available on the market are transgenic. As a result, the terms "genetically engineered" or "genetically modified" are often used as synonyms for "transgenic". Other terms with a similar meaning are "genetically modified organism", "living modified organisms" (LMOs) or "biotech crops" (OECD, 2016[84]).

Terminology around modern plant breeding technologies is often contested, and different actors have different preferred terms to describe products of "modern biotechnology" (OECD, 2016[84]). Several countries have legal definitions of relevant terms, that govern which techniques or organisms are subject to regulation. In addition, as discussions have moved out of the scientific literature and into the media, the terminology has taken on new meaning and significance for the public.

Much of the terminology related to genetically engineered organisms is discussed and defined in the Cartagena Protocol on Biosafety (CBD, 2000[85]) and UN FAO Codex (WHO and FAO, 2009[86]) and the Convention on Biological Diversity (CBD, 1993[87]). In 2000, the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology settled on the use of "genetic engineering" and "genetically engineered organism" in official documents (OECD, 2000[88]). This case study follows OECD practice in using the following terms:

- *Genetic engineering* (GE) when referring to the insertion of genes with desirable traits from the same or different species.
- *Genetically engineered organism (GEO)* when refereeing to an organism that has been genetically engineered.
- *Transgenic* when referring to organisms that have been created by inserting genetic material from a different species.

This case study may at times make use of the terms Genetic Modification (GM) and Genetically Modified Organisms (GMO), e.g. when referring to studies on public perceptions of "GM".

Finally, genetic engineering should not be confused with the more recent technologies related to genome (or gene) editing.

New plant breeding techniques (NPBTs)

Plant breeding methods and technologies have continued to evolve, allowing for considerable increases in precision and speed (Hickey et al., 2019[89]). Recent breakthroughs in the so-called NPBTs could potentially lead to significant reductions in the time needed and cost involved to develop new varieties (Scheben and Edwards, 2017[90]) (Schaart et al., 2015[91]). NPBTs cover a broad range of tools and techniques, including cisgenesis, intragenesis, genome editing through site-directed nuclease (SDN), RNA-dependent DNA methylation (RdDM), or reverse breeding. One of the best-known of these new techniques, the CRISPR/Cas9 nuclease system, has received significant attention because of its range of potential applications and relatively low cost.

Genome (or gene) editing is one of the most prominent of the NPBTs and refers to techniques in which DNA is inserted, modified, replaced, or deleted in the genome of a living organism at predetermined locations, offering higher-precision breeding possibilities. Gene editing distinguishes itself from genetic engineering by its high degree of specificity due to the use of specially modified enzymes that create site-specific breaks in the DNA, which are then repaired using the cell's own repair systems Many of the genome-edited crops do not involve the integration of foreign DNA, and the resulting crops are hence not transgenic. The proceedings of an OECD conference on genome editing provide a review of these techniques and their vast potential for future agricultural developments (Friedrichs et al., 2019[92]).

The site-directed nucleases (SDN) such as CRISPR have the potential to dramatically speed up the breeding process and deliver rapid and targeted development of new varieties (Friedrichs et al., 2019[92]). The ability to more rapidly and cost effectively target development in a specific direction promises to speed up the process of innovation. Possible traits include pest and disease resistance, higher resilience to abiotic stresses such as heat, drought, flooding and soil salinity, and higher nutrient use efficiency, product quality and longevity. The SDN technologies could also enable the domestication of neglected crops and faster plant breeding (Qaim, 2020[93]). SDNs can also be useful for certain vegetatively propagated crops, such as banana and cassava, which are difficult to improve through traditional cross breeding techniques; these crops are important staples in developing countries where poverty, malnutrition and climate change present major threats (Qaim, 2016[21]). Many of the gene edited crops that have been developed so far do not carry any transgenes (Shan-e-Ali Zaidi et al., 2019[94]) and cannot be distinguished from non-genome edited varieties.

Divergent risk management approaches

The various techniques used in modern plant breeding are complex and rapidly evolving. There are important differences between techniques, which matter for their potential benefits and risks.[33] Yet in popular debate, terms such as new breeding techniques, gene editing, transgenics and genetic engineering are often used synonymously. This is unfortunate, as it creates the perception that all modern technologies and products carry the same level of risk.

From a policy perspective, a key question on NPBTs is under which regulatory regime these techniques (or the products which result from them) should fall (Laaninen, 2016[95]). The industry has called for legal certainty and predictability for plant breeding innovation to enable plant breeders to reliably plan their breeding programs, their product development and market potential (ISF, 2018[96]). Some of the concerns expressed by consumers and NGOs about transgenic organisms have now been expressed regarding NPBTs. As a result, plant breeders may be reluctant to adopt a technology which, although deemed safe by risk assessors, could result in a public backlash by consumers and food producers (Friedrichs et al., 2019[92]). It is therefore important for policy makers to not only provide sufficient safeguards to protect public health and the environment, but also ensure that those safeguards are trusted so that important innovations are not slowed or stalled.

When recombinant DNA technologies emerged in the 1980s, little was known about the safety of the products they produced when released into the environment or used for food and feed processing.

Beginning in the mid-1980s, the OECD, and later the World Health Organization (WHO) and Food and Agriculture Organization (FAO), began seeking harmonised international approaches for risk/safety assessments for products of modern biotechnology. On the basis of these deliberations, as well as the processes they described and their application, environmental risk and food/feed safety assessment approaches have been applied to genetically engineered organisms derived through the use of rDNA technology (Jeffrey, 2019[97]). In cooperation with WHO, FAO, and other relevant international organisations and stakeholders, the OECD developed a series of basic concepts, instruments and key documents that set up the founding principles of the safety assessment of genetically-engineered organisms that are still in use today (Box 4.4).

The Codex Alimentarius Commission, a joint FAO/WHO body, also developed principles for risk analysis and guidelines for food safety analysis of foods derived from modern biotechnology.[34] The work of Codex Alimentarius is of particular importance to international trade, as its standards and guidelines are used as an international reference in the context of the World Trade Organization, as discussed below.

Ongoing work at the OECD on biosafety and on the safety of novel food and feed products aims to assist countries in evaluations of potential risks of modern biotechnology products for both environmental and human/animal health in order to ensure high standards of safety. Work at the OECD contributes to limiting duplicative efforts and reducing the potential for non-tariff barriers to trade by sharing updated scientific information in an attempt to harmonise the regulatory frameworks for biotechnology products. The focus is on a science-based risk assessment that is common across countries, even if regulatory approaches are different. Particular attention was paid to agricultural products, especially crop plants as these were the early products, but some work also relates to the biosafety of animals and micro-organisms (Kearns, 2019[98]).

Box 4.4. OECD work on regulatory oversight in biotechnology

From the mid-1980s, the OECD developed the founding principles of the safety assessment of genetically-engineered organisms. For instance the OECD's "Blue Book" on Recombinant DNA Safety Considerations, published in 1986, still constitutes a major reference tool to address the risk/safety assessment issues (OECD, 1986[99]). The document covers scientific considerations on the applications of recombinant DNA techniques, human health and safety, industrial large-scale applications, as well as environmental and agricultural safety considerations. At the same time as the "Blue Book" publication, the OECD adopted the "Recommendation of the Council concerning Safety Considerations for Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment (OECD/LEGAL/0225)" (OECD, 1986[100]). This Recommendation remains in force as an OECD legal instrument, and is currently under review.

Examples of basic principles developed in these early years, which are still used in current biosafety practice, are *case-by-case risk assessment* and the *comparative approach between conventional and modified varieties*. The *case-by-case approach* holds that assessments should be carried out on an appropriate case-by-case basis for each specific product proposed for release, whereby environmental considerations should take into account the deep knowledge of the plant biology and its history of safe use, the trait incorporated and the environment of interest and other elements for building the proper risk assessment process for potential impact on the environment. The *comparative approach* is also used for the assessment of the novel foods and feeds derived from these transgenic plants and is based on a comparison of compositional elements important for food and feed safety (nutrients, anti-nutrients, toxicants, allergens where applicable) to confirm similarities or identify differences of possible concern relative to conventional varieties. The standard-setting body Codex Alimentarius developed a standard addressing the safety assessment of foods derived from recombinant-DNA plants in 2003, completed in 2008 (Codex Alimentarius Commission, 2003; Annexes II and III adopted in 2008[101]).

Using approaches and practices that have been harmonised as much as possible helps to build mutual trust between regulatory authorities in OECD countries or partners. To date, the OECD programmes on the Harmonisation of Regulatory Oversight in Biotechnology and the Safety of Novel Foods and Feeds cover the risk/safety issues for products derived from these innovations. In addition to sharing information on regulatory principles and practices of participating countries, "consensus documents" are developed on the biology or the composition of a range of plants and other organisms and on traits that can facilitate the biosafety and food/feed safety assessment of genetically-engineered organisms. Amongst other things, the OECD consensus documents continue to support the comparative approach and other concepts related to the risk/safety assessment of transgenic organisms and/or products derived from them.

Taking into account the diversity of regulatory situations worldwide, the approach adopted is not constraining; rather, the tools and guidance developed by the programmes are publicly available for regulatory authorities wishing to use them in their biosafety and food/feeds safety frameworks. The consensus documents, in particular, are recognised internationally as key resources and used in many countries. While not legally binding, this OECD work contributes to harmonising approaches and practices and to improve public understanding.

The consensus documents and other key publications can be consulted on the BioTrack website at www.oecd.org/env/ehs/biotrack/.

There is, however, an important difference between risk assessment (where scientific evidence is used to evaluate potential threats) and risk management (which uses the findings of risk assessment processes to mitigate potential risks, e.g. preventing the cultivation of certain transgenic crop varieties in regions where wild relatives occur and genetic drift presents a greater risk). Despite significant work on the harmonisation of risk assessment approaches, risk management mechanisms for biotechnology differ considerably and it remains unclear whose responsibility it is to determine a safe level of risk in different countries.[35] The complexity and lack of harmonisation among countries' risk management mechanisms can create a number of issues, including market fragmentation and barriers to international trade, market entry challenges for SMEs and entrepreneurs, and a reduced uptake of biotechnology in some developing countries.[36]

The different regulatory approaches in the European Union and the United States illustrate this divergence. In the European Union, specific laws were introduced for genetically engineered organisms, which require separate testing and approval by specially established institutions. Subsequently, officials from the European Commission and EU Member countries are given final approval rights and can reject a genetically engineered organism based on the precautionary principle (Qaim, 2016[21]). In the United States, by contrast, although transgenic crops are assessed in detail by three regulatory agencies (USDA, APHIS and EPA) prior to an authorization, if the transgenic crop passes the required tests, then there are no further regulatory requirements for commercialisation and there is no political involvement in the process.

In addition to the divergence between the United States and the European Union, developing countries tend to have less stringent regulations, while EU countries, as well as Japan, tend to have more restrictive GEO regulations; however, even within the European Union there are important differences in GEO rules (Vigani, Raimondi and Olper, 2012[102]).[37] These divergent approaches among countries have resulted in market fragmentation and challenges for international trade (Isaac, Perdikis and Kerr, 2004[103]). Vigani et al. (2012[102]) show that not only the stringency, but also the divergence of GEO regulations reduces trade.[38]

The potential for divergent risk management approaches to restrict international trade has led to disputes in the context of the World Trade Organization (WTO). In particular, the question has been raised whether some regulatory approaches violate the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures. To avoid countries using food safety or animal and plant health regulations as protectionist measures, this agreement allows countries to set their own standards but requires these to be science based, to be applied to the extent necessary to protect human, animal or plant life or health, and to not discriminate between countries where similar conditions prevail. Countries are also encouraged to use international standards and guidelines, as this can help to harmonise approaches. As mentioned earlier, standards developed by the Codex Alimentarius Commission are explicitly recognised by the WTO as an international reference.

In 2003, a WTO dispute panel was established following a complaint by the United States, Canada and Argentina regarding measures put in place by the European Commission. The measures included an alleged *de facto* moratorium on approvals of biotech products, and safeguard measures prohibiting the import/marketing of specific biotech products within the territories of these member states (WTO, 2008[104]). The panel found that the measures put in place by the European Commission were not in line with the SPS Agreement.[39]

The divergence and stringency of GEO regulations have also affected the adoption of biotechnology in emerging economies and developing countries that have been argued to potentially have much to gain from the technology (Hundleby and Harwood, 2019[105]). Many countries in Africa and Asia are hesitant to promote GEO crops because of opposition to such crops in export markets. European attitudes and policy approaches are particularly important, given their longstanding trade connections with African and Asian countries (Smyth, Kerr and Philips, 2013[106]) (Tothova and Oehmke, 2004[107]) (Anderson and Jackson, 2004[108]) (Anderson, 2010[109]). GE-free private standards responding to consumer preferences likely play an important role as well (Vigani and Olper, 2014[110]) (Gruère and Takeshima, 2012[111]).

In addition, the regulatory approval process itself may impact innovation and competition. Smart et al., (2017[112]) found that the regulatory approval process for genetically engineered organisms in both the European Union and the United States is long, roughly 1 800 days and 2 500 days respectively. The associated costs of the approval process are also high. Kalaitzandonakes, Alston and Bradford (2007[113]) estimate between USD 6 million and USD 15 million in the case of genetically engineered maize, while an industry commissioned study by Phillips McDougall (2011[114]) estimated USD 35 million for a new GE crop. Other industry executives suggest costs as high as USD 100 million (Schenkelaars, de Vriend and Kalaitzandonakes, 2011[115]). These numbers are estimates, many of which are sourced from industry, and it is difficult to allocate costs to specific activities or distinguish single country approval from global approval. Yet the costs of regulatory compliance are undoubtedly high given the complexity of the technology and the wide range of factors to be assessed. Miller and Bradford (2010[116]) argue that these costs are prohibitively high for smaller markets, such as certain specialty crops, and have discouraged investment in these areas. As large firms find it easier to bear high regulatory costs, these costs may contribute to other phenomena in the seed sector such as the high level of concentration in markets for genetically engineered traits, and the associated perceptions of corporate power (OECD, 2018[46]).

Regulatory approaches to NPBTs

There is concern that the perceived biosafety risks of transgenic crops will negatively impact the acceptance and uptake of NPBTs. The use of these relatively new technologies does not have a long-established safety record; that said, it is argued that new types of risk are not expected because the point mutations that have so far been developed for commercial use are genetically indistinguishable from natural mutations.[40] In addition, it is argued that the frequency of off-target effects is much lower than for transgenic GEOs and traditional mutagenesis (Grohmann et al., 2019[117]) (Holme, Gregersen and Brinch-Psersen, 2019[118]). Against this background, there is a lack of clarity and consistency in the way that policy makers are approaching the task of regulating NPBTs.

Speakers at an OECD conference on genome editing in 2018 identified three main regulatory approaches to the governance of genome editing:

- *Process-driven regulatory trigger* (e.g. Australia, New Zealand, European Union, and India).[41,]These jurisdictions regulate new technologies based on their development process (Royal Society Te Aparangi, 2019[119]). Many of the countries listed are now reviewing the scope of their regulatory definitions to clarify whether all forms of genome editing fall under their existing GE regulatory framework.

- *Product-driven regulatory trigger* (e.g. Canada and the United States).[42] [43] In these jurisdictions, the novelty of the trait in question is considered on a case-by-case basis, irrespective of the technology used to develop it.
- *Product or technology specific regulations* (e.g. Argentina). In these jurisdictions, the regulatory agency responsible assesses a new technology to determine on a case-by-case basis whether it falls in or out of the national biotech regulatory framework.

In many countries, plant breeders and policy makers are operating in a regulatory and policy framework that was established two or three decades earlier. These historical frameworks may *de facto* impose strict standards on new technologies irrespective of intrinsic risks. For example, in many jurisdictions, traditional mutagenesis induced through chemicals or radiation (which creates multiple, uncontrolled changes in DNA) is less strictly regulated than newer, more precise techniques – a situation which has been likened to "saying that electric cars should attract a greater penalty than petrol cars, because electric cars were not [yet] invented in 1998" (New Zealand Office of the Prime Minister's Chief Scientific Advisor, 2019[120]).

A number of jurisdictions, including the United States, do not regulate gene-edited crops as transgenic crops. Rather, gene-edited crops are regulated in the same way as conventionally-bred crops unless they contain DNA from other species. Australia does not regulate gene-edited crops as GMOs if no nucleic acid template was used to guide repair of SDN activity, while all others are regulated as GMOs. In Switzerland, the classification of new breeding technologies such as CRISPR/Cas9 is still a contentious issue with ongoing legal evaluation procedures and discussions.[44]

In 2015, Argentina passed a resolution on NPBTs that exempted some genome-edited products from being classified as genetic engineering. Along with passing this resolution, officials offered developers the chance to consult regulators at the design stage, and anticipate any new molecular and phenotypical characteristics. This approach seems to have made the regulatory process more affordable and accessible for small and medium-sized plant breeding companies. Previously, applications mostly came from multinationals, with almost no applications from national public research institutes and local SMEs. Under the new regulation, the situation has almost reversed: half of all applications so far have come from national public research institutions and SMEs and only a small number from multinationals (Friedrichs et al., 2019[92]).[45]

The United States is also seeking to streamline regulation around agricultural biotechnology. A presidential order from 2019 (Executive Order 13874) seeks to modernise the regulatory framework by basing the regulatory decisions on scientific and technical documentation and reviewing regulatory applications in a timely and efficient manner. The intent is for the federal agencies USDA, EPA, and FDA to ultimately streamline the regulatory process for agricultural biotechnology.

Risk perceptions among the public

From the point of view of proponents, the regulatory framework surrounding transgenic crops has become needlessly polarised and politicised. Qaim (2020[93]) argues that complex biosafety and food safety regulatory procedures are driven by "overly precautious regulators, highly politicised policy processes, and extensive lobbying efforts of anti-biotech activist groups", as three decades' worth of risk assessments have so far not found any evidence that transgenic products are more risky than conventional varieties (EASAC, 2013[121]) (NAS, 2016[122]) (Leopoldina, 2019[123]).

This body of scientific evidence has had little influence over the risk perceptions of the broader public, however. If the public does not perceive a technology to be safe, the political process is likely to lead to more stringent regulation (Zerbe, 2007[124]). More stringent regulation in turn is likely to feed risk perceptions of the broader public. Even without such a regulatory response, a lack of consumer acceptance may limit adoption of the technology by firms. Gruère and Sengupta (2009[125]) showed that GE-free private standards influenced the decisions of policy makers because of perceived trade losses, while Vigani et al.

(2012[102]) found that downstream traders' and food retailers' private decisions not to purchase GE products were more important than cultivation bans for GE organisms.

Consumer attitudes to genetically engineered products vary across countries. For instance, one study found that US consumers rated "GMO-free" as the 17th most important characteristic for food, while Italian consumers ranked it as the 5th most important characteristic and Japanese consumers as the 7th most important characteristic (McGarry et al., 2012[126]).

The gap between consumer perceptions and scientific views appears to be particularly large in the case of genetically engineered organisms. A study by the Pew Research Center (2015[127]) showed that the views of US citizens differed considerably from those of scientists on a range of scientific topics, with the largest difference found in views on the safety of "GM" foods: while 88% of scientists (and 92% of biomedical researchers) considered "GM" foods safe to eat, only 37% of the broader US public agreed (Pew Research Centre, 2016[128]).[46]

A number of factors may explain these perceptions. First, risk perceptions differ depending on the use of the technology, which can entail different cost/benefit calculations. For example, there is likely to be much less resistance to using genetic engineering to cure deadly diseases, while similar techniques would be evaluated very differently in a context of food safety and security (New Zealand Office of the Prime Minister's Chief Scientific Advisor, 2019[120]). For wealthy consumers who can afford higher food prices, existing genetic engineering technology might seem to hold little or no benefit, so that perceived health risks to consumers or perceived issues about longer-term environmental impacts weigh more heavily than potential effects on agricultural productivity. Consistent with this hypothesis, it is often highly educated and affluent consumers that are the most reluctant to purchase and consume foods that have been produced using GE technology (McCluskey, Swinnen and Vandemoortele, 2015[129]) (Curtis, McCluskey and Swinnen, 2008[130]).[47]

People's views about the safety of foods with "GM" ingredients are also closely related to their perceptions of expert consensus. Non-experts need to make decisions without full information, and therefore rely on experts' claims – and of course there are limits to even expert knowledge. Real or perceived disagreements among experts may also force non-experts to err on the side of caution. Public acceptance and adoption of new technologies is thus related in part to the quality of communication and information received by the public, and to broader trust in institutions. Lusk (2015[131]) highlights the risks of misinformation in a study that found that while a large majority (82%) support mandatory labels on "GM" organisms, a similar proportion (80%) would also support mandatory labels on "foods containing DNA".

Scientific literacy is critical to consumer views on new technologies. In Canada, a study found that people's first impressions of biotechnology are generally positive or neutral (88% combined), and that Canadians generally feel that biotechnology will have a positive impact on their future. However, when the same question was asked of some specific biotechnology applications, such as "genetically modified" plants and animals, this proportion falls below half (Nielsen Consumer Insights, 2017[132]). Both the quantitative and qualitative parts of the research made it clear that people did not have a solid understanding of what gene editing is or, more specifically, how it differed from genetic engineering. Following detailed explanations of gene editing, consumer sentiment was generally quite positive (Nielsen Consumer Insights, 2017[132]).

The quality of information available to consumers is important in shaping public risk perceptions. Lusk et al. (2014[133]) argue that media can frame food technologies by emotionalising an issue and increasing its importance through repetitive messaging. Heiman and Zilberman (2011[134]) find that both positive framing and negative framing affected the likelihood of purchasing "GM" products, but that negative framing had a stronger impact.[48]

Another factor which helps to explain divergent views between scientists and the broader public relates to communication styles, and the persuasive effect of everyday language and the use of individual stories rather than technical terms or scientific evidence.[49] In a variety of contexts, including in relation to the debates over benefits and potential side effects of vaccination, public agencies can struggle to counter over-simplified messaging as they may not be allowed to adopt similar tactics (Fischhoff and Kadvany, 2011[135]).

The broader public is also influenced by the stated positions of policy makers and NGOs. The fact that some policy makers express concern about transgenic organisms may itself reinforce widespread public beliefs that the technology is inherently dangerous (Herman, Fedorova and Storer, 2019[136]). According to Qaim (2020[93]), an important reason why "GM" crops are still feared by some consumers is because the public may trust environmental NGOs more than scientists and the private sector, as NGOs are perceived as not having a hidden or profit-driven agenda. This may in part be due to the context in which GE crops rose to prominence as a public policy issue (Bonny, 2017[38]). In the second half of the 1990s, confidence in institutions and in certain technological advances had suffered as a result of several crises, including mad cow disease (notably in the United Kingdom) and blood transfusions contaminated with HIV (in France), as well as broader food safety crises around E. coli, salmonella and listeria. This led to widespread distrust in both the public and private sectors, who were believed to have disregarded health risks in favour of economic or political interests (Joly and Lemarie, 1998[137]) (Vogel, 2003[138]). This history may also have contributed to concerns that "facts" presented in policy discussions have been distorted by ideology or self-interest.

Moreover, the debate around plant breeding technologies is affected by debates on a number of other issues, which in turn may affect risk perceptions about breeding technologies.

Firstly, one of the dominant transgenic crop applications to date (herbicide tolerance) facilitates the use of broad-spectrum herbicides such as glyphosate. The use of transgenic crops has thus become associated with pesticide use in agriculture – even though the other major GE trait, insect resistance, has allowed important reductions in insecticide use (Qaim, 2020[93]). Many large seed and biotechnology companies also have their origins in the chemical and agrochemical industry (Bonny, 2017[38]), which has fuelled concerns that transgenic crops would promote increasing pesticide use.[50]

A second issue often linked to plant breeding technologies is that of corporate power. Patents on genes, genetic processes, and transgenic plant varieties have been dominated by a handful of large multinational companies. Concerns about corporate power, political influence and lack of accurate information are reflected in consumers' trust in different stakeholder groups and their preferences for stakeholder involvement in policy making when it comes to biotechnology. For example, the majority of Americans want scientists to have a say in policy decisions related to "GM" foods, and majorities also support roles for small farmers (60%) and the general public (57%). However, fewer Americans say that food industry leaders should have a major role in policy decisions related to "GM" foods (42%), and only 24% believe elected officials should have a major role (Pew Research Centre, 2016[128]).

A third issue relates to ethical concerns with human intervention with the building blocks of life, and the ethics of patenting life and genetic materials, with many voicing the opinion that humans "should not play God" or that nature should not be patented (Qaim, 2016[21]). In Canada, it was found that the biotechnology applications viewed less positively tend to be ones in which the science has the potential to upset the 'natural order' (Nielsen Consumer Insights, 2017[132]). Stone (2010[63]) highlighted the views of opponents that genetic engineering was transgressing realms that belong to God, and the related narrative put forward by NGOs portraying "GM" crops as "frankenfood."

4.6. What makes these issues contentious, and what can be done?

A well-functioning seed sector is essential for meeting the triple challenge. For this reason, it is critical to build a policy and regulatory environment that facilitates both innovation and access to seed. Yet as the previous section has illustrated, the seed sector is characterised by a number of highly contentious issues, which may make it difficult to design effective policies. This section offers an interpretation of why plant breeding tends to be so contentious, and what can be done to develop effective and socially acceptable policies.

Sources of friction: Facts, interests, and values

The contentious issues discussed in this case study are not simply disagreements over the most efficient way to meet the "triple challenge" of food security and nutrition, livelihoods, and sustainable resource use and climate change mitigation. If they were, it would be difficult to explain why policy discussions have become so highly polarised. An alternative interpretation is that policy debates in the seed sector are so contentious because they also involve (real or perceived) conflicts between private interests and the public interest, and disagreements over values. In other words, contentious issues in the seed sector form a "wicked problem" (Rittel and Webber, 1973[139]). A wicked problem is one where: stakeholders have differing and sometimes competing definitions of the problem; there are no widely accepted solutions; the problem involves normative judgments which depend on stakeholder values and preferences; and debates about the problem are dependent on and embedded in social dynamics and contexts. Wicked problems cannot be solved by more research, data and experts, but may require a dialogue around societal goals and normative questions to move towards consensus.

The access and benefit sharing mechanisms that govern genetic resources illustrate some of these issues. Genetic resources are a global public good which can be conserved at a modest cost *in situ* and *ex situ* but which can potentially be used around the world to create new varieties. From a pure economic efficiency point of view, these genetic resources should therefore be made available as cheaply and easily as possible, to maximise their use in breeding programmes around the world. The public interest in this case is thus not necessarily in contradiction with the private interests of the plant breeding industry. Yet at the same time, existing genetic resources often represent the efforts of countless generations of farmers and local communities carefully saving and selecting seed. This fact is irrelevant from an efficiency standpoint, but it matters from the point of view of fairness, as many would object to plant breeders earning profits from genetic material selected and curated by local communities without compensating these communities for their historical stewardship.[51] The existing regulatory frameworks for access and benefit sharing seek a balance between principles of fairness on the one hand, and economic efficiency and encouraging innovation by plant breeders on the other hand.

The question of whether and when farmers have the right to save seed provides another illustration of disagreements over values and interests. As noted earlier, new plant varieties are difficult to develop but often easy to replicate, which threatens to undermine incentives for plant breeders to invest in the lengthy process of varietal improvement. From an economic efficiency point of view, PVP thus needs to strike a balance between providing incentives to plant breeders and allowing farmers' access to improved varieties. If farmers can freely save and reproduce seed, this may stimulate them to adopt new varieties more quickly (because they do not have to pay royalties or pay for new seeds each season), but it may also reduce the rate of innovation by undermining incentives for plant breeders. There is thus a question of designing an IPR regime that reconciles the highest possible rates of both innovation and adoption. But intellectual property regimes also have distributional consequences: they influence how much farmers effectively pay for seed, which affects profits for both farmers and plant breeding firms. The IPR regime which maximises profits for either one of these groups is not necessarily the regime which maximises overall innovation and social and economic welfare, and vice versa. Moreover, discussions about IPRs on genetic material again touch on moral questions about whether nature should be "privatised", whether corporations wield too much influence over farmers, and about what kind of agricultural system is most desirable (Stone, 2010[63]) (Schurman and Kelso, 2003[140]) (Goodman, 2003[141]) (Lewontin, 2000[142]) (Magdoff, Bellamy Foster and Buttel, 2000[143]).

The confluence of disagreements over facts, interests and values is also illustrated by debates over plant breeding technologies. Much of the controversy over genetic engineering and NPBTs is about the presence or absence of biosafety risks, but many other factors are at play in these debates. Risk management is never merely about scientific evidence on the magnitude or probability of harmful consequences; it inevitably involves a value judgment about the types and magnitude of risks which are deemed (un)acceptable by society. Even if access to accurate information was equal and the perception of risk among the general public was the same, people may still differ in their values and risk appetite (Fischhoff and Kadvany, 2011[135]).[52]

What complicates these matters further is that risk perceptions of the broader public can diverge from expert judgment. This is true in general and it is also the case for genetic engineering, as noted earlier.

It is possible to identify "clusters" of facts, interests and values in seed policy debates. For example, critics of private-sector plant breeding and modern breeding techniques seem likely to also believe that a handful of multinationals exert too much power over farmers and the overall direction in which the food system is evolving; that GEOs are more risky than the available evidence suggests; and that private-sector plant breeding will not deliver socially optimal outcomes in terms of innovation and genetic diversity. Those with these beliefs are probably also more likely to emphasise the value of diversity as opposed to homogeneity (e.g. monocultures). In terms of interests, they are likely to champion the interests of poor farmers and local communities and may share a wider scepticism about the benefits of globalisation. [53]

By contrast, proponents of private-sector plant breeding and modern breeding techniques seem more likely to emphasise that modern techniques are needed to feed a growing population; that traditional and informal seed systems are insufficiently effective; that scientific risk assessments have demonstrated that GEOs are safe; and that private-sector investments in R&D can deliver societally relevant benefits. Proponents are also likely to advocate for science and technological progress. Taken to an extreme, this view argues that all domestication of nature is in fact genetic modification (Fedoroff, 2003[144]) (Pinstrup-Andersen and Schioler, 2000[145]), and that the term genetic modification itself is only a political construction (Herring, 2008[146]). In the case of plant breeding firms, there are also economic interests related to plant breeders' rights and regulatory approval of new technologies.

Siegrist et al. (2000[147]) explain such clustering of beliefs as a mental shortcut which takes place when people who are not technically trained to evaluate risks and benefits of a technology on their own put their trust in others who have been shown to hold similar values and interests to them. It can subsequently become difficult to express beliefs "inconsistent" with this clustering, affecting the ability to find a middle ground in public debates. For example, when Urs Niggli, Director of the Swiss Research Institute of Organic Agriculture (FiBL), expressed support for the potential role of NPBTs in organic agriculture, he was heavily criticised by the organic movement which has been outspoken against genetic engineering (Maurin, 2016[148]) in Shao, Punt and Wesseler (2018[149])).

The clustering of facts, interests and values makes it difficult to settle debates on contentious issues with reference to facts or evidence alone. It may also make it harder for people to accept evidence contradicting their prior beliefs, especially if there is a lack of trust in the credibility of research conducted at universities or regulatory agencies (prompted, for example, by concerns about conflicts of interest).

Implications for policy makers and key stakeholders

If the above interpretation is correct, controversies over specific seed policies may often reflect much deeper disagreements between clusters of facts, interests, and values. As emphasised in Chapter 3, there are unlikely to be easy solutions to such policy controversies. However, it might be possible to find some "no-regret" actions (which are acceptable to diverse stakeholders), as well as some ways of moving the policy process forward. In doing so, it is important to address not only plant breeders and farmers upstream but also the values and interests of consumers and citizens. At the same time, in order to be most effective, policies need to be informed by science and facts.

Targeting

A first step is to acknowledge that seed policy debates touch on a wide range of issues, but that not all of these issues need to be resolved through seed policy and regulations. As in other areas of the global food system, policies targeting one objective may have trade-offs and synergies with other objectives. However, ideally policy makers should use as many policy instruments as there are objectives to avoid or minimise trade-offs (Chapter 2). For example, concerns around the environmental consequences of monocultures linked to certain plant-breeding technologies could probably be addressed more effectively through targeted agri-environmental policies, allowing for more precise management of trade-offs, rather than through the blunt instrument of restricting the use of those plant-breeding technologies.

A second step is to explore where existing policies have negative spillovers, which could be addressed without compromising the original objectives of those policies. For example, blanket restrictions and excessive regulatory hurdles on NPBTs likely limit innovation and market entry for small firms and new breeders, and the experiences in Argentina mentioned earlier suggest that reform of these regulations can lead to improved market access for national public research institutions and SMEs. Given the concerns about the impact of competition on market concentration and innovation, when pro-competitive adjustments are possible while providing sufficient safeguards on health and environment, they should be pursued.

Enabling competition

Competition helps lower prices, increase variety, and stimulate innovation; given the centrality of the seed sector for the triple challenge, stimulating competition in the sector is thus essential. Moreover, vigorous competition in the seed sector could also help attenuate concerns about corporate power. This requires enforcement by competition agencies, but several complementary options exist to stimulate competition. These include avoiding regulatory barriers, facilitating access to intellectual property and genetic resources, and stimulating both public and private R&D (OECD, 2018[46]).

The regulatory environment can have important effects on competition. OECD Good Regulatory Practices (OECD, 2012[150]) argue for the simplification of regulatory systems where necessary, to make regulations clearer, more transparent, easily accessible, and more coherent across jurisdictions.[54] As discussed earlier, this issue is of particular importance for NPBTs, where policy makers should take care to design a regulatory approach which does not exclude small and medium-sized enterprises (SMEs).

Simplification of public R&D and innovation funding can also help smaller companies access critical funds. For example, OECD work on innovation, agricultural productivity and sustainability found that some policy measures to stimulate R&D such as tax rebates might primarily benefit large firms, which suggests that better targeting could improve effectiveness (OECD, 2015[151]). Strengthening the capacity of smaller domestic companies to engage in research and innovation, possibly using incentives targeted to their needs, is important for the performance of the whole sector (OECD, 2019[39]).

Uptake of new technologies

The potential benefits of plant breeding technologies on the triple challenge are only realised if the technologies are taken up and are meeting local needs of farmers in different agroecological conditions. Uptake involves a wide range of stakeholders along the whole supply chain for food, including policy makers, teachers, researchers, advisors and brokers of innovation, farmers, agri-food companies, co-operatives, non-profit organisations (NGOs), and consumers (OECD, 2019[39]). It is important therefore that these stakeholders find consensus on a way to move forward.

Renewed policy attention is being given to improving the adoption of innovation in farms and firms through improvements in the enabling environment. Farm advisory systems and extension services play an important role in ensuring more effective participation in innovation networks and adaptation to new technologies (OECD, 2019[39]). OECD work on innovation systems shows that countries have higher rates of adoption of innovation at the farm level when training and extension is diverse and services are widely accessible, e.g. through specific programmes focusing on facilitating adoption (OECD, 2015[151]).

Access to information and re-building trust

Although some seed policy debates inevitably involve value judgments which cannot be settled by science alone, credible scientific evidence is essential to clarify the trade-offs and synergies involved and to help achieve coherent policies. In order to ensure smart policies, additional data is needed on innovation, market concentration and access. Fernandez-Cornejo and Just (2007[64]) argue that reliable analysis on market concentration, for example, requires time-series data on firm market shares, R&D investment, output quantities, and prices. Although such data are often considered private and confidential, concerns about market power should make greater public observation and oversight by competition authorities appropriate. Private investment in food and agriculture R&D is also difficult to track in many countries and is often missing or incomplete in official statistics (OECD, 2019[39]). The evaluation of programmes that support research and innovation in private companies should be strengthened to ensure they are efficient and reach their intended beneficiaries.

Initiatives have emerged to improve access to both information and innovation in the crop biotechnology space. For example, the Public Intellectual Property Resource for Agriculture (PIPRA) (PIPRA, 2020[152]) initiative was established to improve transparency and access to IPRs, particularly patents, in plant biotechnology for staple crops in developing countries and specialty crops. Sharing patent and licensing information from major public sector organizations supports better commercialization of agricultural biotechnology innovations from the public sector. Recently PIPRA has increased provision of educational services, capacity building, and professional training.

Related to the issue of data is that of transparency. The review of Innovation, Agricultural Productivity and Sustainability in the Netherlands (OECD, 2015[153]) found that transparency is essential when there is co-operation between science and business, but trust remains an issue for the image of scientists working for or with businesses. A key challenge is to ensure “facts” remain unpolluted to the maximum extent possible by “interests” and “values” and that there is trust in the process – that is, ensuring that scientific research by universities and public agencies is of the highest quality and integrity, avoids conflict of interest problems, and is trusted by the public. While removing all bias is difficult, maximum transparency helps others to make their own assessments as to the credibility of the information.

It is similarly essential that special interests do not obtain excessive influence over public policymaking processes. In the context of seed policies, interest groups include farmers, plant breeders, consumers, and civil society. Within these groups, interests are not necessarily homogeneous; for instance, the global seed industry consists of a small group of major multinationals and a much larger group of small and medium national and regional companies, and these may not always have the same interests (Spielman and Smale, 2017[13]). Interest groups (such as associations or lobby groups) can fulfil an important role in the policy process, as they can provide information on how proposed rules affect various stakeholders. But if some stakeholders can wield disproportionate influence, the resulting policies may benefit special interests at the expense of others in society. Even the perception of such disproportionate influence can undermine trust in the public sector.

Evidence from various sectors has shown that industry-funded research can lead to results and conclusions more favourable to the funder (see Chapters 3 and 6). While industry funding can enable important research efforts and is not inherently problematic, clear governing principles and standards of scientific integrity along with full transparency of research funding and methods are needed to avoid the spread of biased, misleading or wrong information that influences public opinion and the policy process. In the contested area of research and facts in the seeds debate, both industry and NGOs have disseminated research to affect public opinion, with a considerable impact on the GE debate (Paarlberg, 2014[154]).

Ensuring transparency and a level playing field for different interests (e.g. through transparent and participatory processes involving all relevant stakeholders) can help, such as the European Union's better regulation initiative that seeks to engage citizens and stakeholders (EU, 2020[155]). The disclosure of funding sources for scientists and NGOs as well as conflict of interest policies may also help improve transparency. Considerable improvement can also be made in outreach science and communication.

Communication

While scientific evidence on risk assessment can clarify the likelihood and possible magnitude of harmful consequences, different people (and different societies) are still likely to disagree on what constitutes an acceptable risk, particularly when the level of risk may vary between one region and another. This is why communication tools are critical to achieve a good understanding of risks and to ensure coherence in how different risks are managed – e.g. to avoid that an objectively less risky technology is treated with more scrutiny than an objectively riskier technology merely because of misperceptions; or, in the context of international trade, to avoid that unnecessarily restrictive measures are introduced under the pretence of safety standards.

In 1988, the US Environmental Protection Agency developed the *Seven Cardinal Rules of Risk Communication* (EPA, 1988[156]). It includes a range of recommendations for managing public communication including being *honest, frank and open*. In the context of the seed sector, this could include ensuring that information on the seed variety, the breeding techniques used to obtain them, as well as its safety for the environment and human health is easily available and communicated in a form that can be easily understood. This should also include efforts to clarify the use of terminology in the media.

Collaboration and co-existence

Many of the issues discussed go beyond problems of economic efficiency and raise broader questions related to rights, ethics, power and equitable development. There are a number of initiatives to develop policies which address and balance the needs of different "clusters of beliefs" involved in plant breeding debates. The principle of access and benefit sharing for genetic resources is an example. This principle simultaneously acknowledges the importance of easy access to genetic resources, while also acknowledging the historical stewardship of local communities. Other examples might include policies to strengthen public sector R&D and stimulate public-private partnerships, and policies to facilitate the licensing of patented genetic material.

It is critical to develop long-term strategies for breeding that consult a broad range of stakeholders early and often, clarify the role of different organisations, improve co-ordination across research and other organisations, and implement comprehensive evaluation systems. At the 2018 OECD Conference on Genome Editing, Friedrichs et al. (2019[92]) observed that while some experts argued against prohibitive increases in regulatory requirements surrounding NPBTs and genome editing, others argued that each community should first set its policies based on its values and objectives, so that regulation reflects societies' boundaries and not what is scientifically possible. Participants acknowledged that "[e]ffective public acceptance could not follow a 'one size fits all' approach; it requires well-tuned consideration of the prevalent socio-political disposition of each community" (Friedrichs et al., 2019[92]).

In Canada, Value Chain Round Tables (VCRTs) bring together industry leaders along with federal and provincial government policy makers to build long-term strategies, discuss challenges and opportunities and identify research opportunities, as well as policy, regulatory and technical requirements (OECD, 2019[39]). The Netherlands is also working to integrate social issues into its strategic knowledge and innovation agenda (OECD, 2015[153]) and has worked with stakeholders to define concrete goals for a wide range of policy instruments.

Such approaches can be challenging, however. The *Haut Conseil des Biotechnologies* in France (HCB, 2020[157]) is an independent body established by the Genetically Modified Organisms Act (GMO Act) of 25 June 2008 to inform public decision-making. The council reports to the ministries responsible for the environment, agriculture, research, health and consumer affairs. The council is made up of a Scientific Committee (SC) and an Economic, Ethical and Social Committee (EESC) and assesses not only the environmental and health risks of GEOs but also their socio-economic impact. Despite the establishment of such an initiative, perceptions of genetic engineering have not changed much.

Bauer, Allum and Miller (2007[158]) highlight the potential for “institutional neurosis”. They use the example of the 2003 UK GM Nation public debate. Following the debate, the public remained sceptical of “GM” foods and crops and the government responded by blaming environmental NGOs or insisted on continuing the debate until the public changed their minds. If government and companies enter into the consultation process expecting the public to change and not expecting that they might have to, they risk effectively missing the point of a public consultation, which is to value the opinion of the public and take in to consideration their concerns and appetite for risk when making decisions.

It may be possible to find common ground in the face of new challenges. There is a broad and growing consensus around the importance of making progress on the SDGs and on the “triple challenge” of providing food security and nutrition, ensuring livelihoods, and using natural resources sustainably and contributing to climate change mitigation. Efficiency gains through improved varieties could play an important role. Moreover, as new techniques are more precise, the benefits perceived from new plant breeding technologies may be seen as larger than the risks. Yet, it is unlikely that full consensus will ever be achieved on all contentious issues.

An alternative possibility is a system where multiple agricultural systems co-exist in parallel. For example, the formal recognition of orphan crops and heterogeneous material may help ensure a more level playing field for alternative approaches. In the case of genetically engineered crops, the global picture is to a large extent one of coexistence. As a result of divergent regulatory approaches, some countries have high adoption rates of GE crops while others have little or none. Moreover, “GM-free” labels have emerged even in countries where genetic engineering is widely used. If some consumers have a preference for “GM-free” products while others are indifferent, such coexistence would seem a logical outcome. But coexistence based on the principle of consumer choice brings its own difficulties.

First, consumers need to be able to make an educated choice based on clear, accurate, science-based information, for example through the use of product labels. A diverse range of labelling regimes for GE products have emerged across countries (Vigani and Olper, 2013[159]). Labelling may be one step in allowing consumers to make an informed choice, but it assumes that consumers have sufficient scientific literacy to understand the differences between different technologies and agronomic techniques, which may not be the case in practice. Gruère (2006[160]) finds that labelling GE products may also indirectly act as a hazard warning: labelling a product as “free of ingredient X” might give ill-informed consumers the impression that “ingredient X” is risky or bad, even when there is no scientific basis for this claim. Hence, labelling is rarely a neutral communication tool. Design of labelling is also by no means straightforward, including in terms of international coherence.

Second, segregating the supply chains of GE and non-GE products creates significant additional costs in food supply chains. For example, processors may incur a loss of flexibility as they need to dedicate equipment to either GE or non-GE production (Bullock and Desquilbet, 2002[161]).

Third, the coexistence approach can work if the effects of a consumer’s choice only affect that consumer. But the controversy around GE involves perceived externalities, such as risks to the environment. In addition, the controversy involves strongly held values that extend beyond personal consumption choices.

For example, if opponents of GE feels that it is fundamentally unethical to manipulate nature, or that the technology represents a dangerous power grab by a powerful corporate entity, then coexistence will not be a satisfactory solution to them.

4.7. Conclusion

In a recent paper, Qaim (2020[93]) concludes by asking the reader a number of questions regarding the seed sector. How can we ensure that newly developed crop varieties with desirable traits are used sustainably as part of diverse agricultural systems? How can market power by a few multinationals be prevented? How can we facilitate the development of new crops and traits that may not have huge commercial potential but may be particularly beneficial for poor farmers and consumers? How can we ensure that suitable new crop technologies will actually reach the poor through favourable technology transfer mechanisms? What is the appropriate level of IPR protection in industrialised and developing countries?

Policy makers will have to face these questions if plant breeding is to play its critical role in meeting the "triple challenge". In addition, policy makers must deal with the globalised and diverse nature of the seed sector, striking a balance between facilitating international trade and technology exchange through harmonisation and providing a policy environment adapted to highly diverse local contexts, including developing countries and those who will be most affected by climate change and natural resource constraints.

The diversity of the global seed sector also extends to the viewpoints of various stakeholders, making debates on seed policy uniquely contentious. While considerable work has been done to develop policies and regulations which act "upstream" in the plant breeding process, comparatively little has been done to address the concerns of consumers and concerned citizens downstream. Consumer concerns regarding plant breeding technologies can be addressed directly through innovative educational and communication programmes. In addition, concerns about the environment or corporate dominance in the food sector affect citizens' and consumers' perceptions of plant breeding technologies. Addressing these concerns directly, through improved environmental regulations or through policies that support a competitive market and address concerns regarding the impact of market power on innovation and access, is likely to be more effective than trying to address these issues through seed policy (consistent with the principles on policy coherence developed in Chapter 2). Moreover, tackling these issues head on could also help address citizens' and consumers' value-based concerns with new plant breeding technologies.

Certain seed policy debates involve value judgments, which cannot be settled by science alone. Acknowledging the importance of values and ensuring that a range of stakeholders have both access to accurate information as well as input in policy making processes can help ensure that decisions are not only evidence-based but also acceptable to the broader society. At the same time, effective policy development should be clearly targeted, making sure that the appropriate instrument is used for an issue.

It is crucial that to the maximum extent possible facts remain unpolluted by interests, including by promoting full transparency. Plant breeding technologies have suffered from association with both private and public actors who are perceived by the public to have disregarded health risks in favour of economic or political interests. Maintaining the highest standards of transparency and integrity is therefore essential to establish trust in scientific evidence and in the regulatory process.

Finally, policy makers can seek common ground and develop smart policies which facilitate innovation and technology while addressing and balancing the views of different "clusters of beliefs" in seed policy debates. An acknowledgement of the huge progress that must be made to meet the triple challenge may help de-polarise discussions. There are also examples of successfully balancing the interests of different stakeholders, such as the principle of access and benefit sharing or the coexistence of traditional breeding techniques alongside genetic engineering in the same country or region; but considerable effort is needed to develop and implement workable regulations by governments and the private sector as well as more of these mutually acceptable solutions.

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Notes

[1] The OECD has developed a wide body of literature on the broader topic of agricultural innovation, including a framework for analysing the role of government in agricultural innovation systems (OECD, 2013[187]) as well as 12 country reviews and a synthesis report (OECD, 2019[39]).

[2] A note on terminology. A seed is the physical "carrier" of genetic information of a variety. Farmers choose between different varieties when buying seed, and plant breeders aim to develop improved varieties. A variety developed or selected through human intervention is also referred to as a cultivar ("cultivated variety"). Strictly speaking, the term "seed market" or "seed industry" encompasses both the development of varieties (plant breeding) and the physical production ("multiplication"), distribution and sale of seeds. The focus of this study is primarily on plant breeding.

[3] In the 1950s and 1960s, a set of technological innovations and transfer initiatives took place, known as the Green Revolution. These innovations have been attributed with significant increases in agricultural production worldwide, as well as increased use of fertilisers, pesticides, mechanisation and irrigation (Evenson and Golin, 2003[5]).

[4] The term "quality" refers here to seed that has high purity (i.e. the seed sold corresponds to the variety it is claimed to be, and does not have foreign elements such as weed seeds, dirt, and seed of other varieties) and high germination rates, is free from pests and diseases, and has a low moisture content (to prevent early germination and quality losses). These quality parameters are guaranteed by official certification systems in formal seed markets, but are not guaranteed in the case of farmer varieties exchanged in informal settings. However, FAO's Quality Declared Seed System (FAO, 2006[200]) can be used as an intermediate solution, as it provides certain guarantees for the quality of seed and is applicable to local varieties.

[5] For example, Coomes et al. (2015[195]) emphasise the important role of farmer seed networks, where seed is shared among farmers through gifts, barter or purchase outside of the commercial seed sector and formal regulations. While such networks are often described as "informal" (as opposed to formal seed systems, which convey certified seed or registered varieties to farmers), these networks are often governed by social rules and norms, and there is permeability between the informal and formal systems. These farmer networks can be responsive to changes in local conditions, and resilient to environmental and price shocks; they therefore play an important role in ensuring long-term access to diverse crop planting material.

[6] In a number of important agricultural crops, the photosynthetic process (conversion of light to chemical energy) is relatively inefficient, limiting growth. Genetic engineering has recently been used to modify the photosynthesis process to deliver a 41% increase in biomass. Currently this has only been carried out in tobacco plants (chosen as a model species as it is easy to modify) but it has been suggested that similar yield gains could be achieved in staple crops such as soybeans, rice and wheat (South et al., 2019[172]).

[7] Biofortification is not the only means to improve the intake of micronutrients; other policy interventions to improve dietary diversity can play an important role.

[8] *Biotic* stresses are caused by other organisms such as fungi or insects, while *abiotic* stresses include, for example, adverse weather conditions.

[9] There have also been concerns that the Green Revolution contributed to a loss of crop genetic diversity, although evidence on this question is mixed (Pingali, 2017[196]). In general, a loss of genetic diversity could pose risks to global food security by undermining the resilience of agricultural systems to pests, pathogens and climate change (IPBES, 2019[197]).

[10] See Chapter 1 for a discussion on the suitability of incentives and the impact of agricultural support policies and agri-environmental policies on environmental sustainability.

[11] Genetic diversity is related to, but distinct from, biodiversity. While biodiversity refers to the variation at the genetic, species, and ecosystem level, genetic diversity is the total number of genetic characteristics in the genetic makeup of a species.

[12] There is considerable variation in agricultural innovation systems between countries, particularly in terms of ambitions, institutional set-up, and funding mechanisms (OECD, 2019[39]). As such, experiences and perspectives may differ between countries. This case study seeks to summarise the key contentious issues being debated at the national and international level.

[13] The private sector is taking on an increasing role in other agricultural areas too. In 2011, the private sector was carrying out 52.5% of the research on crop breeding, informatics, fertilisers, pesticides and food technologies in developed countries, compared to 42% in 1980 (Pardey et al., 2016[48]).

[14] Public breeding programmes may also benefit from intellectual property systems, which can generate revenues to support future R&D. Examples of public sector plant variety protection and patenting have been seen in Argentina (UPOV, 2017[190]) but comprehensive data on the ratio of public vs private patents is not available.

[15] In 2016, Monsanto was acquired by Bayer and the sale was completed in 2018. From that point, the Monsanto name was discontinued.

[16] Seed marketing regulations define the quality standards that must be met for seed production of agricultural plant species and seed lots if the seeds are to be commercially marketed.

[17] Evidence for the French seed industry similarly suggests that the number of new varieties introduced each year is positively correlated with market size, although this correlation disappears for hybrid crops (Charlot, 2015[173]).

[18] Agricultural R&D may include plant breeding but also other types of research and development initiatives.

[19] Paul Heisey, personal communication.

[20] During the 1980s, agricultural policy reforms in developing countries assumed that seed system deregulation and privatisation would generate investment (Tripp and Rohrbach, 2001[176]; Tripp and Louwaars, 1997[175]; Tripp and Louwaars, 1997[175]). However, many private companies refrained from investing because of continued market failures (Spielman and Smale, 2017[13]). Gilbert (2010[163]) suggests that contractual and reputational risks are also harder to manage in developing country contexts.

[21] A hybrid variety is obtained by crossing two (or more) inbred parent lines. Hybrid varieties often demonstrate more favourable traits (e.g. higher yields) relative to the parent lines, a phenomenon known as “hybrid vigour”. However, if the seed resulting from a hybrid variety is planted again, the next generation loses its uniformity and does not display the same vigour or desired traits. As a result, farmers have less of an incentive to save part of the harvest of a hybrid variety to re-use as seed. Hybridisation is not available for all crops, because hybrid varieties are easier to obtain from plant species which cross-pollinate naturally, but selected hybrid varieties are nowadays common for many staple crops such as maize, cotton, sunflower, rice, as well as fruits and vegetables.

[22] There has been a long-standing tension in policy discussions between the desire to provide intellectual property rights protection to stimulate the development of new varieties on the one hand, and on the other the view that genetic resources are “common heritage of mankind,” in the words of the 1983 International Undertaking on Plant Genetic Resources. The implication that modern varieties are private property while traditional varieties are freely available has contributed to a sense of unfairness in developing countries (Bjornstad, 2004[198]). A similar tension is at work in discussions on access and benefit sharing (Section 4.5). See also Section 4.6 for a discussion of the role of such differences over values and interests in policy discussions.

[23] The International Union for the Protection of New Varieties of Plants (UPOV, after its French name, *Union internationale pour la protection des obtentions végétales*) was established by the International Convention for the Protection of New Varieties of Plants. UPOV's mission is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.

[24] The precise relationship between the UPOV Conventions and the ITPGRFA is complex. For example, the ITPGRFA expressly acknowledges that the implementation of a system that allows farmers to “save, use, exchange and sell farm saved seed” is the responsibility of national governments “subject to national law and as appropriate”.

[25] While plant breeders' rights only cover new varieties, seed marketing legislation covers all varieties marketed to farmers. As discussed in the context of the in situ conservation of genetic diversity below, in many countries varieties can only be marketed to farmers if they meet criteria of distinctness, uniformity and stability (DUS). Such systems were originally introduced to prevent fraudulent claims, but they can result in a de facto ban on the sale of traditional or heterogeneous plant material, unless special provisions are made.

[26] The "Annex I" list was originally developed to clearly define and limit the scope of the international treaty. Negotiations on the scope of the list reflect how perspectives on access and benefit sharing differed between regions (Visser, 2013[191]). Many developing countries viewed the multilateral system as an experiment that had to show its effectiveness and its value in terms of monetary benefit sharing and were therefore cautious in terms of the content of the list. Developed countries saw the access to genetic resources as a major benefit in itself and favoured the inclusion of all plant genetic resources on the list.

[27] Despite the large number of successful exchanges, problems remain. Bjørnstad, Tekle and Göransson (2013[178]) sent seed requests to 121 countries that are Contracting Parties. They received no response from 54 countries, mainly in Africa and Latin America and the Caribbean, and concluded that the "facilitated access" promised by the ITPGRFA is not straightforward.

[28] To facilitate the implementation of access and benefit sharing in domestic policy processes, FAO has developed "ABS Elements" (FAO, 2019[199]).

[29] An accession is a sample of seeds that represents a variety, breeding line or a population and is distinct and uniquely identifiable. It is maintained in storage for conservation and use.

[30] The Commission produces regular global scientific assessments (State of the World reports) of genetic resources for food and agriculture. Based on the trends, gaps, and challenges identified in these assessments, the Commission aims to develop consensus on policy measures that are summarised in Global Plans of Action (GPAs) and other documents through which governments commit to take action to conserve and sustainably use genetic resources for food and agriculture.

[31] Heterogeneous plant material is a group of plants (or seeds) that comes from a single botanical taxon of the lowest known rank (genus or species). The group, however, is characterised by a high level of genetic and phenotypic diversity (hence it is heterogeneous) (Regulation (EU) 2018/848).

[32] In France, the "catalogue des espèces et variétés de plantes cultivées" (see https://www.geves.fr/catalogue/) contains specific lists for conservation varieties that are adapted to local and regional conditions and threatened by genetic erosion, however, these varieties cannot be marketed. The list also recognises old vegetable varieties whose seeds can be marketed in limited quantities in France for commercial production under specific growing conditions.

[33] The biosafety concerns regarding genetically engineered organisms differ depending on the organism (e.g. plants, trees, animals, micro-organisms), the engineering that has taken place and its potential use (e.g. industrial processes, agriculture, food, feed). In the context of agriculture, key concerns include those of gene transfer (the transfer of genetic material from a genetically engineered plant to a naturally occurring plant), potential impacts on non-target organisms, increased use of pesticides such as herbicides and increase in resistance among pests. A number of these issues may also be experienced when using non-GEOs.

[34] The relevant documents are *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003) and guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003), micro-organisms (CAC/GL 46-2003), and animals (CAC/GL 68-2008); see http://www.fao.org/3/a-a1554e.pdf (accessed 11 September 2020).

[35] The separation of risk assessment and risk management roles has been adopted into law in Europe in order to clearly distinguish between the roles of science and politics (Food Safety News, 2013[186]). While this distinction may help clarify the process of science-based policy-making, the precise roles and responsibilities of risk assessors and managers may still create confusion.

[36] A further distinction is between regulations that govern the use of GE seed and those that govern food and feed derived from GE crops. To approve a transgenic seed for environmental release in most countries requires the technology to pass a number of biosafety requirements that are not needed for food or feed commercialisation. For example, only one transgenic crop is currently authorised in the European Union for commercial cultivation (insect-resistant maize grown in Spain and Portugal, see ISAAA (2018[166])) while more than 70 GE soybean, maize, and oilseed rape varieties are authorised for import in the European Union as commodities for feed use (Biotrack, 2020[167]).

[37] Tothova and Oehmke (2004[107]) observed the formation of 'clubs' at the country level in terms of GE regulation. They identify two trading blocs: one in favour, the other against GEOs. Countries in between face a choice between lower production costs (through the adoption of GE crops) or maintaining key export markets by restricting GEO production.

[38] In addition to national regulations, several international bodies and regulatory frameworks govern GE crops. These include the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, as well as Codex Alimentarius and the World Trade Organization (WTO).

[39] The most recent communication from the European Union notes that although mutually agreed solutions have been found with states with Argentina and Canada, discussions with the United States continue (WTO, 2020[201]).

[40] It is worth noting that the same technology could also be used to develop *transgenic* organisms, which can be distinguished from natural mutations (in contrast with cisgenic organisms).

[41] In the European Union, it was initially unclear whether NPBTs fell under the existing legislation on "genetically modified organisms" (EU Directive 2001/18/EU). This legislation exempts a number of techniques, including mutagenesis. However, the text does not precisely define mutagenesis, while the definition of a "genetically modified organism" itself is also somewhat ambiguous (Eriksson, D. et al, 2018[180]). On 25 July 2018, the European Court of Justice clarified the interpretation of the Directive. The Court ruled that varieties obtained using the new plant breeding techniques are Genetically Engineered Organisms and hence fall under the same regulatory framework (Court of Justice of the European Union, 2018[181]).

[42] In March 2018, the United States Department of Agriculture announced that it would not regulate "plants that could otherwise have been developed through traditional breeding techniques," provided that they are not "plant pests or developed using plant pests" (USDA, 2018[179]). This statement implies that new plant breeding techniques such as genome editing will not fall under the same regulatory framework used for genetically engineered organisms.

[43] In September 2020, Health Canada published a Notice of Intent to develop and publish new guidance for the Novel Food Regulations, focussed on plant breeding. (Health Canada, 2020[193]).

[44] According to the Swiss Federal Council (Motion 19.4050) CRISPR/Cas9 mutations are included within the scope of application of the Gene Technology Act and therefore considered as genetic engineering but considerable work is being done on the analysis of the conceptual problem. In 2020, the Swiss Federal Council will publish a proposal for an appropriate modification of this legislation and after a public consultation submit the proposal to the parliament for discussion and adoption.

[45] In addition to facilitating innovation by SMEs and thus potentially stimulating competition, this regulatory approach could also help local farmers by allowing more locally adapted varieties.

[46] These differences extend to other areas of agriculture and food safety: 68% of scientists (70% of biomedical researchers and 81% of chemists) consider food produced with pesticides safe to eat, only 28% of the broader public agreed (Pew Research Center, 2015[127]).

[47] Interestingly, farmers' perceptions of GE appear to be influenced by other factors. A study of farmers in the European Union showed that economic issues such as the promise of a higher income and the reduction of weed control costs were the most important factors for potential adopters of genetically engineered herbicide tolerant crops (Areal, Riesgo and Rodrıguez-Cerezo, 2011[192]).

[48] Several studies suggest that commonly available sources of information have tended to disproportionately emphasise negative aspects of genetic engineering. An analysis of media reports on agricultural biotechnology in five major newspaper sources in the United States and the United Kingdom concluded that "sensationalism and bias" have historically been present in reporting on "GM" biosafety (Marks and Kalaitzandonakes, 2001[168]). Durant and Lindsey (2000[169]) also found that a number of journalists focused on risks, and expressed standpoints opposed to "GMOs", sometimes entering into opposition movements themselves.

[49] For example, Ryan (2014[170]) highlights the use of techniques including imagery, metaphors and celebrity endorsements to encourage momentum against genetic engineering technologies.

[50] A related issue is whether a greater use of herbicides would in turn accelerate the emergence of resistant weeds. For example, the use of herbicide tolerant crops in North and South America induced many farmers to narrow down their crop rotations and ultimately grow these crops as monocultures, often against the recommendation of seed retailers. This in turn led to weeds developing resistance to glyphosate-based herbicides (Fernandez-Cornejo et al., 2014[171]). These agronomic problems are not inherent to transgenic crops (indeed, glyphosate was widely used as a herbicide before transgenic crops were introduced) and are the result of inappropriate use of pesticides, but are now associated with transgenic crops.

[51] Stone (2010[63]) reviews selected articles related to the role of farmers and communities in conserving genetic resources, including Kloppenburg (2004[182]) who places the question of ownership of plant genetic resources within a broader discussion on the appropriation of biological resources from the global south, and Brush (1993[183]) and Cleveland and Murray (1997[184]), who examine the spread of new IPRs and the impact of biotechnology on indigenous peoples, while McAfee (2003[185]) considers IP regimes in the context of the of the Convention on Biodiversity. The issue is closely related to broader discussions about the principle of free, prior and informed consent of indigenous peoples; see Tamang (2005[194]) for an overview.

[52] In terms of the “expected utility” framework in economic theory, scientific evidence can help to assess probabilities and outcomes, but individual consumers differ in their degree of risk aversion.

[53] As an example of this clustering of beliefs, opposition to “GMOs” was first taken up by various environmentalist organisations such as Greenpeace or Friends of the Earth, as well as supporters of Green political parties and organic agriculture associations. The anti-“GMO” movement later expanded to other groups such as farmer's unions and anti-globalisation organisations, adding an “economic” dimension (Bonny, 2003[177]).

[54] See also the OECD Competition Assessment Toolkit (OECD, 2020[188]) and related OECD work on pro-competitive policy reforms (OECD, 2020[189]).

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