Filling in the Blanks: What Defra Didn't Say

An Alternative Analysis of the UK Government's Consultation on the Regulation of Genetic Technologies

A BIGGER CONVERSATION

Opening up the dialogue on food, farming & genetic engineering

FILLING IN THE BLANKS: WHAT DEFRA DIDN'T SAY

An Alternative Analysis of the UK Government's Consultation on the Regulation of Genetic Technologies

A Bigger Conversation, January 2021

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EXECUTIVE SUMMARY

On 7 January 2021 Defra Minister, George Eustice, launched a 10-week consultation on the regulation of genetic technologies in the post-Brexit era.

In doing so, Eustice, perhaps unwittingly, began a process where UK governments and regulatory agencies have to confront – for the first time in many years, possibly ever – the real complexity of the multitude of issues around the regulation of genetic technologies in agriculture.

There is no question that the government's deregulatory agenda is largely supported by the UK research establishment. Even so, Defra has probably been surprised by some of the consultation responses from that quarter.

Just a cursory look reveals unexpected synergies between so-called 'pro-' and 'anti-' factions. A more considered assessment uncovers an across-the-spectrum disquiet about the definitions, framing, inconsistencies and sketchiness of Defra's proposed approach.

Such synergies call into question its conclusions and the government's decision to proceed as quickly as possible with the deregulation of gene-edited organisms.

The consultation received 6440 responses. Defra has indicated it will not make responses to the consultation available for public scrutiny. Given the controversies around the consultation, we believe this decision is unwise and is not in the public interest.

Unusually, it has also not published a list of respondents from public sector, academia, businesses and NGOs.

Not only does this lack of transparency avoid scrutiny of what appears to be Defra's prejudicial treatment of the consultation and public opinion, it also hides the extent of concern over the lack of clarity and coherence of the deregulation proposals. It also fails to support the development of an informed and open public discourse about a technology which claims to be 'disruptive' and 'transformative' and which, therefore, ought to be more fully discussed and debated.

For these reasons, we undertook a review of publicly available responses to the Defra consultation, as well as a handful of 'offline' responses sent to us in confidence. From these, we have produced this short report which fills in some of the blanks in Defra's token analysis and highlights some notable, even surprising, findings.

Ignoring the weight of public opinion

The official Defra report was based on an analysis of 3083 responses (equivalent to 48% of the total responders received) submitted via the Citizen Space platform.

Reporting on the consultation responses Defra said: "*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."

But, stated this way, these figures are disingenuous. Public sector bodies and academic institutions, for instance, made up only around 1% of the responses. Defra says each response was treated equally (i.e., not weighted) but given its decision to press ahead with deregulation, these minority views, which support the government's plans, as stated prior to the consultation, do appear to have carried disproportionate weight.

Just as troubling, was the decision to remove more than half (3357 out of 6440) of responses from the formal analysis of responses. These responses were what Defra called 'campaign' responses. Most (3347) were submitted by email rather than the Citizen Space platform (the remainder being submitted by post).

These 'campaign' responses – defined as "based on a standard template or 'stock response' provided by the campaign organiser, and then submitted via Citizen Space, email or post" – were identified as coming from the supporters of six civil society groups and were reviewed in an appendix of a separate Defra report summarising consultation responses.

Removing standard responses is not an uncommon practice, but there's a lot to question about it – most importantly the assumption that members of the public who have used a template are not expressing genuinely held opinions and concerns. Further, there was nothing on the consultation website or in the documentation provided to alert potential respondents to the fact that if they submitted an email response, or a template response, it would not be 'counted' in the final analysis.

Importantly, even with the culling of 'campaign' responses, the raw numbers of the consultation were clear: 85% of the responses included in Defra's analysis indicated no support for the government's deregulation agenda (for more on this see *1 - A Process Fraught with Problems*).

Views are nuanced not monolithic

We were interested in the contrasts between different respondents but were especially keen to identify areas of agreement between the 'sides' of the GM debate. What we found was that these sides are not nearly as clear cut as many assume.

Indeed, we are aware of the inadequacy of using the shorthand 'pro-' and 'anti-', as we have done throughout this report, given our finding that responses to the consultation were not all monolithic. Indeed, whilst expressing support for, or opposition to, the deregulation of gene editing in agriculture, many of the submissions are thoughtful, qualified and nuanced.

We were interested in the contrasts between different respondents but were especially keen to identify areas of agreement between the 'sides' of the GM debate. What we found was that these sides are not nearly as clear cut as many assume.

Take, for instance, the question of deregulation. Whilst most of the pro- responses expressed a belief that gene editing is a safe technology, those calling for complete deregulation were in a minority. Rothamsted Research, for example, argues, "*It is entirely appropriate that formal regulations are drawn up to cover the development of new technologies*."

Most pro- submissions expressed a desire for some kind of regulation and for a clear and accepted legal definition of gene editing moving forward. Many, on both sides of the ideological divide, suggested a 'case-by-case' assessment.

The British Veterinary Association, which might be expected to take a fairly pro-government view, found itself aligned with Unite the Union and the majority of anti- voices in asserting that it "*strongly supports retained EU law which requires that all gene-edited organisms are classified as genetically modified organisms*".

It continues: "*As gene-editing is still a relatively new process we consider that the risks are currently difficult to quantify, which is why it is essential that regulation and transparent reporting of data continues such that an evidence base can be built. If gene-editing is deregulated then the opportunity to gather data, continually improve on techniques, and achieve better outcomes, will be lost.*"

Widespread criticism of Defra's framing of gene editing

Throughout the consultation document and accompanying statements, Defra refers to gene editing events that "*could have occurred naturally or through traditional breeding*".

However, at no point did Defra Ministers, officials, the Chief Scientist or the consultation materials define what was meant by that in scientific, legal or regulatory terms.

Groups and individuals that question the government's enthusiasm for genetically engineered plants and animals, as might be expected, objected to this framing. But even organisations more favourably inclined towards genetic technologies made compelling criticisms.

The Institute of Food Science & Technology (IFST), for instance, called it "*overly simplistic*"; the Microbiology Society said it was "*purely philosophical*"; the Nuffield Council on Bioethics was "*not convinced that this is either the most proper or most popular framing*"; while the Roslin Institute found it "*exceptionally challenging*".

Defra refers to gene editing events that "could have occurred naturally or through traditional breeding". However, at no point did Defra Ministers, officials, the Chief Scientist or the consultation materials define what was meant by that in scientific, legal or regulatory terms.

The British Veterinary Association refers to it variously as "*fundamentally flawed*" and "*leading, misleading, poorly defined, and likely driven by industry*". The Universities Federation for Animal Welfare (UFAW) suggests: "*The use of traditional breeding methods as a benchmark for what is and what is not acceptable is neither useful, nor scientifically logical*".

The Royal Society calls it "*problematic*" and expands on how rare this phenomenon is; the Royal Society of Biology said it provided "*no clear criteria*" and further noted that "*No clarity can be achieved using this principle" and "we would not recommend using it as the basis for regulation*."

Such views – and this is just a selection, for more see *3 - A Key Point of Agreement* – are a damning indictment, from the heart of the scientific and regulatory establishment, of the rationale that underpins Defra's deregulatory proposals.

Unresolved issues around IPR

Respondents from all parts of the spectrum pointed out that Defra's framing of gene editing as something that could "occur naturally" or through "traditional breeding" is not only unworkable but has far reaching implications for intellectual property rights which were not being addressed.

One large environmental think tank points to the essential contradiction between the "could have occurred naturally" narrative and the question of intellectual property, i.e., if gene edited

organisms are the same as what occurs naturally then they can't, by definition, be patented.

Several other NGOs highlight the same essential contradiction. The Royal Society takes the same view, "*If some GE products are not treated as GMOs, then they should enjoy no greater intellectual property protection than the products of traditional breeding technologies such as plant breeders' rights*."

Similarly, the Sainsbury Laboratory argues against the patenting of gene-edited events so that varieties incorporating them can be bred from by all plant breeders.

Filling in the blanks

Reading through the available consultation responses, the only possible conclusion is that Defra has got it wrong. In its handling of the consultation and the responses it has failed the public, it has failed the research establishment and it has failed to exercise good and responsible governance.

Our efforts to redress this by filling in some of the blanks inevitably fall short as we have only been able to analyse a relatively small number of responses.

The points raised throughout this report highlight views that might come as a surprise – perhaps especially to those in politics and the media who perpetuate the narrative that opinions on this issue are less of a discourse and more of a crude guerrilla war of words.

This is simply not the case and the pages that follow provide a fuller picture of the issues and positions of diverse stakeholders. They highlight the pro-, the anti- and the surprising middle ground made up of uncertainty, caution and ambivalence which characterise the ongoing debate around the use of genetic technologies in farming and food.

1 A PROCESS FRAUGHT WITH PROBLEMS

On 7 January 2021 Defra Minister, George Eustice, launched a 10-week consultation on the regulation of genetic technologies in the post-Brexit era.

Eustice used the occasion of his keynote speech[1] at the 2021 Oxford Farming Conference to announce its launch and to ostensibly set out the government's view.

Fair enough. However, Eustice made the mistake of over-hyping his case for gene editing in a way that was fictitious bordering on falsehood:

"*Gene editing has the ability to harness the genetic resources that Mother Nature has provided, in order to tackle the challenges of our age. This includes breeding crops that perform better, reducing costs to farmers and impacts on the environment, and helping us all adapt to the challenges of climate change*.

"*Its potential was blocked by a European Court of Justice ruling in 2018, which is flawed and stifling to scientific progress. Now that we have left the EU, we are free to make coherent policy decisions based on science and evidence. That begins with this consultation.*"

His statement was speculative, inaccurate and unscientific. Exaggeration might be regarded as par for political rhetoric, but Eustice set the tone for his department's consultation document, accompanying materials and its media briefing.

Much of the research establishment quickly rallied behind the consultation. Rothamsted Research[2], the James Hutton Institute[3], NIAB[4], the Agricultural Biotechnology Council[5] and others "welcomed" it. The Science Media Centre published a round-up of comments,[6] the majority of which were positive and unquestioning about the process.

All of this fuelled concerns that the government had a clear agenda for deregulation from the beginning which made the consultation process essentially a tick-box exercise.

This was evident in the scientifically questionable assertions about genome editing in the supporting materials and in media releases[7] quoting both Eustice and Defra's Chief Scientist, Gideon Henderson, as well as in the unusually short time frame (10 weeks) given to complete the process.

The consultation required "*an extremely high level of specialist knowledge, which is not appropriate for a public consultation*," said GMWatch. Anyone without this knowledge – essentially the majority of 'the public' – was faced with a daunting and off-putting set of questions to wade through.

In its submission GeneWatch UK spoke to a further complication, noting that the consultation was launched "*online during a pandemic, when many people who do not have internet connections cannot take part and other people, such as key workers and those who are home schooling, will not have the time. Thus, the Government is proposing major changes to*

the food that people eat in England, and to their environment, at a time when many people cannot have a say."

All of this, inevitably, raises concerns: was Defra asking the right questions of the right people at the right time and in the right way?

Two organisations, The Food Ethics Council and Beyond GM, felt strongly enough about this to make formal complaints to Defra.

The Food Ethics Council proposed two tests[8] that the regulation of genetic technologies consultation needs to pass:

1. Will the (potential) benefits and harms relating to food and farming as a whole have been properly accounted for?

2. Will the ethical case be clear and robust?

It also posed several questions it felt needed addressing to ensure the ethical case for deregulation was both clear and robust.

Beyond GM filed complaints with Defra and the Cabinet Office arguing that the consultation was not being conducted in line with the Cabinet Office Consultation Principles.[9]

It argued that the consultation was not easy for average citizens to understand, that the government should not be consulting on matters on which it had already largely formed a final view and that the background materials provided for respondents did not assist in a balanced understanding of the issues.

Both organisations noted that these issues made it difficult for respondents to respond fully to the questions asked – something that compromised the integrity of the process.

Our informal discussions with other organisations suggest that several also made complaints but chose not to make these public.

These complaints were either ignored or dismissed by the government. However, any reading of the publicly available responses to the consultation shows that many respondents had concerns about the consultation process and the nature of the questions being asked.

Some voices count more than others

In reporting on the consultation responses[10] Defra said:

"*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.*"

But stated this way these figures are disingenuous. Public sector bodies and academic institutions, for instance, made up only around 1% of the responses.

Defra says each response was treated equally (i.e., not weighted), but given its decision to press ahead with deregulation, these minority views do appear to have carried disproportionate weight

Defra says each response was treated equally (i.e., not weighted), but given its decision to press ahead with deregulation, gives the appearance that these minority views, which support the government's plans, as stated prior to the public consultation, were given disproportionate consideration.

The consultation received 6440 responses. Defra has indicated that it will not make these available for public scrutiny. We think this is

a mistake especially since the methodology for analysing responses has been so widely criticised (see 3 - *A Key Point Of Agreement)*.

Just as troubling was the decision to remove more than half (3357 out of 6440) of responses from its formal analysis and consideration of responses. Most of these (3347) were submitted by email rather than the Citizen Space platform (the remainder being submitted by post).

These were deemed to be 'campaign' responses – defined as "*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 identified as coming from the supporters of six civil society groups and were reviewed in an appendix of a separate report,[11] which provided further data on consultation responses. The organisations were:

- Beyond GM
- GM Freeze
- GMWatch
- Landworkers' Alliance
- RSPCA (Royal Society for the Prevention of Cruelty to Animals)
- Soil Association

All of these responses expressed varying degrees of opposition or concern about the proposals to deregulate gene editing and other GMOs.

Defra subsequently told us that it is common in government consultations to remove campaign responses from its formal analyses.

But nowhere on the consultation website, in the published materials or in any statement by Ministers, Defra officials or the Defra Chief Scientist, nor on the Government's information pages about consultations are potential respondents alerted to the fact that if they submitted an email response, or a template response, their views would not be 'counted' in the final analysis.

This is relevant for any type of public consultation and suggests disregard bordering on disrespect for those making the time and effort to engage with the political process.

The prevailing assumption is that respondents who use templates are not putting forward views that matter to them personally. In fact, the opposite is likely to be the case.

Citizens who have thought about the issue and who do have valid views are using templates because they have limited time or inclination to navigate the dense language, poor structuring and prejudicial questions which are often a feature of government consultations.

Moreover, with regard to genetic engineering in farming and food, citizen polls have been remarkably consistent over decades indicating that the public has a range of coherent views about the issue and do wish to be heard.

Whether respondents submitted original compositions or used a template to help organise and express their views seems to be a crude point of differentiation in this age of sophisticated data and text analysis.

It could further be argued that, given the complexity of the consultation, civil society groups that help guide interested and motivated citizens through the process are performing a public service, helping more citizens to engage with an otherwise daunting undertaking.

Interestingly, the consultation also seems to have initiated a high degree of mobilisation amongst researchers and institutions involved in genetic technologies. This is a commendable

engagement in the democratic process, but it is hard to see a clear line between that mobilisation – and the standardised language used in some of these responses – and what Defra calls "campaigns".

Facing up to complexity

With this consultation, Defra has had to confront – perhaps for the first time in many years – the real complexity of the issues around the regulation of genetic technologies in agriculture. This may go some way towards explaining why the consultation report, when it finally appeared, was more than three months overdue.

There is no question that Defra's deregulatory agenda is largely supported by the UK research establishment. Even so, the Department may have been surprised by some of the answers and, indeed, some of the synergies between so-called pro- and anti- factions.

Even with the culling of campaign responses, the raw numbers were clear: 85% of the responses included in Defra's analysis indicated no support for the deregulation agenda being proposed.

Further, a clear-sighted view of the consultation responses reveals not only little enthusiasm for deregulation, but significant opposition to it. Even amongst the pro-gene technology research community there are important concerns and a significant number of respected public interest bodies have expressed doubts and criticisms.

None of this should come as a surprise. These technologies are relatively new, important and potentially very potent. However, along with putative benefits, they pose challenges to society that, although not unprecedented, are rarely taken into consideration.

What is a surprise is that the government has taken the view that this complexity can be swept aside with public relations rhetoric – and that it seems committed to continuing in this manner, despite the insights provided by its consultation.

Our analysis

Given the combination of Defra's tardy and disappointing analysis and its decision not to publish the list of public sector respondents or to make available all the responses to the consultation, we undertook to do our own review of publicly available responses and a handful of 'offline' responses sent to us.

In all, we looked at 54 responses (33 anti- and 21 pro-) comprising more than 400 pages of text.

The areas where different sides conflict is a fairly well-worn path, so we were particularly interested in areas of agreement between the 'sides' of the GM debate.

With this consultation, Defra has had to confront – perhaps for the first time in many years – the real complexity of the issues around the regulation of genetic technologies in agriculture.

Our work has shown that these sides are not nearly as clear-cut as many assume. Indeed, we are aware of the inadequacy of using the shorthand pro- and anti- throughout this report to indicate different 'sides'.

Responses to the consultation were a broad church both in terms of the views expressed and in the format in which different groups responded. Many respondents chose not to use the Citizen Space platform but to submit their own responses via email. This made analysis challenging for us, as it surely did for Defra.

There are some areas in which the various 'sides' are still very far apart.

But rather than highlight every small area of agreement or disagreement, we were looking for

larger themes and at areas that our own multi-stakeholder discussions have taught us might be fruitful points of agreement.

We therefore began with a general overview that asked whether the respondent:

- Supported regulation of some kind
- Had concerns/complaints about the consultation process or framing
- Indicated or acknowledged uncertainty/gaps in the data
- Mentioned coexistence
- Mentioned alternative agricultural approaches to gene editing, e.g., agroecology
- Recognised factors other than risk/safety (e.g., values, culture, ethics and animal welfare)
- Acknowledged consumer preference

The Bigger Conversation programme has revealed that while some issues remain highly polarised, in these areas the sides of the debate are 'fuzzier' than ever.

Whether this is an indication of more productive engagement to come or an anomaly remains to be seen.

2 DUELLING NARRATIVES

Analysis of the different responses to the Defra consultation is reminiscent of the parable of the 'blind men and the elephant'. Examining the text, it is sometimes hard to make out the elephant of gene editing: the pro- and anti-voices appear to be talking about completely different technologies.

This is especially challenging when faced with opposing views of the safety, potential and even the definition of the technology.

The fact that those in favour and those opposed to agricultural genetic engineering – both old and new techniques – cannot seem to agree on the consequences of its use in plant breeding and food production, its necessity and its wider socioeconomic implications, has long been recognised in the agricultural genetic engineering debate.

Of course, different interest groups will perceive gene editing differently and emphasise different aspects that are of particular concern to them.

But reading these responses puts this observation in particularly sharp relief and may in part explain why the Defra analysts took quite so long to release what was in the end a short – almost perfunctory – final report on the consultation responses.

The divergence is most acute when comparing considerations of coexistence, as well as responses to the question of whether gene editing poses a threat to the environment.

Organisations representing organic farming will, for instance, express significant concern about 'coexistence' between crops that are genetically engineered and those which are organic. For scientists working mostly in the laboratory, however, this issue is a minor concern.

While coexistence emerged as a concern for some, no concrete proposals were put forward (by either side) for how to manage it. Instead, the views could be summed up as 'the supply chain will adapt' or 'the market will sort it out'.

A more pressing concern for developers was to get their gene-edited products into UK markets, the markets of our trading partners and, as well, into the hands of those they believe need their help i.e., farmers struggling with pests, diseases and falling yields, as well as those affected by malnutrition.

In the rush to market few expressed concerns about environmental risks. The Sainsbury Laboratory states, without references, "*There is no plausible and scientifically validated mechanism by which use of the methods per se could confer elevated risk of harm*".

Such blanket statements were common from developers.

Submissions by groups such as the Science Policy Research Unit at Sussex University {SPRU), GeneWatch UK, Econexus, GMWatch, GM Freeze, on the other hand, include pages of scientific references that give cause for concern about

the environmental impacts of gene editing technologies as well as detailing mechanisms by which harms could occur.

Inevitably, several pro- voices will question the scientific credibility of many of those references and the conclusions drawn from them. This long-standing war of the references is an ongoing theme, which not only did the consultation and subsequent analysis fail to address, but further embedded.

Divergence is most acute when comparing considerations of co-existence, as well as responses to the question of whether gene editing poses a threat to the environment.

For example, several anti- voices highlight Recombinetics' hornless cattle which were found to be carrying bacterial DNA and genes that confer resistance to antibiotics, as a salutary tale about unintended consequences of the gene editing process and necessary regulation.

Pro- voices, while not mentioning the Recombinetics case specifically, state that any unintended consequences of the gene editing process, such as the acquisition of stray 'foreign' DNA, would, naturally, be picked up in the laboratory stage, making this a non-issue.

Except in the Recombinetics case, this didn't happen. The anomaly was only picked up by FDA regulators – a fact that would seem to strengthen the case for robust regulation.

That said, many of the respondents at least attempted to look at other parts of the elephant and even to put the elephant in context.

For example, some of the anti- submissions pointed out that there may be a place for properly regulated genetic technologies as part of the necessary overhaul of the global industrial food system, while highlighting that it's not a 'silver bullet' solution or a priority for funding.

Several of the pro- submissions also acknowledge that gene editing is not a 'silver bullet' solution to 'global challenges'.

The Agricultural Industries Confederation (AIC) expresses this view, but also adds that it cannot overlook "*possible opportunities*".

The National Farmers Union (NFU) explicitly states up front that gene editing is no silver bullet, but then goes on to make several silver bullet-like assertions about its role in reducing farming's carbon footprint, responding to the climate emergency and improving food security and resilience and benefiting the health and welfare of livestock.

Agreement that gene editing is not a silver bullet solution to agriculture's problems isn't much of a stretch for either 'side'. The metaphor is a hackneyed, shallow soundbite unsupported by science.

More difficult is to find agreement on what kind of agriculture we need to meet future food system challenges.

Few of the pro- submissions challenge the current model of agriculture and none acknowledge its role in creating many of the problems associated with modern agriculture.

The consultation form did not provide an obvious space in which to discuss this, but several of the anti- submissions did attempt to address it.

In many ways, this is the conflict at the core of the duelling narratives; a conflict around a degree of willingness to accept the current industrial food and farming systems and their role within a globally competitive economic

environment. Risk and benefit evaluation of technology will always come down to where you are on that spectrum of willingness.

Failure to recognise each other's concerns

One of our analysts for this report commented that reading these responses brought back memories of work as a facilitator in 'dual narratives' around the Israel-Palestine conflict – and especially the failure for each side to recognise the others' concerns and grievances.

For example, none of the anti- responses acknowledge the often sincere concerns about sustainability or the frustration that scientists must feel spending years working on research projects they feel passionate about, that may never be commercialised or which, they feel, are unfairly demonised.

On the other hand, those supportive of agricultural genetic technologies, for the most part, belittle or ignore concerns that anti- voices express about the way in which genetic engineering technologies are being pushed into agriculture, while neglecting evidence that questions their disruptive nature and the appropriateness and safety of the technology.

To give another example, several of the pro- responses express a sense of grievance and unfairness about the 2018 European Court of Justice decision that gene editing should be regulated in the same way as GMOs whilst chemical/radiation mutagenesis, which the ECJ recognises is a GMO method, has been exempted from the requirements of the GMO regulations.

Not only does the anti- side fail to recognise what may actually be a legitimate grievance, but some argue that Defra's conflation of chemical/radiation mutagenesis with 'traditional breeding methods' is strategic rather than scientific and allows the government and others to misleadingly argue that traditional breeding is necessarily a process of high-tech interventions which are not, or do not need to be, regulated. This too reflects a sense of grievance.

Both sides have a long history of presenting themselves as victims unfairly targeted by the other – and both sides raise concerns about the ideological biases of the other.

Antis generally believe their opposite numbers are only after money, markets and power while pros generally believe that 'antis' are irrationally afraid of technology and progress and misunderstand or ignore scientific evidence.

In its submission, the National Farmers Union (NFU), for instance, goes so far as to accuse the animal welfare charities Compassion in World Farming (CIWF) and the Royal Society for the Prevention of Cruelty to Animals (RSPCA) of being anti-technology (see *7 – What's Best for Animals?*).

None of the other submissions we read so pointedly criticise fellow stakeholders.

In many ways this is the core conflict at the heart of the duelling narratives; a conflict around a degree of willingness to accept the current industrial food and farming systems and their role within a globally competitive economic environment.

It is not our part to go into the whys, wherefores and justifications here, other than to note that unless individuals and organisations rise above their sense of grievance against the other, discourse in the public interest is not possible.

What is more, for this to happen, Defra, and the government as a whole needs to develop a much more constructive and thoughtful approach to dialogue than it has shown to date.

As yet, we have seen no evidence of a genuine willingness on Defra's part to 'rise above' its own biases. Indeed, its actions in launching the consultation, the nature of the consultation, its briefing materials and its framing of the final reporting– in short, its efforts to 'control the narrative' – seem designed to exacerbate differences rather than address them.

A further illustration of this was the way the consultation report was released, which served to reinforce in-group/out-group silos.

Pro- groups and the media were given an opportunity to see the report ahead of time, and to prepare statements and commentary.[12]

However, our investigations suggest that environmental, animal welfare, food and farming and other civil society groups were sent the media release after the morning press cycle and the report sometime later.

This ensured that few questioning voices were included in press coverage of Defra's announcement that, following the consultation, the government would pursue a deregulation agenda, via a process which includes:

- Use existing powers under the Environmental Protection Act 1990 to change the law in order to make applications for field trials for plants that have been produced by new genetic technologies ("*where the resulting genetic changes could have been developed using traditional breeding methods*") simpler and less costly.

- Amending the current definition of a GMO in English law so that organisms produced by new genetic technologies are not classed as GMOs – again presuming the genetic changes could also have resulted from traditional breeding.

- A longer-term review of how the UK regulates all types of genetically modified organisms in agriculture, with a view to further deregulation.

3 A KEY POINT OF AGREEMENT

Areas of coherence did emerge in the consultation responses, the most important of which were expressed as disappointment ranging towards dismay at Defra's framing of the consultation questions.

Throughout the consultation document Defra refers to gene editing events that "*could have occurred naturally or through traditional breeding*". What is meant by traditional and natural is not defined in the consultation document, on the Citizen Space form or in any of Defra's briefing materials relating to this consultation. Nevertheless, this is the basis on which it proposes to build a deregulatory regime.

Even organisations that are more supportive of gene editing complained about the "could have occurred naturally or through traditional breeding" framing of the document and its questions.

Civil society groups who question the government's enthusiasm for genetically engineered plants and animals, as might be expected, objected to the framing.

One large environmental coalition called it "*potentially misleading*" and "*unproven*"; GMWatch notes the government "*offers no proof that any gene-edited organism has ever been found to be the same as a traditionally bred organism*."

GM Freeze laments that it is left up to respondents to consider what is meant by "*could have been developed using traditional breeding methods*". Beyond GM picks this up too and notes that Defra's position is not scientific and "*is not recognised in any existing markets, either geographically (across the UK, in Europe or beyond) or in certified sectors such as organic*".

Wildlife and Countryside Link suggest there is "*no conclusive evidence*" that organisms created using gene editing could have been achieved through traditional breeding. The Conservative Animal Welfare Foundation found "*no basis*" for Defra's claims, bluntly noting that "*The entire purpose of expanding the use of gene editing in animals is to create animals that do not occur naturally*". The Organic Research Centre says Defra's premise is "*unproven in theory and should not be the basis for changing regulations or removing protections*".

So far, some might argue, so predictable. But even organisations that are more supportive of gene editing complained about the "*could have occurred naturally or through traditional breeding*" framing of the document and its questions.

The coherence in the language used by the two 'sides' is startling.

The Institute of Food Science & Technology (IFST), for instance, called it "*overly simplistic*"; the Microbiology Society said it was "*purely philosophical*"; the Nuffield Council on Bioethics were "*not convinced that this is either the most*

proper or most popular framing"; the Roslin Institute found it "*exceptionally challenging*".

The British Veterinary Association refers to it variously as "*fundamentally flawed*" and "l*eading, misleading, poorly defined, and likely driven by industry*". The Universities Federation for Animal Welfare (UFAW) suggests that: "*the use of traditional breeding methods as a benchmark for what is and what is not acceptable is neither useful, nor scientifically logical*".

The Royal Society called it "*problematic*" and noted how rare this phenomenon is. The Royal Society of Biology said it provided "*no clear criteria"* and further noted that *"no clarity can be achieved using this principle*" and "*we would not recommend using it as the basis for regulation*".

The FSA's Advisory Committee on Novel foods and Processes (ACNFP) said that "*the generic yes/ no answer requested is too simplistic with regards to the science*" and that it is "f*irst necessary to have clarity on what constitutes traditional breeding*". On the question of risk, it notes that it would "*not be possible to say categorically that any modification made via genome editing will present a similar risk to a product from traditional breeding unless it was clearly demonstrated that an equivalent outcome had been achieved*."

These views are a damning indictment of Defra's entire argument and the basis upon which it proposes to deregulate gene edited organisms.

4 ...BUT STILL A BATTLE FOR DEFINITIONS

The Regulatory Horizons Council (RHC) is the only response that succinctly acknowledges that the consultation is, at heart, a battle for definitions. It notes that there are divergent stakeholder *"interests and values"* which mean that some "*strive to ensure that the definition chosen either captures products about which they have negative concerns, or fails to capture products from which they expect commercial, business or societal benefits*."

The way around this, it suggests, is to develop "*a new language*" which will enable "*better guiding regulatory narratives*" that go beyond "*worn out*" distinctions such as product-based versus process-based or gene editing versus genetic modification.

There is certainly merit in developing a common language. However, the RHC does not say who will be in charge of this development. Without equitable input from all sides and agreement from all on what any 'new' terminology means, it will surely be another highly inflammatory exercise, generating far more heat than light.

The last few years has seen the emergence of a multiplicity of names to describe gene editing in an effort to distinguish it from older style GMOs: new plant breeding techniques (NBTs or NPBTs), speed breeding and gene edited organisms (GEOs) or GE, for example.

These have all been criticised as misleading by some and hailed as clarifying by others. At the same time, new descriptive phraseology, alluding to the gene editing process, has come to the fore. This featured quite often in some of the responses from pro- voices with words like 'precise', 'exact', 'targeted' and 'improved' when referring to gene editing.

In response, anti- voices questioned the meaning, value and accuracy of such descriptors, noting that gene editing may be precise but this is not the same as predictable or controllable.

Similarly, submissions referring to 'proportionate' and 'enabling' regulations and aiming to draw a line under past approaches, provoke uncomfortable questions. When the National Farmers Union (NFU) submission says regulation should be "*fit for purpose, transparent, science-based, adaptable, and aligned with international definitions*," it begs the response, fit for whose purpose, based on whose science and adaptable in service of what?

The RHC feels it's all become too complex, stating that "*Capturing all products of genetic technologies (gene editing, synthetic biology, engineering biology) within a regulatory system designed to eliminate those representing the most extreme risks is ... an unnecessarily risk-averse process*." This view underpins its post-consultation recommendations[13] for a proposed shift from the implementation of clear regulations to a more vague 'guidelines and standards' approach.

Notably, however, few submissions support their comprehensive deregulation proposals. Most

expressed a desire for some kind of regulation and for a clear and accepted legal definition of gene editing moving forward.

Rothamsted Research, for example, argues, "*It is entirely appropriate that formal regulations are drawn up to cover the development of new technologies*."

However, it goes on to state that "*It is in our opinion more appropriate to regulate GE crops as non-GMOs on a case-by-case basis using a 'product rather than process-based' legislation. This approach is similar to what has already been adopted by the USA, Canada, Brazil and a number of other countries.*"

It's worth considering also that most new developments in agricultural genetics still employ older style genetic technologies including the use of transgenes.

The NFU, as well as advocating for new "*proportionate*" regulation for gene editing, states that it: "*believes that current GMO legislation is generally suitable for regulating GMOs and the government should continue to use this*".

In other words, older style genetic technologies can continue to be regulated while newer ones can escape regulation.

Natural/not natural

While most of the responses we read rejected the "*could have occurred naturally*" argument, other efforts to create a clear distinction between older-style GMOs and newer gene editing opens hotly debated territory.

The Regulatory Horizons Council argues, for example, that the distinctions between gene editing and GM need to be redefined and that, in its view, gene editing without transgenesis can go in "*the same regulatory bucket*" as products of traditional breeding methods. This emerging definition of a GMO as an organism that contains transgenes (genes from unrelated species) as distinct from a gene-edited organism that is assumed not to contain them, is rapidly gaining ground. The Royal Society of Biology, for instance, refers to "t*ransgenic technology (formerly GM).*"

On this basis, say most pro- voices, gene editing should be exempted from regulation. To do this, however, would require changing the internationally agreed definition of a GMO (upon which so much international regulation is based), which is currently not dependent on the presence of transgenes. Indeed, this is the change that the UK is proposing in its own legislation in order to justify deregulation.

But a further complication is that not all gene editing is created equally. Gene editing can and often does involve transgenes and the majority of 'new' genetically engineered crops being brought to market at the moment utilise older-style GM techniques[14] including transgenesis, in their development.

It could be argued that discussions around gene editing are fraught enough without deliberately introducing unsustainable leaps of logic around the naturalness or otherwise of different genetic technologies.

As the Food Ethics Council states: "I*f an organism has been genetically modified, then quite simply it is a genetically modified organism and should be regulated as such. If regulation were weakened in the way that has been proposed in the consultation, important questions would need to be addressed about where boundaries get drawn as to what constitutes 'could have been produced through traditional breeding' and who gets to decide*."

It's worth considering also that most new developments in agricultural genetics still employ older style genetic technologies

including the use of transgenes. Developers still using these techniques might rightly ask whether this proposed new regulatory process simply sacrifices their work on the altar of the government's 'innovation' drive?

Like much of the consultation, this false distinction between 'natural' gene editing that has not deliberately introduced foreign genes (and which is therefore safe and not requiring regulation), and 'unnatural' transgenesis that has deliberately introduced foreign genes (by association, unsafe and requiring continued regulation) further embeds the scientific and philosophical disagreements between sides.

It portrays one facet of CRISPR technology as a kind of "*genetically modified lite*"[15] and raises inevitable questions such as, how closely related does the source plant have to be to qualify as non-transgenic or able to be produced naturally? Defra and most pro- voices are silent on the answer to this important question.

Do we need a change at all?

Anti- voices, in the main, felt that existing regulations were adequate or might even benefit from strengthening in the face of rapid advances in technology.

Most pointed to existing frameworks and definitions as being science-based, reasonably robust and rooted in the Precautionary Principle, which is a pivotal part of EU law. They argue that the 2018 European Court of Justice (ECJ) ruling – much maligned by pro- voices and the UK government – was the result of a robust two-year review of scientific and legal evidence, which should not be dismissed as mere ideology.

In a diametrically opposed perspective, the Sainsbury Laboratory believes that, "*The Precautionary Principle is based on the possibility that there might be 'unknown bad scenarios that we don't even know we don't know about.' This philosophy is no longer appropriate for the use of a method that has been extant for 38 years, has been used in crops and in the human and animal food chain for 26 years, and that has been used in thousands of labs worldwide for research purposes over the last 35 years. We now know an enormous amount about the use of this method.*"

But agricultural gene editing – which is constantly being framed by pro- voices as 'new', 'innovative' and 'distinct' from GMOs – has not been in use for decades and there, in any case, is still no scientific consensus on the safety of older-style GM.[16]

In stark contrast, and perhaps surprising to some, the British Veterinary Association "*strongly supports retained EU law which requires that all gene-edited organisms are classified as genetically modified organisms*."

It goes on to say that "*As gene-editing is still a relatively new process we consider that the risks are currently difficult to quantify, which is why it is essential that regulation and transparent reporting of data continues such that an evidence base can be built. If gene-editing is deregulated then the opportunity to gather data, continually improve on techniques, and achieve better outcomes, will be lost*."

Again, it seems necessary to say that, given the diverse opinions from across the professional and stakeholder spectrum, it is hard to see how Defra can justifiably continue with its deregulatory agenda in the way it proposes.

5 BIODIVERSITY OR BUSINESS DIVERSITY?

Anti- submissions were mostly sceptical of gene editing proponents' claims of protecting or enhancing biodiversity, working locally with or benefiting farmers. A range of concerns about the impacts on biodiversity from an unfettered roll out of gene editing were expressed.

Nourish Scotland quotes a paper by the FAO that "*explores the worrying decline of the world's biodiversity for food and agriculture, linking this directly to the negative impact of powerful mega-companies and the concentration of power*."

It goes on to express the view that genetically engineered plants disrupt "*the delicate balance of ecosystems and has destroyed regional biodiversity, diminishing natural resilience and causing often unintended damage to regional species. We have witnessed the introduction of GM seeds and breeds introducing monocultures and narrowing global and regional genetic variety. This in itself poses wider long-term risk, especially in the face of climate change*."

Beyond GM suggests that even on-target genetic changes "*could change the way a gene is read and processed into proteins in ways that affect health. The misreading of DNA in a genome-edited plant or animal could also impact biodiversity*."

The Microbiology Society picks up a similar point: "*A potential threat exists if molecular genetic technologies speed up the time to impact on biodiversity, whether crop or farmed animals. Homogeneity in either case could result in increased susceptibility to extensive losses due to infectious disease, for example*," noting that risk assessment should include data on biodiversity impacts.

A few positioned themselves on middle ground. The Royal Society for Plant Breeding, for example, raised concerns about increased pesticide use, eutrophication (if nitrogen fixation is edited in), evolution of super weeds and reducing livestock susceptibility to disease in order to confine them in even smaller spaces.

It is notable that several pro-submissions used the word 'diversity' in relation to business rather than the natural landscape.

It nevertheless states that it is not opposed in principle and felt there was potential "*to help climate adaptation, increase crop diversity, reduce pesticide use and, as mentioned above, potentially in invasive non-native species (INNS) control if appropriately directed and regulated*." Wildlife and Countryside Link expressed a similar position.

Most pro- groups, however, suggest that gene editing will bring biodiversity-enhancing benefits, but fail to provide concrete examples or references to support this view.

The National Farmers Union (NFU) argues that gene editing will benefit the environment "*through increasing biodiversity and reducing climate change*", but offers no data to show how.

Others, including the Agricultural Industries Confederation (AIC), the Country Land and Business Association (CLA), the Royal Society and the Regulatory Horizons Council (RHC) make similarly general declarations of benefit without offering data to back these up.

Corporate control

It is notable that several pro- submissions used the word 'diversity' in relation to business rather than the natural landscape.

It's interesting to juxtapose this with a key concern, primarily of anti- voices, that the technology inevitably becomes concentrated in the hands of a few multinational corporations.

The Landworkers' Alliance, for example, sees deregulation as having an inevitably negative impact on seed patents, farmer's rights, food sovereignty and corporate concentration in the seed industry and across the food chain.

Nourish Scotland agrees, noting that "*This is not only contrary to farmers' human rights, it has also resulted in widespread negative economic impact that has been widely documented… It has also been shown that excessive regulation is not a main barrier for companies entering the gene-editing market. This argument, that is used widely in favour of de-regulation, has no grounds.*"

The Royal Society of Biology's view, however, was typical of those who believed that deregulation could help create and diversify markets, especially where small to medium enterprises (SMEs) were concerned:

"*The UK already lists a number of innovative small and medium enterprises (SMEs) and public research institutions that could develop GE products for locally-adapted and sustainable agricultural projects, both in the UK and in low- and middle-income countries. Unleashing their potential …could encourage SMEs to be set up in resource-poor countries to tackle situations such as local food production problems in orphan crops (especially in centres of origin) which are potentially of no interest to large multinational companies*."

The Institute of Food Science & Technology (IFST) straddles a middle ground, suggesting that an effective regulatory regime must ensure that "*the hurdles to market entry including costs, are comparable to conventional approaches, so that innovators large and small can predict a return on investment and a realistic route to market.*"

The Regulatory Horizons Council notes that, since adapting a regulatory system more favourable to gene editing in 2015 Argentina has attracted a greater diversity of business:

"*Before the regulatory change, 90% of applicants for regulatory approval were from foreign multinational companies and 8% from local companies and public research. In the 4 years following the change, only 9% of applications were from foreign multinationals, 59% were from local companies and public research and 32% from foreign SMEs.*"

The National Farmers Union also cites the Argentina example, suggesting that "*development from 'bench to market' is much quicker, there is a greater diversity of organisations involved and most are SMEs and public research institutes*."

The NFU says its members want to see new genetic breeding technologies available to SMEs and to public sector research organisations, "*to ensure diversity and healthy competition in the market. Affordability and accessibility are therefore essential, so that development is not limited to the largest technology companies*."

Fera Science also argues for business diversity: "*Were gene edited organisms to be removed from the GM regulatory control to fall within the current regulation of traditional breeding, then this would*

enable a greater diversity of businesses to exploit gene editing technologies."

Organic Farmers & Growers (OF&G) has a somewhat different interpretation: "*Although some CRISPR laboratory work begins in SMEs and start-ups, the trends we have seen show that larger businesses will partner with these smaller companies and this often leads to take-overs by larger corporate entities*."

Beyond GM also challenges the business diversity assumption: "*The suggestion that small and medium sized enterprises (SMEs) will benefit from a lower regulatory burden is simply not borne out by the reality of the global marketplace and the way that business is conducted within it*."

SMEs, it notes, do not generally have sufficient resources to gain access to the global market, and "*the best many can hope for is to be bought up by these larger companies in order to recoup investment and make a profit*."

There does seem to be some agreement across the spectrum that putative claims that gene editing can be a force for sustainable development, and for local and regional needs of small as well as large scale farmers, can only be realised if it is not controlled by global corporate interests.

But this is not the current reality and views vary widely as to the extent to which existing regulations, which work in favour of corporate control, could be reversed by a measure of deregulation.

Some expressed the view that the underlying business model of genetic technologies is embedded in global, corporate structures and will remain so, whatever the regulatory architecture. None of the pro- submissions dealt with the finding of research that the patent landscape of CRISPR gene editing technology is overwhelmingly controlled by the agriculture giant Corteva.[17]

Thus, however many small- and medium-sized enterprises develop gene-edited organisms in their research and development programmes, in order to commercialise the products, they will still have to contend with Corteva's near-monopolistic and gatekeeping control of the gene editing patents.

6 THE 'RIGHTS' QUESTION

The corporate control issue is deeply linked to the subject of intellectual property rights, which takes us right back to the question of definitions.

One large environmental think tank raised the essential contradiction between the "*could have occurred naturally*" narrative and the question of intellectual property, i.e., if gene edited organisms are the same as what occurs naturally then they can't, by definition, be patented.

Beyond GM agreed that intellectual property (IP) is relevant to the question of the 'naturalness' of gene-edited organisms, arguing that: "*The fact that organisms created with gene-editing can be patented underscores that they could not have occurred naturally, since patenting requires an 'inventive step' that could not have occurred in nature*."

Deregulation does not free developers from the 'burden' and 'expense' of developing detection methods, since they will still need these in order to protect their IP.

Responses on both pro- and anti- sides were generally in agreement with the thrust of these statements.

The Royal Society argues "*If some GE products are not treated as GMOs, then they should enjoy no greater intellectual property protection than the products of traditional breeding technologies such as plant breeders' rights*."

The Sainsbury Laboratory argues against the patenting of gene-edited events so that varieties incorporating them can be bred from by all plant breeders. This would seemingly prevent corporate control over the technology, which aids in a new public perception of gene editing as being in the public interest. (We could find no evidence, in any of the submissions to indicate whether patent-free gene-edited organisms are even a remote possibility, however).

The National Farmers Union (NFU)U expresses a similar position: "I*t is essential that IP is not a barrier to SMEs and public good breeding, and they have access to the full diversity of germplasm. This is especially important given the immediacy of the climate change emergency and nutritional health challenges that could be mitigated through genetic improvement.*"

SPRU – the Science Policy Research Unit at Sussex University – notes that "*traceability is pertinent to the enforcement of such IP*" within "*the complexity of the international IP landscape*."

It points out that "I*ntellectual property protection under retained EU law (Directive 98/44 on the protection of biotechnological inventions) could be subject to diverse interpretations in the UK and EU nations, and divergence with other trading partners (e.g., the USA) is also likely*."

It seems clear that even if the UK government follows through with the deregulation of gene editing, it does not address the issue of rights. IP will continue to restrict access to the technology to those who can afford it.

Moreover, deregulation does not free developers from the 'burden' and 'expense' of developing detection methods, since they will still need these in order to protect their IP.

Worries about a GMO free-for-all

A few submissions considered the opposite situation – of a world where GMOs were free from patent and regulatory restrictions, giving wider access to more diverse actors. Concerns were expressed about the risk posed by the relatively low cost and accessibility of gene editing technology.

Fera Science expressed serious concerns: "*We consider that GE has a potentially higher risk of intended harm than traditional breeding due to its relative accessibility (measured by lowering technical barriers for undertaking GE research and increased fidelity for manipulation).*"

The European Network of Scientists for Social and Environmental Responsibility (ENSSER) agrees:

"*The overwhelming characteristic of modern GE, such as Crispr-cas9, is that it is easy to do, and commercial kits are on the market for doing so. Therefore, the methods open the possibilities for anyone to carry out any GE manipulation. This has led a US assessment that GE represents the most serious threat, on a parallel with nuclear power or war. For this reason alone, in addition to all others, GE requires a strong regulatory framework comparable to that for gun control, but yet stronger*."

Unite the Union, notes: "*Some of the discussion about gene editing has focused on how accessible it is, suggesting a democratisation of the science as indicated by increasing numbers of scientific papers, many thousands of labs, and hundreds of thousands of geneticists engaged in gene editing. But this very accessibility is one of the threats presented by this technology, as identified by the US global threat assessments*."

The scenario that Unite and ENSSER refers to is an assessment by the Worldwide Threat Assessment of the US Intelligence Community, given to the Senate Select Committee on Intelligence in 2016 by the then Director of National Intelligence, James Clapper.

Clapper noted that while tools like CRISPR can be used to promote health, it's also possible to use them to create weapons of mass destruction. As such he identified CRISPR as a threat to national security.

Whether such an extreme situation would ever come to pass is anyone's guess, but there are unavoidable regulatory, environment, safety and, ultimately, legal questions associated with a GMO or gene editing free-for-all.

A key, but unaddressed, question here is: How does the government envisage monitoring the use – or abuse – of a technology that anyone can use?

7 WHAT'S BEST FOR ANIMALS?

With the publication of its consultation report, Defra has – at least for the time being – kicked the issue of deregulating genetically engineered livestock into the long grass. Since the issue is complex and there are no gene-edited animals anywhere near ready for market, this was not such a difficult decision.

The Roslin Institute, the UK's pre-eminent centre for the development of gene editing animals, understandably favours deregulation by removing gene-edited organisms, including animals, from the definition of a GMO. This view is underpinned by what it sees as the precision of the technique and the belief that there is a similar level of risk between "traditional" breeding and gene editing.

Like many developers, Roslin expressed a sense of unfairness that gene editing should be regarded, and therefore regulated, as a GMO.

Selective breeding is unregulated, it writes, yet "*is rarely applied to achieve a specific genetic change and has a degree of randomness that can result in profound changes to plant and animal phenotypes.*" Similarly, mutagenesis "i*s lightly regulated compared to GMOs, yet is not targeted in any way and has potential for unintended effects*".

Roslin adds, "*We recommend that the technology that is used is not the focus of the regulatory process, rather that criteria are defined that are based on an appropriate risk assessment of the outcomes, because our view is that there are no risks in the application of genetic technologies per* se."

Elsewhere, however, the Roslin submission, notes several hurdles to get over, including potential for negative impacts on animals, consumer preference and trade issues.

The National Pig Association submission also fully supports deregulation of gene edited animals on welfare grounds: "*Genome editing clearly has the potential to save many lives and improve the health of millions of animals*", providing benefits which, it says, cannot be achieved through conventional breeding.

Among these proposed benefits are genetically engineered sterile pigs which do away with the need for castration (though it also admits that castration is rare in the UK), as well as selective breeding of poultry, allergen-free animal products from cattle and poultry and double-muscling (and therefore higher meat yields) in cattle. Significantly, it suggests that "*Improving the health and welfare of pigs also will have a positive effect on the efficiency of production, which is the focus for future policy in the UK.*"

The Sustainable Food Trust, however, says: "*Experience teaches us that commercial pressures will force breeders to focus on growth rates rather than other factors which can result in animals that grow more quickly than their metabolisms are able to support, and cause pain or other health problems.*"

Wildlife and Countryside Link agree, saying: "*Traditional selective breeding has indeed produced extreme traits that cause welfare issues, and there*

is little to suggest that GE technology would not do the same."

The Nuffield Council on Bioethics raises concerns that "*breeding strategies should not be used to mitigate or mask the adverse health effects of unsatisfactory husbandry practices while leaving animals in conditions of poor welfare*."

According to Compassion in World Farming (CIWF), however, comparisons with the 'safety' of conventional animal breeding are misleading. Its submission lists multiple examples of the "*immense harm to animal health and welfare*" associated with genetic selection.

It nevertheless concedes that, in some circumstances, gene editing may be beneficial, but concludes: "*There should be no blanket approval for gene editing. Each proposed use should be judged on its own merits. Gene editing of farm animals should not be permitted other than in the most exceptional circumstances.*"

With the publication of its consultation report, Defra has – at least for the time being – kicked the issue of deregulating genetically engineered livestock into the long grass

It goes on to define "*exceptional circumstances*" as being where an impact assessment shows that:

- There will be no detrimental impact on animal health and welfare
- No less intrusive method of achieving the desired objective is available
- The desired objective does not entail facilitating the use of industrial livestock systems as these have a wide range of inherent disadvantages for animal health and welfare.

The Royal Society for the Prevention of Cruelty to Animals (RSPCA) goes further, suggesting that gene-edited animals, and products made from them, should be strictly regulated as GMOs because:

- Although molecular tools such as CRISPR-Cas are more precise than previous methods, they still cause unpredictable, adverse and unintended changes to the genome.
- Not enough is known about the medium- and long-term effects on animal health and welfare and there is no history of safe use.
- There are significant public concerns about the use of gene editing technologies in sentient animals.

In its well-referenced submission, the RSPCA says it is opposed to the application of gene editing techniques to farm animals and believes there should be a moratorium on their use.

Unreasonable concerns?

The National Farmers Union, however, is very upbeat about the possibility of gene edited livestock and, as previously noted, goes so far as to attack both CIWF and the RSPCA for their concerns:

"*The NFU is concerned that the potential for misinformation and conflating of issues around the ethics and sustainability of livestock production could hold back developments in breeding that could have a significant benefit for environment and welfare, which the public wants to see British farming deliver…If public-facing campaigning organisations such as CIWF and RSPCA are able to consider this potential and help drive applications in those areas rather than rejecting the new technologies on principle, it would assist in informing the public discourse*."

Are the concerns of animal welfare groups really that extreme or unreasonable?

The Royal Society of Biology acknowledges that animal gene editing could lead to "*unwanted artefacts that must be carefully checked for with appropriate validation strategies.*"

The Universities Federation for Animal Welfare (UFAW) also details several adverse effects of traditional breeding and emerging evidence on problems with genetic engineering and says that this "*emphasises the need for stringent protocols and testing of all GE applied to animals, in a manner similar to the careful, staged testing process associated with the approval of new drugs*."

Are the concerns of animal welfare groups really that extreme or unreasonable?

According to the British Veterinary Association (BVA) "*Animal welfare should be given greater prominence in the debate over gene-editing and any legislative reform should, as an ethical imperative, ensure that animal welfare is protected, recognising its key role in achieving sustainability objectives and fostering international trading relationships*."

The Conservative Animal Welfare Foundation (CAWF) suggests that the processes used in gene editing are not comparable to anything that can occur naturally. It highlights some of the complexities of the process of reproductive cloning, a process which it says is "*highly inefficient and it leads to numerous adverse effects on animal welfare."*

CAWF goes on to reference studies showing that "*A single gene edited animal typically requires hundreds (or sometimes thousands) of embryo transfers to create one gene edited mammal. Adverse effects on animals include:* the *effects of egg harvesting procedures on egg donor animals; effects of hormone injections and surgery on surrogate mother animals; miscarriages, stillbirths, deformities and deaths associated with the numerous unsuccessful pregnancies; slaughter of live animals which do not carry the required genome edits; adverse effects of cloning which may occur in surviving animals.*"

Similar concerns were raised by groups like the Landworkers' Alliance, Nourish Scotland, GM Freeze, and GMWatch as well as the submissions of independent scientists and those from several large environmental and welfare groups, which were not in the public domain.

It was also widely noted that consumer resistance to gene-edited animals would limit the 'marketplace' far more than any regulation.

In reading the submissions, it was clear that there are multiple objections to the concept of gene-edited animals and that these objections ranged from the ethical to the scientific to market and consumer acceptability.

It is not surprising therefore, that regarding gene-editing animals, Defra has postponed its deregulation plans. They are, however, likely to reappear eventually because admitting that the gene editing technology is inappropriate in one area of farming and food has implications for its appropriateness and acceptability in other areas.

8 PUBLIC ENGAGEMENT OR PUBLIC PERSUASION?

References to the public in the consultation responses show a clear and interesting split, with pro- voices concerned about how to persuade the public, while anti- voices are generally more concerned with securing acknowledgment of legitimate public concerns which, as GM Freeze notes, are not just about "*foreign genes*" but are "*more nuanced and deeply understood*."

The Royal Society also recognises the wide range of public concerns. It states that there is "*a public perception that GM crops are synonymous with the interests of agrichemical companies in promoting high-input agriculture, which is a significant factor in public concerns about the technology.*"

The Nuffield Council on Bioethics notes that attempts to define GMOs as transgenes and gene editing as more simple edits, is unlikely to persuade the public of its merits. It says that its own literature review on public attitudes to GMOs found that "*the public seem to care less about the technical aspects of the process used than about the nature of the application.*"

Nuffield further notes: "*There are substantive and instrumental, as well as normative, reasons to engage the public (National Research Council, 1996). Furthermore, we believe that a failure to do so in an earnest and open manner risks provoking damaging distrust*."

One large environmental group put it more forcefully: "*If gene editing is truly the transformative technology that it is claimed to be, with potentially wide-ranging impacts on nature and our food and farming systems, then a much wider, deeper and more honest process is needed to fully inform and engage the public*."

Several organisations make clear that the public would not simply accept a change in the definition of a 'GMO' by the 'back door' and warn of an outcry if this is attempted.

The consumer organisation, Which? is particularly strong on this issue. It argues that: "*Deregulating current oversight ... appears a very arbitrary approach that fails to recognise the importance of continuing to take a 'case by case' approach and provide consumers and citizens with confidence that the risks, including any potential unintended consequences have been considered*."

Some pro- responses consider engaging the public through a body analogous to the Human Fertilization and Embryology Authority. As one researcher noted "*with good lay representation, that can be a forum in which the merits or otherwise of GE and GM technologies can be openly and publicly discussed both pre- and post- approval*."

They just need 'educating'

The Royal Society of Biology thinks that public engagement is essential, with citizens as "*active participants in dialogue towards a reform of genetic technologies regulations.*"

It states, "*Experience from the introduction of GMOs in the 1990s indicates that changes to food*

products made without the informed agreement of consumers are likely to be met with resistance and rejection, even when scientists and regulators are satisfied with their safety… A broad public dialogue is necessary, in which clarity and transparency will be essential to obtain and maintain trust."

But, according to the Royal Society of Biology this outreach should not steer reform away from "*an evidence-based approach that supports sustainable and responsible innovation for the benefit of people and the environment*".

This comment echoes what appears to be the strategy of several pro- organisations: engage the public primarily in order to placate and thereby procure wider acceptance of new and emerging genetic technologies.

This is a very different form of engagement from the active listening advocated by anti- voices.

Although not always expressing it such direct terms, some pro- voices share the view of one biotech developer that public concern around GMOs has been "*exacerbated by the campaigns of certain NGOs" and "that certain measures need to be put in place to inform the public and put safety concerns at rest*."

Information is only persuasive, however, if it comes from a trusted source and at the core of public engagement there is an unresolved and ongoing issue of trust

The Royal Society agrees with this sentiment saying that using genetic technologies to address environmental challenges has been made harder *"by organisations campaigning against the use of genome-edited and genetically modified (GM) organisms.*"

It references a Norwegian public dialogue suggesting "*People are willing to accept greater perceived risks from genetic technologies if they deliver greater perceived benefits*."
Some pro- voices believe positivity is the key to public trust. Instead of dwelling on safety concerns, another developer says the merits of growing, for example, blight-resistant GM potatoes in the UK *"should be communicated with regards to how it benefits our biodiversity, the national economy, local farmers and the consumers themselves*."

The Sainsbury Laboratory also believes that public concern can and should be addressed by ensuring more information is made available to the public – but only if the genetic 'event' includes the addition of new genes.

Several submissions recognised the need for public 'buy in'. The Royal Society suggests that as part of an "*outcomes-based approach*" to regulation, the public should decide what constitutes 'public good': "A *public forum in which the rationale and balance of risks and benefits for novel crop varieties are discussed*."

This, it suggests, could help guide developers in understanding what types of gene edited crops would have public support.

The NFU comes at it from a slightly different angle: "*If the first applications that come to market in the UK have clear and direct benefits to the consumer, environment and animal welfare, this would provide an important demonstration to the public of the value and importance of innovation in breeding. This could provide a market pull for more investment and diversity in development. Government can drive this process by getting the regulatory framework right and encouraging these early public-good applications.*"

A matter of trust

Information is only persuasive, however, if it comes from a trusted source and at the core

of public engagement there is an unresolved and ongoing issue of trust; who do individuals and the public collectively trust to listen to their concerns, to give them accurate information and honest perspectives?

This theme of trust is picked up by several organisations.

The Science Policy Research Unit at Sussex University (SPRU) notes that COVID19 provides "*a salutary warning about the need for careful democratic deliberation on the basis of scientific evidence, given lack of trust and emergence of conspiracy theories*."

Antis mistrust the pros…Pros mistrust the antis…The government clearly doesn't trust the public…And does anyone trust the government?

The Soil Association notes the government's suggestion of further public engagement and says "*A UK wide enquiry should take place – not just in England – as the impacts will be felt in all the devolved nations of the UK. As part of this further consultation, public discussion events (both government, stakeholder and grassroots initiated and organised) should be undertaken, which are recorded and reported in a transparent manner*."

The Royal Society of Biology agrees: "*Public support is essential to realising the benefits of genome editing. A broad public dialogue is necessary, in which clarity and transparency will be essential to obtain and maintain trust*."

Nourish Scotland says trust is a specific criteria for deregulation: "*If anyone is going to be persuaded of the potential benefits of this new technology, this will need full engagement and transparency around what is known/remains unknown, trusted and full safety assessments of wider questions (and including assessments conducted outside lab environments), wide efforts into education around all the issues concerned, a large democratic and representative/ inclusive consultation, and public reporting of government's next intended steps and mechanisms around these*."

GeneWatch UK says trust includes multiple actors including the retail sector but points out, "*If (some) gene edited GMOs are not regulated as GM foods, they will not be labelled as GM. This means that consumers that do not want to eat them will not be able to avoid them, even if they wish to do so …it would be difficult for retailers to maintain public trust in the integrity of food supplies or offer customers the choice of avoiding any of these foods or drinks.*"

Unite the Union suggests the consultation "*has the scope to cause damage to consumer trust and engender chaos in the UK food and agriculture industry, threatening our members' livelihoods*."

Trust, it seems, is lacking on all sides.

Antis mistrust the pros: for example, the response from a regional anti-GM group refers to the sense of deception and lack of government respect for the public in covering up unlicensed trials and GM contamination incidents created 15-20 years ago but still ongoing and still widespread.

Pros mistrust the antis: for example, several respondents refer to "*campaigns of certain NGOs*" regarding GMOs and the Royal Society of Biology even implies ulterior motives: "*It has been suggested that appeals to scientific uncertainty used to justify an unduly onerous risk -assessment may in fact be a means to delay cultivation of a GM crop under political pressure*."

On the evidence of Defra's consultation report, which has chosen to ignore the opinions expressed by the majority of respondents, the government clearly doesn't trust the public. And

if more evidence was needed, the Regulatory Horizons Council (RHC) states with astonishing candour that public engagement can "*diminish rather than improve the chances of consensus*".

And does anyone trust the government?

In its submission, Beyond GM is more explicit in its criticism, arguing that: "*Ministerial and departmental media statements have fostered polarising reactions, rather than the nuanced discussion which is urgently needed during this consultation*."

The Nuffield Council on Bioethics hints that the government fears public engagement believing this would result in consumer rejection, when it needs to offer reassurance that its approach "*seeks common ground rather than driving people from it*."

Several submissions make suggestions as to how much-needed trust can be built. Nuffield, for example, proposes:

"*There are substantive and instrumental, as well as normative, reasons to engage the public. Furthermore, we believe that a failure to do so in an earnest and open manner risks provoking damaging distrust*." It adds, "*Public dialogue offers the opportunity to explore how people from different perspectives engage with each other in response to a set of challenges that affect them collectively. It seeks common ground rather than driving people from it*."

Which? wants to see regulation based on the deliberative Food System Challenges dialogues it conducted in 2015 in collaboration with the UK Government Office for Science:

"*People recognise the important of innovation in the food system, but want assurances that this is being undertaken in the public interest and that a precautionary approach is being followed to any longer-term risks that may be pose*d."
In these dialogues, when asked what type of organisations they would trust to monitor the impact of novel technologies, respondents stated that they "*would have to be independent of the food industry i.e., not funded by, or linked to food businesses' because of concerns about changes being made purely for profit and not in the public interest*".

Several other organisations (e.g., Beyond GM and Landworkers' Alliance) mention alternative and more inclusive approaches to public consultations such as the GM Nation enquiries, which spanned several years in the late 1990s-2000s and included science, policy and commercial reviews as well as public debates or the Norwegian system for assessment of GMOs, which includes a public panel. One large environmental group also talks about the need for innovative engagement approaches such as Citizens' Juries.

Public dialogues are challenging and difficult to do well, but that is not a reason to avoid them. They are crucial to a fair and democratic approach to the regulation of genetic technologies in food and farming.

As yet, there is little indication from Defra or the government of an interest in collaborative and respectful dialogue with citizens. We suggest that without this trust in the government's agenda and process will always be lacking.

9 EMERGING ISSUES

The responses submitted to the Defra consultation are as enlightening for what they don't contain as for what they do.

It's a (possibly inevitable) feature of the consultations process that respondents often get shunted down the narrow passages that the government wants them to travel rather than enabling them to address bigger picture issues.

As the GM Freeze submission noted "*we have received many enquiries from the public confused by the phrasing and format of the questions, some of the questions feel like traps in which any answer they give will be used to justify what the government wants to do*."

In this consultation, those passageways – what kind of GMOs do you want/are acceptable to you and how do you want them to be regulated? – greatly eclipsed the associated, and arguably more important questions around what kind of farming systems do we want/do we need and how can we implement them?

Nevertheless, several submissions covered questions relating to the direction of travel of our farming and food system and the need for alternatives to the prevailing industrial system.

A distraction from sustainable alternatives

One large nature conservation charity calls for broader systemic change and states that agroecological approaches may be more effective at addressing the multiple challenges facing the food and farming system. Over-focus on gene editing "*risks distracting away from this*". SPRU (the Science Policy Research Unit at Sussex University), also suggests that a "*disproportionate amount of attention and investment is allocated to genetic (including gene editing) innovations*," and that this investment "*comes at the expense of more systemic, but neglected, social innovations around ecological agriculture, open-source seed production, and participatory farmer collaboration platforms*."

One farming organisation mentions agroecology as an alternative to gene editing, while the Wildlife and Countryside Link observes the lack of alternative options e.g., agroecology mentioned in the consultation.

In contrast, the National Farmers Union (NFU) 'name checks' agroecology not as an alternative but as another 'tool in the toolbox' for addressing sustainability, noting that "*An integrated approach involving science-based agroecological approach must be encouraged for this sector*."

Wildlife and Countryside Link, as well as a number of farming organisations whose submissions are unpublished, make reference to the benefits of agroecology and the frustrating lack of support and serious attention (and funding) it is receiving from the government.

The tools in the toolbox, and indeed the toolbox itself (representing the agricultural system) will, no doubt, feature ever more prominently in the ongoing public and stakeholder debate.

In the mean time, there are issues which, while not explicitly addressed by the consultation, are of direct relevance to the implementation of gene editing within the framework of the current farming system.

Prominent amongst these is coexistence and labelling and the proposed use of gene editing in ecology and nature conservation.

Coexistence and labelling

The coexistence of different farming and food systems has been part of UK and EU farming and food policies for decades and has gained special prominence with the onset of GMOs and the development of the organic sector. Put simply, coexistence is the right of farmers to use the production methods they wish and the right of consumers to buy – or not – food produced using methods they approve or disapprove of.

The Royal Society believes that "*Under current requirements for cultivation of GMOs this risk is mitigated by the rules on coexistence*."

However, as submissions by the Landworkers' Alliance, the Soil Association and others testify, these rules have not been adequately developed either at field level, in the supply chain or in the marketplace. Landworkers' Alliance go so far as to say that the products of gene-editing "*pose dangers to organic and agroecological farming, due to potential impacts on biodiversity, risks of cross-contamination and pressures on local and organic markets*."

The Royal Society acknowledges that "*It is unclear how such risks might be mitigated if some GE products were not regulated as GMOs*", but it is optimistic that "*experience can be gained from countries that do not regulate some GE products as GMOs and have an organic agriculture sector*."

Others share this hazy optimism:

The NFU says: "*Coexistence between conventional and biotech crops is vital to deliver choice for farmers and consumers*". Coexistence, it says, is achievable, though it makes no suggestions for how it can be achieved.

The Country Land and Business Association (CLA), commenting on concerns around contamination within the supply chain, is confident that while there is "*concern that the integrity of food produced to specific standards, such as organic food, could be compromised by allowing GE crops*". It believes this is "*no greater than under conventional breeding*". Nevertheless, it recognises that "*support needs to be given to ensure that traceability standards are maintained and trusted*".

The potential magnitude of that "support", which could include, for example, the development of separate and discrete supply chains, is not discussed.

Respondents often get shunted down the narrow passages that the government wants them to travel rather than enabling them to address bigger picture issues.

The English Organic Forum, however, argues that the challenge is far more wide-ranging and profound, affecting all farmers and consumers who do not wish to use or consume gene-edited products. It says it firmly believes:

"*Coexistence should be equitable and that the organic approach and market should not be undermined, threatened or unfavourably treated in any way; including in the areas of government financial support, R&D funding, supply chain integrity and development, market integrity, policy, public education and messaging*."

Submissions by the Organic Farmers and Growers (OF&G), GM Freeze and Beyond GM, and others echo this point.

An environmental think tank argues that "*On consumer choice, given the strength of feeling on genetic technologies amongst some people, it also seems that clear labelling of gene edited products should be a requirement to enable people to choose what they buy and consume*."

A few others echo this and explicitly state that consumers' and farmers' 'right to choose' should be guaranteed across the food chain.

The RSPCA makes the point that consumers require "*clear product labelling that does not use misleading euphemisms such as 'precision breeding' or 'smart breeding'*".

Responses from one farming organisation and a healthy eating charity both emphasise that Defra must give much more consideration to this difficult issue. The Pasture Fed Livestock Association (PFLA) submission says "*We also need further consultation on issues of coexistence for farmers and growers not using GM technologies, including liability for any damage and contamination resulting from GM use, as we will need legislation and other mechanisms to cover these issues adequately.*"

Issues of environmental benefit quickly become tricky when the arguments move outside the realm of domesticated plants into for example agricultural pests, disease vectors, fungi, micro-organisms and wild or invasive species.

Gene editing in conservation

Given that the natural environment is in constant interaction with the farmed environment it is surprising that this proposed use of a range of genetic technologies (gene editing, synthetic biology and gene drives amongst them) for nature conservation was not prominent in the responses.

There were, however, a handful of both pro- and anti- voices that considered the proposed future role of gene editing in conservation, especially in managing invasive species and plant diseases.

The Royal Society notes that issues of environmental benefit quickly become tricky when the arguments move outside the realm of domesticated plants into for example: "*agricultural pests (especially insects), disease vectors, fungi, micro-organisms and wild or invasive species of conservation concern*".

The Royal Society's submission is the only one of the pro- responses to mention wild organisms in this context. Others mention wild or free growing plants in the context of providing genetic resources for breeders.

Significantly, however, the Royal Society notes that: "*It is unclear whether rules developed in the context of cultivated plants and farmed animals adequately address the risks and benefits of using genetic technologies in wild species.*

Where crops are concerned, the Royal Society contends it's easier to think in terms of a trade-off between risk and human benefit, *"But 'human benefit' is far from easy to specify let alone quantify with non-domesticated species and non-agricultural applications.* Public/private benefit and risk *"are issues that become more complicated outside of the context of agriculture*."

Fera Science suggests special caution is needed where a novel trait "*that may negatively affect wildlife or biodiversity (e.g., by expressing a novel or upregulated plant defence chemical toxic to invertebrates)" could be taken up by wild species through natural crossing*."

The Royal Horticultural Society, on the other hand, suggests that "*Fungus-resistant crops would benefit soil biodiversity and structure and wild ecosystems in general*."

Beyond GM was the only anti- voice to mention conservation, which it did at some length:

"*Proponents argue that these technologies could be a way of, among other things, reviving declining or even extinct species, eradicating* invasive species, *improving soil and therefore plant health and biodiversity. But equally, geese, badgers and bison, for example, are all implicated (some would argue unfairly) in infecting farm animals with various diseases*."

This, it says, raises numerous questions:

- What are the potential consequences of genetically 'editing' these wild animals so they don't impact farm animals and therefore farm profits? Does that count as an 'agricultural use'?

- Could a gene-edited wild animal unwittingly become a reservoir for zoonotic diseases for which we do not yet have viable treatments?

- What happens to engineered soil microorganisms when released in the wild?

- How might they alter the soil structure and microbiome if, for example, genetically engineered organisms become the dominant species?

The drive for deregulation sidesteps all these important and interconnected considerations (and an increasingly wide circle of proposed uses has links into concerns about a GMO or gene editing 'free-for-all' (see *6 - The Rights Question*).

Some of those expressing environmental concerns for the use of genetic technologies in conservation were supportive of their use in agriculture. It's difficult to understand how this technology can be considered environmentally safe in one but not the other. This is a schism that needs more thorough investigation.

CONCLUSIONS

In the end we were only able to view a small handful of the submissions Defra received. Even so, what we have read provokes important questions about the purpose of the consultation and the government's interpretation of the data. It has also strengthened our belief that, given the important changes to the food system which are being proposed, there needs to be a more thoughtful record of what was being said.

The groups who chose to make their responses public were, for the most part, 'old warriors' – well-informed and well-practised at putting their long-held views across and participating in this peculiar form of 'democracy'.

A key feature of what we have read suggests that there are important areas of overlap between traditionally opposing sides and that even amongst the most well-informed respondents expressed views that ranged from insightful and nuanced to inconsistent and unproven within the same document.

Responding to government consultations is difficult. It's time consuming and frustrating because the time spent on creating a response is often disproportionately high in relation to any tangible benefits to be gained. And yet thousands did respond to this consultation.

Given the government's clearly stated plans to deregulate genome editing, even before the consultation was launched, there is a strong argument that this consultation was a hollow and meaningless exercise. Consequently, Defra produced the only possible report it could – a triumph of using lots of words to say nothing particularly new or insightful.

The responses we have read suggest that, in its attempts to push a rather crude and hasty agenda, Defra has failed to notice that it is falling behind on the arguments. Even as the government's position is revealed as immutable, those – from all sides – with greater knowledge of the technology and of the historical landscape of the debate are shifting and reassessing, at least in some areas.

Too often the political and media narrative highlights so-called 'irrational fears' about genetic technologies 'stoked up' by presumed 'anti-science' groups.

But the responses to the consultation which are now part of public record indicate a more broadly-based awareness of how quickly the technology is evolving, of the unhelpful hyperbole around what it is and what it can do and of the need for some form of regulatory control and case-by-case assessment.

Arguably, the most urgent debate centres on the triggers for such assessments and what form that regulation might take. But there are a few other notable takeaways to consider, as detailed below:

Out of step with public opinion

It has long been apparent in the UK that there is a strong promotional push for genetic

engineering technologies from politicians, policy makers, parts of the research establishment, business lobbyists and the media.

Public opinion, however, has remained remarkably consistent, over decades, with a majority of citizens either cautious about or opposed to the use of this technology in farming and food production.

Polls suggesting otherwise should be viewed with some caution as they are too often based on tortuously constructed 'what if' questions along the lines of "*Would you support genetically engineered crops if they could feed the hungry, save the bees and fight climate change?*"

Most people recognise that "what if" is not the same as "what is" and responses to such questions are a poor indication of public views.

Post-Brexit comments by the Prime Minister and other Ministers have been near-evangelical in their enthusiasm to sweep precaution aside and remove all barriers to developing and marketing genetically engineered crops and foods.

Since departing the European Union, Ministers have also been given greater powers to make legislative changes as and when they see fit. The use of statutory instruments (which limits Parliamentary scrutiny) to change the law is now on the cards.

In its attempts to push a rather crude and hasty agenda, Defra has failed to notice that it is falling behind on the arguments.

But as the Science Policy Research Unit at Sussex University (SPRU) suggests, the public are not likely to simply accept deregulation, especially by stealth: "*If the government were to re-define the term 'genetically modified' so as to exclude GEOs by using secondary legislation, in the form of statutory instruments (SIs), then public opposition to such changes would be greater than if primary legislation were used.*"

The intention to push ahead, regardless of very strong public resistance, shows a staggering disregard for citizens and for the public consultation process. It also demonstrates a government that is out of step with its people. This can only end in deeper divisions between the 'sides' and a strengthening public mistrust and resistance.

More than a 'science issue'

It is not possible, nor is it rational, to reduce agricultural genetic engineering to a one-dimensional 'science question', and several submissions were very strong at arguing that decisions about the future of genetic technologies in farming and food should have a greater socio-ethical context.

The Food Ethics Council believes it is "*vitally important that any assessment criteria that are developed extend beyond narrow technical and scientific aspects. Ethics and values-based criteria should also be included*."

Similarly, Nuffield Council on Bioethics states: "*While we may 'follow the science' to estimate the likelihood of a harm occurring, science is necessarily silent about people's appetite for risk, the relative importance they give to different harms, and the relative significance of those possible harms when considered alongside potential benefits. These are questions of value. This is why we believe there is a need for more nuanced understanding of the public interest to inform public policy*."

SPRU argues that science itself doesn't happen in a vacuum and notes that what happens in a lab doesn't necessarily happen in different biophysical and socio-economic environments.

Our reading of the submissions suggests that those organisations content to look

at agricultural genetic technologies from a relatively narrow perspective – e.g., what can be achieved in the lab – continue to overemphasise the positive possibilities. Those that pull back enough to bring other contexts into focus are, perhaps inevitably, more questioning and cautious.

Defra's vision of the regulatory landscape is far too narrow to account for the systemic nature of farming and food production and for the 'down the line' implications of any sweeping changes in regulation.

Missing voices

Notable in our analysis was the fact that an overwhelming proportion of those who chose not to publish or not to publicise their responses to the consultation, were civil society groups that fell into 'anti-' category. Some very large organisations that we know of did not respond to the consultation at all.

This complicated our reporting but also raised a bigger issue: Why are so many environmental and food groups now so reluctant to engage publicly in the GMO debate?

Our research[18] suggests this is not simply a matter of staffing or capacity. Many civil society organisations have not been involved in the GMO debate for many years and no longer have expertise or established campaigns around them.

Our behind-the-scenes interviews with key figures suggest that many large and influential funders are now refusing to provide grants to organisations that question the government's pro-innovation, pro-genetic engineering agenda.

Some organisations feel under pressure from their funders but also from their Defra contacts and other policy 'influencers' to prove they are not 'anti-technology' (an all-purpose derogatory term that is bandied about but poorly defined) and either fudge the issue or take the easier route of ignoring it altogether.

Without the voices of those who question the direction of travel for agritech and who have a sense of the bigger picture of the uses and abuses of technology, the public debate is immeasurably poorer.

Dissent can't be ignored

The government's impatience with nuance, complexity and caution is not specific to genetic technologies. It is being amply demonstrated by what is being called the 'bonfire of the regulations' – a deregulatory drive, launched around the same time as the genetic technologies consultation, that cuts across multiple areas and is being met by dissent in many of these.

In January 2021 it was reported[19] that Prime Minister Boris Johnson had: "*Asked business leaders to help him decide which regulations should be ripped up now that the UK has completed its divorce from the European Union.*"

Businesses reported being "*badgered*"[20] by the government for ideas, suggesting that although there is a desire for reform, the government has little clear idea about what reform involves or looks like or what its impacts might be.

Under these circumstances dissent is a rational response. It is also a necessary part of the democratic process. But Defra's method of dealing with dissent and disagreement around genetic technologies has been to ignore or belittle it. This is undemocratic and, ultimately, escalates a cycle of mistrust.

It doesn't have to be this way. Disagreement on the issue of genetic technologies in agriculture is to be expected and several member organisations responding to the consultation

had to confront the reality that not all their members were aligned on the question on agricultural genetic engineering.

Their responses strived to represent the mixed views of their members in a way that Defra might learn from.

For example, the Microbiology Society response states that "*It is not our intention to speak on the behalf of the microbiology community*." It instead represents the views of members that responded to the consultation which are given equal weight. These views include support for and opposition to deregulating gene editing.

The Country Land and Business Association response also reflects diverse voices within the organisation. As a result, its response reflected support as well as conflict around the implications for deregulation.

The IFST also makes it clear the organisation is not whole-heartedly in favour of genetic technologies in farming and food: "*There are differences of opinion amongst the informed scientists and food technologists who make up the IFST's membership, and this reflects the differences of opinion amongst the UK population.*"

Good public discourse, leading to consensual and rational regulation, is the only way to ensure that whatever potential this technology has for citizens, consumers, animals and the environment is secured.

Tempting as it may be in the post-Brexit world for the UK government to sweep aside regulation of genetic technologies in order to, as Prime Minister Johnson said on his first day in office[21], "*Liberate the UK's extraordinary bioscience sector from anti-genetic modification rules*", limitless, unhindered, unregulated innovation is not what citizens, businesses or the public sector wants and moreover would not be the wisest, or most sustainable course of action.

Choosing to get it wrong?

Post-consultation, Defra has indicated that it is continuing to gather views and evidence to inform policy development with the intention of publishing an evidence report summarising all of the information gathered. That, of course, was also the intention of the consultation report.

Limitless, unhindered, unregulated innovation is not what citizens, businesses or the public sector wants and moreover would not be the wisest, or most sustainable course of action.

It may be that the regulation of genetic technologies in agriculture does need to be reviewed. But many of the deficits that plagued the consultation process, and which are fundamental to good policy making, have still not been addressed.

Defra's process of 'gathering views' is still prioritising the views of the same narrow group of stakeholders and using the same misleading framework as the consultation and appears to have the same predetermined outcome.

We have yet to see any validated impact assessments looking at the costs, benefits and risks of regulatory changes. There are promises, but no real world studies to show that gene editing will deliver against measurements such as sustainability, carbon savings, higher yield or better nutrition.

There is no clear scientific criteria for deregulation and no plan to develop social, ethical or values based criteria that will enrich and guide the approval process for genetically engineered plants, animals and microorganisms. There is no plan to assess alternatives and no plan for involving citizens – as equals – in the

decision-making process. There are no plans for managing coexistence at any point along the supply chain. There is no plan for how to deal with liability issues including intellectual property rights. There is no plan for labelling.

Defra can rescue this process by:

- Publishing its rationale for the framework "could have occurred naturally or through traditional breeding" and providing an open forum for debate on this point.

- Producing validated impact assessment of the expected costs and benefits set against the Government's rationale for deregulation.

- Producing a full plan for coexistence covering the entire supply chain from farm to fork.

- Expanding current assessment for the approval of genetically engineered organisms to include social, ethical and values-based criteria and ensuring that these are assessed as early as possible in the approval process.

- Engaging with citizen and their concerns by bringing them into the assessment process at the earliest possible point.

- Building constructive relationships with civil society groups including those that question the deregulatory process and drawing on their legitimate expertise and experience.

- Publishing its plan for ongoing monitoring of genetically engineered organisms on farm and in the food system and setting up a transparent and user-friendly public register of all genetically modified food, feed and ingredients in the UK.

Currently, no one is holding the government to account for its decisions around genetic technologies in agriculture.

In the rush to deregulate, democracy is not being served, nor is a rational or productive process being followed. In reality, there is no urgency. There are no gene edited products ready for market and crucially no demand from the British public to bring them to market.

We have the tools and the time to get this process right. Why are we choosing to get it so wrong?

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Submissions reviewed

We reviewed 54 submissions in total. Quoted in this report are those from:

- Advisory Committee on Novel Foods and Processes (ACNFP)
- Agricultural Industries Confederation (AIC)
- Beyond GM
- British Veterinary Association (BVA)
- Compassion in World Farming (CIWF)
- Conservative Animal Welfare Foundation (CAWF)
- Country and Land Business Association (CLA)
- Econexus
- English Organic Forum
- European Network of Scientists for Social and Environmental Responsibility (ENSSER)
- Fera Science
- Food Ethics Council
- GeneWatch UK
- GM Freeze
- GMWatch
- Institute of Food Science Technology (IFST)
- Landworkers' Alliance
- Microbiology Society
- National Pig Association
- National Farmers Union (NFU)
- Nourish Scotland
- Nuffield Council on Bioethics
- Organic Farmers & Growers (OF&G)
- Organic Research Centre (ORC)
- Pasture Fed Livestock Association (PFLA)
- Regulatory Horizons Council (RHC)
- Roslin Institute
- Rothamsted Research
- Royal Society
- Royal Society of Biology (RSB)
- Royal Society for the Protection of Birds (RSPB)
- Royal Society for the Prevention of Cruelty to Animals (RSPCA)
- Sainsbury Laboratory
- Soil Association
- Science Policy Research Unit, University of Sussex (SPRU)
- Sustainable Food Trust
- Unite the Union
- Universities Federation for Animal Welfare (UFAW)
- Which?
- Wildlife and Countryside Link (WCL)