HOUSE OF LORDS Library Briefing

Gene Editing: Recent Developments and Scientific Status Debate on 30 January 2020

On 30 January 2020, Baroness Bakewell (Labour) is due to move that "this House takes note of recent developments in the field of gene editing, and its status in scientific research around the world".

Summary

Gene editing is a technique that allows parts of a genome to be precisely replaced or removed from DNA. The technique is also known as genome editing. It is being developed in areas such as biomedical research, human therapies and agriculture. The genome editing market continues to grow as demand from both agriculture and healthcare sectors increases.

Currently there are several genome editing technologies available. These technologies allow genetic material to be added, removed, or altered at locations in the genome. The most recent technology is known as CRISPR-Cas9. Genome editing is cited as having potential biological, medical and environmental benefits. Amongst other things, it has increased understanding of how specific genes are involved in areas such as disease. Recent developments in genome editing include progression in CRISPR-Cas9 technology and regulatory amendments in Europe following a 2018 European Court of Justice ruling.

The 100,000 Genome Project was established in 2012 to sequence 100,000 genomes from 85,000 NHS patients affected by a rare disease or cancer. In December 2018, the project ended when the 100,000th sequence was achieved. The project was delivered by Genomics England, a company which, at the time, was wholly owned and funded by the Department of Health and Social Care. In November 2019, the Health and Social Care Secretary, Matt Hancock, confirmed his future ambitions to see all children receive whole genome sequencing at birth.

Advancement in genome editing has created discussions on the ethical, environmental and regulatory implications of this innovation. Genome editing in the UK is regulated through a combination of European and domestic legislation. However, regulatory provisions across the world remain varied. There have been recent calls from scientists and ethicists for a "global moratorium" on clinical uses of human germline editing, which creates genetic changes that can be inherited by a person's descendants.

Claire Brader | 17 January 2020

Gene/Genome Editing

Gene editing is a technique that allows parts of a genome to be precisely replaced or removed from DNA.[1] The technique is also known as genome editing. A genome is an organism's complete set of DNA, including all its genes.[2] Each genome contains all the information needed to build and maintain that organism.

To date, genome editing is being developed in areas such as biomedical research, human therapies and agriculture.[3] Examples of developments include treatment of certain diseases and aiding better crop production in agriculture. The genome editing market has continued to grow in recent years as demand from both agriculture and healthcare sectors increases.[4] The market is predicted to rise by 18.30% during 2018–2023.[5] Its use in healthcare to develop new medicines and treat genetic diseases is cited as having potential to "open-up new avenues".[6] Following growth in pharmaceutical and biotechnology industries, the market is "dominated" by North America, followed by Europe.[7] In North America, the crop and cattle industry form the largest consumer of genome engineering services.[8] In Asia, "good opportunities" for the market have also been seen following the expansion of leading genome editing companies.[9]

Genome Editing Technologies

There are several genome editing technologies available. These include transcription activator-like effector nucleases (TALENs) and zinc-finger nucleases (ZFNs).[10] These technologies allow genetic material to be added, removed, or altered at locations in the genome. The most recently developed technique is known as CRISPR-Cas9.[11]

CRISPR-Cas9 stands for clustered regulatory interspaced short palindromic repeats and CRISPR-associated protein 9. It has generated interest in the scientific community because it is cited as being "faster, cheaper, more accurate, and more efficient" than other genome editing technologies.[12] In traditional gene therapy, additional copies of the "normal" gene are introduced into cells. In contrast, CRISPR-Cas9 enters the cell and "repairs the problematic gene by removing it or correcting it to restore normal physiological function".[13] CRISPR-Cas9 was developed from a "naturally occurring" genome editing system found in bacteria.[14]

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[1] The Academy of Medical Sciences, 'Genome Editing', accessed 10 January 2020.

[2] US National Library of Medicine, 'What is a Genome?', 7 January 2020.

[3] Parliamentary Office of Science and Technology, *Genome Editing*, 23 November 2016.

[4] Market Watch, 'Gene Editing Market 2019 Global Industry Analysis', 10 April 2019.

[5] ibid.

[6] ibid.

[7] ibid.

[8] ibid.

[9] ibid.

[10] The Academy of Medical Sciences, 'Genome Editing', accessed 10 January 2020.

[11] US National Library of Medicine, 'What are Genome Editing and CRISPR-Cas9?', accessed 10 January 2020.

[12] ibid.

[13] Technology Networks, 'A Highly Precise Cas9 Enzyme, SaCas9-HF, is Added to the CRISPR Toolbox', 7 November 2019

[14] US National Library of Medicine, 'What are Genome Editing and CRISPR-Cas9?', accessed 10 January 2020.

Benefits of Genome Editing

Genome editing is cited to have biological, medical and environmental benefits.

It has increased understanding of how specific genes are involved in areas such as disease.[15] Some state that the technology has the "potential to help, treat or prevent human diseases" by the elimination of genes that cause disease. [16] It is suggested that a wide range of illnesses, such as heart disease and Alzheimer's, could be "cured" through application of genome editing.[17] However, there are still moral questions that remain unanswered. For instance, how should the sector determine which conditions should be treated when "not everyone […] wants to be cured".[18]

In addition to treating diseases, genome editing has the potential to allow hereditary diseases, such as Huntingdon's disease, to be removed from a family line. Whilst screening for genetic disease already exists for in vitro fertilisation (IVF), it is claimed that CRISPR methods may allow "more complex edits".[19] However, ethical considerations are still posed. It has previously been argued that this degree of control in human reproduction crosses an "ethically inviolable line" that touches on "technical, social and religious concerns".[20]

When considering genome editing's role in helping to reduce biodiversity loss, scientists are "eager" to discuss the possibilities but are also cautious.[21] The technology is being trialled on food to determine if it has the potential to help farming sustainability and crop resilience.[22] For coral reef preservation, a trial was also conducted to determine which genes within coral are important for handling stresses to the environment.[23] However, scientists have emphasised that information is needed to determine how genes "operate within a broader community context" and what impact changing genetics may have on wider biodiversity.[24] For example, how changing a plant's size or colour could affect the behaviour of insects.[25] Some argue that the "effects of human interventions are not always predictable".[26] Once a gene-edited species has been released, some say that "controlling any negative effects will be difficult".

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[15] The Academy of Medical Sciences, 'Genome Editing', accessed 10 January 2020.

[16] Ian Sample, 'What is Gene Editing and How Can it be Used to Rewrite the Code of Life?', *Guardian*, 15 January 2018.

[17] National Geographic, '5 Reasons Gene Editing is Both Terrific and Terrifying', 3 December 2015.

[18] ibid.

[19] ibid.

[20] National Academy of Sciences and National Academy of Medicine, *Human Genome Editing: Science, Ethics and Governance*, February 2017.

[21] Ensia, 'Can the Gene Editing Technology Known as CRISPR Help Reduce Biodiversity Loss Worldwide?', 13 September 2019.

[22] ibid.

[23] Proceedings of the National Academy of Sciences of the United States of America, 'CRISPR-Cas9 Mediated Genome Editing in a Reef-Building Coral', 25 April 2018.

[24] Ensia, 'Can the Gene Editing Technology Known as CRISPR Help Reduce Biodiversity Loss Worldwide?', 13 September 2019.

[25] ibid.

[26] ibid.

Recent Developments in Genome Editing

Developments in genome editing include technological progression in CRISPR-Cas9 techniques. Additionally, there have also been regulatory amendments in Europe following a 2018 European Court of Justice ruling: Case C-528/16.

Technological Developments for CRISPR-Cas9

In 2019, CRISPR Therapeutics, a biotech firm, conducted a clinical trial using CRISPR to treat patients with the blood disorder beta thalassaemia.[27] The trial involved the collection and editing of blood cells that were then placed back into the body via a stem cell transplant. The chief executive of the company described this trial as:

> […] an important scientific and medical milestone and the beginning of our efforts to fully realise the promise of CRISPR-Cas9 therapies as a new class of potentially transformative medicines to treat serious diseases.

A biotech firm from Boston, Editas Medicine, is now seeking to restore eyesight using CRISPR-Cas9 technology. [28] The trial plans to see the editing taking place within the patients' bodies and not inside a petri dish.

To date, CRISPR-Cas9 has been regarded as a "powerful tool" in genome editing due to its ability to make gene modification "simple".[29] Until recently, two versions of Cas9, namely 'SpCas9' and 'SaCas9', were commonly used in CRISPR.[30] However, both have been cited as having certain levels of "imprecision or off-target effect".[31]

Researchers in Hong Kong have recently developed a new protein that they argue could help to increase the targeting accuracy in the genome editing process.[32] Dr Zheng Zongli, assistant professor of the department of biomedical sciences at City University of Hong Kong, states that a new CRISPR Cas9 variant has been engineered. 'SaCas9-HF' claims to have "high accuracy" in targeting in human cells "without compromising on target efficiency".

Whilst further research is still needed, researchers are claiming "optimism" about SaCas9-HF's application and accuracy across different cell types.[33] It is believed that SaCas9-HF could be "useful" for future gene therapies in humans that require high precision.[34]

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[27] Hannah Kuchler, 'Crispr Therapeutics Treats its First Human with Gene Editing', *Financial Times* (£), 25 February 2019.

[28] Hannah Kuchler, 'Crispr Puts First Human In-Body Gene Editing to Test', *Financial Times* (£), 7 January 2020.

[29] Science Daily, 'A New CRISPR-Cas9 Protein to Increase Precision of Gene Editing', 6 November 2019.

[30] American Association for the Advancement of Science and EurekAlert!, 'A New CRISPR-Cas9 Protein to Increase Precision of Gene Editing', 6 November 2019.

[31] ibid.

[32] Science Daily, 'A New CRISPR-Cas9 Protein to Increase Precision of Gene Editing', 6 November 2019.

[33] Genetic Engineering and Biotechnology News, 'Precise CRISPR-Cas9 Variants Come in Small Packages', 1 October 2019.

[34] Science Daily, 'A New CRISPR-Cas9 Protein to Increase Precision of Gene Editing', 6 November 2019.

Court of Justice of the European Union: Case C-528/16

In July 2018, the European Court of Justice (ECJ) issued a ruling that impacted the regulatory provisions of genome editing technologies across Europe.

Directive 2001/18/EC (GMO directive) requires genetically modified organisms (GMOs) to be identified, tracked and monitored for their effects on the environment and consumers. Prior to July 2018, there was uncertainty about whether genome editing was subject to the directive's provisions.[35] However, following legal action brought by French agriculture union Confédération Paysanne, the ECJ confirmed that genome editing constituted genetic modification.[36] This means that the GMO directive applies to genome editing also.[37] The ECJ confirmed that:

> […] organisms obtained by mutagenesis[38] are GMOs within the meaning of the GMO Directive, in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally. It follows that those organisms come, in principle, within the scope of the GMO Directive and are subject to the obligations laid down by that directive.[39]

In response to the ruling, scientists argued that this could "hold back cutting-edge research and innovation" and "impose highly onerous burdens on the use of genome editing […]".[40]

On 24 October 2018, a position paper was released by scientists from around the world "urging" for the law to be amended.[41] They argued that crops with "small DNA adaptions", made through gene editing, should come under regulations for conventional methods and not the GMO directive.

In the UK, researchers from UK science, farming and agricultural technology organisations sent a letter to the then Secretary of State for Environment, Food and Rural Affairs, Michael Gove, expressing "concerns" about the ruling's impact.[42] In November 2018, Mr Gove issued a letter to the then chair of the House of Commons Science and Technology Committee, Norman Lamb, confirming the Government's concern about the ECJ ruling.[43]

At a meeting in May 2019, the EU Agriculture and Fisheries Council noted that the ECJ ruling "provided legal clarity" on new breeding techniques, but also "triggered questions and challenges".[44] The council invited the new European Commission to review the European GMO legislation as part

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[35] Paul Rincon, 'Gene Editing is GM, says European Court', BBC News, 25 July 2018.

[36] International Union for Conservation of Nature, 'European Court of Justice Ruling on Genome Editing', 14 August 2018.

[37] Andrew J Wright, 'Strict EU Ruling on Gene-Edited Crops Squeezes Science', *Nature Research Journal*, 25 October 2018, vol 563, pp 15–16.

[38] Mutagenesis is the production of genetic mutations.

[39] Steffi Friedrichs et al, 'An Overview of Regulatory Approaches to Genome Editing in Agriculture', *Biotechnology Research and Innovation*, July–December 2019, vol 3 no 2, pp 208–20.

[40] Paul Rincon, 'Gene Editing is GM, says European Court', BBC News, 25 July 2018.

[41] Magnus Nordborg et al, *Regulating Genome Edited Organisms as GMOs has Negative Consequences for Agriculture, Society and Economy*, October 2018, p 4.

[42] Professor Dale Sanders et al, 'Letter to Secretary of State for Environment, Food and Rural Affairs', 13 September 2018

[43] Department for Environment, Food and Rural Affairs, 'Letter to House of Commons Science and Technology Committee', 29 November 2018.

[44] Council of the European Union, *Outcome of the Council Meeting: Agriculture and Fisheries*, 14 May 2019, p 7.

of its working programme.[45]

Recent Government Initiatives: The 100,000 Genomes Project

The 100,000 Genomes Project (the project) was established in 2012 to sequence 100,000 genomes from around 85,000 NHS patients affected by a rare disease or cancer.[46] Recruitment of participants was completed in December 2018 when the 100,000th sequence was achieved. The project was delivered by Genomics England, a company which, at the time, was wholly owned and funded by the Department of Health and Social Care.

The project aimed to provide the NHS with infrastructure to incorporate whole-genome sequencing into areas such as the treatment of cancer and rare diseases.[47] The project's ambition was to start a self-supporting genomics industry within the UK. Centralised funding for the project has now ended. Future genomics will now be funded by the NHS, other grant providers and applications from industry to access the project's dataset.[48]

In June 2019, Jess Phillips (Labour MP for Birmingham, Yardley) asked the Department of Health and Social Care what plans it had to evaluate the project.[49] The Minister of State, Caroline Dinenage, confirmed that the project had been under regular review by the Infrastructure and Projects Authority. As part of this, Ms Dinenage confirmed that the project had undergone several "significant reviews", with conclusions being shared to delivery partners.

To expand on the project, in October 2018 the Health and Social Care Secretary, Matt Hancock, announced an "ambition to sequence five million genomes in the UK over the next five years".[50] In November 2019, Mr Hancock also confirmed his ambitions to see all children receive whole genome sequencing at birth. He stated that tests would be routinely offered to map out the risk of genetic diseases and offer "predictive, personalised" care.[51] In response, the British Society for Genetic Medicine (BSGM) advised that Mr Hancock's ambition to conduct genomic sequencing of healthy new-borns could be "problematic" because the genetic code of a healthy new-born "will only rarely predict future disease accurately".[52] BSGM stated that:

> Such a venture therefore needs to be carefully researched, and the ethical and societal aspects require careful consideration before roll-out to the general population.

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[45] The new European Commission was due to take office in November 2019. However, the Commission took office in December 2019 following a delay.

[46] Genomics England, 'The 100,000 Genomes Project', accessed 10 January 2020.

[47] Parliamentary Office of Science and Technology, *Preparing for a Changing World*, 28 August 2019, p 14.

[48] ibid.

[49] House of Commons, 'Written Question: 100,000 Genomes Project', 5 July 2019, 269788.

[50] Department of Health and Social Care, 'Matt Hancock Announces Ambition to Map 5 Million Genomes', 2 October 2018.

[51] Laura Donnelly, 'All Children to Receive Whole Genome Sequencing at Birth, Under Ambitions Laid Out by Matt Hancock', *Telegraph,* 5 November 2019.

[52] British Society of Genetic Medicine, 'Genome Sequencing of Healthy Newborns: BSGM Response', 13 November 2019.

Challenges of Genome Editing

Advancements in genome editing techniques have created discussions on the ethical, environmental and regulatory implications of this innovation.

The use of genome editing in germline cells (eggs, sperm and embryos), for example, has seen discussions on ethical viability.[53] This is because changes made to germline cells may be inherited by future generations. There has been "significant" debate cited around the ethics of editing germ cells or human embryo cells. The House of Commons Science and Technology Committee referred to ethical considerations during its inquiry on genomics and genome editing in the NHS in 2018. [54] Ethical considerations included:

- whether or not genome editing of embryos constitutes medical treatment, given that the 'patient' does not yet exist;
- the need for genome editing given alternative treatments, screen tools and options such as adoption;
- the unknown consequences on future generations;
- the inability to obtain consent from future generations; and
- the potential for genome editing to facilitate eugenics or 'designer babies', and what a market for genetic enhancement would mean for equality. [55]

In July 2018, Nuffield Council on Bioethics published findings from its independent inquiry on the social and ethical issues of genome editing in human reproduction.[56] The inquiry concluded that the use of genome editing in human reproduction should be ethically acceptable if "it is intended to secure, and is consistent with, the welfare of a person" and "it is consistent with social justice and solidarity".[57] During a 2018 debate on 'In Vitro Fertilisation: 40th Anniversary', the Earl of Selborne (then Conservative) highlighted:

> The Nuffield Council's conclusion, as the noble Baroness, Lady Deech, reminded us, as to whether human genome editing would ever be ethically acceptable is that interventions of this kind to influence the characteristics of future generations could be ethically acceptable if, and only if, two principles are satisfied. The first is that such interventions are intended to secure, and are consistent with, the welfare of a child who may be born as a consequence. The second is that such interventions would uphold principles of social justice and should not provoke or exacerbate social division or marginalise or disadvantage groups in society.[58]

Currently the consensus is that such practices would be "ethically unacceptable".[59] A recent example of controversy in this area was caused by the now imprisoned Chinese scientist He Jiankui, following

[53] Parliamentary Office of Science and Technology, *Preparing for a Changing World*, 28 August 2019, p 94.

[54] House of Commons Science and Technology Committee, *Genomics and Genome Editing in the NHS*, 20 April 2018, HC 349 of session 2017–19, p 44.

[55] ibid.

[56] Nuffield Council on Bioethics, *Genome Editing and Human Reproduction: Social and Ethical Issues*, July 2018.

[57] ibid, p 10.

[58] HL *Hansard*, 13 September 2018, cols 2437–8.

[59] Parliamentary Office of Science and Technology, *Preparing for a Changing World*, 28 August 2019, p 94.

his claim to have created the world's first gene-edited twins.[60] Russian geneticist Denis Rebrikov has also stated plans to use CRISPR to alter DNA in human embryos.[61] Mr Rebrikov is recently cited as seeking "rigorous ethical and regulatory review" in this area, with some scientists openly supporting his efforts.[62]

From an environmental perspective, considerations surround gene drive applications and genome edited crops.[63] One concern with gene drives[64] is that there is currently no proven way of reversing it. For genome-edited crops, concerns have also been raised about the "possibility of gene flow between crops and close wild relatives".[65]

From a regulatory perspective, the question remains around whether the GMO directive should apply to genome-edited organisms. As these mutations can also occur naturally, it remains "unclear" how the ECJ ruling will be enforced.[66]

Regulation of Genome Editing in the UK

Genome editing in the UK is regulated by European and domestic legislation.

Regulation of Biomedical Research

The use of animals in experiments and testing is regulated by the Animals (Scientific Procedures) Act 1986 (ASPA). This legislation applies to England, Scotland and Wales. Three licences are required by ASPA before testing on animals is permitted:

- A personal licence for each person carrying out procedures on animals.
- A project licence for the programme of work.
- An establishment licence for the place at which the work is carried out. [67]

During 2018, there were 157 establishment licences[68] and 3,136 project licences in force.[69]

Human embryo research is regulated by the Human Fertilisation and Embryology Authority (HFEA). HFEA was established by the Human Fertilisation and Embryology Act 1990 (HFE Act). The HFE Act prohibits all activities involving human embryos outside the body without a licence. HFEA grants licences to fertility clinics and human embryo research centres for up to four years, with new clinics

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[60] Ian Sample, 'Chinese Scientist Who Edited Babies' Genes Jailed for Three Years', *Guardian*, 31 December 2019.
[61] Jon Cohen, 'Embattled Russian Scientist Sharpens Plans to Create Gene-Edited Babies', *ScienceMag*, 21 October 2019.
[62] ibid.
[63] Parliamentary Office of Science and Technology, *Preparing for a Changing World*, 28 August 2019, p 94.
[64] Gene drives can be used to spread a gene rapidly through a population.
[65] Parliamentary Office of Science and Technology, *Preparing for a Changing World*, 28 August 2019, p 94.
[66] ibid.
[67] Home Office, 'Animal Testing and Research: Applying for Licenses', 29 August 2017.
[68] Seven of which did not have any active project licences in 2018.
[69] Home Office, *Annual Statistics of Scientific Procedures on Living Animals Great Britain 2018*, 18 July 2019.

receiving an automatic two-year licence.[70] Inspections are undertaken by HFEA every two years and it publishes a Code of Practice to help licensees comply with the HFE Act.[71] The HFE Act provides that licences are only granted for reasons as prescribed in schedule 2 of the HFE Act. Such reasons include "bringing about the creation of embryos in vitro", and "procuring, keeping, testing, processing or distributing embryos".

Regulation of Genetically Modified Food and Animal Feed

GMOs require authorisation before they can be grown in Europe. The European Food Safety Authority (EFSA) assesses the safety of GMOs and the food or feed derived from them.[72] Authorisations apply to GMOs for food or feed use, food or feed containing or consisting of GMOs, and food or feed produced from or containing ingredients produced from GMOs.[73] This is a requirement under European Regulation (EC) No 1829/2003.[74] Once the EFSA panel has finished its assessment, the European Commission and member states decide whether to grant authorisation of the GMO for use in Europe.[75]

The Traceability and Labelling Regulation (EC 1830/2003) also provides specific labelling requirements for all food and feed which contain or consist of GMOs.[76] It aims to "harmonise" the EU system for identifying genetically modified products throughout supply chains. For animal feed, those which contain genetically modified or genetically modified derived material must be indicated on the feed label.[77]

Regulation of Environmental Research

European Directive 2001/18/EC provides provisions on the deliberate release of GMOs into the environment.[78]

On 29 September 2019, the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 came into force. Their purpose was to implement European Directive 2018/350.[79] This amended Directive 2001/18/EC and made further provision in respect of environmental risk assessments that must be conducted before the release of GMOs into the environment. Similar regulations were also brought in in Wales, Scotland and Northern Ireland.

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[70] Human Fertilisation and Embryology Authority, 'How We Regulate', accessed 9 January 2020.

[71] Human Fertilisation and Embryology Authority, *Code of Practice*, revised December 2019.

[72] Food Standards Agency, 'GM in Animal Feed', 8 December 2017.

[73] Food Standards Agency and Department for Environment, Food and Rural Affairs, *Guidance Notes: Regulation (EC) No 1829/2003, Genetically Modified Food and Feed*, 24 November 2004.

[74] Official Journal of the European Union, *Regulation (EC) No 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed*, 22 September 2003.

[75] Food Standards Agency, 'GM in Animal Feed', 8 December 2017.

[76] Food Standards Agency and Department for Environment, Food and Rural Affairs, *Guidance Notes: Regulation (EC) No 1829/2003, Genetically Modified Food and Feed*, 24 November 2004, p 4, para 1.2.

[77] Food Standards Agency, 'GM in Animal Feed', 8 December 2017.

[78] Official Journal of the European Communities, *Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms*, 12 March 2001.

[79] Department for Environment, Food and Rural Affairs, Explanatory Memorandum to the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019.

European Directive 2009/41/EC provides guidance on the contained use of genetically modified micro-organisms (GMMs).[80] "Contained use" is defined in article 2 of the directive as:

> any activity in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment.

The directive provides measures aimed at protecting human health and the environment. It was implemented in England, Wales and Scotland via the Genetically Modified Organisms (Contained Use) Regulations 2014. Northern Ireland introduced equivalent regulations via the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015.

Regulation of Genome Editing in the USA

The regulation of genome editing across the world is varied. In embryo editing, certain jurisdictions, such as the UK, are cited as taking a "strict but permissive" approach.[81] This involves oversight from a national regulatory body such as HFEA. Internationally however, the institutions, extent and regulatory substance varies between jurisdictions.[82]

In US agriculture, a "product-triggered" regulation under existing laws applies to all biotechnology products.[83] The regulatory status of food (and feed) is managed by the US Food and Drug Administration (US FDA). Regulation is dependent upon the "objective characteristics of that food and independent of the methods used to develop the food".[84]

Unlike the stance taken in the 2018 ECJ ruling, the US Department of Agriculture (USDA) states that it does not regulate crops whose genetic changes could have been produced with conventional breeding.[85] This is "as long as [the crops] are not plant pests or developed using plant pests". The US FDA has suggested it may treat all intentionally edited products as drugs, which could mean "heavy" oversight.[86] However, critics argue that the imposition of government regulations may hinder gene editing.[87]

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[80] Official Journal of the European Union, *Directive 2009/41/EC of the European Parliament and of the Council on the Contained Use of Genetically Modified Micro-Organisms*, 6 May 2009.

[81] Michael Morrison and Stevienna de Saille, 'CRISPR in Context: Towards a Socially Responsible Debate on Embryo Editing', *Palgrave Communications*, 24 September 2019.

[82] ibid.

[83] Steffi Friedrichs et al, 'An Overview of Regulatory Approaches to Genome Editing in Agriculture', *Biotechnology Research and Innovation*, July–December 2019, vol 3 no 2, pp 208–20.

[84] ibid.

[85] US Department of Agriculture, 'Secretary Perdue Issues USDA Statement on Plant Breeding Innovation', 28 March 2018.

[86] Karen Weintraub, 'Crispr Gene-Editing Will Change the Way Americans Eat', *Guardian*, 30 May 2019.

[87] ibid.

Future of Genome Editing Regulations

Recent years have seen an increase in discussion about the disparity of regulations across Europe and worldwide.[88] In June 2018, an Organisation for Economic Cooperation and Development (OECD) conference discussed regulatory aspects of genome editing. [89] Government representatives from six different countries spoke about policy frameworks in their respective countries. Three main regulatory approaches to governance of genome editing were found. For example, Canada and the USA regulate genome edited products according to a product-trigger. [90] The relevant novelty of the trait in question is considered on a case-by-case basis and irrespective of the technology used to develop it.

For clinical uses of human germline editing, there have been recent calls from scientists and ethicists for the introduction of a "global moratorium".[91] The aim is to establish an international framework where nations retain autonomy but "voluntarily commit to not approve any use of clinical germline editing unless certain conditions are met". Several considerations support this proposal, including ensuring that long-term biological consequences are understood for both individuals and for the human species.[92] However, a professor of law from Santa Clara University, Kerry Macintosh, argues a global moratorium on heritable genome editing may "deter or delay basic research" and lead to the enactment of legislation that may "stigmatise" those born with modified genomes.[93]

Within Europe, it has previously been cited that a "reasonable degree" of harmonisation exists on the regulation of somatic cell-based genome editing.[94] However, reflecting on the UK's imminent departure from the EU, research charity the Wellcome Trust cites this as a "unique moment for reform".[95] It advises that the government introduces reforms to "make the UK the world-leader in the oversight of emerging science and technologies".

Brexit Implications on Genome Editing Regulations

The Conservative Party's 2019 manifesto included an aim to improve the quality of food, agriculture and land management through the implementation of "science-led, evidence-based policy".[96] This follows Prime Minister Boris Johnson's statement in July 2019 to "liberate" the bioscience sector from rules against GMOs.[97] Whilst some opponents shared concerns about the impact that new post-Brexit trade deals may have on food products, others, such as the National Farmers' Union,

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[88] Federation of European Academies of Medicine, *The European Landscape for Human Genome Editing*, April 2016.

[89] Steffi Friedrichs et al, 'An Overview of Regulatory Approaches to Genome Editing in Agriculture', *Biotechnology Research and Innovation*, July–December 2019, vol 3 no 2, pp 208–20.

[90] ibid.

[91] Eric Lander et al, 'Adopt a Moratorium on Heritable Genome Editing', *Nature Research Journal*, 13 March 2019, vol 567, pp 165–8.

[92] ibid.

[93] Kerry L Macintosh, 'Heritable Genome Editing and the Downsides of a Global Moratorium', *CRISPR Journal*, October 2019, vol 2 no 5, pp 272–9.

[94] Federation of European Academies of Medicine, *The European Landscape for Human Genome Editing*, April 2016, p 2.

[95] Wellcome, *A Blueprint For Dynamic Oversight*, March 2019, p 2.

[96] Conservative Party, *Conservative Party Manifesto 2019*, November 2019, p 43.

[97] Megan Durisin, 'Boris Johnson's Call for UK GMO Crops Draws Support from Farm Union', Bloomberg, 26 July 2019.

believe that the move may help farmers to be "competitive".[98] However, in November 2019, Michel Barnier, Head of the EU's Task Force for Relations with the UK, reportedly stated that there "will never be a free trade agreement" if the UK government sought to diverge from EU regulatory standards that would "weaken" environmental standards.[99] The final regulatory position for genome editing post Brexit remains to be seen.

In relation to the 2018 ECJ case, the European Council has requested that the European Commission submit a report on the ruling.[100] Finnish agriculture minister Jari Leppa stated that the study should include possible options to update the existing legislation.[101] He confirmed that the European Commission "must be prepared to submit a proposal to amend the GMO directive". The outcome of this report is expected to be published by April 2021.

Further Reading

- Parliamentary Office of Science and Technology, *Advances in Cancer Treatment*, 11 April 2019

  This paper explains the progress that has been made in targeted treatments over the past decade, including genome editing technology.

- Parliamentary Office of Science and Technology, *Human Germline Genome Editing*, 21 January 2020

[98] Megan Durisin, 'Boris Johnson's Call for UK GMO Crops Draws Support from Farm Union', Bloomberg, 26 July 2019.

[99] Euractiv, 'UK Faced with EU-US Biotechnology Dilemma Post-Brexit', 29 November 2019.

[100] Official Journal of the European Union, *Council Decision EU 2019/1904: Requesting the Commission to Submit a Study in Light of the Court of Justice's Judgement Case C-528/16*, 8 November 2019.

[101] International Service for the Acquisition of Agri-biotech Applications, 'EU Calls for Study to Justify 2018 Legislation on Gene Editing', 11 December 2019.