Gene Editing:

Is anyone really being left behind?

GeneWatch UK

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1. Introduction

The rise of novel genetic engineering techniques, such as genome editing, has garnered a huge amount of interest from industry and genetic engineering proponents, who are promoting their rise as a major breakthrough. The rationale goes, that due to these easier, cheaper and faster techniques, genome editing will be able to address a whole manner of societal ills across agricultural, health, environmental and conservation spheres.

Recent arguments to deregulate products of genome editing techniques and exclude them from current legislation covering genetically modified organisms (GMOs), are often based on claims that these techniques are precise, able to engineer genetic changes that are indistinguishable from natural variation and thus safe and, also, more precise than older GM technologies. There are also claims that countries will be “left behind” if they do not invest in, and deregulate, these technologies.

However, those who have been following the genetic engineering debate since the beginning will note familiarity of these claims. Claims that GM crops would revolutionise agriculture. and were thus necessary to end hunger, were also widespread during the initial days of GM crop commercialisation. The huge promises made are yet to come to fruition nearly three decades since the first GM crop was commercialised. Indeed, even certain genome editing tools have been around since the 1990s, yet in countries with permissive regulations, such as the US, genome edited organisms have been slow to materialise, and in fact are almost entirely non-existent.

The possibility of being left behind if regulations are maintained is a common concern within government and policy spaces. Such concerns, however, were also expressed with regard to first generation GMOs, but have since been shown to be overblown. It is crucial that the veracity of claims surrounding genome editing tools are carefully analysed, especially in the context of the limitations of GM technologies to date in achieving their purported aims. Such analyses can assist policy makers to make informed decisions on the most effective way to address the many societal problems facing the global community.

This briefing summarises decades of claims about GM plants and animals, compared to what has been delivered. It then then compares the claims made for future gene edited crops, and discusses the constraints on what might be delivered in reality. It also highlights some potential risks to human and animal health, animal welfare and the environment, if experimental products enter the environment and food chain. This includes the risk that viruses can evolve in response to genome edited disease-resistant plants and animals, causing major biosafety issues. It concludes that deregulation of gene edited plants and animals is a path to failure that will lead to a loss of control over imports, exports, the food chain and the environment.

2. First generation GMOs: Did they deliver on their promises?

Genome editing technologies are once again reviving old promises made regarding the development of first-generation GMOs. GM crops that are already on the market involve introducing genes from other species, or different varieties of the same species, into cells (known as 'transgenesis' or 'cisgenesis'). As discussed further below, the vast majority of GM crops grown today are 'transgenic' (i.e., include genes from other organisms) and are restricted to two dominant traits, herbicide tolerance and insect resistance. These GM crops are commodity crops such as soybeans and maize, grown mainly for animal feed in North and South America. Yet, first generation GMOs were promoted as crops that would increase crop yields to reduce hunger, increase nutritional status, improve farmer livelihoods and agricultural sustainability, and even improve biodiversity by for example, reducing pesticide use. These claims, together with extensive promises for benefits from GM trees and animals, have not been delivered.

2.1 GM crops and trees

As summarised by Gelinsky and Hilbeck (2018)[1], early proponents of GM crops asserted for example, that:

"Genetic engineering is (...) a complementary research tool to identify desirable genes from remotely related taxonomic groups and transfer these genes more quickly and precisely into high yield, high-quality crop varieties."

"Molecular techniques now permit the direct and precise introduction of genes from wild relatives, and cellular methods allow screening for the desired phenotype to proceed more efficiently."

Unrealistic and undelivered claims of benefits have been made for genetically modified organisms (GMOs) since 1981, and repeated, for example in 2010, when 'next generation' GM crops, with a wide range of purported benefits, were supposedly going to be delivered in the next 5 to 10 years (nutritional biofortification in staple crops and sweet potato; resistance to fungus and virus pathogens in potato, wheat, rice, banana, fruits, vegetables; resistance to sucking insect pests in rice, fruits, vegetables; improved processing and storage in wheat, potato, fruits and vegetables; and drought tolerance in staple cereal and tuber crops).[2,3] In 2001, for example, Roger Krueger, of the leading GM crop company Monsanto (now owned by Bayer) stated that: "*As the global population continues to grow and more people demand a higher standard of living, few solutions offer the promise of genetic modification, namely, to increase agricultural productivity while decreasing its impact on the environment*."[4]. He went on to claim: "*Monsanto is also developing new crops with traits that have more direct benefits to consumers. Several crops are under development and field testing to produce the following desirable traits: modified oils, carbohydrates, and amino acids; protein improvements; fiber modifications; enhanced vitamin content; increased yields (resulting in lower prices); the production of pharmaceutical proteins; and biopolymers*".

Promises were made that GM crops could be designed to display improved complex traits that can combat climate change, such as increased tolerance to drought or saline water. Drought resistance has been a stated goal of GM crop development since at least 1981, and this claim has been made repeatedly since then.[5,6] A 2008 Guardian headline illustrates this with the claim, "*Drought resistant GM crops ready 'in four years'*"[7]. Moreover, the article quotes the UK's minister of the time, stating that the UK public would support GM crops if they have demonstrably proven environmental benefits for "*people living in sub-Saharan Africa"*. During the 2008 food crisis also, major media outlets claimed GMOs were the key to solving the problem. As summarised by (Stone & Glover, 2011)[8]:

"*Headlines included 'Gene modified crops the key to food crisis, says scientist' (Harvey and Parker 2008) ... 'Biotechnology Can Help Solve the Food Crisis' (Engineering News Online 2008) ... 'Biotechnology Could Help Solve Food Crisis, Monsanto Asserts' (Copans 2008) ... 'GM crops are part of the answer to food crisis – Monsanto' (Surman 2008) ... 'Radical Science Aims to Solve Food Crisis' (Moskowitz 2008) ... 'Biotechnology a Key to Solving Food Crisis' (Reuters 2008) ... 'Genetic Farming can Help Solve Food Crisis: Expert' (Basu 2008) ... 'Biotechnology May Have Potential to Solve Food Crisis' (Energy & Envirofinland 2008) ... 'Brown must embrace GM crops to head off food crisis – chief scientist' (The Guardian 2007) ...'Genetically modified crops "may be answer to global food crisis"' (The Telegraph 2008) ... 'Biotech crops seen helping to feed hungry world' (Reuters India 2008a) ...and 'World Goes for GM Crops to Tackle Food Crisis' (Commodity Online 2008) – among many others*."

Alongside such claims, genetic engineering proponents warned the EU that regulating GMOs would hold Europe back from biotechnology advances. Stone and Glover (2011) also note that scientists and politicians, for example, claimed that:

"*EU rules are stifling a golden age of biotechnology*" (Freeman, 2014), "*Farmers 'left behind' by EU's block on GM crops*" (Bhat, 2013) and "*Europe must back GM or just be an old tech museum*" (Moody, 2013)."

However, nearly three decades on from the commercialisation of GMOs, in the US where adoption rates are highest and GMOs are effectively deregulated, food insecurity remains stubbornly high, with an estimated 47 million people food insecure in 2023[9]. GM products remain overwhelmingly restricted to a handful of commodity crops that are cultivated for animal feed, biofuels and ultra-processed food ingredients, and are only consumed as a staple crop in one country worldwide – South Africa. Despite widespread cultivation of insect resistant GM crops in South Africa, the nation suffers considerable levels of food insecurity, with 15 % of the country food insecure, and reportedly increasing since 2011.

Poverty, rather than crop yields, is the main driver of food insecurity. Further, GM crops are mainly used in animal feed and biofuels, rather than as food.[10] However, it is also worth noting that a global analysis of studies reported no significant differences in yields between herbicide tolerant GM crops and conventional crops.[11] Despite the US regulations favouring GM adoption, a 2013 study reported that cereal yield gains in Western Europe were accelerating and overtaking those of the USA's major cereal crops.[12,13] In Western Europe, maize crops are non-GM whereas in the US, GMO adoption is near ubiquitous for maize, the most common cereal commodity crop grown.

Nearly three decades on from the first commercialisation of GMOs in 1996, the vast majority of cultivated GM crops remain restricted to two dominant traits: herbicide tolerance and insect resistance. The US Department of Agriculture (USDA)'s most recent figures show 90 % of maize (corn) planted in 2024 was herbicide tolerant, while 86 % was insect-resistant, with approximately 87 % of corn crops stacked with both traits[14]. For soybean, the USDA reports that 96 % of soybeans planted were herbicide-tolerant. Indeed, the most significant evolution in GM 'innovation' of new varieties has been the increased percentage of 'stacked varieties', that carry more than one trait. According to industry figures, globally, in 2019, the area planted to herbicide tolerant crops was 43%, and stacked traits (including both herbicide tolerance and insect resistance) was 45%, meaning that 88% of GM crops by area included herbicide tolerant traits.[15] These GM crops are grown mainly in North and South America (the USA, Brazil, Argentina and Canada). Most of the remaining area of GM crops is insect resistant GM cotton (also known as Bt cotton), grown mainly in India. As detailed below, this is indicative of a lack of concrete innovation in generating useful varieties.

Both herbicide-tolerant and insect-resistant varieties were originally portrayed as traits that would improve food production by reducing pest damage while reducing overall pesticide usage, and replacing environmentally destructive practices such as soil tilling (e.g., ploughing). However, both traits are facing significant challenges to their long-term viability.

Herbicide-tolerant (HT) GM crops have been genetically engineered so they can be blanket-sprayed with the associated herbicides, with the aim of killing weeds whilst the crop still grows. They were first grown commercially in 1996, when they were introduced by the US company Monsanto (now owned by Bayer). Monsanto's glyphosate-based weedkiller has the brand-name RoundUp, hence the first GM generation of herbicide-tolerant crops are tolerant to glyphosate and are known as 'RoundUp Ready' crops. Herbicide-tolerant GM crops cause environmental harm due to blanket spraying of these crops with weedkillers. This harm includes the direct impacts of herbicides on sensitive species, such as frogs and bees, and indirect impacts due to habitat loss for important species, such as the iconic Monarch butterfly in the USA.[16] Following evidence that RoundUp may cause cancers, Monsanto/Bayer have paid more than $11 billion in settlement agreements for 100,000 lawsuits in the USA.[17] Bayer's share price has plunged by more than 70% since Bayer's $63 billion acquisition of Monsanto in 2018, and the company is still seeking to cover potential future costs of U.S. litigation.[18] The widespread use of herbicides in conjunction with herbicide tolerant crops has resulted in a rapid proliferation of herbicide resistant weed species, with 60 resistant species recorded, the first species being detected in 1996.[19] On the two most important GM crops in the US, maize (corn) and soybean, the total applied toxicity of pesticides (not just glyphosate) has increased along with increasing GM adoption, particularly since 2008 as glyphosate resistant weeds became a greater problem.[20] The proliferation of resistant weeds has led industry to develop varieties that are tolerant to multiple herbicides, including older and more toxic herbicides that glyphosate was promoted to replace. As weed resistance grows (caused by blanket spraying), more environmental damage is now being caused by the introduction of these newer GM crops with tolerance to multiple herbicides.[21] Farmers in the USA now face weeds with resistance to these herbicides as well.[22]

For insecticide resistant crops (also known as Bt crops), the industry is facing a lack of new options to stem growing pest resistance problems. Bt crops are genetically engineered to produce toxins, intended to kill pests. The Bt toxins are modified, and more toxic, versions of toxins that derive from a bacterial species (*Bacillus thuringiensis*), that has long been used as a microbial biopesticide. As stated by the Entomological Society of America, "*insect pests have a propensity to overcome control tactics, including GM crops*".[23] They report that over the last 25 years, 19 cases of practical resistance have been documented across 5 major pest species with regard to Bt crops. A list of corn traits available to US farmers in 2024 shows that there are no longer any single toxin traits available[24], with all single as well as some stacked traits now phased out (AcreMax RW, Acre Max TRIsect, Herculex I, Herculex RQ, Intrasect Trisect, Intracect Xtra, Intrasect Ztreme, TRIsect, VT Tripl PRO, YieldGard Corn Borer, YieldGard Rootworm, YieldGard VT Triple). Moreover, of the 35 GM corn varieties still available, all suffer from pests that have now evolved resistance to all of the Bt toxins in the stacked trait package, except for the four varieties carrying the Vip3A toxin. The vast majority of these are also stacked with herbicide-tolerant varieties.

The Entomological Society of America urge for continued innovation to provide novel insect resistant traits by maintaining incentives for developers to continue this work. However, despite continuous investment and consistent promises in this regard, it appears that a bottleneck remains, due to a lack of finding or innovating new insecticidal traits that can be introduced into GM crops. For example, Western corn rootworm became resistant to all four Bt Cry toxins by 2018. However, industry has been long claiming that new traits are in the pipeline to address the problem. In 2016, Dupont made claims that new GM crops had been developed, using non-Bt toxins (sourced from other bacteria), with headlines that "*biotech* *companies promise new insect-killing genes*"[25]. Some of these GM crops use an approach called RNA interference (RNAi), which attempts to silence certain genes in the target pests. None of these products appear, however, to have made it to market. While some recent studies have claimed that insect resistant crops increase yields, meta-analyses such as that by Pelligrini *et al*., (2018)[26] are based on early data preceding widespread resistance development. The lack of trait candidates for first generation GMOs raises important questions regarding the potential for genome editing to improve long term viability of a constant treadmill of traits to keep up an arms race against evolving pests. Indeed, according to the Convention for Biological Diversity's Biosafety Clearing House[27] database, there are only three crops with RNAi technology for insect resistance, two are stacked with older Bt toxins, and one is stacked with glyphosate herbicide tolerance. All three are in maize (MON87411, DP23211 and MON95275) and designed to work against one pest only, the corn rootworm.

Spain, the only country in the EU to grow significant quantities of GM crops (small amounts are also grown in Portugal), has been growing one variety of Bt maize, for use in animal feed. Since 2013, adoption has been declining, and now, according to Spanish media reports, farmers are abandoning the crop *en masse* for both agricultural and economic reasons. While the USDA claimed in 2022[28] that declining cultivation rates in the EU are a result of the 2015 decision for member states to voluntarily 'opt-out' of EU-wide cultivation approvals that came into effect in 2017, the annual cultivation rates indicate otherwise. Annual data submitted by the developer to the European Commission shows that 143 015 hectares were cultivated in 2013[29]. In 2016[30], 2017[31], and 2018[32], the number slowly declined from 136 334, to 131 553 and 120 979 hectares, respectively. However, it is in the last few years that cultivation has dropped sharply, with 100 927 hectares grown in 2021[33], but only 48 225 hectares grown in 2023[34]. Despite higher seed prices farmer organisations are reporting that they "*do not achieve as positive results against the pest as promised by their manufacturers*"[35]. Instead, farmers are using practices such as altered planting times to control pests without having to fork out additional costs for GM seeds. Public rejection has also apparently played a role in discouraging farmers from cultivating GM varieties.

Resistance is an even bigger problem for resource-restricted farmers who may often lack capacity or government subsidies to implement the complimentary resistance management strategies such as non-GM refuges (areas planted with non-GM crops, to attempt to slow the development of resistant pests). As such, experiences with Bt cotton in countries such as India and Burkina Faso have included regular crop failures and farmer indebtedness as a result of resistance development but also additional factors that include seed packages that are ill adapted to non-irrigated fields, and that require synthetic inputs and are also more expensive[36,37]. A recent study has concluded that the emergence and spread of pest resistance to Bt cotton in India "*poses a substantial threat to the sustainability*" of Bt cotton cultivation.[38] Planting of Bt maize, leading to pest resistance, has led to substantial economic losses in the US 'Corn Belt' states.[39,40] Secondary pest infestations have also led to crop failures – an unintended impact of the intended trait working to kill the primary pest, yet failing in its overall goal of increasing yields due to secondary pest infestations that take their place.[41] Similar resistance has now been documented in newly invasive African populations of fall armyworms in Bt maize fields in South Africa[42], despite Bt crops being heralded by developers as a solution for small-holder farmers across Africa.[43,44]

The fall armyworm (*Spodoptera frugiperda*), another major crop pest that is now spreading from the Americas, has proven resistant to all Bt toxins except for one (Vip3A)[45]. Similar resistance has now been documented in newly invasive African populations of fall armyworms in Bt maize fields in South Africa, despite Bt crops being heralded by developers as a solution for small-holder farmers across Africa[46].

Claims of reduced pesticide use for Bt crops are undermined by several issues. One is that insecticides are packaged into a different format whereby the pesticide is expressed within the plant. That this is not included in official pesticide statistics, which has been repeatedly challenged as misleading.[47] Secondly, the vast majority of Bt traits are now stacked with herbicide tolerance, with an increasing number tolerant to multiple herbicides.

Despite widespread research and investment in more complex traits such as nitrogen efficiency, drought tolerance or nutritional enhancement, such desired products have failed to materialise into successful products anywhere in the world to date. For example, Monsanto's (now Bayer) drought-tolerant maize variety MON87460 was rejected by the South African authorities because it: "…*did not provide yield protection in water limited conditions*"[48]. Indeed, "*some trials even showed lower yields than conventional maize"*. The claim of drought tolerance has never been confirmed by independent scientific studies. The claim that the integration of the cspB gene improves tolerance against drought rests entirely on claims by the producer. A study by Monsanto reported a (disappointing) expected 6 % reduction in yield loss from the 15 % loss observed under water-limited conditions over three seasons in the US, with one season observing a 0 % change in yield in comparison to conventional varieties[49]. Though this study purported to show a "*yield increase*", there was, in reality, still a 9 % yield loss under water-limited conditions. South African courts have more recently ruled that Bayer failed to adhere to the Precautionary Principle embedded in their national law to prove that the crop was safe to consume, representing further setbacks to its deployment outside of the US[50]. In the US, where it has been cultivated since 2012, the most recent 2022 data from extension trials in Utah, the crop again failed to consistently yield better than conventional hybrids in either fully irrigated or drought-stress conditions[51]. As the study concludes, "*Five Utah studies comparing conventional and drought tolerant varieties of corn and alfalfa have shown little to no consistent increase in crop yield and performance of the drought-tolerant varieties in contrast to conventional varieties. Therefore, drought tolerant options should be considered carefully until further research can locally verify that the agronomic benefits outweigh the added cost*."

Preliminary reports out of Argentina, the first country in the world to approve a GM 'HB4' wheat variety sold to resist drought, also indicates poor initial yields, though wider information appears unavailable.[52] Transparency is, at least in part, hindered by the lack of regulations on GM organisms that would allow for clearer monitoring of performance, as well as biosafety risks and traceability aspects. However, new reports of poor economic performance may be an early indicator of problems for the company and HB4 wheat and its parallel HB4 soybean product. Although promoted as drought tolerant, HB4 is also genetically engineered to be tolerant to the herbicide glufosinate ammonium, raising significant concerns about environmental impacts associated with the blanket spraying of this crop with herbicide.[53,54]

Nutritionally enhanced crops have also been a failed promise. The most prominent example is Golden Rice, genetically engineered to produce high levels of beta-carotene (which can be converted to Vitamin A when eaten). Golden Rice was initially hampered by low yields, dwarfism, bushy statue, pale leaves, late flowering and low fertility[55,56]. The later version suffered degradation of beta-carotene during storage, with negligible evidence of health benefits[57]. The Philippines, one of only two countries to initially approve the crop for cultivation, recently reversed this decision after farmer organisations went to court due a lack of consensus over safety and potential impacts of farmers[58]. Farmer rejection was predictable given vocal opposition from farmer groups in the country with regard to one of their staple crops[59]. With malnutrition in the Philippines associated with a range of nutrient deficiencies, a singular nutrient approach cannot replace broader approaches to make balanced, healthy diets accessible to all children.

In 2003, a Washington-based researcher claimed that, "*Genetically modified (GM) or transgenic trees are approaching commercialization in forestry*", and concluded that, "*The economics suggest that social benefits could be obtained from lower-cost wood production that might be forthcoming from transgenic tree*s", listing a total of 90 wood tree field tests undertaken in the USA with four types of trees.[60] A subsequent paper again suggests that "*GE* [Genetically engineered] *trees have the potential to provide substantial financial and economic returns under appropriate conditions*" and that these conditions might be particularly favourable in developing countries such as China and Brazil.[61] More than 20 years ago, the International Union of Forestry Research Organisations (IUFRO) Working Party on Molecular Biology of Forest Trees stated that, "*Transgenic technology, wisely used, promises significant economic and environmental benefits*."[62] Yet, despite decades of research, none of these claimed benefits have been delivered in reality.[63]

2.2 GM animals

In 1992, the US National Agricultural Biotechnology Council (NABC) stated, "*When appropriate disease resistance genes are identified, it should be possible to engineer high-producing animals for survival in high-disease environments*" and speculated that "*It is likely that some cows will be designed to produce milk for speciality dairy products whilst most cows may be engineered to produce little or no fat in their milk*". At this time, GM mice, sheep goats and pigs had already been created which could make pharmaceutical products such as clotting factors and growth hormones, for potential use in human medicine. However, the report also notes that, "*Gene transfer usually results in one or two transgenic animals forming the beginning of a transgenic line. It, therefore, does not initially impact a large part of a population and requires artificial insemination, or in vitro production of embryos, or cloning or combinations of the above to produce animals or fish which are commercially useful*". These early attempts at genetically engineering animals were already subject to criticism by those concerned about the welfare of animals, including the use of reproductive technologies such as cloning, which result in large numbers of miscarriages and stillbirths, as well as the adverse effects of genetic engineering.[64] For example, adverse effects of growth hormone transgenes were observed in lambs, which were diabetic and had such severe health problems that they died before reaching puberty.[65]

The first transgenic GM pigs and sheep were first created in 1985, yet there are only two transgenic GM animals approved for food consumption (both produced in the USA). These are GM salmon, which has now ceased production (see below) and a GM pig (known as the Galsafe pig), first reported in the scientific literature in 2003.[66] This GM pig has been genetically engineered to reduce production of certain sugars. It is claimed that this might make it useful for some medical applications, however it has not yet been approved for such uses. At the time of the approval, the company stated that it intended to sell meat from GalSafe pigs by mail order, rather than in supermarkets.[67] It is unclear whether any such meat has actually been sold.

GM salmon have been approved for commercial production, in Canada and the USA, in on-land facilities, yet the company, AquaBounty, has already shut down operations, partly as a result of consumer rejection of the product but also due to other failures.[68] Unintended impacts and poor efficacy were documented, including increased water content, likely resulting in poorer quality meat, as well as a reported failure to grow faster than conventionally-bred salmon, in addition to environmental concerns about impacts on wild salmon should the fish escape.[69,70] This reality is in stark contrast to some of the early claims about the technology: that the company would harvest 160 tonnes of GM salmon in Indiana in 2020, and that it aims to harvest "*55,000 tonnes in just eight years, if it has the right investment*"[71]. The aquafarms built to house the GM salmon were promoted as bringing economic transformation to a small town in Ohio that was set to house a farm. Nearly three years later, there are no fish tanks, no jobs and no delivery of the 1 million a year investment that was promised to the local school[72].

GM insects have been approved for commercialisation in Brazil by the country's GM regulator. However, despite first releasing GM mosquitoes in the Cayman Islands in 2009, GM insect company Oxitec's accounts continue to "*cast doubt on the Company's and group's ability to continue as a growing concern*" and note that, "*The Brazilian operation is still in the early stages of commercialisation and cannot yet demonstrate sufficient projected revenue to support the gross valuation*" of its Brazilian subsidiary.[73] Oxitec has closed operations in multiple countries where it planned or undertook experiments in the past. Two versions of Oxitec's GM mosquitoes were trialled in Brazil, intended to mate with wild mosquitoes, reducing their numbers and hence (in theory), the incidence of dengue fever. The first was abandoned following evidence that, contrary to the company's claims, it had failed to reduce wild mosquito populations in trials in the Cayman Islands and elsewhere, and large numbers of biting female GM mosquitoes had unintentionally been released.[74,75] The second version of these GM mosquitoes was subsequently marketed to consumers. However, large-scale commercial releases have never been approved by the Brazilian health authority ANVISA, which wants to see evidence of benefits to health before giving its approval, in line with recommendations from the World Health Organisation (WHO).[76,77,78] GM fall armyworm (a maize pest) has also been developed by Oxitec and approved for release in Brazil, though the product is designed to delay resistance of the pest to Bt crops and is not expected to work unless in conjunction with Bt crops, which as stated above, are already declining in their efficacy against the pest. Concerns have been raised that GM insects, created by engineering non-native varieties, will spread genes into wild insect populations that could make them more harmful or more difficult to eradicate.[79] There are also practical difficulties in using Oxitec's GM agricultural pests, since they die at the larval stage (after they are expected to have caused crop damage), contaminating crops with dead GM larvae, and also potentially undermine attempts to tackle other pests (which cannot be sprayed during the releases, without interfering with the mating process between the GM and wild pests).[80,81]

3. Gene edited plants and animals: delivering real benefits?

As first-generation GMOs fail to live up to their long-held promises, similar claims are being repeated for genome editing techniques. They echo claims made for genetically modified organisms (GMOs) since 1981. As detailed above, these claims have not been delivered.

Genome editing (also known as gene editing) uses chemicals known as enzymes to cut DNA inside plant or animal cells, and the cell's own repair mechanisms are then used to introduce genetic changes. These methods differ from the old approaches to creating GM crops that are already on the market, which involved introducing genes from other species, or different varieties of the same species, into cells (known as 'transgenesis' or 'cisgenesis'). Nevertheless, genome editing is not 'precise' (as sometimes claimed), and gives rise to unintended effects, as well as technical difficulties in delivering the promised future products, discussed further below.

Statements by the European Academies' Scientific Advisory Council (EASAC) claim that, "*dialogue does not need to continue to be primarily about the value of genome editing technologies, or GMOs, because this value is already demonstrable*", and "*New Breeding Techniques have the potential to contribute much to intensified crop productivity, sustainable agriculture and the response to climate change*". [82,83] EASAC defines the term 'new breeding techniques' as including genome editing. The co-inventor of the genome editing technology known as CRISPR (short for "clustered regularly interspaced short palindromic repeats"), Jennifer Doudna, has made similar claims regarding her own technology's potential, recently stating that "*In the future, as we uncover more and more of those fundamental genetics of* *traits, then CRISPR can come in as a very practical application for creating the kinds of plants that will deal with these oncoming challenges*"[84]. In a statement arguing for the deregulation of genome edited plants in the European Union (EU), the Leopoldina German Academy of Sciences similarly claims that "*More than 100 (potentially) marketable genome edited crops are currently known worldwide; these plants have been created through directed point mutations or deletions of a small number of base pairs and are beneficial for nutrition as well as for productive, low-pesticide and resource-conserving agriculture*".[85] The caveat here is in the word 'potentially', which hides the reality of the failure to deliver marketable gene edited crops, as discussed below.

In England, a leaflet published as part of a consultation held in the lead up to the development of the new Genetic Technologies (Precision Breeding) Act, the Department for Environment, Food & Rural Affairs (Defra) stated, "*Gene editing will give us the opportunity to ensure that animals, plants and crops can be stronger and healthier, and more resistant to diseases*".[86] When the Act was adopted, the Chief Scientist at Defra stated, "*The ability to use gene editing to make precise, targeted changes to the genetic code of organisms, in a way that can mimic traditional breeding, enables development of new crop varieties that are more resistant to pests, healthier to eat, and more resilient to drought and heat as climate changes*."[87] Similar claims were made throughout the development of the Act.

Gene editing is indeed being applied to a very wide range of organisms, including numerous crops (e.g., rice, maize, soybean, tomato, potato, wheat, oilseed rape, watermelon, lettuce, flax[88]), farm animals, fish and shellfish.[89] Gene editing has also been attempted in non-food organisms which may nevertheless contaminate the food chain, such as flies, bees, beetles, butterflies, moths, and grasshoppers, other wild animals and trees. [90,91,92,93,94]

However, large numbers of experiments (and potential releases onto the market and/or into the environment) do not mean that viable products which deliver the claimed benefits are likely to appear. Early experience with gene edited crops suggests that, in contrast to the claims, few commercial products will be delivered and that those that are will be at high risk of commercial failure. For example, in 2019 the US company Calyxt started selling soybean oil from gene edited soybeans to the foodservice industry, but merged with Cibus in 2023, after suffering a sharp drop in revenue and being faced with delisting from Nasdaq.[95] Similarly, Yield 10 Bioscience has announced the shutting down of operations after suffering a catastrophic collapse in share price after failing to deliver on its claims regarding gene edited crops.[96,97] Shares in Cibus fell significantly recently after Bonitas Research issued a report alleging that they "*found no evidence that Cibus' gene-editing technology brings desirable new crops to market*" and reporting, "*farmer complaints of lower crop yields and lost revenues, along with multiple examples of large seed manufacturers and distributors walking away from joint ventures and partnerships with Cibus for a variety of seed types and seed traits*."[98] Most recently, the company announced that its editing platform for rice, is considerably less efficient than previously reported, with editing rates of 10-25 % not reconfirmed in subsequent experiments due to experimental variability[99]. This was described as a "material setback" which "undermines confidence" in their technology platform.[100] Following this announcement, their CEO resigned.[101]

Although gene edited tomatoes, with enhanced levels of a chemical called GABA, are in theory on sale in Japan, this is an experimental product, produced in small quantities for a price of US $68 per kilo.[102] In the case of GM animals, three gene edited fish species have theoretically been made available to the market in Japan from 2021 to 2023.[103] However, these also remain effectively experimental products, with no commercial market. Indeed, according to a 2023 USDA biotechnology update report on Japan[104], the GM fish are not in commercial production. This highlights an important distinction between approvals for commercialisation and products actually being available for market. While products may be officially approved for regulation, this does not necessarily indicate that a product is being cultivated or sold commercially. It is commonplace for approvals for imports to be granted even for products not approved anywhere for cultivation.

Indeed, despite genome editing technologies being around since the 1990's, very few products have been developed, and those that have been approved do not appear to be commercially sold at present, except for the GABA tomatoes, at an exorbitant price. As pointed out recently by an agricultural consultant: "*Even though we've had all of those regulatory decisions, we have very, very few products globally that are gene-edited in the market. I mean literally, there's a single product which currently is still in the market, and that is the editing tomato plant in Japan*."[105] Indeed, DuPont's first CRISPR product, a 'waxy corn' announced in 2016 is yet to be sold despite gaining non-regulated status in the US[106]. 'World first' T4 disease resistant genome edited bananas, developed by researchers in Australia, similarly will not be commercialised, but instead will be reportedly reserved as a safety net.[107] A lettuce variety, recently developed by Pairwise, was also planned to be taken off the market, though Bayer recently took over the product and it remains unclear if it will be put back on the shelves[108]. These early product failures are reflected in the financial downturns in gene editing companies where financial cracks are appearing within the sector that has been built on the basis of the promise of new engineering techniques such as genome editing[109]. Several flagship companies faltered last year in the synbio space, including Ginkgo Bioworks[110]. The company is said to be laying off significant percentages of staff, having failed to deliver on products.

In the case of gene edited plants and animals, reasons to doubt the likely emergence of future useful products include: commercial interests; technical difficulties; misleading claims about beneficial traits; and costs and consumer preferences. These issues are considered in turn below.

3.1 Commercial interests

Commercial interests favour the development of traits that are the most profitable, i.e., crops that are herbicide-tolerant so they survive blanket-spraying with the associated weedkiller (both seeds and weedkiller can be patented and sold by the same agrichemical company). As noted in Section 2, nearly 90% of existing planted GM crops are herbicide-tolerant, with serious well-documented adverse effects on the environment and human health in North and South America, where these crops are grown.[111] Much ongoing research effort is now focused on developing gene-edited herbicide-tolerant crops to avoid the regulations applied to GM crops elsewhere in the world.[112,113,114,115,116,117] Although technical difficulties may limit what can be delivered (see Section 3.2), herbicide-tolerant traits are of the most commercial interest, and therefore most likely to be delivered to the market.

Similarly, the main trait being studied in gene edited animals for agricultural applications is increased yield, usually by altering a gene associated with causing excessive muscle growth, stress and breathing difficulties.[118] There are even proposals to use genome editing to create insecticide-resistant bees, for use in industrial farming.[119,120] Since insecticide-resistant bees could in theory allow these bees to survive blanket spraying with insecticides, these would raise similar concerns to herbicide-tolerant crops, including adverse impacts on other (non-insecticide-resistant) beneficial species and the development of resistant pests.

3.2 Technical difficulties

Numerous technical difficulties limit what gene editing can actually achieve in both plants and animals. Gene editing involves cutting the DNA in plant or animal cells and relying on the cell's own mechanisms to repair the cut whilst introducing changes in the DNA. This process suffers from a variety of problems, including errors in where the DNA is cut (so-called 'off-target effects') and in how the cell repairs itself ('on-target' effects).[121,122,123] In plants, a substantial bottleneck is effective delivery of gene editing machinery to the right plant cells and subsequent regeneration of viable plants, using tissue culture that can introduce new errors and simply does not work in many plants.[124]

Although gene editing is faster to use than older GM techniques, the desired effect in the plant or animal will not necessarily be delivered, even if the desired change is made in its DNA. This is particularly true for complex traits, such as drought tolerance, which depend on many different biological pathways and multiple genes within a plant, with trade-offs between them. For example, a recently developed genome edited rice variety received significant fanfare for potentially increasing photosynthetic rates to boost biomass and grain yields.[125] However, the same researchers recently published evidence that increasing photosynthetic rates also results in increased sugar levels and resultant ‘plant diabetes’, reduced seed setting rates and impaired fertility.[126]

Even without the technical difficulties associated with gene editing, designing new plant types is not trivial since multiple genes, environment and crop management methods interact and are dependent on future weather, farmer choices, and specific location.[127] Hype about the predicted benefits of genome editing is not consistent with reality.[128] In the case of trees, long lifetimes, complex genomes, and difficulties with tissue culture add to the technical difficulties. [129]

Gene edited animals face additional hurdles, as gene editing in animals is highly inefficient and error-prone and it is hard to scale-up from a few founder animals to produce the large herds or flocks that would be needed.[130,131,132] For example, a paper which uses modelling to argue that gene edited hornless cattle could be used to rapidly decrease the frequency of horned cattle in US dairy cattle populations, assumes that the top 1% of bulls would be gene edited and cloned in each generation, an expensive and time-consuming process which also raises significant animal welfare concerns.[133,134]

3.3 Misleading claims about beneficial traits

Claims of benefits often focus on potential beneficial traits such as nutritional enhancement and disease-resistance. Whilst these traits appear easier to deliver than some complex traits discussed above, they also have inherent complexities and risks.

Altered nutrient levels in a single crop do not replace the need for balanced diets and can be harmful in high doses or to specific groups of people. Claims of health benefits associated with single nutrients are often unsubstantiated. For example, the gene edited tomato with enhanced levels of GABA, on sale in Japan, is claimed to reduce blood pressure, but there is no evidence from human trials.[135] Research on nutritional supplements has often found that early health claims are incorrect, whilst large-scale human trials show no evidence of benefit and sometimes evidence of harm.[136,137] Other problems can arise because GM plants are not ‘ingredients’ but living organisms that interact with their environment. For example, one problem with attempts to genetically engineer enhanced iron and zinc content in plants is that such plants may also accumulate toxic metals such as cadmium if they are planted in contaminated soils.[138] In some cases, crops with increased nutrients may also attract pests.[139,140] A 2025 study on using editing to knock down GABA expression in tomatoes (i.e. reducing, rather than increasing GABA) found that reduced GABA increased resistance to bacterial wilt, increased recovery from drought and increased root microbiome diversity.[141] This raises further questions regarding how a tomato with increased GABA would yield if widely cultivated.

Gene edited crops and animals resistant to pathogens (viruses, bacteria and fungi) are a major area of research. However, pathogens are likely to evolve in response to gene edited resistance in a plant or animal, so that the plant or animal is no longer resistant to disease.

In the process, the pathogen may become more virulent or more transmissible, with potentially devastating consequences to crops, animals, or even humans. For example, GM papaya genetically engineered to be resistant to the Papaya ringspot virus (PRSV) is grown in small quantities commercially in the USA (Hawaii), but when grown in China it lost PRSV-resistance and a new variant of PRSV evolved.[142] This problem can also occur with gene editing. In a particularly worrying example, the Economist reports that scientists in the UK attempted to gene edit chickens to switch off a protein that the bird flu virus uses to replicate in cells, however, "*…things did not quite go to plan. Although the chickens seemed protected at first, the virus quickly mutated so that it could exploit the other proteins that had previously been useless to it. In the end, the team had to knock out all three genes to shut down infection, and it is unclear if the chickens can thrive when thus diminished. It was a lesson to scientists, says Dr Sang, to be careful about entering an arms race with a pathogen that humans might lose*." [143] The paper describing these experiments reports that the mutations in the bird flu virus unexpectedly allowed the virus, that is usually limited to birds, to use the two shorter proteins, which also occur in humans, and thus the virus partially adapted itself for replication in mammals (potentially including humans).[144] A related concern is that a gene edited disease-resistant animal may be infected but not show symptoms of disease, perhaps benefitting the individual animal but putting other animals at increased risk.[145] In animals, these problems are compounded by the difficulties described above in scaling up production to create large herds or flocks: this process is likely to be too slow to keep up with fast-evolving pathogens. In plants, disease-resistance is often linked to reduced yield, adding further difficulties.[146]

Parallel problems can be expected for major pest species including weeds and insects that are already understood to rapidly evolve around new selection pressures, putting a limit on the long-term viability of the overall GM approach, whether transgenic or genome edited.

Bayer's (formerly Pairwise's) salad mustard leaf variety, is another example of trade-offs that may undermine any presumed benefits. The deleted compound that confers the bitter taste from the mustard leaves, also plays a role in plant defence[147], and is thought to confer important health benefits including anti-inflammatory, antioxidant and chemoprotective effects[148].

3.4 *Risks*

In GM crops, unintended impacts of the GM process, as well from the introduced trait, have been widely observed[149,150]. Such impacts include molecular effects genetic changes, as well as disturbances in gene expression, protein and metabolite levels. Such risks are recognised in the regulatory context, with both national and international regulations, e.g., the Convention for Biological Diversity's Cartagena Protocol on Biosafety, requiring assessment at the molecular level.[151] Indeed, GM crops to date have suffered a wide variety of associated unintended impacts including on fitness, seed germination, weed suppression, pest resistance, (non-)drought-tolerance, height, yield and flowering time, as well as compositional differences. For example, just for the Bt maize variety MON810, studies have revealed unintended effects including various chemical changes (increased lignin content, altered kernel composition of sugar, osmolytes, branched amino acids, and proteins), decreased numbers of soil organisms (protozoa and nematodes), and drier root soils, increased aphid susceptibility, delay in seed and plant maturation, and higher moisture content.[152] Current assessments have however, been regularly criticised for being permissive and insufficient to detect and ensure against potential risks[153].

New gene editing techniques also present a range of biosafety risks. Biosafety risks of the techniques themselves are already widely documented and fundamentally challenge claims of safety and precision, as discussed below. Nonetheless, the targeted nature of genome editing techniques is sometimes given as justification for deregulation of these new GM techniques. GM proponents regularly claim that such targeted changes, some of which do not intend to insert genetic material but instead generate smaller mutations in a desired sequence, are akin to natural mutations and thus safe. However, accompanying the 'targeted change', if indeed it is achieved, are also well-established unintended changes that are also generated, including at the target site of interest, as well as elsewhere, in 'off-target' locations.

Within the medical research community there is widespread recognition that unintended genomic effects such as unintended on-target alterations, and off-target activity, unintended insertions of transgenic material, as well as larger structural impacts such as chromosomal loss, are associated with these so-called 'genome editing' technologies.[154,155] As such, recent publications from prestigious medical institutions warned that such technologies could have unforeseen effects that may not only adversely impact the individual but that can also be passed to future generations. Following the documentation of unwanted genetic changes in human cell experiments, an author of one of the studies also warned of the serious consequences of unintended effects, explaining that some cells "*were so flummoxed by the alterations that they simply gave up on trying to fix them, jettisoning entire chromosomes, the units into which human DNA is packaged*" [156]. Concerns have been raised that such off-target genetic alterations and chromosomal rearrangements may trigger cancers. Such unintended effects can equally have implications for 'genome edited' plants or animals.

The unintended insertion of genetic material into genome editing organisms reveals another important risk that is often dismissed: the unintended generation of transgenic organisms, due to the use of DNA from other organisms (usually bacteria), during the process of gene editing. However, several regulatory proposals and decisions by national governments include deregulating organisms that are not *intended* to carry inserted genetic material. Basing regulations on the intended final product, rather than a process-based approach will fail to detect these or other unintended outcomes. For example, in 2019, the US Food and Drug Administration (FDA) found that, in an attempt to create gene edited hornless cows, apart from the intended edit, the whole plasmid (a small, circular, double-stranded DNA molecule, derived from bacteria), including a second copy of the repair template and the plasmid backbone, were integrated into the target location of both calves.[157] The findings of the FDA scientists raised biosafety issues, since the plasmid backbone that was unintentionally integrated into the calves' genome also included genes conferring antibiotic resistance. Concerns were expressed that these genes could be taken up by bacteria present in the gastrointestinal tract or the body of the calves.[158]

In addition to the risks associated with these unintended effects, many other concerns remain the same as with older GM techniques, as discussed above: these include, for example, risks to the environment associated with herbicide-tolerant crops; animal welfare concerns associated with the use of reproductive technologies such as cloning and the introducing of harmful traits such as faster growth; the risks that disease-resistant plants and animals cause pathogens to evolve to become more virulent; and the potential for nutrient-altered crops to harm the health of humans or wildlife.

3.5 Costs and consumer preferences

Rather than starting with the introduction of the most potentially profitable, herbicide-tolerant gene edited crops (see Section 3.1), multi-national companies such as Bayer (which now owns Monsanto) are teaming up with smaller companies to introduce supposedly more consumer-friendly-traits, such as gene edited mustard greens with reduced bitterness.[159] However, it is far from clear that such products – if they are delivered - will be either acceptable or affordable for consumers. Profit incentives for such supposedly 'consumer friendly' products are dwarfed by herbicide tolerant crops that allow corporate producers of GM seed and their accompanying herbicide packages to be sold at industrialised scales when applied to commodity crops. Indeed, a significant portion of R&D for genome editing still focuses on the development of herbicide-tolerant traits. Another focus of interest is other traits that are relevant to industrialised monoculture systems.

Seed prices for patented GM seeds (which are under monopoly control) are significantly higher than for non-GM ones in countries such as the USA, where non-GM varieties (protected not by patents, but by less restrictive breeders' rights) are often not available and farmers are also prevented from seed saving.[160] This means that prices for gene edited crops and foods may not be affordable and may fail in the market place, particularly if they offer no benefit for consumers in reality. As noted above, the price for gene edited tomatoes on sale in Japan is reportedly an astronomical US $68 per kilo.[161] Conventionally-bred high-GABA tomatoes exist as an alternative, and other GABA-rich foods are also available.[162,163]

4. Conclusion

Unsubstantiated claims of benefits associated with genome edited plants and animals are being made in order to push policy-makers to deregulate. In reality, as with existing GM plants and animals, most of the claimed future products will not be delivered, due to a combination of technical difficulties and economic and marketing considerations. Authorisation is not the same as commercialisation, and commercialisation does not mean that products are successful, either economically, or in terms of their claimed benefits.

Deregulation of gene edited products will lead to misallocation of resources and significant opportunity costs as public and private investment will increasingly be directed towards more gene editing failures.

Significant harm could be caused to human and/or animal health and welfare and the environment, if experimental products are released without detailed risk assessments (for food/feed, animal welfare and environmental risks), adequate post-market monitoring, and traceability and labelling throughout the food chain. This includes the risk that viruses can evolve in response to genome edited disease-resistant plants and animals, causing major biosafety issues.

Proposals to deregulate gene edited organisms lead to a loss of control over the food chain, environment and trade, including European markets opening up to non-risk assessed imports, and countries rejecting European exports.

Existing GMO legislation has saved Europe from the trade and environmental disaster of GMOs. The attempt to take gene editing out of this successful legislation is a path to failure and should be avoided. The stripping away of risk assessment, risk management, full traceability and consumer labelling, as well as co-existence and liability requirements, will remove the European environment, its farmers and its citizens, from existing successful protections.

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