FACT SHEET

GENE EDITING WHAT YOU NEED TO KNOW

Gene editing is not a specific technology. Instead, it is an umbrella term referring to a range of new genetic engineering techniques that can be applied in plant breeding. The most well-known of these techniques is CRISPR/Cas-9, a type of genetic engineering that is relatively cheap and quick to use.

Other gene-editing (more properly called genomeediting) techniques include zinc finger nucleases (ZFN) and transcription activator-like effector nucleases (TALENs), as well as oligonucleotidedirected mutagenesis (ODM) and directed mutagenesis.

Although they are called 'new' techniques, CRISPR and these other technologies have been around a long time. Several make use of older genetic engineering processes (e.g. ZFN, oligonucleotides). Even so, biotech companies argue that gene-editing is different from older style genetic engineering and should not be regulated under existing regulations.

In agriculture, terms like 'Precision Breeding' and 'New Plant Breeding Techniques' are used – primarily by lobbying interests – as an umbrella term for all genome editing techniques, including gene editing, synthetic biology and gene drives, even though there are significant differences between them.

But the term is also used to indicate any type of GM application or technique that had not been commercialised by 2001, the year when the existing EU directives on Genetically Modified Organisms (GMOs) came into force.

Is the name important?

What we call things and the language we use around them, informs our perceptions.

In the 1990s the term '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 editing from GMOs, align it with traditional plant breeding and, therefore, exempt it from regulation.

Companies developing GMO crops with gene-editing techniques have spent years developing narratives that suggest that man has always 'modified' plants (and animals) and that genetic engineering is simply a natural extension of traditional breeding.

To support this many biotech companies now use social media hashtags like #EmbracingNature and #PlantBreeding to fix these concepts in the wider public consciousness.

The UK's <u>Genetic Technologies (Precision Breeding)</u> <u>Bill</u> being debated throughout 2022, talks about removing regulatory control from GMOs that could have occurred through "natural transformation" or which are deemed to be the same as organisms that could be created with traditional breeding.

If new genetic engineering technologies are partly or fully deregulated under this Bill, their products would not be subject to meaningful risk assessment and foods containing them would likely be unlabelled. This would undermine consumer choice and confidence in non-GMO, artisanal and organic foods, leave us vulnerable to unpredictable and unmonitored risks to the environment and public health and opens the door to imports of GMO foods.

Why are some countries reviewing their GMO regulations?

It may have appeared to come from nowhere, but government and biotech companies' narrative around deregulation has been building for years.

Even though there is no convincing proof that

regulation slows innovation, the biotech research establishment has long blamed robust regulations in the EU for a lack of commercialisation of GMO crops in Europe and for raising costs and blocking innovation in plant sciences.

These concerns became very focused in 2018 when the European Court of Justice ruled that new plant breeding techniques produced GMOs and should be regulated in the same way. After that, the biotech companies began a very public fight for the deregulation of organism produced using genome editing techniques.

What was the European Court of Justice case about?

Very broadly, the ECJ case was about how we define and, therefore, regulate GMOs.

The case began as an action brought by several French NGOs, which argued that herbicide tolerant varieties of rapeseed and sunflower, produced using new directed mutagenesis processes, were 'new hidden GMOs' and should be regulated as such under European law.

The case was referred to the European Court of Justice in 2016 and in July 2018, after reviewing copious scientific evidence, the Court's unequivocal judgement was that organisms obtained by directed mutagenesis are GMOs and are, therefore, subject to the obligations – e.g. risk assessment and labelling – laid down by the EU GMO Directive.

Since directed mutagenesis is a step in many of the new gene editing techniques, these too fall under existing regulations.

The court upheld the notion that plants created by random mutagenesis (mutation breeding) had a history of 'safe use'.

Should all types of mutagenesis be unregulated?

No plant is unregulated. To register a new variety, for instance, a breeder must show that the plant has undergone a series of official tests including the Distinctiveness, Uniformity and Stability (DUS) test.

Arable crops also require a Value of Cultivation and Use (VCU) test. In most countries, the VCU test requires breeders to select for highest yield otherwise they wouldn't be able to bring their crops to market.

There are multiple examples in our food system of

crops that were originally created using some form of mutation breeding, often involving exposing the plant or seed to radiation or chemicals. The practice, which had its heyday in the 1980s, was once so widespread that it is impossible to keep track of which crops were, or were not, subjected to this technology at some point in their development. Mutation breeding is less common these days.

Older style mutation breeding was simply accepted – rather than proven – to be safe. There is an argument that older style mutation breeding, alters the whole plant in a way that could happen in nature and has a long history of safe use. But most plant breeders agree that it probably wasn't safe, isn't really natural, likely did result in multiple off-target effects and probably should have been regulated differently.

The idea that targeted mutagenesis should have parity with an undetermined number of untested plants and that it should enter the food system without testing or regulation is essentially claiming that two wrongs would make a right. We possess more knowledge about genetics now than we did 60 years ago and we should apply it.

Can CRISPR create new varieties faster?

Gene-editing technologies like CRISPR do not, by themselves, create new organisms. In most instances, genome editing tools like CRISPR, sometimes described as 'genetic scissors', are used to cut both strands of the DNA double helix at a predetermined location.

This cut then activates the cell's DNA repair mechanism. This combination of events allows genetic engineers to introduce a genetic modification at a specific location on the genome.

Currently there are three types of procedures that can be used following the 'cut'. In the simplest possible terms these are:

- SDN-1 The cut is made and the organism's normal cellular repair mechanisms are left to make the repair;
- SDN-2 The cut is made and a template is provided to instruct the organism how to repair itself;
- SDN-3 The cut and sometimes multiple cuts

 are made and both a template for repair
 and the simultaneous insertion of transgenes
 are applied.

Beyond CRISPR, the process of creating a new organism is more or less genetic modification as it

has always been practised. Further, whatever type of 'breeding' is used, a time frame of anywhere from 5-15 years is normal for any kind of new plant variety – a fact which challenges promises of genome editing as a form of 'speed breeding'.

While many governments repeat the narrative that 'simple' (i.e. SDN-1) interventions (sometimes dismissed as a 'tweak', 'cut' or 'snip') can produce plants that are drought-, disease- and flood-resistant, higher yielding and more nutritious, it is not really possible to engineer such plants with 'simple cuts'.

Either the scientist must make multiple 'simple cuts' in the genome (which amounts to a very complex process that gives rise to wide-ranging DNA damage) or use more complex engineering (SDN-2 and -3) processes are to make such plants.

Because the results of new genetic engineering technologies are no more predictable than older style ones, it will be challenging (though not impossible) for regulators to test for unexpected or 'off-target' effects.

Where food is concerned, the end product may look the same as a naturally grown or bred food, but it may be producing toxic by-products, or have less of certain nutrients. With genetically modified animals there can be unpredictable adverse effects on growth and reproduction that can significantly impact welfare and wellbeing.

In addition, once in they are out in the open field, new GMOs will be able to crossbreed with natural plants with unknown consequences.

Is gene editing more precise than traditional plant breeding?

Gene editing is promoted as being a more precise type of genetic engineering because the location of the intended 'cut' in the DNA can be precisely targeted. However, precision is not the same as predictable, accurate or controlled.

A single gene can have multiple functions, thus a single change in the way a gene functions can have multiple and profound results throughout the organism. Such changes, when they occur in the human genome are responsible for complex diseases like haemophilia, cystic fibrosis or sickle cell anaemia.

Numerous recent studies are showing that 'precise' CRISPR technology can produce massive and unpredictable disruption in the genome. These effects cannot be predicted or controlled because we simply don't know enough about the genome.

How influential is plant breeding for sustainability?

Breeding is a single component in the complex and interconnected system of agriculture. It is widely recognised that there are limits to what can be achieved, solely through plant breeding, in terms of improvement in plant traits and performance and in terms of the bigger picture of 'feeding the world'.

Since plant breeding is both a slow process and also just one piece in the bigger puzzle of creating a sustainable food system, by itself it possesses no singular or magical answers to food security and sustainability.

To frame it as 'the answer' to sustainability problems is misleading, places an irrational expectation on breeders of all kinds and distracts attention from other meaningful actions.

An understanding of genetics can greatly assist with varietal selection, but more important than how a plant is bred is how it is farmed, the condition of the soil in grows in, the geographical/regional appropriateness of the crop and the knowledge and skill set of the farmer.

Finding ways to tackle waste within the food system is likely to have a greater impact in terms of environmental impact and feeding the world than genetically engineering food crops.

But don't we need more innovation?

It is human nature to 'innovate' and to find better ways of doing things. Part of the argument for deregulating agricultural GMOs is that farmers are in urgent need of innovations to help them farm sustainably.

Certainly, we need a food and farming system that works for people, animals and the planet – one that moves us away from damaging, high-input industrial farming rather than locking us into this failing system. But not every new idea is an innovation and innovation does not always mean a high-tech solution.

Some of the most innovative solutions involve low tech, open source and affordable methods that all farmers and growers can use right now. These include agroecological approaches such as crop rotation, intercropping, soil enrichment and integrated crop and livestock systems. Hi-tech solutions, when they are used in plant breeding, should be both purposeful and responsible. Many breeders, for instance, now use 'molecular markers' to track genes of interest through the breeding process using marker assisted selection (MAS).

MAS is an example of responsible and effective technology that results in a conventionally-bred plant by using our knowledge of genes and genomes to select varieties with desirable traits. Examples of MAS-bred varieties include flood tolerant rice, cassava that is resistant to mosaic disease, and wheat resistant to stripe rust fungus.

Although MAS varieties are subject to patents, the approach to development is 'bottom up' e.g. farmers and growers bring their knowledge to the table and work with scientists to breed new varieties that work for them wherever they farm.

How can we foster responsible innovation?

As technologies designed for use in agriculture have advanced, many are looking to the concept of responsible innovation to help make decisions about appropriate use.

There have been several attempts to codify the principles of responsible innovation into an industry-friendly "Innovation Principle" which some in government and business say should replace the "Precautionary Principle" as a guiding factor in agricultural policy and regulation. Others argue the Innovation Principle is too market focused.

Responsible innovation takes into account not just what a technology can do and how it might help, but what it can't do and how it might harm.

It encompasses legitimately held concerns about the potential for fostering inequality and consolidating power in the hands of the few in food supply chain, ethical and welfare concerns for animals and the potential to lock us in to a wasteful, intensive industrial farming system, which is already long past its 'sell by' date, and which could cause further harm to the environment.

One way to judge the strengths, weaknesses and appropriateness of a new agricultural technology is to look at it <u>through the lens of organic and/or</u> <u>agroecological principles</u>. How, for example, does it measure up to the <u>10 Elements of Agroecology</u>:

- Diversity
- Co-creating and sharing knowledge,

- Synergies
- Efficiency
- Recycling
- Resilience
- Human and social values,
- Culture and food tradition
- Responsible governance
- Circular and solidarity economy

If a technology does not meet any of these criteria, or requires unacceptable trade-offs within or between these elements, it may not be appropriate in farming.

Do we need strong science-based regulation?

We need evidence-based regulation. Genetic engineering in farming and the food system is a disruptive technology. Like all 'disruptive technologies' – driverless cars, social media, drone delivery systems and e-cigarettes – it cuts across multiple sociological, environmental, economic, scientific and regulatory areas. Effective and rational regulation is only possible when evidence from all disciplines/stakeholders is included.

Importantly, the call for science-based regulation does not insulate us from intractable ideology. We applaud scientists who want to 'feed the world' and 'fight climate change', but the belief that hi-tech-fixes are the best or only solutions is ideologically-driven.

Moreover, this ideology, however well-meaning, addresses only a small piece of these complex puzzles. Progress, rational regulation and depolarisation of the GMO debate can only evolve from a wider, more systemic view of the problems agriculture faces and an honest look at all the evidence around proposed solutions.

Should we ban GMOs in agriculture?

Some people think we should. But even though there are those who feel this is desirable, it is not realistic. Research into genetics is an important part of our understanding of the world around us. But genetic engineering in agriculture is a disruptive technology. For other disruptive technologies we accept that some form of regulation is both desirable and necessary. If genome editing is here to stay, then we must push for robust regulation.

This leaflet was produced for the Seed Sovereignty Programme by Beyond GM/A Bigger Conversation

