The regulation of genetic technologies
A response to the public consultation

Organic Research Centre, March 2021

Introduction

As a member of the English Organic Forum (EOF), the Organic Research Centre is in agreement with the Forum's response to the Defra consultation on gene editing, including its basic principles that:

- gene editing is a genetic engineering technology[1] and its process and products are GMOs as defined by the EU Directive on GMOs[2] (Directive 2001/18). Consequently, all gene editing should be regulated as GMOs, in accord with the European Court of Justice Ruling of July 2018.[3] This is consistent with scientific concepts and terminology and international treaties such as the Cartagena Protocol on Biosafety[4] to the Convention on Biological Diversity.
- gene editing is a developing technology which is likely to play a role in future farming and food systems. Some farmers will wish to use the products of gene editing and some consumers will be willing to purchase gene edited products.
- therefore, different approaches to agriculture (in particular organic, non-GM conventional and GM conventional) should coexist and thereby enable farmers to choose which approach they wish to follow and give consumers the possibility of buying products from the farming system they wish to support.
- such co-existence should be equitable and the organic approach and market should not be undermined, threatened or unfavourably treated in any way; including in the areas of government financial support, R&D funding, supply chain integrity and development, market integrity, policy, public education and messaging.

Informed by the work of EOF and other background briefing[5], in this response we would like emphasise the importance of two core recommendations with respect to the current consultation, namely that:

1. all forms of gene editing should be subject to robust regulation and risk assessments.

2. proper recognition and investment should be given to the whole diversity of different available approaches to transforming and delivering a sustainable and healthy food system, including organic and other agro-ecological farming.

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[1] IFOAM EU New plant breeding techniques – Position Paper: https://www.organicseurope.bio/content/uploads/2020/10/ifoameu_policy_npbts_position_final_20151210.pdf?dd

[2] EU Directive on GMOs: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018

[3] European Court of Justice ruling on GMOs: https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf

[4] Restrictions on GMOs: International Protocols: https://www.loc.gov/law/help/restrictions-on-gmos/international-protocols.php

[5] We have drawn in particular from the Beyond GM/GM Freeze briefing: Key Issues in the Deregulation of Gene Editing: https://www.gmfreeze.org/publications/political-briefing-key-issues-in-the-deregulation-of-gene-editing/

All forms of gene editing should be subject to robust regulation and risk assessments

Immediate deregulation is inconsistent with the precautionary approach required with respect to genetically edited organisms.

The UK is a signatory to the Cartagena Protocol on Biosafety, which emphasises the importance of protecting human health and the environment from potential negative outcomes of modern biotechnology. At the same time it recognises the potential for the positive outcomes of such innovation, including in the area of agricultural development.

An important application of the Protocol is the strong regulation of GMOs in Europe. Whether gene editing falls within the scope of the EU GMO Directive 2001/18 was tested in the European Court of Justice in 2016 as a result of an action brought by French NGOs. They claimed that herbicide tolerant varieties of rapeseed and sunflower, produced using new directed mutagenesis processes, should be regulated under European law. This led to the unequivocal ECJ ruling in July 2018 that organisms resulting from directed mutagenesis are GMOs and so are subject to the obligations laid down by the EU GMO Directive[6]. These obligations include full case-by-case risk assessments, traceability and labelling. It is important to emphasise that this judgement was founded on extensive, two-year long review of the most up-to-date scientific evidence.

Any change to this scientifically-based position should only be countenanced through an equally rigorous review of the latest scientific findings. The current public consultation, based on prejudicial and contested claims about genetic editing, is not such a process. For example, the premise that gene editing produces organisms with no difference to those produced naturally or by traditional breeding is unproven in theory and should not be the basis for changing regulations or removing protections.

The precision of gene editing techniques does not equate to the accuracy and certainty of outcomes[7]. Gene editing encompasses a number of processes that for the most complex desired traits (e.g. pest or drought resistance) need to be used in combination, i.e. involving multiple interventions at the genetic level, each of which carries the risk of unintended effects. Furthermore, new gene editing techniques give access to parts of the genome that are generally 'protected' against mutations (DNA damage) and create a higher risk of unintended changes. These can be both on-target (at the intended part of the genome) and off-target where genes with different and sometimes vital functions can be affected.

For the above reasons the potential benefits of gene editing need to be balanced by recognition of potential risks, through a well-regulated, precautionary approach. Further transparent and independent research is therefore required in the full range of risk domains, including:

- ***Environmental impact:*** the implication of the introduction of herbicide-resistant crops on herbicide use[8] and the emergence of herbicide-resistant "super-weeds"[9]; the emergence in

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6 European Court of Justice | CURIA (2018) http://curia.europa.eu/juris/documents.jsf?num=C-528/16

7 Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture | Environmental Sciences Europe (2020) https://enveurope.springeropen.com/articles/10.1186/s12302-020-00361-2

8 e.g.: Genetically engineered crops and pesticide use in US maize and soybeans | Science Advances (2016) https://advances.sciencemag.org/content/2/8/e1600850

9 Impacts of genetically engineered crops on pesticide use in the US: The first sixteen years | Environmental Sciences Europe (2012) https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24

insects of resistance to insecticides bred into GE plants[10]; whether the increase in yields and land sparing achieved by the roll-out of existing GM crops warrants the environmental risks associated with their use; cross-pollination and the potential for transgenic pollution and its impact on natural and agricultural biodiversity and integrity of organic production.

- ***Animal welfare:*** the incidence of stress or pain in animals as a result of gene editing procedures; whether development of abuse-tolerance in animals leads to less humane industrialised and crowded animal units; the risk of unpredictable results of gene editing in farm animals[11].
- ***Consumer attitudes and acceptance:*** how acceptable are GE crop and animal products to the public at large[12,13], and what are the implications for markets and producer profitability.
- ***Trade:*** the impact of potential cross contamination on farm or in factory on export to Europe of organic farm products or processed foods.

Recognition must be given to the diversity of potentially transformative approaches

Organic and other agro-ecological farming systems offer more balanced and sustainable solutions to the challenges that gene editing is seeking to meet.

Gene editing may have a role to play in achieving a more sustainable farming and food system. However, there is the danger that too much focus on this biotechnology can distract from impactful innovation in other areas. We urge the Government to give full consideration and support to a range of approaches that deliver healthy and sustainable food production alongside the restoring of natural capital and delivery of ecosystem services.

Organic and other agro-ecological farming approaches offer lower-risk, more holistic and effective solutions to the challenges that gene editing and other genetic modification practices aim to meet. Farming in harmony with the local ecology and without recourse to intensive inputs can achieve the following benefits that often exceed the reach of biotechnological fixes:

- pest and disease control, for example through encouragement of natural predators;
- control of weeds without pollution of soils and water courses;
- greater resilience to drought through restoring soil health and in-field and on-farm crop diversification;
- nutritional quality enhancement through the incorporation of pulses and under-utilised or under-developed cereals into the rotation;
- reduced carbon footprint through reduction in inputs and build-up of organic matter in soils and biomass;
- greater levels of agrobiodiversity including populations of pollinators;
- improved soil fertility and reduced use of finite resources through green manures and fertility building leguminous leys.

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[10] Surge in insect resistance to transgenic crops and prospects for sustainability | Nature (2017) https://www.nature.com/articles/nbt.3974

[11] Big tongues and extra vertebrae: the unintended consequences of animal gene editing | Wall Street Journal (2018) https://www.wsj.com/articles/deformities-alarm-scientists-racingto-rewrite-animal-dna-11544808779

[12] Post-Brexit public policy | National Centre for Social Research (2020) https://natcen.ac.uk/news-media/pressreleases/2020/october/after-four-years-of-brexit,-british-socialattitudes-reveals-voters%E2%80%99-hopes-and-fears-for-lifeoutside-the-eu

[13] Thinking about post-Brexit public policy: voters' perspective on immigration and regulation | Economic and Social Research Council and UK Research and Innovation (2021) https://whatukthinks.org/eu/wp-content/uploads/2020/12/WUKTEU_Initial-Deliberation-Findings-Paper_v5.pdf

Organic farming strongly contributes to the agenda of public goods delivery being implemented through the Environmental Land Management scheme. Yet investment in research and development in agro-ecological farming systems, and especially organic production as the most proven such approach, is woefully inadequate. Such approaches hold comparable or more potential compared to biotechnology to transform the UK food system to a more sustainable and healthy model, and for this reason must not be neglected as a result of the current excitement about gene editing. Wider questions, for example on food waste[14] and food sovereignty, also need to be urgently addressed. Plant and animal breeding and technological solutions have a part to play in the systemic changes required, but many other solutions are needed too.

Conclusions

Overall, we recognise that gene editing is a powerful technology and acknowledge it may, depending on circumstances and context, bring benefits as well as risks to the development of a more resilient and sustainable farming and food system. It should be pursued, but cautiously and under continued strong regulation. To meet today's challenges, this technological development should be rooted in a more ambitious and wide-ranging, joined-up suite of agro-ecological, farming system based approaches including organic production, a system that is proven to be more resilient and sustainable compared to the current, prevalent, non-organic (so called 'conventional') farming.

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[14] Understanding food loss and waste – why are we losing and wasting food? | Foods (2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6723314