Consultation outcome

Genetic technologies regulation: government response

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1. Foreword from George Eustice, Secretary of State for Environment, Food and Rural Affairs

The UK is home to some of the world's leading agricultural research institutes, including the John Innes Centre in Norwich, the National Institute of Agricultural Botany, the James Hutton Institute, Rothamsted Research and the Institute of Biological, Environmental and Rural Sciences. Our departure from the European Union has given us the opportunity to adopt a more scientific and proportionate approach to the way that we do things like the regulation of organisms produced by genetic technologies such as gene editing.

The Prime Minister has been clear that we will become a 'science superpower' by 2030. The UK is already a world leader in genetics and genomics, and we want to foster an environment that encourages innovation in farming at a time when we must address today's most pressing challenges. As we consider future policy, what we really need to achieve is a fusion of the traditional principles of good farm husbandry with the best technology available to us in the 21st century.

Earlier this year, we consulted on the regulation of genetic technologies, and this response sets out how we will clear a path for genetic technologies such as gene editing.

These technologies have great potential and will enable our farmers to grow plants that are more nutritious, more resilient to climate change, and less reliant on pesticides or fertilisers. Together with other emerging areas of Agri-innovation, this will help us tackle food system challenges, climate change and biodiversity loss, support our commitments in the 25 Year Environment Plan to protect our environment and help meet our ambitions on Net Zero and climate adaptation.

Gene editing and the genetic technologies we are considering do not result in the introduction of DNA from different species but produce targeted changes to the existing DNA in an organism that could be made more slowly using traditional breeding methods or occur naturally.

We intend to use existing powers under the Environmental Protection Act 1990 to lay a Statutory Instrument by the end of this year. This will make research and development easier for plants that have been produced by genetic technologies where the resulting genetic changes could have been developed using traditional breeding methods.

Our next step will be to review the regulatory definitions of a GMO to exclude certain organisms produced by gene editing and other genetic technologies if they could have been developed by traditional breeding. We will also consider the appropriate measures needed to enable gene edited products to be brought to market safely and transparently, considering consumer choice and traceability. This will be followed by a review of our approach to GMO regulation more broadly.

Genetic diversity is what gives life itself resilience. The billions of genes that exist in the millions of plant and animal species on our planet are a memory of all the challenges that have been encountered in the past and can help us prepare for the challenges of the future.

We have the ability to harness the genetic resources that nature has provided to tackle the challenges of our age and to replace some of the practices that led to environmental harm in the past.

If we are to deliver the ambitions we have for the environment and make space for nature, then we must rebalance the incentives in our future agriculture policy to encourage sustainability, but we must also use the tools that science provides to ensure that profitable food production and sustainable land management go hand in hand.

2. Introduction

The Department for Environment, Food and Rural Affairs (Defra) held a public consultation from 7 January to 17 March 2021, to gather views on the regulation of genetic technologies in England. A total of 6,440 consultation responses were received from individuals, businesses, NGOs, academia and other bodies.

Part One of the consultation sought views on the Government's proposal to change existing English regulations for GMOs. It focussed on organisms, which are the product of genetic technologies (such as gene editing) that result in genetic changes similar to those found naturally in varieties of the same species, or in very similar species that could be combined by traditional breeding. It proposed that they are no longer regulated in the same way as genetically modified organisms (GMOs).

Part Two of the consultation started gathering initial views on the wider regulatory framework that controls the use of GMOs in England. These preliminary views will be used to inform Defra's longer-term plan for better regulation of genetic technologies. The rest of this Government response therefore responds to Part One of the consultation only.

We have taken into account the responses to the consultation and we aim to take a cautious stepwise approach as we move forward with revising the way in which we govern the use of organisms developed using genetic technologies such as gene editing where the end product could have been produced by traditional breeding methods. We will start by looking to ease some of the burdens which currently apply to research and development for gene edited plants, while maintaining the present regulatory system for animals and other organisms. This will be followed by further careful consideration of proportionate regulatory measures to enable products produced using gene editing to be authorised and brought to market.

3. What benefits could genetic technologies bring?

Genetic technologies (such as gene editing) include a range of breakthrough approaches, which provide a rapid and precise way of introducing genetic changes that could also be selected for over a much longer time period through traditional breeding, or be found in nature.

Harnessing nature's genetic resources through gene editing could help address food security challenges, climate change and biodiversity loss, contributing to the United Nations Sustainable Development Goals. These technologies may help deliver drought and disease resistant crops, disease resistance in animals and reductions in agricultural greenhouse gas emissions and agrochemical use, thereby improving farming practices, helping the natural environment and enhancing soil quality. For consumers, they have the potential to deliver health benefits more easily and cheaply and to help tackle allergens such as gluten.

The UK is a world-leader in genetics and genomics and we host leading agricultural research founded on scientific excellence. Our farmers are increasingly embracing new technologies, such as precision agriculture, to drive efficiency, maximise yields and protect the environment. The Government wants to foster an environment that incentivises innovation and captures the benefits of genetic technologies for all, while managing any risks in a way that is supported by sound science. We want to progress towards building an approach in which people can be confident about the governance, regulation and use of genetic technologies. To start this journey, we know that listening to the views of the public and those of stakeholders from industry, the scientific community and civil society is vital. That is why we ran this public consultation on the regulation of genetic technologies between January and March 2021.

4. Summary of consultation views and our response

A detailed analysis and summary of the responses has been published separately. We have also provided a summary here, including key points of consideration raised, and our responses to them:

- The majority of academic institutions[footnote 1](63%) and public sector bodies[footnote 2](82%) stated that there was a similar level of risk of harm to human health or the environment from gene editing compared with naturally bred counterparts. However, most individuals (87%) and businesses (64%) felt that they posed a greater risk. NGOs were evenly split on this question[footnote 3].
- A slightly higher proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate products of gene editing as GMOs, where the resulting genetic changes are similar to those found naturally in organisms of the same species, or in very similar species that could be combined by traditional breeding. Most individuals (88%) and businesses (64%) supported continuing to regulate the products of gene editing as GMOs. Non-governmental organisations (NGOs) were evenly split on this question.
- The consultation received no new scientific evidence indicating that gene edited organisms should be regulated as GMOs, and a number of responses expressed the view that GMOs are demonstrably different to the products of gene editing. The advice from our scientific experts and the response from the Royal Society likened the risks of gene edited organisms to those arising in organisms of the same or very similar species developed through traditional breeding methods.
- Some respondents highlighted non-scientific concerns too, including around trade, specifically in relation to exporting products to the EU, as well as issues around selling products within the UK. However, some respondents noted that removing certain gene edited products from GMO legislation could result in trade benefits with some countries.

4.1 Expert advice from the Advisory Committee on Releases to the Environment (ACRE)

Respondents who felt that the products of gene editing and other similar genetic technologies pose a greater risk compared with their traditionally bred counterparts commonly raised concerns regarding the unforeseen and unintended consequences of genetic technologies. Concerns were also raised in relation to human health, animal welfare and the environment, including the potential for cross-contamination between gene edited and non-gene edited crops and impacts on genetic diversity.

Defra asked the independent scientific Advisory Committee on Releases to the Environment (ACRE) to advise on the above issues and other safety aspects associated with organisms produced by gene editing. ACRE's role is to provide statutory advice to Ministers on the risks to human health and the environment from the release of GMOs. The views of the Food Standards Agency's Advisory Committee on Novel Foods and Processes (ACNFP) were also sought.

ACRE drew on a significant scientific evidence base. Their advice has been published in full (https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies) and is summarised as follows:

ACRE's view is that an organism produced by gene editing would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism, as a result of how it was produced. ACRE and other expert groups have cited an evidence base which demonstrates that the genetic material of organisms is not fixed and immutable, but is frequently subject to high levels of natural variation and selection, occurring in real time within species and individuals, and sometimes in response to environmental stimuli.

Traditional breeding relies on the dynamic nature of genetic material and makes use of a range of genetic changes, including major structural variations which occur naturally within species and their close relatives that are used in breeding programmes. Therefore, ACRE's view is that where gene editing introduces genetic alterations and combinations that are of the type that are selected for in

traditional breeding, any associated health and environmental risks would be comparable. In this way, it believes that the environmental release of these organisms should not be regulated in the same way as the environmental release of GMOs.

This view was supported by the response received from the Royal Society, which stated that “genome editing is likely to involve fewer such changes than traditional breeding techniques” and that “these are no more likely to pose a risk to human health or the environment than non-editing derived mutations, which occur spontaneously in each new generation”.

ACRE also concluded that many unintended (sometimes called ‘off-target’) effects are the same as those which can arise from other forms of mutagenesis including traditional breeding. In response to the concern that ‘off-target’ effects might adversely affect food or environmental safety and/or animal welfare, ACRE identified that whilst such effects are known to occur occasionally, they are not necessarily harmful and can usually be removed by segregation in subsequent breeding steps. This underlines the importance of developing scientifically credible regulatory options.

The second type of unintended effect (introduction of DNA from a different species) has most notably been observed during the production of gene edited animals. ACRE concluded that:

- Such occurrences do not necessarily lead to harmful properties in the altered organism, as it is very unlikely that an inserted DNA fragment would have an effect on the gene edited animal’s physical characteristics. Moreover, screening techniques to reduce the likelihood of these events are available and could be mandated via regulation.
- Secondly, the most often quoted examples of this occurrence involved non-typical or older versions of gene editing technology and more recent methodologies[footnote 4]are demonstrably less likely to produce such unexpected changes.
- Thirdly, from a regulatory perspective, it is clear that most countries who have reviewed their assessment procedures for gene edited organisms have also acknowledged the importance of providing a degree of assurance either that no exogenous DNA (originating from outside the organism) has been inserted, and/or that no unacceptable risks are presented by the new trait.

If the legislative changes proposed in the consultation were to be made this would not impact on other existing regulated product regimes including Novel Foods and Animal Feed regulatory frameworks. It is the intention that regardless of proposed changes to the GMO regulatory framework, the existing regimes will remain in place to continue to regulate Novel Foods and animal feed accordingly. The independent Advisory Committee on Novel Foods and Processes (ACNFP) supports the idea of a proportionate approach to the safety assessment of food that takes account of the scale of effect of any change on the food. They note that off-target effects or the presence of recombinant DNA, whether intentional or unintentional, may pose no greater risk than traditional breeding. However, this is entirely dependent on the site and size of the off-target effect or recombinant DNA fragment. We will seek to ensure that any new regulatory measures will be designed to take account of this concern.

In the consultation, concerns were raised that the increased use of gene edited organisms might have an adverse impact on the environment, for example through transmission of gene edited traits to wild relatives and/or a greater ability to persist. However, ACRE could find no scientific justification that the use of crops and livestock improved by gene editing, which could have been developed using traditional breeding, would lead to a greater likelihood of persistence of these organisms in the wider environment. This effect is rarely observed for traditionally bred organisms.

In considering the type of criteria that should be used to determine whether an organism produced by gene editing, or another genetic technology, could have been produced by traditional breeding, ACRE favoured a fully transparent procedure which would enable developers to consult with regulators early in the development of a product. The process of assessment (for example, for a gene edited product) should consider whether the organism could have been produced using

traditional breeding methods. Applicants would also need to demonstrate that the organism was free of any exogenous genetic material (that is, from a species which could not be crossed with the target species in a conventional breeding programme); and consideration would be needed on the extent to which the genetic alteration could have been selected for as a result of traditional breeding methods.

4.2 Trade

We recognise that international harmonisation in the governance of products developed using genetic technologies, such as gene editing, would facilitate trade. We also recognise the importance of providing clarity for our third country trading partners on the UK's regulatory systems and controls.

If gene edited seeds were to be grown and marketed in the EU, they would have to be authorised under the EU's legislation on GMOs before they could be placed on the EU single market, as happens now. Similarly, food and animal feed products developed using genetic technologies, such as gene editing, must be authorised by the EU before they can be sold on the EU's single market.

On 29 April 2021 the European Commission published its review[footnote 5] of the impact of the 2018 judgement by the Court of Justice of the European Union (CJEU)[footnote 6], which found that that all gene-edited organisms should be regulated as GMOs. This review acknowledges that gene editing and other similar genetic technologies have the potential to contribute to the United Nations Sustainable Development Goals, and that there are strong indications that the GMO legislation is not fit for purpose for some genetic technologies and their products. It recognises that it may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risks as is the case for traditionally bred plants and those obtained from certain genetic technologies. The review concludes that a purely safety-based risk assessment approach may be insufficient to promote sustainability objectives; and undertakes to review the relevant policy instruments with a view to reaping benefits from innovation while addressing concerns.

We will continue to monitor UK/EU trade implications for products developed using genetic technologies such as gene editing, maintaining our ongoing relationships with the EU institutions and working to mitigate any possible impacts where these arise.

All agri-food products imported into the UK under existing or future free trade agreements will, as now, need to comply with our import requirements. An increasing number of countries are revisiting their existing regulations concerning gene edited organisms, given rapid advances in this technology; some have already decided to regulate gene edited crops and food in the same way as conventional products, if they do not contain exogenous DNA[footnote 7].

The revolutionary impact of gene editing and the growing deployment of the technology has already been discussed at dedicated conferences within the international community, such as those held by the OECD[footnote 8]. With the global market value for gene editing estimated at £2.7bn in 2020 and expected to rise to over £7bn by 2026[footnote 9], moving to a more progressive, scientifically based approach to governing the use of gene edited products and products generated using other genetic technologies could create significant economic opportunities for the UK.

We have noted the needs of industry stakeholders to have reliable and ready access to information on the products of genetic technologies, as well as straightforward procedures to ensure traceability controls. We will work with businesses as we develop our policy thinking on these issues.

As we develop new trading relations and work to achieve wider environmental and sustainability goals through our trade policies, collaboration and co-operation with other countries will always be encouraged. This will help us to ensure transparency and promote the valuable exchange of information on scientific evidence and governance processes, as well as helping businesses adopt and use innovation and new technologies, as appropriate.

4.3 Transparency and labelling

Many responders called for clear labelling information to allow consumers to be informed and exercise choice over whether to buy the products of genetic technologies. However, questions were also posed about the benefit of such labelling where it would not otherwise be possible to tell the difference between the products of genetic technologies and those arising from traditional breeding practices.

Food and feed are only placed on the UK market if deemed safe through a system of risk assessment. Consultation responses and the Food Standards Agency's (FSA) previous work on consumer choice have indicated consumers' preferences for making informed choices supported by labelling. We have also heard from some responders that labelling of food and drink products derived from genetic technologies is integral to consumer acceptance of those products.

It is not expected that gene edited products arising from any change in UK regulation would appear on shelves in the UK for some years. In the meantime, we will explore options for labelling gene edited foodstuffs and other products derived from genetic technologies. Our work will be informed by public dialogue and insights work, including the National Food Strategy and the FSA's latest consumer research findings.

4.4 Animal Welfare

Responses to the consultation have indicated strongly held ethical concerns regarding the application of gene editing in animals. These focussed around ensuring that we maintain our high animal welfare standards and improve them over time as new research and evidence emerges.

Genetic improvement through breeding has been at the heart of livestock production since modern agriculture began. Selective breeding and, more recently, genomic selection using genetic marker data, have been transformational for livestock productivity and health. Gene editing has a vital role to play in helping address animal welfare concerns and reducing the carbon footprint of livestock production.

The use of animals for research, including any which have been the subject of genetic technology processes, is regulated in the UK under the Animals (Scientific Procedures) Act 1986 (ASPA). In addition, all livestock are protected by comprehensive and robust animal health and welfare legislation.

The UK has a proud history of championing and taking action on animal welfare, and the Government fully recognises the important issues around maintaining animal welfare as part of genetic improvement through breeding. We are fully committed to maintaining our high animal welfare standards and to improving them over time as new research and evidence emerges. We will continue to work closely with stakeholders and experts to ensure our high standards are embedded in our approach to genetic technologies.

5. Next steps

Science-driven technological innovation in genetic technologies is expanding rapidly. A small number of gene edited products are beginning to reach markets internationally but are not expected to be available for some years in the UK. We have an opportunity to observe and learn from a range of agricultural regulatory systems worldwide, and to establish a system of governance for genetic technologies that supports public benefit and is world leading. This could create global opportunities for growth that help develop new markets, which support a sustainable economy in a way that enhances the natural environment.

In response to the consultation, we are now setting out the Government's next steps for revising our approach to how we govern the use of organisms developed using genetic technologies such as gene editing where the end product could have been produced by traditional breeding methods. This will allow us to reap the future benefits of this innovative technology whilst ensuring the points raised in the consultation are also addressed.

We will take a two-step approach:

5.1 Step 1

As a first step we will work to ease burdens on developers undertaking research and development work involving plants developed using genetic technologies, such as gene editing. We will use existing powers in the Environmental Protection Act 1990 to lay a Statutory Instrument, by the end of this year, which will help free up gene editing of plants at the research and development stage, to be more in line with those developed using traditional breeding methods.

Plant scientists will be able to carry out field trial research in England and test the safety and benefits of the new gene edited crops that could have been developed through traditional breeding methods, without requiring risk assessments and consents, which we see as unnecessary regulatory burdens at the field trial stage. Research scientists will continue to be required to notify Defra of these trials, and the commercial cultivation of these plants and any food or animal feed products derived from them will still need to be authorised in accordance with existing GMO rules.

To date, research involving gene edited animals has been carried out under the existing GM 'contained use' regulations[footnote 10]. These regulations will continue to apply, along with the ASPA controls, to uphold our animal welfare standards.

5.2 Step 2

As our next step we will seek to bring forward primary legislation at a suitable opportunity to amend the regulatory definitions of a GMO to exclude organisms that have genetic changes that could have been achieved through traditional breeding or which could occur naturally. We will also consider the appropriate regulatory measures needed to enable gene edited crops that are equivalent to those produced through traditional breeding to be brought to market.

We recognise that regulations relating to GMOs are a devolved matter and we will work closely with the devolved administrations of Scotland, Wales and Northern Ireland to understand the impacts of future policy changes on their territories. We will also consider issues relating to the gene editing of animals, recognising that any changes may come later, in light of due consideration being given to ethical questions raised in the consultation. We also have no plans, at this stage, to change the regulatory requirements for research involving microorganisms produced using genetic technologies. Our independent scientific committee, ACRE, has advised that we address microorganisms separately from plants and animals when developing regulatory procedures. This is consistent with responses submitted to our consultation.

Regardless of proposed changes to the GMO regulatory framework, the existing Novel Foods and Animal Feed regulatory frameworks will remain in place.

We will continue to engage with interested parties and will seek opportunities to participate in future public dialogue processes around genetic technologies, taking the views expressed by respondents and the evidence provided by experts into account. We will proceed slowly and carefully in revising regulations related to GMOs, taking an evidence-based approach and seeking to fully address public concerns, while aiming to maximise potential public and economic benefits and secure the market advantage of a more open regulatory landscape. We look forward to continuing our engagement and thank all those that contributed to the consultation.

1. Academic institutions include UK and international universities and research institutes
2. Public sector bodies included both UK and international government organisations and arms-length bodies
3. Based on the 3083 responses submitted to Citizen Space. Individuals = 2750; businesses= 198; non-governmental organisations = 100; academia = 24; public sector bodies = 11). Respondents self-identified with respondent types
4. plantphysiol.org (http://www.plantphysiol.org/content/183/4/1453)
5. ec.europa.eu (https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en)
6. curia.europa.eu (https://curia.europa.eu/juris/documents.jsf?num=C-528/16)
7. geneticliteracyproject.org (https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/canada-animals/)
8. oecd.org (https://www.oecd.org/sti/emerging-tech/geneticsandgenomics.htm)
9. gminsights.com (https://www.gminsights.com/industry-analysis/gene-editing-market?msclkid=4364a67d425212a5c0e0c6907da0d8c1)
10. The Genetically Modified Organisms (Contained Use) Regulations 2014 (legislation.gov.uk) (https://www.legislation.gov.uk/uksi/2014/1663/contents/made)