‘The Regulation of Genetic Technologies’

Response by the Landworkers’ Alliance

15 February 2021

Section 2 – Questions on Gene-Editing

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?

Yes – they should continue to be regulated as a GMO

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

We strongly object to the framing of the consultation and the biased material that has been circulated by DEFRA in favour of gene-editing, which fails to recognise complexities of the discussions and which stands in the way of an open conversation with space for all views.

We also object to the premise in the question that the new gene-editing techniques provide results that are identical to those produced naturally or through traditional breeding:

- Genetic technologies, including gene editing, are artificial laboratory-based genetic engineering procedures, which, by definition, produce novel GMOs. This has been confirmed by the ruling of the European Court of Justice in 2018, which was the result of a thorough, two-year long review of the most up-to-date science.
- The UK Government is effectively trying to change the definition of GMOs by excluding techniques that bring changes that ‘could have been produced by traditional breeding’ – yet it is unclear what this really means.
- Conventional breeding is different from genetic engineering because it uses sexual reproduction rather than lab-based techniques to make changes. Gene editing is set out to create traits in plants, animals and micro-organisms that do not exist in nature, even if they could – entirely theoretically – exist in nature.

We support process-based regulation to provide protection against the risks of gene editing as a new and experimental technology:

- Gene editing processes can bring both intended and unintended changes and can impact on targeted parts of the genome but may also have ‘off-target effects’ on genes that may have vital functions. Introducing complex traits is not a simple task and may likely involve multiple interventions, which have the potential of causing unintended impacts. Whilst the UK may no longer be part of the EU, it still has obligations under international law, notably the Cartagena Protocol, to provide an adequate level of protection for the safe transfer, handling and use of GMOs, which is to be achieved in accordance with the precautionary principle.

- A focus on how a new organism is created (the 'process' of genetic engineering) as is the case under current regulations, rather than a focus on the characteristics of the end 'product' as favoured by DEFRA, provides an essential safety net to protect against the risks of new and/or experimental technologies.
- Regulations provide a package deal, including procedures for risk assessment and management, monitoring plans and labelling rules. It allows decision-makers to both identify and manage (potential) risks. Such risks may, for example, relate to the invasiveness of the plant for natural habitats of other agricultural production systems, such as the organic and agroecological systems of our members. Or they may relate to intended or unintended impacts on the natural environment, which underpins our entire food system. Understanding all these risks is key and can only be secured if all GMOs are regulated and if they are regulated well.
- Exempting (some) GMOs from regulation, does not only mean that their cultivation, production, import, marketing and consumption is not subject to regulatory oversight, but it also means that consumers are not able to 'vote with their wallet' for the kind of agricultural production they want to support. There is no way of knowing for them whether they are consuming the products of genetic engineering and there are no ways for farmers to guarantee that their produce is GM-free.

Exempting gene-editing techniques from the scope of regulations puts the UK at odds with many other markets, may restrict access to export markets and may put pressure on relations between the UK nations:

- Gene-editing is classed as GMOs in most countries in the world, and, notably, in the EU. The Court of Justice of the European Union found in 2018 that all gene-editing techniques fall, in principle, within the scope of the EU's regulatory framework on GMOs. This means that all GMOs must be authorised before entering the EU market and must be clearly labelled. If England deregulates certain types of GMOs, it is likely to lose access to the EU market – not only for GM products but on a much wider scale due to a lack of traceability and risks of contamination.
- Importantly, whilst the proposals will apply only to England, the above also highlights concerns for the UK internal market and the position of the devolved nations. Scotland, Wales and Northern Ireland have always taken a more cautious approach. Yet, they may face risks of contamination in border areas and may be forced under the Internal Market Act to sell unchecked and unlabelled GM foods, regardless of the devolved regulatory rules on gene editing and GMOs.

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?

Answer: Greater

Please provide evidence to support your response including details of the genetic technology, the specific risks and why they do or do not differ. Please also state which applications/areas your answer relates to (for example: does it apply to the cultivation of crop plants, breeding of farmed animals, human food, animal feed, human and veterinary medicines, other applications/ areas).

Traditional breeding is generally accepted to have a history of safe use stretching back millennia, whereas no genetic engineering technique has a history of safe use. While the industrial lobby promotes gene editing techniques, many scientists have stated that there are risks involved. In 2017, the European Network of Scientists for Social and Environmental Responsibility (ENSSER) published a statement that underscores the importance of process-based regulation for new genetic technologies to protect against unintended and unpredicted risks. The 2018 judgement of the Court of Justice of the European Union also found that gene editing techniques pose environmental and health risks similar to those GMOs produced through transgenesis (the introduction of foreign material) and should therefore be regulated in a similar way and in line with the objectives of the EU's regulations on GMOs to provide for a high level of protection. It is reiterated that whilst the UK may no longer be part of the EU, it still has obligations under international law, notably the Cartagena Protocol, to provide an adequate level of protection for the safe transfer, handling and use of GMOs, which is to be achieved in accordance with the precautionary principle.

We believe that the government is deliberately downplaying the nature of gene-editing by using flawed comparisons with traditional breeding. In line with the 2018 ruling by the EU court of justice, we see the products of gene-editing as GMOs and, as such they pose dangers to organic and agroecological farming, due to potential impacts on biodiversity, risks of cross-contamination and pressures on local and organic markets.

We emphasise the importance of process-based regulations to protect against the risks of new and experimental technologies. Whether a particular GMO has similar or greater risks than organisms that – theoretically – could have been achieved through traditional breeding, should be assessed on a case-by-case basis through proper risk assessment and management and the safety of such a gene edited GMO should not be assumed through deregulation.

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?

Answer: Yes

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

There are many critical societal issues to consider. These may or may not be indirectly related to issues of safety (for the environment and health) but they should never be seen as being secondary to such risk-related considerations. The consultation document repeats a common misconception that GMOs are necessary to tackle issues such as food security and climate change, and thereby presupposes the societal benefits of genetic engineering. We promote a food system within which farmers work together with nature and within which people are empowered to decide on what they eat, to tackle the problems of our time. We believe that it is crucial that we do not reduce the discussion on gene-editing to a technical debate dominated by a small group of experts, but that we use this opportunity to ask and answer a bigger question, namely whether gene-editing and GMOs more broadly are compatible with a sustainable vision for our food system.

In particular, we want to highlight the following concerns of small- and medium-scale organic and agroecological farmers:

- Negative Impacts of Patents on Farmers' Rights

Patenting living organisms is still a relatively new phenomenon, yet within the EU, 3500 of such patents had already been granted by 2018 and most of those concern patents for the products of genetic engineering. In theory, patents as intellectual property rights would enable innovation and make sure that research costs can be recuperated by innovators. In practice, however, re-investment in research & development on genetic engineering is very low. The patenting of living organisms is in itself a very controversial phenomenon, but gene editing and notably deregulated gene editing techniques add a further threat to food sovereignty and internationally recognised farmers' rights. Indeed, the biotech industry is pushing for gene edited GMOs to be exempted from important regulations that protect us all against environmental and health risks but will itself be heavily relying on intellectual property (IP) law and industry lawyers to protect its 'inventions' against 'infringements'.

The consultation document seeks to emphasise how similar gene edited organisms are to organisms produced through traditional breeding techniques, but it is precisely these potential similarities that may cause issues under IP law. Under current GMO regulations, there is an obligation to publish details on technological processes to be able to distinguish between GMOs and natural organisms or those that result from traditional breeding. In absence of such data, a patent on 'genetic information' may extend to any naturally occurring or traditionally bred organisms with the same genetic information. Most farmers will not be able to oppose infringement proceedings due to prohibitive costs and will, therefore, *de facto,* be prevented from continuing to use their seeds. This is contrary to farmers' rights recognised under the Declaration on the Rights of Peasants and Other People Working in Rural Areas and Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture – which the UK is a party to and bound by – which allow farmers to freely choose, reseed, maintain, control, protect, develop and sell their seeds. For more information: https://www.eurovia.org/wp-content/uploads/2020/04/Fact-sheet-EN.pdf.

- (Further) market concentration and impacts on farmers and biodiversity

The patent model that is at the heart of the development and marketing of (gene edited) GMOs also encourages concentration of the seed market. Globally, the seed market is dominated by only four firms which control more than 60% of markets: Bayer (which acquired Monsanto in 2018), DowDupont, ChemChina (which acquired Syngenta in 2017) and BASF (which acquired Bayer's seed divisions). In the 1980s the market share of the 10 largest companies was less than 15%, which makes market concentration an accelerating problem. In the European Union, figures from 2013 showed that the five largest companies controlled over 95% of the vegetable seed market. Many of these companies also hold significant market shares in other parts of the agri-food chain, notably for agro chemicals (in 2017 Syngenta-ChemChina and Bayer Cropscience-Monsanto alone held more than 50% of market shares in the agrochemical sector).

The 2017 report 'Too Big To Feed' by the International Panel of Experts on Sustainable Food Systems (IPES-Food), co-chaired by Olivier de Schutter, the former UN Special Rapporteur on the Right to Food, found that the concentration in the seed market has led to the disappearance of most small-and medium-sized seed companies, making farmers

dependent on a handful of suppliers. This dependency has led to significant, oligopoly-driven increases in seed prices and experiences from other countries such as Canada and the United States illustrate the potentially disastrous impacts on farmers (see: https://www.eurovia.org/wp-content/uploads/2020/04/M-Torshizi-Presentation-for-ECVC-Feb-20-20.pptx).

It has also reinforced the tendency of the industry to focus on a limited number of profitable crops, and only 9 plant species account for 66% of production (Source: FAO Report 2019 on The State of the World's Biodiversity for Food and Agriculture). The limited focus of industry and research greatly impacts biodiversity in farmers' fields leading to genetic erosion which poses a dangerous threat to food security.

- Exacerbating rather than contributing to solutions for the challenges of our time

The concentration of the seed and agro-chemicals market and the nature of the businesses behind agro-biotech inventions is important to keep in mind when deciding whether gene editing and GMOs more broadly will tackle the important challenges of our time, as put forward by this consultation. Whilst promises for food security, biodiversity protection and climate change are often cited as reasons to embrace genetic engineering technologies, it is important to look beyond the initial 'sales pitch' to evaluate the likelihood of this potential being realised. The current commercial developments paint a bleak picture as these gene-edited GMOs – similarly to most transgenic GMOs – only provide for herbicide-resistance which is widely known to increase use of pesticides (that are most often produced by the same companies behind the biotechnological invention).

- Undermining freedom of choice for consumers – the importance of labelling

Regulations provide a package deal, including procedures for risk assessment and management, monitoring plans, traceability and labelling rules. Exempting gene edited GMOs from these requirements, notably on traceability and labelling, means that consumers will have no way of knowing that the products that they buy are or contain GMOs.

Food labelling laws have been recognised as a way to protect the human right of individual consumers to adequate food, as recognised in Article 25 of the Universal Declaration of Human Rights and Article 11 International Covenant on Economic, Social and Cultural Rights. This human rights' standard does not only refer to food safety and nutritional value, but also to the cultural acceptability of a food. Labelling is a legitimate, democratic action that enables choice and that is feared by those who prefer to hide information on what people grow and eat.

- Undermining freedom of choice for producers – coexistence and market access

Co-existence of the production of GMOs with other farming systems is a key part of the current regulatory framework for GMOs and aims to avoid the unintended presence of GMOs in other crops and ensure "producers choice for the different production types" (see in an EU context: https://ec.europa.eu/food/sites/food/files/plant/docs/plant_gmo-agriculture_coexistence-new_recommendation_en.pdf). This producers' choice is, however, greatly undermined by deregulation and, consequently, delabelling as producers may unintentionally use gene edited genetic material and their produce may be contaminated by the natural spread of GMOs.

This situation will impact disproportionality on our members as small- and medium-scale organic and agroecological farmers and landworkers, who mostly sell under organic labels for which they will have made significant investments, or who rely more heavily than other producers on their 'GM free' characteristics to market their products. However, it is reiterated also that all producers – small and large – may lose access to GM-free markets, notably the EU, if England fails to regulate gene editing and trace these products and, therefore, cannot secure the GM-free status of its products within other markets.

- Negative impacts on food sovereignty

Where access to markets with regulations for gene edited is restricted, including the EU, it is likely that the UK will have to shift its focus to other markets like the USA and Canada which are dominated by much larger scale producers. Competition from these cheaper imports may increase reliance on imports over locally grown produce, taking into account that the UK is already heavily reliant on food imports. Such a shift may also have negative impacts on communities and farmers.

A greater emphasis on genetic technologies to tackle the challenges of our time is likely to exacerbate the current problems with our food system. The need to reframe our food system to one oriented on the principles of food sovereignty is urgent. We promote and support an alternative, agroecological food system which recognises biodiversity as the foundation of sustainable food production, and which is based on principles of food sovereignty and thus seeks to empower farmers, communities and consumers to decide on their own food futures.

- A threat to devolution – the significance of the Internal Market Act

The topic of GMOs has long divided the UK, with England taking a more permissible approach and Scotland, England and Wales trying to maintain a GM-free stance. Before Brexit, most procedures for authorisation were harmonised at EU level but with regard to cultivation of GMOs, divergence of approaches between nations and regions was permitted under the EU regulations (Directive 2015/412). Post-Brexit, matters related to the environment, agriculture and food remain devolved and cooperation and coordination between the devolved nations is encouraged through UK common frameworks.

The Internal Market Act introduces the concept of 'mutual recognition'. Although there are still many uncertainties regarding how the interactions between the Internal Market Act, devolution and common frameworks are to work themselves out, the Internal Market Act is likely to mean that the devolved nations will still be able to restrict the cultivation of GMOs on their territory, but that they will not be able to stop gene edited GM products or any GMOs from being exported from England into their territory – even if the products were imported into England from elsewhere (e.g. the USA). It would also stop Scotland, Wales and Northern Ireland from imposing labelling requirements on products imported from England. The potential impacts on our members in Scotland, Wales and Northern Ireland are thus significant: (1) they face contamination threats – particulallyin border regions; (2) they face competition from potentially cheaper, unlabelled GM products; and (3) they may see restrictions for their products on access to foreign markets and, notably, the EU, if GM products are not traced and labelled within the UK market and it is, therefore, hard if not impossible to guarantee the organic or GM-free status of products exported from any part of the UK.

- Animal welfare

Gene editing often involves cloning, which can inflict severe or lasting pain on animals, violates their integrity and reduces them to a mere instrument or tool. Errors can occur due to unintended consequences. It raises many ethical questions which should be carefully considered.

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?

We believe that the government is deliberately downplaying the nature of gene-editing by using flawed comparisons with traditional breeding. We see the products of gene-editing as GMOs, in line with the 2018 ruling of the EU court of Justice. Both pose dangers to organic and agroecological farming, due to potential impacts on biodiversity, risks of cross-contamination and pressures on local and organic markets.

We oppose the premise in this question that criteria should be developed to determine whether gene edited GMOs could have been developed by traditional breeding. We emphasise the importance of process-based regulations to protect against the risks of new and experimental technologies like gene editing, and the need for a precautionary approach.

Section 3 – Questions on Broad Reform

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? Please indicate in the table whether, yes, the existing non-GMO legislation is sufficient, or no, existing non GMO legislation is insufficient and additional governance measures (regulatory or nonregulatory) are needed.

Please answer Y/N for each of the following sectors/activities:

	Cultivation of crop plants	Breeding farmed animals	Human food	Animal feed	Human and veterinary medicines	Other sectors/activities
Yes (sufficient governance)	☐	☐	☐	☐	☐	☐
No (insufficient governance)	☑	☑	☑	☑	☐	☐

Please provide evidence to support your response

See below under Question 15.

Question 15. Where you have answered no (existing, non-GMO legislation is insufficient to deal with organisms produced by genetic technologies), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors).

The process-based regulations on GMOs provide for requirements on risk assessment and management, monitoring, traceability and labelling that cannot be replaced by existing non-GMO regulations, which would provide a piecemeal approach and which risks leaving considerable gaps in legal protection. We believe that any replacement of current GMO regulations with non-GMO counterparts for a particular sector should be subject to in-depth study.

However, in the context of the broad reform of legislation governing organisms produced using genetic technologies, the government should use this opportunity to identify and address shortcomings in current GMO legislation. In particular:

- The EU has made progress in recent years to address shortcomings regarding the transparency and sustainability of EU risk assessment (Regulation 2019/1381) and it is important that these efforts are recognised and used as a starting point for further reform in the UK. In particular, the EU has responded to criticism regarding the undue influence of the biotech industry in the authorisation procedure, by broadening the knowledge base of risk assessment. Regulating gene editing and GMOs more broadly is insufficient if the procedures do not provide space for consideration of all evidence and for broad stakeholder involvement.
- Current regulations focus disproportionately on the potential safety risks of genetic technologies, often disregarding many important societal concerns (Question 3) and prioritising scientific expertise over the knowledge of farmers and society at large. This revision provides an opportunity to put at the centre of GMO regulations, the question whether the particular GMO has public benefits/societal utility or not, notably for the realisation of broader, democratic visions for a sustainable food future. Examples of a more balanced assessment which includes societal questions in addition to safety analyses and which provides for broad stakeholder involvement already exist and should be used for inspiration. See notably the Norwegian ‘dual’ system for the assessment of GMOs: https://www.bioteknologiradet.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf.