

In focus

Genome editing and the food industry

Navigate this diverse regulatory landscape with technical and market knowledge



The scientific community has made great strides in the use of genome editing to optimise the physical properties of crops. These developments hold much potential for global food production, but legislation surrounding the trade of genome-edited products and ingredients is fraught with complexity. This white paper examines the current regulatory landscape for some key markets and considers what the future might hold.



A polarising technology

Genome editing (GE) offers ways to improve productivity, reduce waste and address food insecurity as the global population continues to grow. Yet opinions and regulations surrounding the use of GE technology in the agrifood sector vary greatly in different parts of the world. In this white paper, we look at current developments with the technology itself and spotlight regulatory matters in key markets.

Benefits of genome editing for crops

Put simply, GE refers to a group of technologies that enable scientists to manipulate an organism's DNA in order to control physical traits and generate specific outcomes.

In relation to plants, GE can focus on the improvement of yield and disease resistance, which offers clear benefits for crop production. Compared to conventional breeding and genetic modification, it brings significant technical advantages. These include targeted and high-precision rearrangement of plant genomes¹ as well as precise breeding which reduces product development costs^{2,3}. It's also possible to develop crops with a wide spectrum of improvements more cost-effectively through the clear-cut insertion of favourable traits or removal of undesirable traits⁴.

In recent years, new GE technologies such as CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) have further accelerated this method of crop improvement versus imprecise and lengthy conventional breeding⁵. The technologies are also being applied in more sophisticated ways. For instance, GE has been used to augment the oil profiles of crops such as soybeans, enhance the flavour of tomatoes and prevent browning in apples and potatoes⁶.

¹Puchta, H. (2017). Applying CRISPR/Cas for genome engineering in plants: the best is yet to come. *Current Opinion in Plant Biology*, 36, pp. 1-8.
²Bortesi, L. and Fischer, R. (2015). The CRISPR/Cas9 system for plant genome editing and beyond. *Biotechnology Advances*, 33, pp. 41-52.
³Georges, F. and Ray, H. (2017) Genome editing of crops: a renewed opportunity for food security. *GM Crops & Food*, 8, pp. 1-12.
⁴Abdallah, N.A., Prakash, C.S. and McHughen, A.G. (2015). Genome editing for crop improvement: challenges and opportunities. *GM Crops & Food*, 6, pp. 183-205.
⁵Yin, K.Q., Gao, C.X. and Qiu, J.L. (2017). Progress and prospects in plant genome editing. *Nature Plants*, 3 pp. 17107.
⁶Lassoued, R., Macall, D.M., Hesseln, H., Phillips, P.W.B. and Smyth, S.J. (2019). Benefits of genome-edited crops: expert opinion. *Transgenic Research*, 28, pp. 247-256. expert opinion. *Transgenic Research*, 28, pp. 247-256.

The regulatory response to genome editing in agrifood

At a global level, much disparity exists between the various regulatory frameworks surrounding GE in the development of crops for human consumption. A lack of accumulated safety data makes it difficult for different markets to reach a common consensus. The same is true of environmental considerations.

Consumer attitudes vary greatly in different parts of the world too. For instance, European consumers are more likely to be opposed to any agricultural or industry practice involving either native DNA manipulation or the addition of foreign materials. However, US consumers have historically responded more favourably to the use of genetic engineering techniques.

This varied legislative landscape coupled with diverse consumer perceptions makes the introduction of food products including GE plant ingredients highly complex.



The EU stance on genome editing

All EU laws and policies are guided by the precautionary principle, designed to prevent adverse impacts for humans, animals and the environment. This has a direct bearing on decisions related to GE.

In 2018 the European Court of Justice (ECJ)⁷ which oversees application and implementation of EU law decreed that:

“Organisms obtained using new techniques of directed mutagenesis (including those popularly known as ‘gene editing techniques’) are GMOs and are subject to the legal requirement of GMO legislation.”

Article 2(2) of Directive 2001/18 of the EU defines a genetically modified organism (GMO) as ‘an organism in which the genetic material has been altered in a way that does not occur naturally, and/or introducing foreign DNA’.

Mutagenesis does occur spontaneously in nature. However, GE involves the intentional manipulation of genetic code. So, for the purposes of trading in the EU, genome editing equates to genetic modification. And within the EU, any food containing or consisting of genetically modified ingredients is subject to strict legislative requirements. The import and marketing of these products is authorised on a case-by-case basis. And where authorisation is granted, products must be labelled to ensure traceability and to allow consumers to make informed choices.

It is worth noting that organisms obtained by conventional breeding and genetic technologies which have a long safety record are not considered GMOs. The EU judgment allows Member States a certain amount of autonomy in how their national authority deals with such organisms. They can either be subjected to the GMO rules or other relevant EU laws.

Mutagenesis techniques⁸

Zinc Finger Nucleases (ZFNs) and **Transcription Activator-Like Effector Nucleases (TALENs)** were the first genome editing systems to be developed. They both target DNA sequences using custom engineered protein sequences. **Clustered Regularly Interspersed Short Palindromic Repeats (CRISPR/Cas9)** is a more recent technique that has become widely used as a research tool because the customised guides are easier and cheaper to make. It consists of a nuclease (Cas9) coupled to a guide sequence.

⁷Court of Justice of the European Union. (2018). *Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive.* [online]. Available at: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

⁸The Parliamentary Office of Science and Technology. (2016). *Genome Editing. POSTnotes*, (541) [online]. Available at: <https://researchbriefings.files.parliament.uk/documents/POST-PN-0541/POST-PN-0541.pdf>

Beyond the EU

UK

Following full departure from the EU single market and customs union, the UK may consider changing the regulatory status of genome editing technologies. One option would be to deregulate genetic engineering techniques as was mooted with a proposed amendment to clause 42 of the Agricultural Bill.

The Agricultural Bill provides a post-Brexit legislative framework for the UK agricultural sector when it leaves the EU's Common Agricultural Policy (CAP). The clause 42 amendment would empower the Secretary of State to propose changes to the Environmental Protection Act 1990 in relation to New Plant Breeding Techniques (NPBTs).

If NPBTs were no longer regulated as GMOs, they could be used in UK agriculture and food without the requirement for GMO authorisation and labelling. Passing this amendment would enable the UK to diverge from the EU ruling and potentially move towards the NPBT stance of other international regions.

Anti-GMO associations and groups in the UK called for a rejection of this amendment on the basis that genome editing needs to be regulated because it is prone to errors and has no history of safe use. However, those supporting the amendment argue that regulating genome-edited products as GMOs gives major corporations an unfair advantage due the costs associated with the rigorous trials required for GM plants.

For now, the proposed amendment has been withdrawn, but the UK Government has pledged to conduct a public consultation on the issue.

Norway

Norwegian authorities are currently holding discussions on how to regulate gene-edited products.

In December 2018, The Norwegian Biotechnology Advisory Board (NBAB) published suggestions for amendments to GMO regulations. These included a three-tier system whereby changes that already exist or that can occur naturally would require a simple notification to the authorities. Other species-related changes would fall into the mid-tier, with an accelerated system for assessment and approval. Cases concerning genes from other species or artificial genes would face higher level assessment and approval requirements, in line with the current Gene Technology Act.⁹

Norway appears to be taking a forward-looking, considered and flexible approach. It acknowledges the progress made in genetic engineering, the potential benefits it offers for sustainable agriculture and the role it can play in market competitiveness. Nevertheless, this is balanced with the need for consumer trust and environmental protection.

⁹The Norwegian Biotechnology Advisory Board. (2018). *A forward-looking regulatory framework for GMO*. [online]. Accessible at: [HYPERLINK "http://www.bioteknologiradet.no/filarkiv/2018/12/2018-12-03-Sammendrag-genteknologiloven-Bioteknologir%C3%A5det-ENGELSK-for-web.pdf"](http://www.bioteknologiradet.no/filarkiv/2018/12/2018-12-03-Sammendrag-genteknologiloven-Bioteknologir%C3%A5det-ENGELSK-for-web.pdf) Summary statement on The gene technology act.pdf (bioteknologiradet.no/)

¹⁰Norwegian Government Security and Service Organisation. (2005). *Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc (Gene Technology Act)*. [online]. Accessible at: <https://wipolex.wipo.int/en/text/245117>

Japan

In Japan, foods derived from genome editing technology either go through a notification procedure or a safety assessment. This is determined on a case-by-case basis by the Ministry of Health, Labour and Welfare (MHLW).

On 29 March 2019, the Japanese MHLW released a regulatory policy stating that gene-edited food will fall into two categories. Those incorporating 'foreign' genetic material would be subject to a GMO safety review and management process. However, foods using 'native' genetic material would not be classed as GMOs.

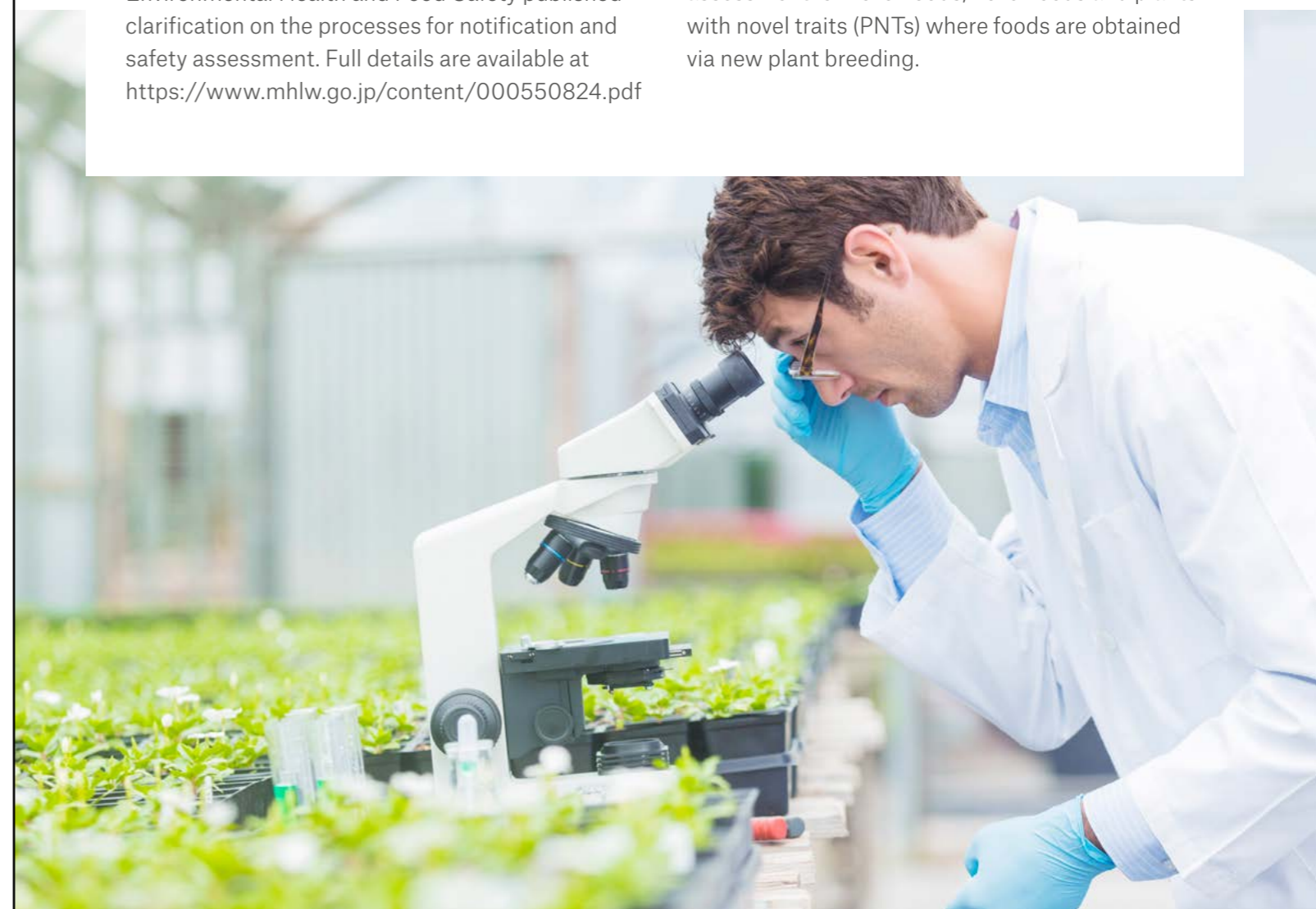
In September 2019, the Councillor for Environmental Health and Food Safety published clarification on the processes for notification and safety assessment. Full details are available at <https://www.mhlw.go.jp/content/000550824.pdf>

Canada

Plants in Canada are regulated according to the traits expressed, not the method used to introduce those traits. Novel Plant Products may be produced by conventional breeding, mutagenesis or recombinant DNA techniques. And gene-edited food in Canada is only classified as 'novel' if it is deemed to contain a plant with a novel trait.

Health Canada is the authority responsible for assessing the safety of foods. It also authorises their use in Canada, according to Division 28 of Part B of the Food and Drugs Regulations (Novel Foods).

These regulations require a pre-market assessment for novel foods, novel feeds and plants with novel traits (PNTs) where foods are obtained via new plant breeding.



Genome editing regulation summary

The 2018 ECJ ruling surrounding genome editing makes the use of products or ingredients derived from these technologies challenging for food business operators targeting the EU. However, there are indications that some individual European countries are trying to move towards a lighter-touch approach to regulation. The debate is set to continue in the UK when the Government holds a public consultation on the proposed amendment to clause 42 of the Agricultural Bill. And in Norway there appears to be a clear intention to take a more flexible and progressive stance.

Further afield, Canada's decision to place genome-edited foods in the 'novel foods' category also suggests a more open regulatory approach than that of the EU. The same can be said of Japan's decision to require a notification or a safety assessment, depending on the nature of the GE process.

Conclusions

Depending on the market, a GE food product or ingredient might be classed as a GMO or a novel food, then subjected to the local regulations for these classifications. On the other hand, if the GE process would be feasible in nature, some markets may not regulate products derived from it at all.

For many countries, developing a clear regulatory positioning on GE technologies will take time. While the technologies are improving, barriers preventing their widespread adoption include ethical and political factors. Overcoming these is a complex matter, and robust data evidencing the safety of products derived from GE will play a critical role in the reassurance of consumers and policy decisionmakers.

In the short to medium term, food business operators looking for opportunities to place GE foods can prioritise markets where legislation is less stringent. It's also important to monitor the wider GE environment to keep track of emerging evidence surrounding their safe application.

How Leatherhead can help

We support our members in navigating the intricate regulatory landscape surrounding GE at a global level. This is achieved through the exploration of upcoming changes in various regions as well as the identification of markets where the use of these technologies is received more favourably. In doing so, we enable food business operators to make best use of the advantages of agrifood GE in the current environment, while taking steps to maximise future potential.



References

- The European Commission. (2018). *A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive*. [online]. Available at: https://ec.europa.eu/info/sites/info/files/2018_11_gcsa_statement_gene_editing_1.pdf
- The European Commission. (2019). *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration*. [online]. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0018>
- Byrne, J. (2020). UK campaigners oppose plans to deregulate genome editing. *Feed Navigator*, [online]. Available at: <https://www.feednavigator.com/Article/2020/07/28/UK-campaigners-oppose-plans-to-deregulate-genome-editing>

About Leatherhead Food Research ▾

Leatherhead Food Research provides expertise and support to the global food and drink sector with practical solutions that cover all stages of a product's life cycle from consumer insight, ingredient innovation and sensory testing to food safety consultancy and global regulatory advice. Leatherhead operates a membership programme which represents a who's who of the global food and drinks industry. Supporting all members and clients, large or small, Leatherhead provides consultancy and advice, as well as training, market news, published reports and bespoke projects. Alongside the member support and project work, our world-renowned experts deliver cutting-edge research in areas that drive long term commercial benefit for the food and drink industry. Leatherhead Food Research is a trading name of Leatherhead Research Ltd, a Science Group Company.

help@leatherheadfood.com

T. +44 1372 376761

www.leatherheadfood.com

About Science Group plc ▾

Science Group plc (AIM:SAG) is a science-led advisory and product development organisation. The Group has three divisions:

- R&D Consultancy: providing advisory, applied science and product development services cross-sector helping clients derive maximum return on their R&D investments.
- Regulatory & Compliance: helping clients in highly regulated markets to launch, market and defend products internationally, navigating the frequently complex and fragmented regulatory ecosystems.
- Frontier Smart Technologies: designing and manufacturing chips and modules for the DAB/DAB+ radio markets with 80% market share (excluding the automotive market).

With more than 400 employees worldwide, primarily scientists and engineers, and speaking more than 30 languages collectively, the Group has R&D centres in Cambridge and Epsom with more than ten additional offices in Europe, Asia and North America.

info@sciencegroup.com

www.sciencegroup.com