NFU Consultation Response

To: consultationreply@defra.gov.uk

Date: 16 March 2021
Contact: Dr Helen Ferrier
Tel: 07817725984
Email: helen.ferrier@nfu.org.uk

The NFU represents 55,000 members across England and Wales. In addition, we have 20,000 NFU Countryside members with an interest in farming and rural life.

A public consultation on the regulation of genetic technologies

The NFU sees benefits for the environment, consumers, animal welfare and farmers in the use of genetic technology in agriculture, believing it should be effectively regulated. Legislation must be proportionate, fit-for-purpose, based on robust science and enable fair access and choice. Access to both internal and EU markets must not be compromised by a new legislative framework. The NFU urges government to take greater responsibility for showing independent leadership, not only in policy but also in dialogue with consumers and supply chains to deliver understanding and confidence in both the technologies and their regulation.

Introduction:

The principles of NFU policy on biotechnology have remained consistent for over 15 years. We regularly review and refresh our policy in the context of political, regulatory, commercial, scientific and societal developments.

As part of the current consultation process, we have engaged with farmers and growers across the NFU membership, with interactive meetings across the country by farming sector and by region involving scientists as well as policy experts. NFU members hold a range of opinions about biotechnology and whether it could or should have a place in their sector or business. There is concern amongst some in the NFU membership about consumers' perception of gene editing and reaction to the proposed regulatory changes.

The NFU policy on genetic technologies in agriculture is as follows:

- British farmers and growers, as part of a resilient, progressive and innovative industry, must have the choice to access the best tools and technologies to farm sustainably and profitably.
- British farming faces challenges associated with volatile weather; achieving net zero; pests, weeds and diseases; animal welfare; the need for resource efficiency; greater environmental performance; food and feed quality and safety; high input and labour costs; nutritional health needs and the competitive global agri-food marketplace. Biotechnology, particularly in the form of genetic modification and genome editing, holds genuine and exciting solutions.
- The NFU does not think biotechnology is a silver bullet. It is a set of powerful precision breeding techniques that can help produce better crops and livestock to benefit farmers, animal welfare, consumers and environment. New breeding techniques should be seen as part of a broad set of tools and approaches that enable UK farmers to take a more sustainable path, including IPM, resource use efficiency, wildlife management and high animal health status. Genetic improvement has been part of farming around the world since the birth of agriculture 1000s of years ago.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

- As with so many aspects of agriculture and horticulture, crop and livestock breeding are already subject to strict regulations. These are important to protect health and the environment and to give farmers and consumers confidence. Legislation for biotechnology must be fit for purpose, robust, science-based, transparent and enabling, encouraging innovation and investment in delivering products for the UK market.
- GM crops have been grown commercially for 25 years and are now an established part of the global supply chain. Coexistence between conventional and biotech crops is vital to deliver choice for farmers and consumers. Based on practical and scientific evidence, the NFU believes coexistence is achievable. The safety of GM food and feed is not in doubt.
- World class science is essential for the farming industry to progress. Field trials of biotech crops and development of biotech animals in the UK for both public and private sector research must be supported.
- The NFU sees great potential in new precision breeding techniques (NBTs) such as gene editing and would like to see more R&D in both public and private sectors in applications of value to British food and farming.
- The NFU urges regulators to ensure legislation for NBTs is fit for purpose, transparent, science-based, adaptable, and aligned with international definitions. With robust risk management controls in place, ensuring health and environmental safety are not compromised, we believe the UK will continue to be able to trade with the EU on the basis of these rules just as other third countries currently do.
- The agrifood market, with a basis in sound information and regulation, should ultimately decide if GM and GE crops and livestock are produced in the UK, not politicians, NGOs, journalists or single-issue groups.

The NFU has long worked in partnership with other organisations in industry and research to discuss and promote innovation in agriculture. On this particular issue, we have been and continue to work closely with members of the Crop Innovation Network (NFU, abc, BSPB, AIC, CPA), which arose from the SCIMAC group, and stakeholders of the All Party Parliamentary Group on Science and Technology in Agriculture (including AIC, abc, AHDB, BGA, BSPB, CPA, MAGB, nabim, NFU, NIAB). The NFU is also a member of the Arable Chain Advisory Group (alongside NFUS, AIC, MAGB, UK Flour Millers, GAFTA, SCOPA, Fed of Bakers, Pet Food Manufacturers, FDF sectors and others) which has agreed a position supportive of the government proposals on gene editing regulation.

NFU response to the consultation questions:

The NFU agrees with the government position as stated in the consultation documents that it "*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*".

The NFU also agrees with the central proposal that "*organisms produced by GE or by other genetic technologies should not be regulated as GMOs if they could have been produced by traditional breeding methods*."

Part 1: the regulation of GMOs which could have been developed using traditional breeding methods

Question 1
Currently, organisms developed using genetic technologies such as GE are regulated as genetically modified organisms (GMOs) even if their genetic change(s) could have been produced through traditional breeding.
Do you agree with this? Please explain your answer, providing specific evidence where appropriate. This may include suggestions for an alternative regulatory approach.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

The NFU does not agree that organisms developed such that their genetic changes could have been produced through traditional breeding should continue to be automatically regulated as GMO.

Genetic modification and gene editing are different scientifically, with most gene editing techniques involving precise and targeted changes within the organism's own DNA sequence. It would therefore not be evidence-based, proportionate or fit-for-purpose legislation in terms of ensuring health and environmental safety to regulate these organisms as if they were GMOs. It would not be consistent with innovative, progressive countries around the world and it would be out of step with internationally recognised definitions. It would hinder innovation and investment in breeding solutions for the challenges and opportunities in agriculture and horticulture.

A great deal has been written in recent years about the policy and regulatory issues related to gene editing in agriculture. We would urge the government to learn from experiences around the world as well as analysis of the EU and post-Brexit UK situation. Key sources are the output of the Genome Editing and Agriculture: Policy, Practices and Public Perceptions (GEAP3) Network.[i] ; and the OECD Genome Editing Hub, which holds the proceedings of a conference in Paris in 2018 'Genome Editing: Applications in Agriculture"[ii]. The Conference had three themes: Applications in plant and animal breeding, risk and safety, and regulatory aspects.

The report by Estel Consult Ltd[iii]. in January 2020 describes the **characteristics of functional regulatory frameworks that foster innovation**. It explores how countries around the world are modernising their regulations to keep pace with new developments in precision breeding.

The report's recommendations include "*(1) the need to set clear policy goals for sustainable agriculture coupled with transparent protection goals, (2) adoption of a risk-based approach to safety assessments, (3) fostering technical excellence of UK risk assessors, (4) avoidance of overly prescriptive safety assessment guidelines and (5) adoption of a system that allows for pre- and post-consultation with innovators which will result in the generation of regulatory data that is proportional to the risk of the introduced product".*

It is clear that political will is the key to enabling innovation to reach the market and deliver benefit. **The NFU is very encouraged that the government wants to put the UK in this strong position.**

For **crops**, commercial plant breeding is the only route to market for the genetic improvement required to enable farmers in all systems to improve their performance, build resilience and meet their obligations to environment and consumers[iv]. **Commercial plant breeders require a legislative environment that provides the certainty** and enabling regulations for them to invest in the needs of the domestic market. The proposed regulatory change will therefore be a critical part of meeting climate change targets[v], addressing health and nutrition challenges, increasing environmental protection, improving resource use efficiency and building food security.

There are already sufficient laws, regulatory controls and processes in place to protect human, animal and environmental health in the form of existing plant variety and breed registration requirements, animal welfare, food safety and environmental protection legislation and novel foods regulations. These would all be applicable to products made using gene editing. In addition, the agrifood supply chain already operates a sophisticated and market-driven system to identify and preserve products of particular specifications, alongside various assurance schemes, enabling consumer choice.

For **crops**, all new plant varieties must undergo rigorous field and laboratory testing over at least two years prior to their approval, whatever breeding method is used. Seed can only be marketed under strict conditions related to plant health, quality and freedom from impurities. The UK registration of plant varieties is an outcomes-focused regulatory system that ensures only varieties offering a demonstrable improvement over older varieties will be authorised for use.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

For **livestock**, UK animal breeding legislation controls the activities of recognized breed societies, requires zootechnical certificates and the need for all breeding organisations to create and publish a breeding programme for each breed they support[vi]. Use of gene editing in commercial livestock production is many years away. We understand that the use of the technique in farm animals is currently limited to specialist research labs due to the complexity of delivering the gene cutting tools into reproductive cells[vii]. However, innovation in laboratory techniques is moving fast and any new legislative framework the UK puts in place must be able to not only respond but help drive commercial applications for the good of animals, environment, industry and society.

Genetic improvement through breeding has been at the heart of livestock production since modern agriculture began. Artificial insemination in the mid-1940s started the big gains in performance. Selective breeding and more recently genomic selection using genetic marker data have been transformational for livestock productivity and health in all sectors and systems. GE would enable more precise and larger gains over a shorter time, although research is at a much earlier stage than for crops and the pathway from discovery to commercialisation are not yet established[viii]. This barrier, alongside the need for a concerted research effort to identify target genes to edit, will hold back progress. Undetected off-target effects and other ethical considerations will also need to be fully investigated[ix]. **It is important that the potential for gene editing to help reduce pressure in terms of both carbon footprint and animal welfare in livestock production both globally and in the UK can be fully realised.** This will require excellent regulation and well as excellent science, and the UK could and should be a world leader in both, as much for animals as it is for plants.

The NFU is concerned that the potential for misinformation and conflating of issues around the ethics and sustainability of livestock production could hold back developments in breeding that could have a significant benefit for environment and welfare, which the public wants to see British farming deliver. If public-facing campaigning organisations such as CIWF and RSPCA are able to consider this potential and help drive applications in those areas rather than rejecting the new technologies on principle, it would assist in informing the public discourse. If there is no harmonised global regulatory approach to the use of genome editing in farm animals, breeders will find it difficult to effectively achieve sustainable breeding objectives[x], including responding to the climate emergency and the health and welfare needs of livestock. Further detailed discussions are essential within the farming and livestock breeding community and with society about how to ensure the legislative framework in the UK can foster innovation in the sector and enable consumer, environment and animal welfare benefits to be realised, while maintaining public confidence.

Question 2
Do organisms produced by GE or other genetic technologies pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced?
Please provide evidence to support your response including details of the genetic technology, the specific risks and why they do or do not differ. Please also state which applications/areas your answer relates to.

The NFU believes such organisms pose no additional risk to human health and the environment compared to conventionally bred equivalents. There are risks associated with all genetic combination both in nature and with human intervention; As with conventional breeding of plants and animals, gene editing techniques use naturally occurring genetic variation within organisms to achieve desired improvements. We are not aware of any robust evidence that suggests the breeding method by which an organism is produced affects the safety of the final product or its risk to human, animal or environmental health. In late 2020 EFSA found that genome editing does not pose any additional hazards compared to conventional breeding or other genetic modification methods[xi] . It concluded existing risk assessments are applicable but with fewer data requirements.

It is important there continues to be proportionate and risk-based regulation of plant varieties, seeds and livestock breeds used within farming. The legislative process must be functional, encourage

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

innovation and be flexible in order to develop as the science and adoption of new breeding techniques progresses.

Food safety, environmental safety and animal welfare must all be maintained and risks in all these areas must be assessed appropriately, case by case. The legislative framework as a whole must ensure that development and use of genetic technologies in all farming sectors happens in a responsible way and for the widest possible benefit.

Transparency and open dialogue are essential as these techniques develop. The science and technology communities in both public and private sectors have a responsibility to make a strong case for the ethical and responsible use in food and farming around the world, just as they do for biomedical applications. **The NFU urges government to take greater responsibility for independent leadership, not only in policy but also in communication with consumers and supply chains to deliver understanding and confidence in both the technology and its regulation. It must encourage and facilitate the scientists it funds in engaging fully with civil society, to inform, address concerns and ensure that misinformation is challenged. We urge breeding companies to be as open and engaging as they can be with farmers, consumers and civil society groups to increase understanding of their R&D pipelines and strategies.**

Question 3
Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs? Please provide evidence to support your response and expand on what these non-safety issues are.

The NFU believes there are other non-safety issues that need to be considered if these changes to regulation are made.

NFU members want to see these new breeding technologies available to SMEs and to public sector research organisations, to ensure diversity and healthy competition in the market. Affordability and accessibility are therefore essential, so that development is not limited to the largest technology companies. We are very encouraged to see reports from Argentina[xii] analysing the 4 years since it introduced regulatory criteria to assess whether or not NBTs should be classified as GMOs. The preliminary analysis suggested that development from 'bench to market' is much quicker, there is a greater diversity of organisations involved and most are SMEs and public research institutes. Investment in precision breeding technology innovation is essential to further reduce cost barriers and increase access by SMEs and public sector. A supportive regulatory regime will ensure there is return on investment from this investment for economy and society by providing a route to market.

The NFU believes it is vital that the UK is still able to trade with the EU and the internal UK market remains functional should England take a different approach to regulating new precision breeding techniques such as gene editing. Movements of food, feed, breeding stock and genetic material must not be impacted. **Government must analyse market access implications of the proposed changes as a matter of urgency.**

UK internal market:
The NFU is aware that regulation in this area is a devolved matter. However, the UK internal movement of goods is determined by the UK Internal Market (UKIM) Act, passed in 2020. Under this legislation there are two key market access principles for goods: mutual recognition and non-discrimination. In practice, this means that goods produced using methods legal in one part of the UK but not in another can still freely move throughout the UK (but noting that the Northern Ireland Protocol overrides the UKIM). Furthermore, goods legally imported into one part of the UK can then freely move throughout then UK. In terms of gene editing, this means that should England authorise the use of gene editing in agricultural production, but Scotland and Wales do not then goods produced in England using gene

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

editing techniques can legally be sold in the other nations. **The NFU is very concerned for farmers in the devolved nations who would be at a competitive disadvantage if they did not have equitable access to the same technologies as their English counterparts.** This could also have significant implications in terms of wider UK politics and functioning of the internal market, which must be addressed by Government.

We also note the Scottish Government and Welsh Assembly Government have both been clear in their opposition to cultivation of GM crops in their countries and do not seem to be differentiating on GE. ScotGov has said it will wait for the outcome of an EU commission study on future regulation of GE in April before deciding how to proceed and is expected to align with the EU position. In Wales, Minister of Environment, Energy and Rural Affairs Lesley Griffiths has also stated that Wales will maintain a precautionary approach to genetic modification, including gene editing. The Northern Ireland position on gene editing is not entirely clear but in 2015 Stormont decided to not allow GM cultivation, when EU member states were given sovereignty to do so; and the chairman of Stormont's Committee on Agriculture, Environment and Rural Affairs was cautious in his reaction to the consultation, citing concerns about divergence and disruption.

Scottish research organisations represent a vital part of the landscape for agricultural genetic technology research in both crops and livestock, with internationally excellent institutes such as Roslin, Moredun and James Hutton along with the University of Edinburgh. In Wales, IBERS is internationally renowned for its public good plant breeding. Such leadership would be damaged if the Scottish and Welsh Governments decided to take a disproportionate and unscientific stance on gene editing.

It is vital that Defra Ministers and officials fully appreciate how this consultation and the issues it raises interacts with the current political situation and sensitivities between the nations of the UK. In terms of the NI protocol, political and legal developments must be reflected and longer-term solutions must be taken into account in the context of rules on genetic technologies in agrifood to ensure trade with Northern Ireland can continue. **NFU would like to see Defra working closely with counterparts in the devolved administrations to advocate evidence-based decision making and fit for purpose legislation for gene editing**.

Europe:
It was clear at the time of the European Court ruling on mutagenesis in July 2018 that some member states including the UK were not content. Indeed, the French agriculture minister in January 2021 called for NBTs not to be regulated like GMOs[xiii]. The fact that the Council asked the Commission to assess the impact and make recommendations shows that the EU position is not set. It is critical to the successful reform of regulation that developments at both EU and member state level are watched carefully and responded to diplomatically and constructively. The NFU will be talking to DG Sante in coming months as part of our advocacy activities in Brussels. **The NFU would like to see the UK government taking a lead in policy, diplomacy and communication to the public, showing how the right regulatory regime can bring swift benefits for European consumers, environment, industry and science.**

The **Farm to Fork (F2F) strategy** is at the heart of the **European Green Deal** and aims to contribute to a more sustainable food system. While the F2F strategy highlights the importance of innovative solutions across the entire food value chain, including plant breeding and crop production, there are concerns that the continued uncertainty regarding the regulatory status of genome edited organisms will present obstacles to reaching the aims of the Green Deal and F2F strategy. It is hard to see how a 50% reduction in pesticide use and a 20% cut in fertiliser use could be achieved in less than 10 years without either a significant reduction in agricultural production or the adoption of precision breeding and other innovations.

Since the 2018 ruling there has been a great deal of interest in Europe about the role of gene editing for genetic improvement in farming[xiv]. EU agriculture ministers have backed the technology, arguing it could underpin a transition to eco-friendly food production. Frans Timmermans, the European

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

Commission's executive VP for the European Green Deal, said last year that farmers must have the tools to boost sustainable food production. "*That's how we limit our dependency on pesticides*," Timmermans told the EU Green Week conference in September 2020. "*Going to ecological farming doesn't mean we all have to munch on grass and live in caves. We need to use the latest technology to get us there*."

The **EU farming organisation Copa-Cogeca** warned at the time that the ECJ ruling would put European agriculture at a disadvantage. Copa-Cogeca's Secretary General Pekka Pesonen said "*EU legislation should be fit for purpose, encouraging innovation in plant breeding and helping farmers to continue to provide safe and traceable food whilst protecting resources… EU farmers are facing many challenges like extreme weather conditions, price volatility etc, therefore they need the availability of improved breeds*." More recently, Copa-Cogeca has responded positively to the EU Strategy on Adaptation to Climate Change, which emphasises crop resilience through updated legislation on seeds and propagating materials and calls for engagement in close international cooperation. Copa-Cogeca stresses the importance of new breeding techniques and precision farming to help the sector play its part in achieving the Strategy's key aims.

To inform the NFU response to the current consultation and future policy development, the British Agriculture Bureau, which represent the NFU (as well as NFU Cymru, NFUS, UFU and NPA) in Brussels, is discussing the key issues with EU farming unions. So far, farming unions from Sweden, Germany and Denmark have all expressed support for a science-based approach. They identified the benefits of gene editing as helping to address many of the EU's targets within the Farm 2 Fork Strategy and wider challenges faced by agriculture. There is strong agreement that the EU classification of gene editing as GMO is wrong and hope that this will be addressed in the upcoming Commission review. Many of the member state authorities are recognising that developments must be made in these areas in order to address issues such as climate change, food security and resilience, and the distinction between gene editing and GMO is being increasingly made.

In terms of **implications for EU-UK trade under the Trade and Cooperation Agreement,** gene editing could prove to be an early test of the level playing field provisions and processes set out in the TCA, most likely in relation to environmental standards. As these processes are newly established it is difficult to predict exactly how they will operate in practice. We are aware that the TCA does not explicitly prohibit measures such as gene editing, and there is precedent for the EU to allow the import of authorised GM products. However, **the NFU urges Defra to address the likely political questions arising**, which may come to the fore at this stage rather than legal or technical issues. It is vital that the risk of retaliatory measures that could impact UK exports of agri-food goods to the EU is mitigated now.

In terms of the TCA, the UK should argue that regulating gene editing properly is not a regression but represents the advancement of standards, particularly in relation to the environment, by supporting the development of varieties or species which have a lower environmental impact due to increased pest or disease resistance, reduced resource demands, or greater productivity potential. Furthermore, under the SPS chapter of the TCA, there are commitments to combat antimicrobial resistance and promote sustainable food systems. This could also provide a foundation for the UK to argue that gene editing is an advancement on existing standards.

International:
As countries review and develop their regulatory frameworks, it can be seen that there are a range of approaches being taken. A very accessible and updated source of information on regulations on gene editing around the world can be found here[xv]. **The NFU urges Defra to learn from the best in the world and note the practical experiences and outcomes.** In 2018, 13 nations including Canada, Argentina, Australia, Brazil and the USA, issued a joint statement to the World Trade Organization supporting relaxed regulations for gene editing, stating that governments should "avoid arbitrary and unjustifiable distinctions" between crops developed through gene editing and crops developed through conventional breeding.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

It is clear that political will has a significant role to play in a functional regulatory framework that can swiftly deliver social, environmental and economic benefit from scientific advances[xvi]. The current experience of authorising vaccines for Covid-19 are testament to that.

It is also important to consider how those countries the UK is prioritising for future trade deals approach gene editing, and the potential implications this might have on those deals. Annex 2 sets out in more detail, as we understand it, the legislative frameworks currently operated in Canada, Australia, New Zealand, and the United States, as well as Argentina, Brazil and Japan. In brief:

Canada: Product-based approach to 'novelty' applies to gene-edited products, conventional breeding, mutagenesis and genetic engineering. New guidance has just been published so that gene-edited organisms that do not contain foreign DNA will not be subject to GMO safety assessments by Health Canada and the Canadian Food Inspection Agency unless they are "novel" or pose an obvious risk. Health Canada has also introduced a voluntary transparency initiative, so that developers can agree to publish information on their gene edited plants.

Australia: Responsibility for interpretation and enforcement lies with the Federal, State and Territory food enforcement agencies. Following a review in 2019 Food Standards Australia New Zealand (FSANZ) is now proposing to amend regulatory code definitions to better reflect existing and emerging genetic technologies, and to exclude foods derived from gene editing. In addition, in 2019 the Gene Technology Regulations were amended based on comparing the risk from the organisms compared to those from naturally occurring or conventionally bred genetic variation. NBTs that cut the genome at a specific location but do not control or specify what DNA sequence is inserted into the cut do not come under the GTR.

New Zealand: All gene editing techniques, even where no foreign genes are incorporated, are tightly regulated as genetic modifications by the Environmental Protection Agency (EPA) under the Hazardous Substances and New Organisms (HSNO) Act 1996. There is a focus on export markets but in 2018 the Environment Minister called for an update to the HSNO Act, citing a need for a clear route to market for gene edited organisms. Food standards including pre-market approval and labelling are set by FSANZ and Australia New Zealand Food Standards Code, including gene edited food (see above re. Australia).

USA: For crops, regulations are based on the characteristics of the final product, as opposed to the process used to create it, and gene edited plants which could have been developed through conventional breeding are exempt from GMO regulations. FDA regulates animal biotechnology, with all intentional alterations to genes in animals, including those that could be achieved via conventional breeding, strictly regulated as a veterinary drug. This is under review and there is a commitment to developing a clear route to market for gene edited animals and taking a risk-based approach, but no changes have yet been made by FDA.

Argentina: In 2015 Argentina became the first country to develop specific regulations for gene editing, determining that gene edited crops would be treated as conventional plants unless they contain foreign DNA. The same evaluation process will be used for livestock. Genetically edited animals will not be subject to genetic engineering regulations unless they contain foreign DNA. Gene edited organisms are assessed case-by-case based on which techniques are used in its production, the genetic change that has occurred, and whether there is a transgene in the final product. There is no legal requirement to label genetically engineered food.

Brazil: As in Argentina, gene edited crops/food are regulated as conventional products unless they contain foreign DNA. In January 2018 new changes determined that the majority of NBTs would not be regulated as GMOS as they do not involve inserting foreign genes. Products are regulated case by case, with regulations focusing on the characteristics of the final product. Assessments will consider the risk levels, whether new genetic material was introduced, and if the product has been approved elsewhere.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

Japan: In Japan, gene edited products must be notified to the government, with information on the techniques used and genes targeted, and are independently risk-assessed on a case-by-case basis. No safety or environmental assessments are required unless the product contains foreign DNA. If a gene edited crop is crossed with another crop (either conventional or gene edited) then another notification must be made. Local governments may also set additional regulatory requirements for gene-edited crops, although these do not address labelling requirements.

More details on the positive aspects of the approaches taken in Canada, Argentina, Australia and New Zealand can be found in Garcia-Alonso and Holt, 2020[ix]

Globally, the political, scientific and commercial situations are fast moving in this area. It is not yet clear how the proposed change or any future regulatory reform for agricultural biotechnologies might be viewed by the EU, individual member states or other countries around the world. While innovation in breeding must be facilitated by investment and the best regulations, it is vital that the UK's position does not harm trade and market access for its agricultural goods. **The NFU would like to continue dialogue with Defra about the potential for impact on trade and the internal market.**

The NFU is fully supportive of a **transparency proposal** being developed through the All Party Parliamentary Group on Science and Technology in Agriculture:

"Members and stakeholders of the APPG on Science & Technology in Agriculture have welcomed positive confirmation from the British Society of Plant Breeders (BSPB) that BSPB and its members support the proposal to be transparent where gene editing has been used to create new plant varieties.

While there is no scientific basis in terms of food or environmental safety for Government to require statutory segregation or labelling of GE products, as evidenced by numerous studies and reports confirming that the use of gene editing poses no new or additional safety concerns compared with traditional plant breeding, enabling choice and openness of information is at the forefront of this proposal.

BSPB has committed to entering an open dialogue with DEFRA on this topic to develop a timetable for practical and fair means of implementation.

In the interests of promoting transparency about the use of these promising new breeding techniques, this proposal complements statutory requirements within the plant variety registration process to declare that a variety is not, or does not contain, a GMO, and also to determine whether any material derived from the variety is a novel food or food ingredient under existing novel food regulations.

The proposal also supports the proven systems of statutory seed certification and marketing, which already deliver an assurance of quality, sustainability and traceability and a fit-for-purpose regulatory framework to match the objectives society expects from agriculture in the face of challenges such as food security, climate change and environmental protection.

The proposal has been developed and presented under the auspices of the APPG on Science and Technology in Agriculture, whose members first led calls for regulatory reform on the gene editing issue. It follows consultation with the Regulatory Horizons Council, which is currently conducting an inquiry into better regulation of genetic technologies.

The proposal is supported by scientists, plant breeders, seed suppliers, farmers, grain merchants, primary processors and food manufacturers."

We urge Defra to work with the industry on developing this proposal to facilitate the regulatory changes being proposed and to ensure that it can become a workable part of the future legislative framework for new breeding techniques.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

We believe that this significant commitment on transparency would facilitate choice by providing the information supply chains would need to differentiate if the market demanded it at some point in the future. It builds on the proven systems of statutory plant variety registration and seed certification that deliver to the supply chain an assurance of quality, sustainability and traceability in relation to each new crop variety.

The NFU does not believe that providing information to consumers on the use of non-GM gene editing techniques through statutory labelling of the final product would be appropriate at this stage. Indeed, it could be legally problematic given that analysis would not be able to distinguish the breeding technique used if it falls outside of GMO regulations and a label could fall foul of the Food Information to Consumers regulations by misleading consumers. Since 2002 the European Network of GMO Laboratories (ENGL) has been one of the main EU organizations developing methods for screening seeds, grains, food, and feed for signs of unauthorized bioengineering. In a 2019 report[xvii], ENGL outlined problems with detecting imported GE material. For example, edits of a single nucleotide are harder to pick up with PCR than the large sequences usually inserted into GMOs. Additionally, the technique cannot distinguish gene-edited organisms from those in which the same mutation arose naturally. This leaves the EU unprepared for detecting gene-edited organisms should it be forced to due to inappropriate legislation. The UK should guard against putting itself in this position.

Consumer-level labelling is certainly not something that should be decided upon at this early stage, before there are any products near to being placed on the retail market. As discussed with reference to the transparency proposal under development, **the NFU believes that if the market should demand such labelling in the future this could be possible in theory, as long as it did not lead to consumers being misled.** Indeed, we expect the first products on the market to have benefits of direct interest to consumers providing health, safety or environmental qualities. Considering the crops and traits currently in pipelines globally, we do see a possible future where the supply chain will want to label products as carrying a particular consumer benefit even if this does not refer to the breeding technique used. If the organic regulations continue to not allow techniques such gene editing then consumer choice based on breeding technique is provided through the current distinction between organic and conventional products.

Intellectual property:
The plant and livestock breeding and research communities across Europe are working proactively to ensure future IP regimes support innovation, driven by the need for both return on investment and accessibility for future exploitation of discoveries and genetic material. However, it is expected that as NBTs develop there will be increasing overlap and grey areas between patents, PVRs, breeders and farmers exemptions in plant breeding. The uncertainty and contentious debates already happening do not help to reassure farmers and growers that the value from new genetic technologies will flow to them rather than just to technology companies and distributors. However, it is difficult to know at this early stage how intellectual property case law will emerge and adapt in terms of patent scope and exemptions. Indeed, this is an issue for technological innovations in any sector and is independent of GMO legislation and definitions currently under scrutiny around the world.

There are a number of initiatives being developed in Europe to address transparency and accessibility in plant breeding, as well as the application to patent licensing of FRAND (Fair, Reasonable, and Non Discriminatory) principles. **The NFU would like to see the best models applied to the commercial use of gene edited plants to ensure farmers are protected in the market and diversity is maintained.**

For example, the electronic licensing platform www.ilp-vegetable.org is in place for vegetable crops and is likely to be followed by similar platforms for other crops. Also, the Patent Information and Transparency Online database (PINTO) www.euroseeds.eu provides transparency for users and breeders if plant varieties contain patented elements. In 1998 the Directive on the Legal Protection of Biotechnological Inventions was adopted. It includes provisions for the use of patented plants as farm-saved seed, which is essential for giving growers choice. Discussions are taking place in many

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

countries to incorporate provisions for plant breeders to access patented plants for further breeding with no reach-through claim from the owner if the patent is not exploited by the subsequent breeder. In Europe plant varieties and plants developed from "essentially biological processes" such as crossing and selection cannot be patented but traits and technologies can. It is not clear what this means for gene editing techniques where the plant itself makes the mutation, although patenting is an inevitable element alongside PVR (CRISPR-Cas9 tool must be licensed from the US universities where it was invented, although is available free for non-profit use).

These issues and developments make it all the more important for Government to work collaboratively with stakeholders on all elements of future legislative frameworks. Much has been written about seed market concentration, royalty systems, public-private partnerships in breeding and the distribution of benefits including with reference to 25 years of GM crop production[xviii]. Legal uncertainty around IP and regulation, including in the context of international arrangements for access and benefits sharing, puts at risk the full realisation of the potential of genetic technologies for British food and farming. **It is essential that IP is not a barrier to SMEs and public good breeding, and they have access to the full diversity of germplasm. This is especially important given the immediacy of the climate change emergency and nutritional health challenges that could be mitigated through genetic improvement.** Some of these targets may not be commercially viable for large companies focussing on major crops and targets such as yield, or not provide enough return on investment. This could limit development especially in horticulture and niche crops and markets. However, with proportionate regulation and open-source access and fair licensing arrangements, smaller companies and public good plant breeders could enter this space.

In **animal breeding**, we understand only offspring of animals with DNA changes produced through technological intervention and that do not happen naturally is patentable. Genome editing in commercial livestock breeding is many years away and it is not yet clear how IP would be protected when this happens. However, there are already many patents on reproductive processes and techniques such as culturing embryos, cloning, marker assisted selection tools[xix]. Some protect methods for detecting genetic variation that directly influence production traits. This is particularly seen in the pig sector. There are implications from subsequent controls and the collection of royalties that need to be explored further by Defra. Working with the breeding and livestock research sectors, government needs to determine whether legislative frameworks could ensure equitable access and fair commercial conditions for the whole sector. As with plants, diversity is essential to ensure SMEs and public sector research can operate and so that applications for 'public good' environmental and welfare outcomes are developed.

Question 4
What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not? Please provide evidence to support your response.

The NFU believes criteria should be developed in collaboration between regulators, breed and seed companies and scientists. They should be based on the most robust and up to date science. They should be flexible so that they can be updated as techniques and applications develop. The speed of development from discovery to market has been swift and the technologies themselves are also being refined all the time. They should ensure that there is clarity and certainty for breeders and proportionate regulatory costs and administration to enable a diversity in R&D in terms of size of company; crop or livestock species; trait and target; and both public and private sectors. Ideally, they should enable harmonisation internationally such that trade barriers do not arise. A harmonised or complementary approach globally will also help companies and organisations of all sizes in both public and private sectors to work collaboratively to use breeding technologies to address the challenges and opportunities in agriculture and food.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

This part of the consultation is designed to start the process of evidence gathering to inform how Defra should reform its approach to regulating novel organisms in the longer term.

There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies.

Question 1
Do you think existing, non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed?

The NFU believes that current GMO legislation is generally suitable for regulating GMOs and the government should continue to use this. However, it must immediately seek opportunities to improve the functioning and implementation of the regulatory process for GMOs. It has been acknowledged for many years in the UK and around the world that the political process through the EU regulates GMOs is dysfunctional. It has led to significant problems of trade disruption and economic harm due to asynchronous approvals. The priority now should be to take the opportunity to get the regulation of GE right, based on the fact that most GE techniques are not GM. Currently it is most appropriate to keep UK aligned with international definitions, treating GMOs as different to non-GM breeding techniques. We have already set out how existing rules on food and feed safety, novel foods, animal and plant breeding, animal welfare and environment provide sufficient controls and risk assessments for products of new breeding techniques that could have been made using conventional breeding. The NFU sees benefits for farming from the full range of biotechnologies, including GM. Indeed, combinations of technologies are already developing crops that could be transformational[xx].

In the longer term, it may be possible and pragmatic to reform regulation of breeding further as technologies and regulatory frameworks develop globally. A careful step-by-step approach is needed to avoid unintended consequences in the future. **We would like to see this being developed in close dialogue with the agricultural and food supply chains to ensure that the practicalities of any changes are considered as well as the purely scientific and theoretical considerations**. It is also vital that any new regulatory approach for agricultural biotechnologies can move with development of other legislation in the UK and around the world e.g. on animal welfare, feed additives, crop protection and environment. This is a long game and if the UK does not keep up with global legislative developments it will lose out in terms of the knowledge and innovation economy and the delivery of public goods as well as competitively.

It is important to note how regulatory frameworks for regulatory 'novelty' in agrifood are developing around the world. The more scientifically defensible the government's regulatory position is, the more likely it will be able to keep up with technological developments and those countries where commercial application is happening most quickly. However, in the short term there must be a recognition of the level of uncertainty and disruption created by Brexit with new domestic agriculture policy and trading arrangements. Investment decisions in both private and public sectors are being made in this context. There is the need for a period of stability and predictability, and better regulation is at the heart of this. In practice, genetic improvement in crops and livestock will continue to be dominated by conventional breeding programmes for many years and the right conditions must be right for this to flourish and grow.

The goal guiding the design of a new regulatory framework should be that the UK establishes farming, breeding and research sectors that are world-leading, innovative, progressive, coordinated, able to respond to the market, and diverse in terms of scale, system and technological approach. Having this in the UK's shop window would attract investment to the UK. It would also contribute to the UK delivering on its obligations on climate change, food security, nutritional

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

health, biodiversity, animal welfare, and economic stability, and play a central role in global efforts in all these areas.

Some new precision breeding techniques such as CRISPR-Cas9 are much quicker and cheaper to use. If the legislative system is functional and proportionate and gives certainty to those involved in genetic improvement, these exciting new techniques will be accessible to SMEs and research organisations in this sector. It also means that the market signals can be more easily acted upon by both public and private sector scientists and the risks of investing will be lower. This should provide a much more diverse landscape and market and reduce the dominance of the biggest global companies. In addition, the type of products that are in the R&D pipeline will be (and already are) much more diverse and will not have to be limited to the major global commodity crops as has been the case with genetic modification.

Euroseeds published a peer reviewed paper in September 2020 for which 62 private plant breeding companies (53% small, 37% medium and 10% large companies) were surveyed to capture their interest in using the new breeding techniques[xxi]. Very high level of interest was reported in using new breeding techniques. A wide range of crop species and traits are being looked at from agronomic and food and feed quality, biotic and abiotic stress resistance, ornamental value and post-harvest quality. Almost all companies with NBTs in their R&D pipelines operate internationally. It is still early in terms of timeline to market, with some saying 5 to 10 plus years and some not projecting a timeline. They cite the negative impact of the current regulatory situation in the EU on companies' decisions for investments.

It is very important to NFU members that opportunities from innovation can be fully realised in the pursuit of farming's net zero ambitions and to give environmental, consumer and societal benefits. They must see value for their farming systems and markets if they are to access new breeding technologies. It is encouraging that, in the four years since Argentina put in place the kind of regulatory framework Defra is proposing, there has been greater diversity in the types of products being developed both in terms of trait and organism[xxii]. We can also see that a large number of the applications in research and development around the world are in minor crops and in horticulture, with consumer quality traits as key targets. If the first applications that come to market in the UK have clear and direct benefits to the consumer, environment and animal welfare this would provide an important demonstration to the public of the value and importance of innovation in breeding. This could provide a market pull for more investment and diversity in development. Government can drive this process by getting the regulatory framework right and encouraging these early public-good applications.

Although new precision breeding techniques are not an option for organic farmers, science and innovation have played a vital role in enabling organic production to thrive and for market demand to be met. An integrated approach involving science-based agroecological approaches must be encouraged for this sector. Scrutiny of the application of gene editing and a full and transparent assessment of unintended consequences will be required. Discussion is happening around the world about which breeding techniques are consistent with organic principles and whether, indeed, gene editing may have a place in organic systems[xxiii] [xxiv]. However, it is essential that businesses, whether or organic or conventional, who do not wish do use products arising from these new breeding techniques still have access to their chosen seeds and breeds. They must be able to deliver products to the specifications their customers demand.

The NFU has already fed into the work of the Regulatory Horizons Council and the Engineering Biology Leadership Council on alternative regulatory approaches for genetic technologies making the points we raise in this consultation response. The NFU is also taking part in discussions with the new Taskforce on Innovation, Growth and Regulatory Reform chaired by Ian Duncan-Smith. We are also aware of a new Better Regulation Cabinet Committee. It is vital that Defra works very closely with these groups and with BEIS to ensure learnings from both consultation processes are considered. This is important both for the immediate proposals on regulating some new precision

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

breeding techniques separately from GMO but also in considering how all genetic technologies should be regulated in the future.

NFU members and sector specialists have identified challenges and opportunities for new precision breeding applications in British food and farming. A non-exhaustive list is provided in Annex 1. Sugar beet, as an integrated sector facing many pest and disease challenges, has provided further details in the form of a case study.

If you would like to discuss any of the points made in the NFU's response, please contact the NFU Chief Science and Regulatory Affairs Adviser, Dr Helen Ferrier.

Annex 1

Challenges and opportunities for new precision breeding applications in British food and farming.

Sector	Target challenge or opportunity for solution through genetic improvement
All	Climate change mitigation and adaptation; net zero
Sugar	Virus yellows (3 yellowing viruses) Cercospora Rhizomania Sustainability Nitrogen use efficiency
Arable	Pest and disease resistance (CSFB; BYDV etc) Reduced pesticide use Nitrogen use efficiency P and K liberation Increased quality and yield Reduced allergenicity (coeliac tolerance, low gluten) Abiotic stress; drought and flood tolerance Improved food safety (low acrylamide; mycotoxins) Nutritional health (high fibre, iron, zinc) Black grass
Horticulture	Marketable quality Extend seasonality Soil protection Higher yield, lower input Water use efficiency Increase nutrient uptake Reduce food safety risks Waste reduction Higher nutritional quality (vitamins & minerals; antioxidants) Tackle human nutrient deficiencies / biofortification Resilience to abiotic stress & extreme weather Disease resistance DED resistant elm trees Reduced browning in celery & pinking in lettuce Reduced allergenicity in celery
Soft fruit	Flavour Shelf-life Disease resistance Reduce waste on farm, in store, in supply chain.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

Potatoes	Late blight Eel worm Potato cyst nematode Potato virus Y Vitamin C Storage
Poultry	Avian influenza Sexed embryos; eliminate culling male chicks Nutritional quality of eggs Allergen free eggs Disease resistance Feed conversion
Dairy and beef	bTB resistance Extended lactation Low methane emissions Forage crops – tolerance of extreme weather; high quality conserved forage (dry matter, proteins, sugars) Eating quality & consistency Alternative protein feed crops Disease resistance and parasite tolerance Temperament Calving ease Mastitis Improve daily live weight gain; reduce age to slaughter Optimise carcass weight to grade
Pigs	PRRSV resistance ASFV resilience Boar taint Carcass quality Birth and weaning weights Feed conversion Lactation

Case study: Sugar beet (provided by NFU Sugar)

Sugar beet is an important crop grown on around 100,000ha in the UK but it faces enormous challenges because of pests and diseases. For the 3000 growers with sugar beet as an integral part of their arable rotation, crop losses from virus yellows disease were as high as 80% in the 2020/21 season, with devastating consequences for farming families.

The sector urgently requires fit for purpose, science-led regulation to pave the way for a sustainable path to tackling virus yellows disease. UK adoption of new breeding techniques will provide an important opportunity for the sugar beet sector to reduce the impact of pests and diseases, while driving improved yield over time.

Currently, sugar beet growers have just one on-label approved plant protection product to control aphids (the vector of virus yellows disease). The sector therefore faces great uncertainty each year about how significant the pest threat will be, and if or how growers will be able to control the pest problems they face. Consequently, the sector relies on the emergency authorisation process to access the plant protection products that growers require to protect their crops, but only using them if clear and defined thresholds are met. The emergency authorisation process is costly and time-consuming for all involved and creates uncertainty for growers. For growers trying to decide what crop to grow, and how

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

to plan and implement IPM, not knowing how or if they will be able to control pests poses a significant problem.

Using conventional breeding to find a genetic solution to virus yellows disease is difficult because there are three different viruses responsible for the disease. Trying to identify resistance genes in wild relatives which can then be bred into conventional varieties is a slow, long-winded process. A targeted gene editing approach provides the opportunity to speed this process up, potentially providing a future solution to virus yellows. In addition to addressing diseases caused by viruses, gene editing also has the potential to help provide solutions to pests and diseases where plant protection products are not available, for example: fungal diseases such as Cercospora, and pests such as Free Living Nematodes. Gene editing also has the potential to help address issues such as drought tolerance and improved nitrogen use efficiency.
Though the correct regulation of gene editing, both the food system and the environment should benefit: the former through improvements in food security, the latter through increasing biodiversity and reducing climate change.

It is important to note that gene editing does not negate the need for plant protection products completely as the nature of pests and diseases evolve over time, rather it forms part of a wider, integrated solution to the problems the sector faces.

This consultation is an important step towards sustainable solutions to the key issues facing the UK sugar beet industry. NFU Sugar, representing the 3000 sugar beet growers in the UK, support the adoption of new breeding techniques, in particular gene editing, in agriculture.

Annex 2

Gene editing legislation around the world

More information on regulations on gene editing around the world can be found here.

Canada: Under Canadian regulations, novelty, and therefore whether a pre-market assessment is required, is defined by the final traits found in the end product and is not defined by the process used to arrive at the end product. This approach provides flexibility in the Canadian system in that it can accommodate new technologies without requiring regulatory amendment. As a result, Canada's product-based approach applies to gene-edited products, in the same way as it does for products of conventional breeding, mutagenesis and genetic engineering.

Both Health Canada (HC) and the Canadian Food Inspection Agency (CFIA) have a role in regulating novelty, using a science-based approach. HC regulates novel foods, and the CFIA regulates novel feeds and environment release. New rules have just been announced such that those products developed using gene editing techniques that do not meet the regulatory definition of "novel" are considered equivalent to existing counterparts and no pre-market assessment is required. When a submission is made, developers may voluntarily agree to publication of information about their plant products as part of a new transparency initiative.

It is important to note that the Government of Canada regulates plants, animal feed and human food under different legislation. Therefore, the regulatory requirements for each are somewhat different and considered separately. This approach allows the Canadian regulatory system to focus safety assessments on products with new traits and efficiently adjust to any new scientific developments. All seeds, feed and food, whether conventional or products of biotechnology, are regulated in Canada. They must comply with all relevant standards and regulations for safety and quality, even when pre-market assessments are not needed.

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

More information on the CFIA's approach to regulating plants developed using gene editing is available on the CFIA's website.

In 2018, Canada and 12 other nations, including Argentina, Australia, Brazil and the USA, issued a joint statement to the World Trade Organization supporting relaxed regulations for gene editing, stating that governments should "avoid arbitrary and unjustifiable distinctions" between crops developed through gene editing and crops developed through conventional breeding.

Australia: Under the Australia New Zealand Food Standards Code any 'food produced using gene technology' is regulated as GM food, and therefore is subject to pre-market approval in Australia and requires an application to Food Standards Australia New Zealand (FSANZ). The Code however does not explicitly state that this would cover gene editing, and it is a matter of interpretation; responsibility for interpretation and enforcement lies with the Federal, State and Territory food enforcement agencies

FSANZ completed a review in December 2019 that considered how the Code applies to food derived using new breeding techniques, including genome editing. The review concluded the current definitions are no longer fit for purpose as they lack clarity, are outdated and do not reflect the diversity of techniques now in use. FSANZ has therefore commenced a new proposal in February 2020 to amend the definitions in the Code to make them clearer and better reflect existing and emerging genetic technologies including new breeding techniques. This includes a consideration on whether to exclude certain foods, including those derived through gene editing, from a revised definition. The current proposal and previous FSANZ review can be found here.

Live and viable GMOs in Australia and regulated through the National Gene Technology Scheme (the Scheme) administered by the Office of Gene Technology Regulator. This Scheme takes a science-based approach to manage risks, and allow a predictable path to market, and works alongside other national regulators for a cohesive approach.

In 2019 the Gene Technology Regulator completed a technical review of the Gene Technology Regulations 2001, ensuring that new technologies are regulated in a manner which reflects the risks they pose. This review amended the legislation to clarify that most gene editing techniques do require regulation under the legislation. The exception to this is SDN-1, as organisms produced using this technique present no different risk than organisms carrying naturally occurring genetic variations and cannot be distinguished from conventionally bred animals or plants. These legislative and ensure that the new technologies are regulated in a manner commensurate with the risks they pose.

In 2018 Australia issued a joint statement to the WTO, alongside 12 other counties including Canada and the USA, supporting a relaxation of regulations for gene editing.

New Zealand: In New Zealand, all gene editing techniques, even where no foreign genes are incorporated, are tightly regulated as genetic modifications by the Environmental Protection Agency (EPA) under the Hazardous Substances and New Organisms (HSNO) Act 1996. This is part of New Zealand's 'wait and see' approach, which has a specific focus on the regulations in countries New Zealand exports to. In 2018 the NZ Environment Minister, alongside researched, called an update to the HSNO Act, citing a need for a clear route to market for gene edited organisms.

As with Australia, food standards are set by FSANZ and Australia New Zealand Food Standards Code, including gene edited food. This requires pre-market approval and clear labelling standards for food produced using gene technology (including imported food). FSANZ completed a review in December 2019 which concluded the current definitions are no longer fit for purpose as they lack clarity, are outdated and do not reflect the diversity of techniques now in use. FSANZ has therefore commenced a new proposal in February 2020 to amend the definitions in the Code to make them clearer and better reflect existing and emerging genetic technologies including new breeding techniques. This includes a

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

consideration on whether to exclude certain foods, including those derived through gene editing, from a revised definition. The current proposal and previous FSANZ review can be found here.

America: The USA takes significantly different approaches to gene editing regulation between crops and animals, with light regulation for crops, but quite stringent regulation in animals.

For crops, there are no unique regulations for gene editing in crops, although there is wider regulation for genetically engineered organisms, which is separately managed by the USDA, FDA and EPA. The regulations are based on the characteristics of the final products, as opposed to the process used to create it. This approach to focus on characteristics of gene edited plants was reaffirmed by President Trump's 2019 Executive Order which called on federal agencies to streamline the regulatory process by exempting low-risk products, which was followed in 2020 by the USDA's 'SECURE' rule, which made gene edited plants which could have been developed through conventional breeding exempt from GMO regulations.

Meanwhile, the regulation of animal biotechnology is overseen by the FDA, which takes a stricter approach to gene editing. Draft guidance released in 2017 proposed that all intentional alterations, including those that could be achieved via conventional breeding, to genes in animals should be regulated as a veterinary drug; this approach is unique to the USA.

Having said this, in 2018 the FDA did commit to a plan to clarify gene editing policies, including developing a clear route to market for gene edited animals. This will take a risk-based approach, and in 2019 work began to identify low-risk animals that would be exempt from a safety review. This approach has, however, also been challenge by the FDA's own analysis of gene editing in cattle, which supports the 2017 decision that all animals created using gene editing should be subject to mandatory premarket review and substantial safety testing.

In 2018 America issued a joint statement to the WTO, alongside 12 other counties including Canada and Australia, supporting a relaxation of regulations for gene editing.

Argentina: in 2015 Argentina became the first country to develop specific regulations for gene editing, determining that gene edited crops would be treated as conventional plants, unless they contain foreign DNA. Note that while the regulations have so far only been applied to crops, the same evaluation process will be used for animals. Genetically edited animals will not be subject to genetic engineering regulations unless they contain foreign DNA.

Under this evaluation process, gene edited organisms are assessed on a case-by-case basis, based on a dossier which is submitted to the CONABIA, the Argentine Biosafety Commission, who must respond within 60 days as to whether the organism will be subject to GMO regulations. If a product is not submitted to CONABIA for assessment it is automatically regulated as a GMO. In this process CONABIA consider the techniques used in its production, the genetic change with has occurred, and whether there is a transgene in the final product. The key to whether a product is deemed a GMO will depend on the process used, and whether foreign DNA is added in the process; Therefore, most gene editing techniques are not subject to additional regulation.

There is no legal requirement to label genetically engineered food. Even if a product is determined to be exempt from GMO regulations, if there are concerns that it may still pose a significant risk then it may be subject to further monitoring by authorities.

Brazil: As in Argentina, gene edited crops/food are regulated as conventional products unless they contain foreign DNA. In January 2018 new changes came into force which determined that the majority of NBTs would not be regulated as GMOS as they do not involve the use of inserting foreign genes.

Products are however regulated on a case-by-case basis, overseen by the National Technical Commission for Biosafety (CTNBio), with regulations focusing on the characteristics of the final product,

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual

as opposed to the process used. Assessments will consider the risk levels, whether new genetic material was introduced, and if the product has been approved elsewhere.

Japan: In Japan, while gene edited products must be notified to the government, with information on the techniques used and genes targeted, and are assessed on a case-by-case basis, no safety or environmental assessments are required unless the products contain foreign DNA. If a gene edited crop is crossed with another crop (either conventional or gene edited) then another notification must be made.

Genetically engineered crops and food are regulated by the Ministry of Agriculture, Forestry and Fisheries (MAFF), the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The Food Safety Commission (FSC), an independent risk assessment body under the Cabinet Office, performs food and feed safety risk assessment. Local governments may also set additional regulatory requirements for gene-edited crops, although these do not address labelling requirements.

References

[i] GEAP3 Network Genome Editing and Agriculture: Policy, Practices and Public Perceptions
[ii] Genome Editing: Applications in Agriculture - Genome Editing (oecd.org)
[iii] *Fostering innovation in agriculture through enabling regulatory policy*, Garcia-Alonso and Holt, Estel Consult Ltd. January 2020 Innovation in Agriculture report Jan 20 - final.pdf (appg-agscience.org.uk)
[iv] *IP in Plant Breeding*, Maplestone, IPAN Topic Brief. February 2018
[v] Gene Editing for the Climate: Biological Solutions for Curbing Greenhouse Emissions | ITIF Giddings, Rozansky and Hart September 14, 2020
[vi] Guide to zootechnical rules and standards - GOV.UK (www.gov.uk)
[vii] *On-farm livestock genome editing using cutting edge reproductive technologies, McFarlane et al. 15 Nov 2019* Frontiers | On-Farm Livestock Genome Editing Using Cutting Edge Reproductive Technologies | Sustainable Food Systems (frontiersin.org)
[viii] Livestock 2.0 - genome editing for fitter, healthier, and more productive farmed animals**,** Tait-Burkard et al. 26 Nov 2018, Genome Biology.
[ix] Genome-edited livestock: Ethics and social acceptance , Ishii, April 2017, Animal Frontiers.
[x] *Genetic modification in food animals*, Van Eenennaam, April 2017. Current Opinion in Biotechnology. Genetic modification of food animals - ScienceDirect
[xi] *Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis*. EFSA, 24 November 2020 https://www.efsa.europa.eu/en/efsajournal/pub/6299
[xii] *Gene Editing Regulation and Innovation Economics*, Whelan, Gutti and Lema. Front. Bioeng. Biotechnol., 15 April 2020 Frontiers | Gene Editing Regulation and Innovation Economics | Bioengineering and Biotechnology (frontiersin.org)
[xiii] *France backs non-GMO regulation for gene-editing in EU,* Reuters. 19 January 2021
[xiv] Genome Editing for Crop Improvement | (allea.org)
[xv] Global Gene Editing Regulation Tracker and Index (geneticliteracyproject.org)
[xvi] *Fostering innovation in agriculture through enabling regulatory policy*, Garcia-Alonso and Holt, Estel Consult Ltd. January 2020
[xvii] *Detection of food and feed plant products obtained by new mutagenesis techniques.* European Network of GMO Laboratories (ENGL), 26 March 2019 JRC116289-GE-report-ENGL.pdf (europa.eu)
[xviii] Concentration in Seed Markets: Potential Effects and Policy Responses | en | OECD; "Wheat Research Funding in Australia: The Rise of Public-Private Partnerships" | InSTePP: International Science & Technology Practice & Policy (umn.edu); The size and distribution of the benefits from the adoption of biotech soybean varieties : Handbook on Agriculture, Biotechnology and Development (elgaronline.com);
[xix] Frequently asked questions on Patent Watch (effab.info)
[xx] Where GM meets GE | Rothamsted Research; *Genetically modified plants are an alternative to oily fish for providing n-3 polyunsaturated fatty acids in the human diet*. West et al. Nutrition Bulletin, 2020
[xxi] *Potential, Challenges, and Threats for the Application of New Breeding Techniques by the Private Plant Breeding Sector in the EU*, Jorasch, Front. Plant Sci., 25 Sept 2020
[xxii] *Gene Editing Regulation and Innovation Economics*, Whelan, Gutti and Lema. Front. Bioeng. Biotechnol., 15 April 2020
[xxiii] Is there a place for CRISPR gene editing in organic farming? Many farmers say 'yes' | Genetic Literacy Project
[xxiv] Organic farming with gene editing: An oxymoron or a tool for sustainable agriculture? (theconversation.com)

Although every effort has been made to ensure accuracy, neither the NFU nor the author can accept liability for errors and or omissions. © NFU

NFU supported by NFU Mutual