INBRIEF

Key Issues in the Deregulation of Gene Editing

A briefing on issues raised by the current government Consultation on the Regulation of Genetic Technologies

February 2021

On 7 January 2021, Defra launched a ten-week Consultation on the Regulation of Genetic Technologies.[1]

GM Freeze and Beyond GM have prepared this briefing to set out key issues and concerns. We are asking MPs and peers to support calls to reject Defra's proposal and put in place a more meaningful exploration of how best to regulate the use of gene editing in food and farming.

Key points covered in this briefing include:

- The consultation asks respondents to accept Defra's claim that gene editing gives nature a helping hand when, in fact, it is a complex and highly invasive process with potential for errors and unintended consequences, for our food, for farmers, and for the environment.
- Regulation exists is to protect people, society and the environment. There is ample evidence that all forms of genetic engineering have the potential to cause harm and should be subjected to case-by-case risk assessments, monitoring, traceability and labelling to allow consumers, and others, to make an informed choice. Defra's proposals would remove these essential safeguards from a technology with no history of safe use.
- Deregulation of gene editing could have detrimental impacts on UK trade with the European Union, on the UK's own internal market and on organic and other non-GM supply chains. It will also be extremely unpopular with UK citizens who remain overwhelmingly opposed to genetically engineered foods.

MPs and Peers concerned about these issues can:

- Sign Early Day Motion 1547 – Regulation of genetic technologies in food and farming.
- Raise your views about the importance of robust regulation of gene editing with Environment Secretary George Eustice and share any response with us.
- Ask a Parliamentary Question about one of more of the concerns that farmers, civil society, scientists and citizens have raised about the Consultation on the Regulation of Genetic Technologies. We can provide a draft question if you would find this helpful.
- Press Defra to engage in efforts to create a more rational and inclusive UK-wide discussion around the need for, and the regulation of, genetic engineering technologies in agriculture.

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Gene editing, GMOs and other technologies

The terms 'gene editing' and (more scientifically) 'genome editing', cover a wide range of genetic engineering techniques that focus on changing the DNA within an organism.

Gene editing is often used alongside older genetic engineering techniques including transgenesis (adding genes from another species) and cisgenesis (adding genes from the same or a closely related species). It is designed to be more targeted than older techniques but still involves many steps each of which are prone to a range of errors and unplanned outcomes.

Genetically modified organism (GMO) and genetic modification (GM) are terms used in the EU regulation on genetic engineering. When these terms were first coined it was common for genetic engineering applications to add genes from another species; but transgenesis was never part of the definition of a 'GMO'.

The recent use of GMO to mean only transgenic organisms is a marketing and political choice - rather than a scientific one - intended to support deregulation of gene editing (see *Is the terminology important?*, right).

The questions in the Defra consultation also ask about "other genetic technologies". This term is not widely used and has no specific meaning, but we take it as a very broad term to encompass anything that can, or could in the future, be done to alter the DNA of a living organism in a way that cannot happen in nature.

How gene editing works

Contrary to the over-simplified descriptions used by proponents, gene editing is a complex molecular modification process and technologies like CRISPR do not, in themselves, create new organisms.

In most instances, gene editing tools like CRISPR are used to cut both strands of a DNA double helix at a targeted location. This molecular injury then activates the cell's DNA repair mechanism. Genetic engineers use this combination of events to introduce a genetic modification at a desired location on the genome.

Is the terminology important?

In the 1990s 'genetically modified organism' replaced the more accurate description, 'genetic engineering', in common use as a way of making the technology seem less invasive and extreme.

The current name change is an extension of this and aims to separate genome, or gene editing from GMOs and equate it with traditional plant breeding. Terminology, therefore, forms a key part of the argument for deregulation.

In reality, the term gene editing refers to a suite of genetic engineering techniques that can be used to create new plants and animals. The most well-known of these techniques is CRISPR/Cas-9 a type of genetic engineering that is relatively cheap and quick to use for research purposes.

Other genome editing techniques include zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENs), and oligonucleotide-directed mutagenesis (ODM) and directed mutagenesis. Although they are called 'new' techniques, CRISPR and these other techniques have been in use for many years.

In the agricultural debate, terms like 'Precision Breeding', 'Speed Breeding' and 'New Plant Breeding Techniques' are pseudo-scientific marketing terms. They are also often, wrongly, used to describe all genome editing techniques, including gene editing, synthetic biology and gene drives, even though there are significant differences between these – and each comes with its own unique risks.

Currently there are three types of gene editing:

- SDN-1 the DNA is cut and the organism is allowed to repair itself;
- SDN-2 the DNA is cut and a template is provided to instruct the organism how to repair itself;
- SDN-3 the DNA is cut, sometimes in several places, a template for repair is provided and genes from other species are inserted.

After one or more of these gene editing processes, the creation of the final organism involves the same stages of cell culture, selection and replication as older genetic engineering techniques.

A time frame of anywhere from 5-15 years is normal for the creation any kind of new plant variety – a fact which challenges promises of genome editing as a form of 'speed breeding'.

While gene editing is promoted as being a more precise type of genetic engineering because intended DNA changes can be targeted to a particular location on the genome, precision is not the same as predictability, accuracy or control.

Gene editing in practice

Many claims are made for potential future uses of gene editing, mirroring the unfulfilled promises of the first generation of GM crops since the 1990s.

Only two gene-edited crops are grown commercially anywhere in the world – a herbicide-tolerant oilseed rape (SU Canola[6]) and Calyxt's soybean[7] designed for the fast-food industry. Gene-edited non-browning mushrooms have been approved for the US market, but have not yet been commercialised.

Complex traits such as pest or drought resistance, improvements in yield or resilience in the face of climate change, cannot be achieved through simple genetic 'edits' or 'tweaks' and, in fact, are already being addressed through conventional breeding and agroecological approaches.

A single 'targeted' gene can have multiple functions, thus even a single DNA change can have multiple and profound effects throughout the organism. These effects cannot be predicted or controlled because scientists don't know enough about the genome.

Numerous recent studies are showing that 'precise' CRISPR technology can produce massive and unpredictable disruption in the genome[8] – a good reason for robust regulation.

The Defra consultation

The Defra consultation has drawn a great deal of criticism not least because it appears that government is consulting on a matter on which it has already formed an opinion[9].

It was launched without any terms of reference, but its tone and content suggest it is based on the government's belief that gene editing simply speeds up genetic changes that could have occurred through traditional breeding. It assumes that respondents will accept this notion before asking them to comment on various aspects of regulation and to provide evidence to justify their answers.

The timing of the consultation launch – just seven days after the end of the Brexit Transition Period and at the height of the COVID-19 crisis – also suggests the government views the deregulation of gene editing as a flagship Brexit "win".

The European Court of Justice ruling

The government's plan to deregulate gene editing involves disapplying a 2018 ruling of the European Court of Justice (ECJ) and changing the definition of a GMO in England.

Beyond agricultural uses

Part 2 of the consultation asks about broad reform of GM legislation in areas such as genetically engineered crops, farmed animals, human food, human and veterinary medicines, animal feed and other "unspecified sectors".

This has led to concerns that the focus on deregulating gene editing is a prelude to a broader deregulation agenda, including newer more radical applications of genetic engineering including gene drives[2] and synthetic biology[3].

Proposals to genetically manipulate wild species are already being advanced in the name of conservation.[4] Trials of gene drive insects that over-rule the natural laws of inheritance are taking place globally[5].

Synthetic biology – a specialist form of gene editing – is being proposed as a way of creating meat analogues in large industrial vats, with no more need for farmers.

Each of these proposals has vast and largely unexamined consequences for health, the environment and the economy.

Very broadly the ECJ case was about how we define and, therefore, regulate GMOs. It began as an action brought by several French NGOs, arguing that herbicide tolerant varieties of rapeseed and sunflower, produced using new directed mutagenesis processes, were 'new hidden GMOs' and should be regulated under European law.

The case was referred to the European Court of Justice in 2016. After reviewing copious scientific evidence the Court's unequivocal judgement in July 2018 was that – legally and scientifically – organisms obtained by directed mutagenesis are GMOs[10] and are, therefore, subject to the obligations laid down by the EU GMO Directive, including case-by-case risk assessments, traceability and labelling.

Likely impacts of deregulating gene editing

Removing regulatory controls from genetically engineered plants and animals has consequences.

Trade with Europe

The European Union is the UK's largest trading partner. Robust GM regulations in Europe cover all forms of gene editing, and require full traceability and post-market monitoring for those GMOs that are allowed into the food chain.

Deregulation in all or part of the UK would make it impossible for producers to identify gene-edited organisms. UK producers working with crops and animals that are gene edited would lose access to the EU market. But Europe's precautionary approach to genetically engineered organisms means that those producers who choose not to grow gene-edited plants or animals may also lose out due to concerns about traceability or a contaminated supply chain.

Rejection of GM is not just a political matter in the EU. European consumer group BEUC surveyed 11,000 consumers in 2019[11] and found amongst other things that consumers most spontaneously associate "sustainable food" with "low environmental impact" (48.6%), "use of GMOs and pesticides to be avoided" (42.6%) and "local supply chains" (34.4%).

Devolved nations

Although the Defra consultation officially only covers England, in reality any legislative changes will have impacts throughout the UK. The Scottish and Welsh Governments, for instance, have been clear that they wish to maintain their prohibition on producing GMO crops and animals, but UK internal market rules could stop them taking action to prevent sales of GMO products approved in England.

Equally, since unregulated, unlabelled GMO products are unlawful in the EU, the push for deregulation is a cause for concern in Northern Ireland[12].

Environmental concerns

Environmental impacts must also be considered. Although there are no gene edited crops or animals being farmed in any volume anywhere in the world we can draw some conclusions from the environmental impacts of existing genetically engineered crops in the Americas, where their uptake has been most widespread and where there

Equitable co-existence

UK farming and food policy states that we should encourage and develop a range of agricultural systems and that these must co-exist together.

This policy has been popularised by the phrase "tools in the toolbox". It assumes that farmers should be free to choose whether to farm conventionally, using GMOs or some version of organic/agroecology. It also assumes that consumers should be free to choose, or not, the products of these different and co-existing systems.

However, these very different systems can only "coexist" if one system of production does not negatively impact the others. Organic and other non-GM supply chains may be especially vulnerable to the effects of deregulation.

There has been no meaningful discussions in the UK for well over a decade about how this co-existence will work if genetic engineering technologies are deregulated and the Defra consultation has brought no clarity to this issue.

The fact remains that regulation, transparency and labelling are the best ways to achieve an equitable co-existence.

Different approaches to regulation

Gene editing is currently regulated as a form of genetic modification (GM). This means that any crop or animal produced with gene editing must undergo a risk assessment before it can be farmed, imported or eaten. If it passes those checks it must be traced and monitored after release to allow for a recall if a problem is discovered later.

Any food destined for human consumption in the UK or the EU must declare the presence of genetically modified ingredients, including those produced with gene editing techniques, on the label (or menu in a restaurant, café or take away).

GM regulation is often referred to as 'process-based' because it is triggered by the way in which an organism is produced. This recognises that direct intervention at the genetic level is different from traditional breeding and can result in multiple and unexpected errors across the genome, some of which may pose a threat to people, animals or the environment.

Industry is calling for 'product-based' or 'trait-based' regulation which would stop any consideration of how a plant or animal was created. Essentially this process means taking the genetic engineering company's word for it that the only DNA changes made were the intended ones and that these changes will only have the impact(s) that they planned.

In practice, the current system looks at both process and product, since the process is what triggers an investigation of the product.

What's missing are larger questions, asked much earlier in the R&D timeline about things like need, benefit, socioeconomic impact and the ethics of proposed new organisms.

Such questions are a key part of, for instance the Norwegian approach to regulation which uses five 'pillars' to assess genetic engineering in food and farming: health, environment, sustainability, ethics and economics (as opposed to the UK's singular focus on safety).

have been no real environmental gains and some important losses.

Gene editing, for instance, is being used to produce crops that are resistant to a range of different herbicides. But a 2012 study from Washington State University[13] found that this type of GM crop quickly encourages the development herbicide resistant 'superweeds' and, as a result, increases herbicide use.

By 2016 research was demonstrating that glyphosate-resistant weeds had led to a 28% hike in herbicide use on GM soybeans compared with non-GM.[14] This rise has also been reported in other countries such as Canada[15], Brazil[16] and Argentina[17].

In 2017 insects had begun to show resistance to the insecticides bred into GM plants[18] causing farmers to use more, and more dangerous mixtures, of other pesticides to control them.

Genetically engineered crops are reputed to increase yields and therefore contribute to land sparing and lower carbon agriculture. In reality there has been no consistent improvement in yields attributable to GMOs and US government data shows yields from GM crops can be lower than their non-GM equivalents[19].

In 2016 an in depth analysis by the New York Times[20], based on United Nations data, concluded that genetic modification in the US and Canada has failed to bring the expected increases in crop yields. That same year a National Academy of Sciences report found that "there was little evidence" that the introduction of genetically modified crops in the US had led to yield gains beyond those seen in conventional crops[21].

Animal welfare

Gene editing of animals raises significant welfare concerns. The process usually involves cloning or alternatives that cause severe pain, distress and the destruction of large numbers of embryos.

Proposed gene editing applications for farm animals largely involve creating abuse-tolerant animals that can survive in crowded industrial units. Rather than changing the system for the benefit of animals we are being asked to give the green light to changing the animals in order to support the system.

Research is already showing the unpredictable results of gene-editing in farm animals. For example, gene editing super-muscly rabbits, pigs and goats resulted in animals with enlarged tongues and pigs having an extra spinal vertebra[22], even though no DNA had been inserted.

Why is UK interest in GMOs so low?

In the UK, the 'GM Nation' debate, conducted in the summer of 2003, concluded there were no public or environmental benefits from genetically engineered crops and no economic benefits for UK Plc[23].

This was in part because of lack of enthusiasm from the general public, lack of crops suitable for cultivation in the UK but also the business model for genetic engineering, which favours large multinational corporations. This has not changed.

Defra claims that gene editing will be a boon for small and medium sized businesses, many of which are involved in gene editing research. But the reality is that, while early stage research is often done by smaller businesses, taking commercialised gene-edited products to market is simply beyond the capacity of these smaller enterprises.

This is because gene-editing technologies and their products are patented. While research licenses to use these patented technologies can be gained cheaply or for free, commercial licenses are extremely expensive[24].

In reality only a handful of very large international companies will have the financial resources to take any gene-edited product through the long and costly process of patenting and commercialisation.

As an illustration, a 2016 report from the UK government Intellectual Property Office[25] noted that just seven companies (six since the Monsanto/Bayer merger) control 71% of the global seed market.

Deregulating gene editing will not change this business model.

Limits to what genetics can achieve

It is widely recognised that, for both plants and animals, there are limits to the agricultural improvements that can ever be achieved through genetics alone.

An understanding of genetics can greatly assist with varietal selection but the way in which crops and animals are farmed; the condition of the soil; the suitability of the varieties and farming method to local conditions; and the skillset of the farmer are all vital elements of a sustainable food system.

The Food and Agricultural Organization (FAO) reported that approximately one-third of all foods produced for human consumption (1.3 billion tons of edible food) is lost and wasted every year across the entire supply chain[26].

Finding ways to tackle waste within the food system is likely to have a greater impact in addressing hunger than further genetic engineering of food crops and animals.

What does the public want?

The UK public remains overwhelmingly against genetically engineered foods. A 2020 survey by Food Standards Scotland[27] found that genetically engineered foods are a top issue of concern for 57% of consumers, second only to chlorinated chicken.

Conventional breeding delivers

Genetic engineering receives considerable media and political attention, usually around its claimed potential benefits. In fact, little of this potential has actually been realised.

Meanwhile, conventional plant breeding has built up an impressive track record in producing impactful new crops.

An inventory of conventional plant breeding spanning 2004-2020[28] lists a large number of crops and varieties delivering increased yields, disease resistance, drought and flood resistance, salt tolerance and nutritional enhancement across cereals, maize, rice, tomatoes, potatoes, legumes and fruits which are important for the developing and the developed world.

The introduction of genome mapping, sequencing and marker-assisted selection has revolutionised conventional plant breeding in the last 10 to 15 years. Plant breeders have used these tools, rather than genetic engineering, to reduce the time and increase the precision of trait selection.

Another 2020 study[29] conducted by the National Centre for Social Research, which focused on Brexit-related issues, found that 59% wish to maintain a ban on genetically engineered crops.

Yet another survey, in 2021, by the UK's Economic and Social Research Council found that 64% of those who took part were opposed to the cultivation of genetically engineered food[30].

Although not specifically focused on GMOs, a study published in January 2021 by Unchecked UK[31] of so-called "Red Wall" swing voters, most of whom voted to leave the European Union, showed strong opposition to the weakening of food laws, a move that would be seen as a betrayal of their Brexit vote.

This echoes the findings of a 2017 poll for Bright Blue, which looked at opinions around a green Brexit and found that 61% of Conservative voters wanted a ban on the production of GM crops[32]. Looked at through the lens of 'leavers' and 'remainers', the survey also found that a similar percentage, on both sides, favoured maintaining or strengthening regulations around GM crops.

In the UK more than 5000 people have signed the joint petition by Beyond GM and GM Freeze to keep GM labelling post-Brexit.[33] Likewise, nearly 2400 UK citizens have added their photos and comments to the GM Free Me 'visual petition'[34], which provides rolling insights into how people from across the social spectrum feel about genetically engineered products in the UK food supply.

Regulation is not a ban

Regulation is a safeguard, not a ban. Its purpose is to protect individuals and/or the environment. It is a societal tool for dealing with uncertainties such as gaps in scientific knowledge.

While the notion of "science-based" regulation has become popular, what is really needed is evidence-based regulation. The potential scope and pace of development of gene editing defines it as a disruptive technology[35]. Prime Minister Boris Johnson acknowledges this disruptive potential[36].

Like all such technologies (e.g. artificial intelliigence, social media, drone delivery systems and e-cigarettes), its disruptive potential has sociological, environmental, economic, scientific and ethical implications that require mutifaceted and robust regulation. This type of regulation is only possible when evidence from all disciplines and stakeholders is considered.

Importantly, the call for science-based regulation does not insulate us from intractable ideology. It is important to encourage scientists who want to 'feed the world' and 'fight climate change', but the belief that hi-tech-fixes are the best or only solutions misunderstands and will never solve complex societal problems.

Progress, effective regulation and depolarisation of the GMO debate can only evolve from a wider, more systemic view of the problems agriculture faces and a transparent and independent assessment of all the evidence around proposed solutions.

What we want MPs and Peers to do

MPs and Peers who share any of the concerns detailed in this briefing, please:

- Sign Early Day Motion 1547 – Regulation of genetic technologies in food and farming.
- Raise your views about the importance of robust regulation of gene editing with Environment Secretary George Eustice and share any response with us.
- Ask a Parliamentary Question about one of more of the concerns that farmers, civil society, scientists and citizens have raised about the Consultation on the Regulation of Genetic Technologies. We can provide a draft question if you would find this helpful.
- Press Defra to engage in efforts to create a more rational and inclusive UK-wide discussion around the need for, and the regulation of, genetic engineering technologies in agriculture.

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