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IEA Discussion Paper No.117

## HARVEST TIME

Why the UK should unleash the power of gene editing

Cameron English December 2022



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## About the author

**Cameron English** is the Director of Bio-Sciences at the American Council on Science and Health (ACSH), a consumer advocacy group dedicated to promoting evidence-based public policy and refuting health scares. Prior to joining ACSH, Cameron was the Managing Editor at the Genetic Literacy Project.

#### Summary

- On the one hand, gene editing is a process of modifying the existing genetic material of an organism. On the other hand, genetic modification involves the introduction of genetic material from another organism.
- Gene-editing technology is a powerful tool that can boost sustainable farming, fight nutrient deficiencies and reduce consumer food prices.
- Dozens of countries have already enacted evidence-based regulations that allow their farmers to grow gene-edited crops engineered for disease resistance, increased nutrient content and many other useful traits.
- Following its departure from the European Union (EU), England is poised to liberalise its food safety regulations and allow the commercial use of gene-editing technology in plant and animal breeding.
- UK scientists have already begun to develop products that will benefit farmers and consumers and yield enormous economic and environmental dividends should the pending regulatory changes take effect.
- The shifting regulatory landscape has drawn intense criticism from activist groups and organic food producers. While their objections to gene editing are well intentioned, they do not stand up to scientific scrutiny.
- The UK is moving in the right direction by rolling back its restrictions on agricultural gene editing in England. Policymakers should move quickly, however, to embrace all forms of genetic engineering, including the technology used to produce genetically modified organisms (GMOs). Ample scientific evidence shows that these breeding tools are safely used in food production, generating billions in additional income for farmers and significantly lowering food prices for consumers.

### Introduction

The agricultural gene-editing revolution is underway around the world. Using powerful precision breeding tools such as CRISPR-Cas9, scientists in developed and developing countries are engineering enhanced food crops and animals that will yield enormous economic and environmental benefits. From disease-fighting tomatoes to drought-tolerant crops, gene-edited products will address a variety of problems that have plagued farmers for many years and give consumers wider access to safe, nutritious and less expensive food.

The UK government has recently announced plans for regulatory reforms in England that would grant scientists permission to develop gene-edited organisms and farmers the authorisation to cultivate and sell these products. This long-overdue policy prescription has widespread support in the science community, though it has met fierce opposition from a handful of politically influential environmental activist groups and organic food producers. These stakeholders view gene editing, and indeed any method of genetic engineering, as a threat to their ideological and economic goals.

In what follows, I make the science-based case for agricultural gene editing, documenting the clear economic and sustainability benefits it has already yielded and anticipate future successes that experts see on the horizon should they be freed to employ the full capabilities of gene editing.

Two points will become clear as we proceed. First, objections advanced by critics of gene editing cannot withstand scientific scrutiny. Second, the government's proposed gene-editing legislation is an important step in the right direction – but that is all it is. The government could do much more to unleash the power of genetic engineering by also reforming its restrictions on transgenic (GMO) crops and animals, which have generated extensive economic and sustainability benefits for decades in other parts of the world.

# The science-based case for precision breeding

'Gene editing' describes a variety of techniques used to make specific changes to the DNA of plants and animals widely consumed as food. Unlike earlier transgenic technology used to produce 'GMOs', organisms enhanced with CRISPR-Cas9 and other gene-editing methods generally do not contain DNA from other species. Instead, scientists use these tools to delete or modify the plant's or animal's existing genetic material. For this reason, experts often describe gene editing as an acceleration of traditional breeding techniques, or 'precision breeding' (Cheng et al. 2019).

Moreover, there is no way to distinguish a mutation induced by gene editing from one induced by a traditional or conventional breeding technique.<sup>1</sup>

In practice this means that breeders can engineer enhanced organisms much faster than traditional techniques would allow, enabling them to quickly develop products that meet the needs of farmers and consumers. According to cell biologist Dr Mary Mangan:

gene-edited crops may be essentially identical to conventionally bred plants; the only difference is that gene editing dramatically speeds up the breeding process, saving time, money and getting

Viewpoint: Greenpeace-funded study backfires, undermining case to treat gene-edited crops as GMOs', *Genetic Literacy Project*, 13 October 2020 (https://geneticliteracyproject.org/2020/10/13/viewpoint-greenpeace-funded-studybackfires-undermining-case-to-treat-gene-edited-crops-as-gmos).

enhanced seeds into farmers' fields much more quickly than was previously possible...^2  $% \left( \frac{1}{2}\right) =0$ 

As a rule, the UK lightly regulates conventional crops and animals because the traditional breeding practices that produce them have an established history of yielding safe food products (Advisory Committee on Novel Foods and Processes (ACNFP) guidelines). Because gene editing merely accelerates the process of discovering useful traits, there is a strong scientific case for regulating gene-edited products in a similar fashion. Importantly, these precision-bred products will undergo the same field evaluation and safety testing that all new crops go through.

# Gene-edited crops around the world

Countries that have liberalised their crop gene-editing rules are beginning to see the benefits this powerful technology can unlock. In February 2019, US-based biotechnology firm Calyxt commercialised a heart-healthy cooking oil derived from gene-edited soybean. The oil contains nearly 80 per cent oleic acid and zero grams of trans fat per serving compared with conventional soybean oil.<sup>3</sup> Recent research indicates that consuming oleic acid may reduce the risk of coronary heart disease (Guasch-Ferré et al. 2020).

At the height of the COVID-19 pandemic in 2020, Calyxt helped alleviate America's biggest soy shortage in decades by selling all of the gene-edited grain it produced that year to agricultural merchant Archer Daniels Midland. Excluding a brief news report from Reuters, few people noticed this development,<sup>4</sup> indicating that the crop posed no unique risk to public health. This case also illustrated that biotechnology can help stabilise food supplies in times of crisis – an important realisation in the wake of price spikes and shortages caused by the war in Ukraine.

The following year, Japanese regulators approved the sale of a geneedited tomato developed by Sanatech Seed called the Sicilian Rouge High GABA. The crop contains higher amounts of a naturally occurring amino acid that helps prevent high blood pressure, a risk factor for heart

<sup>3 &#</sup>x27;First commercial sale of Calyxt high oleic soybean oil on the U.S. market', Calyxt, 19 February 2019 (<u>https://calyxt.com/first-commercial-sale-of-calyxt-high-oleic-soybean-oil-on-the-u-s-market</u>).

<sup>4 &#</sup>x27;Calyxt to sell 2020 gene-edited soybean grains to ADM', *Reuters*, 14 December 2020 (https://www.reuters.com/article/calyxt-soybeans-archer-daniels/calyxt-to-sell-2020-gene-edited-soybean-grains-to-adm-idUSL4N2IU2CS).

disease and stroke.<sup>5</sup> Many more gene-edited plants have been approved by regulators around the world. The US Department of Agriculture (USDA) has green-lighted more than seventy such crops so far, including canola (rapeseed) resistant to a fungal infection that can cut yields by up to 50 per cent.<sup>6</sup>

Officials in China aren't far behind, following the Ministry of Agriculture's recent announcement that it will regulate gene editing with a light touch. Chinese scientists anticipate that the new rules will reduce approval times from six years to just one or two, which should allow them to introduce products ranging from disease-resistant wheat to healthier soybeans and more aromatic rice.<sup>7</sup> Research is also underway to engineer crops that can capture more carbon dioxide, the goal being to reduce existing atmospheric CO<sub>2</sub> levels and help mitigate climate change.<sup>8</sup>

<sup>5 &#</sup>x27;CRISPR revolution: Hypertension-fighting, gene-edited tomatoes debut In Japan', American Council on Science and Health, 24 September 2021 (<u>https://www.acsh.org/news/2021/09/24/crispr-revolution-hypertension-fighting-gene-edited-tomatoes-debut-japan-15827</u>).

<sup>6 &#</sup>x27;Cibus advances gene-edited crops', *Chemical and Engineering News*, 14 October 2020 (https://cen.acs.org/food/agriculture/Cibus-advances-gene-edited-crops/98/i40).

<sup>7 &#</sup>x27;China's approval of gene-edited crops energises researchers', *Nature*, 11 February 2022 (https://www.nature.com/articles/d41586-022-00395-x).

<sup>8 &#</sup>x27;This CRISPR pioneer wants to capture more carbon with crops', *MIT Technology Review*, 14 June 2022 (<u>https://www.technologyreview.com/2022/06/14/1053843/</u> <u>carbon-capture-crispr-crops</u>).

# Fewer rules spur economic growth

Science-based gene-editing regulations could also yield a number of important economic benefits. Ironically, these include outcomes that critics of the technology explicitly endorse. For instance, activist groups have routinely argued that the genetically engineered seed market is dominated by a handful of international agriculture conglomerates.<sup>9</sup>

Usually overlooked is the fact that only large corporations have the resources to move new products through regulatory review. According to a study published in April 2022, 'the cost of bringing a new biotechnology-derived genetic trait to the point of commercialisation between 2017 and 2022 was on average \$115 million' – \$43.2 million (37.6 per cent) of which covers registration and regulatory affairs (AgbioInvestor 2022).

Reducing the regulatory hurdles smaller developers have to leap in order to commercialise a novel trait would create new competition for more established firms. Small and medium-sized companies could begin developing gene-edited crop varieties knowing that they wouldn't have to spend hundreds of millions of pounds and many years to earn regulatory

<sup>9 &#</sup>x27;Anti-GMO groups struggle to preserve Europe's stringent crop gene-editing rules in post-Brexit UK', *Genetic Literacy Project*, 30 March 2021 (<u>https://geneticliteracyproject.org/2021/03/30/anti-gmo-groups-struggle-to-preserve-europescrop-gene-editing-rules-in-post-brexit-uk</u>).

approval.<sup>10</sup> The end result: farmers would gain access to a wider variety of seed, putting downward pressure on their production costs and ultimately on consumer food prices.

The same phenomenon has been documented many times over in the agricultural sector. Disease-resistant crops, for example, reduce the amount of pesticide farmers require to protect their yields, again lowering their production costs. Harmful microbes that infect plants can also cause serious human diseases – up to and including cancer, so gene-edited crops immune to disease-causing pests could help mitigate this public health threat, saving lives and cutting healthcare costs associated with treating related diseases.<sup>11</sup>

Finally, gene editing has been used to engineer agricultural animals with natural protection against deadly diseases and reduced environmental footprints (English 2021). British scientists have already bred pigs that are resistant to porcine reproductive and respiratory syndrome (PRRS), a highly transmissible disease that may cost farmers more than half a billion pounds annually. Beyond cutting production costs for farmers, these traits improve animal welfare and reduce agricultural pollution – two causes many activist groups have championed for years.<sup>12</sup>

<sup>10 &#</sup>x27;Uncertain future: Will Europe's Green Deal encourage or cripple crop gene-editing innovation?', Genetic Literacy Project, 2 February 2021 (<u>https://geneticliteracyproject.</u> org/2021/02/02/uncertain-future-will-europes-green-deal-encourage-or-cripple-cropgene-editing-innovation).

<sup>11</sup> Fight mycotoxin contamination with modern technology', Consumer Choice Center, 24 November 2020 (<u>https://consumerchoicecenter.org/fight-mycotoxin-contamination-with-modern-gene-editing</u>).

<sup>12 &#</sup>x27;Breaches of English farm pollution laws rise as rules remain largely unenforced', *The Guardian*, 21 April 2022 (<u>https://www.theguardian.com/environment/2022/apr/21/</u> <u>breaches-of-english-farm-pollution-laws-rise-as-rules-remain-largely-unenforced</u>).

<sup>13 &#</sup>x27;Viewpoint: News or propaganda? UK newspaper the Guardian paid over \$800k to publish anti-farming 'investigation', *Genetic Literacy Project*, 1 June 2020 (<u>https://geneticliteracyproject.org/2020/06/01/viewpoint-news-or-propaganda-uk-newspaperthe-guardian-paid-over-800k-to-publish-anti-farming-investigation</u>).

# Is gene editing safe? Addressing common concerns

Despite its realised and anticipated successes, genetic engineering has generated intense opposition from activist groups and organic food producers who view the technology as a threat to their ideological goals and economic interests. Their objections stem from two primary concerns: genetically engineered organisms, both GMO and gene-edited varieties, are 'unnatural' and they could have unintended health and ecological consequences.

As a result, they argue, England should maintain the strict genetic engineering regulations it inherited from the EU, which give officials the authority to prevent the technology from causing harm. 'What has been removed is the need for an independent risk assessment and the need for transparency,' Liz O'Neill, director of the activist group GM Freeze, said of the government's effort to reform its gene-editing rules.<sup>14</sup>

New technologies always carry some level of risk; no expert denies this fact. Nonetheless, there is little reason to suspect that gene editing poses a novel threat to human health or the environment. Evaluating the risk posed by CRISPR, by far the most widely used gene-editing technology, the authors of a study published in *Nature* (Young et al. 2019) explained that 'CRISPR-Cas based genome editing is very precise compared to other crop improvement technologies such as traditional or mutational breeding ... Our data confirms previous reports demonstrating high-specificity of CRISPR-Cas9-mediated genome editing in plants.'

<sup>14 &#</sup>x27;Government sends gene-edited food bill to Parliament', BBC, 25 May 2022 (https://www.bbc.com/news/science-environment-61563299).

The researchers added that plant breeders have long known how to prevent potentially harmful new plant varieties from entering the food supply:

...[R]egardless of the breeding method, standard practices of commercial crop development include advancement of candidate lines following extensive agronomic evaluations specific for a given crop. This has proven to be an effective tool to eliminate plants with undesirable characteristics resulting in crops with a history of safe use. Therefore, concerns related to specificity of CRISPR-Cas9 technology in crop improvement have little relevance.

It is perfectly reasonable to express concern about the risks posed by innovation. Indeed, we should demand that regulators properly assess the potential harms associated with new technologies and ensure that these tools are deployed responsibly. However, precautionary policies designed to bear no technological risk, which biotech sceptics have promoted for 30 years, cannot achieve this result (English 2021). Instead, regulators and scientists generally recognise that sound public policy must be based on evidence-based risk assessments that consider the costs and benefits of a given product.

The assertion that genetic engineering techniques are unnatural is equally spurious. CRISPR was effectively copied from bacteria that use it to fend off invading viruses. And as explained elsewhere, 'A wide variety of microbes, insects and plants naturally exchange DNA with distant species, including globally important food crops such as rice, maize, wheat and sugarcane' (English 2021). In sum, genetic engineering is a skill we learned from nature.

### Precision Breeding Bill: an important step forward

In June 2022, the government proposed legislation that would authorise the commercial cultivation and sale of some products derived from precision-bred plants and animals (Parliament 2022). The bill would eliminate some unnecessary biotechnology regulations inherited from the EU, while maintaining appropriate restrictions designed to safeguard public health, animal welfare and the environment.

The Department for Environment, Food And Rural Affairs (DEFRA) summarised the government's case for the Precision Breeding Bill in a May 2022 factsheet, explaining that gene editing

... enables the development of crops that are more nutritious, resistant to pests and disease, resilient to climate change and more beneficial to the environment. This in turn could reduce the need for pesticides, increase food production and reduce costs to English farmers.<sup>15</sup>

There are a number of impressive examples of such crops developed by English scientists for English farmers and consumers:

 British Sugar announced in March 2021 that it had begun work on gene-edited sugar beets resistant to virus yellows disease, which can

<sup>15</sup> Genetic technology (precision breeding) bill factsheet 1 – overview, *DEFRA*, May 2022 (https://publications.parliament.uk/pa/bills/cbill/58-03/0011/FactsheetGenetic.pdf).

cut crop yields up to 50 per cent.<sup>16 17</sup> For now, farmers can only control the disease by killing the insect that transmits the virus using tightly regulated insecticides.<sup>18</sup>

 Researchers led by the John Innes Centre recently developed a geneedited tomato designed to fight vitamin-D deficiency, a condition that can have serious health consequences and afflicts one in six UK residents and a billion people globally.<sup>19</sup>

<sup>16 &#</sup>x27;Gene-edited sugar beet could be grown in UK within five years', *Farmers Weekly*, 26 March 2021 (<u>https://www.fwi.co.uk/arable/sugar-beet/gene-edited-sugar-beetcould-be-grown-in-uk-within-five-years</u>).

<sup>17</sup> Ibid.

<sup>18 &#</sup>x27;Statement on the decision to issue – with strict conditions – emergency authorisation to use a product containing a neonicotinoid to treat sugar beet seed in 2021', *DEFRA*, 2 March 2022 (<u>https://www.gov.uk/government/publications/neonicotinoid-productas-seed-treatment-for-sugar-beet-emergency-authorisation-application/statementon-the-decision-to-issue-with-strict-conditions-emergency-authorisation-to-use-aproduct-containing-a-neonicotinoid-to-treat-sugar-beet).</u>

<sup>19 &#</sup>x27;In defence of Britain's CRISPR, vitamin-D fortified tomato', American Council on Science and Health, 25 May 2022 (<u>https://www.acsh.org/news/2022/05/25/defense-britains-crispr-vitamin-d-fortified-tomato-16329</u>).

# How will precision-bred organisms be regulated?

If enacted, the law would require developers to register precision-bred organisms with DEFRA.<sup>20</sup> The legislation would create two notification systems, one for organisms used in scientific research and another for organisms intended for marketing purposes. Data collected through these notification systems would be published on a public register on GOV.UK.<sup>21</sup> Anyone seeking to market a precision-bred plant must meet several additional requirements. According to an August 2022 research briefing published by Parliament:

a person with a precision-bred organism (PBO) under their control must follow notification rules before they may release the PBO – or the organism must be a marketable precision-bred organism or its progeny. To be classed as a marketable PBO, a 'marketing notice' must be submitted to [DEFRA's] Secretary of State, who will take advice from the Advisory Committee before confirming or not confirming its status as precision bred in a confirmation notice.<sup>22</sup>

DEFRA's Secretary of State may revoke an organism's confirmation if 'no longer satisfied that the organism is precision bred'. Any food or feed

<sup>20 &#</sup>x27;UK draft bill permits 'precision bred' gene-edited plants, animals and products', *Covington*, 13 June 2022 (<u>https://www.globalpolicywatch.com/2022/06/uk-draft-bill-</u> <u>permits-precision-bred-gene-edited-plants-animals-and-products</u>).

<sup>21</sup> Genetic Technology (Precision Breeding) Bill 2022-23 research briefing, UK Parliament, 10 August 2022 (<u>https://commonslibrary.parliament.uk/research-briefings/ cbp-9557</u>).

<sup>22</sup> Ibid. p. 44.

marketing authorisation based on the confirmation notice would also 'be treated as revoked', though these decisions may be appealed.<sup>23</sup>

The marketing authorisation process for animals is more complex. A person must submit a marketing authorisation request alongside an animal-welfare declaration, which must explain any health or welfare risks to the animal. A welfare advisory body will review the application before the minister makes a decision. These authorisations may also be suspended or revoked if 'new information about animal health or welfare' comes to light or if an applicant fails 'to comply with information reporting requirements on a relevant animal's health and welfare'.<sup>24</sup>

Regulators will take a 'stepwise approach' once the legislation is passed, authorising commercial use of precision breeding in plants followed by animals at a later date. The government has announced that the bill's provisions will not apply to animal breeding until specific animal-welfare regulations are enacted. The legislation authorises the Secretary of State to introduce these measures by 'secondary regulation'.<sup>25</sup>

The legislation would also empower the Food Standards Agency (FSA) to conduct a risk assessment before any such product could be commercialised. It announced that 'precision bred foods will only be permitted if our risk assessment judges them ... not to present a risk to health, not to mislead consumers, and not to be nutritionally disadvantageous'.<sup>26</sup>

The specifics of the FSA's risk assessment have not yet been finalised, though DEFRA's impact assessment of the Precision Breeding Bill (DEFRA 2022) noted that the process will retain aspects of the existing GMO legislative framework and the framework applied to traditionally bred organisms. In other words, 'the level of regulatory scrutiny is somewhere between that of GMOs and traditionally bred organisms'. DEFRA added that:

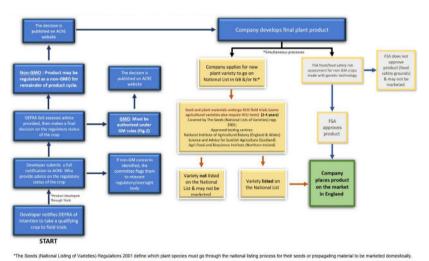
<sup>23</sup> Ibid. p. 47.

<sup>24</sup> Ibid. p. 48.

<sup>25</sup> Ibid. Summary.

<sup>26 &#</sup>x27;FSA 22-06-08 - The Genetic Technology (Precision Breeding) Bill, Food Standards Agency, 1 June 2022 (<u>https://www.food.gov.uk/about-us/fsa-22-06-08-the-genetic-technology-precision-breeding-bill</u>).

... A new scheme ... capturing PBOs, as described by the Bill, will be introduced by the FSA under secondary legislation. This will involve a lighter-touch risk assessment of food and feed products ... The FSA will draw on the expertise of the Advisory Committee on Novel Food Processes (ACNFP) for this process.



## Figure: Proposed system for PB plants in bill – (blue = proposed new steps)

Note: While the details of the FSA's risk assessment remain to be finalised, the Precision Breeding Bill outlines how gene-edited plants may make their way to commercialisation. Image credit: DEFRA.

The Precision Breeding Bill is an important step away from the EU's hypercautious 'GMO' regulations. It grants plant breeders and farmers access to technology that will yield a variety of important benefits. Moreover, the bill doesn't require that precision-bred products be labelled at the point of sale. Instead, the FSA is developing a consumer education project designed to give the public accurate information about how and why precision breeding will be allowed in food production.

### A better Precision Breeding Bill

Despite the significant regulatory progress it represents, the Precision Breeding Bill could be improved in two important ways: regulators could authorise the commercial use of precision breeding in plants and animals at the same time, and they could also allow the use of other genetic engineering methods in food production. A sound scientific case can be made for both proposals.

#### 1. Allow precision animal breeding right away

There is no scientific reason for officials to relax regulations on precisionbred plants and animals at different stages. The 'stepwise' approach discussed in the previous section is intended to assuage the concerns of critics who assert that 'not enough is known about the medium to long term effects on animal health and welfare'.<sup>27</sup> While nobody can perfectly predict the future, existing evidence indicates that animal gene editing is actually *less risky* than traditional breeding.

Experts have pointed out that the genomes of domesticated cattle contain more than 86 million mutations, all of which resulted from traditional breeding and most of which were unintentional.<sup>28</sup> The many generations of breeding that led to these mutations have not harmed agricultural

<sup>27 &#</sup>x27;Genetic technology bill: A serious step back for animal welfare', RSPCA, 26 May 2022 (https://www.rspca.org.uk/-/news-gene-editing-statement#:~:text=%20The%20 RSPCA%20has%20numerous%20serious%20concerns%20about,current%20 rules%20and%20regulations%20around%20Genetically...%20More%20).

<sup>28 &#</sup>x27;FDA defends CRISPR-edited animal rules likely to block most uses: Is the agency trying to avoid litigation from anti-GMO groups?' *Genetic Literacy Project*, 11 February 2020 (<u>https://geneticliteracyproject.org/2020/02/11/fda-defends-crispr-edited-animalrules-likely-to-block-most-uses-is-the-agency-trying-to-avoid-litigation-from-anti-gmogroups</u>).

animals in any way.<sup>29</sup> But it is still curious that critics of precision breeding have not expressed any concern about the 'medium to long term effects' of traditional breeding given its comparative imprecision.

In contrast to traditional breeding, gene editing allows scientists to make very specific modifications to an animal's DNA; research has shown that this highly precise technique poses little risk to the animal itself. For instance, a US study published in April 2022 (Trott et al. 2022) found that the offspring of gene-edited dairy cows 'did not differ in their growth, health or development compared with controls'.

The study's results speak to an important but oft-overlooked point: breeders and farmers want to employ tools that won't endanger the animals they work with. Like most people, these agricultural professionals strive to behave ethically; they are also incentivised to do so. As one farmer put it, 'Healthy, happy animals grow better and produce more, high-quality meat, milk, and other products. High-quality animal welfare makes sense!'<sup>30</sup> Additionally, the UK long ago enacted robust animal-welfare regulations. According to DEFRA:

Animals must have a suitable environment and diet, and be able to exhibit normal behaviour patterns. Animals must be protected from pain, suffering, injury and disease, and be housed according to their specific needs. This basic duty of care applies in all situations...<sup>31</sup>

For these reasons, the Precision Breeding Bill should authorise the use of gene editing in crop and animal agriculture simultaneously.

#### 2. Authorise the use of all genetic engineering methods

While the government's case for precision breeding is sound as far as it goes, much more could be said in defence of crop and animal genetic engineering more generally. There is no scientific reason the UK should allow researchers and farmers in England to breed and cultivate gene-

<sup>29</sup> Ibid.

<sup>30 &#</sup>x27;Better animal care equals greater profits', *AgDaily*, 9 November 2021 (<u>https://www.agdaily.com/livestock/farm-babe-better-animal-care-equals-greater-profits</u>).

<sup>31 &#</sup>x27;Animal Welfare: Advice and guidance on protecting animal welfare on farms, in transport, at markets and at slaughter', *DEFRA*, 10 August 2022 (<u>https://www.gov.uk/</u> <u>guidance/animal-welfare#on-farm-animal-welfare</u>).

edited organisms but maintain restrictions on transgenic (GMO) products inherited from the EU. While precision breeding and transgenesis are technically different techniques, the latter does not pose a greater risk than the former. All foods should be regulated based on the risk they may pose to human health and the environment, not the breeding method that produced the food.

DEFRA argued in a May 2022 factsheet that 'precision-bred organisms pose no greater risk than their traditionally bred or naturally arising counterparts'.<sup>32</sup> This is certainly correct, but it is also true of GMO plants and animals. In the decades since GMOs were first commercialised, several thousand studies have shown that these organisms pose minimal risk to human health and the environment.<sup>33</sup>

Indeed, there is substantially more data confirming the safety of GMOs than there is in support of gene-edited products. Since DEFRA recognises that precision breeding is a low-risk technology and endorses a 'science based and proportionate approach' to regulation,<sup>34</sup> consistency dictates that the government should also endorse the cultivation of GMOs and regulate them as it intends to regulate gene-edited products.

The technology used to produce a food product has little bearing on its safety profile. Any potential risk the food poses to public health or the environment arises from its characteristics and use. DEFRA has endorsed this product-based approach to risk assessment, arguing in its January 2021 precision-breeding consultation that 'our position follows the science, which says that the safety of an organism is dependent on its characteristics and use rather than on how it was produced' (DEFRA 2021). This observation further undermines the department's rationale for exempting only precision breeding from existing regulations.

Finally, experts recognise that gene editing, powerful as it is, has important limitations.<sup>35</sup> Scientists have endowed food crops with many traits farmers

<sup>32</sup> Genetic Technology (Precision Breeding) Bill factsheet 1 – overview, DEFRA, May 2022 (https://publications.parliament.uk/pa/bills/cbill/58-03/0011/FactsheetGenetic.pdf).

<sup>33 &#</sup>x27;Are GMOs safe?' *Genetic Literacy Project* (<u>https://geneticliteracyproject.org/gmo-faq/are-gmos-safe</u>).

<sup>34</sup> Genetic Technology (Precision Breeding) Bill factsheet 1 – overview, *DEFRA*, May 2022 (<u>https://publications.parliament.uk/pa/bills/cbill/58-03/0011/FactsheetGenetic.pdf</u>).

<sup>35 &#</sup>x27;U.K. set to loosen rules for gene-edited crops and animals', Science, 26 May 2021 (https://www.science.org/content/article/uk-set-loosen-rules-gene-edited-crops-andanimals).

find useful, but these results were achieved with earlier transgenic (GMO) technology, not precision breeding. Canola (oilseed rape), sugar beet and maize, all grown in England, have been engineered for herbicide tolerance, helping farmers in dozens of countries more efficiently control weeds, yet these crops are not available to English farmers.<sup>36</sup> Researchers have also developed a blight-resistant potato that could help English growers manage an ever-present threat to their yields.<sup>37</sup> Unfortunately, all these crops are regulated as GMOs and therefore much more difficult to commercialise. In an ironic twist, the potato was engineered using technology developed by the Sainsbury Research Lab at Norwich, UK, which licensed the innovation to the US firm Simplot.<sup>38</sup>

<sup>36 &#</sup>x27;What GMO crops are currently available on the market?' *GMO Answers*, (<u>https://</u>gmoanswers.com/gmos-in-the-us).

<sup>37 &#</sup>x27;How to tackle worrying emerging potato blight strains', *Farmers Weekly*, 16 July 2021 (<u>https://www.fwi.co.uk/arable/crop-management/disease-management/how-to-tackle-worrying-emerging-potato-blight-strains</u>).

<sup>38 &#</sup>x27;2Blades partners with The Sainsbury Laboratory and J.R. Simplot Company to develop resistance against potato diseases', 2 Blades Foundation, 8 March 2016 (https://2blades.org/2016/03/08/2blades-partners-with-the-sainsbury-laboratory-and-jr-simplot-company-to-develop-resistance-against-potato-diseases).

### Conclusion

Genetically engineered organisms have been produced and consumed around the world for the better part of 30 years. In that time, researchers have affirmed two important conclusions.

First, and most importantly, foods produced with the help of biotechnology do not present an increased risk to human health. The FSA agrees, noting in a recent consultation on nine imported GMOs that the use of these products would '... not pose a risk to human health when consumed' (FSA 2022).

Critics who assert that genetic engineering is dangerous wrongly assume that modifying the DNA of plants and animals in a laboratory is inherently risky. But, as two experts explained recently, we've been altering the genetics of our food for centuries:

Humans have been modifying the DNA of our food for thousands of years (even though we didn't know that DNA was mediating the changes until the 20th century). We call it *agriculture*. Early farmers (>10,000 years ago) used selective breeding to guide DNA changes in crops and animals to better suit our needs.<sup>39</sup>

<sup>39 &#</sup>x27;Is there a difference between a gene-edited organism and a 'GMO'? The question has important implications for regulation', *Genetic Literacy Project*, 12 May 2021 (https://geneticliteracyproject.org/2021/05/12/is-there-a-difference-between-a-geneedited-organism-and-a-gmo-the-questin-has-important-implications-for-regulation).

The only difference between modern and ancient agriculture in this respect is that relatively recent advances in molecular biology have enabled scientists to make very specific changes to the genomes of plants and animals. These innovations have made food production safer and more sustainable.

Second, cultivating genetically engineered crops is enormously profitable. According to recent estimates, the UK has forfeited somewhere between £65 million and £82 million annually by denying its farmers access to GMO crops their counterparts in other countries grow without incident. This amounts to nearly £2 billion in losses since 1996 (English 2021). To put this figure in context, 'the value of UK farm output in 2020 was £26.7 billion', the USDA has reported.<sup>40</sup>

The government deserves praise for moving to relax agricultural geneediting regulations. This evidence-based effort will allow England's science community to begin solving some of the food production and environmental challenges they have the ability to address. But this should be the first step in a series of broader policy changes that will allow England's agricultural sector to utilise all the tools of biotechnology, including GMO crops and animals that have demonstrated their utility time and again.

The government has recently said it wants Britain to regain its 'scientific superpower' status.<sup>41</sup> A full-throated endorsement of genetic engineering would go a long way in proving that the UK's leadership means what it says.

<sup>40 &#</sup>x27;What Is "Brexit" and what could it mean for U.S. agricultural trade with the UK?' USDA, 22 July 2022 (<u>https://www.ers.usda.gov/topics/international-markets-u-s-trade/</u> countries-regions/european-union/brexit-and-u-s-agricultural-trade).

<sup>41 &#</sup>x27;New UK science minister takes on ambitious research agenda', *Nature*, 24 September 2021 (<u>https://www.nature.com/articles/d41586-021-02609-0</u>).

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