



Department
for Environment
Food & Rural Affairs

The regulation of genetic technologies

A public consultation on the regulation of genetic technologies

January 2021

We are the Department for Environment, Food and Rural Affairs. We're responsible for improving and protecting the environment, growing the green economy and supporting our world-class food, farming and fishing industries.

We work closely with our 33 agencies and arm's length bodies on our ambition to make our air purer, our water cleaner, our land greener and our food more sustainable. Our mission is to restore and enhance the environment for the next generation, and to leave the environment in a better state than we found it.



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Policy background

Building back greener is integral to creating a healthier, more resilient world for future generations and the Prime Minister has highlighted the need to take a more scientifically credible approach to regulation to help us meet some of the biggest challenges we face.

Green growth can help create new markets that support a sustainable economy and enable UK businesses to compete globally. Improving agricultural productivity in a way that enhances the natural environment can help us address challenges in the food system and tackle climate change and biodiversity loss. Innovative technologies are a powerful tool and there have been substantial advances in recent years across many areas – including gene editing (GE), which is the focus of this consultation.

GE has the potential to make producing abundant, healthy food part of reducing the environmental impact of a growing global population. It could fine tune and speed up the natural breeding process targeted towards environmental gains in England and help us reach climate and biodiversity goals. It could also help us produce pest and disease-resistant crops and disease resistant or resilient livestock to help us adapt to the changing climate. And in many cases, the potential to reduce inputs into agricultural production will also indirectly reduce carbon emissions.

While GE is unlikely to be able to address all these complex challenges, a whole range of innovative approaches could help us make progress over time. These could include increasing agro-ecological approaches for land management, the use of robotics and artificial intelligence, vertical farming, and the development of undervalued protein sources.

Background and scope of the public consultation

GE describes a range of technologies that can achieve genetic changes of the type that are selected for in traditional breeding, such as insertions, deletions and, occasionally, translocations of genetic material. The advantage GE has over traditional breeding methods is that the changes it makes are more targeted. Whilst GE makes the breeding process more efficient and responsive, research has focused on improving the efficiency of different GE tools to avoid the unintended genetic changes that can also occur through traditional approaches to retaining desirable characteristics and breeding out undesirable ones. **This consultation is primarily focused on GE organisms possessing genetic changes which could have been introduced by traditional breeding.**

Importantly GE can also be used to introduce novel combinations of genetic material into organisms that would not result from traditional breeding methods, for example the introduction of genetic material from a different species. Whilst this approach is not the primary focus of the consultation, **we are taking this opportunity to begin separately gathering evidence concerning the wider regulatory framework governing genetically modified organisms (GMOs).**

This consultation focuses on research and marketing of gene edited organisms (GEOs) and GMOs that takes place outside of the laboratory (in other words activities under the 'Contained Use' regulations are not in scope).

Regulation of GMOs in the UK is contained in a body of EU legislation supplemented by domestic legislation including Part VI of the Environmental Protection Act 1990. The EU legislation will continue to apply in the UK at the end of the transition period (from 31 December 2020) as amended by exit legislation to make it operable; this EU legislation is now known as retained EU law. Retained EU law, together with domestic legislation, will continue to regulate the use of all GMOs as currently defined, including plants, animals and microbes in a range of applications including agriculture, food, medicine and environmental sensors.

The underlying EU legislation was written more than thirty years ago in response to the development of new genetic technologies that enabled scientists to transfer sections of genetic material from one species to another. Whilst this can occur in nature, it is not typical in traditional breeding. Therefore, as a precautionary measure, the law requires that every GMO must be assessed and authorised before it can be released into the environment for research and development purposes or placed on the market.

The need for a public consultation

Now the transition period has ended, retained EU law requires that all GE organisms are classified as GMOs irrespective of whether they could be produced by traditional breeding methods. This was confirmed by a Court of Justice of the European Union (CJEU) judgment in 2018¹. This is not consistent with the position taken by most countries who have reviewed their respective regulations like Argentina, Australia, Brazil and Japan, which have concluded that certain GEOs should not be regulated as GMOs.

Our position follows the science, which says that the safety of an organism is dependent on its characteristics and use rather than on how it was produced. This is the basis for our proposal, which is that organisms produced by GE or by other genetic technologies² should not be regulated as GMOs if they could have been produced by traditional breeding methods.

This proposal does not apply to organisms which introduce genetic material from other species.

¹ C-528/16 - Confédération paysanne and Others

² Gene editing may not be the only genetic technology capable of making changes that could have been produced by traditional breeding methods.

We believe we need a fit-for-purpose regulatory system that builds on UK science strengths to help achieve the UN's Sustainable Development Goals (SDGs), address food security challenges, tackle climate change and biodiversity loss. This is why we are consulting on the implications of ending the regulation of organisms developed by GE and other genetic technologies as GMOs, in cases where their genetic changes could have been produced by traditional breeding. It is important that we understand any safety or non-safety issues associated with this approach, including potential impacts on trade and animal welfare. This element constitutes part 1 of the consultation (see Section 2).

Defra takes a robust, science-based approach to regulating the research and marketing of GMOs, which focuses on human and environmental safety. However, the existing GMO legislation is more than thirty years old and Defra is taking the opportunity of this public consultation to start gathering evidence on broader legislative reform. As part of this initiative, Defra will also consider legislative frameworks adopted elsewhere in the world. This element (i.e. longer-term reform of the GMO legislation) constitutes part 2 of the consultation (see Section 3).

Outcomes of the consultation

Defra recognises that there is a spectrum of opinions on these topics, and this consultation is intended as an opportunity for a wide range of views to be shared. The responses we receive will help to inform our policy development and engagement plans, which we will be discussing with stakeholders over the coming months.

Depending on the results of part 1 of the consultation, on the regulation of GE organisms, Defra may seek to amend the statutory definition of a GMO as it applies in England. This would mean that GM legislation would no longer apply to organisms produced by GE and other genetic technologies if they could have been developed using traditional breeding methods. Currently GMOs are defined in section 106 of the Environmental Protection Act 1990 (as amended) while techniques of genetic modification are set out in regulation 5 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2002/2443) (as amended).

Amending the definition of a GMO in this way would also affect which food and animal feed products are regulated under GM legislation, including the GM Food and Feed Regulation³. This is because food or feed which is not produced from or does not contain or consist of GMO(s), is not covered by the GM Food and Feed Regulations. Food or feed produced by GE, even if it were no longer considered to be GM, would still be regulated to ensure its

³ Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

safety. Depending on the results, responses to part 1 could lead to legislative change in the next 1-2 years.

The consultation responses on wider GMO reform (part 2 of the consultation) forms the start of a separate engagement process. Your views will be used to inform next steps in policy development and shape our stakeholder engagement plans.

These responses on wider GM reform will be considered separately from responses on the regulation of GE organisms (part 1) and will not lead to legislative change at this early stage in policy development. Further consultation will be needed on proposals before this could happen.

We welcome views and comments on the questions in parts 1 and 2 of the consultation. In accordance with standard principles we intend to publish a response to the consultation within 3 months of it closing.

Section 1 – About you

1. Would you like your response to remain confidential?

- a. Yes
- b. No

If you answered yes to this question, please give your reason.

2. What is your name?

3. What is your email address?

4. Please tell us who you are responding as?

- a. An individual – You are responding with your personal views, rather than as an official representative of a business / business association / other organisation.
- b. Non-governmental organisation – In an official capacity as the representative of a non-governmental organisation / trade union / other organisation.
- c. Business – In an official capacity representing the views of an individual business.
- d. Public sector body – In an official capacity as a representative of a local government organisation / public service provider / other public sector body in the UK or elsewhere.
- e. Academia – In an official capacity as a representative of an academic institution.

If responding as an individual

5. Where do you live?

- a. England
- b. Wales
- c. Scotland
- d. Northern Ireland
- e. Other (please state)

If responding as an organisation, business, public body or academic institution

6. What is the name of your business/ organisation?

7. Which of the following areas are you interested in? Please select all that apply.

- Cultivation of crop plants
- Breeding farmed animals
- Human food
- Animal feed
- Human and veterinary medicines
- Other sectors/activities

8. Where does your business/organisation operate?

- a. England
- b. Wales
- c. Scotland
- d. Northern Ireland
- e. Other (please state)

Section 2 – Part 1: the regulation of GMOs which could have been developed using traditional breeding methods

This part of this consultation addresses the regulation of GMOs produced by gene editing (GE), or other genetic technologies, but which could have been developed using traditional breeding methods.

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?

Yes – they should continue to be regulated as a GMO / No – they should not continue to be regulated as a GMO

Please explain your answer, providing specific evidence where appropriate. This may include suggestions for an alternative regulatory approach.

[open response]

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?

[Similar] [Lesser] [Greater]

Please provide evidence to support your response including details of the genetic technology, the specific risks and why they do or do not differ. Please also state which applications/areas your answer relates to (for example: does it apply to the cultivation of

crop plants, breeding of farmed animals, human food, animal feed, human and veterinary medicines, other applications/ areas).

Open response

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?

[Yes/No]

Please provide evidence to support your response and expand on what these non-safety issues are

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?

Please provide evidence to support your response

[open response]

Section 3 – Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

This part of the consultation is designed to start the process of evidence gathering to inform how Defra should reform its approach to regulating novel organisms in the longer term. There are two questions that focus on areas where views and evidence would be welcome.

These questions do not apply to the use of genetic technologies in contained use conditions (e.g. in laboratories) or to the use of genetic technologies in humans (e.g. gene editing of human embryos).

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? Please indicate in

the table whether, **yes**, the existing non-GMO legislation is sufficient, or **no**, existing non-GMO legislation is insufficient and additional governance measures (regulatory or non-regulatory) are needed.

Please answer Y/N for each of the following sectors/activities:

Sector / activity	Yes (sufficient governance)	No (insufficient governance)
a) cultivation of crop plants		
b) breeding farmed animals		
c) human food		
d) animal feed		
e) human and veterinary medicines		
f) other sectors/activities		

Please provide evidence to support your response

[open response]

2.

Where you have answered **no** (existing, non-GMO legislation is insufficient to deal with organisms produced by genetic technologies), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors).

Please provide evidence to support your response

[open response]

How to respond

Consultation launched: 7 January 2021

Please respond by 17 March 2021 at 23:59.

Please respond through the online survey (Citizen Space) accessible via the following link:
<https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/>

If you cannot respond online, you can request a copy of the consultation document by emailing consultationreply@defra.gov.uk. Queries and responses can also be sent here.

Alternatively, you can respond by post at the address below:

Consultation Coordinator
Defra
2nd Floor
Foss House
Kings Pool
1-2 Peasholme Green
York
YO1 7PX

Privacy Notice and data protection

1. Who is collecting my data?

The data controller is the Department for Environment, Food and Rural Affairs (Defra). You can contact Defra's Data Protection Officer at:

Address:

Data Protection Manager
Information Rights Team
Department for Environment, Food and Rural Affairs
Area 1E, Nobel House
17 Smith Square
London, SW1P 3JR.

Email: data.protection@defra.gov.uk

Any questions about how we are using your personal data and your associated rights should be sent to the above contact.

2. What of my data is being collected and how is it used? What is the legal basis for the processing?

Your personal data (contact information) is collected and stored on our secure server to process the responses collected during this public consultation.

This consultation is being conducted in line with the Cabinet Office “Consultation Principles” which can be found at:

<https://www.gov.uk/government/publications/consultation-principles-guidance>.

A summary of responses to this consultation will be published on the government website at: www.gov.uk/defra. An annex to the consultation summary may list all organisations that responded but will not include personal names, addresses or other contact details.

Defra may publish the content of your response to this consultation to make it available to the public without your personal name and private contact details.

If you click on ‘Yes’ in response to the question asking if you would like anything in your response to be kept confidential, you are asked to state clearly what information you would like to be kept as confidential and explain your reasons for confidentiality. The reason for this is that information in responses to this consultation may be subject to release to the public or other parties in accordance with the access to information law (these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA)). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances. In view of this, your explanation of your reasons for requesting confidentiality for all or part of your response would help us balance these obligations for disclosure against any obligation of confidentiality. If we receive a request for the information that you have provided in your response to this consultation, we will take full account of your reasons for requesting confidentiality of your response, but we cannot guarantee that confidentiality can be maintained in all circumstances.

If you click on ‘No’ in response to the question asking if you would like anything in your response to be kept confidential, we will be able to release the content of your response to the public, but we won’t make your personal name and private contact details publicly available.

The legal basis for processing is consent.

3. Who will my data be shared with?

Your personal data will be shared by us with other members of the internal Defra group stakeholders, including Defra group agencies and public bodies, such as the Food Standards Agency and Defra’s Advisory Committee on Releases to the Environment. Responses may be shared with other government departments. No data will otherwise be shared with or disclosed to any party outside Government without your explicit consent.

4. Can I opt out?

Yes, If you wish to opt out you will not be part of the consultation process. You can opt out until 31 March 2021 by emailing consultationreply@defra.gov.uk who will delete all your personal data.

5. What will happen if I opt out?

If you opt out, your personal data and response provided as part of this consultation will be deleted, and you will not be part of the consultation process.

6. Retention period or criteria used to determine the retention period

Your personal data will be kept by us for five years in line with our standard information retention policy.

7. Will my data be used for automated decision-making or profiling?

The information you provide is not connected with individual decision making (making a decision solely by automated means without any human involvement) or profiling (automated processing of personal data to evaluate certain things about an individual).

8. Will my data be transferred outside of the EEA? If it will, how will it be protected?

The data you provide will not be transferred outside the European Economic Area.

9. What are my rights?

A list of your rights under the General Data Protection Regulation and the Data Protection Act 2018 (DPA 2018), is accessible at:

<https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/>

10. How do I complain?

You have the right to lodge a complaint with the ICO (supervisory authority) at any time. Should you wish to exercise that right full details are available at: <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/>