Beyond GM response to

Defra Consultation on the Regulation of Genetic Technologies

This document is our response to the above consultation and we consent to it being made public.

Beyond GM is a UK-based civil society organisation. Its aim is to raise the level of the discussion around genetic engineering in food and farming to make it more intelligent and more inclusive. To this end we undertake a range of activities from public-facing engagements and publications to more structured and formal events aimed at deep-dive discussions.

Whilst we have no particular animus towards genetic engineering as a technology, its use in agriculture raises numerous legitimate questions which we believe have been historically – and which continue to be – diminished, dismissed and ignored.

Questions around the efficacy and need for genetic engineering technologies in agriculture, as well as its ethical considerations and its socio-economic impact, are absolutely relevant to regulation and we do not believe that regulation can be said to be 'fit for purpose' unless and until these factors are included. For this reason we find the UK government's approach to regulation, and indeed to this consultation, to be narrow and incomplete.

We have serious concerns about this consultation process including the multiple ways in which it breaches Cabinet Office Consultation Principles, which we have detailed in our complaint to Defra. At the time of writing, this complaint remains unacknowledged and unanswered.

These include the concern that the consultation has been hastily thrown together, is biased in its presentation of background information (and therefore divisive), it lacks key definitions and a clear explanation of scope and, spanning just 10 weeks instead of the normal timeframe of 12, it does not provide enough information or time for those who may not have pre-formed views to make a full assessment of the issue.

The questions are structured in such a way that respondents are expected to accept the Government's premise that gene editing is the same as traditional plant breeding. If one does not accept this premise, it's difficult to answer in a way that fully reflects that different perspective.

It is not targeted at a general public and many of the questions are nearly impossible for lay people to answer. Most importantly, Cabinet Office Consultation Principles state that the Government should not consult on matters where it has already formed a final view – and it is clear that the Government has already formed a view on the necessity for deregulation, is pursuing this end and regards it as a pathway to 'innovation'.

Part two of the consultation is particularly inappropriate for a non-specialist audience and we believe it presents a serious impediment to average people who may wish to participate.

Taken as a whole, the only conclusion that can be drawn from the consultation is that the Government is not just seeking to alter the regulation of gene editing but that it is also paving the way for reduced regulation for the use of genetic engineering technologies across a whole range of areas. Given the disruptive potential of the technology, we believe this to be a premature and potentially reckless move.

Beyond GM Ltd, 99 Brentwood Road, Brighton, East Sussex BN1 7ET
Email: info@beyond-gm.org | Web: www.beyond-gm.org and www.abiggerconversation.org
Registered in England and Wales. Company no: 9078147

Beyond regulation – what really limits innovation?
In the context of this consultation we feel it is also important to challenge the notion, promoted by the Government and the biotechnology research establishment, that regulation is a limiting factor for progress and innovation.

It is our view that regulation is being used as a scapegoat for the slow progress and outright failures of agricultural biotechnology and that this effectively creates a smokescreen which prevents a clear sight and consideration of where real limitations may lie.

For example, it is argued that regulation in this area has hindered R&D innovation. Yet, according to the EU's Joint Research Centre (JRC) – a body which includes leading UK researchers – Europe, which has some of the most comprehensive regulations on genetic engineering technologies in the world, has carried out almost 50% of the global research in this field. The simplistic claim that regulation shackles R&D innovation is, therefore, open to challenge.

As we note in the report from our 2019 roundtable, The Boundaries of Plant Breeding, it was acknowledged by participants from across the spectrum that regulation is not the only, or even the most important, limitation on the development of agricultural genetic engineering technologies. Limits can be, and are, set by multiple intrinsic and extrinsic factors.

In recent decades, several factors – other than regulation – have played a part in placing or influencing limits on genetic engineering approaches to agricultural products, including:

- Differing values and worldviews.
- Differing perspectives about causes and priorities relating to environmental concerns.
- Differing perspectives on the desirability and scope of biological limits.
- A lack of consensus regarding the importance and scope of conceptual and ethical factors.
- Power concentration and monopolisation within industry.
- Economic factors including uncertainty of return on investment for various players.
- Time pressures within the context of changes in the market and supply chains.
- Inconsistent and variable public acceptance.
- The presence of viable non-tech or low-tech alternatives.

It can be argued that collectively these factors, in addition to regulation, have constituted a limitation to the roll-out and expansion of genetic engineering technology. But they are not a limit to innovation itself; rather they are the real world context in which innovative ideas must grow and thrive.

No single one of them is the turnkey factor which, if removed, will open the door to a technological promised land. Remove one – including regulation – and all the others still remain. It is delusional to believe otherwise.

Regulation is not a ban
Regulation is a safeguard, not a ban. Its purpose is to protect individuals and/or the environment. It is a societal tool for dealing with uncertainties such as gaps in scientific knowledge.

While the notion of "science-based" regulation has become popular, what is urgently needed is evidence-based regulation. Genetic engineering in farming and the food system is a disruptive technology in the same vein as artificial intelligence, mass surveillance, driverless cars and 3-D printing. As such, it cuts across multiple sociological, environmental, economic, scientific and regulatory areas. Effective and rational regulation is only possible when evidence from all disciplines, stakeholders and citizens – those who too often fall outside a narrow definition of 'stakeholder'– is included.

Progress, rational regulation and depolarisation of the GMO debate can only evolve from a wider, more systemic view of the problems agriculture faces and a transparent and independent assessment of all the evidence around proposed solutions.

A way forward
Since its inception, Beyond GM has aimed to encourage a more contextualised and questioning approach to the use of genetic engineering in farming and food. We strive to engage a wider audience – and in particular to support those groups and voices that are consistently marginalised in the debate. The largest of these groups is the general public.

In the last few years via our A Bigger Conversation initiative we have begun to bring key actors with differing perspectives around the table for discussions about the need for, and the use of, genetic engineering technologies in agriculture and for discussion around broader regulatory reform.

This divisive, inexpertly designed and poorly thought-out consultation has set back the progress that was being made, by ourselves and others, on developing amicable, nuanced and productive discussions around genetic engineering technologies in food and farming.

It has also, in our view, been undertaken before the Government has taken the logical step of a full and transparent review of the science around agricultural genetic engineering, as well as an honest consideration of its value and necessity.

The last comprehensive investigation into genetic technologies in agriculture was 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. The conclusion drawn from that work was that there were no public or environmental benefits from genetically engineered crops and no economic benefits for UK Plc.

Although there were concerns, even then, that the wider public was not being properly engaged and that the process had other flaws, the experience of GM Nation provides a useful framework for how Defra could proceed, if it was really serious about a public consultation.

Such a framework is already being pursued in Norway where a public committee has recently been appointed to conduct a broad professional review of the technological status and regulatory frameworks, the need for independent research, possible new risk aspects and ethical dilemmas around gene editing. Rather than a hasty 10-week consultation, the Norwegian panel is in the midst of an 18-month-long review.

In the Norwegian system it's not just laboratory science – and certainly not the shifting sands of pseudo-scientific concepts like 'precision breeding', 'speed breeding' and 'nature identical' – that underpins regulatory decision-making. The process also encompasses five interconnected 'pillars' in the GMO debate: health, environment, ethics, sustainability and economics.

The need for gene-edited plants and animals and how these may or may not be regulated must be assessed in this wider context.

This kind of independent, broad and democratic assessment involving civil society, individuals representing a range of special interests and expertise and members of the public, should have taken place in the UK before any public consultation on regulatory matters.

In our communications to George Eustice, exchanges with Defra and also with the National Food Strategy, this is what we have suggested – though it has fallen largely on deaf ears.

We maintain, however, that there is a need to develop an exercise akin to the GM Nation enquiries and that this should include:

- A UK-wide enquiry – not just in England as the current consultation is.
- An independently assessed review of the science and safety aspects.
- An independent review of the social and ethical as well as the economic (including trade) aspects. This would need to include a consideration of different impact scenarios for UK agriculture and related businesses along the supply chain.
- An independent review of regulatory frameworks for transparency, labelling and co-existence with other agricultural approaches.
- Public discussion events (including government, stakeholder and grassroots initiated and organised) which would be recorded and reported in a transparent manner.

The results of this kind of process could usefully lead to a Green Paper, in which the Government sets out its proposals for the regulatory system, including environment and food safety aspects, market transparency and co-existence.

Gene editing makes many bold promises for what it can achieve, but it has yet to deliver on any of these. It may yet prove to be a 'transformative', 'powerful' and 'game-changing' technology. But at the moment, given the contested state of the science and the lack of commercially viable products, deregulation of any kind of genetic engineering technology, including gene editing, is an irrational response to an experimental technology that has yet to prove itself.

Our view is that if it's powerful it should be regulated; if it's transformative it should be regulated; if it comes with numerous unknowns it should be regulated.

Whilst regulations should evolve with knowledge and experience, we believe that robust and transparent regulation – which looks at social and ethical considerations alongside issues of risk – remains necessary for all forms of genetic engineering and that anything less than this is irresponsible and a dereliction of the Government's duty to its citizens.

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PART 1 – The regulation of GMOs which could have been developed using traditional breeding methods

Question 1 – Currently, organisms developed using genetic technologies such as GE are regulated as genetically modified organisms (GMOs) even if their genetic change(s) could have been produced through traditional breeding. Do you agree with this?

YES, we agree that organisms developed using gene editing should be regulated – and defined – as Genetically Modified Organisms (GMOs).

However, we challenge the premise of this question. The possibility that gene editing can create organisms that are identical to those produced through traditional breeding is entirely theoretical.

The concept of gene editing events that "could have occurred naturally or through traditional breeding", which is used throughout this consultation, is not defined in the consultation document, on the Citizen Space form or in any of Defra's materials relating to this consultation.

Without a clear definition, respondents must assume that, in this context, the term refers to all types of gene editing.

In framing its questions this way, this consultation asks respondents to accept a position that 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.

The term "traditional breeding" is also not defined and it is impossible to know what Defra means by this. Traditional breeding is a broad field. Without an understanding of which aspects of traditional breeding are being referred to, the comparison is meaningless.

Broadly speaking however, we take traditional breeding to mean breeding which relies on sexual reproduction to create offspring with desirable traits such as higher yields or resistance to drought, pests and diseases. This type of breeding has been used by farmers and breeders for eons to produce both crops and livestock.

By comparison, genetic engineering is a relatively new technology in agriculture and gene-editing is still almost entirely experimental.

When using genetic engineering, including newer gene editing techniques, researchers directly alter the genetic material of an organism using laboratory techniques to create novel, patentable genetically modified organisms that could not occur in nature. It is this direct alteration at the genetic level, combined with the novelty of the resulting organism, which defines 'genetic engineering' and underpins the definition of a GMO in the United Nations and the European Union.

The 2018 ruling of the European Court of Justice (ECJ) further clarified that, scientifically and legally, gene editing is genetic engineering and that gene-edited crops and animals are GMOs.

New gene editing techniques induce targeted mutations (DNA damage) in order to produce new traits in plants, animals and other living organisms.

The ECJ ruling – which was the result of a two-year-long review of the most up-to-date science – was that organisms produced by gene editing (referred to in the ruling as "new techniques of

mutagenesis" or "directed mutagenesis") are GMOs. This means that they fall within the scope of the EU GMO Directive 2001/18, which currently forms the basis of UK regulations on GMOs.

We see no rational or scientific reason why England, or the rest of the UK, should seek to diverge from this ruling.

Question 2 – Do organisms produced by GE or other genetic technologies pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced?

Organisms produced by gene editing or other genetic technologies can potentially pose a GREATER RISK OF HARM to human health and the environment compared with their traditionally bred counterparts. This is a direct result of how they were produced.

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

In truth, gene editing methods vary. This has not been recognised in the information accompanying this consultation, but any productive discussion of regulation and evaluation criteria must take this into account.

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

In addition, although gene editing can be used to target a single gene, it can also be used to target several genes, either at once or successively. Because gene editing produces unintended effects, each additional edit made using this approach multiplies the risk of such effects. For this reason each of these processes should be evaluated for the specific risks that it entails.

There are, very broadly, three types of gene editing:

- SDN-1 – the DNA is cut and the organism is allowed to repair itself.
- SDN-2 – the DNA is cut and a template is provided to instruct the organism how to repair itself.
- SDN-3 – the DNA is cut, sometimes in many places, a template for repair is provided and genes from other (related and/or unrelated) species are added.

After one or more of these gene editing processes, the creation of the final organism involves the same stages of cell culture, selection and replication as older GM techniques.

Although gene editing is too often simplistically described as a process of 'tweaking' or making a 'simple cut' in the DNA of an organism, in most cases it involves these much more invasive processes of SDN-2 and SDN-3.

Even so, SDN-1 procedures have also been found to lead to unwanted mutations. For this and other reasons, they may not equate to organisms that could be found in nature or produced through traditional breeding.

For instance, in so-called 'non-browning mushrooms' which were the first CRISPR organisms to be deregulated by the USDA (though still not commercially available), several copies of one gene were deleted to block the production of a specific enzyme. This is not a 'simple' edit and it is unlikely that a similar mushroom could ever develop naturally.

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

In 2017 scientists from around the world signed a statement on gene editing, published by the European Network of Scientists for Social and Environmental Responsibility (ENSSER). It recommended that, because of our lack of knowledge and the possibility of unintended errors, the products of new genetic modification techniques should be strictly regulated as GMOs.

Since then, studies have found that CRISPR can inadvertently cause extensive deletions and complex rearrangements of DNA. These deletions and rearrangements may cause important parts of the gene (those coding for protein production) to be "missed" when the DNA is read. This misreading of DNA has the potential to produce altered proteins. Food allergens are mostly proteins, so altered proteins could have significant implications for food safety.

A recent example, cited in a 2021 EFSA analysis of risk assessment for gene editing, was a gene-edited wheat with a greatly reduced gluten content. The study noted that "the large number of mutations required to achieve gluten-free wheat is far beyond any plant previously assessed" and that complex analysis of the bread wheat would be necessary "to prevent the accumulation of any peptide fragments associated with initiation of the inflammatory cascade."

In other words, attempts to lower gluten via gene editing also raise the possibility of creating more gluten peptides within the organism that can trigger food allergies, exacerbating the very problem it aims to solve.

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

While the Government claims that gene editing does not involve the use of 'transgenes' (genetic material from unrelated species), this is also not true. The introduction of foreign genes can happen deliberately for instance with SDN-3 techniques, but it has also been shown to occur by accident. For example, gene-edited mice have been shown to carry bovine and goat DNA as a result of the use of a standard culture medium for mouse cells, which can be derived from body fluids extracted from cattle and goats.

Even the few countries that have deregulated gene editing have only done so with one type of gene editing – SDN-1 – which does not use a repair template. SDN-2 and SDN-3 continue to be regulated as GMOs and it is important to note that the complex traits such as pest or drought resistance,

improvements in yield, nutrition or resilience in the face of climate change and lower-gluten wheat cannot be achieved through 'simple' SDN-1 genetic 'edits' or 'tweaks'. They require the more interventionist approaches of SDN-2 and SDN-3 processes.

All of this suggests that detailed risk assessment encompassing issues such as genetic errors, changes in gene expression and the potential impact on health and the environment must be carried out even if no additional genes are inserted.

Question 3 – Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs?

YES, there are non-safety issues to consider if gene edited organisms were not regulated as GMOs. These include:

Environmental impact
Assessing harm to non-target organisms or loss of plant diversity can be difficult because environmental harm often only becomes apparent slowly and over time.

As noted in our answer to Question 2, a small insertion or deletion of DNA within a gene, even if on-target, 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.

For example, if the chemistry of a genome-edited plant or animal were changed by the misreading of DNA, it could produce a compound that is toxic to the wildlife that feeds on it. These types of concerns mean that gene-edited organisms need to be analysed for any on-target effects, and the implications of on-target effects need to be carefully evaluated.
Apart from two crops grown in a very limited area for a very limited market in the American mid-west – Cibus's herbicide-tolerant oilseed rape (SU Canola) and Calyxt's soybean, designed primarily for the fast-food industry – there aren't any commercialised gene-edited crops, and there are no gene-edited animals in production at all, and so there's not enough information for us to understand how these organisms might interact with their environment.

We can, however, draw some conclusions from the environmental impacts of existing genetically engineered crops in North America, where their uptake has been most widespread.

In the 25 years since the introduction of GM crops, we have seen no real environmental gains and some important losses.

Gene editing is being used to produce crops that are resistant to a range of different herbicides. A 2012 study from Washington State University found that GM crops quickly encouraged the development of herbicide resistant 'superweeds' and as a result increased herbicide use. By 2016, research was demonstrating that glyphosate-resistant weeds had led to a 28% hike in herbicide use on GM soybeans compared with non-GM. This rise has also been reported in other countries such as Canada, Brazil and Argentina.

By 2017, insects had begun to show resistance to the insecticides bred into GM plants causing farmers to use more – and more dangerous mixtures of – pesticides to try and control them.

Genetically engineered crops are promoted as a way to increase yields and therefore contribute to land-sparing and lower-carbon agriculture. In reality, there has been no consistent improvement in yields attributable to GMOs and US government data shows yields from GM crops can be lower than their non-GM equivalents.

In 2016, an in-depth analysis by the New York Times, based on United Nations data, concluded that genetic modification in the US and Canada has failed to bring the expected increases in crop yields. That same year, a National Academy of Sciences report found that "there was little evidence" that the introduction of genetically modified crops in the US had led to yield gains beyond those seen in conventional crops.

Since agricultural use of gene editing is also focussed on insects (both beneficial and harmful) the recent attempt to control mosquito-borne diseases like yellow fever, dengue, chikungunya and Zika in Brazil, with the release of gene-edited, gene drive mosquitoes is also instructive.

The insects were supposed to breed with native mosquitoes and produce weak offspring that would die quickly without passing on their altered genome. Instead, the offspring have proved to be robust and are now breeding beyond their original breeding grounds.

This is a good example of why interconnected public health, ecosystem and societal risks and benefits should be carefully weighed before new man-made organisms are introduced into uncontained, shared environments that people live in and depend on.

Impact of new and future uses for genome editing

Whilst the main focus of the current gene-editing discussion is laboratory constructs, newer forms of gene editing use the living environment as a laboratory.

The use of gene drives is of particular concern. Gene drives essentially convert the environment into the laboratory, and can affect not only target organisms, but non-target organisms as well. This has implications for all kinds of plants, including crops (and perhaps especially organic crops) that could easily be contaminated through inadvertent contact with gene drive 'biomachines'. As the example of gene drive mosquitoes cited above illustrates, it also has implications for other living organisms.

In fact, we don't know the full extent of how gene drives – which force genetic changes through entire species in open fields – might interact with the natural world.

An increasing number of scientists, however, are raising concerns. Among them is Prof Kevin Esvelt of MIT, developer of the gene drive. Esvelt believes that early and irresponsible promotion of the technique means: "We are walking forwards blind. We are opening boxes without thinking about consequences. We are going to fall off the tightrope and lose the trust of the public."

Similarly, interfering RNA (RNAi) sprays, hailed as an alternative to conventional pesticides, spread 'edits' throughout insect species in the field. Once sprayed, they trigger a process inside the insects' cells to switch off or 'silence' genes that are essential for survival – like those needed to make new, healthy cells – thus killing them. Evidence shows that RNAi-related genetic modifications could, in some cases, be passed on for up to 80 generations.

Given both the rapid decline in insect populations globally and the demonstrated abilities of 'pests' to rapidly evolve to become resistant to commonly used pesticides, comprehensive assessment is needed before such products are used in open environments and regulation should ensure close monitoring of their use.

Finally, we should also be clear that it is only a very small step from engineering agricultural plants and animals to engineering plants and animals in the wider environment (something that falls under those 'other sectors/activities' in Part 2 of the consultation). Proposals to use gene drives and another gene-editing technology, synthetic biology, to advance conservation efforts are already in the public arena.

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. In the context of gene editing this 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 genome-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.

Animal welfare

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

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

Regardless of whether cloning is used or not, genetic engineering (including gene editing) raises multiple other ethical and welfare concerns.

For instance, using microinjection instead of cloning requires a large number of animals to act as 'mothers' for the implantation of genetically engineered embryos. On average, 24 embryos are needed to produce one gene-edited pig.

Creating hornless cattle via gene editing has been proposed as a solution to injuries sustained by cattle kept in close proximity to each other. But Brazil's plans to breed hornless dairy cattle, gene-edited with TALENs, were recently abandoned when a study by the US Food and Drug Administration revealed that one of the experimental animals contained a sequence of bacterial DNA, including a gene conferring antibiotic resistance.

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

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

Conventional breeding has been shown to push farmed animals beyond their physiological limits, leading to poor health and welfare outcomes, including bone and metabolic diseases, lameness, reproductive issues, breathing problems and mastitis. We see little evidence that gene editing, which is being used to create animals that will produce more, eat less, and 'fit in' to crowded industrial livestock units (which also have environmental impacts) will do anything other than exacerbate these issues.

Co-existence

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

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

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

Regulation, transparency and labelling are necessary if we are to achieve fair coexistence.

At present there are no proposals for how coexistence will work at farm level, within the supply chain and at the consumer interface. Farmers, food producers, civil society and consumers should all have a say in the development and implementation of effective coexistence rules and this discussion needs to take place before any action on deregulation is considered.

Trade within the UK

With regard to trade, deregulation has inevitable impacts on devolved nations. The Scottish and Welsh governments are clear that they will maintain their prohibition on producing and selling GMO crops and animals. We note, also, Stormont's concern about negative consequences for trade with Northern Ireland, given that the unregulated, unlabelled products of genetic engineering are unlawful in the EU.

Trade with the EU

We also believe deregulation constitutes a clear breach of the EU-UK Trade and Cooperation Agreement (TCA) principle of non-regression, which states: "A Party shall not weaken or reduce, in a manner affecting trade or investment between the Parties, its labour and social levels of protection

below the levels in place at the end of the transition period, including by failing to effectively enforce its law and standards."

The 2018 ECJ ruling, notes that exclusion of the products of gene editing from the regulations would reduce the scope of the directive in a way that "would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement."

In any event, significant divergence with the EU on regulation of agricultural gene editing and GMOs will have a major and adverse impact on UK food and drink exports to the EU and other countries.

Intellectual property

Intellectual property (IP) has special relevance to the question of the 'naturalness' of gene-edited organisms. 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.

Beyond that we don't consider IP to be directly relevant to the deregulation issue.

IP does have some implications for food sovereignty and seed saving and a prohibition on saving patented seeds may be particularly deleterious for smaller farmers in developing nations where seed saving can mean the difference between making ends meet or not.

Although rarely mentioned in popular discourse, IP issues are also blocking the commercial exploitation of gene editing in a way that regulation does not. The most widely used gene editing tool, CRISPR, is currently the subject of a long running and global legal battle over ownership of the patent to the technology. There is currently no end in sight to this dispute and given the chequered patent landscape, it is likely that different groups will end up with monopoly positions in different parts of the world. The complexity of the patent and licensing landscape has much greater implications for companies seeking to commercialise CRISPR technologies than the regulatory landscape.

Impact on SMEs

Since the 2018 ECJ ruling, regulation has been represented, by the government and the biotechnology industry, as an insurmountable hurdle for smaller companies and public researchers active in agricultural biotechnology. But while the average cost of bringing a new trait to market is around $136 million, at most 25% of this is related to regulation with the remaining 75% attributed to research and development costs.

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.

At the research and development stage, there are very few regulatory hurdles and because licenses to use gene editing technologies in R&D are relatively cheap it is probably the least costly part of the whole process of bringing a genetically modified organism to market.

The real cost is at the commercialisation stage where a handful of very large companies own the patents on the technology and can demand cripplingly high payments, in the form of commercial licence fees and royalty payments on product sales, for the use of their technology.

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

It should be noted also that SMEs that fail to develop a viable product bear the cost of their failure alone. The current R&D business model for gene-editing allows large companies to outsource a significant part of the research to SMEs but still take advantage of the profits from commercialisation while, at the same time, offloading some or all of any losses incurred.

Consumer choice

A wide range of surveys and in-depth studies have shown that there is significant public concern about growing or eating genetically engineered organisms and no public support for deregulation of any kind.

It is our belief that, for consumers, continuity of clear and transparent labelling is a red line.

The UK public remains overwhelmingly against genetically engineered foods. A 2020 survey by Food Standards Scotland found that genetically engineered foods are a top issue of concern for 57% of consumers, second only to chlorinated chicken.

Another 2020 study conducted by the National Centre for Social Research, which focused on Brexit-related issues, found that 59% wish to maintain a ban on genetically engineered crops.

Yet another survey, in 2021, by the UK's Economic and Social Research Council, found that 64% of those who took part were opposed to the cultivation of genetically engineered food.

Although not specifically focused on GMOs, a survey published in January 2021 by Unchecked UK of so-called "Red Wall" swing voters, most of whom voted to leave the European Union, showed strong opposition to the weakening of food laws, a move that would be seen as a betrayal of their Brexit vote.

This echoes the findings of a 2017 poll for Bright Blue, which looked at opinions around a green Brexit and found that 61% of Conservative voters wanted a ban on the production of GM crops. Looked at through the lens of 'leavers' and 'remainers' the survey also found that a similar percentage, on both sides, favoured maintaining or strengthening regulations around GM crops.

In Europe consumer group BEUC surveyed 11,000 consumers in 2019 and found, amongst other things, that consumers most spontaneously associate "sustainable food" with "low environmental impact" (48.6%), "use of GMOs and pesticides to be avoided" (42.6%) and "local supply chains" (34.4%).

On a global scale, the Lloyd's Register Foundation World Risk Poll, which surveyed 150,000 people in 142 countries, also looked at a range of future risks and found that up to 60% of people worldwide are worried the food they eat will harm them in the next two years. Genetically modified (GM) food was seen as a high risk by 48% of those surveyed.

Consumers are suspicious of, don't want and don't see the need for GM food. Using deregulation and any consequent absence of labelling to mislead consumers into buying and eating GM food is cynical, dishonest and undemocratic.

Social and ethical considerations
All technological advances bring new risks and, therefore, ethical questions, such as: *Why are we doing this?*, *How will it be used?* and *What will its impact on society be?* This is particularly true with gene editing, where what is being created could outlast us and be passed onto future generations. In addition to assessing risk to health and the environment, the Government has a duty to consider and assess, on a case-by-case basis, the value and ethics of adopting each new application of gene editing.

Issues that arise in this area include perceived naturalness but also the redefinition of 'natural' and 'nature' to suit business and industrial goals; heritability and therefore control and contamination of non-GM crops (especially with gene drives and RNAi pesticide sprays); impacts on agricultural employment, consumer choice and therefore the need for information and labelling of food products.

This kind of assessment should take place as early as possible in the research and development phase.

But there are also broader questions about agency and where the Government's unquestioning allegiance to technological advancement is leading us. If, as a society, we don't allow ourselves to place rational limits on – as well as the possibility of saying no to – proposed technological interventions, we lose the ability to shape our world, as well as our accountability for the things we shape.

Question 4 – What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not?

It is not enough to simply determine whether an organism could have been produced by so-called "traditional breeding". As we have outlined above, there is a critical need to define and describe what is meant by "gene editing" and "traditional breeding". Rational and meaningful criteria can only be developed once this is agreed – and it must be agreed through a consensus within society and not imposed by scientific and technology interests.

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

In February 2021 the European Food Safety Authority (EFSA) published a further report on the risk assessment of plants developed with new genetic engineering techniques and concluded that detailed risk assessment must be carried out even if no additional genes are inserted. EFSA concludes that these complex patterns of genetic change go beyond what has been achieved in genetic engineering and conventional breeding thus far.

This supports the view that gene-editing does not produce organisms which are natural or which could be achieved via traditional breeding.

In order to further determine if this is the case we suggest the need for:

- **The development of scientific criteria** There are no agreed scientific criteria to determine whether an organism produced by gene editing, or another genetic technology, could have been produced by traditional breeding. We know that genetic engineering technologies (including gene editing) can create many unintended genetic changes, so even if the

intended trait could have been produced by traditional breeding, the overall genetic makeup of the gene edited organism will not be the same. To scientifically determine that a gene-edited organism is the same as one produced by traditional breeding it would be necessary to examine the sequence of the entire genome and the detailed composition of the gene-edited organism, including the proteins and metabolites – as revealed in analytical methods known as 'omics. The technologies to do this are available and have been recommended for inclusion in GMO risk assessments.

- **A record-keeping and audit trail criteria** As some impacts of the gene editing process may not be immediately identifiable, we need an international public register of gene editing events used in the specific product (crop, animal or microorganism) that will enable tracing and monitoring over time. This register would form the basis of a supply chain audit and product labelling of the type already used in farming and food in various provenance schemes and most notably in the regulations governing organic certification. The methods and protocols of such schemes are well-developed and could be readily adapted.

Beyond this we suggest a complementary need for:

- **A social, ethical and values-based criteria** The national and international discussion over gene editing has recognised that, with such a far-reaching technology, assessment criteria must go beyond narrow scientific and technological aspects. Social, ethical and values-based criteria have been put forward and, as previously noted, some countries, such as Norway, have begun to use them in their legal and regulatory frameworks for genetic engineering technologies. It has also been acknowledged that citizens, specialists in the social sciences and ethics and members of civil society have a key role to play in developing and implementing such criteria. Citizen panels and assemblies are likely to be an important part of this process at all levels of decision-making.

- **Economic impact assessment and criteria** One of the Cabinet Office Consultation Principles, requires that public consultations should "Include validated impact assessments of the costs and benefits of the options being considered." As noted in our complaint to Defra, these calculations have not been done.

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PART 2 – Questions on broad reform of legislation governing organisms produced using genetic technologies

We reiterate our concerns, outlined in our complaint to Defra, that the information being sought in this section is highly specialised and complex and that it is not appropriate to expect a lay audience to comment in the detail requested.

As a background to our answers we would also like to make the following points:

As noted in our introductory remarks, regulation is not a ban. Its primary purpose is to protect people and the environment, not to build markets or strengthen trade relations. This, nevertheless, appears to be the Government's direction of travel.

For this reason, in addition to changing the definition of a 'GMO', we are concerned that the Government is also seeking to change the definition of 'regulation', altering both its concept and scope in an opaque manner that avoids public scrutiny.

We have observed a trend of euphemisms such as 'enabling', 'proportionate' and 'flexible' creeping into the regulatory discourse – including the Government White Paper, Regulation for the Fourth Industrial Revolution. These words will no doubt feature in the responses to this consultation from the biotechnology research establishment.

While superficially appealing, these words are not defined anywhere and therefore it is impossible to decipher their actual meaning within the context of regulation. We would therefore ask: *Enabling for whom? Proportionate to whose needs*? and *Flexible for the benefit of whom?*

We are also aware of much theoretical discourse on how to remove regulatory 'burden' (e.g. Nesta's Renewing Regulation: Anticipatory Regulation in an Age of Disruption and Deloitte's The Regulator's New Toolkit). We note that the BEIS research paper Regulator Approaches to Facilitate, Support and Enable Innovation acknowledges that little robust analysis has been carried out around the impacts of removing this so-called 'burden'.

Another concerning aspect of this discourse is the seemingly growing acceptance that disruptive technologies like gene editing are "blurring the lines between the physical, digital and biological worlds".

We've seen no discussion at government level about whether, or why, we should acquiesce to this blurring. While blurring these lines may have advantages for business and what is loosely described as 'innovation', its advantages for citizens and the environment are less obvious and concrete.

In the absence of any meaningful analysis, the Government's argument, in a nutshell, seems to be that things are changing quickly, that regulators are having difficulty keeping up with these changes and that removing regulations, and thereby the responsibility to keep up with and work methodically through, difficult challenges, is the best solution.

We do not believe this is responsible governance and ask that Defra 'shows its work' with regard to the impact of proposed changes in the direction of lighter-touch regulation and/or complete deregulation of gene editing.

It is our contention that changing either the definition of regulation or the regulation itself is likely to be a high impact action that a) affects a large number of businesses and individuals; b) introduces a radical change to existing regulations; c) requires government to acknowledge a high degree of uncertainty and a large number of factors which need to be considered to estimate the impact of such an action; d) likely to have disproportionate impact on one group of businesses (such as small businesses, or businesses in one sector) and e) is novel and contentious and may not, in the end, meet stated objectives.

Defra must, therefore, provide assessments of these factors and, given the high levels of uncertainty around gene editing, a clear explanation of how it will judge these levels of uncertainty against proposed actions.

Question 1 – There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies. Do you think existing non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed?

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

The question also asks respondents to indicate whether non-GM regulations are sufficient to control the use of genetically engineered organisms in the following sectors: a) cultivation of crop plants, b) breeding farmed animals, c) human food, d) animal feed, e) human and veterinary medicines, f) other sectors/activities.

NO – we do not believe that non-GM regulations are sufficient to regulate these areas – each area requires separate, additional regulation and monitoring.

We would also add that, in all cases, the current regulatory framework for genetically engineered crops and foods lacks independence, transparency and citizen engagement.

- Except in the case of human medicines, the regulatory process for GMOs in the UK is conducted through quasi-independent advisory bodies, such as the Advisory Committee on Releases in the Environment (ACRE) which advises Ministers or the Food Standards Agency (FSA), and its Scottish equivalent.

- Those with decision-making powers constitute a small and tightly-knit group. ACRE, for example, is an advisory non-departmental public body, sponsored by Defra. Its members are appointed by Defra Ministers and it has long been dogged by criticisms of a lack of openness and demands for closer scrutiny. The FSA, is a non-ministerial government department, but its board is mainly appointed by the Secretary of State for Health and Social Care. Although minutes and some meetings are open to the public, in practice business is conducted through specialist and so-called expert panels, with much information protected on grounds of confidentiality. The Chair and Members of its advisory body, the Advisory Committee on Novel Foods and Processes (ACNFP), are not independent but instead are appointed by the FSA.

- Post-Brexit, Ministers have been given even greater decision-making powers. But there is limited parliamentary scrutiny of Ministerial decisions and no opportunity for 'alternative' views to be heard, let alone considered.

- Overall, policy and strategy is largely conducted as a 'closed shop' with limited, if any, citizen and civil society engagement. This is also true for scientific and technical decisions, none of which is subject to citizen or civil society review or recall.

- There is a particular deficit in consideration of social and civil society needs and non-technical and non-commercial justification for any decision.

Question 2 – Where you have answered no, please describe what additional regulatory or non-regulatory measures you think are required, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures should be triggered.

Existing GM regulations should be kept and extended to include social and ethical considerations. Citizens should have a meaningful role to play in deciding what is, and is not, allowed. 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.

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

- These assessments should begin at the funding application stage in all developments (including R&D) involving the use of taxpayer funds or taxpayer-funded institutions.

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

- Civil society groups, especially those like Beyond GM that have specific expertise in the subject, should be considered equal stakeholders, and their views given equal weight, in the discussion and development of regulatory plans. Eschewing specialist group engagement in favour of engagement with groups that campaign more generally on food and farming, is inadequate for such a complex subject.

- Understanding the costs, benefits and risks of any new measure or proposal is fundamental to good policy making. As previously noted, a full Impact Assessment (IA) including the expected costs and benefits against the rationale for Government intervention should be performed before any regulatory changes are considered.

- These assessments and processes should become standard and subject to well-defined trigger points. However these trigger points cannot be defined unless – and until – there is agreement on key definitions and a clear statement of the scope and purpose of proposed changes in regulation and not before a full impact assessment has been made.