# Response to UK Government's Consultation on the Regulation of Genetic Technologies

*By Claire Robinson, editor, GMWatch.org*
*and Dr Michael Antoniou, molecular geneticist based at one of the UK's leading universities*

The UK Government's Department for Food and Rural Affairs (DEFRA) is proposing to weaken regulations so that some types of genetically modified (GM) plants, animals and foods can be produced in England and enter the environment and the food chain without proper risk assessments, public information about their whereabouts, or genetically modified organism (GMO) labelling.[1] This is our response to the public consultation on this proposal.

Claire Robinson is responding as a representative of GMWatch.org, an organization that is based in England but operates both nationally and internationally (including in Scotland, Wales, and Northern Ireland). Dr Michael Antoniou is responding as an individual. We are both resident in England. We are particularly interested in crop cultivation, human foods, animal feed, animal breeding, and the environment.

**General points about the consultation process**

We have serious concerns about the process of the consultation.

According to the Cabinet Office Consultation Principles, consultations should be "easy to understand and easy to answer".[2] However, the questions in the consultation demand an extremely high level of specialist knowledge, which is not appropriate for a public consultation.

It is also unacceptable that members of the public are expected to provide evidence for their views, whereas both the consultation questions and accompanying UK Government information materials, including the DEFRA press release[3] and the "Explainer" document,[4] provide no references to back up their claims, scientific or otherwise. They repeatedly make statements and claims that are scientifically false, are not backed by any evidence, and are contradicted by existing evidence.

For example, question 1 of the consultation states, “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.”

Yet the UK Government offers no proof that any gene-edited organism has ever been found to be the same as a traditionally bred organism, either at the level of the genome or in terms of its molecular composition (the proteins and natural chemicals that make up the structure and function of the organism). Indeed, no such proof exists, because the notion that gene editing can produce nature-identical changes is entirely theoretical.

Furthermore, gene editing has been shown in many research studies not to be precise but to produce extensive genetic errors.[5] Such errors, with respect to their magnitude, type, and frequency, have never been shown to arise from natural breeding. Therefore not only is there no evidence to support the assumption within question 1, but there is evidence to suggest that it is incorrect and misleading.

Question 4 of the consultation, “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?”, implies – correctly – that:

1) no agreed criteria exist that could determine equivalence between a gene-edited organism and one produced by traditional breeding, and
2) no evidence exists to support the assumption in question 1 that such an equivalence could ever occur. If there were such evidence, DEFRA would surely produce it in support of its stance.

These facts render question 1 misleading and what could be called a “trick question”.

See our response to Question 4 for further comments on this topic.

We have extensively detailed the falsehoods and misleading statements present in DEFRA’s “Explainer” document and it would be redundant to repeat them here.[6]

## Section 2

**Question 1**

*Currently, organisms developed using genetic technologies such as GE [gene editing] 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 – these products should continue to be regulated as GMOs.

However, the question is badly worded. “Could have been produced through traditional breeding” is not defined, though we interpret it to mean that gene-edited organisms can be the same as traditionally bred organisms.

We disagree with the premise of the question. There is no evidence that anyone has produced a gene-edited organism that could have been produced through traditional breeding. If someone wanted to claim that they had done so, they would need to prove that the organism was the same as a traditionally bred one, in terms of the genetic sequence and the molecular composition.

We consider the likelihood of such proof ever appearing to be vanishingly small. Indeed, if someone were to produce a gene-edited organism that was the same as a traditionally bred one, this would call into question any patent on the gene-edited version, since patents require an “inventive step” that could not occur in nature. It would also call into question the need to produce the organism using a risky experimental technology like gene editing.

Therefore the possibility that a gene-edited organism would be the same as a traditionally bred one is entirely theoretical. The government should not weaken regulations designed to protect health and the environment on the basis of unproven theories.

Genetic modification technologies, including gene editing, are artificial laboratory-based genetic engineering procedures, which, by definition, produce novel genetically modified organisms. This was confirmed by the ruling of the European Court of Justice (ECJ) in 2018 which stated that gene editing is genetic engineering and that gene-edited crops and animals are GMOs.[7]

Gene-editing techniques induce targeted mutations (DNA damage) in plants, animals and other living organisms in order to confer new traits. The ECJ ruled 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 seeks to protect human health and the environment by ensuring GMOs are subjected to a full risk assessment and must be labelled.

There is no reason for the UK to override this thorough, carefully considered judgement, which is in accord with the science underpinning gene editing.

Those who claim that a gene-edited organism can be the same as a traditionally bred organism are only able to reach this conclusion by ignoring the process by which the gene-edited organism is developed. Current GMO regulations are process-based, in that they recognize that the way in which an organism is produced is relevant to the risks it presents to health and environment.

Technically and scientifically, genetic modification procedures (including gene editing) are radically different from traditional breeding. GM is an artificial laboratory-based technique in which researchers directly alter the genome. This direct intervention in the genome defines genetic modification, underpinning the definition of a GMO in the EU[8] and the United Nations' Cartagena Protocol on Biosafety.[9]

Gene-editing processes vary widely – a fact not acknowledged in the DEFRA consultation document. However, when analysis is carried out with adequate screening methods, they are all found to produce a large number and wide variety of genetic errors (mutations, also known as damage to DNA) and unintended effects: see, for example, the list of references collected by GMWatch.[10,5]

**Gene-edited rice researchers warn of "uncertainties and risks regarding genome editing"**

Unintended effects of gene editing include large insertions, deletions, and rearrangements of DNA. These have been found to occur even in a so-called SDN-1 gene-editing procedure in rice (SDN-1 refers to the gene disruption type of editing, where no foreign DNA or repair template are deliberately inserted; this term is not to be confused with the name of the gene targeted in this study, SD1). This was a surprise because the researchers were only intending to make small insertions and deletions in the genome.[11]

The authors of the new paper warned that CRISPR "may be not as precise as expected in rice". They said, "early and accurate molecular characterization and screening must be carried out for generations before transitioning of CRISPR/Cas9 system from lab to field". They added, "Understanding of uncertainties and risks regarding genome editing is necessary and critical before a new global policy for the new biotechnology is established".[11]

This study shows that SDN-1 gene editing, in which no foreign DNA or genes were inserted, can cause widespread genetic damage, which may have

implications for public health and the environment.

**Unsubstantiated assumptions**

There is no sign that the UK government has attempted to understand the uncertainties and risks of gene-editing techniques. Instead it is trying to change policy on the basis of unsubstantiated assumptions. Risks are not limited to the introduction of foreign DNA or genes but can arise from attempts to delete or modify an existing gene within the organism.

The UK Government has presented no evidence that the types of changes brought about by gene editing, such as the large insertions, deletions, and rearrangements of DNA that were found in the gene-edited rice, can occur in traditionally bred organisms, and if so, with what frequency (greater, lesser, or the same). Instead the government is expecting the public to accept their unproven assumption that gene-edited organisms are the same as organisms produced with traditional breeding.

Gene editing can be used to insert foreign DNA or genes (so-called SDN-3 procedures), though this is not acknowledged in the public consultation documents. It is not clear whether the government intends to deregulate even SDN-3 procedures.

What is more, even in SDN-1 and -2 gene editing procedures, which do not intend to introduce foreign DNA or genes, foreign DNA can be unintentionally inserted.[12] There is no guarantee that these unintentional insertions will be bred out by back-crossing via traditional breeding, unless regulation requires it.

This is confirmed by experience with first-generation GM crops, which shows that insufficient backcrossing is done to remove unwanted mutations that can lead to risks. For example, unintended protein and metabolic alterations were found in GM NK603 maize, which were a direct result of the GM transformation process and that could affect nutritional quality.[13] These unwanted changes may explain adverse health impacts observed from consumption of the maize.[14] In the case of GM MON810 Bt insecticidal maize, it contained an allergen, zein, that was not present in the parent crop.[15]

In the case of vegetatively propagated crops, like potatoes, bananas and fruit trees, unwanted mutations stemming from the GM or gene-editing transformation process cannot be bred out but will remain in the final marketed product.

Regulations must be in place to require developers to check for inadvertent insertion of foreign DNA and all genetic errors. These regulations must be

process-based so that knowledge of the process can inform regulators about which data to require of developers and what to look for in those data.

**"Nature-identical" claims cannot be trusted: Case of gene-edited hornless cattle**

Developers' claims that their gene-edited products are nature-identical should be viewed with extreme scepticism and tested via stringent regulatory requirements, as shown by the case of the gene-edited hornless cattle.

In 2019 researchers at the US Food and Drug Administration (FDA) analysed the genomes of two calves[16] produced by gene editing and animal cloning. The calves had been gene edited not to grow horns by the biotech company Recombinetics, using the TALEN tool in a so-called SDN-3 (gene insertion) procedure. The genetic modification aimed at inserting into their genome the POLLED gene, taken from conventionally bred hornless cattle.

A commentary by academic researchers, some of whom were associated with Recombinetics, claimed that the gene editing used in the cattle was precise, that the changes brought about were largely identical to what could have arisen naturally, and that any animals with unwanted traits would be excluded from breeding programmes.[17] This is the same "nature-identical" narrative that the UK government is using as a justification for deregulation.

Recombinetics scientists had claimed that the gene editing used in the cattle was so precise that "our animals are free of off-target events".[18] The company's executives said, "We know exactly where the gene should go, and we put it in its exact location," and "We have all the scientific data that proves that there are no off-target effects."[19]

However, all these claims were proven false by the FDA scientists' analysis.

At one of the target sites of the gene-editing procedure within the calves' genome, the POLLED gene had inserted as planned. But at the other intended gene editing site, two copies of the entire circular plasmid DNA construction that carried the POLLED sequence, which acted as the repair template DNA in the SDN-3 procedure, had been unintentionally integrated. These unintentionally integrated plasmids contained complete gene sequences that confer resistance to three antibiotics (neomycin, kanamycin, and ampicillin).[16]

It is not known if the antibiotic resistance genes could affect the health of the animal or of people who consume its products. Those questions need to be evaluated in a detailed risk assessment, such as would not be done if the UK

government deregulates gene editing. One risk that merits investigation is the possibility that these genes could transfer to disease-causing bacteria, which would then become resistant to antibiotics, adding to an already massive public health problem for both humans and animals.[20]

**Self-regulation by GMO developers is unacceptable**

Even though the UK government might respond that it does not intend to deregulate SDN-3 gene editing, the fact that it has not defined "Could have been produced through traditional breeding" allows GMO developers to claim that their gene-edited organisms are the same as could arise from traditional breeding, even when that is totally inaccurate.

Developers cannot be trusted to self-regulate and determine for themselves whether the changes induced by gene editing are safe or the same as could happen in nature. Strict regulation must be in place to ensure thorough screening for unintended effects. As commonly used screening methods miss many mutations,[21] a combination of long-range PCR and long-read DNA sequencing must be used. In addition, safety studies must be conducted to better understand the risks to public health and the environment posed by the gene-edited organism.

In sum, gene editing is an immature technology involving direct human intervention in the genome. It causes changes with potential consequences that are not understood by scientists but which could affect the health of consumers and/or the environment. It is premature to relax the safeguards around the technology.

**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 pose a greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced.

Traditional breeding is widely accepted to have a history of safe use stretching back millennia. In stark contrast, genetic engineering (and especially gene editing) is so new that we are only just beginning to understand what can go wrong. The European Court of Justice judgement of 2018 supported this view. It argued that newer techniques (most of which

have yet to reach the marketplace) do not have a history of safe use and therefore “the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those that result from the production and release of a GMO through transgenesis”.[7]

A large and ever-growing number of scientific studies in human, animal and plant cells show that gene editing is not precise but gives rise to numerous genetic errors, also known as unintended mutations (DNA damage). These occur at both off-target sites in the genome (locations other than that targeted for the edit) and on-target (at the desired editing site). The types of mutation include large deletions, insertions, and rearrangements of DNA.[10,21,22]

These mutations occur at various stages of the process, including stages that gene editing has in common with old-style transgenic GM methods, such as tissue culture and GM transformation by *Agrobacterium tumefaciens* infection (in which this soil bacterium is used to insert the foreign genetic material into the DNA of plant cells).[23]

Even the intended changes can cause unintended (“pleiotropic”) effects in the edited organism,[24] since genes and their protein or RNA products act in networks and not in isolation.

Even the simplest application of gene editing (so-called SDN-1), which is intended to destroy a gene function, can lead to unwanted mutations.[25,26,27] These mutations can lead to the creation of new gene sequences producing new mutant proteins, with unknown consequences to the health of consumers of the gene-edited organism. In addition, alterations in the pattern of gene function can take place within the organism whose genome has been modified. In plants, these alterations can lead to compositional changes, which, scientists warn, could prove to be toxic and/or allergenic to human or animal consumers.[21,22,28]

Unintended mutations and their effects are under-researched in plants compared with human and animal cells. But since the mechanisms of gene editing and subsequent DNA repair are the same between animals and plants, there is every reason to believe that the types of unintended mutations seen in human and animal cells will also be found in plants. Research in rice plants attests to this fact.[11]

These unintended genetic changes will alter the pattern of gene function within the organism. In plants, this can alter biochemical pathways and lead to compositional changes, which, scientists warn, could include the production of novel toxins and allergens or altered levels of existing toxins and allergens.[21,22,28]

This means that gene-edited organisms, even if they are not intended to carry any foreign DNA, must be carefully assessed for their safety before they are allowed on the European market.

A statement published by the European Network of Scientists for Social and Environmental Responsibility (ENSSER) was signed by 61 international scientists who are independent of the agricultural biotechnology industry. The statement recommended that, because of our lack of knowledge, the possibility of unintended errors, and the consequent risk of gene-edited foods containing new toxins and allergens, or unexpectedly altered levels of such substances, the products of new genetic modification techniques should be strictly regulated as GMOs.[28]

**Mutations from gene editing are different from those from conventional or mutation breeding**

Evidence shows that mutations induced by gene editing are not the same as those induced by chemicals or radiation in mutagenesis breeding. For example, a scientific review shows that gene editing can produce changes in areas of the genome that are otherwise protected from mutations. In other words, gene editing makes the whole genome accessible for changes.[29]

Mutations induced by mutation breeding will more often than not occur in areas of the genome that are non-coding and non-regulatory and therefore are unlikely to affect gene function.

With gene editing, in contrast, mutations are more likely to happen at locations in the genome that directly affect the function of one or more genes. First, there is intentional targeting of a gene's coding region or its regulatory elements to alter its function. Gene editors will preferentially target sites that are relevant for protein production and gene regulation for alterations, since the objective is to change a trait. Second, much of the off-target mutation-causing activity of the gene-editing tool will occur at locations within the genome with a similar DNA sequence to the intended target site. This means that if the intended gene editing target site is a gene's coding region or its regulatory elements, off-target mutations will occur in other genes with a similar DNA sequence.

As a result, off-target and unintended on-target mutations are likely to affect important protein-coding gene regions and gene regulatory activity.

A separate scientific review shows that gene-editing techniques enable complex alterations of genomes that would be extremely difficult or impossible

to achieve with conventional breeding or mutation breeding. In gene editing, so-called multiplexing approaches allow the targeting and alteration of multiple gene variants, which can be members of the same or different gene families.[21]

In summary, gene editing can cause specific unintended effects and can be used to generate novel genetic combinations that cannot readily be achieved using conventional breeding or mutagenesis techniques. It can overcome genetic limitations that exist in conventional breeding.[21]

These unique attributes of gene-editing applications show that they pose unique risks, justifying strict regulation.

**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 many non-safety issues that must be considered when deciding how to regulate genetic technologies.

**Damage to our trading relationship with the EU**

No EU country will accept food products, commodities, seed or other imports from the UK that might include unauthorised GMOs. If gene-edited organisms are not regulated as GMOs in England, English farmers, food producers and exporters will not know whether they are using GMOs. It will be impossible for them to prove that their goods are acceptable for import into the EU.

Even where GMOs are approved for import into the EU, they must be labelled (making them traceable) and subjected to post-market monitoring to check for any problems and allow for unsafe products to be recalled. When GMOs are used in food, they must be labelled. If gene-edited organisms are not regulated as GMOs in England, English farmers, food producers and exporters will not be able to meet these requirements. And if anything goes wrong, for example, if a gene-edited food is found to cause allergic reactions, the cause will not be able to be traced.

**Undermining the UK's devolved nations**

Food and agriculture are devolved areas of competency, meaning that Scotland, Wales and Northern Ireland are responsible for GM regulation in their own countries. All three of the UK's devolved countries have sceptical policies on GM and in 2015 all three used EU Directive 2015/412 to ban the cultivation of GM crops on their territory.

This consultation is said to only apply to England, but if DEFRA changes the definition of a GMO it will affect Scotland, Wales and Northern Ireland. The Internal Market Act could force Scotland and Wales to allow English food producers to sell non-safety checked, unlabelled gene-edited foods, whatever the rules at home. Food businesses in Northern Ireland could be prevented from selling or handling any food produced in England because it might include GMOs that breach EU rules.

**Gene editing raises animal welfare concerns**

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.[30] However, 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 the RSPCA[31] and Compassion in World Farming,[32] inflicts severe or lasting pain on animals, violates their integrity, and reduces them to a mere instrument or tool.

Cloning in cattle has a very low success rate, with typically fewer than 10% of the cloned animals surviving till birth.[33] This means 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.[34] Defects include premature death, pneumonia, liver failure and obesity.[35] A study on cloned mice found that up to 4% of the genes in the placenta were abnormally expressed.[36]

Regardless of whether cloning is used or not, genetic engineering (including gene editing) raises multiple other ethical and welfare concerns.[37,38] 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.[39]

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 farming operations. For instance, gene editing pigs for disease resistance could lead to the animals being raised in less hygienic conditions. Similarly, gene editing cows to not grow 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 genes are not inserted into the animal. For example, gene editing to produce super-muscly animals resulted in rabbits, pigs and a goats with enlarged tongues and pigs having an extra spinal vertebra,[40] even though no DNA had been inserted.

**Co-existence with non-GM crops and livestock**

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 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.[41,42]

Many consumers will not wish to buy products produced using genetic engineering, including gene editing technologies, and many farmers will not wish to use seeds and planting stock produced with such methods.

The 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 and consumers should all have a say in the development and implementation of effective coexistence rules.

**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 on to 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. This kind of assessment

should take place as early as possible in the research and development phase.

If we don't allow for the possibility of saying no to proposed technological interventions, or allow ourselves to place rational limits on them, we lose the ability to shape our world, as well as our accountability for the things we shape.

**Undermining consumer choice and confidence**

UK consumers do not want to grow, buy or eat genetically engineered foods. A 2020 survey by Food Standards Scotland found that, next to chlorinated chicken, genetically engineered foods are a top issue of concern for 57% of consumers.[43] A 2020 study by NatCen Social Research, which focused on Brexit-related issues, found that 59% wish to maintain the ban on genetically engineered crops.[44] A 2021 survey by NatCen Social Research found that 64% of those who took part were opposed to the cultivation of genetically engineered foods.[45]

British food is associated with high standards but this perception will be quickly undermined once people know that new, experimental products of genetic engineering are being distributed, unlabelled and without any traceability or accountability, throughout our food system.

**A distraction from key sustainability issues**

Gene editing is promoted with a long list of inflated claims have almost no foundation in science. Many of the same claims were made for the first generation of GMOs when they emerged in the 1990s and yet these older style GMOs have not resulted in higher yields,[46,47,48,49] lower pesticide use,[50] better profits for farmers,[51] lower seed prices,[52] or increased farmer choice of seeds.[53] GMOs have also failed to 'feed the world'. Around 40% of GM crops are turned into biofuels, while the rest are used as animal feed or as ingredients – mostly oils and sugars from corn, soy and cottonseed – for unhealthy highly processed human food.[54]

An understanding of genetics can greatly assist with both plant and animal breeding. Nevertheless, it is widely recognised that there are limits to what can be achieved solely through genetics in terms of improvement in plant variety/performance and in terms of the bigger picture of 'feeding the world'.

To frame gene editing as an answer to farming's problems is not just unproven and misleading, it distracts attention from meaningful actions which are likely to have a greater and more immediate beneficial impact. Instead of

deregulating gene editing the government should be addressing the real problems, such as soil health and waste in the food system.

**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?*

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.

However, in our view, if a developer wished to scientifically determine if a gene-edited organism is the same as one produced by traditional breeding, they would have to examine the sequence of the entire genome and the detailed composition of the gene-edited organism, including the proteins and metabolites – as can be revealed in analytical methods known as "omics".[55] Omics technologies are available and have been recommended for inclusion in GMO risk assessments.[21]

Nevertheless, given the large number of unintended effects from gene-editing tools (see our response to question 1, above), even if the intended trait could have been produced by traditional breeding, the overall genetic makeup of the gene-edited organism and composition will almost certainly not be the same.

## Section 3

**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 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 regulation and monitoring.

Existing UK laws will not effectively manage the specific and novel risks of gene editing, which arise from the processes by which these organisms are made (see above). These risks must be independently assessed prior to marketing of the gene-edited product, to protect public health and the environment.

The following brief analysis of the existing laws explains why they are not adequate to regulate gene-edited foods, crops and livestock.

The Food Safety Act 1990 attempts to ensure food safety by making illegal the act of rendering "any food injurious to health" by adding something to it, subtracting something from it, or subjecting it to a process or treatment, with the intent that it shall be sold for human consumption. It also makes illegal the act of selling "food not of the nature or substance or quality demanded."[56]

But it is far from clear that a gene-edited food would fall under this description. In addition, the law requires the consumer to prove that a certain GM gene-edited food has injured their health. This would be virtually impossible to prove outside of controlled laboratory conditions.

The current UK and EU GMO laws, in contrast, put the onus on the developer to prove that their GMO is safe for consumption *before* it can be approved for marketing — a precautionary approach that puts the burden of proof of safety on the GMO industry. It is not left to the public to prove that the food is unsafe after it's already out there in the marketplace and the fields, potentially doing harm.

The Environmental Protection Act 1990 may not in the future protect the environment from effects of GMO releases because the Act is based on the EU's GMO laws,[57] which require safety checks on environmental impacts of GMOs before marketing, but which the UK government wishes to jettison.

Amendment 275, introduced in the House of Lords in 2020 in a bid to deregulate gene editing, contained the demand that the Environmental Protection Act 1990 be changed to alter the definition of a GMO.[58] Clearly, therefore, the public cannot rely on the Act retaining its environmental protections regarding GMOs, including gene-edited GMOs.

New plant varieties are required by the Plant Varieties Act 1997 to be shown to be distinct, uniform, stable and new.[59] But the law contains no requirements to show safety for human and animal consumption or for the environment. The EU's GMO laws recognise that GM plants can pose risks to the health of consumers and environment and demands that these safety aspects are checked prior to marketing.

The Novel Foods (England) Regulations 2018 do cover food safety, and any novel food needs to be authorized prior to marketing.[60] However, these regulations are based on EU law (and thus are at risk of being rewritten or jettisoned post-Brexit). In addition, it is highly likely that if gene-edited foods, crops and livestock are deregulated on the (false) assumption that they could arise via conventional breeding, they will not be seen as "novel" and would fall outside the remit of these regulations. Finally, these regulations have no requirement for the types of tests that could examine the safety aspects of gene-edited foods, such as whole genome sequencing, with analysis of all genetic errors, and determination of molecular composition by "omics" analyses.

In sum, we have no confidence that the existing non-GMO-specific regulations will be sufficient to protect health and the environment.

**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.*

Assessment of all GMOs (including gene-edited GMOs) 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 rollout pathways, including intellectual property rights, provision for long-term safety assessments, the use of whole genome sequencing (using long-read DNA sequencing technology) to look for all unintended effects and appropriate multi-omics analysis in the case of food and feed, and a provision for post-release monitoring in the case of releases into open environments.

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

These assessments and processes should become standard and subject to well-defined trigger points.

**References**

1. DEFRA. The regulation of genetic technologies. consult.defra.gov.uk. Published January 7, 2021. Accessed February 2, 2021.

https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/

2. UK Government Cabinet Office. *Consultation Principles 2018*. UK Government Cabinet Office; 2018. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/691383/Consultation_Principles__1_.pdf

3. UK Government. Gene editing creates potential to protect the nation's environment, pollinators and wildlife. GOV.UK. Published January 7, 2021. Accessed March 9, 2021. https://www.gov.uk/government/news/gene-editing-creates-potential-to-protect-the-nations-environment-pollinators-and-wildlife

4. DEFRA. *Gene Editing: What Are the Benefits of Gene Editing?* DEFRA; 2021. https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/

5. GMWatch. Gene editing: Unexpected outcomes and risks. GMWatch.org. Published August 3, 2020. Accessed January 11, 2021. https://www.gmwatch.org/en/67-uncategorised/19499-gene-editing-unexpected-outcomes-and-risks

6. Robinson C. GMWatch mythbuster exposes UK government misinformation on gene editing. GMWatch.org. Published February 16, 2021. Accessed March 9, 2021. https://www.gmwatch.org/en/news/latest-news/19697-gmwatch-mythbuster-exposes-uk-government-misinformation-on-gene-editing

7. European Court of Justice. *C-528/16 - Confédération Paysanne and Others: Judgement of the Court.*(European Court of Justice 2018). Accessed September 27, 2019. http://curia.europa.eu/juris/documents.jsf?num=C-528/16

8. European Parliament and Council. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. *Official Journal L*. 2001;106:1-39. http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0018

9. Conventional on Biological Diversity. Text of the Cartagena Protocol on Biosafety. http://bch.cbd.int. Published July 16, 2013. Accessed February 4, 2021. http://bch.cbd.int/protocol/text/

10. Robinson C, Antoniou M. Science supports need to subject gene-edited plants to strict safety assessments. GMWatch.org. Published November 20, 2019. https://www.gmwatch.org/en/news/latest-news/19223

11. Biswas S, Tian J, Li R, et al. Investigation of CRISPR/Cas9-induced SD1 rice mutants highlights the importance of molecular characterization in plant molecular breeding. *Journal of Genetics and Genomics*. Published online May 21, 2020. doi:10.1016/j.jgg.2020.04.004

12. Ono R, Yasuhiko Y, Aisaki K, Kitajima S, Kanno J, Hirabayashi Y. Exosome-mediated horizontal gene transfer occurs in double-strand break repair during genome editing. *Commun Biol*. 2019;2(1):1-8. doi:10.1038/s42003-019-0300-2

13. Mesnage R, Agapito-Tenfen SZ, Vilperte V, et al. An integrated multi-omics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process. *Scientific Reports*. 2016;6:37855. doi:10.1038/srep37855

14. Séralini G-E, Clair E, Mesnage R, et al. Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Environmental Sciences Europe*. 2014;26(14). doi:10.1186/s12302-014-0014-5

15. Zolla L, Rinalducci S, Antonioli P, Righetti PG. Proteomics as a complementary tool for identifying unintended side effects occurring in transgenic maize seeds as a result of genetic modifications. *J Proteome Res*. 2008;7:1850-1861. doi:10.1021/pr0705082

16. Norris AL, Lee SS, Greenlees KJ, Tadesse DA, Miller MF, Lombardi HA. Template plasmid integration in germline genome-edited cattle. *Nat Biotechnol*. 2020;38(2):163-164. doi:10.1038/s41587-019-0394-6

17. Carroll D, Van Eenennaam AL, Taylor JF, Seger J, Voytas DF. Regulate genome-edited products, not genome editing itself. *Nat Biotechnol*. 2016;34(5):477-479. doi:10.1038/nbt.3566

18. Carlson DF, Lancto CA, Zang B, et al. Production of hornless dairy cattle from genome-edited cell lines. *Nature Biotechnology*. 2016;34:479-481. doi:10.1038/nbt.3560

19. Regalado A. Gene-edited cattle have a major screwup in their DNA. *MIT Technology Review*. Published online August 29, 2019. Accessed March 20, 2020. https://www.technologyreview.com/s/614235/recombinetics-gene-edited-hornless-cattle-major-dna-screwup/

20. Nawaz MA, Mesnage R, Tsatsakis AM, et al. Addressing concerns over the fate of DNA derived from genetically modified food in the human body: A review. *Food Chem Toxicol*. 2018;124:423-430. doi:10.1016/j.fct.2018.12.030

21. Kawall K, Cotter J, Then C. Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environmental Sciences Europe*. 2020;32(1):106. doi:10.1186/s12302-020-00361-2

22. Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark O-G, Myhr AI. Revisiting risk governance of GM plants: The need to consider new and emerging gene-editing techniques. *Front Plant Sci*. 2018;9. doi:10.3389/fpls.2018.01874

23. Tang X, Liu G, Zhou J, et al. A large-scale whole-genome sequencing analysis reveals highly specific genome editing by both Cas9 and Cpf1 (Cas12a)

nucleases in rice. *Genome Biology*. 2018;19(1):84. doi:10.1186/s13059-018-1458-5

24. Eckerstorfer MF, Dolezel M, Heissenberger A, et al. An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). *Front Bioeng Biotechnol*. 2019;7. doi:10.3389/fbioe.2019.00031

25. Tuladhar R, Yeu Y, Piazza JT, et al. CRISPR-Cas9-based mutagenesis frequently provokes on-target mRNA misregulation. *Nat Commun*. 2019;10(1):1-10. doi:10.1038/s41467-019-12028-5

26. Mou H, Smith JL, Peng L, et al. CRISPR/Cas9-mediated genome editing induces exon skipping by alternative splicing or exon deletion. *Genome Biology*. 2017;18:108. doi:10.1186/s13059-017-1237-8

27. Smits AH, Ziebell F, Joberty G, et al. Biological plasticity rescues target activity in CRISPR knock outs. *Nat Methods*. 2019;16(11):1087-1093. doi:10.1038/s41592-019-0614-5

28. European Network of Scientists for Social and Environmental Responsibility (ENSSER). ENSSER Statement: New genetic modification techniques and their products pose risks that need to be assessed. ensser.org. Published November 8, 2019. https://ensser.org/publications/2019-publications/ensser-statement-new-genetic-modification-techniques-and-their-products-pose-risks-that-need-to-be-assessed/

29. Kawall K. New possibilities on the horizon: Genome editing makes the whole genome accessible for changes. *Front Plant Sci*. 2019;10. doi:10.3389/fpls.2019.00525

30. Farm Animal Welfare Committee. *Opinion on the Welfare Implications of Breeding and Breeding Technologies in Commercial Livestock Agriculture*. Farm Animal Welfare Committee; 2012. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/324658/FAWC_opinion_on_the_welfare_implications_of_breeding_and_breeding_technologies_in_commercial_livestock_agriculture.pdf

31. Dukes J, Wrathall J, Hawkins P, Coughlan E, Collins S. *RSPCA Response to Genome Editing and Farmed Animals, Nuffield Council for Bioethics Call for Evidence, September 2019*. RSPCA; 2019. https://www.rspca.org.uk/documents/1494939/7712578/RSPCA+response+-+Genome+Editing+and+farmed+animals.pdf/77d17c92-0bc5-6eb0-1837-1bc430fbd97f?t=1584525808480

32. Pickett H. *Farm Animal Cloning*. Compassion in World Farming; 2010. https://www.ciwf.org.uk/media/3816935/farm-animal-cloning-report.pdf

33. Biase FH, Rabel C, Guillomot M, et al. Massive dysregulation of genes involved in cell signaling and placental development in cloned cattle conceptus and

maternal endometrium. *PNAS*. 2016;113(51):14492-14501. doi:10.1073/pnas.1520945114

34. National Human Genome Research Institute. Cloning fact sheet. Genome.gov. Published August 15, 2020. Accessed March 8, 2021. https://www.genome.gov/about-genomics/fact-sheets/Cloning-Fact-Sheet

35. Holden C, 12:00. Multiple gene defects found in clones. *Science | AAAS*. Published online September 12, 2002. Accessed March 8, 2021. https://www.sciencemag.org/news/2002/09/multiple-gene-defects-found-clones

36. Humpherys D, Eggan K, Akutsu H, et al. Abnormal gene expression in cloned mice derived from embryonic stem cell and cumulus cell nuclei. *Proc Natl Acad Sci U S A*. 2002;99:12889-12894. doi:10.1073/pnas.192433399

37. Yunta E. Ethical issues in genome editing for non-human organisms ssing CRISPR/Cas9 system. *Journal of Clinical Research & Bioethics*. 2017;8(2). doi:10.4172/2155-9627.1000300

38. Bruce A. Genome edited animals: Learning from GM crops? *Transgenic Res*. 2017;26(3):385-398. doi:10.1007/s11248-017-0017-2

39. Tan W, Proudfoot C, Lillico SG, Whitelaw CBA. Gene targeting, genome editing: From Dolly to editors. *Transgenic Res*. 2016;25:273-287. doi:10.1007/s11248-016-9932-x

40. Rana P, Craymer L. Big tongues and extra vertebrae: The unintended consequences of animal gene editing. *Wall Street Journal*. https://www.wsj.com/articles/deformities-alarm-scientists-racing-to-rewrite-animal-dna-11544808779. Published December 14, 2018. Accessed February 10, 2021.

41. Moldenhauer H. Give the people what they want: Non-GMO sells. www.euractiv.com. Published July 22, 2019. Accessed March 8, 2021. https://www.euractiv.com/section/agriculture-food/opinion/give-the-people-what-they-want-non-gmo-sells/

42. Byrne J. Awareness of non-GMO label in Germany nearly doubles, non-GMO salmon product set to hit shelves. feednavigator.com. Published November 15, 2019. Accessed March 8, 2021. https://www.feednavigator.com/Article/2019/11/15/Awareness-of-non-GMO-label-in-Germany-nearly-doubles

43. Food Standards Scotland. Survey of food concerns in relation to Brexit - Wave 1. www.foodstandards.gov.scot. Published September 2020. Accessed March 8, 2021. https://www.foodstandards.gov.scot/publications-and-research/publications/survey-of-food-concerns-in-relation-to-brexit-wave-1

44. NatCen Social Research. After four years of Brexit, British Social Attitudes reveals voters' hopes and fears for life outside the EU. natcen.ac.uk.

Published October 8, 2020. Accessed March 8, 2021. https://natcen.ac.uk/news-media/press-releases/2020/october/after-four-years-of-brexit,-british-social-attitudes-reveals-voters%E2%80%99-hopes-and-fears-for-life-outside-the-eu

45. Curtice J, Davies C, Fishkin J, Ford R, Siu A. *Thinking about Post-Brexit Public Policy: Voters' Perspective on Immigration and Regulation*. NatCen Social Research; 2021. https://whatukthinks.org/eu/wp-content/uploads/2020/12/WUKT-EU_Initial-Deliberation-Findings-Paper_v5.pdf

46. Fernandez-Cornejo J, Wechsler S, Livingston M, Mitchell L. *Genetically Engineered Crops in the United States*. US Department of Agriculture; 2014. https://www.ers.usda.gov/publications/pub-details/?pubid=45182

47. Russell K, Hakim D. Broken promises of genetically modified crops. *The New York Times*. https://www.nytimes.com/interactive/2016/10/30/business/gmo-crops-pesticides.html, https://www.nytimes.com/interactive/2016/10/30/business/gmo-crops-pesticides.html. Published October 29, 2016. Accessed December 13, 2020.

48. Heinemann JA, Massaro M, Coray DS, Agapito-Tenfen SZ, Wen JD. Sustainability and innovation in staple crop production in the US Midwest. *International Journal of Agricultural Sustainability*. Published online June 14, 2013:71-88. http://www.tandfonline.com/doi/full/10.1080/14735903.2013.806408#.UrnaHfYnuUc

49. National Academies of Sciences, Engineering, and Medicine. *Genetically Engineered Crops: Experiences and Prospects*. National Academies of Sciences, Engineering, and Medicine; 2016. Accessed July 18, 2017. https://www.ncbi.nlm.nih.gov/pubmed/28230933

50. Benbrook C. Impacts of genetically engineered crops on pesticide use in the US – The first sixteen years. *Environmental Sciences Europe*. 2012;24(24). doi:10.1186/2190-4715-24-24

51. Gómez-Barbero M, Rodríguez-Cerezo E. *Economic Impact of Dominant GM Crops Worldwide: A Review*. European Commission Joint Research Centre: Institute for Prospective Technological Studies; 2006. http://ftp.jrc.es/EURdoc/eur22547en.pdf

52. Benbrook CM. *The Magnitude and Impacts of the Biotech and Organic Seed Price Premium*. The Organic Center; 2009. http://www.organic-center.org/reportfiles/Seeds_Final_11-30-09.pdf

53. Hilbeck A, Lebrecht T, Vogel R, Heinemann JA, Binimelis R. Farmer's choice of seeds in four EU countries under different levels of GM crop adoption.

*Environmental Sciences Europe*. 2013;25(1):12. doi:10.1186/2190-4715-25-12

54. Foley J. It's time to rethink America's corn system. *Scientific American*. Published online March 5, 2013. Accessed April 9, 2015. http://www.scientificamerican.com/article/time-to-rethink-corn/

55. European Food Safety Authority. *EFSA Scientific Colloquium 24 – 'omics in Risk Assessment: State of the Art and next Steps*. EFSA; 2018. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1512

56. UK Government. *Food Safety Act 1990*. Statute Law Database; 1990. Accessed March 7, 2021. https://www.legislation.gov.uk/ukpga/1990/16/contents

57. Feikert-Ahalt C. Restrictions on Genetically Modified Organisms: England and Wales. *Law Library of Congress*. Published online March 2014. Accessed March 7, 2021. https://www.loc.gov/law/help/restrictions-on-gmos/england-wales.php

58. Lord Cameron of Dillington. Amendment 275. TheyWorkForYou. Published July 28, 2020. Accessed March 7, 2021. https://www.theyworkforyou.com/lords/?id=2020-07-28b.204.0

59. UK Government. *Plant Varieties Act 1997*. Statute Law Database; 1997. Accessed March 7, 2021. https://www.legislation.gov.uk/ukpga/1997/66

60. UK Government. *The Novel Foods (England) Regulations 2018*. Queen's Printer of Acts of Parliament; 2018. Accessed March 7, 2021. https://www.legislation.gov.uk/uksi/2018/154/made