English Organic Forum
Online Response to the Defra Consultation on Genome Editing
17th March 2021

Defra GE ONLINE consultation questions

Part 1:
The regulation of GMOs which could have been developed using traditional breeding methods
This part of this consultation addresses the regulation of GMOs produced by gene editing (GE), or other genetic technologies, but which could have been developed using traditional breeding methods.

Question 10
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?

We believe that genetic techniques such as GE should be regulated as GMOs in line with the ruling of the European Court of Justice (ECJ) in 2018.
Gene editing is an artificial laboratory-based procedure which produces novel genetically modified organisms which do not occur in nature. It is not akin to traditional or conventional breeding as the genetic material of an organism is directly altered using laboratory techniques.

As such it falls in the category of GMOs as defined by United Nations and the European Union.

There is no clear, uncontested scientific evidence that the impacts of gene editing could have been produced using conventional or traditional breeding techniques.

In our view how an organism is produced is an important factor in regulation because direct intervention at the genetic level can result in multiple and unexpected errors across the genome, some of which may pose a threat to people, animals or the environment.

Furthermore, gene editing consists of a number of processes which can be used in several ways leading to unexpected on and off target effects and a high risk of unintended changes across the genome.

It is a major flaw in this consultation that neither gene editing nor “traditional breeding” are defined and described.

Question 11
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?

We believe that gene editing and potentially other genetic technologies pose a greater risk of harm to human health and the environment compared with their traditionally bred counterparts as a result of how they were produced.

Firstly, there is no history of safe use and as the technology is being developed research is demonstrating an increasing number of unexpected findings which – whilst not unusual at the R&D phase – requires precaution in a wider roll out.

The European Court of Justice judgement of 2018 was clear about this as are a significant number of scientists who, in 2017 produced a statement published by the European Network of Scientists for Social and Environmental Responsibility (ENSSER).

Secondly, the level of reported unintended effects causes us concern. As gene editing is a collection of processes the level of unintended effects and their interaction should be subject to robust and not reduced evaluation. In the case of plants for example, 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 can each produce unintended changes or genetic errors. Each of these processes should be evaluated for the specific risks that it entails.

Thirdly, whilst gene editing is claimed to make 'precise' cuts in DNA the subsequent 'repair' process is not as it is not under the control of the genetic engineer but is carried out by the cell's own repair processes. This repair often results in many genetic errors, known as 'off target' and 'on target' effects. Additionally, errors or accidents in the lab or the development process have been shown to create some worrying and unintended effects, for example, gene-edited mice carrying bovine and goat DNA.

Fourthly, as with "old style" GMOs gene editing involves fundamental changes to the biochemistry of crops which leads to the possibility of the creation of new allergens or toxins, higher levels of existing allergens or toxins, or other changes that could impact the health of people or animals consuming the plants and the wider ecosystem.

Fifth, there has been very limited research on gene editing in livestock – either from the perspective of human or animal health. However, a 2019 a study by the US Food and Drug Administration (FDA) found numerous irregularities in gene-edited 'hornless' cattle, including the unintended incorporation of antibiotic resistance genes in the genomes of the cattle. FDA said that its findings "demonstrate that there is good reason for regulators to analyse data on intentional genomic alterations in animals to determine whether there are any unintended results, either on- or off-target and, if so, to determine whether they present any cause for regulatory concern."

Sixth, genetic engineering of farm animals is largely intended to address the problems of industrial factory farms. It also supports livestock systems that have been shown to have multiple negative impacts on human health and the environment including soil, water and air pollution and the spread of antibiotic resistance.

Seventh, we are firmly of the view that releasing genetically novel organisms into the environment disrupts the delicate balance of nature and risks a range of unpredictable harms. Altered genes can spread to wild relatives, changing or polluting the natural ecosystem in ways that are very difficult to predict, control or repair. If plants or animals are genetically altered to make them resistant to pests or diseases, it does not take long for those pests or diseases to evolve in response. This has been widely seen with herbicide tolerant and insect-killing GM crops around the world: weeds and pests have quickly adapted and new problems of herbicide-resistant weeds and insecticide-resistant pests have emerged.

Question 12

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?

We believe there are many non-safety issues that must be considered when choosing how to regulate genetic technologies.

Equitable co-existence

As representative of the UK's organic farming sector, the English Organic Forum is very aware of potentially adverse impacts on organic production and market posed by deregulation of gene editing in farming and food. However, to varying degrees the same impacts threaten all farmers and consumers who do not wish to use or consume gene edited products.

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.

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

Adverse impacts on existing markets in the EU and other parts of the world

The UK organic sector has a growing export market and great potential, as does other quality UK food and farming goods.

No EU country and many non-EU ones 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 or not they are using GMOs. It will be impossible for them to prove that their goods are acceptable for import into these markets.

Disruption within the UK market

Food and agriculture are devolved areas of competency. All three of the UK's devolved countries have sceptical policies on GM and in 2015 all three used a new EU Directive (2015/412) to ban the cultivation of GM crops on their territory. Deregulation in England will result in a massive disconnect within the UK internal market

Adverse impacts in consumer confidence

Historically, UK consumers have not wanted to buy or consume genetically engineered foods. This has continued in recent years:

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. Another 2020 study conducted by the National Centre for Social Research, which focused on Brexit-related issues, found that 59% wish to maintain the ban on genetically engineered crops. A 2021 survey by the UK's National Economic and Social Research Council found that 64% of those who took part were opposed to the cultivation of genetically engineered food.

This might change somewhat with respect to gene edited foods but there is no question that a significant number, possibly the majority of people will wish to exercise choice which means transparency and labelling. Sleight of hand legislation which merely alters definitions will undermine consumer confidence and the market in all quality produce that are built on identity and provenance,

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. 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 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. Defects include premature death, pneumonia, liver failure and obesity. For example, a study on cloned mice found that up to 4% of the 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.

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 for super-muscly animals resulted in rabbits, pigs and a goats with enlarged tongues and pigs having an extra spinal vertebra, even though no DNA had been inserted.

Question 13
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?

Overall, we find this consultation to be flawed and this question exemplifies that. It borders on the ridiculous to frame the question in such away without any indication of the context or direction of

travel indicated. Without clarity on what Defra defines as gene editing or which of the several approaches to gene editing are being consulted on the question is so broad as to be almost meaningless. Similarly, the use of the term "traditional breeding" without description or definition is woefully remiss – or deliberately deceptive.

A commitment to clarity and transparency is needed to underpin any consideration of criteria.

We would then like to see:

A process to develop and agree a process for democratic and citizen engagement at all levels and stages of the process – from the use of taxpayer money at the development stage right through to product labelling and ongoing health and environment monitoring.

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. 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.

Regulatory criteria

Gene editing methods vary. This has not been recognised in the information accompanying this consultation but any rational discussion of regulation and evaluation criteria must take this into account.

Although gene editing is often described as using a process of 'tweaking' or making a 'simple cut' in the DNA of an organism, in most cases it involves much more invasive processes including the insertion of a genetic repair 'template' containing instructions for how the organism should repair itself after it has been damaged by the initial cut. It can also involve the insertion of foreign or 'trans' genes.

Even the few countries that have deregulated gene editing have only done so with one type of gene editing (known as SDN-1) which does not use a repair template. The other methods continue to be regulated as GMOs.

However, these (SDN-1) procedures should not be assumed to lead to effects that could be found in nature or through traditional breeding. Even SDN-1 procedures have been found to lead to unwanted mutations (see here and here).

We would like all assessments of gene editing to be based on the analytical methods known as 'omics.

We would like to see record keeping and audits as part of the regulatory system based on an international public register of gene editing events used in the specific product (crop or animal) 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 most notably in organic certification.

We believe that assessment criteria must go beyond narrow scientific and technological aspects. Social, ethical and values-based criteria have been put forward and some countries, such as Norway, have begun to use them in their legal and regulatory frameworks for genetic engineering technologies.

We believe 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.

Part 2

Questions on broad reform of GM legislation

In this section the government is looking for signs of public support to pave the way for looser controls on all forms of genetic modification including 'old type' GMOs and whatever might emerge in the future. The questions are framed in a way that is very off-putting for non-specialists. We offer some suggestions here but registering disquiet or dissatisfaction with Defra's approach is also a valid response.

Question 14

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?

We do not believe that non-GM regulations are 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 regulation and monitoring.

Further, with regard to regulations currently in place for genetically engineered organisms (GMOs), there is insufficient governance for all areas listed. These are: a) cultivation of crop plants, b) breeding farmed animals, c) human food, d) animal feed, e) human and veterinary medicines, f) other sectors/activities.

- In all cases, the regulatory framework for genetically engineered crops and foods lacks independence, transparency and citizen engagement. Except in the case of human medicines the process is conducted through advisory bodies, such as the Advisory Committee on Novel Foods and Processes and the Advisory Committee on Releases in the Environment which advises Ministers or the Food Standards Agency (FSA) and its Scottish equivalent.
- The FSA itself is a non-ministerial government department but its board members are appointed by Ministers. 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.
- Overall policy and strategy is largely conducted as a 'closed shop' with limited, if any, citizen engagement. This is also true for scientific and technical decisions none of which is subject to citizen review or recall.
- There is limited parliamentary scrutiny of Ministerial decisions and no opportunity for 'alternative' views to be heard let alone considered.
- There is a particular deficit in consideration of social and civil society needs and non-technical and non-commercial justification for any decision.

Question 15

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.

Understanding the costs, benefits and risks of any new measure or proposal is fundamental to good policy making. 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.