Voluntary _ Public

Date: 2/2/2018

GAIN Report Number:

United Kingdom

Post: London

UK Government Paves Way For Genome Editing

Report Categories:

Biotechnology and Other New Production Technologies

Biotechnology - GE Plants and Animals

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Report Highlights:

"Genome editing" has been singled out as an innovative biotechnology that is to be nurtured and supported by the UK government as it prepares to depart the EU. The UK government is aligning its business, innovation, agriculture and environmental agendas in order to better support research and development as well as commercialization of technologies and products from the life science sector, including agricultural biotechnology. Although commercial products of transgenic "Genetic Modification" are unlikely to flourish after Brexit, genome editing may be accepted if the many aspects involved align to make conditions favorable.

UK Aims to be a Leader in Innovative Biotechnologies

Gene or genome editing – a suite of technologies involving the targeted genomic insertions, deletions or mutations – is evolving rapidly, both locally and globally. This genetic engineering evolution is increasingly involving key commodity and horticultural crops and agriculturally-important animals as it can enhance a wide range of valuable characteristics and remove undesirable ones. The regulatory status of these applications is the subject of debate as to whether they need to be classified under EU "genetically modified organism" rules to gain regulatory approval. After departing from the European Union (EU) the UK could pursue an independent line of regulation, but public acceptability of these technologies is uncertain and their use would also have implications for exporting commodities and food products into the EU and other markets. That being said, the UK is aiming to increase research and development funding allocated to genome editing, and to enable translation of blue-sky laboratory work to bring commercially-viable products to market.

The UK received 1.6 times as much total science funding from the EU as it had put into the central EU pot between 2007 and 2013. Negotiations for the UK's withdrawal from the EU are ongoing and the outcome is likely to affect research and development funding allocations and routes to the UK. Stakeholders have called on the UK government to ensure that any funding lost in exiting Europe is replaced.

A U.S. citizen (Dr. Kathy Niakan), leading a team at the Francis Crick Institute in London, became the first to receive permission from the UK Human Fertilization and Embryology Authority (HFEA) to use 'CRISPR-Cas9' in human embryos; a world first in using genome editing to understand early human embryo development. Agriculture and food applications also have technical and ethical questions to navigate, but the success of the embryo work shows that the UK can build enabling regulatory frameworks in this scientific arena.

Increasingly Vocal Political Support

In a speech to the farming sector in early January 2018, Michael Gove, Secretary of State for Environment, Food and Rural Affairs specifically highlighted innovative breeding techniques:
"there are bio-tech changes coming which also challenge us to think about the future, and how best to shape it. Genome editing technology could help us to remove vulnerabilities to illness, develop higher yielding crops or more valuable livestock,"

Also, during a press conference after his speech the Secretary of State said:
"I alluded to the fact that genome editing in the future could provide all sorts of opportunities" and *"The science is still in its infancy but I do think it's important that we regard genome-editing as a means of science helping us do faster what farmers have been doing for generations, which is to essentially accelerate the process of breeding and evolution."*

UK central government continues to follow a science-based policy in relation to genetic engineering and other advanced crop breeding techniques. It sees them as one of the options for making agriculture more efficient and sustainable, and a means to help address future challenges and threats to food production. The UK government also wants farmers and businesses to have access to the best technology available to remain competitive and encourage economic growth. It is increasingly publicly supportive of the opportunities that advanced breeding techniques could bring.

UK Regulatory Landscape Uncertain

The United Kingdom (UK) government has not yet decided how best to convert existing EU regulations covering genetic engineering of plants and animals into UK law. The transition phase of the UK's departure from the EU will begin at the end of March 2019, and the EU has indicated that this phase could end on 31 December 2020.

The Department for Environment, Food and Rural Affairs (Defra) based in London has overall competency for policy on genetic engineering (GE) of plants and animals. However, the devolved administrations in Scotland, Wales and Northern Ireland get to decide agricultural policy on a local level. All three of these countries have invoked the ability to ban GE cultivation under the opt-out Directive (EU) 2015/412. It is not yet clear how the devolved assemblies view innovative biotechnologies, although Scotland is home to the Roslin Institute, a world leader in animal biotechnology research.

The Food Standards Agency (FSA) in England, Wales and Northern Ireland and Food Standards Scotland lead on the marketing of genetically engineered products when it comes to food or animal feed. These bodies are likely to continue to have this role after the UK departs the EU.

The UK has not indicated which innovative biotechnologies it may deem to fall in or outside the current regulatory regime for "genetically modified organisms". However, in 2011 U.S. company Cibus formally approached the UK government and asked for an opinion on their Oligonucleotide-Directed Mutagenesis (ODM) derived canola. The UK's Advisory Committee on Releases to the Environment (ACRE) reviewed this product back in 2011. Its conclusion follows:

"*ACRE considers that herbicide tolerant (HT) oilseed rape plants produced by Cibus LLC have been developed using a form of mutagenesis. It considers that this technique does not involve the use of recombinant nucleic acid molecules. Consequently, the HT oilseed rape plants could be excluded from the GMO Deliberate Release legislation in accordance with Annex 1B of Directive 2001/18/EC.*"

The UK is likely to wait for the EU to clarify the legal status of innovative biotechnologies before publicly announcing its regulatory approach – providing that the EU provides sufficient clarity before the UK departs the bloc. However, the EC is unlikely to make any decisions on the regulation of NPBTs (new plant breeding techniques) until the ECJ rule on a series of specific questions regarding mutagenesis posed by the French State Council. This is expected by summer 2018. A preliminary statement from the European Court of Justice (ECJ)'s Advocate General published on January 18, 2018

has resulted in media statements by both anti-biotechnology groups and pro-biotechnology academia and industry.

Anti-biotechnology groups have focused on this sentence: *"He observes that that Directive does not require the insertion of foreign DNA in an organism in order for the latter to be characterised as a GMO, but merely says that the genetic material has been altered in such a way that does not occur naturally"*. These groups have seized on the consistency of this statement in saying that all induced mutations are "GMOs" because that is what Directive EC/2001/18 defines. Anti-biotechnology campaigners also say that use of recombinant nucleic acid molecules means that these techniques should not be exempted from full scrutiny under the EU "GM" regulations. Source: GM Watch

Biotechnology supporters have interpreted the below excerpt from the statement as a positive indicator since it could open up the possibility that newer techniques for mutagenesis may be included in the category that is exempt from the "genetically modified" regulation:
"The Advocate General points out that neither the historical context nor the internal logic of the GMO Directive support the contention that the EU legislature only intended to exempt safe mutagenesis techniques as they stood back in 2001. He considers that a generic category labelled 'mutagenesis' should logically encompass all those techniques that are, at the given moment relevant for the case in question, understood as forming part of that category, including any new ones."

The statement by the Advocate General also says: "*by inserting the mutagenesis exemption, the EU legislature did not wish to regulate that matter on the EU level . . . . provided that the Member States respect their overall EU law obligations, they can legislate with regard to organisms obtained by mutagenesis.*" As yet, it is unclear by what mechanism individual Member States could legally regulate separately. Several are likely to explore that avenue which will inevitably complicate innovation, commercialization and trade in genome edited products.

Overall this statement is being taken as a somewhat positive indicator for future proportionate regulation of the innovative biotechnologies. It is not legally binding, but the ECJ has a history of following the Advocate Generals interpretation.

UK Consumer Acceptance Not a Given

UK commercial production of traditional genetically engineered plants or animals has essentially been ruled out at this present time. There is too much negativity associated with the technology owing to 20 years of sustained media hysteria on the subject, an expensive and unclear path to regulatory approval, and the unwillingness of supply chains and stores to stock GE products.

Products derived from innovative biotechnologies such as genome editing may also be subject to anti-biotech NGO campaigning, trial by media and rejection by consumers. Successful introduction in the UK will depend on the type of product being engineered, who is bringing it to market, the origin/characteristics of the trait, and the inherent benefits and benefactors.

Genome edited livestock applications face a particularly uphill task. Following the Secretary of State's

call to explore the opportunities of genome editing, media reports have circulated with headlines touting his support for "Frankencows". It's clear that bringing genome edited agricultural animals and, to a lesser degree, horticultural produce to market would raise political and moral questions, and provides uncertainty for would-be investors.

UK Investment in Productivity

The UK considers itself to have a world-leading science base that could contribute to spurring growth in the economy post-departure from the EU. Agricultural biotechnology development in the UK is likely to benefit from the targeting of life sciences under the UK's Industrial Strategy launched by the Department for Business, Energy, and Industrial Strategy (BEIS). The UK is aiming to cultivate a world-leading life sciences sector. It is currently one of the UK's fastest developing industries, with a turnover in excess of BPS 64 billion, employing 233,000 people.

Launched on November 27, 2017, the UK's "Industrial Strategy: building a Britain fit for the future" aims to raise total government research and development spend in the UK (all sectors) to 2.4 percent of Gross Domestic Product by 2027. If realized, additional streams of grants and funds should be available to small to medium sized enterprises working in the biotechnology space. Investment from the Industrial Strategy Challenge Fund needs to be matched by commercial investment.

The UK also has a specific Agri-Tech Strategy Fund (currently capped at British Pounds Sterling 160 million). This fund is split into two main parts. Seventy million BPS has been allocated to the Agri-Tech Catalyst fund to help new agricultural technologies get to market quicker, and ten million pounds of this will support the transfer of technology and new products to developing countries. Ninety million BPS is dedicated to four innovation centers:

Agrimetrics – using data science and modelling to underpin sustainability and efficiency. It is a partnership between four founder partners: Rothamsted Research, The University of Reading, National Institute of Agricultural Botany (NIAB) and SRUC, Scotland's Rural College. The Agrimetric Centre is headquartered at Rothamsted Research, just outside London.

Centre for Crop Health and Protection (CHAP) – to revolutionize how farmers manage pests and diseases. A multi-partner initiative including chemical companies, grain trade, retailers, manufacturers, the UK's levy board Agricultural and Horticultural Development Board (AHDB), and several academic institutions. CHAP's executive team is based at the National Agri-Food Innovation Campus in York, Northern England.

Centre for Innovation Excellence in Livestock (CIEL) – to create new livestock technology and products to boost profitability and productivity. Managed by Innovate UK, CIEL is a membership organization made up of leading academic institutions and industry partners.

Agricultural Engineering Precision Innovation Centre **(Agri Epi Centre)** – to develop precision

agriculture technologies e.g. remote sensing, weather mapping to increase productivity and sustainability. The Agri Epi Centre is a membership organization made up of leading academic institutions and industry partners.

Research and development funding for genetic engineering of plants and animals in the UK is routed via the Biotechnology and Biological Sciences and Research Council (BBSRC). BBSRC is funded by BEIS. BBSRC received an additional BPS 16.6 million from the Industrial Strategy Challenge Fund (ISCF) to develop new agricultural technologies and industrial bioprocesses.

BRACT (Biotechnology Resources for Arable Crop Transformation) is a research facility based at the John Innes Centre in Norfolk, England providing access to a range of crop transformation and genome editing resources. The facility operates on a 'not-for-profit', cost recovery basis and supports researchers worldwide.

BRACT services at the John Innes Centre, include;

- Wheat transformation
- Barley transformation
- *Brassica oleracea* transformation
- *Brassica napus* transformation
- Potato transformation
- RNA-guided Cas9 mediated genome editing
- Constructs including design and assembly
- Training courses
- Opportunities to develop collaborative projects
- Transformation protocols

In addition, The Roslin Institute, affiliated to the University of Edinburgh, is at the forefront of genome editing of farm animals such as pigs and chickens for animal disease control.

UK Open For Business?

As the UK departs the EU, the government is attempting to open the market up further to global business. It hopes to cultivate a business environment that encourages and rewards research and innovation through tax credits, tax relief for patents developed in the UK and strong Intellectual Property (IP) protection. It intends to gain economic growth/inward investment from setting challenging goals on climate change, environment and protection of natural capital/biodiversity.

With the launch of a 25 year Environment Plan on January 11, 2018, the Prime Minister stated: "*When the United Kingdom leaves the European Union, control of important areas of environmental policy will return to these shores. We will use this opportunity to strengthen and enhance the protections of our countryside, rivers, coastline and wildlife habitats enjoy, and develop new methods of agricultural and fisheries support which put the environment first.*"

As the UK negotiates its departure from the EU and sets out to achieve the above aim, it is unclear what role for genome editing will come to the fore. The UK may continue to be a hot-house for basic scientific research in this area for commercialization elsewhere. Homegrown products will need to demonstrate an environmental or consumer benefit, rather than purely an agronomic one. Publicly funded research that is commercialized via small to medium-sized enterprises, not through large global players, is also likely to be more palatable to supply chains. If simple genome editing has a route to market without being regulated as a "GMO" there could be many new crop varieties marketed over the next 25 years that include targeted genome edits.

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