THE POSSIBLE DEREGULATION OF CERTAIN GMOS IN THE EU:

WHAT WOULD THE IMPLICATIONS BE?

A PATHWAYS ANALYSIS

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ACKNOWLEDGEMENTS

This report was commissioned and funded by the Greens/EFA Group in the European Parliament. The authors are grateful to Franziska Achterberg for providing critical comments on earlier drafts of the document. The authors exercised full editorial control over the content of this report. All conclusions and opinions, as well as any factual errors, are the responsibility of the authors.

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SUGGESTED CITATION

Ely, Adrian, Patrick van Zwanenberg, Elise Wach and Dominic Glover (2023) The possible deregulation of certain GMOs in the EU: What would the implications be? A pathways analysis. Brussels, BE: The Greens/EFA group in the European Parliament.

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EXECUTIVE SUMMARY

The European Commission (EC) is set to propose the deregulation of certain genetically modified (GM) plants that have been produced using gene editing, a set of techniques within genetic engineering. This report looks at the possible implications and consequences of such a deregulation for the European Union (EU), considering the Union's efforts to achieve wider policy objectives with respect to sustainable food and farming systems, consumer choice, innovation, competitiveness, and other strategic goals.

The report reviews the social, technological and environmental changes to agri-food systems in countries that have allowed GM crops to be cultivated with few restrictions, where farmers have planted them at scale–notably, the United States. It draws out insights that can inform current decisions regarding the future regulation of gene-edited organisms in the EU.

The report describes how patented GM crops have enabled a handful of large, transnational agribusiness companies to concentrate and dominate agricultural input markets at global and national scales; and locked agriculture in GM-adopting countries into a pathway of input-dependent, industrialised farming practices that have negative implications for sustainability. It explains the mechanisms that have driven agriculture along this unsustainable path.

In the context of existing intellectual property regimes, deregulation of certain GMOs would likely lead to European agriculture becoming more dependent on external inputs, bundled into proprietary technology packages and controlled by a small number of multinational companies. Smaller and specialised seed companies would likely lose out. Crop research and development would likely be steered down narrower technological paths, and innovation would likely decline in speed and variety as competition decreased in the seed sector. Organic, agroecological and non-GM seed businesses, farms, food supply chains and consumers could be negatively affected by a reduced availability, diversity and choice of seeds suitable for different regions and styles of agriculture. Segregation and cross-contamination of GM and non-GM seed supply chains, farms, and post-harvest value chains would impose additional costs and risks, which would fall most heavily on the pioneers carving out innovative niches in which to explore and develop more sustainable and inclusive alternatives to the concentrated, input-dependent agrifood systems of today.

In sum, deregulation of certain GM crops and foods could have wide and long-term implications, not only for the use of specific crop biotechnologies in farming and food production in Europe, but for the broader sustainable and equitable development of European agri-food systems. The report argues that these potential implications should be weighed carefully in a broad and democratic debate, which should prioritise the desired sustainable directions for European agriculture and food systems, rather than placing a naïve faith in the supposed power of a singular technological pathway that locks farmers, input suppliers, food companies and consumers into an input-dependent technology treadmill.

INTRODUCTION

Policy makers in the European Union (EU) are considering the potential deregulation of certain genetically modified (GM) plants that have been produced using gene editing. This report looks at the possible implications and consequences of such a deregulation for the EU, including the Union's efforts to achieve wider policy objectives with respect to sustainable food and farming systems, consumer choice, innovation, competitiveness, and other goals.

The document reviews the experiences of countries that have adopted GM crop cultivation, particularly the USA; assesses the experiences of EU countries, which have largely avoided GM cultivation and widespread consumption of GM foods; and considers how the deregulation of gene-edited organisms in the EU could affect the EU's farming and food systems.

The report applies a pathways approach (Leach et al. 2010), which was conceived as a framework to address the inherent complexity of sustainable development as a challenge for public policy and governance (see Box 1).

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The report highlights what is at stake in decision-making around the regulation of gene edited organisms in European agriculture. The report's objective is to inform democratic deliberation and decision-making relating to the future regulation of gene-edited organisms in EU agriculture and food.

ORGANISATION OF THIS REPORT

The next section provides background information about the regulation of genetically modified organisms (GMOs) in the EU and the expected proposal that certain kinds of gene editing should be deregulated. The main section of the document follows, and it is organised into three parts. In Part 1, we review international evidence from countries that have embraced GM technology in agriculture and food, focusing principally on the USA, in order to consider how GM crop technology has affected pathways of change in the agri-food sector—often with negative or ambiguous implications for the current and potential sustainability of agriculture and food systems.

In Part 2, we use a pathways analysis to consider the potential implications of the proposed deregulation of some kinds of gene-edited organisms for the future of agriculture and food systems in the EU. In Part 3, we consider whether the proposed deregulation is likely to support the EU's wider policy objectives and strategies in relation to agriculture and healthy food, biodiversity, environmental integrity, competition, innovation and industrial development. Part 3 is followed by a short conclusion, which summarises the analysis and highlights some key implications for EU policy.

Key supplementary information is provided in Box 1 and Box 2. Box 1 (below) describes the pathways approach used in this report. Box 2 (within the section Background and Context) provides background information about gene editing techniques, how they differ from previous techniques of "classical" genetic modification, and how they have been classified into different categories for the purposes of risk assessment and regulatory oversight.

BOX 1: A PATHWAYS APPROACH

The pathways approach was conceived as an analytical and conceptual framework to address the inherent complexity of sustainable development as a challenge for public policy and governance (Leach et al. 2010).

The evolution of societies and economies, and their relationships with landscapes and environments, are shaped by interacting developments in science, technology, industry, culture, law, politics, conflict, and other dynamic, evolutionary processes. These interactions give rise to pathways of change that are complicated, multidimensional and difficult to comprehend, let alone control or manage (Leach et al. 2010).

Achieving sustainable development in such a complex world is inescapably a multi-dimensional and political (rather than merely technical) problem–characterised by inherent uncertainties, inevitable contestations around values, competition between rival interests, trade-offs among alternative objectives and strategies, unintended consequences, feedbacks, cross-scale effects, and so on. In this context, the pathways approach can be useful, both to interpret and understand the shaping of historical trajectories leading to the present, and to clarify and weigh up the alternative policy choices available in a given place and time (Leach et al. 2010).

The pathways approach helps policy analysts and decision makers be sensitive to the alternative directions of socio-technical change, the diversity of approaches used to address sustainability challenges, the distribution of costs, benefits and risks entailed by any given policy choice, and the democratic inclusiveness, transparency and accountability of decision-making (the 4D framework) (Leach et al. 2020).

The pathways approach shines a light on key problems that can arise, for society and for sustainable development, when a technological trajectory becomes dominant and entrenched. This occurs when a favoured technology attracts investment, is supported by policy incentives and regulatory measures, builds a community of practitioners and career professionals, embeds social habits and behaviours–in short, a particular socio-technical pathway can develop a self-reinforcing and self-perpetuating momentum, often referred to as "lock-in", which becomes difficult to change. The pathways approach helps analysts and decision-makers to be sensitive to the unsustainable risks that can accumulate, and the blockages to change that can arise, when unsustainable socio-technical trajectories become locked in, social and technological alternatives are squeezed out, and policy options are narrowed down and closed off (Leach et al., 2010).

A good example of this sort of lock-in effect, which can be observed in today's world, is the dependence of our energy, industrial and transportation systems on fossil fuels and their associated technologies. We have become aware that this dependence on hydrocarbon technologies has exposed humanity to great danger. We now know that our energy sources and power systems need to change, but changing them is difficult, because so much about our modern societies depends on them (Smil, 2019). Sustainable alternatives to hydrocarbon technologies have been neglected until recent times, but now we need them to be rapidly developed, deployed and scaled up. Entire “ecosystems” of practices, skills, knowledge, relationships, policies and regulations need to be built around new and more sustainable energy sources and technologies.

A similar process of lock-in can be observed in global agriculture during the post-Second World War period. A range of modern technologies, including mechanisation, mineral fertilisers, pesticides and high-yielding plant varieties were introduced to increase the production and productivity of crops, especially major commodities such as wheat, rice and maize. However, new farming practices that became possible because of those technologies then became dependent on continued pesticide and fertiliser use. For example, mixed farms gave way to specialised farms that grow genetically uniform crop varieties in large fields, using short crop rotations, which, although efficient in terms of yield and farm management, heightens vulnerability to pest damage, and so requires continued chemical pesticide use. Farmers had little choice but to adopt external input-intensive forms of production or risk going out of business, as farm gate prices of crops fell to match productivity improvements. Besides depending on high inputs of energy, industrial agricultural systems contributed to various kinds of pollution, including greenhouse gas emissions (Campbell et al 2017). There were knock-on effects in food systems and nutritional outcomes.

The pathways approach helps us to understand how modern, input-intensive agriculture became unsustainable in multiple ways, how lock-in effects perpetuate those practices and close off options for alternatives, and why we must be careful about policy and regulatory choices we make today, which will shape the agriculture, agri-businesses and food systems of the future.

BACKGROUND AND CONTEXT: *REGULATION OF GMOS IN THE EU*

The focus of current policy discussions within the EU is on the proposed deregulation of specific types of gene editing, known as SDN-1, SDN-2 and ODM. The European Commission is expected to publish a regulatory proposal in July 2023, which is anticipated to propose exempting these types of GMOs from product labelling and traceability rules, as well as from certain risk assessments, which are currently required for GM crops in the EU. (See Box 2.)

BOX 2: GENETIC MODIFICATION, GENE EDITING, MUTAGENESIS, AND REGULATION

Conventional techniques of genetic modification are generally used to integrate DNA from one organism into another organism, often an unrelated species. The resulting GMOs are sometimes known as "transgenics," and this mixing of genetic material from sexually incompatible organisms has been perceived as a key source of public concern about GMOs and their safety for people and the environment.

Some newer techniques of genetic modification exploit features of living organisms' immune systems to cut targeted sections of DNA and reconnect them, with modifications. These techniques can be used to remove or insert genetic sequences, or "knock out" or modify the expression of genes. This is known as gene editing. Gene-editing tools can be used to change the DNA of living organisms, without necessarily inserting exogenous DNA from another organism—but gene editing can also be used to achieve a stable introgression of transgenes.

A specific gene editing technique, known as CRISPR[1], has been heralded as a precise, accessible and versatile tool, which can be used to edit existing genes, introduce transgenes, or make several genetic modifications in one go.

Genetic engineers and regulatory scientists have proposed to classify gene editing techniques into three types—SDN-1, SDN-2 and SDN-3.[2] The distinction hinges essentially on the degree to which exogenous DNA is introgressed stably into the resulting GMO—and this has implications for regulation. Genetic engineers argue that SDN-1 and SDN-2 lead to small genetic changes, which are similar to mutations that could have occurred naturally, or could equally be created using long-established methods used in conventional breeding, including techniques, in use since the 1930s, that use chemicals or radiation to induce genetic mutations (mutagenesis) (Waltz, 2012; Wolt et al., 2016).

1 CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats. These are strands of DNA that help to guide the immune responses of bacteria and archaea.
2 SDN stands for 'site-directed nuclease.' Gene editing uses nucleases, a type of enzyme, to cut targeted sections of DNA.

Another technique of genome editing, which also does not lead to the stable insertion of exogenous DNA, is oligonucleotide-directed mutagenesis (ODM).

The European Commission's forthcoming proposal is expected to accept the proposition that SDN-1, SDN-2 and ODM organisms are less risky than GMOs produced using conventional genetic engineering techniques, and therefore should be regulated more lightly (see below; EFSA GMO Panel 2012; 2020).

BIOSAFETY

The current EU regulatory framework for GMOs emerged from debates in the 1980s, which led to new biosafety (Council Directive 90/220/EEC, 1990) and intellectual property (Council Directive 98/44/EC, 1998) legislation for the European Community. Parliamentary debates on these pieces of legislation focussed on the potential sanitary and phytosanitary impacts of GMOs and on the wider impacts of GMO cultivation and consumption on the structures and characteristics of European agriculture and food systems.

In the aftermath of the controversial introduction of the first GM crops and foods into European markets, Council Directive 90/220 was repealed in 2001 and replaced with Council Directive 2001/18/EC (2001) on the deliberate release into the environment of genetically modified organisms and Regulation (EC) No 1829/2003 (2003) on genetically modified food and feed. Directive 2001/18 laid out, among other rules, new requirements for environmental risk assessment and monitoring, whilst Regulation 1829/2003 and 1830/2003 described requirements for labelling and traceability of GM food and feed. The latter requirements were widely considered to be important in support the European consumer's right to choose.

In comparison to the relatively stringent approach taken in the EU since 2001, a comparatively permissive regulatory framework in the USA has enabled large-scale GMO commercialisation. Biosafety regulation in the USA has focussed on a narrow range of physical risks, and only recently have any labelling requirements been introduced (Ely et al. 2022). The EU's GMO traceability and labelling requirements, on the other hand, have since 2013 allowed the EU to restrict the cultivation of GMOs, whilst allowing imports of GMOs in food and especially livestock feed.

The European Court of Justice (ECJ) was asked to rule on whether Directive 2001/18 and the aforementioned Regulations applied to organisms obtained by new techniques of mutagenesis (such as gene-editing). In July 2018, the ECJ concluded that "organisms obtained by mutagenesis are GMOs" and fall within the scope of Directive 2001/18; but that techniques of mutagenesis "which have conventionally been used in a number of applications and have a long safety record" are exempted from the Directive's rules (ECJ 2018). This refers, for instance, to mutagenesis techniques that use radiation or chemicals to create genetic variation.

This decision was widely understood to have determined that organisms created using gene editing techniques would be covered by Directive 2001/18, because the technique used to create them was novel, i.e. it lacked a long track record of safe use. Many stakeholders, including companies with interests in the commercial development of gene edited organisms, objected to this ruling. Shortly afterwards, the Council of the European Union (2019) requested the European Commission to review the regulatory framework for genetically modified organisms in the EU and, if appropriate, make a proposal for reform. The Commission's study was published in 2021 (EC 2021) and the proposal for regulatory change is scheduled to be published in June 2023.

INTELLECTUAL PROPERTY

The upcoming legislative proposal is expected to affect how GM crops created using SDN-1, SDN-2 and ODM techniques are treated with regard to biosafety, traceability and labelling. It is not expected to address the intellectual property rules applicable to these products, which, however, are also relevant for the present report (as discussed in the following sections).

GMOs are patentable under Directive 98/44/EC (1998) and the European Patent Convention (EPC). Following the recent decision by the Expanded Board of Appeal of the European Patent Office (EPO 2020), plants arising from marker-assisted selection or conventional breeding are not patentable, as they rely on "essentially biological processes" (excluded from patentability under Article 53.b of Directive 98/44/EC and Rule 28(2) of the EPC). The European Patent Office's Guidelines for Examination (EPO 2023), however, state that plants modified through targeted mutagenesis (e.g. CRISPR) are patentable, provided that the patent application discloses the relevant genetic sequence and the technical means through which the modification can be achieved. As such, although certain gene-edited plants may have genetic changes that could have occurred through natural mutation, these plants are still patentable, meaning that they raise different questions in terms of their potential socio-economic impacts. The patent holder's permission is required before any variety bred from a patented SDN-1, SDN-2 or ODM plant may be commercialised.

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PART 1: *HOW ADOPTION OF GM TECHNOLOGY HAS SHAPED THE AGRIFOOD SECTORS IN COUNTRIES THAT HAVE EMBRACED GMOS*

Many of the effects of GM technology on agricultural and food system sustainability are indirect. They arise from the ways GM technology has evolved in conjunction with other characteristics of agri-food sectors. For example, as we describe below, GM crop technology is not commercially viable unless firms can recoup large investments in research and development, so private investment in the new crop technology would likely not have happened without the ability to patent engineered gene sequences and associated products. The extension of patent law to cover gene sequences created new and profitable business models, which, over the last thirty years, have enabled concentration of the global seed industry in the hands of a small group of transnational agrochemical firms.

In this part of the report, we consider how the commercialisation of GM crops has been intimately connected to a host of related developments in the agri-food sectors of countries that have embraced GMOs. This includes intellectual property rules, biosafety and other product regulations, business models, industry structures, and crop research and development and innovation strategies. GM technology has interacted with these factors to shape pathways of change in the agri-food sectors of the countries in question, with marked implications for the sustainability of farming and food systems.

PATENTS, GM CROP TECHNOLOGY AND SEED MARKET CONCENTRATION

During the 1980s, patentability rules in the United States were extended to enable the products and methods of plant genetic engineering to be patented—and the effects were felt beyond the borders of the USA. The change radically altered the profit opportunities in plant breeding, which historically had been a low-profit activity. This is because a patented engineered gene sequence can be licensed for commercial use in different plant varieties and crops, in various countries, generating an income stream for the patent owner in the form of royalties. Competitor seed firms are not allowed to use germplasm that contains patented GM sequences in their own breeding programmes without permission and without agreeing to pay royalties on any new varieties that they develop. Royalties can be claimed on multiple seed varieties that contain the engineered gene sequence, including all their future offspring. Furthermore, farmers are not allowed to save and replant seed varieties that contain a patented gene sequence. In effect, farmers rent the technology for one growing season at a time, and must purchase fresh seed each year, paying a royalty on each occasion.

By contrast, firms that create a plant variety using conventional breeding alone are only granted a monopoly on the initial variety. The intellectual property rules which, in most countries, govern conventional seed innovation (known as plant variety protection or PVP rules) explicitly recognise the cumulative nature of plant improvement, so they permit conventional varieties, including new traits they may contain, to be freely used by competing firms in their own breeding programmes (this is called the "breeders' exemption"). In many cases, farmers can save and reuse conventionally bred seed too (this is known as the "farmers privilege"). Conventional seed breeders must make their money in the period immediately after launching a new variety, and from that variety only.

Triggered by the new profit opportunities that patentable GM seed enabled, a handful of US and European multinational pesticide firms began purchasing biotechnology startup companies and investing heavily in their own in-house biotechnology capabilities.

Triggered by the new profit opportunities that patentable GM seed enabled, a handful of US and European multinational pesticide firms began purchasing biotechnology startup companies and investing heavily in their own in-house biotechnology capabilities (Wright & Pardey 2006; Schenkelaars et al 2011). The same firms also embarked on a wave of acquisitions of hundreds of small, medium and large seed companies, in order to gain control over those companies' germplasm resources and seed distribution networks. This resulted in a dramatic concentration in the structure and ownership of the global seed industry (Howard 2015).

In the USA, for example—which accounts for 40% of global GM crop production by area—multinational pesticide firms had bought up all the major seed firms by the end of the 1990s (Graff et al 2003). In the process, they acquired most of the nation's germplasm resources, at least for major crops like soybean and maize. The OECD (2019) estimated that in 2016, just four companies controlled 91% of the U.S. market value in cotton seed markets, 82% in maize, and 69% in soybean. The independent seed firms that account for the small remainder of the US market in those crops rarely have their own breeding programmes; they depend on seed varieties licensed from the big multinational firms (Tang et al, 2014).

By the early 2020s, just four agrochemical firms - Bayer, Corteva, BASF and ChemChina - accounted for over 50% of the global proprietary seed market.

By the early 2020s, following further mergers and acquisitions, just four agrochemical firms—Bayer, Corteva, BASF and ChemChina—accounted for just over 50% of the global proprietary seed market (ETC Group 2022).

This concentration of the seed industry would not have been possible under an intellectual property regime based on plant variety protection only. In the 1970s, attempts by multinational pharmaceutical and chemical firms to become players in the conventional seed market failed: lacking sufficient economies of scale—which are now enabled by patent protection—the new entrants were outcompeted by smaller, regional seed-breeding firms, so the new seed divisions of those multinationals were sold off (Schenkelaars et al, 2011).

Concentration in the ownership of patents and other crop intellectual property is even higher than in seed sales. Combining data on both plant variety protection for new seed varieties and patents on crop traits, gene sequences, marker identification, and breeding methods, indicates that in 2022 the largest four firms (Bayer, Corteva, ChemChina and BASF) owned 97% of U.S. intellectual property over oil seed rape, with corresponding shares of 95% of maize, 84% of soybean, 51% of wheat, and 74% of cotton (U.S. Department of Agriculture 2023, p. 42).

In short, on a global scale, the last thirty years has seen a relatively diverse seed industry come under the control of a highly concentrated pesticide industry. Today, a handful of giant pesticide-and-seed firms command portfolios of pesticides, GM technology and seeds, exercising oligopolistic dominance over key crop markets. (We refer to these companies below as "pesticide–seed" firms.) This has important implications for the kinds of GM crop innovations that have been developed and commercialised in the countries that have chosen to embrace GM crop technology, as well as for rates of growth in herbicide, fungicide and insecticide use, for the contraction of farmers' seed choices, for increases in seed prices, and for the operational scope of smaller seed firms, seed dealers and retailers. In short, the embrace of GM technology has been accompanied by, and helped to shape, sweeping changes that have had major implications for the direction and diversity of innovative activity in plant breeding and the distributive effects in the wider agri-food system.

On a global scale, the last thirty years has seen a relatively diverse seed industry come under the control of a highly concentrated pesticide industry.

WHERE HAS GM TECHNOLOGY BEEN ADOPTED AND IN WHICH CROPS AND TRAITS?

Plant genetic engineering R&D is costly and so is meeting biosafety requirements for new GM crops. The American Seed Trade Association suggests that the cost of bringing a new genetically modified trait through the research, development, regulatory and commercialization process to be about US$ 115 million (USDA 2023, p. 47). Obtaining and defending patents is expensive too. In fact, large U.S. seed biotechnology companies reportedly spend more on legal counsel than on R&D (Louwaars et al. 2009).

The high costs of GM crop development and commercialisation mean that only certain kinds of GM crop innovations are profitable. As one biotechnology industry executive explained in the early 2000s, those costs are such that a new GM crop trait needed to generate annual revenues, at peak sales, in the range of US$ 175–200 million in order for the large investments involved to pay off, but "[r]elatively few transgenic crop product concepts can achieve these high hurdle rates…" (Goure, 2004, p. 265). This means that only some kinds of GM traits, which can be incorporated into major commercial crops that have large international markets, and which can command relatively high prices—for example because they substitute for other costly inputs—are likely to be viable.

The high costs of development also mean that small companies and public institutions do not introduce GM crop innovations—while large companies use these costs to justify demanding high prices for their technology, while insisting that they need strong intellectual property protection to achieve this (Louwaars et al. 2009). Even discounting the costs of complying with biosafety regulation, the combined costs of R&D and of securing and defending patents still make it likely that only large companies are in a realistic position to develop and commercialise novel GM traits.

In practice, the only GM crops that are widely grown today are maize, soya, oil seed rape and cotton, and the only two GM traits that have succeeded on a large scale are for insect resistance (Bt) and tolerance to various herbicides.

In practice, the only GM crops that are widely grown today are four internationally traded commodity crops: maize, soya, oil seed rape and cotton, and the only two GM traits that have succeeded on a large scale internationally are for insect pest resistance (based on Bacillus thuringiensis genes (Bt)) and herbicide tolerance (HT, to various herbicides) (NAS Committee on Genetically Engineered Crops 2016). This is partly because Bt crops have helped to substitute for inputs of labour and chemical insecticides, while HT crops provide flexibility in weed control. But another reason why HT crops have dominated is because the business model of the global seed and agrochemical firms has been to maximise commercial synergies between the firms' seed and pesticide assets: they sell herbicides alongside proprietary HT crops. Seed contracts with farmers typically oblige the farmers to buy proprietary (branded) versions of the pesticide–seed firms' herbicide products, rather than cheaper, off-patent alternatives. The centrality of this marketing strategy is reflected in the branding of GM seeds as "Roundup Ready" and "Liberty Link". Very nearly all of the GM crop acreage in the U.S. comprises crops that have one or more HT traits, and this has very substantially increased the sale and use of the linked herbicides.

In the early 2000s, revolutionary promises were claimed for GM technology, which was going to alleviate hunger and poverty, address nutritional deficiencies, produce cheap vaccines, and make farming sustainable (Smith 2000; Royal Society et al 2000). Corporate and scientific narratives about the huge diversity of useful GM traits "in the pipeline" glossed over the commercial realities. Aside from the Bt and HT crops described above, other traits, for example longer shelf life, higher vitamin content, and disease resistance, have been engineered—however, most are not in commercial production (NAS Committee on Genetically Engineered Crops 2016). Virus resistance has been very rarely commercialised, with variable outcomes: virus-resistant papaya has seen success in some locations (Gonsalves et al 2007), whilst other examples (e.g. virus-resistant sweet potato in Kenya—see New Scientist 2004) have not. Drought-tolerant transgenic crops have proved more difficult to develop to commercialisation, with slow progress in soy and maize and some "false dawns" in wheat (Araus et al 2019). Biofortified crops have also proved more difficult to bring to the market than once hoped. These experiences suggest that ambitious claims being made for genetic engineering, including genome editing, should be examined sceptically.

In 2019, 98% of the global acreage of GM crops was confined to 10 countries, whilst about 85% was accounted for by just four countries—the U.S., Brazil, Canada and Argentina (ISAAA 2019). Most jurisdictions do not grow GM crops, or do so in very small quantities. Public scepticism about the need for GM technology, as well as concern about potential risks associated with GM crops, combined with mandatory labelling of foods containing GM ingredients, has meant that GM crops are not cultivated in the EU (except for small quantities in Spain), or in many other countries too—sometimes because of the same concerns, but also because Europe is a major destination for agricultural exports, and exporting countries do not wish to risk losing access to European markets.

TRENDS IN CONSUMPTION OF PESTICIDES AND HERBICIDES

Data up to 2012 indicated that the adoption of GM crops in the U.S. had driven an increase in total pesticide use by 183 million kgs since 1996, compared to the levels of pesticide use that could have been expected in the absence of HT and insect-resistant varieties. HT crop technology led to a 239 million kg increase in total herbicide use in the U.S. in the 16 years following the initial commercialisation of GM crops (1996—2011). Insect-resistant crops led to a reduction in chemical insecticide spraying of 56 million kilograms, although, when the in-plant Bt insecticide is added back, there was no net reduction in overall insecticide application (Benbrook 2012). Other data illustrates similar trends. In 2017, for example, the U.S. Environmental Protection Agency (EPA) recorded a 34% increase in agricultural herbicide use over the period 2005 to 2012 (cited in U.S. Center for Food Safety 2022).

In Brazil, a greater than three-fold increase in pesticide use in soybean production occurred following the commercialisation of GM varieties, while overall pesticide use increased 1.6-fold.

A similar picture is evident in other countries that have embraced GM technology. In Brazil, for example, a greater than three-fold increase in pesticide use in soybean production occurred over a 13-year period following the commercialisation of GM varieties, while overall pesticide use increased 1.6-fold (Almeida et al 2017).

RESISTANT WEEDS

The emergence and spread of glyphosate-resistant weeds is assessed to be the most important factor driving up herbicide use on land planted to HT varieties in the U.S. Weeds evolve rapidly to become resistant to herbicides to which they are exposed. Glyphosate-resistant weeds were practically unknown before the introduction of glyphosate-tolerant crops in 1996, but have now become a major problem for economic farm management, driving substantial increases in the number and volume of herbicides applied, as discussed in the previous section (Benbrook 2012). A similar effect has been seen in other countries that planted HT crops. Within a few years of the widespread adoption of glyphosate-tolerant soybeans, glyphosate-resistant weeds had become a major problem in many Latin American countries (Peterson et al 2017).

By 2015, there were 32 glyphosate resistant weeds in the world, of which 14 were in the USA, particularly in soybean, corn, and cotton fields, as well in orchards and vineyards on which glyphosate has been repeatedly applied. Some weeds have developed resistance to multiple herbicides, making them difficult to control by any chemical means—and multi-resistance is spreading (Bonny 2016). In 2012, the area affected by glyphosate-resistant weeds was about 6.3 million ha globally, of which approximately 95% was in the USA, in cropping systems using glyphosate-tolerant crops.

Within a few years of the widespread adoption of glyphosate-tolerant soybeans, glyphosate-resistant weeds had become a major problem in many Latin American countries.

Other assessments place a much higher estimate on the size of the problem. Bonny (2016) cited one 2013 survey that reported up to 28 million ha. of U.S. farmland was affected by glyphosate-resistant weeds. A 2017 industry survey of 4,000 farmers across the U.S. found that 73% of farmers reported glyphosate-resistant weeds (cited in Centre for Food Safety 2022), while the U.S. Department of Agriculture (USDA) has estimated that glyphosate-resistant weeds reduce maize and soybean farmers' returns by $5.4 billion per year (ibid.)

The emergence of glyphosate-resistant weeds has meant not only that farmers must use additional herbicides, as discussed above—leading to an increase in the total cost of herbicides used and driving greater overall toxicity to the environment—farmers also lost the practical convenience they had originally derived from spraying glyphosate over glyphosate-tolerant crops. The pesticide-seed firms have also responded to glyphosate-resistant weed problems by introducing new GM crops that can tolerate combinations of glyphosate and additional herbicides, such as Dicamba and 2,4-D. The pesticide-seed firms dominate the relevant markets, and can and have withdrawn previously available crop varieties, leaving farmers with no alternative other than to buy new varieties with multiple "stacked" HT traits.

Critics of this trend have warned that this arms race chiefly benefits the firms that produce GM crops and crop protection chemicals, rather than farmers or consumers (Ceccarelli 2014). Here is a good example of a lock-in effect, driven by a biological dynamic, which entrenches a pathway of technological development that has negative effects overall, but which becomes difficult to escape. Farmers become locked into a technology treadmill.

The critics of GM-dependent weed management argue that the short-term fix provided by stacked HT traits encourages the continued neglect of public research and extension in alternative methods of weed control, such as integrated weed management (IWM) (Mortensen et al. 2012). Herbicide-resistant weeds can and have developed, in Europe and elsewhere, in the absence of GM HT crops—but a scientific discussion of prevention and mitigation strategies in Spain, where GM HT crops are currently available, focuses on IWM strategies, rather than advocating wider adoption of HT crops (Montull and Torra 2023). Crops with stacked HT traits are likely to eventually increase the severity of resistant weed problems. Already, weed species resistant to multiple herbicide modes of action are becoming more widespread and diverse (Ceccarelli 2014; Montull and Torra 2023).

Weed species resistant to multiple herbicide modes of action are becoming more widespread and diverse.

RESISTANT INSECTS

A similar issue has arisen with Bt insect-resistant crops. Initially, and for several years, Bt technology afforded farmers a convenient and effective way to combat some kinds of pests, however, after a few seasons, populations of Bt-resistant insects appeared and began to cause problems. Today, field-evolved resistance to Bt has been reported in 26 cases, involving 11 pest species, across seven countries.[3] Seventeen more cases show early warning signs of resistance emerging (Tabashnik et al. 2023). Strategies exist to prevent and retard the emergence of evolved pest resistance, but these strategies entail some management complexity and costs for farmers, collective-action challenges for stakeholders, and monitoring and surveillance costs for stakeholders and society (Carrière et al. 2020). As we saw in the case of herbicide-resistant weeds, the pesticide–seed industry advocates a response to resistant insects that involves stacking multiple genetically engineered Bt traits, encompassing more than one different mode of action against insects.

Field-evolved resistance to Bt has been reported in 26 cases, involving 11 pest species, across seven countries.

Insect-resistance has not been a universal effect of Bt crop cultivation. A review by Tabashnik et al. (2023) found 30 cases worldwide in which no evolved pest resistance to Bt toxins has been detected. Within the EU, pest resistance to Bt has yet not been reported in Spain, where Bt maize has been cultivated since 1998. Scientists assert that this shows the effectiveness of resistance-management strategies and monitoring systems in the EU; however, the scientists also fear that pest resistance to Bt is more likely to evolve if Europe's farmers are permitted to plant only the single Bt transgenic "event" that has been approved to date for planting in the EU (García et al. 2023). Allowing the commercialisation of multiple, stacked GM Bt traits would likely involve a side-effect of tying farmers more tightly into a proprietary GM seed system dominated by large, transnational pesticide–seed companies—the next section turns to this issue.

FARMERS' SEED CHOICES

There are other aspects of the pesticide–seed firms' commercial strategies that lock U.S. farmers into increasing pesticide use. The companies often bundle their own fungicides and insecticides with GM seeds, in the form of chemical seed treatments. In the U.S., almost 100% of corn seed, the majority of soybean seed, and the seeds of many other

3 Each 'case' represents 'the response of one pest species in one country to one Bt toxin produced by one or more Bt crops' (Tabashnik et al. 2023: abstract).

crops are routinely coated with neonicotinoid insecticides, which are known to harm pollinators (Wood and Goulson 2017), and multiple fungicides (US Center for Food Safety 2022). Since the seed market in the U.S. is almost completely dominated by the global pesticide–seed firms, especially for the major crops of soya, maize, oilseed rape and cotton, "[f]armers have little or no choice of 'bare' seed, and often have little knowledge of the pesticidal coatings or their purpose" (US Center for Food Safety 2022, p. 11-12). This has become another driver of pesticide-intensive agriculture in the U.S. and other jurisdictions where GM crops have been commercialised.

U.S. farmers' organisations and other commentators on the U.S. agricultural sector are concerned that GM crop commercialisation has restricted farmers' choices of seeds and technologies. In part, this is because fewer conventional (non-GM) crop varieties are available, as the large pesticide–seed firms have removed many such varieties from the market. In part, the problem stems from the consolidation of the seed industry, which has led to a decline in locally and regionally adapted varieties (USDA 2023). The variety of farming systems that are catered for by the seed industry has diminished, as the large pesticide–seed firms focus primarily on industrial farming systems, while smaller seed firms that cater for alternative production systems, such as organic farming, or even for seed varieties that are not pre-treated with fungicides and insecticides, struggle to stay in business.

The American Antitrust Institute has noted that Monsanto (which was acquired by Bayer in 2018) repeatedly discontinued the seed lines of companies it acquired and cited the seed industry press as reporting that "[s]eed companies have either cut back on non-biotech offerings or have dropped them" (American Antitrust Institute 2022, p. 7). The U.S. Organic Seed Alliance (2022) has noted that some firms selling GM maize have eliminated non-GM options altogether, and have released new high-yielding varieties only with stacked GM traits incorporated. This means that farmers can only access the newest elite germplasm (combining disease resistance, high yield potential, and other valued traits) by paying for GM HT and/or insect-resistance traits.

This has made farmers more dependent on the GM seed-and-herbicide cropping systems and locked them into technology treadmill. Independent seed firms find it hard to provide alternatives for farmers who want them. The largest biotechnology companies own most of inbred maize seed lines (which are used for breeding), and have been unwilling to license them to seed companies wishing to develop maize varieties suitable for organic production, without the chemical seed treatments, which the big pesticide–seed companies routinely apply but which are prohibited in the national organic standards. According to the president of one seed company, out of more than 1,940 hybrid lines available, only 8% are available as a non-GM line and in an untreated form (Organic Seed Alliance 2022, p. 21).

Some farmers in the U.S. have been forced to purchase herbicide-resistant varieties when they otherwise would choose not to, because of the problem of herbicide drift. The HT trait facilitates spraying of herbicide applications over the top of the HT crop during the growing season rather than prior to planting. When this is done, the herbicide droplets can drift onto neighbouring fields and damage crops that lack the relevant HT trait. The USDA has noted that some farmers plant HT

Some farmers in the U.S. have been forced to purchase herbicide-resistant varieties because of the problem of herbicide drift.

crops, not necessarily because the varieties are superior, but because planting herbicide-susceptible seeds carries an unacceptable risk of having crops damaged by herbicide drift (USDA 2023). Here, we see another mechanism of lock-in, where farmers use herbicide-dependent farming practices, not because they are best for their business, but because they want to protect themselves from products and practices with which they cannot coexist.

The USDA and EPA believe that such "defensive" planting has contributed to rapid adoption rates for Dicamba-tolerant GM seeds. They anticipate that seed companies may not be able to successfully commercialise any new variety in some regions, unless it has the Dicamba-tolerance trait (USDA 2023).

The switch into GM-centric farming practices has other lock-in effects. For example, intercropping is a farming practice that contributes to greater resilience to pests, diseases and climate variability, improved soil retention, and improved water usage. Intercropping depends on cultivating several companion crops alongside one another. GM HT cropping systems are based on an entirely different conception of input-dependent farming: unless all the crops in the system are herbicide-tolerant, herbicides cannot be used, and GM HT crops are irrelevant (Altieri 2005).

REVENUE MODELS, MARKET POWER AND COMPETITION

As noted earlier, the business models of the very large pesticide–seed companies typically involves bundling GM traits and patented seed varieties with herbicides and pesticides. The revenue model usually involves "leasing" GM seeds (i.e. permitting farmers to use the patented seed for one growing season) under individual contracts. The firms also license GM traits and germplasm to crop breeders and seed companies, both to their large competitors and to smaller seed firms, and as noted earlier, can as a result collect substantial royalties from multiple varieties in the market that contain their patented traits. In the soya sector in Argentina, for example, Monsanto's herbicide tolerant GM trait, which was commercialised in the 1990s, was licensed to all other seed firms selling soya, and is present in virtually all commercial soya seeds. Each year, Monsanto (now part of Bayer) receives about two thirds of the retail price of those seeds in the form of royalties (Marin et al 2023), even though Monsanto itself has a negligible share of the soya seed variety market in Argentina. The size of that royalty is notable, because the seeds also contain many other valuable traits that have been introduced over many years by conventional breeding. As the sole owner of the GM herbicide tolerance trait, made commercially valuable within the context of an industrial farming system that increasingly depends on supplying combinations of HT crops with proprietary herbicide formulations, Monsanto possesses considerable market power in negotiating licences.

In Argentina, Monsanto's herbicide tolerant GM trait is present in virtually all commercial soya seeds.

In the U.S., smaller seed firms typically no longer have their own breeding programmes. Instead, they license varieties and patented traits from the large pesticide–seed companies, but the terms and conditions under which they do so are skewed to benefit the large firms, which exercise near-monopoly control over key seed markets. The U.S.

Independent Professional Seed Association has noted that, in order to license patented traits and varieties, seed companies "must provide a multinational corporation with a list of all our customers, (complete with addresses), the amount of seed purchased by product for each customer, as well as our complete company financials. After giving them all our company information [which includes costs and profit margins, as well as complete information on their market and customers] we need to try to compete against their company and owned brands" (cited in USDA 2023, p. 48).

In effect, the dominant market players can deny a licence to any smaller seed company that pursues a strategy which the licensor does not like, such as by trying to combine biotech traits from one firm with germplasm from another firm, or to sell generic chemical inputs alongside seeds that incorporate patented GM traits (USDA 2023). For example, in Argentina, Monsanto insisted that one major domestic soya seed breeder could introduce Monsanto's stacked traits into only the top 15% of the domestic firm's most productive soybean varieties. This had the effect of associating Monsanto's GM technologies with the best-performing germplasm on the market, which artificially elevated farmers' perceptions of the value provided by the stacked GM traits. This was an important tactic for Monsanto, in a context where farmers had hitherto been reluctant to buy the new GM varieties, which they regarded as too expensive because they delivered insignificant management gains and had relatively lower yields (O'Farell 2020).

The average cost of soybean seed increased by 60% over the 20 years prior to the introduction of GM varieties, then rose by 325% in the following 16 years.

The monopoly power of a very small number of very large pesticide–seed firms has prompted concerns about their ability to impose high seed prices on farmers. The US Center for Food Safety (2022) has referred to USDA data, which shows that the average cost of soybean seed increased by 60% over the 20 years prior to the introduction of glyphosate-tolerant varieties in 1996, then rose by 325% in the 16 years to 2011. Similar trends were seen for maize and cotton seeds. Other USDA data indicates that seed prices of GM crops increased about three times faster than those of other field crops between 1990[4] and 2013 (USDA 2023, p. 47).

In principle, higher GM seed prices might be compensated by increases in farm productivity and profits for farmers, however Benbrook (2009) argued that rising GM seed prices have been claiming an ever-greater share, not only of farmers' operating costs, but also of their gross crop income and net returns per acre, suggesting that the increased cost of GM seeds is offsetting any economic benefits they provide—representing a transfer of income from farmers to the pesticide–seed industry. Similarly, the American Antitrust Institute cited USDA data showing that GM seed price increases have outpaced yield increases over time, "the very problem that biotechnology is purportedly designed to solve" (American Antitrust Institute 2022, p. 9).

The size and economic importance of the small number of global pesticide–seed firms also enables them individually to exercise more significant political power over national governments than any single company could in a more diversified seed sector. In Argentina, Monsanto threatened to provide no further access to its GM crop technologies

4 GM varieties of major field crops were first commercialised in the USA from 1996 onwards.

until the domestic intellectual property regime was reformed in its favour (Arza & van Zwanenberg 2014).

IMPACTS ON INNOVATION

Decisions to embrace GM crops are likely to have consequences for the overall level of innovative activity in seed breeding, and for the direction and diversity of innovative activity. Those consequences stem indirectly from the commercialisation of GM crops: they are associated with how patentable GM traits have enabled new business models and driven concentration in the seed industry. The large pesticide–seed firms can and do use patents to prevent germplasm that contains their proprietary traits from being used as a basis for further adaptation breeding and crop improvement, whether by other seed firms, public sector breeders, or farmers. This power to exclude stems directly from the income model of the pesticide–seed industry, which depends on the royalties that patent protection enables. Hitherto, anybody could use any germplasm for breeding purposes and have the right to commercialise the resulting varieties. A reduction in the genetic variation available for plant breeding programmes is likely to drive a decline in the genetic diversity available to farmers in commercial seed varieties (Louwaars, et al. 2009).

The USDA has warned that the increased concentration and economies of scale for dominant companies may pose significant barriers to entry for small and medium-sized enterprises and reduce innovation.

An analysis carried out by USDA economists in the early 2000s found that "[t]hose companies that survived seed industry consolidation appear to be sponsoring less research relative to the size of their individual markets than when more companies were involved." The authors extrapolated that "fewer companies developing crops and marketing seeds may translate into fewer varieties offered" (Fernandez-Cornejo & Schimmelpfennig 2004).

A later study by the USDA (2023) confirmed that consolidation in the seed industry has resulted in fewer and larger companies concentrating research and development in higher volume and higher value seed markets. US farming groups complain that seeds for regional production niches, minor crops and less widespread agricultural systems, which used to constitute viable markets for smaller seed companies, have been neglected (Hubbard 2009; U.S. National Farmers Union 2022). The USDA has warned that increased economies of scale in crop biotechnology implied that "only very large companies can hope to compete in these sectors" and that "taken together, the increased concentration and economies of scale for dominant companies may pose significant barriers to entry for small and medium-sized enterprises and reduce innovation" (USDA 2023, p. 45).

This trend is particularly evident in the large-scale commercial crops where GM technology dominates, such as maize and soybean. In the U.S., almost all the elite germplasm in these key crops is owned by a handful of large pesticide–seed firms. The barriers to entry for a new firm proposing to enter such markets would be staggeringly high. No would-be entrant could replicate quality germplasm—the product of millennia of selection and breeding—without using breeding material controlled by the big firms.

In seed systems dominated by seed patents, the absence of an exemption for farmer seed-saving removes another driver of innovation. In the past, "agriculture has been a field where farmers substantively contributed to developing and improving existing and new plant varieties" (The National Family Farm Coalition, cited in USDA 2023, p. 53). The argument of farmers' associations is that farmers' own practices of seed-saving, selection and cross-breeding have provided an important impetus for seed firms to innovate, since those companies had to regularly introduce valuable genetic improvements that would incentivize farmers to return to the market to purchase new seed, rather than save the previous years' seed (USDA 2023, p. 53).

The USDA has recently expressed its concern that reductions in the number of breeding companies and breeding programmes, and the associated decline in the number of crop varieties being developed for each region of the country, increases the vulnerability of the U.S. agricultural system to major environmental and price shocks. The USDA fears that the lack of crop and varietal diversity may be more pronounced in the U.S. than in other agricultural regions, such as Europe (USDA 2023).

In their recent report, the USDA noted: "We heard from several people knowledgeable about the industry that essentially all the genetic diversity in our current maize crop is available in off-patent lines, meaning that there has been little to no introduction of new genetic diversity to the germplasm pools of the largest companies for at least 20 years. The current genetics have just been continuously recombined and [sic] introduced traits that offer different types of pest and herbicide resistance, with an increasingly narrower genetic base" (USDA 2023, p. 63, emphasis added).

Embracing GM crop technology has also steered the direction of crop innovation. The strategy adopted by the big pesticide–seed firms, to maximise synergies between their pesticide and seed assets, appears to have skewed their research agendas away from breeding for superior disease resistance, for example. The U.S. Center for Food Safety (2022, p. 3) cited field trials data obtained from the Information Systems for Biotechnology at Virginia Tech, which show that field releases of disease-resistant GM crops dropped from about 25—35% of all field releases in the late 1980s and 1990s to about 5% in the 2000s, which was a major phase of pesticide–seed industry consolidation. The Centre for Food Safety's interpretation is that "...the once vigorous efforts to develop disease-resistance traits flagged once the seed firms working on such traits were acquired by the pesticide industry, which saw a conflict with their interests in marketing more fungicide products" (ibid.).

Crop varieties optimised for the best yields in external input-dependent systems are not well suited to low-input systems, such as organic and agroecological farming systems (Murphy et al. 2007). For example, the dominant trend in cereal crop breeding has favoured low nutrient-use efficiency in the presence of high levels of inorganic nitrogen inputs. The resulting varieties do not perform well in farming systems which lack excess nitrogen, such as organic systems. This bias in breeding creates obstacles for the development and growth of alternative cultivation methods and helps to lock-in farmers into high-input farming systems (Lammerts van Bueren et al. 2011; Lammerts van Bueren, et al. 2002; Wolfe et al. 2008).

COMPARATIVE ASSESSMENTS OF AGRICULTURAL PRODUCTIVITY AND SUSTAINABILITY

As described in the preceding sections, GM-fuelled pathways of change in the agri-food sectors of countries where the technology has been embraced—the U.S. in particular, where more evidence is available than elsewhere in the Americas—suggests that pathways of change have been characterised over time by higher seed prices, fewer seed choices, a decline and narrowing in innovative activity, a transfer of income from farmers to input suppliers, a sharp increase in the use of pesticides (especially herbicides), and the emergence of herbicide-resistant weeds across wide areas of agricultural land.

How do these trends compare to regions where GM technology has not been widely adopted, Europe in particular? Unfortunately, detailed comparative studies are rare (EC 2021, p. 126; Mammana 2014, p. 9). More generally, few analyses are available which show how the European agri-food sector has evolved over time along a non-GM pathway.

Seed market consolidation is a global phenomenon, however, the European Commission considers the EU seed market to be much less concentrated compared to the world seed market and especially in comparison to the U.S. (EC 2015; 2021). Nonetheless, industry concentration within Europe does appear to be increasing over time, with uneven effects-- with the markets for some agricultural seeds being already highly concentrated. For example, Lianos et al. (2016) estimated that five firms controlled 95% of the EU vegetable seed market, whereas five firms controlled just over 50% of the EU maize seed market. The latter estimate contrasts with another estimate by Mammana (2014), who estimated that five companies constituted around three quarters of the EU market for maize seed. The difference in these estimates reflects the difficulty of obtaining reliable, published data on the structure of seed markets in the EU (or elsewhere).

The European Commission considers the EU seed market to be much less concentrated in comparison to the U.S.

The influence of market concentration on seed prices in the EU is unclear (OECD 2018; EC 2021). The European Commission has noted that European farmers faced an overall increase in seed prices of 30% between 2000 and 2010, but that this overall trend varied across Europe, with some Member States seeing increasing prices and others a decline. The European Commission also noted that market concentration may have an effect on innovation and seed choice, but provided no data on these effects (ibid.).

Two comparative U.S.—European studies of agricultural productivity and aspects of sustainability following the adoption of GM technology in the U.S. have been published in the academic literature. They are informative about the relatively greater diversity of seed choice and intensity of seed innovation in Europe compared to the U.S. In the first of these studies, Heinemann et al. (2013) compared yields of maize, rapeseed, soybean and cotton between North America, where almost all of these four crops are now GM, and Western Europe, where almost all of these four crops are still conventional. Examining data up to 2012, Heinemann and colleagues found no yield advantage or other significant benefit for GM-centric agriculture in the United States compared to the overwhelmingly non-GM systems Europe. They found that GM crops maintained or increased US pesticide use relative to equally advanced competitors, and that "[t]he pattern and quantities [of pesticide] unique to the use of GM-glyphosate-tolerant crops has been responsible for the selection of glyphosate-tolerant weeds… The use of Bt crops is associated with the emergence of Bt resistance and by novel mechanisms in insect pests" (Heinemann et al 2013, pp. 83-84).

Hilbeck et al. (2011) found a similar picture: during the period of rapid GM crop adoption in the USA, between the mid-1990s and 2011, they found that yields in non-adopting European countries stayed competitive with yields in GM-adopting countries. European maize yields were regularly as high or higher than in the USA, except when European production was undermined by severe drought (Hilbeck et al 2011).

Hilbeck et al. (2011) also compared the availability of maize seed varieties for farmers in three non-GM European countries (Austria, Germany and Switzerland), and Spain, where farmers have unrestricted access to approved GM maize varieties. They found that farmers in the three non-GM countries had more maize cultivars available to them in 2011 than they had in the 1990s, despite restricting GM maize. In Spain, the seed market was more concentrated, with fewer differentiated cultivars on offer. Non-GM cultivars were being replaced by GM cultivars and the overall numbers of maize cultivars declined.

SUMMARY OF PART 1

The commercialisation of GM crop technology in the U.S. and in a small number of other countries, largely in the Americas, has influenced pathways of change in those jurisdictions' agri-food sectors in significant ways, exacerbating the ways those societies have become locked-in to the industrial agriculture pathway that developed after the Second World War. The patentability of GM technology has enabled an oligopolistic seed industry structure to emerge, based on the acquisition of much of the seed industry by a handful of multinational pesticide firms. GM crop technology, coupled with the extension of patent rights to cover GM crops, has created new, very profitable business models based on developing and licensing engineered gene sequences for incorporation into numerous seed varieties in a handful of important commodity crops. These seeds have been bundled with proprietary herbicides, as well as insecticides and fungicides. Corporate R&D strategies have been designed to support this profit model, creating an innovation bias which favours new crop varieties that are optimised for cultivation alongside pesticides and fertilisers.

The pathway of technological change in GM-adopting countries has led to the disappearance of many small seed firms, constrained access to proprietary germplasm for those firms that remain independent, and a restricted scope for the associated breeding and adaptation.

This pathway of technological change in GM-adopting countries has led to the disappearance of many small seed firms, constrained access to proprietary germplasm for those firms that remain independent, and a restricted scope for the associated breeding and adaptation.

Many non-GM varieties have been withdrawn from markets, and the genetic diversity of the available cultivars has narrowed, increasing the vulnerability of cropping systems. Intensive herbicide spraying has become an essential feature of GM cropping systems and, when herbicide-resistant weeds inevitably emerged, the pesticide–seed industry has responded by proposing GM crop varieties that are resistant to multiple herbicides.

Farmers have increasingly been locked-in to a certain style of farming, which is incompatible with alternative, more ecological approaches. Some farmers, who might otherwise choose non-GM seeds, have felt constrained to adopt HT crops as a precaution against spray drift damage from neighbouring GM farms. Meanwhile, a disproportionate fraction of farm income is being transferred to a handful of input suppliers.

The commercialisation of GM crops has had profound direct effects and indirect ramifications. GM crops have been widely adopted in countries that have embraced them, not chiefly because they are exceptionally productive or profitable for farmers, but because they have been packaged and marketed as part of a business model that generates billions of dollars in royalties for the large agribusiness conglomerates, which combine pesticides and seeds. Farmers and the rest of the seed industry have had to adapt to these structural changes and constraints; they have had little choice other than to rely on and contribute to a system of crop production that has highly problematic consequences for sustainability, in terms of crop biodiversity, ecological health, and the economic prosperity of farmers, rural communities, and small seed firms. This represents a good example of lock-in in action.

PART 2: *POTENTIAL IMPLICATIONS OF DEREGULATION OF SOME GMO TECHNOLOGIES IN THE EU*

To predict the exact pathways along which gene editing would evolve within EU agriculture and food, in the aftermath of the proposed deregulation, would be impossible. The precise terms of any new regulatory framework governing the commercial use of gene-edited organisms will strongly shape the impacts on different stakeholders, in conjunction with two other major considerations: intellectual property protection, and external trade.

GMOs created by SDN-1, SDN-2 and ODM techniques are being patented at international and national/EU levels (Jefferson et al 2021). The evolving patent landscape is dynamic and complicated. It involves a multitude of public and private organisations and claims. The stacking of complex traits is generating concerns that "patent thickets" and "patent minefields" are emerging, which threaten to entangle the sector in complex litigation, negotiation and cross-licensing (Kock 2021). Institutional solutions, such as patent "pools" or "clubs," "clearing houses," open-source licences and IP donations are being proposed and explored. Whether or not these arrangements are instituted, patents look set to remain the key instruments of intellectual property regulation in this space, and in such a scenario, we expect the market power dynamics described above, with respect to countries where GM crops have been embraced, to continue.

There are concerns that "patent thickets" and "patent minefields" could entangle the sector in complex litigation, negotiation and cross-licensing.

Several of the EU's most important trading partners (including the USA, Argentina, Brazil and Australia) have recently exempted certain GMOs from their biosafety regulatory frameworks that govern transgenic technologies. At the World Trade Organisation, GM-adopting countries have been arguing that regulatory approaches should be "science- and risk-based, transparent, predictable, timely, and consistent with relevant international trade obligations" (WTO 2018, section 2.3). Whilst the regulatory approaches taken across the world are not uniform, and unilateral deregulation of gene-edited organisms in the EU would not guarantee frictionless international trade in these commodities, we assume that deregulation would lower barriers to both inward and outward trade in the affected GMOs.

Based on the above assumptions, we consider potential scenarios that might flow from deregulation in the EU, and explore the potential impacts on different EU stakeholders—including multinational agri-businesses, start-up enterprises, seed companies and farmers—that are involved in gene-editing, conventional food and farming sectors, and organic and agroecological sectors.

POTENTIAL IMPACTS ON MULTINATIONAL PESTICIDE–SEED BUSINESSES

Multinational agri-businesses, in particular the largest four pesticide–seed firms (Bayer, Corteva, ChemChina and BASF), benefit from being able to operate in similar ways across global markets. Deregulation in the EU market would enable these companies to further increase economies of scale in their operations, and further lock-in the pathways described above.

Under a scenario in which navigating entangled thickets and minefields of patents becomes essential to doing business, the market power of the Big Four pesticide–seed firms seems likely to increase even further. Innovating and bringing improved varieties to the market will be constrained by the need to assemble critical pieces of intellectual property. The more complex the genetic modification—involving multiple, stacked traits—the more complex and potentially costly the intellectual property licences could be. Only those (large) firms that possess the requisite legal resources will be able to overcome such constraints with relative ease. They are strongly positioned to benefit most from the emerging patent landscape, not only because they have the resources to acquire patents and licences and have large legal departments, but also because they can use their own patent portfolios as chips to bargain for access to intellectual property owned by other players in the sector. Each of the Big Four firms has secured licences to foundational patents on CRISPR that are owned by The Broad Institute (Global 2000 et al. 2022). The patent landscape for CRISPR applied to crop plants appears to be dominated by Corteva, at least up till 2020 (Testbiotech 2021).

In theory, regulatory policies restricting pesticides and other synthetic inputs in European farming could incentivise large pesticide–seed firms to turn away from their current strategies of bundling seeds with agrochemicals. However, despite long-standing commitments to reduce pesticide consumption in the EU, there are few signs of progress (European Court of Auditors 2020). The most recent attempt—to establish a target to reduce pesticide use by 50% within a revised Sustainable Use of Pesticides Directive—has been delayed and may be diluted, following strong resistance from the pesticide industry, farmers organisations, parts of the Commission, and many Member States (Bounds 2022).

Despite long-standing commitments to reduce pesticide consumption in the EU, there are few signs of progress.

The first crop produced using CRISPR that was submitted for approval under EU Regulation 1829/2003 was DowDupont/Corteva's Maize DP915635, which is resistant to the herbicide glufosinate. This example (as well as the example of Cibus' 5715 HT rapeseed (canola), which has been commercialised elsewhere) casts some doubt on the claim that gene editing is being used to move away from chemical-dependent farming and improve the environmental performance of agriculture.

As discussed in Part 1, regulatory costs for GMO clearance have entailed significant costs, which may have acted as a barrier to entry for small seed firms (NAS 2016). Large multinational firms possess the financial resources and technical capabilities needed to comply with these regulations. They can also leverage this investment across the multiple markets where they operate, thus benefiting from economies of scale in regulatory science—while also keeping their regulatory data confidential, in a similar way to trade secrets, so that other firms cannot take advantage of it. It is plausible that, if deregulation were to occur in the EU—the multinational pesticide–seed firms' comparative advantage in regulatory compliance would be reduced, which in theory would open them up to increased competition from other public and private entities. The likelihood of this happening is discussed in the next section.

POTENTIAL IMPLICATIONS FOR EU ENTITIES INVOLVED IN GENE EDITING

A number of smaller firms, research institutes and other organisations have capabilities in gene editing and are making investments in research to improve crop yields or the nutritional profile or processing qualities of crops, or to enhance resilience to biotic and abiotic stresses—alongside a smaller proportion of investment targeting herbicide tolerance (Modrzejewski et al 2019; Jorasch 2020). There exists a theoretical potential that gene editing would be used to develop traits that could disrupt existing patterns of chemical-intensive agriculture and contribute to the EU's wider goals around sustainable agriculture and food and nutrition security. However, the technical capabilities for developing traits like these are only a small subset of the capabilities required to bring such products to market. In most cases, small firms or public sector breeders would be obliged to partner with, or license their intellectual property to, larger firms that would navigate the regulatory, marketing and distribution challenges involved in successful commercialisation. The power to make or break the commercial success of such gene-edited crops would, in many cases, depend ultimately on the willingness of the big pesticide–seed firms to invest in and promote them. Therefore traits such as disease resistance and nutritional improvement might well end up being stacked with the large firms' proprietary HT traits in order to reach the market. Large firms are capable of acquiring smaller firms that develop intellectual property assets that would enhance their existing portfolios, or could threaten their business models. This would reinforce a "world as we know it" scenario (Kock 2021), in which multinationals remain dominant.

Small firms or public sector breeders would be obliged to partner with, or license their intellectual property to, larger firms that would navigate the challenges involved in successful commercialisation.

Public sector organisations, such as universities, are also among those acquiring intellectual property around gene-edited crops. This has led to calls for such organisations to waive gene editing licences for non-commercial activities to help "meet food needs in low income countries", with Wageningen University in the Netherlands setting a precedent in this regard (Van Oost and Fresco 2021). Often, however, patents represent an obstacle to public-good research. As the breeders' exemption does not apply in the context of patented seed, independent researchers and breeders can be prevented from innovating with patented gene-edited varieties, even before they attempt to bring the resultant products to market. For a variety of reasons (explored by Vanloqueren and Baret 2010), research and development systems continue to be constituted in ways that favour the production of patentable knowledge and GM technologies, rather than more open-source insights that can more readily be applied in agro-ecological farming. Deregulating some GMOs will not alter this situation in the EU.

POTENTIAL IMPACTS ON CONVENTIONAL SEED COMPANIES, FARMERS, FOOD PROCESSORS/ MANUFACTURERS, RETAILERS AND CONSUMERS IN THE EU

The deregulation of SDN-1, SDN-2 and ODM types of gene editing in the EU is likely to remove the need for labelling and traceability of these products. This would hinder segregation and traceability, undermine transparency, remove the freedom to choose GM-free products along the supply chain, and eliminate the possibility of long-term monitoring of unintended effects. This would have major implications for all actors in the food chain that currently avoid GMOs—including conventional seed companies, farmers, food processors/ manufacturers, retailers or consumers. Experiences with the earlier generation of GMOs have demonstrated that these are key concerns for European consumers and other supply-chain actors, leading to the current EU context, in which negligible GMO cultivation takes place.

Experience with the earlier generation of GMOs has illustrated the challenges, modalities and costs of various approaches to co-existence at different stages along the supply chain (Bertheau et al 2009; Venus et al 2017). In the current context in the EU, where labelling of GM food products is required, a segregated market has developed, in which most dominant retailers avoid the presence of GM food ingredients above the 0.9% threshold. Non-GM material attracts a price premium, and labelling has been sufficient to disincentivise GM farming across most of the EU.

Where feed imports are required to sustain livestock production, the development and maintenance of a non-GM supply chain has required extensive efforts by initiatives such as the GMO-free Regions Network, which has linked livestock producers in Europe with non-GM soya suppliers in America, Asia, and Eastern Europe (Layadi 2012). The challenges of maintaining a food- and feed-supply system free of GMOs would be further exacerbated if the EU follows other countries, such as the USA, Argentine, Brazil and Canada, which export to the EU, in permitting the cultivating and trade of gene-edited products, as well as “classical” GMOs.

The difficulties of segregating GM and non-GM supply chains and maintaining traceability are significantly increased with gene-edited products, because detection technologies and methods are currently non-existent, unproven, unreliable and/or costly. The costs and difficulties usually fall on the non-GM producers, processors, retailers and consumers. PCR-based approaches, which are commonly used to detect transgenic products, can be used to detect known sequences in gene-edited products (for example, Chhalliyil et al [2020] developed a quantitative PCR test to identify Cibus’ gene-edited canola), but the design of such tests relies on having reliable information about the sequence to be detected. There have been calls for a mandatory international registry of biotech products to be established, which would provide a reference for testing and detection methods (Eckersdorfer et al 2019; Ribarits et al 2021). No such registry yet exists that provides adequate, authoritative and comprehensive information that would support systematic testing.

The reliability of PCR tests also depends on whether similar genetic sequences exist in other varieties of the same species (Chhalliyil 2020b) or even other species (Weidner et al 2022)—if such similarities do exist, these tests can produce false positive results.

Emerging technologies that employ bioinformatics approaches are claimed to provide a "straightforward, rapid means" (Ginkgo Bioworks 2022) of identifying who is using whose intellectual property. Technologies like these could potentially be developed and adapted to screen samples for the adventitious presence of gene-edited products in food and feed supply chains, however, the practical utility and eventual cost of these emerging approaches is still unclear.

Existing approaches to traceability in some food and feed supply chains rely on stringent and reliable record-keeping throughout the chain, rather than enforcement based on detection of genetic sequences. These kinds of traceability systems are used in specialised value chains, such as organic, halal, fair trade, and non-GMO. Consumer demand for product segregation and labelling justifies the introduction of public or private standards to ensure the separation of supply chains, potentially at significant cost—and these costs often fall on the producers and consumers who demand and value the separation.

There is a demand within the EU food system for products that exclude all forms of genetic modification—e.g. organic, agro-ecological and non-GM foods. Sustaining a diversified agri-food system that supports these alternatives, and protects European consumers' right to choose may justify significant efforts on the part of EU authorities. Further studies would help to clarify the costs and benefits of the range of policy options available to address these issues, in a context of ever-changing technologies.

There is a demand within the EU food system for products that exclude all forms of genetic modification.

POTENTIAL IMPACTS ON ORGANIC AND AGROECOLOGICAL SECTORS

The organic farming sector has been growing rapidly in Europe, with a 50% increase in organic farming from 2012 to 2020. Consumer demand in the EU for organic products doubled between 2015 and 2020. The Farm to Fork Strategy aims to increase the organic market share from its current level of about 9.1% to 25% by 2030 (EC 2023). There are many other farms which are not certified organic, but which farm in ways that aim to be ecologically sustainable or regenerative. These farms tend to be smaller in size, and they often supply local markets. The use of GM (including gene editing) is not permitted within the EU organic food and farming sector (Regulation 2018/848) and is opposed by European social movements promoting agroecology (Levidow & Boschert, 2008, ECVC 2018).

In this context, what will the proposed GM deregulation imply for the organic and agroecological farming and food sectors in the EU? Three main pathways could restrict the growth of organic and agroecological production: (i) reducing the availability of seeds appropriate for these production systems; (ii) increased costs and risks from cross-contamination of GM and non-GM seeds, crops and foods; and (iii) an increased use of herbicides and pesticides in GM production systems.

The continued availability of existing organic plant varieties and the development of new organic varieties are vital for the organic, agroecological and non-GM food and farming sectors to thrive in Europe. A lack of investment in plant breeding for low-input systems is a significantly limiting factor in the development and growth of these sectors (Fess et al., 2011; Malandrin and Dvortsin, 2013). In accordance with European Organic Regulation 2018/848, the use of non-organic seed in organic agriculture is due to be phased out by 2036. Demand for organic seed currently outstrips supply in Europe (Solfanelli et al., 2022), and a Delegated Act allows for the use of seedlings and seeds originating from conventional seed and parent plants in cases where no organic planting material exists (Commission Delegated Regulation (EU) 2022/474). The use of non-organic seed in the organic sector has increased in recent years (Solfanelli et al., 2022), as the supply of organic seed has not met demand. This mismatch has been blamed on organic breeders lacking accurate data about demand for specific kinds of organic seeds (i.e. by crop, variety and location), as well as the relatively low economic returns available from organic breeding (Solfanelli et al 2019). As discussed in Part 1, the narrow profit margins in organic seed reflect the historical pattern for the seed industry as a whole in the days before patented seeds were integrated with proprietary agri-chemicals in a consolidated pesticide–seed sector. To achieve the EU's policy objectives to promote organic farming, public funding may be required to support the organic seed sector and ensure that supply more accurately meets demand (Solfanelli et al 2019). Market forces are currently driving the seed sector in the opposite direction, as described in Part 1.

GM deregulation could exacerbate this problem, since it would likely intensify the concentration of the seed industry. If smaller seed firms are bought out by larger firms or go out of business, a likely consequence is a narrowing the genetic diversity of seeds and a decline in the availability of organic seeds. This would be a problem in itself for the organic seed industry—there are currently over 800 businesses in Europe that supply organic seeds (Solfanelli et al 2019). It would also significantly impact organic farmers. As discussed in Part 1, farmers in countries of Europe which adopted GM have had less choice of seed varieties than those in EU countries which have remained GM free (Hilbeck et al. 2013). Further, given that the overall seed sector has developed in favour of varieties that depend on intensive applications of pesticides and mineral fertilisers, the conventional varieties available to farmers tend not to perform well under organic or agroecological conditions (Lammerts van Bueren et al. 2011).

Conventional varieties available to farmers tend not to perform well under organic or agroecological conditions.

GM deregulation could also affect the seed varieties available to organic and agroecological producers if GM material mixes or crosses with cultivars and populations intended for organic cultivation. Recent EU rules (Regulation EU 2021/1189) have permitted the use and marketing of "organic heterogeneous material," in recognition of the ability of varietal diversity to support organic and agroecological agricultural practices. Commercial seed varieties normally have to comply with requirements for distinctness, uniformity and stability (DUS), but organic heterogeneous material is characterised by a high level of phenotypic and genetic diversity and is dynamic, rather than stable in nature. Heterogeneity allows for greater resilience, through a "not all eggs in one basket" approach. For example, a field cultivated with 200 varieties of wheat, rather than just one DUS variety, results in improved yield stability and reliability in the context of unpredictable factors such as drought, rust (a plant disease), or other challenging growing conditions (Döring et al., 2015).

Heterogeneity of cultivars and populations also allows plants to evolve and adapt over time to different growing and climatic conditions (Costanzo and Bàrberi 2016; Döring et al. 2015; Weedon and Finckh 2019). The development and maintenance of heterogeneous material therefore offers an important pathway, both for supporting agroecological and organic farming and for enabling the entire farming sector to adapt to climate change, which may bring new or increased pests, diseases, invasive weeds and climatic shocks (Calzadilla et al. 2013; Ceccarelli and Grando 2020; Evans et al. 2008). Further, heterogenous cultivars and populations lend themselves to participatory and farmer-led plant breeding strategies, and enable crop varieties to be tailored to the specific needs of different farmers and sites, in ways that seed varieties meeting DUS criteria often cannot (Almekinders and Louwaars 1999).

Deregulation of GMOs could significantly threaten the availability and quality of heterogeneous material. This is because the natural evolutionary processes that are encouraged among heterogeneous cultivars and populations, which benefit from seed mixtures and adventitious cross breeding, imply that these types of crops are at higher risk of incorporating gene-edited material, unless the latter are carefully segregated. Cross-contamination of genetic material from gene-edited crops could result in irreversible consequences for heterogeneous cultivars and populations, for example, certain alleles can be quickly lost when not maintained, or if the population decreases below a certain size (Hodgkin et al. 2007, Louette, 2005). This has been experienced in Mexico, where heterogenous maize cultivars, which had been developed and maintained over thousands of years, were irreversibly altered by introgression with transgenic material (Dyer et al. 2009; Quist and Chapela 2001).

Deregulation of GMOs could significantly threaten the availability and quality of heterogeneous material.

Cross-contamination of non-GM and GM crops has been documented in 63 countries (Price & Cotter, 2014). It can occur through pollen transfer, seed mixing, and post-harvest crop processing (Knispel and McLachlan 2010). It can affect both self-pollinated (e.g. oilseed rape) and cross-pollinated crop species (e.g. maize). Cross-contamination can sometimes be lessened through careful spatial arrangement and separation of GM crops and non-GM crops (Belcher, Nolan, and Phillips 2005). However, if GM crop regulations do not specifically require segregation then cross-contamination is liable, sooner or later, to occur. When it happens, the question arises—who bears the cost of cleaning up, and who gets compensated?

Cross-contamination of GM and non-GM germplasm has significant financial implications for the organic and non-GM food and farming sectors. Organic producers rely on price premiums to meet higher costs of ecological production. A 2008 study estimated the economic cost of GM cross-contamination to the organic sector, based on an analysis of 15 cases of cross-contamination between GM and organic crops. It found considerable financial losses to organic producers and food companies due to lost sales, lost markets, lost certifications and negative publicity (Hewlett and Aziz 2008). A deregulation of new GM technologies could be detrimental to this significant and growing sector, in that non-GM producers generally bear the costs for product segregation and monitoring. These costs would significantly increase were new GM technologies to be deregulated, because new GM technologies might be more difficult to test for, and because of the lack of protocols for reducing the risks of cross-contamination.

Another way in which organic and agroecological sectors could be impacted by deregulation of gene editing is if GM cultivation stimulates an increase in agrochemical inputs. As discussed in Part 1, most GM crops in use to date have entailed higher rates of herbicide use. Herbicide "drift" can result in crop losses and sometimes loss of certification for organic, non-GM and agroecological producers (Ory, 2017). Additionally, pesticide and herbicide use negatively impacts soil microbiology for decades after these products have been used, because chemical residues can remain in soils. The presence of these residues can make it hard for farmers to obtain organic certification in the future (Riedo et al., 2021).

SUMMARY OF PART 2

In sum, organic, agroecological and non-GM seed businesses, farmers, processors, retailers and consumers may be negatively affected by a more widespread usage of GM technologies in European agriculture. Deregulation would likely shape technological pathways by further compromising the supply of varieties and seeds appropriate for organic, agroecological and non-GM production, by increasing the risk of cross-contamination of GM and non-GM products, by increasing the intensity of herbicide- and pesticide-use in agricultural areas, and discouraging farmers from transitioning to organic and non-GM production. An agricultural sector dominated by proprietary GM crops would likely undermine innovation and reduce diversity of varieties available, which would compromise the resilience and ability of agriculture in the context of climate change. The deregulated use of GM crops in the EU therefore risks undermining key EU policy goals, such as of the Farm to Fork Strategy. The next section addresses these possible ramifications.

Organic, agroecological and non-GM seed businesses, farmers, processors, retailers and consumers may be negatively affected by a more widespread usage of GM technologies.

PART 3: *ANALYSIS*

The proposed deregulation of some kinds of GMOs in the EU is likely to have important, although uncertain, consequences for pathways of change in the European agri-food sector, and in turn for the wider sustainability of agricultural and food systems in the EU. Before reflecting on what those pathways of change might look like, it is important to recall the food and agriculture sustainability ambitions that are sought by wider EU policy.

The European Commission's proposal for a European Green Deal was launched at the end of 2019. The Green Deal is Europe's response to the imperatives contained in the United Nations 2030 Agenda for Sustainable Development and, above all, to the existential challenges posed by climate breakdown and the accelerating collapse in global biodiversity. The Green Deal seeks to "transform" the EU by putting European societies and economies onto pathways towards net zero emissions by 2050, a circular economy, the elimination of pollution, and the protection and restoration of biodiversity.

A key component of the Green Deal is the Commission's 2020 Farm to Fork Strategy. The Strategy aims to create a "fair, healthy, and environmentally friendly food system" (European Commission 2020). It sets out a range of objectives, targets and associated actions to "accelerate our transition to a sustainable food system". The targets are concrete and ambitious: to reduce the use and risks of chemical pesticides by 50%, reduce fertiliser consumption by 20%, dedicate a quota of 25% of EU arable land to organic farming, and reduce sales of antimicrobials by 50%—all to be achieved by 2030.

Beyond those targets, the Farm to Fork Strategy is more abstract. What might constitute a "sustainable food system" is not clearly specified. Instead, the Commission explains that a sustainable food system should enable, amongst other things, a neutral or positive environmental impact; mitigation of and adaptation to climate change; a reversal of biodiversity loss; food security, nutrition and public health; fairer economic returns; the competitiveness of the EU supply sector; and the promotion of fair trade. This lack of clarity has likely enabled the Commission to find agreement amongst diverse food system actors, who have fundamentally different ideas about what future food system they envision, and how to get there (Schebesta & Candel 2020). On topics such as biotechnology, the Farm to Fork Strategy says little.

Given the ambiguity within the Farm to Fork Strategy as to what a sustainable food system should actually look like, and the backlash that has already greeted some of the Strategy's proposals, there are likely to be contending claims about what kinds of technologies and practices will constitute sustainable pathways of change for European food and agriculture. Much of the agrochemical industry and some governments are likely to advocate a "sustainable intensification" pathway, based on technologies such as gene-edited crops, precision agriculture, and Big Data. Other groups are likely to advocate an "ecological agriculture" pathway, based on the diffusion of low external input agroecological practices. Debates about the possible merits and drawbacks of deregulation of gene edited crops will likely pivot around this wider question—the desired directions and outcomes for European agriculture. In Parts 1 and 2 of this document, we have taken a retrospective and prospective approach to understanding what could be the likely effects of a turn towards gene editing in the EU.

Part 1 discussed pathways of change in agri-food systems in countries where GM crops have been embraced, concentrating on the USA. In GM-adopting countries, it is difficult to see how the evolving characteristics of agri-food systems would be compatible with most of the targets and ambitions set out in the Farm to Fork Strategy. The scope for shifting those GM-centric pathways in more sustainable directions is also reducing as small seed firms disappear, available seed varieties are reduced in number, farmers' choices are eroded, crop diversity is diminished, and the power of incumbent pesticide–seed firms to influence public policy increases. Along such a pathway of change, the kinds of ambitions set out in the Farm to Fork Strategy would become increasingly difficult to envisage, let alone attain.

Along a GM-centric pathway of change, the kinds of ambitions set out in the Farm to Fork Strategy would become increasingly difficult to attain.

In short, GM-influenced pathways of change in settings such as the U.S. are rendering agriculture more dependent on a pesticide- and fertiliser-intensive, monoculture-based production model, and are further eroding the agency, autonomy and incomes of farmers and smaller firms in the seed sector. These GM-centric pathways are further locking in the unsustainable agricultural and food system pathways that evolved after the Second World War—which the European Green Deal and the Farm to Fork Strategy are explicitly intended to transform.

Part 2 sketched out plausible pathways of change that could lead from the deregulation of gene-edited crops in the EU. Large multinational pesticide–seed firms would likely benefit from deregulation as their markets for gene edited crops would expand, and economies of scale and scope would become available. This would likely imply further lock-in to the kinds of industrial agricultural pathways that are already prevalent in Europe, as smaller seed firms were outcompeted or acquired by larger firms—a scenario that the Farm to Fork Strategy is intended to move away from.

Superficially, deregulation would benefit smaller firms and public sector research institutes that want to carry out gene-editing research and potentially commercialise gene-edited organisms. In reality, there would still be formidable obstacles to bringing onto the market new kinds of crop innovations that might better support a more sustainable agricultural system. Even in the absence of regulatory expenses, small firms would have to partner with (or licence their IP to) larger firms, in order to navigate the contractual, marketing and distribution challenges involved in successful commercialisation. As happened with the earlier wave of GM crop innovations, the initial promise of diverse gene-edited traits and crops could converge on a handful of traits and crops with large potential markets and economies of scale, which the large pesticide–seed firms are best placed to take advantage of.

For conventional seed companies, farmers, food processors and manufacturers, retailers and consumers, the deregulation of gene editing is likely to entail losing the freedom to choose to produce, trade in and/or purchase non-gene edited products—or being obliged to pay for the infrastructure necessary to maintain segregated supply chains and sustain the right to choose.

For the organic and agroecological farming sectors, deregulation of gene edited crops is likely to be detrimental to growth. More innovation, organic breeding and heterogenous cultivars are needed to support these sectors, but GM deregulation could instead lead to further seed-sector consolidation, a narrowing of varieties available to farmers, and a permanent loss of important genetic diversity in varieties and breeding populations. As discussed in Part 2, the EU has recently legislated to enable the circulation of heterogeneous planting materials when they are destined for use in organic and agroecological farming systems, by providing an exemption to the DUS requirements for seed—an explicit recognition of the value of varietal diversity for climate resilience and its appropriateness for low-input, ecological cultivation methods. Seed sector consolidation would likely undermine the intent of that regulation, because it would likely lead to a reduction in the availability of diverse varieties.

As discussed in Part 2, organic, agroecological and non-GM producers in the EU would also be adversely affected, as a result of gene edited crop diffusion, by increased risks of cross-contamination. This would result in higher monitoring costs, losses of sales, and potential loss of certification for farms, processors and food companies, while increased agrochemical usage could both contaminate existing organic and agroecological farms and make it harder for farms to transition to organic methods in the future, because of the persistence of agrochemical residues in soils and the risks of organic farming in proximity to chemical farming. This is another example of lock-in. Intensive use of herbicides and pesticides in GM agriculture could compromise long-term transitions towards more ecological and sustainable farming systems by stifling pathways towards organic and agroecological cultivation practices.

CONCLUSION

A decision to deregulate certain kinds of GMOs in the EU would be a consequential policy choice, which would shape future pathways and possibilities for the EU's agrifood system over the long-term. In this paper, we have used a pathways approach to analyse the possible consequences for agricultural and food systems in Europe.

A decision to deregulate certain kinds of GMOs would shape future pathways and possibilities for the EU's agrifood system over the long-term.

Deregulation of gene edited crops and foods could have wide and long-term implications, not only for the use of specific crop biotechnologies in farming and food production in Europe, but for the broader sustainable and equitable development of European agri-food systems. The breadth and significance of those implications calls for further democratic debates and parliamentary scrutiny around future regulatory frameworks for gene editing techniques.

This report has examined how, in countries that have opted for permissive regulation of GMOs, various social, economic and institutional factors have helped to lock agriculture into an unsustainable system pathway. Recent analyses of the regulation of transgenic crops over previous decades (Ely et al. 2022) have shown how regulatory frameworks themselves have been subject to lock-in dynamics, which are difficult to reverse or change on the basis of emerging evidence; the US "product-based" approach and the EU's "process-based" approach have both constrained the potential for policy changes over decades, despite political and technological developments. The proposal to deregulate some classes of gene-edited GMOs would constitute a substantial change to the existing regulatory and policy landscape in the EU, which can be expected to have significant and hard-to-reverse implications over the following decades. Such a move calls for prudent, careful, circumspect consideration that looks beyond the level of individual crop, food and feed products, to the wider social, economic and institutional relationships and systems in which they are embedded.

Calls to deregulate GMOs in the EU are typically grounded within a discourse of risk for the EU—fears of a loss of competitiveness in science and agriculture, of a decline of innovative activity, of falling behind in a global technological race, of missing out on technologies that can solve the major environmental and societal challenges that face European society. But have the USA and other GM-adopting countries gained a decisive advantage over the EU through embracing GMOs? Evidence to support such a conclusion is mixed, to say the least. We have reviewed international experiences with the cultivation of GM crops and the wider impacts which GM agriculture has had on the productivity, structure and sustainability of agriculture and food systems. A broad view, through the lenses of political economy and sustainability, certainly does not support the view that GM crops have enabled the USA to gain a decisive advantage over Europe.

Agrifood systems on both sides of the Atlantic face enormous challenges. Conventional agricultural production in both regions is heavily dependent on pesticides and fossil fuels. A balanced review does not support a simplistic conclusion that GMOs are essential for, or even that they are necessarily connected to, improvements in agricultural production, sustainable development, innovation, competitiveness, or other socially valuable outcomes. On the contrary, the record is quite mixed, with numerous shortcomings and downsides associated with GMOs in agriculture, including corporate concentration, declining biodiversity, and negative impacts for particular stakeholders (such as businesses and consumers in organic, agroecological and non-GM sectors). The observed effects are not solely due to GM technology but to regulatory and policy frameworks and the political economy of agribusiness, farming and food with which they are linked. As such, we have shown how the introduction of patented GM technologies has in various ways exacerbated and further locked in the unsustainable industrial agriculture pathway that developed after the Second World War.

Claims that gene-edited crops will resolve serious sustainability problems represent a return to a rhetoric of the 1990s, when companies and scientists championed similar claims about the previous generation of GMOs.

Claims and expectations that gene-edited crops will resolve serious sustainability problems represent a return to a rhetoric of the 1990s, when companies and scientists championed similar claims about the previous generation of GMOs—setting up hopes which have not been realised in practice. Gene editing is associated with a business model, based on patents, which will likely promote a political economy in plant breeding and seed systems that reinforces the current oligopolistic position of large pesticide-seed companies at the expense of smaller seed firms and farmers. It remains likely that firms that develop and commercialise gene-edited crops will use their market power to build in herbicide tolerance, entrench herbicide use, and reinforce established systems of monocultural production on specialised farms, which will further concentrate power, undermine varietal diversity and biodiversity, and undermine climate resilience.

What implications does this raise for current decisions around the possible deregulation of some GMOs in the EU? A pathways approach (described in Box 1) is sensitive to the 4Ds, which can help policy makers, legislators and voters to avoid or mitigate locking our agricultural and food systems into unsustainable pathways. The EU's policies and regulatory frameworks governing GMOs can help to steer agricultural and food system pathways in sustainable or unsustainable **directions**—towards sustainability in multiple dimensions, including nutrition, food security, climate mitigation and resilience and biodiversity, or towards the further entrenchment of industrial farming systems, fossil fuel dependence, impoverished biodiversity and barren rural landscapes. Attending to **distribution** means ensuring that we do not systematically exclude or marginalise small-scale producers, family farmers, innovative food businesses, non-GM and agroecological producers, and organic and GM-free consumers. **Diversifying** pathways helps to ensure that we do not "place all our eggs in one basket," by supporting diverse and alternative innovations that could contribute to the wider objectives of EU agri-environment policy. Promoting **democratic** legitimacy means ensuring that the potential consequences of regulatory change are debated in public forums and inclusive deliberations, not determined by technocrats, bureaucrats, lawyers, or corporate lobbyists.

Policies governing GM crops in the EU should be aligned with wider ambitions and goals to change the **direction** of European agri-food systems, including the Farm to Fork strategy and its associated targets for reduced greenhouse gas emissions and pesticide use, enhanced biodiversity, organic agriculture, and fair economic returns for primary producers. The reorientation of European agri-food systems, which is necessary to achieve these objectives, requires a turn away from existing pathways of industrial agriculture, into which European and global agriculture have in recent decades become increasingly locked. This implies adopting policies that disrupt the incumbent power of multinational pesticide–seed firms and providing support instead for alternative approaches that are better aligned with the Farm to Fork strategy.

The **distribution** of costs, benefits and risks associated with gene editing under different policy options is a complex matter. The analysis above has shown how implications differ for the various stakeholder groups affected, but the detail of any proposed regulatory changes (as well as intellectual property and trade conditions) will play a decisive role. Policy questions should be asked about appropriate impact monitoring frameworks, mechanisms for compensation and redress, biosafety risk assessments, and so on, and about how the costs should be borne, and by whom.

Policy makers and regulators could choose to consider a range of alternative regulatory options that may be available, which could open up **diverse** innovation pathways. For example, there are concerns throughout industry that intellectual property rights could restrict access to technologies in the agricultural sector. Legislators could consider the possibility that alternative rules could allow easier access to technologies, so as to avoid some of the negative scenarios that have unfolded in GM agriculture. They might also consider rules that protect and support alternative pathways that currently do not include (GM or) gene editing technologies, but would suffer negative consequences from their deregulation.

The negative effects on stakeholders such as non-GM growers, organic seed companies, agroecological farmers, and consumers should be taken into account.

Finally, the potential consequences of the proposed deregulation of some kinds of GMOs in the EU raise important questions for **democratic** decision-making and accountability, which are often neglected by technocratic processes or regulatory impact assessments. Decisions taken today will have long-term, systemic impacts, which will go beyond the safety of individual traits, products or technologies, or impacts that can be quantified in purely economic terms. A wider array of impacts and effects should be taken into account, especially the negative effects on some stakeholders, who are likely to be disempowered in the longer term–such as non-GM growers, organic seed companies, agroecological farmers, and consumers. This calls for more substantial democratic inputs and deliberation than have informed the Commission's proposal for new GMOs to date. The current juncture provides an opportunity structure (Ely et al 2022) for an inclusive and democratic discussion about the implications of gene-edited crop deregulation, rather than narrow and technocratic discussion informed by restrictive regulatory impact assessments.

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