Department
for Environment
Food & Rural Affairs

Summary of responses to a consultation on the regulation of genetic technologies

29 September 2021

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Executive summary

Background

Defra held a public consultation from 7 January to 17 March 2021, to gather views on the regulation of genetic technologies in England. The consultation had two parts:

1. Whether the products of genetic technologies should continue to be regulated as genetically modified organisms (GMOs), if they could have been produced by traditional breeding methods.
2. Longer-term reform of legislation governing organisms produced using genetic technologies.

In total, 6440 consultation responses were received via an online platform (Citizen Space), email and post. Responses were treated equally regardless of respondent type (i.e. responses were not weighted). This summary of responses is not an exhaustive list of all points raised, but represents the most prevalent views. The findings are not necessarily reflective of the wider population's views. This document is a summary of consultation responses. The government's response to the consultation is published alongside this summary.

Findings

Part 1

We asked **whether organisms developed using genetic technologies should be regulated as genetically modified organisms (GMOs)**, even if their genetic changes could have been produced through traditional breeding:

- Most individuals (88%) and businesses (64%) supported continuing to regulate such organisms as GMOs. Non-governmental organisations (NGOs) were evenly split (50%). A slightly higher proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate such organisms as GMOs.[1]
- Those in favour of continuing regulation viewed traditional breeding methods as having an established safe history, and the scientific understanding of GE (gene editing) as incomplete. They supported regulating organisms based on the method used to produce them, and referred to the European Court of Justice ruling in 2018

[1] 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.

which took this view. Those in favour of changing the regulations viewed GEOs (gene-edited organisms) as providing benefits including related to climate change.

We asked **whether 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:

- the majority of individuals (87%) and businesses (64%) stated that there was a greater risk, whereas the majority of academic institutions (63%) and public sector bodies (82%) stated there was a similar risk. NGOs were evenly split.[1] Those that stated there was a lesser risk were in the minority across all groups.
- Respondents who said there was a greater risk raised concerns about unintended consequences, potential environmental, human health and animal welfare issues, and cross-contamination with non-GEOs. Respondents who stated the risks were the same (or lesser) indicated GE was more precise than traditional breeding and noted benefits such as disease tolerance and less pesticide use.

We asked **whether there are non-safety issues to consider 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**:

- The majority of NGOs (93%), individuals (93%), academic institutions (92%) and businesses (89%) stated there were non-safety issues to consider. Public sector bodies' responses were mixed.[1]
- Respondents raised concerns about accountability and transparency, including the importance of consumer choice, and favoured product labelling to indicate whether a product is derived from gene-editing. Other topics mentioned included ownership and intellectual property relating to GEOs, and views about how the proposed changes may affect trade, including exports, and trade within the UK.

We asked about **criteria to distinguish GEOs from traditionally bred organisms**:

- Respondents commonly stated it would not be possible to distinguish GEOs from traditionally bred organisms.
- Where criteria were suggested, the most common views were scientific criteria should be established to assess risk, and to test for the presence of genetic material from a different species.
- Views differed on whether regulations should be process-based or product-based.

Part 2

We sought views on longer-term reform of legislation governing organisms produced using genetic technologies. A large proportion of respondents did not answer this question. Notably for NGOs, businesses, academics and public sector bodies, and across some sectors non-response was in the majority. Of those that did respond, a larger proportion of individuals, businesses and NGOs stated existing non-GM legislation was insufficient to deal with all organisms. In contrast, academics and public sector bodies varied in their response based on the sector. Views varied about what regulatory measures might be

required for GMOs. Some responses suggested the regulations should include views from a diverse range of stakeholders, and consider social, ethical and economic factors.

Glossary of terms

DNA	deoxyribonucleic acid
ECJ	European Court of Justice
EU	European Union
GE	gene editing
GEO	gene edited organism
GM	genetic modification
GMO	genetically modified organism
NGO	non-governmental organisation

Introduction

Background to consultation

A consultation was held to gather views about the regulation of genetic technologies. It mainly focused on the regulation of gene edited (GE) organisms possessing genetic changes which could have been introduced by traditional breeding, as well as gathering views on the wider regulatory framework governing genetically modified organisms (GMOs). This document summarises the responses received to the consultation. The government's response to this consultation is published alongside this summary.

This two-part consultation gathered a range of views and evidence from individuals, businesses, NGOs, academic institutions and public sector bodies on:

1) the regulation of organisms produced by GE, or other genetic technologies, but which could have been developed using traditional breeding methods (i.e. the Government proposal to remove certain GEOs from GMO legislation)
2) Longer-term and broader reform of legislation governing organisms produced using genetic technologies.

The proposed regulatory change to the definition of GEOs would only apply in England, however views from individuals and organisations based elsewhere in the UK, or outside the UK, were also welcomed.

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

The Government thanks everybody who responded to our consultation.

Consultation dates and timings

The consultation ran for ten weeks, opening on Thursday 7 January 2021 and closing on Wednesday 17 March 2021. The consultation was hosted on the government consultation portal, Citizen Space. Responses could also be made by email or submitted to a postal address.

Consultation questions

This section describes the structure of the consultation, and provides an overview of the consultation questions reported in this summary.

The consultation had an ‘About You’ section asking about respondent’s demographic information, and 6 main questions, structured into two parts. Part 1 had four questions and Part 2 had two questions. In Part 1 of the consultation, Defra asked respondents for their view on whether organisms developed using genetic technologies such as GE, which could have been produced through traditional breeding, should continue to be regulated as genetically modified organisms (GMOs). The other three questions in Part 1 asked for respondents’ opinion on whether organisms produced by GE or other technologies, posed a greater, similar or lesser risk than traditionally bred counterparts, the non-safety risks of GE and for the criteria which could be used to establish whether a GE organism could have been produced through traditional breeding.

Part 2 sought to gather views on the wider regulatory framework governing GMOs. A full list of consultation questions can be found in the annex.

Methodology

Methodology and Caveats

The consultation was hosted on the online platform Citizen Space, but responses were also collected via post and email.

Closed text responses (i.e. where there was a limited range of answers to select from) were calculated for each respondent type. To process and summarise all the ideas submitted in the open-text responses, inductive (open) coding was used, whereby themes were developed as they arose directly from the responses. Open coding involved reading each response line-by-line and capturing the points covered. For instance, if a respondent stated that they supported ‘process-based regulation’ this response was categorised under that theme. The approach assigned the same level of specificity and importance to each point raised. In each section of this report, the most common views have been summarised, reflecting where the views of respondent types were similar or differed. This summary of responses is not an exhaustive list of all ideas provided by respondents but summarises the most common concerns and opinions. Therefore, a range of qualitative terms are used, such as ‘many’, ‘some’, ‘most’ and ‘a few’.

Alongside these responses, respondents provided evidence and references to academic literature. This will be considered as part of the wider evidence base but is not summarised in this report.

One of the main caveats to this consultation is that it is not necessarily representative of the wider population. Since anyone could submit their views to the consultation,

respondents with a propensity to following genetic technologies, were more able and likely to participate in the study. The implication of self-selection bias is that an assessment of views can only be made for the respondents who chose to participate and will not represent the entire target population, but rather a smaller sub-set. As such, the findings should be interpreted with caution.

Further, as there is a disparity between the number of individuals responding compared to NGOs, businesses, academics and public-sector bodies, each group is treated separately and equally, and no attempt to weight responses by respondent type has been made.

Campaign responses

As part of the consultation, we received 3904 campaign responses from 6 campaigns. These are responses based on a standard template or "stock response" provided by the campaign organiser, and then submitted via Citizen Space, email or post. Campaign responses were predominantly used by individuals, but also by some businesses and organisations. In these campaign responses, respondents could add their name and contact details to the standard response, and then submit their response. These are referred to as **standard campaign responses**. Some responses were adapted, as respondents supplemented the 'standard' response with additional supporting evidence. These responses are referred to as **personalised campaign responses**.

Campaign responses were grouped by identifying responses which contained identical or very similar passages of text. As noted above some campaign responses also contained personalised passages or pieces of text. These were reviewed in addition to the standard text, although this was minimal in the campaign responses received. Identified campaign responses have been analysed and summarised separately from other responses.

Although a large number of responses were identified as part of campaigns, due to some level of personalisation of some responses and lack of self-identification, this number is a conservative figure. Where there was a high level of personalisation the response has been included in the main summary of responses. Therefore, the figures quoted for each campaign in this document are also conservative, based on the number of responses containing standard campaign text. The annex provides an overview of the identified campaigns.

Summary of responses

Overview of respondents

In total 6440 responses were received, of which: 3083 were submitted via the online platform, Citizen Space, 3347 via email and 10 by post. The figure below shows the breakdown of how responses were submitted to the consultation and the split of unique responses and responses associated with a coordinated campaign.

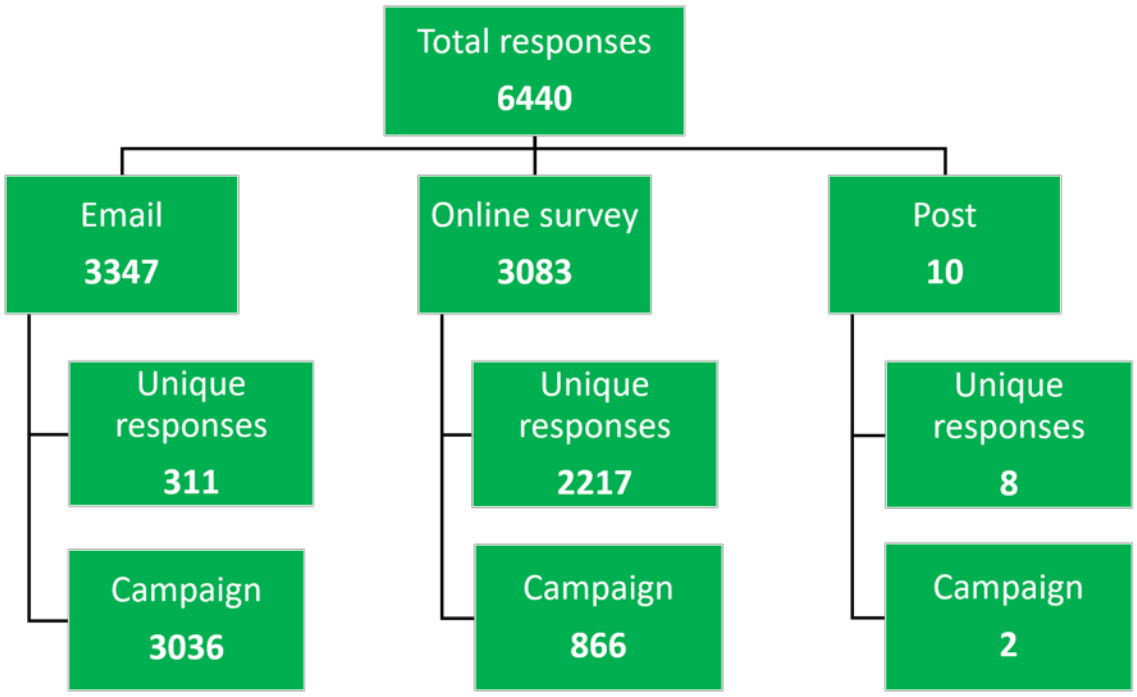

Figure 1. Breakdown of responses to the Genetic Technologies Consultation by submission type.

Chart description: A chart showing the breakdown of responses by how they were submitted to the consultation. There were 6440 responses in total of which; 3083 were submitted via Citizen Space (the online survey platform) - 2217 unique responses and 866 associated with a coordinated campaign, 3347 responses were submitted via the consultation mailbox – 311 unique responses and 3036 associated with a coordinated campaign, 10 responses were submitted via post – 8 unique responses and 2 associated with a coordinated campaign.

Types of respondents

The consultation sought a range of views from individual citizens, non-governmental organisations (NGOs), businesses, academics and public sector bodies, on a proposed change to the regulation of genetic technologies.

Respondents defined as an NGO, business, public sector body or academic are those who stated they were responding in an official capacity representing the views of an NGO, business, public sector body or academic institution. It is important to note that 'academic' respondents only refer to respondents who are responding on behalf of an academic institution rather than academics who responded as individuals.

Citizen Space respondents

On Citizen Space, respondents self-selected the respondent type with which they most identified. The majority of responses came from individuals – the breakdown of respondents is shown in Figure 2 below.

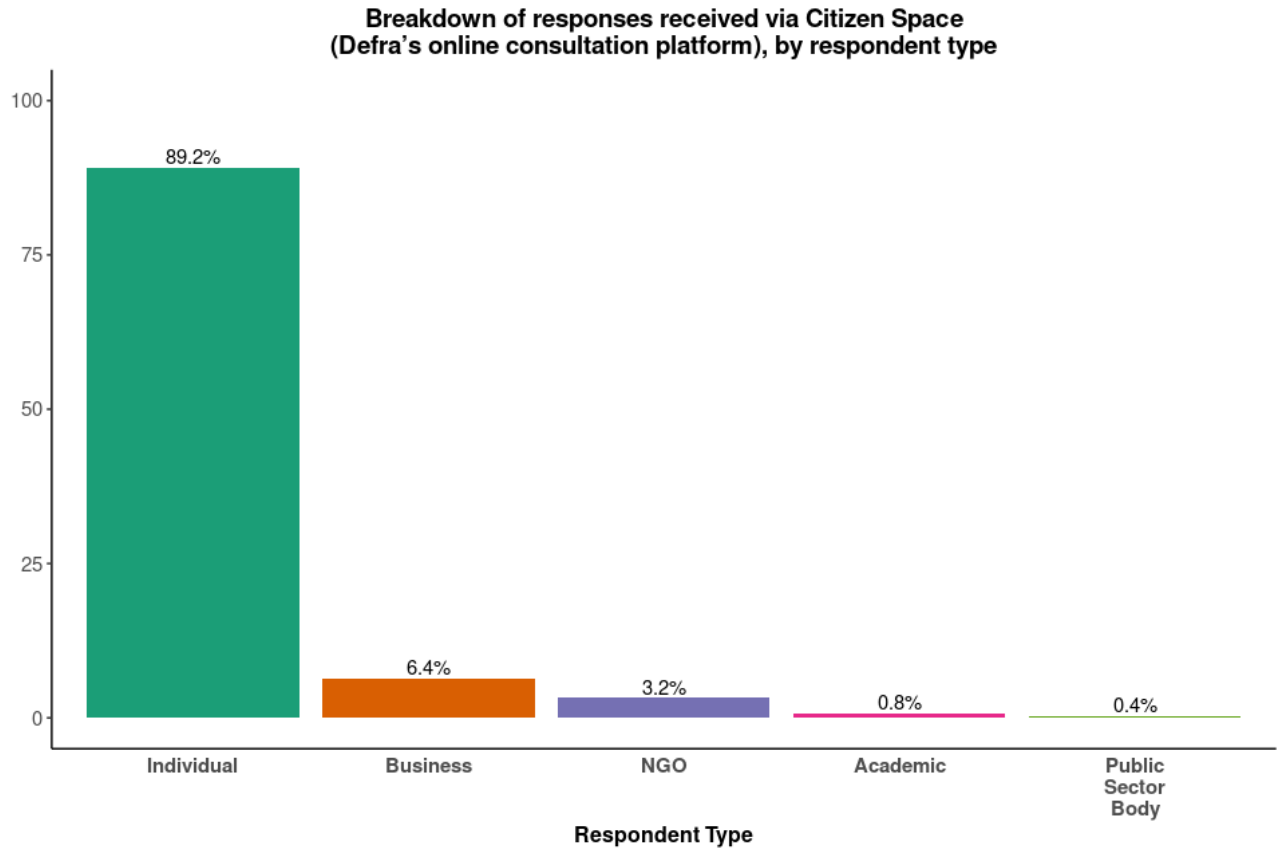

Figure 2. Breakdown of responses submitted to Citizen Space by respondent type. (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description: A bar chart showing the breakdown of respondents who submitted their response via the Citizen Space online survey platform. Of the 3083 responses

submitted via Citizen Space, 2750 (89%) were submitted by **individuals**, 198 (6%) by **businesses**, 100 (3%) by **NGOs**, 24 (<1%) by **academics** and 11 (<1%) by **public sector bodies.**

Respondents also had the option to state where they live. The majority of Citizen Space respondents said they lived in England (73%) with other respondents living in Scotland (9%), Wales (4%), Northern Ireland (<1%) and 'other' (3%). The remainder of respondents (11%) did not provide a location. Although the proposed regulatory changes would only apply to England, the consultation was open to respondents from any location, therefore, no comparisons between different locations have been made.

Email and postal respondents

The respondent types of responses submitted to the consultation mailbox and via post were identified during the analysis process. However, not all respondents specifically stated who they were, so this has not been quantified in this section. For the purposes of summarising, the small number of responses who did not identify their respondent type have been treated as individuals.

Part 1: The regulation of GMOs which could have been developed using traditional breeding methods

Question 1. Regulation of genetic technologies as GMOs

1.1 Question 1a

Question wording:

> *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*

The majority of individuals (88%) and businesses (64%) supported continuing the regulation of GEOs as GMOs. NGOs were evenly split (50%). On the other hand, a slightly higher proportion of public sector bodies (55%) and academics (58%) did not support continuing to regulate such organisms as GMOs compared to those in support.

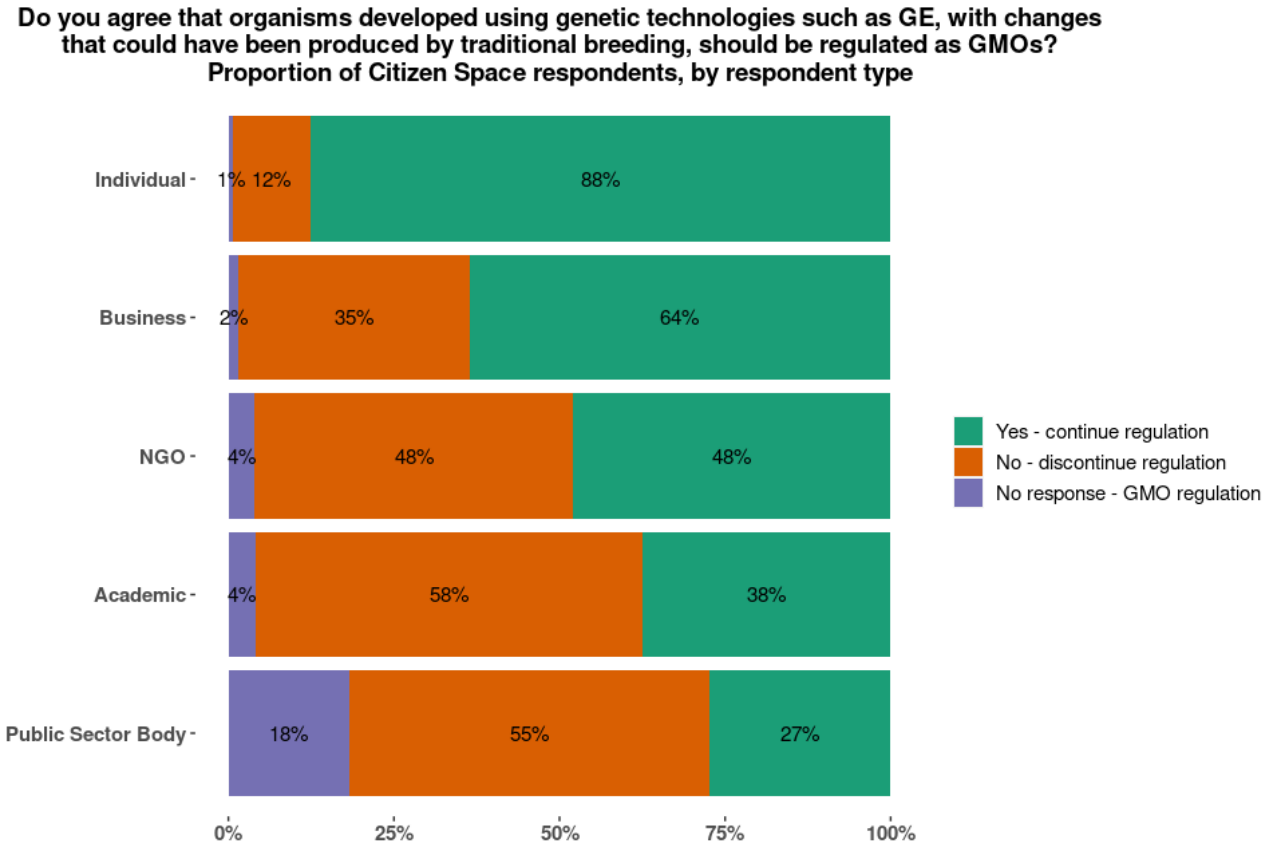

Figure 3. Proportion of Citizen Space respondents who stated GEOs should be regulated as GMOs, where the changes could have produced by traditional breeding (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description: a stacked bar chart showing responses to the question about how organisms produced using genetic technologies should be regulated. For **individuals**, 1% did not answer, 12% said such organisms should not be regulated as GMOs, and 88% said such organisms should continue to be regulated as GMOs. For **businesses**, 2% did not answer, 35% said such organisms should not be regulated as GMOs, and 64% said such organisms should continue to be regulated as GMOs. For **NGOs**, 4% did not answer, 48% said such organisms should not be regulated as GMOs, and 48% said such organisms should continue to be regulated as GMOs. For **academia**, 4% did not answer, 58% said such organisms should not be regulated as GMOs, and 38% said such organisms should continue to be regulated as GMOs. For **public sector bodies**, 18% did not answer, 55% said such organisms should not be regulated as GMOs, and 27% said such organisms should continue to be regulated as GMOs.

1.2 Question 1b.

Question wording:

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

Summary of key themes

- Those if favour of continuing regulation felt that whilst traditional methods have a history of being safe, the scientific understanding of gene editing was currently incomplete.
- Concerns were also raised around consumer choice and public trust, with many individuals in support of labelling.
- Those in favour of discontinuing regulation acknowledged the potential role of GE technologies in responding to sustainability and climate change issues and the benefits of GE technologies for farmers.
- Many businesses and NGOs called for improving awareness and understanding of GE through public campaigns and better education.

1.2.1 Individuals

Individuals in support of continuing regulation felt there was an incomplete scientific understanding of GE technologies and/or there was an inherent difference between traditional breeding and GE technologies. These individuals were more inclined to support the ECJ ruling[2], or process-based regulation whereby organisms are regulated based on the method used to produce them. In contrast, individuals in support of the proposed policy noted three main points: GE is more precise than traditional breeding; GE is similar to traditional breeding; and GEOs are inherently different to GMOs. They also focussed on what they perceived to be the benefits of using GE technologies for the environment and farmers. These individuals also tended to be more in favour of product-based regulation, whereby regulation would be based on the assessment of the characteristics of the final product/trait, irrespective of the production method.

For all individual respondents, the most common view was that whilst traditional methods have a history of being safe, the scientific understanding of gene editing was currently incomplete. These individuals felt that this lack of understanding might lead to irreversible negative consequences, often drawing parallels with public health scandals occurring in the past due to incomplete scientific understanding. Respondents were concerned about ‘off-target’ events, referring to unintended changes made to genes other than those targeted. Finally, some respondents viewed GE as being ‘unnatural’ and expressed a concern with humans interfering in nature and having a negative irreversible impact on the food chain.

Some respondents also discussed the possible risks of genetic technologies such as GE including implications to human health, the environment and biodiversity. More detail on the risks described is provided in section 2.1.

[2] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of Genetically Modified Organisms

Concerns were also raised about consumer choice and public trust. Individuals stated that public trust and transparency of the production process is important and there needs to be a way for supply chains to remain accountable. Individuals expressed the concern that the proposed policy could affect their ability to make informed decisions, as they would be unaware if their food was created as a result of GE. As such, many of these respondents were in favour of clear labelling of GE products.

Many individuals were also concerned about their ability to purchase organic products due to unintentional cross-contamination and reduced the options for organic alternatives due to competition.

Related to this, respondents supported additional measures, including ongoing environmental and health monitoring of products post-release and a commitment to transparency in how foods are produced, if the regulation of GEOs is changed.

1.2.2 Businesses and Non-Governmental Organisations (NGOs)

Businesses and NGOs mostly expressed similar views in response to this question. Most respondents agreed that some form of regulation of organisms produced by GE is required, though there was a variety of views on what this should look like. Most respondents stated that introducing novel traits to an organism should trigger a more substantive risk assessment. Factors that should be assessed via a risk-assessment included: negative environmental impact; the accumulation of a potential allergen; the safety for consumption; and animal welfare.

Businesses and NGOs held mixed views about whether regulation should be product-based or process-based. Those that supported a product-based approach felt it would enable a single approach applicable to all forms of breeding. They also emphasised that such a regulation should be flexible, incorporating future methodological developments as and when needed.

Many businesses and NGOs noted GEOs are inherently different to GMOs because the latter involves the insertion of foreign DNA, bringing traits in from another species. However, slightly more businesses stated that GE technologies are similar or no different to traditional breeding. Another distinction commonly made was that GMOs can be traced through the identification of foreign DNA being present, whereas GEOs cannot. Additionally, businesses and NGOs often focused on how GEOs mimic traditional breeding methods and/or how GE is more precise compared to traditional breeding methods, often stating that it ‘accelerated’ natural processes.

Many businesses and NGOs acknowledged the potential role of GE technologies in responding to sustainability and climate change issues and the benefits of GE technologies for farmers. For example, the development of disease-resistant crops which could reduce the need for pesticide applications. However, there was a general agreement between NGOs and businesses, whether for or against the proposal, that no single development can address these complex challenges, and GE could be among the tools available to deliver the UK’s sustainable development goals.

Some businesses felt that concerns relating to consumer acceptance of GE technologies was disproportionate. These organisations explained that in their experience, few people have sufficient information to make an informed opinion about whether GE technologies should be subject to regulatory change and would be interested in the benefits. A few businesses noted that the availability of scientifically verified facts is imperative to avoid misunderstanding of GE technologies. A few NGOs stated that consumer confidence in GEOs could be improved through public campaigns, whilst some said there should be improved education on the benefits. These NGOs stated that it is the responsibility of stakeholders, including governing bodies, to translate science into accessible language, to enable greater understanding amongst consumers and more informed decision-making.

A few businesses and NGOs advocated for 'information sharing' if GE products were not regulated as GMOs in the future, enabling better control of compliance, easier market access, and providing consumers with trust in the provenance of food. A minority of businesses recommended the use of patent registers as a method for identifying GE products, though noted that this was not globally uniform and may not provide a robust traceability approach.

1.2.3. Academics and Public-Sector bodies

The points raised by academics and Public Sector bodies were similar and have therefore been grouped together (though overall number for these groups were very low). Those in favour of continuing regulation raised similar points to individuals. On the other hand, those in support of not regulating some GEOs as GMOs noted that GE technologies could benefit human health, as advances could improve nutrition density and food security, as well as increasing efficiency in agriculture, helping to ensure an affordable food supply, whilst reducing the environmental cost of production. Similar to businesses and NGOs, a few public-sector bodies noted the benefits GE could have on the environment.

1.2.4. Campaigns

Responses received as part of organised campaigns were all in favour of GEOs continuing to be regulated as GMOs. Some responses questioned the wording of the question stating that it was biased, lacked accurate technical explanations of the terms used and misleading (by stating that GE organisms could be produced by traditional breeding methods).

There were many common points raised such as the need for greater understanding of genetic technologies due to unknown/unintended consequences, especially in comparison to the long history of safe use of traditional breeding methods. Respondents expressed support for the ECJ ruling and process-based regulation as well as concerns surround the risks of GE to animal welfare, the environment, human health (including allergens and toxins), traceability, and trading relationships with the EU and devolved nations. Some campaigns stated that changes to the food system and farming practices were needed but that genetic technologies were not the solution. They suggested a better method to improve the food system would be a greater adoption of agroecological methods,

reduction in food waste and an increase in food sovereignty. Some of these responses also viewed the government as trying to obscure where our food comes from.

Question 2: The risk of harm to human health or the environment.

2.1 Question 2a.

Question wording:

> *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?*
>
> - *Greater risk*
> - *Similar risk*
> - *Lesser risk*

Respondents were asked whether gene edited organisms posed a similar, lesser or greater risk of harm to human health or the environment in comparison to their traditionally bred counterparts, as a result of how they were produced.

The majority of **individuals** (87%) and **businesses** (64%) stated that there was a **greater risk.** The majority of **academics** (63%) and **public sector bodies** (82%) stated that there was a **similar risk**. Responses amongst **NGOs** were mainly split across **greater risk** (45%) and **similar risk** (38%). Those that stated there was a **lesser** risk were in the minority across all groups.

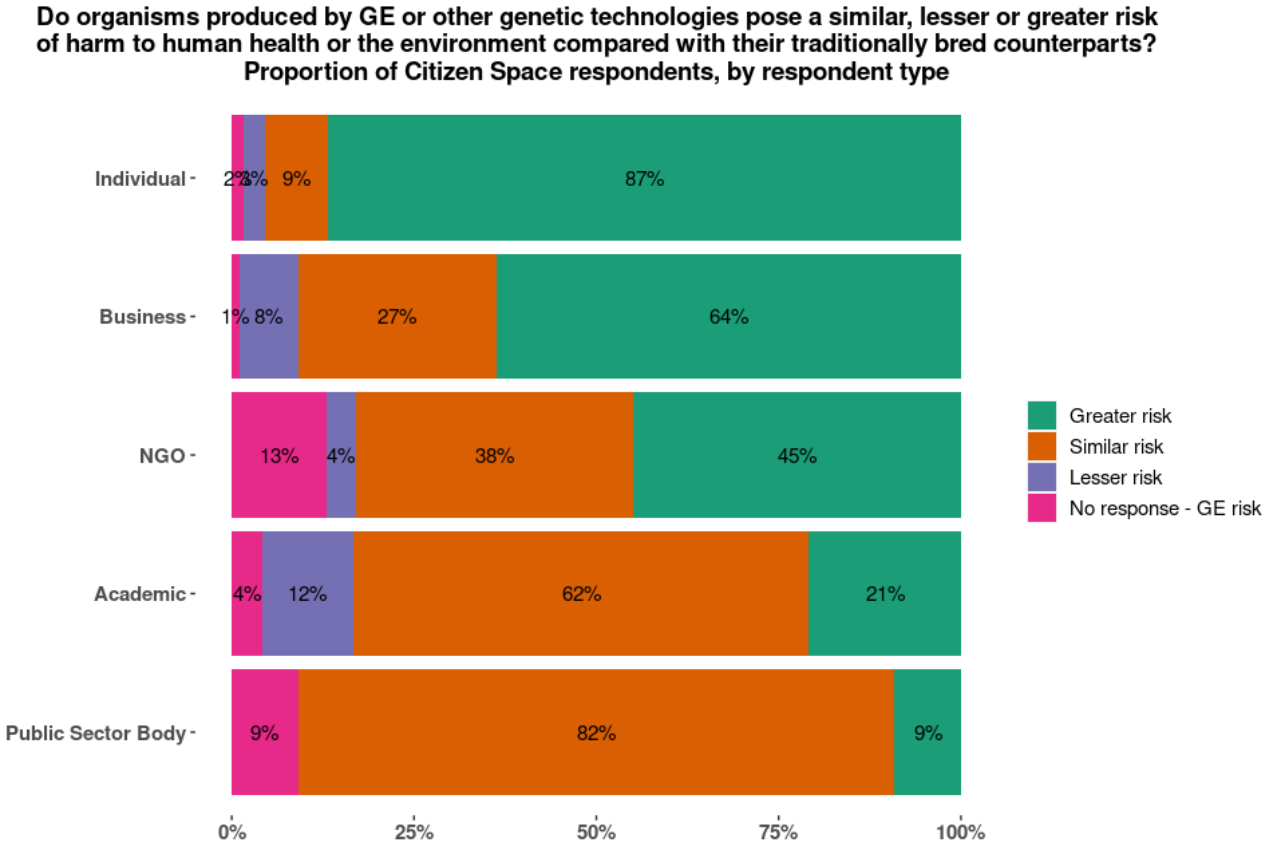

Figure 4. Proportion of Citizen Space respondents who stated there was greater, similar or lesser risk of genetic technologies compared to traditional breeding methods (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description: A stacked bar chart showing how each respondent type responded to the risk question via Citizen Space. For **individuals**, 87% stated there was a 'greater risk' of GE technologies compared to traditional breeding methods, 9% said 'similar risk', 3% said 'lesser risk' and 2% did not provide a response. For **businesses**, 64% stated there was a 'greater risk', 27% said 'similar risk', 8% said 'lesser risk' and 1% did not provide a response. For **NGOs,** 45% stated there was a 'greater risk', 38% said 'similar risk', 4% said 'lesser risk' and 13% did not provide a response. For **academics**, 21% stated there was a 'greater risk', 62% said 'similar risk', 12% said 'lesser risk' and 4% did provide a response. For **public sector bodies**, 9% stated there was a 'greater risk', 82% said 'similar risk' and 9% of individuals did not provide a response. No public sector bodies answered 'lesser risk'.

2.2 Question 2b.

Question wording:

> *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).

Summary of key themes

- Respondents that stated there was a **greater risk** commonly raised points relating to unforeseen and unintended consequences of genetic technologies, such as off-target effects.
- Risks were also raised in relation to human health, animal welfare and the environment, including cross-contamination between GE and non-GE crops, and impacts on genetic diversity.
- Respondents that stated there was either a **similar** or **lesser risk** commented that GE was more precise than traditional breeding.
- The benefits of GE organisms were also raised, including resistance/tolerance to disease and climate change, enhanced nutrients, less pesticide use and increased crop yields.

2.2.1. Individuals

Individuals who stated there was **greater risk** provided a number of different possible risks associated with GE, including risks to the environment, biodiversity, human health and animal welfare.

Specific environmental risks included potential increases in fertiliser and pesticide use, herbicide and insecticide intolerance, impacts on soil and water quality, impacts on genetic diversity and the possibility of cross-contamination between GE and non-GE crops. Respondents who expressed a concern about the impacts of GE on human health mentioned allergies and possible reactions to GMOs or ‘unnatural’ produce, particularly if there is any unintended cross-contamination to non-GE. Respondents also expressed concerns for impacts of GE on animal welfare, particularly on farm animals. Concerns included the possibility that GE developments could enable animals to withstand less humane treatment or could lead to animals ingesting GE organisms which could cause them harm.

Many respondents also mentioned risks associated with the technology and science used in GE. Respondents highlighted that genetic technologies are relatively new compared to the long history of traditional breeding methods and that there may be unforeseen and unintended consequences (such as off-target effects) with GE technologies, particularly as GE makes changes at a faster rate than traditional breeding.

Some respondents stated that genetic technologies go against nature and that humans should not interfere. Other respondents mentioned that there does not appear to be a universal consensus surrounding GE technologies and that more research and evidence into these technologies is required before any changes to regulation are made.

Some individuals who stated that there was a **similar risk** of GE technologies to traditional breeding methods commented that GE was similar to, or more precise than, traditional breeding. However, this group also commented on the incomplete scientific understanding of GE and possible unforeseen consequences.

There were differences between the individuals mentioned above and those who responded that there was a **lesser risk**. Some of these respondents commented on the enhanced precision of GE compared to traditional breeding and the possible benefits of GE to the environment, humans and farming.

2.2.2. Businesses

Many businesses who responded to this question commented on the possible impacts that GE could have on the environment, human health and farming. They provided both risks and benefits in relation to these considerations. Businesses that stated there was a **greater** risk outlined similar points to those raised by individuals, including and insufficient understanding of GE technologies and possible off-target effects.

Businesses who stated benefits to the environment, humans and farming/farmers stated that there was **lesser** or **similar risk** of GE compared to traditional breeding. The benefits mentioned by businesses included the possibility of GEOs that: are resistant/tolerant to disease and climate change, have enhanced nutrients, require less land or pesticides, lead to reduced carbon emissions from farming and have increased crop yields. Some businesses believed these would bring benefits to consumers, producers and the environment.

Some businesses also commented that genetic technologies are similar to or more precise than traditional breeding methods.

2.2.3. Non-governmental organisations

NGOs' responses mentioned similar risks to individuals' responses such as implications to human health, impacts on the environment and biodiversity, animal welfare concerns and concerns surrounding the technology of GE such as unforeseen and unintended consequences.

There was a lack of consensus among NGOs around the precision of GE compared to traditional breeding. Those that felt GE had a **greater** risk commented on the imprecision of GE, including off-target effects, whereas those that felt there was a **similar** or **lesser** risk commented that GE was similar to, or more precise than, traditional breeding methods

NGOs also commented on the possible benefits of GE to the environment, human health and farming.

2.2.4. Academics and Public sector bodies

Those responding on behalf of public sector bodies or academic institutions most commonly discussed the same risks, therefore these two groups have been summarised together. The majority of academics and public sector bodies stated that there was a **similar risk** of GE to traditional breeding and focused on the similarities of GE techniques to traditional breeding methods, with some stating that GE has greater precision than traditional breeding. Some respondents also commented on the benefits that GE technologies could bring to human health and impacts on the environment.

2.2.5 Campaigns

Responses received through campaign organisations shared many common points in their response to this question. Campaign responses stated that there was **greater risk** of harm when using genetic technologies compared to traditional breeding methods. Responses commented that genetic technologies are different to traditional breeding methods, that they lack a history of safe usage and as such are riskier due to possible off-target effects. Responses mentioned risks to animal welfare, cross-contamination of GE to non-GE organisms, negative impacts on the environment and to human health.

Question 3. Non-safety issues

3.1 Question 3a.

Question wording:

> *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*

We asked respondents whether there were any non-safety issues to consider if organisms produced using genetic technologies (which could have been produced naturally or through traditional breeding) were not regulated as GMOs.

The majority of **NGOs** (93%), **individuals** (93%), **academics** (92%) and **businesses** (89%) stated that there were non-safety issues to consider. Whilst, **public sector bodies**' responses were split between saying there were non-safety issues (45%) and no non-safety issues to consider (27%).

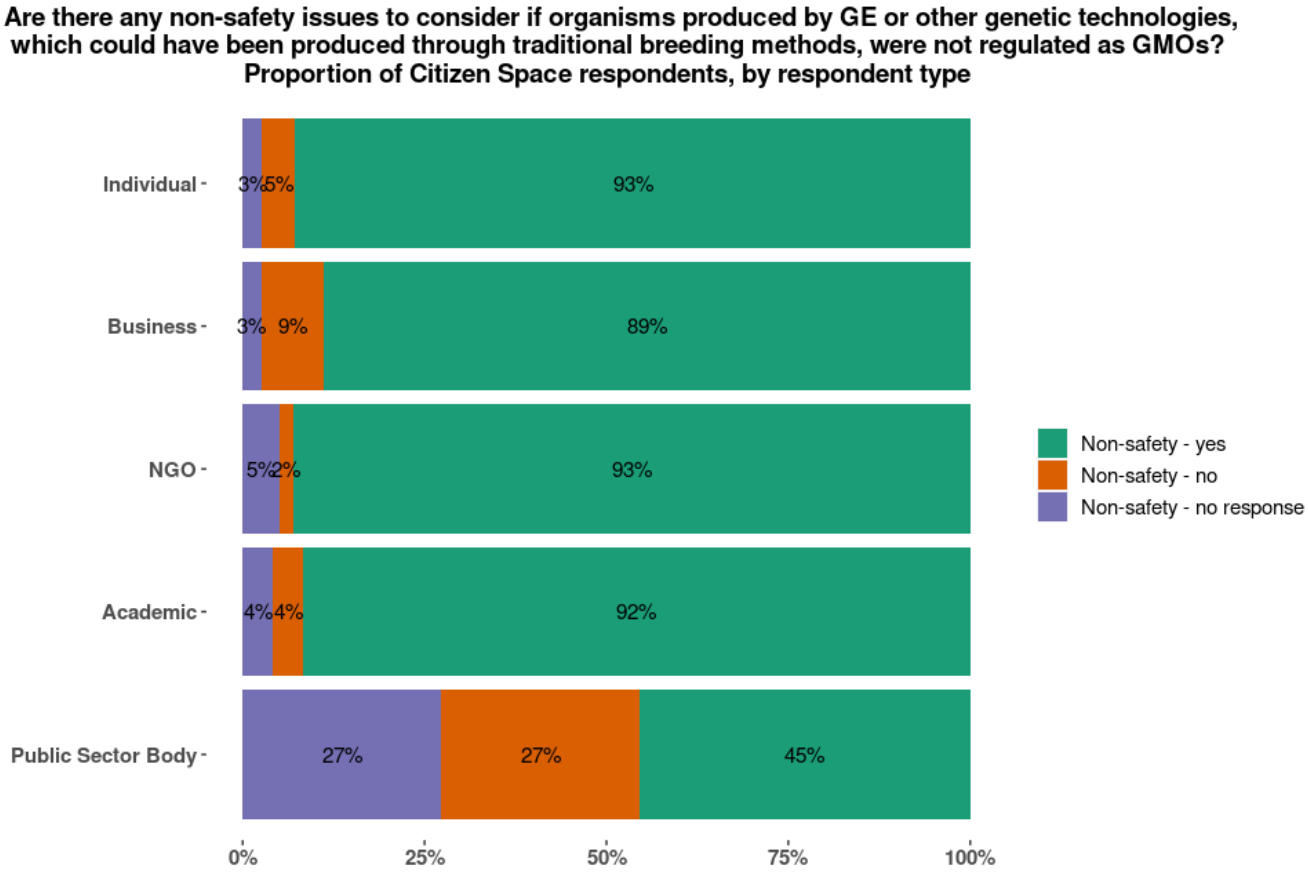

Figure 5. Proportion of Citizen Space respondents who stated there were non-safety issues to consider if GE technologies, that could have been produced naturally or through traditional breeding methods, were not regulated as GMOs (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11)

Chart description: A stacked bar showing how the different respondents types responded to the non-safety question on Citizen Space. For **individuals**, 93% said 'yes, there are non-safety issues to consider', 5% said 'no' and 3% did not provide a response. For **businesses**, 89% said 'yes', 9% said 'no' and 3% did not provide a response. For **NGOs**, 93% said 'yes', 2% said 'no' and 5% did not provide a response. For **academics**, 92% said 'yes', 4% said 'no' and 4% did not respond. For **public sector bodies**, 45% said 'yes', 27% said 'no' and 27% did not respond.

3.2 Question 3b.

Question wording:

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

Summary of key themes

- Many respondents stated the need to clearly label products that were produced using GE so that consumers could make an informed choice. Though businesses and NGOs noted there may be issues in the ability to accurately label products containing GEOs if the genetic changes were indistinguishable from traditional breeding methods
- A number of concerns were raised around ownership and intellectual property rights, including the growing power of big businesses leaving smaller businesses unable to compete. This included concerns around farmers not wanting to use GE.
- Trade concerns were also highlighted, specifically in relation to exporting products to the EU, as well as issues around selling products in the devolved nations. However, some respondents noted that removing GE from GMO legislation could result in trade benefits with some countries.

3.2.1. Individuals

Individuals mentioned many different non-safety issues. Many respondents stated that they wanted any products produced using GE to be clearly labelled so that they could make an informed choice. In relation to labelling, some respondents expressed concern for any cross-contamination of GEOs with other produce, and whether when choosing products labelled as “organic”, they would be certain that they were free from GE. Some respondents expressed concern that the cross-contamination of GE with non-GE products would remove a consumer’s ability to choose not to consume GE products.

Some respondents were concerned about the ownership and intellectual property rights of GEOs. This also included concerns around the growing power of big businesses to take control of the rights to GEO, leaving smaller businesses unable to compete. Some respondents questioned the government’s motivation in consulting on regulatory change related to genetic technologies, indicating scepticism that this wasn’t motived by corporate interests or lobbying.

Individual respondents also expressed concern about the potential impact that changing the way GE is regulated would have on farming, including the welfare of livestock, organic farmers, small farms and the future of sustainable and agroecological farming techniques. Responses mentioned how genetic selection has pushed livestock to their biological limits through fast growth and high yields, often with immense impact on animal welfare. Some respondents suggested that genetic technologies, such as those to increase antibiotic resistance in livestock, could lead to further stresses placed upon animals and lower their quality of life. Other respondents expressed concern that farmers who did not want to use GE would be unable to compete with the production rates of those utilising GE. Respondents suggested that it would better for the environment if there was a shift towards sustainable and agroecological farming techniques rather than changing the way that genetic technologies are regulated.

Respondents highlighted potential issues surrounding trade with other countries including the EU and the devolved nations. Some responses mentioned that changing the way GE

is regulated in England could damage the ability to export English produce. Some respondents suggested that due to possible GE cross-contaminants in non-GE produce there may be issues with exporting non-GE produce to these countries too. Some respondents also commented on possible issues surrounding the selling and labelling of GE products between the devolved nations if England were to independently change the way that GE technologies are regulated.

3.2.2. Businesses, NGOs and public sector bodies

Respondents who identified as a business or an NGO most commonly suggested the same non-safety issues. Businesses and NGOs had similar concerns to individuals surrounding labelling, consumer choice, intellectual property, the power of large corporations in the GE market, and possible issues in farming. Regarding labelling, businesses and NGOs also suggested that there may be issues in the ability to accurately label products containing GEOs if the genetic changes were indistinguishable from traditional breeding methods. Whilst, public sector bodies commented that labelling may be necessary to enable consumer choice.

Similar to individuals, many businesses, NGOs and public sector bodies commented on possible damage to trading relationships with the EU and other countries who have different GE regulations. Some respondents highlighted that removing GE from GMO legislation in England could generate possible trade benefits with countries such as the US, Canada, Argentina and Norway who may be more willing to market GE products in the UK. Some respondents noted that the international picture surrounding genetic technologies is evolving, with more countries moving towards deregulation.

Many businesses and NGOs reiterated their concern for potential negative impacts on the environment that are discussed further in section 2.2.1. Additionally, in response to this question, these respondents restated possible benefits to the environment as detailed in section 2.2.2.

3.2.3. Academics

Academics responded with similar non-safety issues to consider as individuals, businesses and NGOs. Although some academics highlighted that these were issues to consider but not necessarily issues that could not be resolved. Academics commented that any change in the way that genetic technologies are regulated needs to consider public perceptions of GE and consumer choice. Responses also included considerations of both positive and negative impacts on trade, animal welfare and the environment.

3.2.5. Campaigns

Responses received via campaign organisations all agreed there were non-safety issues to consider. Common issues mentioned across these campaigns included; damage to trading with the EU, other countries and the devolved nations, concerns around cross-contamination of GE and non-GE products (and the impacts this could have on trade), labelling of GE products and consumer choice. Some campaign responses mentioned that GE was not the answer to problems in the environment and farming. One campaign

commented on patent law and the power of big businesses in the seed market stating that this could infringe farmers' rights to save seed and breed, especially with the risk of cross-contamination. This could subsequently affect farmers' ability to sell products with organic or GM-free labels. Some campaign responses also mentioned ethical considerations, commenting on the possible off-target effects, potential permanence and impact of GE on future generations.

Question 4: Criteria

4.1 Question 4a.

Question wording:

> *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?*

Summary of key themes

- Individuals most commonly stated that there are no suitable criteria to determine whether an organism produced by GE or other genetic technologies could have been produced by traditional breeding.
- Where specific criteria were suggested, the most common view was that scientific criteria should be developed examining potential genetic errors and off-target effects, and assess the level of risk to the environment, humans and animal health.
- NGOs and academics also stated the deciding factor should be the presence or absence of inserted DNA from another species which could not have naturally reproduced with the target organism.
- There were differing views on whether to take a process-based or product-based regulatory approach

4.2.1 Individuals

21% of individuals said that they did not have the necessary expertise to provide an answer to this question or left their response blank. The individuals who did respond, most commonly stated that there are no suitable criteria to determine whether an organism produced by GE or other genetic technologies could have been produced by traditional breeding. A second predominant view was that scientific criteria should be developed to determine whether an organism produce by GE or other genetic technologies could have been produced by traditional breeding or not. These responses focused on the necessity to examine the range of potential genetic errors (‘off-target effects’) and validate, or otherwise reject, any assumptions and premises regarding the potential risks of gene-edited organisms for the environment, human and animal health. The third most common point was in support of taking a process-based regulatory approach, whereby organisms are regulated based on the method used to produce them.

4.2.2 Non-Governmental Organisations (NGOs) and Academics

Respondents who answered on behalf of an NGO or academic institution most commonly suggested the same criteria and have therefore been grouped together. Similar to individuals, the most frequent view given by NGOs and academics was that scientific criteria should be developed in order to determine whether an organism produced by GE or other genetic technologies could have been produced by traditional breeding. Some NGOs stipulated that environmental organisations should be involved in setting such criteria.

NGOs and academics also stated the deciding factor should be the presence or absence of inserted DNA from another species which could not have naturally reproduced with the target organism. In other words, they would regard any organism (or product derived from the same) containing recombinant DNA or novel DNA constructs to be a GMO and that it should be regulated as such, Some respondents noted that the decision to classify a GE organism/product as equivalent to one produced by traditional breeding could also require analytical testing to rule out off-target effects.

4.2.3 Businesses

In a similar vein to NGOs and academics, the two most frequent views given by businesses was that there needs to be development of scientific criteria, and the presence or absence of inserted DNA from another species which could not have naturally reproduced with the target organism. Many businesses also advocated for criteria to be based on product-based regulation, whereby regulation would be based on the assessment of the characteristics of the final product/trait, irrespective of the production method.

4.2.4 Public-Sector Bodies

Many public-sector bodies concurred with businesses, suggesting criteria should be product-based, whereby the trait or product is regulated rather than the process. The next most frequent view given by public-sector bodies aligned with that of NGOs and businesses, that criteria should include analytical testing to assess for off-target effects.

4.2.5. Campaigns

The majority of campaigns did not provide any criteria, their reasons were that the statement “could have been produced by traditional breeding” did not matter as GEOs are not produced by traditional breeding, with some campaigns challenging the premise of the question stating that it was too technical for respondents, especially with little technical information in the consultation. Some campaigns also stated that there were no criteria needed as they stated that GEs should continue to be regulated as GMOs.

Points were also raised about a need for transparency of GE products through labelling, a public register and citizen panels to allow for effective tracing and monitoring and to enable consumers and producers to make an informed choice. Although these responses stated there was no agreed scientific criteria and there were issues surrounding unwanted mutations in GE organisms, respondents suggested that assessing genetic stability and examining the genome sequence were possible options, and an expert review of the science and public scrutiny was needed.

Part 2: the broad reform of legislation governing organisms produced using genetic technologies

5.1 Question 5a

Question wording:

> *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.*

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		

Respondents were asked whether non-GM legislation is sufficient to deal with all organisms irrespective of how they were produced, across six different sectors: crop plants; farmed animals; food for human consumption; animal feed; human and veterinary medicines and other sectors/activities.

Responses varied considerably by respondent type and sector. A large proportion of respondents did not answer this question, notably NGOs, businesses, academics and public sector bodies, and across some sectors this was in the majority. Of those that did respond to this question, a larger proportion of individuals, businesses and NGOs stated that legislation was insufficient across all sectors. In contrast academics and public sector bodies varied in their response based on the sector.

Results are displayed in Figure 6 to Figure 11 with a written description in the caption below each of the figures.

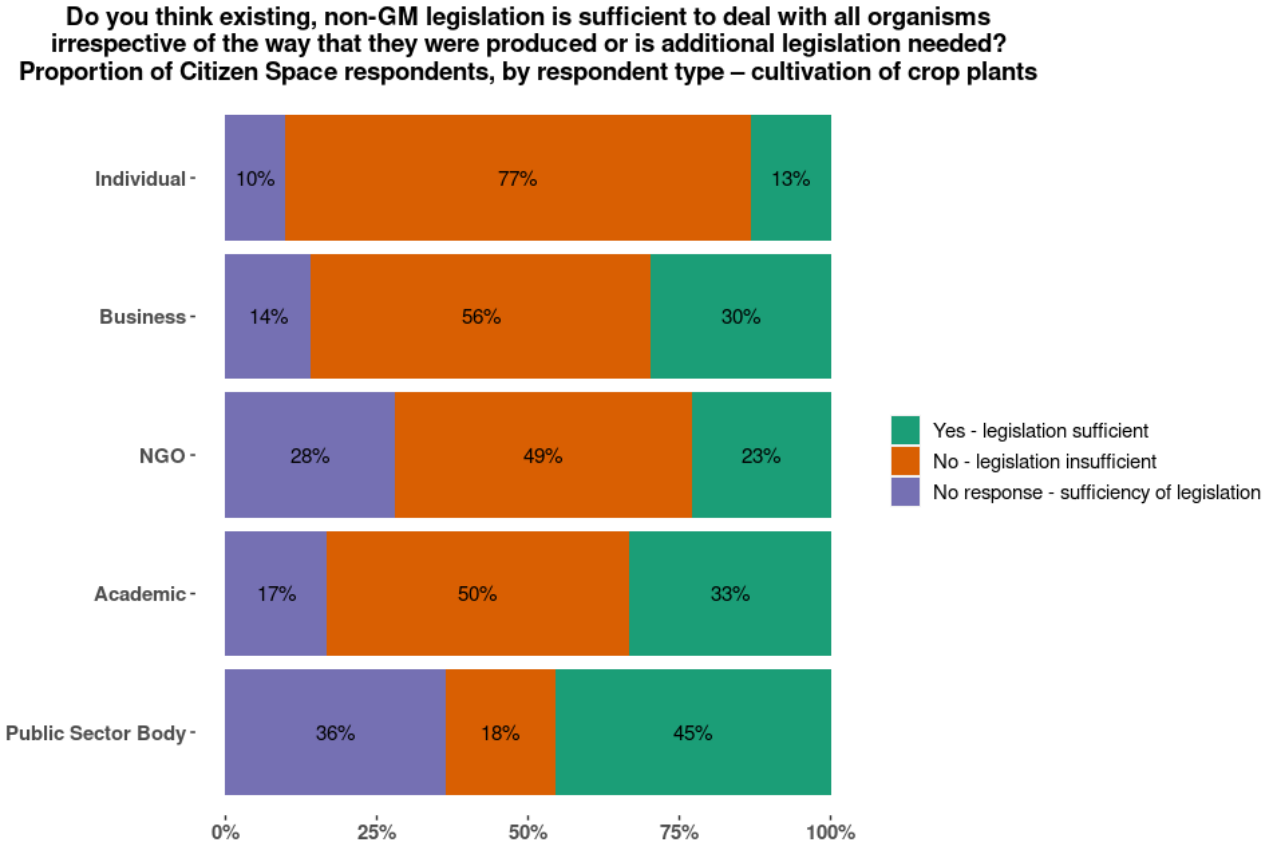

Figure 6. Sufficiency of existing legislation for (a) cultivation of crop plants (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description

A stacked bar chart showing how Citizen Space respondents answered the question about sufficiency of existing legislation for **crop plants**. For **individuals**, 10% did not answer the question, 77% said existing legislation was insufficient, and 13% said existing legislation was sufficient. For **businesses**, 14% did not answer the question, 56% said existing legislation was insufficient, and 30% said existing legislation was sufficient. For **NGOs**, 28% did not answer the question, 49% said existing legislation was insufficient, and 23% said existing legislation was sufficient. For **academia**, 17% did not answer the question, 50% said existing legislation was insufficient, and 33% said existing legislation was sufficient. For **public sector bodies**, 36% did not answer the question, 18% said existing legislation was insufficient, and 45% said existing legislation was sufficient.

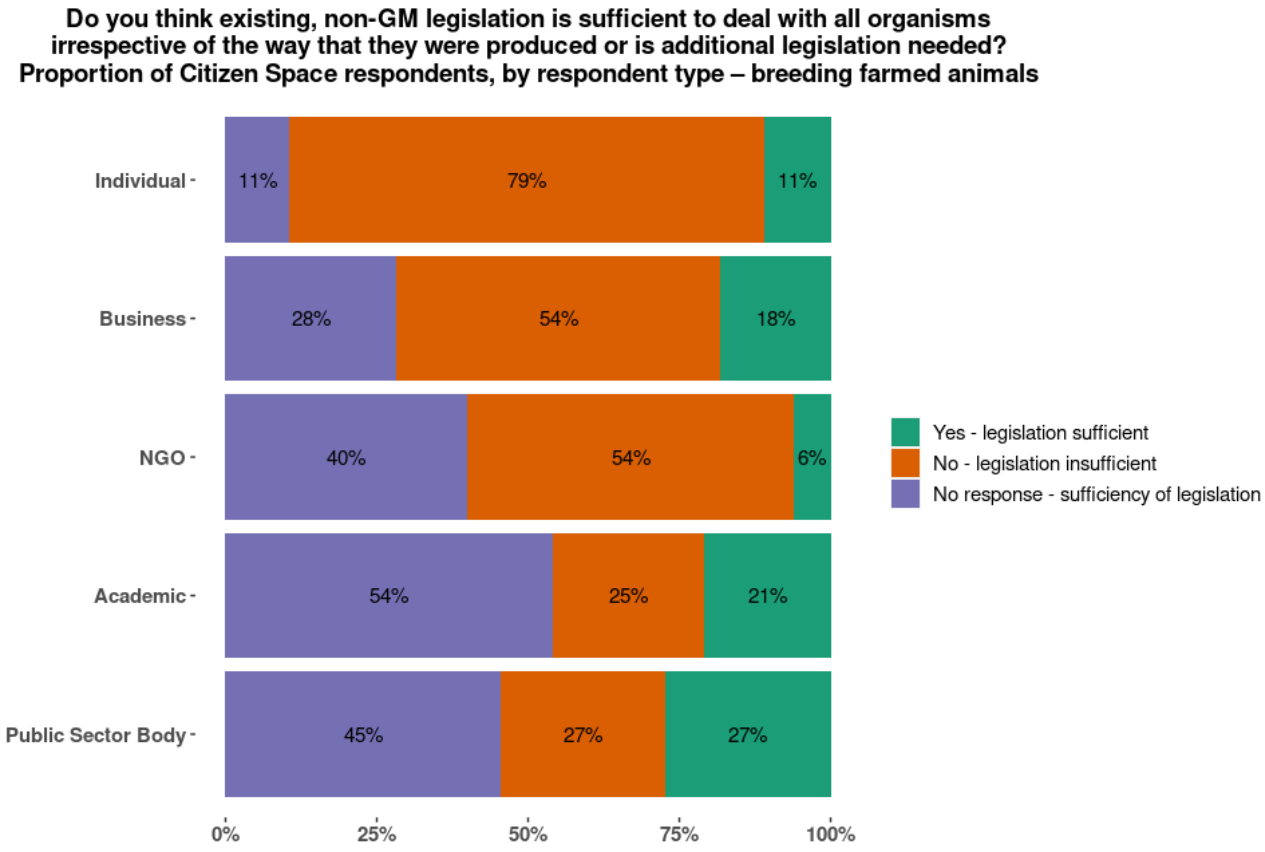

Figure 7. Sufficiency of existing legislation for (b) breeding farmed animals (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description

A stacked bar chart showing how Citizen Space respondents answered the question about sufficiency of existing legislation for **breeding farmed animals**. For **individuals**, 11% did not answer the question, 79% said existing legislation was insufficient, and 11% said existing legislation was sufficient. For **businesses**, 28% did not answer the question, 54% said existing legislation was insufficient, and 18% said existing legislation was sufficient. For **NGOs**, 40% did not answer the question, 54% said existing legislation was insufficient, and 6% said existing legislation was sufficient. For **academia**, 54% did not answer the question, 25% said existing legislation was insufficient, and 21% said existing legislation was sufficient. For **public sector bodies**, 45% did not answer the question, 27% said existing legislation was insufficient, and 27% said existing legislation was sufficient.

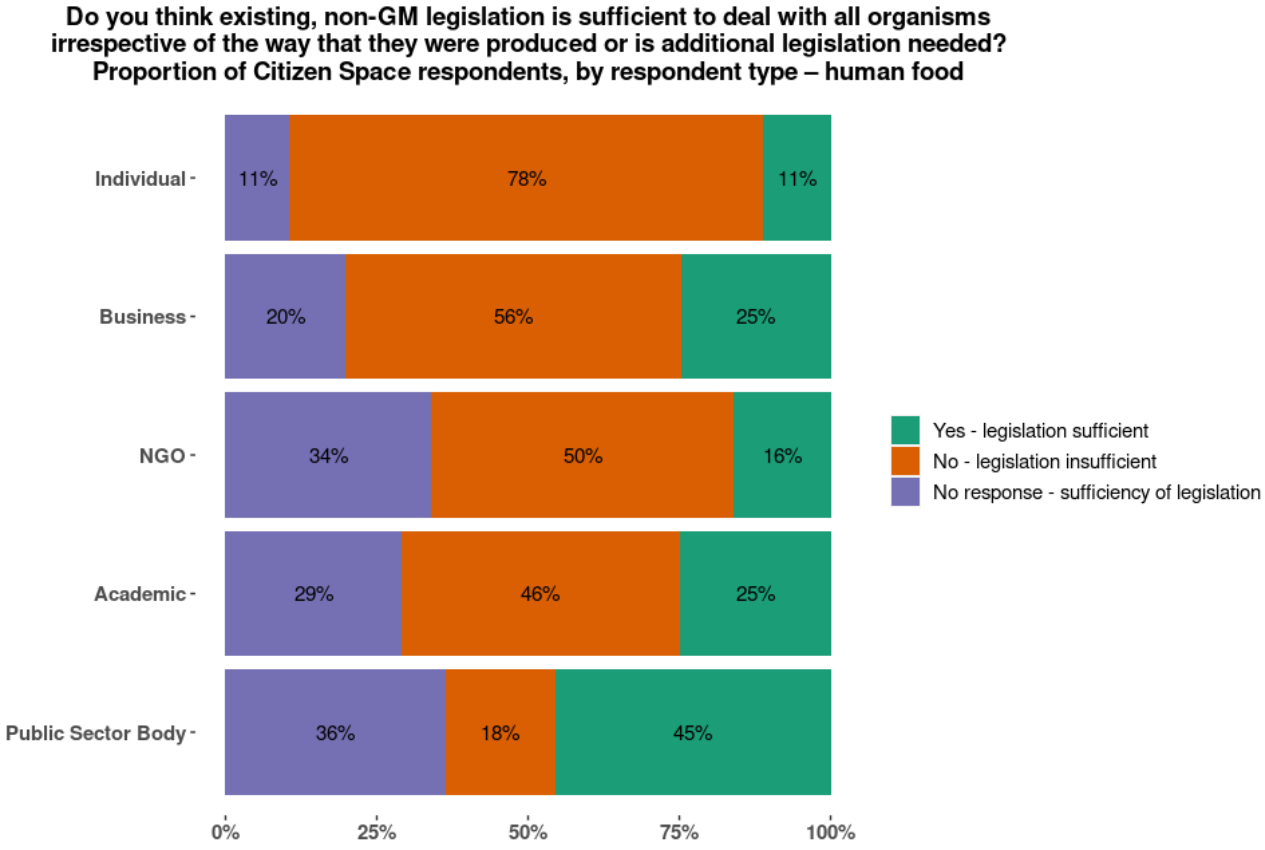

Figure 8. Sufficiency of existing legislation for (c) human food (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description

A stacked bar chart showing how Citizen Space respondents answered the question about sufficiency of existing legislation for **human food**. For **individuals**, 11% did not answer the question, 78% said existing legislation was insufficient, and 11% said existing legislation was sufficient. For **businesses**, 20% did not answer the question, 56% said existing legislation was insufficient, and 25% said existing legislation was sufficient. For **NGOs**, 34% did not answer the question, 50% said existing legislation was insufficient, and 16% said existing legislation was sufficient. For **academia**, 29% did not answer the question, 46% said existing legislation was insufficient, and 25% said existing legislation was sufficient. For **public sector bodies**, 36% did not answer the question, 18% said existing legislation was insufficient, and 45% said existing legislation was sufficient.

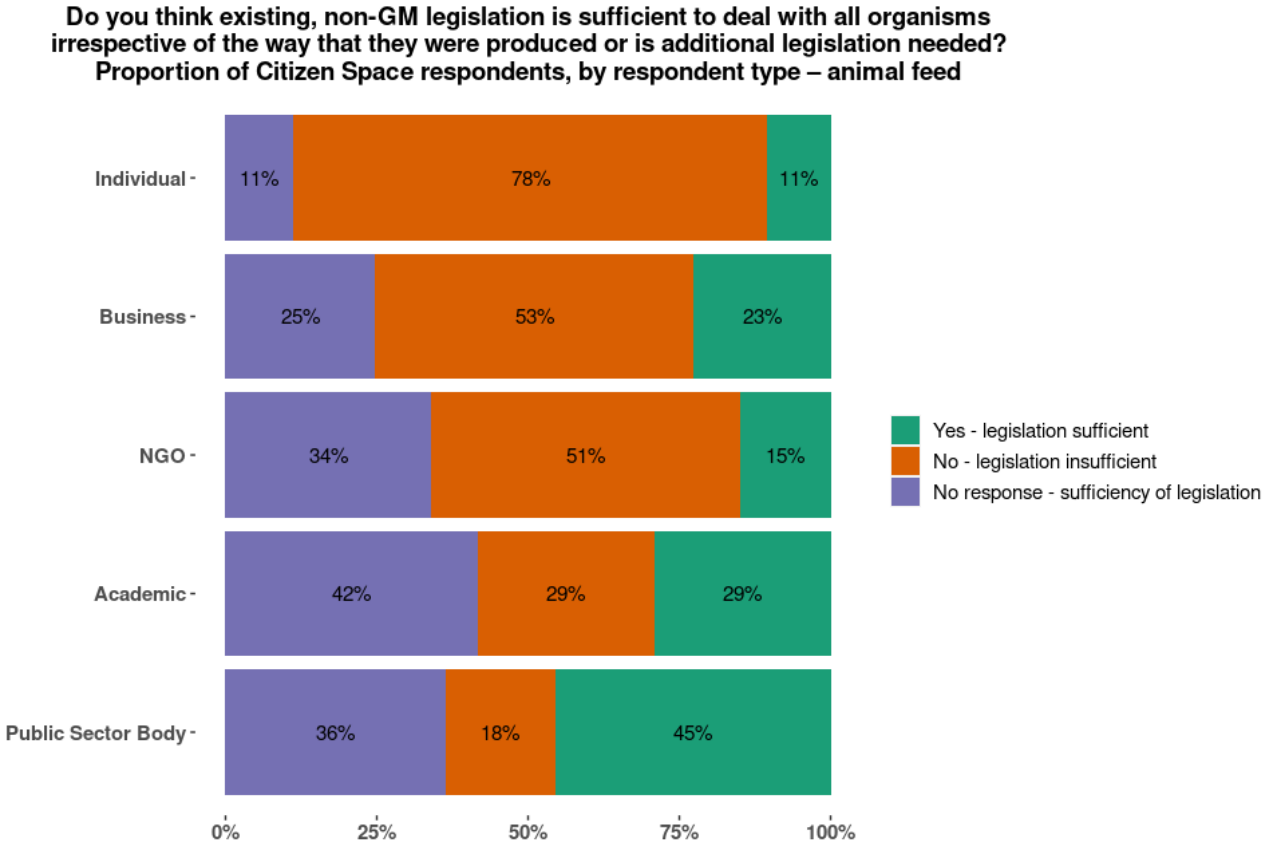

Figure 9. Sufficiency of existing legislation for (d) animal feed (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description

A stacked bar chart showing how Citizen Space respondents answered the question about sufficiency of existing legislation for **animal feed**. For **individuals**, 11% did not answer the question, 78% said existing legislation was insufficient, and 11% said existing legislation was sufficient. For **businesses**, 25% did not answer the question, 53% said existing legislation was insufficient, and 23% said existing legislation was sufficient. For **NGOs**, 34% did not answer the question, 51% said existing legislation was insufficient, and 15% said existing legislation was sufficient. For **academia**, 42% did not answer the question, 29% said existing legislation was insufficient, and 29% said existing legislation was sufficient. For **public sector bodies**, 36% did not answer the question, 18% said existing legislation was insufficient, and 45% said existing legislation was sufficient.

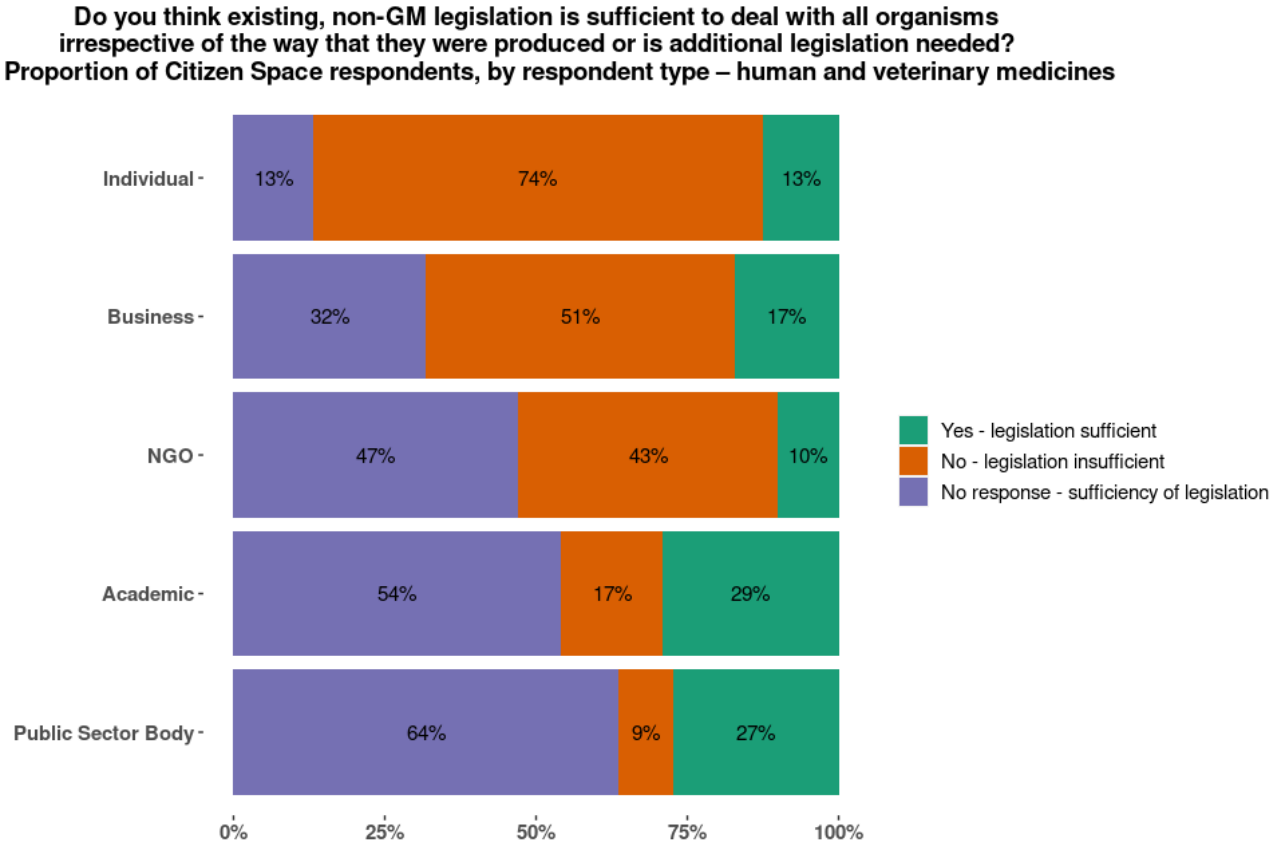

Figure 10. Sufficiency of existing legislation for (e) human and veterinary medicines (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description

A stacked bar chart showing how Citizen Space respondents answered the question about sufficiency of existing legislation for **human and veterinary medicines**. For **individuals**, 13% did not answer the question, 74% said existing legislation was insufficient, and 13% said existing legislation was sufficient. For **businesses**, 32% did not answer the question, 51% said existing legislation was insufficient, and 17% said existing legislation was sufficient. For **NGOs**, 47% did not answer the question, 43% said existing legislation was insufficient, and 10% said existing legislation was sufficient. For **academia**, 54% did not answer the question, 17% said existing legislation was insufficient, and 29% said existing legislation was sufficient. For **public sector bodies**, 64% did not answer the question, 9% said existing legislation was insufficient, and 27% said existing legislation was sufficient.

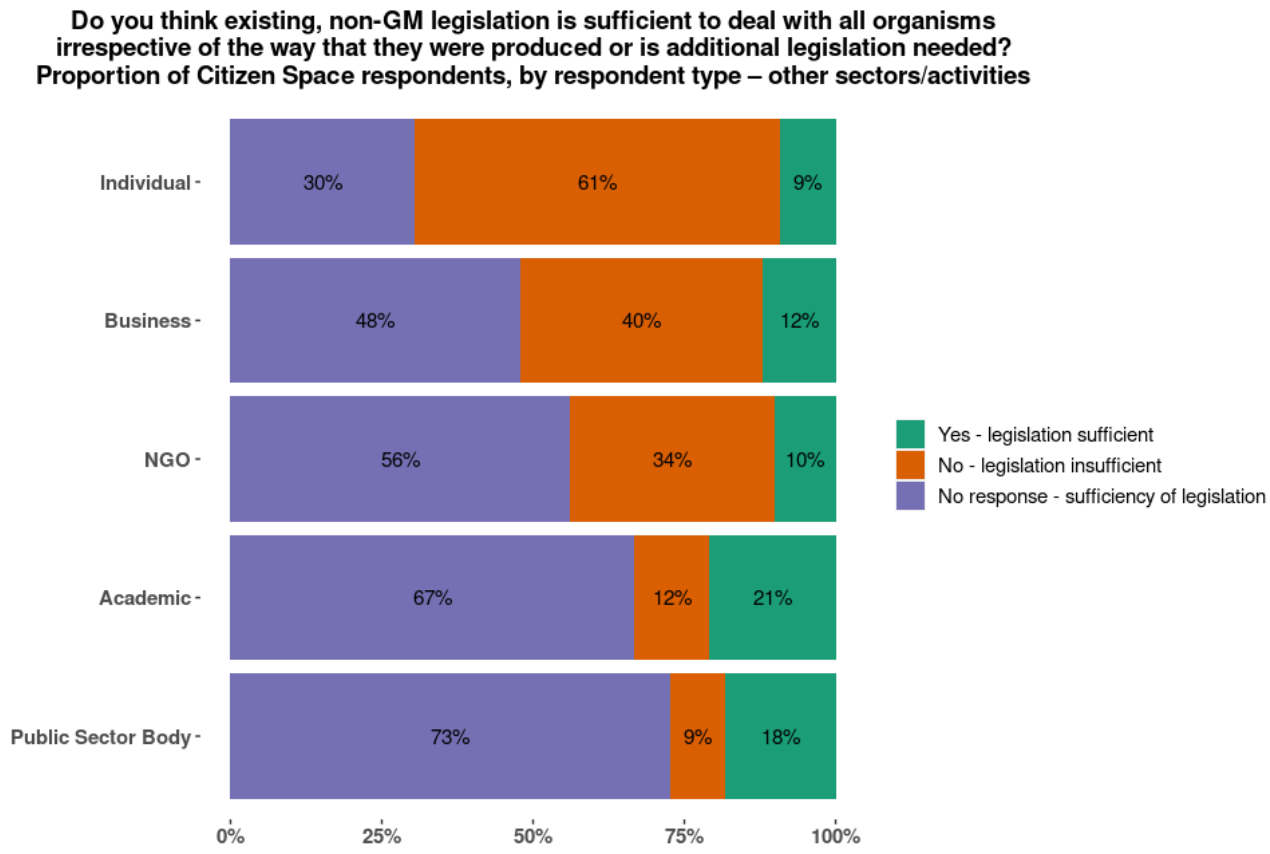

Figure 11. Sufficiency of existing legislation for (f) other sectors / activities (Citizen Space responses only, n = 3083. Individuals = 2750; business = 198; non-governmental organisation = 100; academia = 24; public sector body = 11).

Chart description

A stacked bar chart showing how Citizen Space respondents answered the question about sufficiency of existing legislation for **other sectors / activities**. For **individuals**, 30% did not answer the question, 61% said existing legislation was insufficient, and 9% said existing legislation was sufficient. For **businesses**, 48% did not answer the question, 40% said existing legislation was insufficient, and 12% said existing legislation was sufficient. For **NGOs**, 56% did not answer the question, 34% said existing legislation was insufficient, and 10% said existing legislation was sufficient. For **academia**, 67% did not answer the question, 12% said existing legislation was insufficient, and 21% said existing legislation was sufficient. For **public sector bodies**, 73% did not answer the question, 9% said existing legislation was insufficient, and 18% said existing legislation was sufficient.

5.2 Question 5b

Question wording:

> *Please provide evidence to support your response.*
>
> *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*

There was a large amount of overlap across the two open questions, therefore the responses for both questions have been reported together. Just over a quarter of Citizen Space respondents did not answer these questions.

Summary of key themes

- Respondents suggested a review of existing legislation to help understand whether it is sufficient to regulate all organisms. Some specific examples were provided about where legislation was deemed sufficient and insufficient.
- Views varied about what level of regulatory measures are appropriate for GMOs.
- A range of ideas was provided about developing the regulations, such as incorporating views from a wide range of stakeholders, considering social, ethical and economic factors, and ensuring transparency.
- On the question about regulatory triggers, views again varied, but suggestions included legislation being triggered by some kinds of GM (but not all), by any form of GM, and decided on a case-by-case basis.

5.2.1 Individuals and Businesses

Views held by individuals and businesses were largely similar, and therefore have been grouped together.

Regarding what regulatory measures are required, many respondents suggested strengthening current regulations governing GMOs, however a smaller number said regulations should be kept the same. Some businesses supported a scientifically sound regulatory approach that is proportionate to the risk, and others suggested a review of existing legislation to identify regulatory gaps.

Many respondents wanted accountability and transparency over regulation of GMOs (including labelling to distinguish GM and non-GM products), and a consideration of social, ethical and economic factors in deciding the appropriate long-term regulatory approach. Individuals and businesses also suggested engaging with the public to better incorporate their views in regulation (e.g. using citizen panels). A few respondents suggested

consumer choice was important for any future regulatory approach. Concerns were also raised about corporate power, including the ownership and control of genetic technologies by private companies, and a concern about the relationship between large businesses and government. A few respondents stated there are vested interests in regulatory decisions about GMOs. Intellectual property arrangements were also noted, with respondents describing potential impacts patents may have on the food supply chain.

Regarding how regulations might be triggered, the most common idea suggested by Individuals and businesses was a case by case assessment of applications of GM (with input from experts) to decide the appropriate approach. This suggestion was also made by some business and NGO respondents.

5.2.2 Non-governmental organisations (NGO)

Similar to businesses, NGOs supported a review of existing legislation to identify regulatory gaps.

Regarding the regulatory measures that are required, views were mixed about whether this should be stronger or less restrictive than current regulations. There was also no consensus on whether regulations should be process-based (i.e. dependent on how an organism has been produced) or product-based (i.e. dependent on the characteristics of an organism). NGOs suggested points to help shape the regulatory approach that were also shared by some individual and business respondents, including accountability and transparency, engaging the public, incorporating social, ethical and economic factors into the regulatory approach, and also some concerns over corporate power and intellectual property. Some NGOs also suggested future GMO regulations should protect non-GM and organic food production. A few NGOs suggested domestic GM regulations should be aligned with other countries or regions internationally.

On the question relating to triggers, two points were raised by some NGOs, firstly the case by case risk assessment including expert input (the same as some individuals and businesses), and secondly, that additional legislation should be triggered by some genetic technologies but not all.

5.2.3 Academics and Public sector bodies

Similar to businesses and NGOs, academics and public sector bodies suggested a review of the regulations.

With regards to what regulatory measures are required, the most common view was support for product-based regulations. There was a broad range of views amongst both groups covering points also noted by individuals, NGOs and businesses.

On the question of how additional legislation should be triggered, a few academic and public sector body respondents raised the same two points as NGOs.

5.2.4 Campaign

Campaign responses viewed existing non-GM legislation as insufficient to deal with all organisms.

On the regulatory measures required, responses stated process-based regulation was appropriate for organisms produced by any form of genetic engineering. Current regulations were seen as a good starting point, however, there were concerns over the existing regulatory framework including a view that it lacks sufficient transparency. Another concern was the current approach places too great a focus on the views of scientific experts when determining the regulatory approach for genetic technologies. To address this, responses suggest including views from a more diverse range of people such as the public and farmers. In addition to social factors, responses suggested considering ethical factors, including in relation to animal welfare. Responses also raised a more fundamental point that clearer justification is required for the use of genetic technologies. Responses made several recommendations for regulations, including long-term safety assessments (to check for unintended effects), post-release monitoring, the opportunity for ‘recall’ of organisms, and labelling. Responses suggested future regulatory measures should clearly take account of potential economic impacts of genetic technologies, including in relation to intellectual property and the food supply chain. Lastly, responses raised a concern about how to consider differing approaches to regulation of genetic technologies between the devolved nations.

On the question of how regulatory measures might be triggered, campaigns were consistent in stating that the trigger for regulation should be any form of genetic engineering.

Annex

Campaign responses

Background

This section provides further details about the campaign responses received and the organisations.

Campaign responses were received via Citizen Space, by email and post. Most campaign responses were submitted by respondents who identified as individuals. Some respondents who identified as businesses and NGOs also submitted campaign responses.

Campaign responses were received by the following organisations:

- Beyond GM
- GM Freeze
- GM Watch
- Landworkers' Alliance
- RSPCA (Royal Society for the Protection of Animals)
- Soil Association

Some of the campaign responses were clearly related to a single organisation. Other campaign responses shared text, for example Beyond GM and GM Freeze developed text which provided advice about how to response, with support from GM Watch, Logos Environmental and EcoNexus[3]. For this reason, content within these campaigns has been considered and reported on together.

Views of each campaign response

A summary of some of the key points made by each of the identified campaigns is provided below (this is not an exhaustive list). In addition, specific points relevant to each of the consultation questions are presented in the main summary.

All campaign responses described below shared the view that organisms produced using genetic technologies should continue to be regulated as genetically modified organisms.

RSPCA (Royal Society for the Prevention of Cruelty to Animals; approx. number of responses: 2732)

These responses focussed on part 1 of the consultation. The responses expressed concern over the use of gene editing techniques on farmed animals. Specific concerns related to unintended effects of genetic technologies on animals, and a lack of knowledge

[3] https://www.gmfreeze.org/gene-editing-consultation/ (accessed 18/05/2021)

around medium- and long-term effects of genetic technologies. Responses stated alternative approaches are available to improve animal health and welfare, and wider environmental and food supply aims. Reponses stated an Animal Welfare Impact Assessment should be undertaken before applying gene editing technologies.

In addition to points about animal welfare, concerns were raised around areas including consumer choice, devolution and trade. Responses stated consumer choice (and confidence) could be compromised if products produced using genetic technologies were not labelled as such. Responses raised concerns over potentially different regulatory approaches being supported within the UK nations, and the potential impacts on trade.

Beyond GM and GM Freeze (with support from GM Watch, Logos Environmental and EcoNexus, approx. number of responses: 604)

There was some overlap in material provided between Beyond GM, GM Freeze, GM Watch, Logos Environmental and EcoNexus, therefore the points relating to campaign responses from these organisations are presented together.

For part 1 of the consultation, these responses supported process-based regulation of organisms produced using genetic technologies, and specifically support the ruling of the European Court of Justice in 2018 resulting in regulation of gene edited organisms as GMOs. Responses raised concerns around the use of gene editing techniques on both plants and animals. These included the potential for unexpected / accidental errors created by gene editing. Responses also stated that altered genes may spread from cultivated varieties into wild relatives, which could present risks to the wider environment. For animals, responses raised two broad concerns about animal welfare. Firstly, these related to potential physiological pressures from traits introduced by gene editing. Secondly, introducing traits such as disease resistance into animals was stated as leading to animal being kept in less hygienic and more crowded conditions. Process-based regulation was seen to provide a ‘safety-net’ for new technologies. Responses also commented on the justification for gene-editing organisms, stating food systems challenges are complex and would not be solved by genetic technologies, but instead require wider system change.

Concerns were also raised about consumer confidence, coexistence and trade. For consumers, responses described consumer opposition to foods developed using genetic engineering. Connected to this, responses raised concerns over how gene-edited and non-gene-edited organisms could be kept separate within the food supply chain. Responses suggested transparency (e.g. a public register of gene-edited events), audit and labelling to support effective coexistence. For trade, responses stated there could be trade challenges within the UK nations (connected to the Internal Market Act), and with other regions such as the European Union if differing approaches were taken for the regulation of organisms developed using gene editing. These responses suggested the use of a scientific approach to determine whether an organism produced using genetic technologies was the same as produced via traditional breeding. However, responses also suggested social and ethical criteria inform the regulatory and decision-making processes.

For part 2, these responses saw existing non-GM legislation as insufficient to deal with all organisms. Specific points raised included concerns over the transparency of regulatory decisions, and a deficit in considering views from wider society. General points stated by responses included a requirement for an independent justification for the use of proposed novel organisms, an assessment of commercial impacts (including connected to intellectual property), long-term safety assessments and monitoring, consumer labelling, and the involvement of citizen panels in assessment and approval.

Soil Association (approx. number of responses: 299)

For part 1, these responses noted risks to human health and the environment posed by genetic engineering. Whilst these responses stated gene editing is more targeted than GM techniques, gene editing was not seen as precise or predictable. Responses supported a wider assessment of food system problems and comparison of all options for addressing, not just genetic technologies. Questions posed in these responses related to topics including potential corporate control and intellectual property arrangements, and potential trade-offs between animal welfare and increased productivity. Three points relating to trade were stated, firstly a request to understand how organic and non-GM businesses would be protected (and how consumers would know whether foods include gene edited organisms). Secondly, responses asked about trade with regions that have different rules (e.g. Europe). Lastly, responses asked how regulatory change would take into account views across the UK devolved nations. Responses called for further public engagement, including democratising innovation to ensure ordinary people have a say, and a proper assessment of social, ethical and economic risks.

Landworkers' Alliance (approx. number of responses: 267)

These responses support process-based regulation and specifically referred to the European Court of Justice ruling in 2018. Regulation was stated to provide protection against environmental and health risks. A wide range of concerns were raised. These included consumer, market, trade, environment and welfare issues. For consumers, responses stated a concern that gene-edited products would not be labelled as such. Market concerns raised included the impact of intellectual property agreements, if they infringe on farmers' rights to save seed. Market concentration was another concern, if there is dependency on a small number of seed suppliers and potential price increases. Responses supported open pollinated seed varieties, small seed firms, and on-farm seed saving. Another market issue stated by these responses was a concern about how farmers (e.g. organic) who do not want to use gene-edited material will be protected, and associated labelling costs required to support this. Trade concerns were raised, firstly relating to access to the European market, and secondly potential issues within the UK connected to the Internal Market Act.

Responses talked about the justification of gene edited organisms. Responses stated that gene-edited organisms may potentially increase the use of agro-chemical inputs. Animal welfare concerns were mentioned, and more broadly the rationale for introducing gene editing. Responses supported food sovereignty principles and agroecological farming techniques as a solution to food system challenges, rather than gene-editing. Lastly, and

similar to some other campaign responses, responses supported a stronger inclusion of social factors in GMO legislation, and including views from a range of people (such as farmers and wider society) in addition to scientific experts.

Consultation questions

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]