How to respond to the UK consultation on the deregulation of gene editing

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The recently launched *Consultation on the Regulation of Genetic Technologies* provides an opportunity for members of the public to air their views on whether plants and animals created using new experimental genetic engineering technologies (commonly referred to as gene-edited or genome edited) should be deregulated. Deregulation means the removal of vital safety checks and possibly no GMO (genetically modified organism) labelling.

The scope of regulatory changes being considered in this consultation covers an entire chain of events from the research and development to the marketing of gene edited plants and animals. Deregulation could mean the loss of essential protections for people, animals and the environment. In the case of gene edited crops and foods, this could mean that new toxins or allergens could go unnoticed. In the case of gene edited livestock, the inherent animal welfare issues add another layer of concern.

The proposed changes threaten food standards and safety; our right to choose what we are buying and eating; and the ability of those who want to farm in harmony with nature to keep doing so.

It is vital that everyone who is interested in food, farming and/or the environment responds to this consultation by Wednesday 17 March 2021.

In this document you will find advice on how to respond. The document is long and hyperlinks on the web version of this document can help with navigation to specific areas below once you are ready to write your response:

If you only have 5 minutes

If you only have 5 minutes to spare, copy and paste some of our pre-written responses into an email to consultationreply@defra.gov.uk. Remember to put "Consultation on the Regulation of Genetic Technologies" in the subject line.

You should also consider personalising your email where you can. Government pays more attention to personalised responses than it does to form letters (see our suggestions under Getting started).

The consultation closes **Wednesday 17 March 2021** – remember to have your say before then.

If you have a little more time for a more detailed response

If you can spare time to make a more detailed response to the consultation, thank you. In the sections that follow we've included some background information, instructions on how to respond effectively and guidance on the key areas that are of most concern.

Getting started

There are three ways to submit a written response to the consultation on the regulation of genetic technologies:

- You can provide your response via the Citizen Space online form. When you submit your response, you will be sent a receipt and a link to a PDF copy of your answers.

- You can also respond by email in your own words or using/adapting our pre-written text: consultationreply@defra.gov.uk (please put "Consultation on the Regulation of Genetic Technologies" in the subject line). Let them know the purpose of your email is to respond to this public consultation. You will also need to say whether you want your submission to be kept confidential or whether you are happy for it to be published on the consultation website (published responses are anonymised).

- You can post your response to: Consultation Coordinator, Defra, 2nd Floor, Foss House, Kings Pool, 1-2 Peasholme Green, York, YO1 7PX.

All responses must arrive by Wednesday 17 March 2021.

If you are responding by email or letter we recommend linking each point in your response the specific question numbers in the consultation document.

While there is no right way to respond to a consultation, a few guidelines apply: Keep your answers short and to the point, be direct but polite, be mindful of the deadline and try to submit your response well before that. In addition:

- We recommend that you personalise your response by providing an introductory paragraph on why you are responding to the consultation and why this issue is important to you. Remind Defra that as a UK citizen you are a key stakeholder in the future of food and farming in the UK.

- If you have evidence that you wish to submit to support your view please include it in your response.

- Use the advice below to inform your response to each question

- Send a copy of your email to your own MP so that they can see that this issue matters to the people in their constituency. Ask them to raise your concerns with George Eustice, the Environment Minister driving the plan to deregulate gene editing. Make sure you include your home address so that your MP knows that he or she was elected to represent you.

- Let us know that you have written and send us a copy of any response that you receive.

Background

This consultation on the regulation of genetic technologies comes as a result of the defeat of a last minute House of Lords amendment to the UK's Agriculture Bill in July 2020. The proposers of the amendment agreed to withdraw it when the government promised to consult more widely on the issue.

But it is also part of a much wider political agenda for drastic deregulation across many and diverse sectors, including chemicals and scrap cars as well as genetically modified food. The

Westminster government has given businesses an open invitation to suggest what regulations they would like to see scrapped. Essential safeguards that protect human health and the environment are being undermined.

The government wants to change the law on gene editing in food and farming within the next one to two years. It only has the power to make these changes in England, but the way that some other post-Brexit agreements work will likely mean that Scotland, Wales and Northern Ireland will be required to follow Westminster's lead.

The problem

The purpose of regulation is to protect people and the environment. It is one of the ways that society deals with uncertainty. As genetic engineering technologies such as gene editing advance, so does the realisation that our knowledge of gene functioning is still very incomplete. By proposing to remove existing safeguards, the government appears to have decided that what we don't know does not matter and that we should take our chances with potential adverse effects on people, animals and the environment.

What's happening now?

The government has two goals: 1) to deliver the promised consultation on deregulation and 2) to consult more widely on what kind of regulation we want across a wide range of food and farming issues. This is why the consultation is divided into two parts.

If you feel you only want to respond to Part 1 on the deregulation of gene editing, you are free to do so.

This consultation on the regulation of genetic technologies is unusual in that it is asking for a high level of 'evidence' from respondents. But remember, not everyone is expected to provide that evidence. You are entitled to express your views without feeling pressure to provide academic references for every point.

The guidance below should help you with this.

It should also be noted here that the background material provided by the Department for Environment, Food and Rural Affairs in its consultation document has come under heavy criticism for being both biased and inaccurate. None of its claims for the benefits of gene editing are scientifically proven and the document itself offers no evidentiary proof of the type that the government is demanding from respondents to this consultation.

Once the consultation is closed, the data collected will be analysed and Defra intends to publish a response around mid-June.

Below are some suggested responses. **Responses expressed in your own words will have more impact on Defra**. Do use some of our words if you wish, but don't hesitate to add other comments and concerns of your own.

Our suggested responses are based on the premise that: a) the government is not just seeking to alter the regulation of gene editing but that it is are also paving the way for reduced regulation for GMOs in general; and b) whilst regulations should evolve with knowledge and experience, robust and transparent regulation remains necessary for all forms of genetic engineering.

We are grateful to our colleagues at GM Freeze, GMWatch, Logos Environmental and EcoNexus for working with us on this document

Overarching concerns

We've broken down the guidance that follows into sections relating to the four main questions asked in Part 1 of the consultation and tried to cover the key areas of concern in each.

A major flaw in this consultation is that, for each question, the government expects respondents to accept its proposition that gene edited organisms could occur naturally or through traditional breeding. **You do not have to accept this proposition** and if you disagree with it, you should say so at the top of your response to the question.

The overarching themes to bear in mind as you respond are:

Product- vs process-based assessment

Current GM regulations ensure that when genetic engineering is used, there are at least some checks on whether the genetic engineering has introduced any errors before that crop or animal can be farmed and/or eaten. This is often referred to as 'process-based regulation'. Process-based regulation acknowledges that how an organism is produced is relevant. This approach 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 or the environment.

Shifting to 'product-based regulation' means that regulators will no longer have to consider how a plant or animal was created. This amounts to taking the genetic engineer's word for it that they have only made the DNA changes that they have planned and declared. Any unexpected effects, such as new allergens or toxins, may go unnoticed. This is not safe or sensible.

Technofixes vs system change

Our food system needs to change, but the changes we need include the widespread adoption of agroecological farming systems, a massive reduction in food waste, and food sovereignty, which gives people around the world control over their own food supply.

Gene editing makes big promises: to improve yields, fight climate change, stop biodiversity loss and secure the competitiveness of the UK economy. Behind these promises is the suggestion that complex societal, political and economic problems are rooted in plant and

animal breeding and can be ‘fixed’ by ‘tweaking’ the genes of living organisms. The problems of agriculture are more complex and systemic than that and continuing to pin our hopes on short-term technofixes is one of the things preventing real systemic change.

Transparency and the removal of essential protections

People everywhere want to know what they are eating. They want to know that it is safe and has been produced in ways that do not harm people, animals or the environment. Regulation is an essential safeguard ensuring that everyone plays by the rules. This consultation is part of an ongoing government campaign to obscure where our food comes from and how it was produced while giving risky new technologies free rein within the food system.

Section 2 – Questions on deregulation

The consultation is divided into three parts. The first part asks a few questions about you; the second part asks four questions about deregulation; and the third part asks two questions on broad reform of GM legislation in the UK. The advice that follows relates to parts 2 and 3 of the consultation (**NOTE:** while the sections and questions are the same, the online Citizen Space form numbers the sections and questions differently). Please choose one or all of the points below each question and try to use your own words to express your views as clearly and strongly as you are able.

Question 1

Currently, organisms developed using genetic technologies such as GE are regulated as genetically modified organisms (GMOs) even if their genetic change(s) could have been produced through traditional breeding. Do you agree with this?

Our recommendation

We recommend answering YES – these organisms should continue to be regulated as GMOs. You may also wish to make some of the points below:

Challenging the question

We consider this question to be biased, misleading and open to challenge. The possibility that gene editing can produce organisms that are identical to those produced naturally or by traditional breeding is entirely theoretical. The government should not change regulations or remove protections on the basis of unproven theories.

If such organisms do exist in nature or can be produced by traditional breeding then we do not need a poorly understood experimental technology like gene editing to create them.

Gene editing produces GMOs

Genetic technologies, including gene editing, are artificial laboratory-based genetic engineering procedures which, by definition, produce novel genetically modified organisms. This was the ruling of the European Court of Justice (ECJ) in 2018 which made it clear that scientifically and legally, gene editing is genetic engineering and that gene edited crops and animals are GMOs.

New gene editing techniques induce targeted mutations (DNA damage) in order to produce new traits in plants, animals and other living organisms. The ECJ ruling – which was the result of a two-year long review of the most up-to-date science – was that organisms produced by gene editing (referred to in the ruling as "new techniques of mutagenesis" or "directed mutagenesis") are GMOs. This means that they fall within the scope of the EU GMO Directive 2001/18, which seeks to protect human health and the environment by ensuring GMOs are subjected to a full risk assessment and must be labelled.

There is no reason for the UK to override this thorough, carefully considered and scientifically-based judgement.

Gene editing is very different from traditional breeding

Conventional breeding uses sexual reproduction to create offspring with desirable traits such as higher yields or resistance to drought, pests and diseases. It has been used by farmers and breeders for eons to produce both crops and livestock. With genetic engineering, including newer gene editing techniques, researchers directly alter the genetic material of an organism using laboratory techniques. It is this direct alteration at the genetic level that defines 'genetic engineering', underpinning the definition of a GMO in the United Nations and the European Union.

Implications of deregulation

Current GM regulations ensure that when genetic engineering is used, the crop or animal cannot be farmed, imported or eaten until checks are made to ensure that the process has not altered the organism in a way that poses risks to human health or the environment. This is often referred to as 'process-based regulation'.

Process-based regulation acknowledges that how an organism is produced is relevant. It 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.

Shifting to 'product- based regulation' means that regulators will no longer have to consider how a plant or animal was created. This amounts to taking the genetic engineer's word for it that they have only made the DNA changes that they intended to make. Any unexpected effects, such as new allergens or toxins, may go unnoticed.

The safety net of process-based regulation

It's important to recognise that gene editing isn't a single process but a collection of processes that can be used singly or in combination. Complex traits such as pest or drought resistance, improvements in yield and resilience in the face of climate change, cannot be achieved through simple genetic 'edits' or 'tweaks' but are likely to involve multiple interventions at the genetic level . With each intervention the risk of unintended effects multiplies.

The type of deregulation being proposed by the UK government ignores the unintended genetic changes that are common with gene editing. New gene editing techniques give biotech developers access to parts of the genome that are generally 'protected' against mutations (DNA damage) and thus not accessible to traditional breeders. This creates a higher risk of unintended changes occurring both at the intended edit site (on-target effects) and at other locations in the genome (off-target effects). These unintended changes are considered by researchers to be both a major challenge and a major concern, not least because they can affect genes with completely different, often vital, functions.

Process-based regulation looks at how an organism was created and whether the genetic engineering process has introduced any unintended changes in the organism. It is an essential safety net where new and/or experimental technologies are concerned.

Question 2

Do organisms produced by GE or other genetic technologies pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced?

Our recommendation

We recommend answering that organisms produced by gene editing or other genetic technologies pose a GREATER risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced. You may also wish to make some of the points below.

No history of safe use

Traditional breeding is generally accepted to have a history of safe use stretching back millennia. In stark contrast, genetic engineering (and especially gene editing) is so new that we are only just beginning to understand what can go wrong.

The European Court of Justice judgement of 2018 supported this view. It argued that newer techniques (most of which have yet to reach the marketplace) do not have a history of safe use and therefore "the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those that result from the production and release of a GMO through transgenesis".

In 2017 a statement published by the European Network of Scientists for Social and Environmental Responsibility (ENSSER) was signed by scientists throughout the world. It

recommended that, because of our lack of knowledge and the possibility of unintended errors, the products of new genetic modification techniques should be strictly regulated as GMOs.

Unintended effects

Claims that gene editing only produces small or very few changes in the genome ignore the reality of how these techniques can and will be used.

Gene editing isn't a single process but a collection of processes (for example, in plants, Agrobacterium insertion of the gene-editing tool, the use of plasmids containing foreign genes encoding the gene-editing tool, tissue culture and use of antibiotic marker genes), each of which can produce unintended changes or genetic errors. Each of these processes should be evaluated for the specific risks that it entails.

Gene editing tools make it possible to make 'precise' cuts in DNA, but however precisely targeted the initial cut is, the subsequent 'repair' process is not under the control of the genetic engineer but is carried out by the cell's own repair processes. This repair is often not precise or clean, but results in many genetic errors, known as 'off target' and 'on target' effects.

In addition, although gene editing can be used to target a single gene, it can also be used to target several genes, either at once or successively. Because gene editing produces unintended effects, each additional edit made in this approach multiplies the risk of such unintended effects.

While the government claims that gene editing does not involve the use of 'transgenes' (genetic material from unrelated species), it has been shown that this can happen by accident. For example, gene-edited mice can end up carrying bovine and goat DNA as a result of the use of standard culture medium for mouse cells, which can be derived from body fluids extracted from cattle and goats.

Genetic engineering of plants poses a greater risk of harm

The types of traits proposed in the widespread promotion of gene editing include similar claims to those made when the first generation of genetically modified organisms emerged in the 1990s. Such traits, if they were ever to be achieved, involve fundamental changes to the biochemistry of crop-producing plants. This is why they must be assessed for potential new allergens or toxins, higher levels of existing allergens or toxins, or other changes that could impact the health of people or animals consuming the plants and the wider ecosystem.

In practice, only two gene-edited crops are being grown commercially anywhere in the world: Cibus's herbicide-tolerant oilseed rape (SU Canola) and Calyxt's soybean with an altered oil profile. Cibus's oilseed rape brings with it the same risks from increased herbicide use as the older-style GM herbicide-tolerant crops, including biodiversity reduction,

devastating impacts on particular wildlife species and the evolution of herbicide-tolerant 'superweeds'.

Calyxt's soybean oil is largely intended for use in fast food restaurants where, according to the manufacturers, it gives a 3-fold greater fry life compared to conventional soybean oil. In other words, fast food restaurants can save money/increase profits by frying food in the same batch of gene-edited oil for even longer than other oils. The growth of the fast food sector represents a direct harm to human health.

Genetic engineering of animals poses a greater risk of harm

Nobody knows if eating genetically engineered animals or their products (milk, meat, eggs) is safe as there have not been any animal feeding studies to prove or disprove this. There is, however, sufficient uncertainty about gene editing in higher organisms such as animals (and humans) to justify robust regulation based on the Precautionary Principle.

Genetic engineering of farm animals is largely intended to address the problems of industrial factory farms. It also supports livestock systems that have been shown to have multiple negative impacts on human health and the environment including soil, water and air pollution and the spread of antibiotic resistance.

In a 2019 a study by the US Food and Drug Administration (FDA) found numerous irregularities in gene-edited 'hornless' cattle, including the unintended incorporation of antibiotic resistance genes in the genomes of the cattle. FDA said that its findings "demonstrate that there is good reason for regulators to analyse data on intentional genomic alterations in animals to determine whether there are any unintended results, either on- or off-target and, if so, to determine whether they present any cause for regulatory concern."

Genetic engineering of plants or animals disrupts the environment

Releasing genetically novel organisms into the environment disrupts the delicate balance of nature and risks a range of unpredictable harms.

Altered genes can spread to wild relatives, changing or polluting the natural ecosystem in ways that are very difficult to predict, control or repair. If plants or animals are genetically altered to make them resistant to pests or diseases, it does not take long for those pests or diseases to evolve in response. This has been widely seen with herbicide tolerant and insect-killing GM crops around the world: weeds and pests have quickly adapted and new problems of herbicide-resistant weeds and insecticide-resistant pests have emerged.

Question 3

Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs?

Our recommendation

We recommend answering YES – there are many non-safety issues that must be considered when choosing how to regulate genetic technologies. You may also wish to make some or all of the points below.

Damage to our trading relationship with the EU

No EU country will accept food products, commodities, seed or other imports from the UK that might include unauthorised GMOs. If gene edited organisms are not regulated as GMOs in England, English farmers, food producers and exporters will not know whether or not they are using GMOs. It will be impossible for them to prove that their goods are acceptable for import into the EU.

Even where GMOs are approved for import into the EU, they must be labelled (making them traceable) and subjected to post-market monitoring to check for any problems and allow for unsafe products to be recalled. When GMOs are used in foods for human consumption they must be labelled. If gene edited organisms are not regulated as GMOs in England, English farmers, food producers and exporters will not be able to meet these requirements. And if anything goes wrong, for example, if a gene-edited food is found to cause allergic reactions, the cause will not be traced.

Undermining the UK's devolved nations

Food and agriculture are devolved areas of competency, meaning that Scotland, Wales and Northern Ireland are responsible for GM regulation in their own countries. All three of the UK's devolved countries have sceptical policies on GM and in 2015 all three used a new EU Directive (2015/412) to ban the cultivation of GM crops on their territory.

This consultation is said to only apply to England, but if Defra changes the definition of a GMO it will affect Scotland, Wales and Northern Ireland. The Internal Market Act could force Scotland and Wales to allow English food producers to sell unchecked, unlabelled gene edited foods, whatever the rules at home. Food businesses in Northern Ireland could be prevented from selling or handling any food produced in England because it might include GMOs that breach EU rules.

Gene editing raises animal welfare concerns

Conventional breeding has been shown to push farmed animals beyond their physiological limits leading to poor health and welfare outcomes, including bone and metabolic diseases, lameness, reproductive issues, breathing problems and mastitis. However, claims that gene editing can bring improved animal welfare are unconvincing.

For instance, the process of gene editing animals usually involves a cloning step which, according to both the RSPCA and Compassion in World Farming, inflicts very severe or lasting pain on animals, violates their integrity and reduces them to a mere instrument or tool.

Cloning is typically only successful 10-25% of the time, meaning that most embryos transferred into hosts' wombs do not result in a full-term pregnancy and are aborted. For those cloned animals that survive, birth defects are common. Defects include premature death, pneumonia, liver failure and obesity. For example, a study on cloned mice found that up to 4% of the genes were malfunctioning during pregnancy.

Regardless of whether cloning is used or not, genetic engineering (including gene editing) raises multiple other ethical and welfare concerns. For instance, using microinjection instead of cloning requires a large number of animals to act as 'mothers' for the implantation of genetically engineered embryos. On average, 24 embryos are needed to produce one gene-edited pig.

Using genetic engineering as a sticking plaster for disease and injuries that result from over-crowding can both perpetuate and cover up poor animal management, particularly in intensive farming operations. For instance, gene editing pigs for disease resistance could lead to the animals being raised in less hygienic conditions. Similarly, gene editing cows without horns could lead to animals being kept in more crowded enclosures.

Genetic errors created by the gene-editing process can occur as an unintended consequence of genetic engineering, even if new genes are not inserted into the animal. For example, gene editing for super-muscly animals resulted in rabbits, pigs and a goats with enlarged tongues and pigs having an extra spinal vertebra, even though no DNA had been inserted.

Co-existence with non-GM crops and livestock

Most farming methods in the UK – and most of the food produced and sold here – do not involve the use of genetic engineering. This will continue to be the case in the future, whatever the potential of gene editing. Additionally, there are significant markets, in the UK and abroad, for certified non-GM products. In the EU, retailers are already reaping the commercial benefits of selling certified non-GMO food products.

Many consumers will not wish to buy products produced using genetic engineering, including gene editing technologies, and many farmers will not wish to use such methods.

The right to choose is a long established part of UK farming and food policy. It recognises that conventional, organic and genetically engineered crops and animals can only 'coexist' if one system of production does not negatively impact the others.

Regulation, transparency and labelling are necessary if we are to achieve fair coexistence. At present there are no proposals for how coexistence will work at farm level, within the supply chain and at the consumer interface. Farmers, food producers and consumers should all have a say in the development and implementation of effective coexistence rules.

Social and ethical considerations

All technological advances bring new risks and, therefore, ethical questions, such as, "Why are we doing this?", "How will it be used?" and "What will its impact on society be?" This is

particularly true with gene editing, where what is being created could outlast us and be passed on to future generations. In addition to assessing risk to health and the environment, the government has a duty to consider and assess, on a case-by-case basis, the value and ethics of adopting each new application of gene editing. This kind of assessment should take place as early as possible in the research and development phase.

If we don't allow for the possibility of saying no to proposed technological interventions, or allow ourselves to place rational limits on them, we lose the ability to shape our world, as well as our accountability for the things we shape.

Undermining consumer choice and confidence

UK consumers do not want to grow, buy or eat genetically engineered foods.

A 2020 survey by Food Standards Scotland found that, next to chlorinated chicken, genetically engineered foods are a top issue of concern for 57% of consumers. Another 2020 study conducted by the National Centre for Social Research, which focused on Brexit-related issues, found that 59% wish to maintain the ban on genetically engineered crops. A 2021 survey by the UK's National Economic and Social Research Council found that 64% of those who took part were opposed to the cultivation of genetically engineered food.

British food is associated with high standards but this perception will be quickly undermined once people know that new, experimental products of genetic engineering are being distributed, unlabelled and without any traceability or accountability, throughout our food system.

A distraction from key sustainability issues

Gene editing is promoted with a long list of boasts and promises that have almost no foundation in science. Many of the same claims were made for the first generation of GMOs when they emerged in the 1990s and yet these older style GMOs have not resulted in higher yields (see data here, here and here), lower pesticide use (see data here and here), better profits for farmers, or lower seed prices (see data here and here). GMOs have also failed to 'feed the world'. Around 40% of GM crops are turned into biofuels, the rest are used as animal feed or as ingredients – mostly oils and sugars from corn, soya and cottonseed – for unhealthy highly-processed human food.

An understanding of genetics can greatly assist with both plant and animal breeding. Nevertheless, it is widely recognised that there are limits to what can be achieved solely through genetics in terms of improvement in plant variety/performance and in terms of the bigger picture of 'feeding the world'.

To frame gene editing as the answer to all farming's problems is not just unproven and misleading, it distracts attention from meaningful actions which are likely to have a greater and more immediate beneficial impact. Instead of deregulating gene editing the government should be addressing the real problems, such as soil health and waste in the food system.

Question 4

What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not?

Our recommendation

We recommend you use your own words to make one or more the following points:

A commitment to transparency

In order to ensure ongoing environmental and health monitoring, as well as farmer and consumer choice, criteria enabling transparency at all levels (including product labelling) should be developed.

Development of scientific criteria

There are no agreed scientific criteria to determine whether an organism produced by gene editing or another genetic technology could have been produced by traditional breeding. We know that genetic engineering technologies (including gene editing) can create many unintended genetic changes, so even if the intended trait could have been produced by traditional breeding, the overall genetic makeup of the gene edited organism will not be the same.

To scientifically determine that a gene-edited organism is the same as one produced by traditional breeding it would be necessary to examine the sequence of the entire genome and the detailed composition of the gene-edited organism, including the proteins and metabolites – as revealed in analytical methods known as 'omics. The technologies to do this are available and have been recommended for inclusion in GMO risk assessments.

Regulatory criteria

Gene editing methods vary. This has not been recognised in the information accompanying this consultation but any rational discussion of regulation and evaluation criteria must take this into account.

Although gene editing is often described as using a process of 'tweaking' or making a 'simple cut' in the DNA of an organism, in most cases it involves much more invasive processes including the insertion of a genetic repair 'template' containing instructions for how the organism should repair itself after it has been damaged by the initial cut. It can also involve the insertion of foreign or 'trans' genes.

Even the few countries that have deregulated gene editing have only done so with one type of gene editing (known as SDN-1) which does not use a repair template. The other methods continue to be regulated as GMOs.

However, these (SDN-1) procedures should not be assumed to lead to effects that could be found in nature or through traditional breeding. Even SDN-1 procedures have been found to lead to unwanted mutations (see here and here).

A recent study on rice, for instance, found that SDN-1 gene editing using CRISPR unexpectedly caused large insertions, deletions, and rearrangements of DNA. This raises the possibility that the function of genes other than the one being targeted could have been altered. The researchers warned: "Understanding of uncertainties and risks regarding genome editing is necessary and critical before a new global policy for the new biotechnology is established".

Record keeping and audit trail criteria

As some impacts of the gene editing process may not be immediately identifiable, we need an international public register of gene editing events used in the specific product (crop or animal) that will enable tracing and monitoring over time.

This register would form the basis of a supply chain audit and product labelling of the type already used in farming and food from the Red Tractor Scheme through to organic certification. The methods and protocols of such schemes are well developed and could be readily adapted.

Social, ethical and values-based criteria

The national and international discussion over gene editing has recognised that with such a far-reaching technology, assessment criteria must go beyond narrow scientific and technological aspects. Social, ethical and values-based criteria have been put forward and some countries, such as Norway, have begun to use them in their legal and regulatory frameworks for genetic engineering technologies.

It has also been acknowledged that citizens, specialists in the social sciences and ethics, and members of civil society, have a key role to play in developing and implementing such criteria. Citizen panels and assemblies are likely to be an important part of this process at all levels of decision making.

Section 3 – Questions on broad reform of GM legislation

In this section the government is looking for signs of public support to pave the way for looser controls on all forms of genetic modification including 'old type' GMOs and whatever might emerge in the future. The questions are framed in a way that is very off-putting for non-specialists. We offer some suggestions here but registering disquiet or dissatisfaction with Defra's approach is also a valid response.

Question 1

There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies. Do you think existing non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed?

Our recommendation

We recommend answering NO – non-GMO regulations are not sufficient to control the use organisms created using genetic engineering techniques, including gene editing. Organisms created by genetic engineering are novel, patentable organisms crated using an 'inventive step' that does not occur in nature. As such they require separate regulation and monitoring.

Further, with regard to regulations currently in place for genetically engineered organisms (GMOs), there is insufficient governance for all areas listed. These are: a) cultivation of crop plants, b) breeding farmed animals, c) human food, d) animal feed, e) human and veterinary medicines, f) other sectors/activities.

We suggest you also consider making the following points:

- In all cases, the regulatory framework for genetically engineered crops and foods lacks independence, transparency and citizen engagement. Except in the case of human medicines the process is conducted through advisory bodies, such as the Advisory Committee on Novel Foods and Processes and the Advisory Committee on Releases in the Environment which advises Ministers or the Food Standards Agency (FSA) and its Scottish equivalent.
- The FSA itself is a non-ministerial government department but its board members are appointed by Ministers. Although minutes and some meetings are open to the public, in practice business is conducted through specialist and so-called expert panels, with much information protected on grounds of confidentiality.
- Overall policy and strategy is largely conducted as a 'closed shop' with limited, if any, citizen engagement. This is also true for scientific and technical decisions none of which is subject to citizen review or recall.
- There is limited parliamentary scrutiny of Ministerial decisions and no opportunity for 'alternative' views to be heard let alone considered.
- There is a particular deficit in consideration of social and civil society needs and non-technical and non-commercial justification for any decision.

Question 2

Where you have answered no, please describe what additional regulatory or non-regulatory measures you think are required, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures should be triggered.

Our recommendation

Points you may like to make which are relevant to all categories:

- In all the areas listed, assessment should be extended to include social, ethical and values based criteria. This should include assessment and justification of social and environmental need, a consideration of alternatives, full transparency of the commercial roll out pathways including intellectual property rights, provision for long-term safety assessments, the use of whole genome sequencing to look for all unintended effects and appropriate multi-omics analysis in the case of food and feed, as well as the provision for post-release monitoring in the case of releases into open environments.

- Citizen panels and assemblies should be involved in the assessment process and determination of information dissemination and labelling.

- These assessments and processes should become standard and subject to well-defined trigger points.