Global Counsel

Is the UK about to go its own way on gene editing?

Blog post by Research Analyst Ana Mendes, 18 January 2021

Earlier this month, the UK's Department for Environment, Food and Rural Affairs (DEFRA) launched a consultation on the regulation of genetic technologies, prompting speculation that gene editing (GE) in agriculture may, in the coming years, be permitted in the UK. As the UK settles into its newly acquired independence from EU regulation, there is an opportunity for it to reconsider the rules that prevent gene editing of crops and livestock. Any changes to agriculture regulation may trigger parallel consultations of GE use in healthcare and research. However, this could provoke a backlash from the public and NGOs, particularly considering the sensitive ethical considerations of these changes. So, what might this mean?

Whilst the growth and sale of certain GMO crops is permitted in the UK under EU legislation, GE is strictly forbidden under similar laws for use in crops. Unlike genetically modified organisms (GMO), where a preferred gene from organism A is inserted into organism B to seemingly improve the characteristics of organism B, GE involves introducing a very precise change in a living organism's existing DNA. CRISPR-Cas9 (Clustered regularly interspaced palindromic repeats-Cas9) is an innovative, and highly precise, gene editing tool used to perform genetic alterations. Within agriculture, this technology has been used in China to alter yield-related traits of rice and soybean, and in the US to produce a variety of waxy corn used as a thickener in many food products. Within health, it has been used to treat blood diseases, develop cancer treatments and beyond.

The tone of DEFRA's consultation and the expert advice it has been receiving suggests it might revisit the EU approach. That advice has pointed to several key uses of gene-editing in health: genome-edited immune cells; 'somatic cell' editing, involving modification of adult cells in affected tissue; and 'germline' editing of gametes, in which genetic changes would be inherited. The latter is still a long way from reality owing to limited research and complex bioethics. However, the first two uses are already underway. CAR-T therapy, involving genetically engineered immune cells, is available on the NHS to treat leukaemia in young people and children, whilst human trials using CRISPR-Cas9 for the treatment of sickle cell anaemia and lung cancer in the US have already showed the technology's potential at safely treating these conditions.

If the UK does decide to lift restrictions, the implications are important. The relative ease and efficiency of GE has the potential to disrupt existing frameworks and practices within biosciences and health care. The realm of opportunities includes transforming precision medicine, developing disease models and advancing pharmacological research to accelerate drug discovery. The increase of lifestyle-orientated diseases, rising prevalence of genetic disorders and an ageing population are major factors driving demand for CRISPR research.

Change would build on an established strength. The UK is thriving in the field of genomics, having sequenced 100,000 whole genomes in 2018, and has shown its commitment to innovative science

through a new policy package to support uptake and adoption of innovation in the NHS, as outlined through the launch of the Genomic Medicine Service and in the Life Sciences Sector Deal. Yet, if the UK wants to continue as a global hub for researching, developing and manufacturing advanced treatments, it will have to consider how to more deeply incorporate GE into Industrial Strategy. In particular, there are questions over whether the intellectual property framework should be revised to decide who has access to gene editing tools, and to reduce barriers to the development of commercial GE companies in the UK.

Gene editing also challenges social norms. Progress in this field has been so rapid that the ethical frameworks may not be keeping up. Key issues that will require substantial consideration, according to the UK Science and Technology Committee's 2017 genomics and genome-editing report, include whether there will be limits to the conditions GE should be used to treat, fears over 'eugenics' and 'designer babies', and the risk of 'off-target events', where changes are made to genes other than those targeted. A crucial challenge will be how to encourage a transparent and informed debate between experts, government, patients, and the public. The covid-19 pandemic has been a reminder of the ways in which the media can be a source of misinformation and work against evidence-based public health messaging. The same risk will exist when the time comes to contemplate changing gene editing policy.

All of this suggests that change may be incremental and contested. Responses from DEFRA's consultation, which closes in March, will be used to amend the definition of GMO and to inform policy development on wider GE legislation. But with regulators clearly interested in innovative new approaches and new scope to define a UK strategy outside of the EU, change is almost certainly coming.