Food Ethics Council submission for regulation of genetic technologies consultation

Part 1: The regulation of GMOs which could have been developed using traditional breeding methods

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

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

Regardless of what genetic changes have been made, we believe organisms developed using gene editing should be regulated as GMOs.

The implied assertion in the consultation that gene-edited GMOs possessing genetic changes "could have been produced through traditional breeding" is in our view highly contestable.

Traditional or conventional breeding has been used by farmers and breeders for a long time to produce crops and livestock. Hence, understanding of traditional breeding, and its long-term implications, has been built up over centuries. This is very different from genetic engineering where the genetic material of an organism is altered using laboratory techniques. Even though the outcome may be similar, it is different at the genetic level, which could result in hugely different impacts on the organism itself and/ or the wider environment. Any negative outcome may be hard to predict and may not manifest itself for some time, hence why it is so important to apply the precautionary principle as part of strict regulation.

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

We also challenge the suggestion that "the safety of an organism is dependent on its characteristics and use, rather than on how it was produced".

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?

It is not possible to answer this categorically without seeing the scientific evidence behind the claimed benefits and an ethical justification. However, because of how they are produced, organisms produced by gene editing or other genetic technologies have potential

to pose additional risk of harm to humans and the environment. We should therefore apply the precautionary principle.

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):

There are only very limited numbers of gene-edited crops grown commercially anywhere in the world - e.g. Calyxt's soybean oil and Cibus's oilseed rape – on which experiences can be drawn. Genetic engineering of plants should be assessed for changes that could impact people and animal health, plus the wider ecosystem. There is not any or sufficient history to indicate safe use and to claim otherwise would be scientifically inaccurate and misleading.

It is too early in the development of genetic engineering (particularly gene editing) to be able to understand its implications and the possibility of unintended (negative) consequences. In contrast traditional breeding has a history of safe use over many centuries. This view was supported by the European Court of Justice in its 2018 judgement.

Genetic engineering of animals raises particular concerns. We are not aware of any studies to prove (or disprove) that eating animal-derived products from genetically engineered animals is safe for humans. Similarly, we would raise questions about health and wellbeing outcomes of farmed animals.

Gene editing tools mean 'precise' cuts can be made in DNA. However, the subsequent process of 'repair' is not under the control of those doing the genetic engineering. The repair itself is not necessarily precise or clean, and can result in genetic errors, known as 'off target' and 'on target' effects.

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?

Yes

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

There are multiple non-safety issues that it is vital to consider.

On trade, the UK currently imports a high proportion of its food from the EU and also exports considerable amounts of food and drink to the EU (which the government and many food businesses are keen to increase). If the UK were to weaken regulation in the way it proposes, then that could make it significantly more difficult for food and farming businesses in the UK to export to the EU. No EU country will accept food, seed or other imports from the UK that might include unauthorised GMOs. If gene edited organisms are not regulated as

GMOs in England, then English businesses involved in food will not know whether they are using GMOs – hence they will not be able to demonstrate their goods are acceptable for import into the EU.

While the consultation only applies to England, if Defra goes ahead with weakening of this regulation, then it will affect all the Devolved Nations. The Internal Markets Act could force Devolved Nations to allow English food producers to sell gene edited foods (unlabelled) into e.g. Scotland and Wales, even if those governments want strong regulation of GMOs in their nations. This is likely to further disenfranchise those pushing for independence and may contribute to the breakup of the United Kingdom, which would have profound impacts for our food systems and beyond.

The vast majority of the UK public want high food standards, both in food produced in the UK and in food and agricultural products we import. Over three-quarters (77%) of those surveyed in a September 2020 poll by Yonder – commissioned by the Food Ethics Council, Eating Better and Hubbub (representative sample of 2,095 people in the UK) - agreed that the government should assess future trade deals for their impact on human health and the environment.

Unregulated GM will most likely be accompanied by an absence of labelling about whether it has been genetically modified or not. If it is not possible to differentiate, citizens will not be able to exercise choice.

From an animal welfare perspective, concerns noted above are about the lack of studies demonstrating genetic engineering will (at worst) not have an adverse impact on farmed animal welfare health and wellbeing. There is a real concern that genetic engineering would be used as a sticking plaster for animal welfare issues created, or exacerbated, by poor management of farmed animals, especially in intensive farming operations.

Agroecological research for the public good would be likely to be further undermined if regulation on genetic technologies is weakened. This would come at a time when there is rising interest in agroecological, biodiversity-enhancing farming systems that offer genuine hope for ways of farming with nature, producing nutritious food and empowering people in communities to participate in localised food systems. This progress risks being undone if there is a push for weakened regulation on GMOs as a way of propping up unsustainable industrial food systems.

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?

The assertion that an organism produced by gene editing or another genetic technology "could have been produced through traditional breeding" is in our view highly contestable. Therefore it is problematic to ask what criteria should be used.

In addition, the phrase 'another genetic technology' is vague.. Does it relate to transgenic engineering or something else? Unless this is specified, then it is very hard to comment on.

Please provide evidence to support your response:

A GMO is not an organism produced by traditional breeding and only the production of an organism produced by traditional methods will provide a true source of comparison.

As the Food Ethics Council, we believe it is vitally important that any assessment criteria that are developed extend beyond narrow technical and scientific aspects. Ethics and values-based criteria should also be included. For the consultation as a whole to have been meaningful, there are two critical tests it needs to pass. Firstly, will benefits and harms relating to food and farming be properly accounted for? And secondly, will the ethical case be clear and robust? At the moment, the consultation does not look to set these tests.

We support the shift from consumerist to food citizenship mindset, where we treat each other as food citizens, rather than only as consumers (whose only sense of agency is at the point of purchase and depends on how much money they have in their pocket). Part of this involves encouraging and empowering people to participate in policymaking, so that we have better, democratised decision-making. We would push for citizens' assemblies as an important part of any decision-making process on contentious technologies and/ or regulation of such technologies. Citizens' panels should also be incorporated, to hold government, regulators and businesses to account.

We believe it is important to push for greater, not less, transparency, in how crops and animal products are produced. We want traceability, transparency and openness, not weakening of regulation that will only confuse and challenge the public, farmers, food manufacturers and exporters.

Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

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 non-regulatory) are needed. Please answer Y/N for each of the following sectors/ activities:

No, existing non-GMO legislation is insufficient and additional governance measures (regulator or non-regulatory) are needed.

Please provide evidence to support your response:

Non-GMOs are different from GMOs. The control of GMOs requires separate regulation particularly in relation to human and environmental safety. The Precautionary Principle should be properly applied. Any new GMO should be scrutinised separately – it should be

considered on a case-by-case basis, depending on its application and on controls in place to mitigate harm. If GMOs and non-GMOs are treated the same way for regulatory purposes, then there is a risk that procedures to evaluate human and environmental harms are weakened. This would be to the detriment of the health of people and the biosphere.

Regulations exist for a reason. In this context, they provide important safeguards against health, agricultural and environmental risks through assessments, monitoring and traceability and rules on labelling (currently in place across the EU, using the Precautionary Principle). We believe all GMOs should be kept under a single regulatory framework implemented under the Precautionary Principle.

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):

We want existing GM regulations maintained and, indeed extended, to allow meaningful citizen involvement and proper consideration to be given to ethical concerns.

Please provide evidence to support your response:

We believe that having greater citizen scrutiny and greater citizen involvement in decision-making is important (i) to empower the public and give them a genuine voice, putting decision-making in public hands (ii) so that the government can listen, and respond, to the voices and concerns of the general public (iii) to ensure that the public good is prioritised, rather than hearing exclusively from those with vested interests.

Oversight of research priorities and the regulatory framework needs to be more democratic and independent of corporate and research interests. It should be geared to the interests of people (as food citizens), not corporations, i.e. to natural not legal persons.

Linked to this consultation, the government should provide an ethical justification for genetic engineering in UK agriculture (and food systems more broadly). The consultation document does not specify the ethical framework within which the final decision will be made. No full ethical appraisal has been made available. If that does not yet exist, will that ethical analysis be done before any final decision is made about whether to approve the weakening of regulations?