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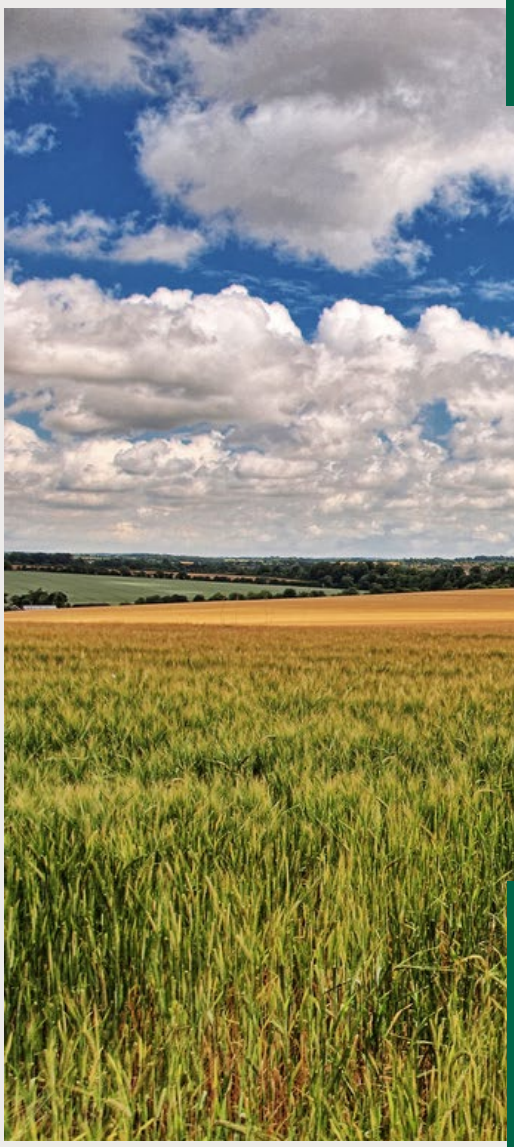
Genetic Technology (Precision Breeding) Bill 2022-23



Summary

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Summary

A Genetic Technology (Precision Breeding) Bill [PDF] was introduced to the House of Commons on 25 May 2022. The Bill's second reading is scheduled in the House of Commons on 15 June 2022.

What would the Bill do?

The May 2022 Queen's Speech [PDF] said the Bill's aims are to "encourage agricultural and scientific innovation" in the UK" and that "legislation will unlock the potential of new technologies to promote sustainable and efficient farming and food production."

The Bill applies to precision bred plants and vertebrate animals (excluding humans), meaning they are gene edited, and would remove them from the regulatory system for genetically modified organisms (GMOs).

What is precision breeding?

The Government's Genetic Technology fact sheet published with the Bill [PDF] describes precision breeding as a range of breeding technologies, such as gene editing (GE), that enable DNA to be edited "much more efficiently and precisely than current breeding techniques".

Precision breeding technologies can make targeted genetic changes to produce beneficial traits that can also occur through traditional breeding and natural processes. This makes it **different to genetic modification** (GM) where modern techniques are used to insert functional DNA from an unrelated species into another species.

Scientists consider that precision breeding will allow a range of foods with health, environmental or commercial benefits to be developed more quickly than traditional breeding methods. Policy makers hope these will help to tackle global food security, climate change and human health challenges. GE crops may currently be cultivated in several countries including Canada, China, the US, Australia, and Brazil (with varying regulation).

Examples of current GE products include soybean oil with reduced saturated fat sold in the USA and a tomato sold in Japan that accumulates a chemical that lowers blood pressure. For the future, a range of wheat, chickpea, and peanut products with health benefits are in development,

alongside products aimed at consumer convenience such as seedless fruits and corn that is higher in thickening starch.

How will the Bill change the regulation of precision breeding?

The Government said the primary policy objective of the Bill is to ensure plants, animals and food and feed products developed using precision breeding technologies are "regulated proportionately to risk" [PDF]. The Bill will "introduce simpler regulatory measures to enable these products to be authorised and brought to market more easily."

GE and other new precision breeding techniques are currently regulated under the complex regime that applies to all genetically modified organisms (GMOs). EU rules on GMOs currently continue to apply in the UK, (although 2022 regulations amended the rules in England for certain GE plants used for research and development).

Regulations define a GMO as an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or both. The European Court of Justice in 2018 determined that the GMO regulations should include new breeding technologies such as GE developed in the last 30 years. This ruling was contentious and the EU is currently consulting on possible loosening of restrictions for plants resulting from GE technology.

The Government has said leaving the EU provides the UK with the opportunity to adopt a "more science based and proportionate approach to the regulation" of precision bred organisms [PDF]. This could "drive innovation and investment" in the UK.

According to the Government, it should cost less to take a precision-bred crop to market, compared to under the current GMO process. These savings would predominantly benefit the plant breeding sector, but also, indirectly, the rest of the food chain. The overall time taken to comply with existing regulation for getting precision bred crops to market will be reduced from an estimated 10 years to 12 months.

The main policy changes in the Bill [PDF], as set out by Defra, are to:

1. Remove plants and [vertebrate] animals [excluding humans at any developmental stage] produced through precision breeding technologies from regulatory requirements applicable to the environmental release and marketing of GMOs.

2. Introduce two notification systems; one for precision bred organisms used for research purposes and the other for marketing purposes. The information collected will be published on a public register on GOV.UK.

3. Establish a proportionate regulatory system for precision bred animals to ensure animal welfare is safeguarded. The Government said it would not introduce changes to the regulations for animals until this system is in place.

4. Establish a new science-based authorisation process for food and feed products developed using precision bred organisms.

The Government said the changes mean the level of regulatory scrutiny for precision bred organisms is "somewhere between that of GMOs and traditionally bred organisms" [PDF].

The Government has said the application of the Bill's measures to precision breeding of animals will not take place until an appropriate regulatory regime is in place. Nevertheless, the Bill provides powers for the Secretary of State to introduce the measures by secondary regulation.

The inclusion of animals in the proposed changes raises issues about the health and welfare of animals. GE could be used for breeding disease-resistant animals for example, but some stakeholders warn of the need to ensure animal welfare is not compromised by breeding to select certain traits. The Bill is drafted to apply to all animals, not just those used in agriculture. It includes a provision for animal welfare to be considered but does not include any specific restrictions on what can be marketed.

Stakeholder reactions

The Government said the independent Advisory Committee on Releases to the Environment (ACRE) considered that precision bred organisms "posed no greater risk than their traditionally bred or naturally arising counterparts" [PDF]. However, stakeholders have divided views on regulatory changes.

Health and animal welfare

In 2021, Defra consulted on possible broad changes to GE regulation [PDF]. Most individuals (88%) and nearly two-thirds of businesses responding wanted GE regulation to continue as now, under the GMO regime. However, more than half of academic institutions (58%) and non-governmental organisations supported change.

Similarly, views were divided on the risks posed by GE organisms. Some 87% of individuals and 64% of businesses considered they posed a greater risk to human health and the environment compared to traditionally bred counterparts. In contrast, 63% of academic institutions and 82% of public sector bodies considered they posed the same level of risk.

Scientists are broadly in favour of removing GE from wider GMO regulation, as are many food producers and farmers including the

National Farmers' Union and livestock producers. However, some groups such as the Soil Association, GM Freeze and Beyond GM are concerned that there is insufficient knowledge about the effect on organisms and the environment, and that claims about benefits for tackling food supply and health issues are overstated. Others, such as the RSPCA, are concerned that changes could lead to lower animal welfare standards.

Market concerns

There are also concerns about transparency for consumers. Ministers have said food and feed from precision bred organisms are unlikely to need to be labelled as such. This could be an issue for products authorised under this legislation in England which are sold in other UK nations.

Although regulation of genetic technologies is a devolved matter, under the UK Internal Market Act 2020, precision bred products legally marketed in one nation may be marketed in the other UK nations. Northern Ireland is the exception to this as it continues to follow EU rules under the Northern Ireland Protocol.

Previously, the Scottish and Welsh Governments indicated they do not plan to change regulation of GE technologies for food and feed. The Scottish Government also said it would block the application of this Bill in Scotland.

1 Background

The Queen's Speech on 10 May 2022 [PDF] included a Genetic Technology (Precision Breeding) Bill to "encourage agricultural and scientific innovation at home." It said: "legislation will unlock the potential of new technologies to promote sustainable and efficient farming and food production".[1]

The Bill was introduced on 10 May and Second Reading is scheduled in the House of Commons on 15 June 2022. The Bill mainly applies to England.

What is precision breeding?

The Bill contains measures to change the regulatory regime relating to precision bred organisms. Gene (or genome) editing (GE) is included as a precision breeding technology within this definition. Genome editing encompasses a variety of techniques that add, remove, or replace DNA at targeted locations within the genetic code of living cells (the genome).

Defra's factsheet on Genetic Technology published with the Bill defines precision breeding as:

> a range of breeding technologies, such as gene editing, that enable DNA to be edited much more efficiently and precisely than current breeding techniques. Precision breeding technologies can make targeted genetic changes to produce beneficial traits that can also occur through traditional breeding and natural processes. This makes it different to genetic modification where modern techniques are used to insert functional DNA from an unrelated species into another species.[2]

Clause 1 of the Bill provides definitions of key terms. For example, to be classed as precision bred, an organism's genome must have been altered "using modern biotechnology, that such alterations made must be stable and that all features of its genome could also have arisen either by traditional processes or via natural transformation" (Clause 1(2)).[3]

GE can also be used to introduce novel combinations of genetic material into organisms that would not result from traditional breeding methods,

1 Prime Minister's Office, The Queen's Speech 2022, 10 May 2022, page 8
2 Department for Environment, Food and Rural Affairs, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022
3 Subsections define these terms further, as discussed under the section below on The Bill, Clause 1. Plants are defined as residing within the group Archaeplastida, or Phaeophyceae. Animals are defined as residing in the group Metazoa but excluding humans at any developmental stage as well as human admixed embryos.

however these would be outside the scope of the Government's proposed reforms. In effect, the definitions in the Bill exclude such organisms from begin defined as precision bred. [4]

1 What is genome editing?

Traditional breeding uses the DNA changes (mutations) that spontaneously occur every time DNA replicates in nature (e.g., 120 mutations per seed of wheat). To transfer a desirable trait into a cultivated crop in this manner requires a long breeding process. By contrast, genome editing enables the creation of targeted mutations (e.g., a single, or a few DNA base changes) that mimic the changes that occur in nature. It increases the efficiency of introducing single and multiple traits and can remove undesirable genes without removing nearby (genetically linked) desirable genes. Although some opponents disagree, proponents argue that genome editing may shorten the eight to 20-year development of conventional crop breeding to three to four-years.

Genome editing, involving techniques such as the widely used method called CRISPR/Cas, can be achieved in several ways. One method uses a soil bacterium (Agrobacterium) to deliver Transfer-DNA (T-DNA) carrying genes to achieve the editing. This T-DNA inserts into the plant genome to create the molecular tools to 'search' for and 'add/remove/replace' DNA in a different area of the plant genome that is pre-defined by the operator. The next generation of plants bred will include some plants that are free of the (bacterial) 'foreign' T-DNA. In other methods no foreign DNA is integrated into the genome; either the instructions to build the molecular tools or the protein tools themselves are delivered into plant cells.

Source: POSTnote 0663, Genome edited food crops, January 2022

Potential uses of precision breeding techniques

The Parliamentary Office for Science and Technology Genome edited food crops POSTnote provides further details on the potential uses and perceived benefits of gene editing.[5] It says:

> experts across government, academia and industry largely agree that genome editing could help breeders enhance crops. Genome editing can introduce small changes in the DNA sequences of specific genes known to affect traits of interest to achieve the desired genetic outcome of breeding

4 The Government has published ACRE's Guidance on Genetic Technologies that result in qualifying higher plants. This sets out more detail on various precision breeding technologies. Research and analysis, Technical guidance on using genetic technologies (such as gene-editing) for making 'qualifying higher plants' for research trials, 11 April 2022

5 Parliamentary Office for Science and Technology, POSTnote, Genome edited food crops, 24 January 2022

techniques more accurately and efficiently. However, other commentators do not agree that proposed benefits are likely to be realised. Mutations are more likely to occur by nature and conventional breeding, but unintended sequence alterations might occur during genome editing. If they result in a safety concern, these lines will not be commercialised. Proponents of genome editing consider it could be a routine tool in the box for crop improvement. Others have highlighted concerns about over-hyping the technology, and have questioned whether the proposed timelines for benefits will be delivered. Public acceptance, in terms of potential risks and benefits, emphasise the importance of traceability, transparency and public engagement, impacts on farming and trade.[6]

Examples of gene editing

Examples of current products which have been bred using GE for health benefits including soybean oil (in the USA only) with reduced saturated fat and a tomato (in Japan only) that accumulates a chemical that lowers blood pressure. Products in development with other potential health benefits include: wheat with reduced carcinogens upon baking; wheat with higher dietary fibre; chickpea with higher protein; peanuts that are allergen-free; and wheat that is gluten-free. Products aimed at consumer convenience include fruits that are seedless; coffee with reduced caffeine; and corn that is higher in thickening starch.[7]

For farm animals, the benefits are often focused on improving animal husbandry or stock. For example, UK scientists using gene editing are working to develop pigs resistant to Porcine Reproductive and Respiratory Syndrome for commercial use.[8] Gene editing to produce dehorned cattle is also often referred to as an example, and has been achieved by US scientists, who have produced a gene edited dehorned bull, which has passed on the trait to offspring.[9] Dehorning of dairy cattle is carried out to reduce injury risk.

2 Some benefits of precision breeding

Pesticide reduction: Virus Yellows can cause yield losses of up to 50% in sugar beet. A UK Research and Innovation funded study has identified several sources of genetic resistance that can be introduced through precision breeding. This would reduce the need for pesticides, helping to protect the environment, increase food production and reduce costs to farmers.

Climate resilience and food security: John Innes Centre researchers in Norwich have used gene editing techniques to identify a key gene in wheat

6 Parliamentary Office for Science and Technology, POSTnote, Genome edited food crops, 24 January 2022
7 Parliamentary Office for Science and Technology, POSTnote, Genome edited food crops, 24 January 2022
8 Edinburgh University, Agreement targets disease-resistant gene-edited pigs, 30 July 2021
9 UC Davies, Genome-Edited Bull Passes on Hornless Trait to Calves, 7 October 2019

that can be used to introduce traits such as heat resilience whilst maintaining high yield. This discovery presents an opportunity to identify variations of the gene that can give wheat varieties resilience to climate change.

Public health: Heating foods such as potatoes and cereals to a high temperature forms acrylamide (a probable cancer-causing compound) from asparagine. Rothamsted Research are testing a wheat that has been gene edited to have lower levels of asparagine thus reducing the risk of acrylamide formation with benefits for public health.

Source: Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]

2 How is precision breeding currently regulated?

Current UK regulation

Gene editing (GE) and other new precision breeding techniques are currently regulated under the overarching regime that applies to genetically modified organisms (GMO). EU rules on GMOs currently continue to apply in the UK.

Under the Genetically Modified Organism (GMO) Release Directive (2001/18/EC), a GMO is defined as an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or both. However, new breeding technologies have been developed in the last 30 years, leading to uncertainty as to whether these new techniques fall within this definition of a GMO. A 2018 European Court of Justice case brought legal clarity by ruling that these new techniques did in fact fall within the GMO Directive.[10] The UK and some other EU Member States and organisations did not support this approach at the time and subsequently the EU Commission has said the regulatory regime is not fit for purpose. The EU Commission is currently consulting on amending the regulation of GE plants (see International Approaches, below).

The Bill's Explanatory Notes set out in paras 10-13 how EU regulations have been implemented in UK law. This was principally through Part VI of the Environmental Protection Act 1990 (EPA) and subsequent secondary legislation and (after the UK left the EU) retained direct EU law. The Explanatory Notes set out that the EPA (Section 106, Part VI) and the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (Regulation 5) use the EU definition of a GMO from Directive 2001/18/EC. The EPA introduces the additional concept of 'artificial modification' which more clearly establishes that it is the techniques used to develop an organism that determines its GM status; whether the genetic changes could have occurred naturally or by traditional methods has no bearing.[11]

10 Court of Justice of the European Union Press Release, Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive, 25 July 2018 [pdf]

11 Explanatory Notes, paras 10-13. These paragraphs further explain that the Deliberate Release Regulations list techniques developed in the 1980s, aligned with the 2018 EU Directive, as well as listing "natural processes and traditional breeding methods that are not regarded as being GM techniques".

The Retained EU GM Food and Feed Regulations (1829/2003/EC) govern the use of GM for human food and animal feed. This covers food and feed products containing living GMOs as well as non-living products derived from them. Persons intending to market GMOs can seek authorisation to cultivate GM crops under these regulations, in addition to seeking approval to use them as food and feed. Alternatively, they can seek authorisation for cultivation under the GMO Deliberate Release legislation and separately, seek authorisation for their use in food and/or food. If the organism is not intended for food or feed, use it can be authorised for marketing under the GMO Deliberate Release legislation.[12]

The Bill's Impact Assessment (IA) sets out what steps must be followed to gain authorisation to cultivate and/or market GM organisms.[13] This is a complex process requiring each GMO to be authorised before use. The IA explains that, for field trials:

> each GMO is assessed and authorised on a case-by-case basis before it can be used in field trials. This process for plants (animals are governed by the Genetically Modified Organisms (Contained Use) Regulations 2014) involves a risk assessment, a public consultation, and the publication of details of when and where the research trial will take place - requirements which do not apply to their traditionally bred counterparts.

For plant research and field trials, the (Genetically Modified Organisms) Deliberate Release (Amendment) (England) Regulations 2022 were introduced this year. These regulations altered GMO legislation so that a subset of plants created by genetic technology, which could have occurred naturally or been produced by traditional breeding, may be taken to field trials for research and development purposes without the requirement for Government approval.

The IA also explains that for marketing a GMO, as for field trials,

> each organism is assessed and authorised on a case-by-case basis. This process involves a risk assessment, a public consultation, and the publication of information to a public register. The information dossier is reviewed by the Advisory Commission on Releases to the Environment (ACRE), who provide advice to the relevant competent authority on the environmental safety aspects of the organism.
>
> All applications for marketing purposes must include information on identification by validated testing methods, as well as a post-market monitoring and evaluation plan.

The IA notes that marketing approvals last for a maximum of 10 years. It also sets out the further testing and assessments to be undertaken, including by the Food Standards Agency, for example to test for possible allergens or changes to toxicity.[14]

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12 HCB 11, Explanatory Notes, paras 10-13 [pdf]

13 Genetic Technology (Precision Breeding) Bill Impact Assessment [pdf] figure 2

14 Genetic Technology (Precision Breeding) Bill Impact Assessment [pdf]

The Bill's Explanatory Notes note that the Government does not consider that the Cartagena Protocol on Biosafety applies to organisms produced using modern biotechnologies. The Cartagena Protocol is an international treaty governing the movements of GMOs from one country to another.[15]

Recent UK policy developments

Defra gene editing consultation

Defra consulted in 2021 on the future regulation of gene editing techniques [pdf].[16] The Department published a summary of responses in July 2021:

- Most individuals (88%) and businesses (64%) responding supported continuing to regulate GE organisms as GMOs. Non-governmental organisations (NGOs) were evenly split. A slightly higher proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate such organisms as GMOs.

- Respondents were asked if they considered that organisms produced by GE or other genetic technologies posed 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. Views were again split. Most individuals (87%) and businesses (64%) stated that there was a greater risk, whereas most academic institutions (63%) and public sector bodies (82%) stated there was a similar risk. NGOs were evenly split.[17]

The summary of consultation responses highlighted the following key themes:

- Those in favour of continuing regulation felt that whilst traditional methods have a history of being safe, the scientific understanding of gene editing was currently incomplete.

- Concerns were also raised around consumer choice and public trust, with many individuals in support of labelling.

- Those in favour of discontinuing regulation acknowledged the potential role of GE technologies in responding to sustainability and climate change issues and the benefits of GE technologies for farmers.

15 This is implemented by retained EU Regulation 1946/2003, which establishes a system for notifying and providing information for the transboundary movements of GMOs. The Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 provide for enforcement of this Regulation in England.

16 Consultation 20210106 Gene editing consultation document FINAL.pdf (defra.gov.uk)

17 Defra, Summary of responses to a consultation on the regulation of genetic technologies, 29 September 2021 [pdf]

- Many businesses and NGOs called for improving awareness and understanding of GE through public campaigns and better education.[18]

The Advisory Committee on Releases to the Environment (ACRE) advised Defra on its consultation and published its advice in full.[19] The advice addressed key potential safety concerns raised by some commentators about GE technology – this is discussed further below in the section on stakeholder views.

Government response and next steps

The Government's response to the consultation was published in September 2021. Defra said that its first step would be to "change the rules relating to gene editing to cut red tape and make research and development easier".[20]

Subsequently, in March 2022, the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 came into force. The SI amends the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (applying as EU retained law). The amendment means that genetically modified (GM) plants which could have occurred naturally or through traditional methods will be classed as "qualifying higher plants". Such plants will not be required to follow existing rules covering, for example, public consultation prior to their release. However, Defra must be notified prior to planting the seed (for germination/growing). Only plants released for "non-marketing purposes" are covered by the Regulation.

The House of Lords Committee on Secondary Legislation's report on the draft SI expressed concerns about a lack of guidance on the criteria for naturally produced/traditionally bred GMOs and on safeguards on the release of GMOs under the proposed Regulation. It saw strength in the argument that primary rather than secondary legislation would have been more appropriate for an issue of such strong public interest.[21] ACRE published guidance in April 2022 on techniques used to produced GE organisms and how the new Regulations apply to them.[22]

Defra's consultation response set out that the Government would "seek to bring forward primary legislation at a suitable opportunity" on the wider issues of regulatory definitions of GMOs and the regime for marketing

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18 As above, p14

19 ACRE advice concerning Defra's consultation on the regulation of genetic technologies - GOV.UK (www.gov.uk)

20 Defra, Summary of responses to a consultation on the regulation of genetic technologies, 29 September 2021 [pdf]

21 House of Lords, Secondary Legislation Scrutiny Committee, 29th Report of Session 2021–2, HL Paper 156

22 The Government has published ACRE's Guidance on Genetic Technologies that result in qualifying higher plants. This sets out more detail on various precision breeding technologies.[Research and analysis, Technical guidance on using genetic technologies (such as gene-editing) for making 'qualifying higher plants' for research trials, 11 April 2022

such crops. It said the legislation would amend the regulatory definitions of a GMO to exclude organisms that have genetic changes that could have been achieved through traditional breeding or which could occur naturally.[23]

More widely, the Government response said it would consider issues relating to the gene editing of animals, "recognising that any changes may come later, in light of due consideration being given to ethical questions raised in the consultation". There were no plans as part of this process to change the regulatory requirements for research involving microorganisms produced using genetic technologies.[24]

The response noted that legislative changes proposed in the consultation would not impact on other existing regulated product regimes, including Novel Foods and Animal Feed regulatory frameworks.[25] It said that the independent Advisory Committee on Novel Foods and Processes (ACNFP) supported the idea of a proportionate approach to the safety assessment of food that takes account of the scale of effect of any change on the food. The Government response added that:

> The ACNFP considered that off-target effects or the presence of recombinant DNA, whether intentional or unintentional, may pose no greater risk than traditional breeding. However, this is entirely dependent on the site and size of the off-target effect or recombinant DNA fragment. We will seek to ensure that any new regulatory measures will be designed to take account of this concern.[26]

The Government response also noted that regulations relating to GMOs are a devolved matter and that Defra would work closely with the devolved administrations of Scotland, Wales, and Northern Ireland "to understand the impacts of future policy changes on their territories".[27]

International approaches

The EU is planning changes to its regulatory regime. A recent EU study on the status of New Genomic Techniques questioned whether current EU regulations are fit for purpose. The European Commission has responded by launching a public consultation on the future regulation of gene editing techniques in EU crop production, with the intention of introducing proposals for a new legal framework in 2023.[28] The European Commission's consultation is on a proposal to create a legal

23 Defra, Response to Genetic Technologies Regulation consultation, 29 September 2021, para 5.2

24 Defra, Response to Genetic Technologies Regulation consultation, 29 September 2021para 4.1

25 Novel foods guidance from the Food Standards Agency states that novel foods are foods which have not been widely consumed by people in the UK or European Union (EU) before May 1997. This means that the foods don't have a 'history of consumption'. Such foods need to be authorised before they can be placed on the market in Great Britain (GB)

26 Defra, Response to Genetic Technologies Regulation consultation, 29 September 2022

27 Defra, Response to Genetic Technologies Regulation consultation, 29 September 2022, para 5.2

28 Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]

framework for plants obtained by targeted mutagenesis (the production of genetic mutations) and cisgenesis (where genes are artificially transferred between organisms that could otherwise be conventionally bred) and for their food and feed products. This aims to bring legislation in line with modern techniques. The Commission stated that the planned regulation aimed to maintain a high level of protection for human and animal health and the environment and would "enable innovation in the agri-food system and contribute to the goals of the European Green Deal". The consultation closes on 22 July 2022 with adoption of the proposal planned for the second quarter of 2023.[29]

The Government published information on international regimes for regulating GMOs in the Impact Assessment published with the Bill.[30] It said that progress on GE technology globally was moving ahead of the UK and the EU:

> Both UK and EU innovation in this space has stalled under the current regulatory regime compared to world leaders; only 4.8% of world patents in CRISPR-related agriculture[31] down from 5.9% in 2017.[32]

The IA cited Argentina as a model for a more "risk-proportionate regulation" that differentiated between GMOs and organisms produced by genetic technologies which could have been produced by traditional breeding. Canada bases its regulations on the properties of the organism, not on the technology by which it is produced. As the website Global Gene Editing Regulation Tracker notes:

> Canada takes a unique stance on gene editing by regulating any products that contain novel traits, including gene edited animals, regardless of the process (e.g. conventional breeding, mutagenesis, transgenesis or gene editing) used to develop the product. Any animals that contain novel traits require environmental and safety assessments to be approved. Most mutagenic products currently being developed are not considered organisms with novel traits, and it is likely that this will also be the case for most gene edited organisms, which will therefore be regulated as conventional.[33]

Trade Issues

Defra's factsheet referred to the potential impact on trade of aligning UK regulation with other countries' approaches:

> Argentina, Brazil, Canada, Japan, and the US have taken a different approach to the EU in deciding that organisms that could have been produced by traditional breeding techniques are not to be regulated as

29 European Commission: Legislation for plants produced by certain new genomic techniques, 29 April 2022
30 Genetic Technology (Precision Breeding) Bill Impact Assessment [pdf]
31 CRISPR (short for "clustered regularly interspaced short palindromic repeats") is used to selectively modify the DNA of living organisms. CRISPR/Cas9 has two essential components: a guide RNA to match a desired target gene, and Cas9 (CRISPR-associated protein 9)—an endonuclease which causes a double-stranded DNA break, allowing modifications to the genome
32 Genetic Technology (Precision Breeding) Bill Impact Assessment [pdf], p10 (Box 2)
33 Global Gene Editing Regulation Tracker, Canada [Accessed 31 May 2022]

> GMOs. In 2018, 13 countries issued a joint statement to the World Trade Organisation, stating that governments should "avoid arbitrary and unjustifiable distinctions" between those crops developed through precision breeding technologies, such as gene editing, and those developed through conventional breeding.

The factsheet added that the Bill would enable the creation of potential new export markets for UK-based producers and "could also lead to a greater willingness of companies to invest and sell products in the UK relative to the EU due to the creation of a more favourable regulatory environment". Although it is consulting on possible changes, as noted above, the EU currently regulates the use of all genetic technologies such as precision breeding as GMOs. This means any precision bred products entering the EU from Great Britain will need to be authorised and labelled as GMOs. [34]

[34] Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]

3 How will the Bill change regulation of precision breeding?

3.1 What are the broad aims of the Bill?

The Government said the Bill would remove "unnecessary barriers inherited from the EU" to enable the development and marketing of precision bred plants and animals. This would "drive economic growth and position the UK as the leading country in which to invest in agri-food research and innovation".[35]

The Government said the main benefits of the Bill would be:

> Enabling precision breeding technologies to improve the sustainability, resilience, and productivity of agricultural systems. Technologies such as gene editing have the potential to increase disease resistance in crops, which can reduce pesticide use, lower costs to farmers and increase food production.
>
> Unlocking innovation to help us cement our place as a science superpower, and to help meet the ambitions in the Government's 25 Year Environment Plan.[36]

The Government described the primary policy objective of the Bill as ensuring "plants, animals, and food and feed products developed using precision breeding technologies are regulated proportionately to risk" by introducing "simpler regulatory measures" allowing these products to be sold more easily. [37]

The Government acknowledged concerns about animal welfare:

> Whilst there is great potential for increasing innovation, we recognise that there is a need to safeguard animal welfare in the new regulatory framework. That is why we are taking a stepwise approach, enabling commercial use of precision breeding technologies with plants first followed by animals later.[38]

There are four key policy changes in the Bill:

- Remove plants and animals produced through precision breeding technologies from regulatory requirements applicable to the

35 Queen's Speech Lobby Pack, 10 May 2022
36 As above
37 As above
38 As above

environmental release and marketing of GMOs (Genetically Modified Organisms),

- Introduce two notification systems; one for precision bred organisms used for research purposes and the other for marketing purposes. The information collected will be published on a public register on GOV.UK.

- Establish a proportionate regulatory system for precision bred animals to ensure animal welfare is safeguarded. We will not be introducing changes to the regulations for animals until this system is in place.

- Establish a new science-based authorisation process for food and feed products developed using precision bred organisms.[39]

The way in which these broad changes are incorporated in the Bill is set out in more detail in the section below on The Bill: Clause by Clause.

The Bill does not cover the use of GMOs in medicines, vaccines, research in humans or human genome editing.[40]

Rationale for the changes

The Government considers that GMO legislation, developed 30 years ago, has "not kept pace with our knowledge of precision breeding technologies, such as gene editing". It stated that since the 2018 European Court of Justice [pdf] ruling that GE organisms are regulated as GMOs, "around 40% of small businesses and 33% of larger companies involved in plant breeding in Europe have stopped or reduced research and development activities relating to precision breeding technologies".[41]

The Government considers that GE technologies could help improve crop yields by increasing their resistance to pests and climate change, as well as developing foods with health benefits, such as reduced cancer-forming properties or enhanced vitamin content.[42] (Some examples of such products developed or in development are set out in Chapter 1.) Defra's factsheet notes that greater use of GE technologies could:

> reduce the need for pesticides, increase food production and reduce costs to English farmers. Precision breeding can also enhance the health and welfare of animals through greater resistance to diseases and reduced use of antibiotics, and improved resilience to the impacts of climate change.[43]

39 Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]
40 Genetic modification is used in the production of certain medicines and vaccines, such as insulin and the hepatitis B vaccine. Clinical trials (research in humans) may also involve genetically modified microorganisms.
41 Defra, Impact Assessment, p8 [pdf]
42 Queen's Speech Lobby Pack, 10 May 2022
43 Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]

The Government also said that it wanted to "drive UK innovation and investment to help make a positive impact on the food system and generate wider benefits into the UK economy".[44]

The Bill's Impact Assessment (PDF) notes the new regulatory framework for precision bred organisms would:

> contain aspects of both the GMO legislative framework, which will remain in place for all other organisms made using modern biotechnology, and the framework as it applies to traditionally bred organisms. As such, the level of regulatory scrutiny is somewhere between that of GMOs and traditionally bred organisms.[45]

According to the IA, it should cost less to take a precision-bred crop to market, compared to the current GMO process. These savings would predominantly benefit the plant breeding sector, but also, indirectly, the rest of the food chain. The IA estimates the overall time taken to comply with existing regulation for getting precision bred crops to market will be reduced from around 10 years to 12 months.[46]

3.2 How does the Bill affect the UK nations?

The Defra factsheet [PDF] accompanying the Bill notes the regulation of the production, release into the environment and marketing of precision bred plants and animals, and food and feed derived from them, are devolved matters.

The provisions of this Bill generally apply in relation to England only. The main exception is that, as Clause 41 amends the Environmental Protection Act 1990 which extends to England and Wales and Scotland, that clause (and the definitions in Part 1 of the Bill to which those amendments refer) likewise extend to England and Wales and Scotland. The general provisions in clauses 42 to 48 extend to England, Wales, Scotland and Northern Ireland.[47]

Response from Scotland and Wales

Currently, both the Scottish and Welsh Governments want precision bred organisms to continue to be regulated as GMOs in their territories.[48]

The Welsh Government policy position on GM [PDF] maintains a "precautionary and restrictive approach "to the growing of GM crops within the parameters of legislation. The Scottish Government has long been opposed to genetic modification in food production, announcing a

44 Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]
45 Defra, Impact Assessment, figure 4 [pdf]
46 Defra, Impact Assessment, p26 [pdf]
47 HCB 11, Explanatory Notes [pdf]
48 Defra, Genetic Technology (Precision Breeding) Bill Factsheet 1 – Overview, May 2022 [pdf]

ban on genetically modified crops in 2015. The Scottish Government has also said it would block the "imposition" of this Bill in Scotland and wished to consider the implications of the legislation further.[49] Regulation in Northern Ireland on GMOs continues to follow EU rules.[50]

Despite this, the Bill could have consequential implications for Scotland and Wales because precision bred products that can be legally produced in or imported into England can be legally placed on market in Scotland and Wales (but not Northern Ireland). The Explanatory Notes state this is without the need for consent under Part 6 of the Environmental Protection Act 1990. It says:

> The mutual recognition principle in the United Kingdom Internal Market (UKIM) Act 2020 will apply to precision bred plants and animals, and food and feed derived from them, which are produced in or imported into England, meaning that it would be possible to place them legally on the market in Scotland and Wales if they can be marketed lawfully in England as a result of this Bill and the delegated legislation to be made under it. Owing to the Northern Ireland Protocol, precision bred organisms and food and feed derived from them will only be able to be imported into Northern Ireland if they undergo a full GMO authorisation.[51]

Opposition to changes in England

Some organisations are opposed to the unilateral changing of GE regulation by England. Organisations opposed to GM regulatory changes wrote to UK supermarket CEOs in 2021, highlighting the potential impact on the operation of the UK internal market and the UK nations' ability to pursue their own approaches. They said it could create "consumer confusion" and problems for retailers:

> The push for deregulation has ramifications for trade and we particularly note Stormont's concern about negative consequences for trade with Northern Ireland, as these products are unlawful in the EU. We are very aware of the very real difficulties your stores are experiencing having to deal with dual regulations in your Northern Ireland retail estate. Deregulation has the very real potential to compound these difficulties significantly. The Scottish and Welsh Governments have been clear that they will maintain their prohibition on producing GMO crops and animals, but UK internal market rules could stop them taking action to prevent sales of GMO products approved in England. This is a recipe for consumer confusion and significant operational difficulties for retailers.[52]

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49 Holyrood, Scottish Government says it will block Westminster bid to impose GM food technologies on Scotland, 25 May 2022

50 Regulation in Northern Ireland remains aligned with the EU regulations under the Northern Ireland Protocol.

51 HCB 11, Explanatory Notes [pdf]

52 Beyond GM, GM Freeze, Soil Association and others, Joint letter to supermarket CEOs on deregulation of gene editing, 29 January 2021

Labelling genetically edited products

There are also concerns about transparency for consumers. Ministers have said that food and feed from precision bred organisms is unlikely to need to be labelled as such.[53] This could be a particular issue for products authorised under this legislation in England which are placed on the market in other UK nations.

However, farmers in Scotland want the approaches in this Bill to be considered in Scotland. The NFU Scotland (NFUS) called for the Scottish Government to "examine, properly and thoroughly, the case for developing precision breeding techniques within Scotland". The NFUS said that:

> Scottish Government Ministers had recognised that precision breeding techniques have potential to improve sustainability, respond to the climate emergency and reduce the need for pesticides.
>
> This recognition is welcome: we strongly maintain that there are a multitude of positive sustainability benefits which could accrue from the adoption of this new technology.[54]

53 inews, Gene-edited mushrooms and tomatoes could hit supermarket shelves next year, 20 May 2022

54 NFU Scotland, Statement on Precision Breeding Techniques, 6 November 2020

4 How do stakeholders think precision breeding should be regulated?

4.1 Overview

Regulation of GM food and feed is controversial. There were markedly different responses to the Defra consultation in 2021 on the future regulation of precision breeding techniques [pdf].[55] The Department published a summary of responses in July 2021.[56] As noted above, most individuals (88%) and businesses (64%) supported continuing to regulate such organisms as GMOs. Non-governmental organisations (NGOs) were evenly split (50%). A slightly higher proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate such organisms as GMOs. In terms of whether respondents considered that organisms produced by GE or other genetic technologies posed 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, views were again split. Most individuals (87%) and businesses (64%) stated that there was a greater risk, whereas most academic institutions (63%) and public sector bodies (82%) stated there was a similar risk. NGOs were evenly split.[57]

Farmer groups such as the National Farmers' Union have welcomed the Bill's proposed changes because they offer benefits to the agricultural sector.[58] NFU Vice President David Exwood said that:

> This science-based legislative change has the potential to offer a number of benefits to UK food production and to the environment and will provide farmers and growers with another tool in the toolbox as we look to overcome the challenges of feeding an ever-growing population while tackling the climate crisis.[59]

55 Defra, Consultation on the Regulation of Genetic Technologies, January 2021 [pdf]
56 Defra, Summary of responses to a consultation on the regulation of genetic technologies, 29 September 2021 [pdf]
57 As above, p4
58 NFU Consultation Response, A public consultation on the regulation of genetic technologies, March 2021
59 BBC News, Government sends gene-edited food bill to Parliament, 27 May 2022

The livestock sector largely welcomed the inclusion of animals in the proposed new regulatory framework. For example, the National Pig Association (NPA) said that:

> Genetic technologies such as gene editing offer us the opportunity to speed up the improvements we make from natural breeding – with breakthrough work such as Porcine Reproductive and Respiratory Syndrome (PRRS) resistant pigs already having begun we know there is huge benefit to not just for the health and welfare of our pigs, but also the productivity of our national pig herd. NPA has called for legislative reform to enable the research, and subsequent application, of technologies such as gene editing for a long time.[60]

However, the NPA expressed some concerns about the impact of differing rules on the trade of GE products. The horticultural sector, whilst also welcoming the broad approach, expressed some reservations on this point too. The British Tomato Growers' Association warned that there had been a lack of consultation by the Government with the food sector leading to a disconnect between researchers and the industry.[61]

Other groups, such as Beyond GM and GM Freeze more strongly oppose the Government's broad approach to GM policy.[62] Liz O'Neill, director of GM Freeze, a non-profit that campaigns for a moratorium on GM farming in the UK, warned that unregulated gene editing was "a food crisis in the making" as "gene editing is GM with better PR".[63] Friends of the Earth considered that that gene editing is genetic modification by a different name: "It still focuses on altering the genetic code of plants and animals to deal with the problems caused by poor soils, the over-use of pesticides and intensive farming".[64] Pat Thomas, from Beyond GM, said in a 2021 blog that the Government's overall approach to GE was:

> not about food or farming. It's not about climate, or biodiversity or feeding the world. [It is…] the result of a blind faith in entrepreneurs over farmers, cut and paste technology over acquired knowledge and skill and, ultimately, in business-as-usual over urgently needed transformation.[65]

Many scientific bodies responded positively to the publication of the Bill. The scientific community in the main considers gene editing technologies to offer a safe method to develop new crops and livestock. The Bill's Explanatory Notes state that the Bill aligns with the scientific view of groups such as the EU Commission's Scientific Advice Mechanism, the European Academies' Scientific Advisory Council and the UK's Royal Society, as well as the Advisory Committee on Releases to the Environment (ACRE), which "consider that it is the nature of the genetic

60 National Pig Association, New Bill to unlock genetic opportunities, 13 May 2022
61 The Grocer, Fresh produce industry urges government caution following gene editing announcement , 26 May 2022
62 Beyond GM, Response to Defra Consultation on Deregulating Gene Editing, 17 March 2021
63 The Grocer, Fresh produce industry urges government caution following gene editing announcement , 26 May 2022
64 The Guardian, Gene editing could increase food security, UK adviser says, 25 May 2022
65 Pat Thomas, Farming the Future Blog, Deregulating gene editing – opening a door to what, exactly? 26 November 2021

change – and not the technique by which it was produced – that determines the risk posed by an organism and should therefore determine whether an organism should be regulated as a GMO".[66]

The Explanatory Notes also state that Defra's public consultation held from 7 January to 17 March 2021 on genetic technologies "received no new scientific evidence indicating that precision pred organisms should be regulated as Genetically Modified Organisms (GMOs), and many responses expressed the view that GMOs are demonstrably different to the products of precision breeding".[67]

4.2 Concerns over unintended consequences

Some stakeholders opposed to any relaxation in the regulation on genetically edited organisms focus their concerns on the lack of knowledge about unintended consequences of the use of this technology. These concerns relate to consequences both at an individual organism level, when the technology makes genetic changes unintentionally, and at an environmental level. For example, the Soil Association said that:

> The outcome of gene-editing is to manipulate and alter the genome in a laboratory to make a new organism. This is the very definition of genetic engineering, and gene-editing risks introducing similar uncertainties and unintended consequences as genetic modification of DNA.[68]

Friends of the Earth published a report in September 2018 highlighting unintended consequences that it considered could arise from the use of genetic editing techniques. The report noted that:

> In the U.S., companies are racing to incorporate genetically modified organisms (GMOs) produced using new genetic engineering technologies such as CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) and other "gene editing" (or "genome editing") techniques into our food system with little to no oversight and public disclosure, despite scientific research that is demonstrating the potential for significant unintended consequences. For example
>
> […] studies found that gene-edited plants such as soybeans had off-target effects, in which gene editing occurred at unintended locations with DNA sequences similar to the targeted location.[69]

The report cited additional concerns about gene editing applications in agriculture as including "increased agrochemical use, effects on pollinators, impacts from stacking genetically engineered traits and genetic contamination of crops' wild relatives". It called for more

66 HCB 11, Explanatory Notes, para 5 [pdf]
67 HCB 11, Explanatory Notes, para 6 [pdf]
68 Soil Association news release, Gene-editing technologies pose risks, 30 November 2018
69 Friends of the Earth UK and US, Gene-edited organisms in agriculture: Risks and unexpected consequences, summary, 12 September 2018 [pdf]

research to understand the implications of CRISPR and other engineering techniques on non-target genes and surrounding ecosystems.[70]

The report expressed particular concerns about the use of "gene drives". An example of this approach is genetically engineering mosquitoes to prevent effective reproduction, thus reducing the mosquito population as a vector of diseases or altering the genes of agricultural pests to suppress their populations. The report stated that:

> Gene drives, using CRISPR, are proposed to engineer the genetics of entire populations by forcing a specific trait through generations of a species and bypassing the process of natural selection. Once released, gene drive organisms cannot be recalled, and any changes to the genetic makeup of the population they induce are most likely irreversible. Hence, the genetic changes to a population are likely to persist for a very long time, possibly permanently. This may result in far-reaching and unpredictable consequences for society and the environment.[71]

Many of these issues have been addressed by the Advisory Committee on Releases to the Environment (ACRE).

Advisory Committee on Releases to the Environment (ACRE) advice to Defra

The Advisory Committee on Releases to the Environment (ACRE) advised Defra on its consultation and published its advice in full.[72] The advice addressed key potential safety concerns raised by some commentators about GE technology: firstly unintended or 'off-target' effects which are known to sometimes occur during gene-editing; and secondly the unintentional introduction of DNA from a different species to the one undergoing gene editing.

On the first, ACRE concluded that there was "no scientific reason to suppose" that GE techniques which led to 'off-target' alterations in DNA sequences would result in "greater safety concerns" than those which result from other forms of mutagenesis.[73] ACRE said that:

> Indeed off-target effects introduced by GE methods are very significantly rarer than those produced during the course of conventional methods of plant breeding. Similarly, there is good evidence to suggest that GE-induced mutagenesis in animals is no greater than the background rate of de novo mutation. However, from a regulatory perspective, it is clear that most countries who have reviewed their assessment procedures for GE organisms, have also acknowledged the importance of providing a degree of assurance either that no exogenous DNA has been inserted, and/or that no unacceptable risks are presented by the new trait.[74]

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70 As above

71 As above

72 ACRE advice concerning Defra's consultation on the regulation of genetic technologies 29 September 2021

73 Mutagenesis is the process by which mutations are induced in the cells of organisms. Mutations can have beneficial effects, deleterious effects, or no consequences in organisms.

74 ACRE advice concerning Defra's consultation on the regulation of genetic technologies, 29 September 2021

On the second issue, ACRE noted that the phenomenon of unintended introduction of DNA from other species has been observed most notably during the production of gene-edited animals:

> After DNA strands are cut by the gene editing 'machinery' at a predetermined site, their repair is driven by the cell's own mechanisms. If left to chance, the repair process is random, with nucleotides from within the cell or the surrounding media occasionally being incorporated in the repair. Since bovine or caprine serum is frequently used in culture media for mammalian embryos, this has led to reports of bovine or caprine sequences being incorporated into target sites.
>
> This effect can be mitigated to some extent by using a repair template, but some unintended insertions although uncommon have been reported in the past (below), which may suggest that some level of genome screening at target sites prior to establishing pregnancies may be useful if a high level of insertion accuracy is required. Avoiding the need to use bovine and caprine serum in culture media would also be expected to reduce the level of risk for target site 'contamination', and research is on-going in that area.[75]

The ACRE advice noted that 2020 a paper was published which reported that the genomes of two polled (hornless) Holstein bulls produced in 2015 were found to include unintended DNA from the carrier plasmid. However, ACRE noted that:

> the presence of the plasmid DNA had no observable effects on the bulls' natural development (or expression of the polled characteristic) or that of the progeny of one of the bulls which were produced and screened in a later study. Further, it is important to note that the use of a carrier plasmid was a requirement for the specific editing technology used in the study. A carrier plasmid would not be required when using CRISPR-Cas9, which is the technology now most commonly used.

ACRE's advice to Defra also addressed a further concern: that GE organisms, and/or the genetic material of GE organisms, might become preferentially established in the environment and cause harm. ACRE noted that, in plant breeding over millennia, humans have "tended to select against the ability to persist in the environment so that farmed crops are now generally unable to do so". ACRE added that:

> in animal breeding a combination of contained management systems and high levels of domestication mean that very few 'wild' crossable populations remain especially in the UK. In our view this makes the transfer of genetic material to wild animal populations very unlikely. Furthermore, GE relies on the creation of the same types of genetic variation that are selected for in traditional breeding.[76]

ACRE concluded that "there is no scientific reason that the application of GE technology for crop and livestock improvement would lead to a

75 As above
76 As above

greater likelihood of persistence of these organisms in the wider environment, which is rarely observed for traditionally bred organisms".

However, ACRE cautioned that different parameters applied to the potential environmental release of GE micro-organisms:

> given the high levels of horizontal gene transfer that are known to occur between micro-organisms in natural environments, gene flow is more likely to be a realistic possibility. This should be an important consideration in the context of developing any new regulatory procedures for micro-organisms produced using gene editing and/or other genetic technologies.[77]

It said it would be important to consider micro-organisms separately to plants and animals when developing new regulatory procedures for GE organisms. Micro-organisms are outside of the scope of the Bill (which applies to plants and vertebrate animals, excluding humans at all stages of development).

4.3 Animal health and welfare

The Government has said that the application of the Bill's measures to precision breeding of animals will not take place until an appropriate regulatory regime is in place. Nevertheless, the Bill provides powers for the Secretary of State to introduce the measures by secondary regulation, rather than primary legislation. The inclusion of animals in the proposed regulatory changes raises issues about the health and welfare of farmed animals. There are animal welfare benefits claimed from the use of GE, for breeding disease resistant animals for example, but some stakeholders warn of the need to ensure that animal welfare is not compromised by breeding to select certain traits.

3 Animal welfare legislation and codes of practice

Animal welfare is devolved in the UK. The approach and legislation are similar in all four devolved administrations, with the following key pieces of legislation:

The Animal Welfare Act 2006 which covers England and Wales.

The Animal Health and Welfare (Scotland) Act 2006

The Welfare of Animals Act (Northern Ireland) 2011

[77] Defra, Response to Genetic Technologies Regulation consultation, 29 September 2022, para

The legislation applies to farm and companion animals. All make it an offence to cause unnecessary suffering to an animal in one's care by an act, or by a failure to act. It is also an offence not to take reasonable steps to meet the needs of an animal in your care. The needs listed in legislation include the need:

- for a suitable environment
- for a suitable diet
- to exhibit normal behaviour patterns
- to protected from pain, suffering, injury and disease.

In addition to primary legislation there is a range of secondary legislation, including the Welfare of Farmed Animals (England) Regulations 2007. There are also Codes of Practice for specific farmed animals, which provide guidance on complying with the legislation. There are similar codes of practice for dogs, cats, horses (and other equidae) and privately kept non-human primates. It is not an offence to fail to comply with the Codes of Practice, although failure to do so could be considered evidence of failure to comply with the legislation.

Animal experiments, which includes genetically modified and edited animals, are regulated through the Animal (Scientific Procedures) Act 1986.

The Animal Welfare (Sentience)Act 2022 recognises vertebrates and some invertebrates as sentient, and provides for an Animal Sentience Committee that will be able to scrutinise and report on whether the Government is taking into account the adverse effect of any policy "on the welfare of animals as sentient beings". The ASC will not have an advisory or enforcement role.

The December 2021 Nuffield Council on Bioethics report genome editing and farmed animals noted that:

> Genome editing is the precise, targeted alteration of a DNA sequence in a living cell. In farmed animal breeding, it could be used to produce animals with specific traits that might be difficult to achieve using conventional selective breeding approaches. For example, it could be used to make animals that are resistant to certain viruses, saving many animals from the effects of disease and bringing economic benefits to the agricultural sector.

The report however cautioned that a reduction in the risk from disease should not be used as a reason to pay less regard to the welfare of animals and their needs for appropriate conditions and care:

> Without appropriate checks and controls in place to guide the use of genome editing, its introduction into farmed animal breeding risks

> becoming a new route by which to accelerate some existing unethical breeding practices in the current system".[78]

A key conclusion of the Nuffield Council on Bioethics was that a revision of the regulatory regime be preceded by a "thoroughgoing policy review that addresses the effects of any proposed change on the wider food and farming system". It added that the development of policy, law and regulation on new farmed animal breeding techniques be informed by public views. The Council recommended further that:

> All commercial breeders of farmed animals should adopt an explicit and recognised set of breeding standards, with independent oversight. We recommend the development of more detailed breeding standards (than those currently available) that may be enforced by a national competent authority. In particular, these should seek to ensure that animals are not bred to enhance traits merely so that they may better endure conditions of poor welfare, or in ways that reduce their capacity to live a good life. [79]

The Council also recommended the adoption of breeding indices that "reflect characteristics of animals that are of public or social, as well as economic, value should be explored as a possible regulatory measure". It proposed a 'traffic light' system to assess the impact of breeding programmes on the lives of animals:

> Animals assessed to be in the 'red' category – where targeted breeding programmes have led to the production of animals with physiological traits that make it difficult for them to enjoy a good life – should not be used in commercial farming. This category might include, for example, fast-growing lines of broiler chicken. However, we envisage this approach working in an anticipatory way, to sound a warning when breeding is overreaching and to steer it towards more desirable outcomes. This system would apply to commercial breed developers and would need to be overseen by an independent regulatory authority. We also recommend that an independent body should monitor the longitudinal development of breeding lines and report on these matters to the public authorities responsible for the oversight of farmed animal breeding.[80]

Responding to the publication of the Bill, Peter Mills, Assistant Director at the Nuffield Council of Bioethics tweeted that elements of what the Nuffield Report had argued for were included in the framework for regulation, but the Bill included no overall "anticipatory and democratic forms of governance". This meant that:

> we are asked to place our faith in the probity of technologists and technocrats. There is little space in this for anticipatory and democratic forms of governance, or the pursuit of a coherent vision of the future food and farming system which is arguably what is needed to address the multiple challenges facing our food and farming system. The Bill will

78 The Nuffield Council on Bioethics, Genome editing and farmed animals December 2021

79 As above

80 The Nuffield Council on Bioethics, Genome editing and farmed animals December 2021

> though, no doubt, give a fillip to the UK's ambitions as an international service provider of advanced science and technology.[81]

Mr Mills noted that many details of the system would be determined by regulations and not debated with the Bill.[82]

Animal welfare charities have also expressed reservations about amending regulation of precision bred animals. The RSPCA expressed "serious concerns" about the GE process in responding to the Government's 2021 consultation. It cited the following reasons:

- There is no history of safe and reliable use;
- Genetic technologies can cause unpredictable and unintended changes to the genome;
- Not enough is known about the medium to long term effects on animal health and welfare;
- The current rules and regulations around GMOs are still essential for regulating GEs until there is greater scientific evidence available;
- There are alternative approaches to achieving the proposed benefits of genetic technologies e.g. reducing food waste, with 12% of all meat and animal products produced globally lost or wasted every year, and improving animal husbandry;
- GE products have been withdrawn from approval in the USA following the Regulator's concerns on the transfer of other genes during the GE process;
- GE produced food could be forced onto supermarket shelves in Scotland and Wales despite those countries objecting to its production and sale.[83]

Compassion in World Farming expressed several concerns about the Bill's potential to impact negatively on farmed animal welfare:

> Whilst it appears the Bill's focus is to speed up production of gene-edited crops – gene-editing proposals must not be extended to farm animals simply to enable them to cope better with the overcrowded and unnatural conditions on intensive factory farms.
>
> Gene editing for increased disease resistance will be beneficial in some cases. However, many diseases arise from animals being kept in crowded, stressful conditions. Precision technology should not be used to mask the

81 Peter Mills (@PeterFRMills) "A quick thread on the publication of the Genetic Technologies (Precision Breeding) Bill, pending a longer response to follow." (Twitter), 26 May 2022 [accessed 9 June 2022]. Available from: https://twitter.com/PeterFRMills/status/1529875243891924997

82 As above

83 RSPCA webpages, Wales/Gene Editing [accessed 31 May 2022]

adverse health effects of intensive farming methods, allowing animals to continue to suffer in conditions of poor welfare.[84]

CIWF further said that using gene editing was likely to "push animals to faster growth and higher yields" and "exacerbate the severe welfare problems that have arisen through selective breeding for increased productivity". The organisation cited selective breeding of broiler chickens for fast growth, which led to millions each year suffering from painful leg deformities, and genetic selection for high milk yield being the major factor causing poor welfare and health problems in dairy cows. CIWF acknowledged some benefits of precision technologies, such as preventing the development of male chicks to "avoid the industry practice that sees millions of them inhumanely killed every year". However, CIWF called for the legislation to be phrased to exclude the use of this technology for "applications that will perpetuate factory farming systems that inherently cause suffering".[85]

4.4 Labelling

Defra Secretary of State, George Eustice, is reported to have said that precision bred organisms created under the Bill's framework will not have to be labelled as such because they are "fundamentally natural". This is a concern to groups such as GM Freeze which warned that the bill "would lead to the removal of labels that allow consumers to choose what they are buying and eating".[86]

Defra's summary of responses to its 2021 genetic technologies consultation noted that labelling was a key issue for many consumers. Concerns were raised around consumer choice and public trust, with many individuals in support of labelling.[87]

The Food Standards Agency (FSA) published the result of a survey of consumer views of labelling of genome edited food in 2022. This found that "some participants felt regulation and transparent labelling of GE foods would be important, should they reach the UK market".[88] Key findings of the survey included:

- Most consumers felt labelling should always inform the consumer of the presence of GE ingredients using the full term 'genome edited'.
- Overall, consumers wanted thorough regulation and transparent labelling if GE foods reach the UK market, and they suggested social

84 Compassion in World Farming news release, Fear gene editing Bill proposals will drive further factory farming, 25 May 2022
85 As above
86 The Guardian, Gene editing could increase food security, UK adviser says 25 May 2022
87 Defra, Summary of responses to a consultation on the regulation of genetic technologies, 29 September 2021 [pdf]
88 Food Standards Agency news release, UK consumers give their views on genome edited food, last updated 9 May 2022

> media information campaigns and TV documentaries would help educate the public on GE food.[89]

The December 2021 Nuffield Council on Bioethics report genome editing and farmed animals recommended that:

> Labelling of foods containing animal products should include scientific advice on food safety, nutrition, and health, and provide access to traceable attributes of interest to consumers, which may include factors such as breeding practices and technologies used; the animal's living conditions and diet; region of origin; and the ways in which products are processed.[90]

As noted above, a lack of labelling of GE products is likely to be a contentious issue for the sale of GE products from England in other UK nations.

89 Food Standards Agency webpage, Consumer perceptions of genome edited food 21 July 2021
90 The Nuffield Council on Bioethics, Genome editing and farmed animals December 2021

5 Political views

There is some consensus between the Government's position and the Labour Party position about the value of using genetic technologies to improve food security and improve health. The Labour Party's 2013 Feeding the Nation report stated that biotechnology "can be one of the tools used to ensure better resilience in the UK food chain, and to reduce environmental damage" . A further statement reiterated that "GM may have a role in UK food security and environmental protection" although the Party recognises that "public views – informed by science – must also be heard".

Labour Defra spokesperson, Daniel Zeichner, said in the March 2022 debate on the draft Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 that "Labour is pro-science and pro-innovation. We want our scientists to succeed and use their skills for good here in the UK, and we know that crop development and innovation has brought us all huge gains". However, he said:

> it is right to be careful, because this is about balancing risks, knowing that alongside the benefits—which absolutely should include significant environmental gains, such as reduced use of pesticides—there may be the danger that either mistakes are made, or there are things we simply do not know. That cannot paralyse us from action, because every intervention has risks attached, but we need a system that allows us to manage those trade-offs and those risks. [91]

Mr Zeichner raised questions about the definition of organisms that could have been bred by traditional methods as the basis for regulation:

> The Roslin Institute says:
>
> "It is exceptionally challenging to define which changes to the genome could have been produced by 'traditional' breeding."
>
> The Royal Society says:
>
> "This question is problematic as there is a difference between what could be produced by traditional breeding in theory and in practice".
>
> The Royal Society of Biology says:
>
> "No clear criteria can be described that would determine whether an organism produced by genome editing or other genetic technologies could have been produced by traditional breeding. This means no clarity can be

[91] Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022, Delegated Legislation Committee, 2 March 2022, c5

> achieved using this principle, and it is not appropriate as the basis of regulation".[92]

Mr Zeichner also noted that there were challenges around the operation of the internal market given that "the Scottish and Welsh Governments have expressed concerns and are not pursuing equivalent changes" so different parts of the UK would be taking different approaches.[93]

The Liberal Democrats are largely in agreement with the other two parties on GM. In 2013 Lady Parminter (the Lib Dem spokesperson on Food, Environment and Rural Affairs) said that "Lib Dems are not opposed to GM" and that it "should be a science-led decision".

The Green Party's General Election manifestos have opposed genetic engineering, considering that the technology would "not solve the problems created by industrialised agriculture and it may add to them". The Party stated that GM crops simply "secure large profits for a few multinational companies" and that "the use of GM crops in poor countries has proved disastrous to farming communities". The Greens promised that if in power they would "uphold the rights of consumers, farmers and local authorities to choose GM-free food and to establish GM-free zones". Green Party Peer, Baroness Jones, said during a Lords debate in March 2022 that GM technology was:

> not properly regulated in the past and created a public backlash we are still living with today. The public rightly want to be assured, on both public health and environmental grounds, that the existence of artificially modified organisms in the land and air, and ultimately in their food, is safe. If we are to persuade them that this is the case, we need to proceed with the best independent scientific evidence and the utmost transparency.[94]

The Scottish National Party said that the SNP Scottish Government took the decision to opt out of the use of GM crops to protect Scotland's environment and support Scottish agriculture:

> Scotland is world renowned for its natural, high quality food and drink, and this is greatly promoted both at home and abroad by our reputation for being clean and green. This is a key strength of Scottish agriculture – so it's important that we take steps to protect this.
>
> The use of GM crops could threaten the integrity of this brand, and therefore banning their cultivation is central to its protection and promotion.
>
> We will maintain our status of GM free cultivation.

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92 Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022, Delegated Legislation Committee, 2 March 2022, c7

93 As above, c9

94 Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022, HL Deb 14 March 2022, vol 820, col 126& 127

As noted in sections above, the Scottish Government does not support "imposition" of the measures in the Bill on Scotland.

6 The Bill: Overview

The Genetic Technology (Precision Breeding) Bill [pdf] was introduced to the House of Commons on 25 May 2022. The Parliament Bill page includes Explanatory Notes, an Impact Assessment, Delegated Powers Memorandum and a Defra factsheet.

The Bill "makes provision about the release and marketing of, and risk assessments relating to, precision bred plants and animals, and the marketing of food and feed produced from such plants and animals; and for connected purposes".[95] Whilst discussion on the Bill has focused on agricultural applications, the Bill provides broader powers and does not include the detail of what applications would fall within regulations. For example, it does not specify whether plants or animals that fall under the marketing regime would be for agricultural use only.

The Bill has 48 clauses, split into five sections:

- Part 1: Precision bred organisms: definitions.
- Part 2: Precision bred organisms: release, marketing and risk assessments.
- Part 3: Food and feed produced from Precision bred organisms.
- Part 4: Enforcement.
- Part 5: General provisions.

General purpose of the Bill

As set out in the Explanatory Notes to the Bill [EN, pdf], the Bill aims to reduce "the regulatory burden and financial barriers in place for researchers and commercial breeders using precision breeding technologies". It removes plants and animals produced using modern biotechnologies, and the food and feed derived from them, from Genetically Modified Organisms (GMO) regulation if those organisms could have occurred naturally or been produced by traditional methods. The EN states that the Bill "replaces GMO controls with more proportionate and scientific measures".[96]

The Bill includes provisions to:

95 Genetic Technology (Precision Breeding) Bill [pdf], HCB 11, 25 May 2022

96 HCB 11, Explanatory Notes [pdf]

- Bring in two mandatory notification systems for precision bred organisms (PBOs): one for non-marketing purposes (research and development) and one for marketing purposes;
- Allow for new powers to introduce on-going obligations to report information relating to the health and welfare of precision bred vertebrate animals, and to prescribe the processes and powers the Secretary of State can use to take the necessary action in response to this post-marketing animal welfare information;
- Create a duty on the Secretary of State to create and maintain a new public register of notified information. The register is to be kept in electronic form and accessible on gov.uk;
- Grant powers to create a new regulatory framework for food and feed derived from PBOs, ensuring that appropriate regulation is in place before placing these products on the market. This framework will include a procedure for making precision bred food and feed marketing authorisations including a new proportionate risk assessment. The framework will also set out the requirements to be satisfied before the Secretary of State could issue a food and feed marketing authorisation;
- Grant powers for the Food Standards Agency (FSA) to establish, publish and update a public register for PBOs authorised for food and feed use. An entry on this register would indicate that the Secretary of State has made a determination to authorise the PBO, and products derived from it to enter the market for food and feed uses based on the recommendation of the FSA;
- Grants powers to create an inspection and enforcement regime, including civil sanctions, in order to secure compliance with the obligations under the Bill.[97]

Delegated powers

Defra's Memorandum for the Delegated Powers and Regulatory Reform Committee [pdf] states that the Bill contains three Henry VIII powers (i.e. a power that allows legislation to be amended by secondary legislation, subject to varying degrees of scrutiny). The Memorandum sets out the purposes for which the delegated powers may be used.

Money Resolution

A money resolution is required for this Bill.[98]

97 HCB 11, Explanatory Notes [pdf]
98 As above, para 258

Extent and entry into force

The regulation of precision bred organisms is a devolved matter. The provisions of this Bill generally extend to England and Wales only and apply in relation to England only. The exceptions are:

- Clause 41 amends the Environmental Protection Act 1990 which extends to England and Wales and Scotland, so that clause (and the definitions in Part 1 of the Bill to which those amendments refer) likewise extend to England and Wales and Scotland.

- The general provisions in clauses 42 to 48 extend to England and Wales and Scotland and Northern Ireland.

Clause 47 sets out the Extent and application to sea areas. The Bill applies to (a) the territorial sea adjacent to England as it applies in England; and (b) any area designated under section 1(7) of the Continental Shelf Act 1964 as it applies in England.

Clause 48 sets out the timetable for provisions to come into force:

- Part 1 comes into force on the day on which the Act is passed.

- Parts 2 to 4 and sections 39 and 40 come into force— (a) so far as necessary to enable the exercise of any power to make regulations, on the day on which this Act is passed; (b) for remaining purposes, on such day as regulations may appoint.

- Part 5 - Section 41 comes into force on such day as regulations may appoint. The rest of Part 5 comes into force on the day on which the Act is passed.

7 The Bill: clause by clause

Below are summary notes of the Explanatory Notes on the Bill's clauses.

7.1 Part I - Clauses 1 and 2: precision breeding definitions

Clauses 1 and 2 define key terms used in the Bill. The removal from current GMO regulatory provisions of precision bred organisms requires a clear definition of what is and what is not classed as precision bred. These clauses align the definitions in key respects, such as what constitutes artificial alteration, with those used in existing Regulations.

Key provisions are:

- Clause 1 (2) establishes that to be precision bred "the genome of such organisms must have been altered using modern biotechnology, that such alterations made must be stable and that all features of its genome could also have arisen either by traditional processes or via natural transformation". 1(4) dictates that to be deemed 'stable', the genomic feature must be "capable of being passed on to subsequent generations whether by sexual or asexual means".

- Clause 1 (3) outlines the definition of modern biotechnology: this aligns what is or is not considered to constitute 'artificial alteration' with the techniques listed in regulation 5(1)(a) or (b) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443). [99]

- Clause 1(5) outlines matters to be disregarded when conducting the test of whether an organism made using modern biotechnology could also have arisen via traditional processes. These are: "the number of times a genomic feature repeats in the genome (copy number), the set of chemical modifications to the genome and its associated proteins (epigenetic status), and the position of a genomic feature within the genome (location)". 1(6) describes an exemption

[99] Regulation 5(1)(a) of those Regulations lists techniques which are considered to constitute artificial alteration of an organism for the purposes of Part VI of the Environmental Protection Act 1990, while regulation 5(1)(b) lists techniques which are not considered to constitute artificial alteration

to the test of whether an organism made using modern biotechnology could also have arisen via natural transformation.

- Clause 1(7) lists the range of genomic alterations that could occur through traditional processes.

  Regulations made under clause 1 are subject to the draft Affirmative Procedure

- Clause 2 defines "plant" and "animal". 2(1) defines plants as residing within the group Archaeplastida, or Phaeophyceae. 2(2) defines animals as residing in the group Metazoa but excludes humans at any developmental stage as well as human admixed embryos.

- Clause 2(3) outlines what is and is not considered an 'organism' in this context. This includes an embryo and all subsequent developmental stages, a seed or vegetative propagule (in plants) but excludes a gamete. Clauses 2(4) and 2(4) define the meaning of 'gamete' and embryo for the purposes of the Bill.

7.2 Part 2: Clauses 3 – 25: Precision bred organisms, release, marketing, and risk assessments

Part 2 contains some of the main elements of the new regulatory framework and prescribes processes for the authorisation of the release of precision bred organisms, their marketing and risk assessments on animal health and welfare. This part also sets out the role of the Advisory Committee which will advise the Secretary of State on whether organisms are precision bred and on the Animal Welfare advisory body which will advise Ministers on risks to animal health and welfare. The former is the same committee (ACRE) as that set up by section 124(1) of the Environmental Protection Act 1990. The latter body may be a new body or one already established under existing legislation.

A person with a precision bred organism (PBO) under their control must follow notification rules before they may release the PBO - or the organism must be a marketable precision bred organism or its progeny. To be classed as a marketable PBO, a 'marketing notice' must be submitted to the Secretary of State, who will take advice from the Advisory Committee before confirming or not confirming its status as precision bred in a confirmation notice. For animals, a person must apply to the Secretary of State for a precision bred animal marketing authorisation and must include an animal welfare declaration. The application is referred to the Welfare Advisory body before the Minister makes a decision.

A public Precision Breeding Register will be kept electronically. Ministers may determine that information is not disclosed if it is deemed commercially confidential.

Many of the requirements for how and what information must be submitted will be determined in secondary regulation. The details of the specific clauses in this part are summarised below:

Release

Clause 3 sets out provisions on restrictions on the release of precision bred organisms in England. It specifies that a person who has a precision bred organism under their control may not release that organism into the environment in England unless either certain requirements are met including the notification requirements set out in Clause 4; or the organism is either a marketable precision bred organism (as defined in 5(2)[100]) or the qualifying progeny of such an organism (as defined in Clause 24).

Further subsections define when an organism is under a person's control (3(2) and when it is considered to be released (3(3)).

Clause 4 sets out notification requirements for the release of a precision bred organism. These are satisfied if a person gives the Secretary of State a notice of the intention to release an organism (with any required information) and if has paid the fees required by regulations made under section 40, and any minimum period required by regulations has elapsed between satisfying the requirements and releasing the organism. 4(3) sets out a power to make regulations on the details of the release notification form, such as the form and content of the release notice, and any other required information. 4 (4) provides that these regulations may prescribe who can be specified in relation to a notice.

Regulations under this clause may be made by the Negative Procedure.

Marketing

Clause 5 sets out the notification requirements for the marketing of a precision bred organism in England.

Under 5(1) a person must not market a precision bred organism in England unless the organism is a marketable precision bred organism or is the qualifying progeny of a marketable precision bred organism (as defined in 5(2)).[101] Further provisions define terms including what it

[100] Clause 5(2) In this Act "marketable precision bred organism" means a precision bred organism in respect of which— (a) a precision bred confirmation is in force, and (b) if it is a relevant animal, a precision bred animal marketing authorisation is in force.

[101] 5 (2) defines a "marketable precision bred organism" as one which will have to have received a precision bred confirmation (under section 8(1)(a)), and, for a relevant animal, have an animal marketing authorisation.

means to market precision bred organisms and what is meant by confirmation or authorisation being in force.

Precision bred confirmation

Clause 6 describes the application process for a precision bred confirmation. Regulations made under this section are subject to the Negative Procedure.

6 (1) establishes that a person may apply for confirmation, from the Secretary of State, that an organism is a precision bred organism by giving them a "marketing notice". 6(2) provides for regulations to establish the form and of this notice content and information accompanying it.

6 (3) requires the Secretary of State to refer the marketing notice and any required information that accompanied it to the advisory committee as soon as practical after receiving this information (and after receiving any fee that is required under section 36).

Report by advisory committee

Clause 7 sets out the requirements for the report of the advisory committee where a marketing notice has been referred by the Secretary of State.

7 (2) specifies 90 days as the timeframe in which the advisory committee must provide a report to the Secretary of State. This report must outline whether the advisory committee considers the organism to be precision bred and its reasons for that conclusion. 7 (3) provides that the committee may request further information from the notifier.

7 (5) provides for the committee report to be subject to regulations made under section 23 regarding time limits.

Clause 8 provides for the Secretary of State, upon receipt of the advisory committee report, to issue the notifier with a precision bred confirmation if the Secretary of State is satisfied the organism is precision bred. If not satisfied, the Secretary of State must give notice to the notifier with reasons for that conclusion.

Clause 9 provides for the revocation of a precision bred confirmation if the Secretary of State is no longer satisfied that the organism is precision bred.

Regulations must include provisions for publication of such revocation, allowing the persons affected by the revocation to make representation about it, the consequences of such revocation, and the details of information which will be published on the Precision Breeding (PB) Public Register.

9 (3) provides that if a precision bred confirmation is revoked, any marketing authorisations issued under regulations under Part 4 authorising the use of an organism for food and feed that relied on that confirmation, and for animals, the animal marketing authorisation relating to that organism must be treated as revoked.

Regulations made under this section are subject to the negative procedure.

Relevant animals: precision bred animal marketing authorisation

Clause 10 defines a "relevant animal". Under 10 (1) for the purposes of this Bill an animal is a vertebrate.[102] Clause 10 (2) provides that regulations may be made in order to extend the definition of a "relevant animal" if the definition in the Animal Welfare Act 2006 is extended to include invertebrates of any description.

Regulations made under this section are subject to the draft affirmative procedure.

Clause 11 sets out the application process for a precision bred animal marketing authorisation. A person may apply to the Secretary of State for a precision bred animal marketing authorisation and must under 11(3) include an animal welfare declaration.

Clause 11 (5) allows for the form and content of an application for a precision bred animal marketing authorisation and related documentation to be set out in regulations and allows for regulations to require additional information to be provided with the application.

Clause 11 (6) requires the Secretary of State to refer such an application and any related information to the welfare advisory body. (This duty does not apply if the Secretary of State decides not to issue a precision breeding confirmation in relation to the relevant animal.)

Clause 11 (9) allows for regulations to set out when a person other than the notifier can apply for a precision bred marketing authorisation for a precision-bred animal.

Regulations made under this section are subject to the negative procedure.

[102] Clause 10(3) explains that the meanings of "vertebrate" and "invertebrate" are set out in the Animal Welfare Act 2006, as follows: "vertebrate" means any animal of the Sub-phylum Vertebrata of the Phylum Chordata and "invertebrate" means any animal not of that Sub-phylum

Report by welfare advisory body

Clause 12 refers to the report by the welfare advisory body. Subsections set out what must be included in the advisory body's report and within a set timeframe (to be set out in regulations). The welfare advisory body may request further information from an applicant under an 'information notice' before the end of the reporting period.

Regulations made under this section are subject to the negative procedure.

Issue of precision bred animal marketing authorisation

Clause 13 sets out the process for issuing a precision bred marketing authorisation. Subsections set out what the Secretary of State must do on receipt of the advisory body report, including deciding whether to issue an animal marketing authorisation and providing reasons for not issuing such an authorisation.

13 (2) states that the Secretary of State must consider whether the notifier's declaration explains the traits produced by precision breeding and identifies any risks to the health or welfare of the animal or its qualifying progeny (as defined in clause 24). If s/he is satisfied with how these elements have been considered, the Secretary of State may issue a precision bred animal marketing authorisation.

Clause 14 provides for reporting obligations concerning precision bred marketing authorisations. Draft Affirmative regulations may make provisions requiring the notifier, or other person, to report animal welfare information to the Secretary of State. This could relate to the relevant animal and/or its qualifying progeny. (14 (1) (a) to (b) and 14(2))

Clause 15 provides for the suspension and revocation of a precision bred marketing authorisation, including under 15 (1) because of new information about animal health or welfare of because of a failure by any person to comply with information reporting requirements on a relevant animal's health and welfare.

The Clause sets out processes to be followed by the Secretary of State including who should be notified and who can appeal, what the effect of the suspension or revocation is and what changes should be made to the register of precision bred organisms. 15 (3) confirms that regulations under this section can also confer a function to the welfare advisory body as part of the process if needed.

Regulations made under this section are subject to the negative procedure.

Reviews and appeals relating to Part 2

Clause 16 provides for reviews and appeals relating to Part 2. Provisions require the Secretary of State to make regulations for reviews and appeals against decisions made under this part. Subsections set out further detail on what the regulations must provide for.

Regulations made under this section are subject to the negative procedure.

Restrictions on importation and acquisition of precision bred organisms in England

Clause 17 provides for restrictions on importation and acquisition of precision bred plants and animals in contained use conditions. Clause 17 (1) provides that regulations may be made requiring a person to carry out an environmental risk assessment for precision bred organisms that are imported to a place in England or that are acquired in England. The Explanatory Notes state that the Government intends that this should have limited application in that it:

> envisages it only applying to precision bred animals and plants before they are released into the environment or marketed (after which point, they are subject to the regulatory provisions on release and marketing in this Bill). It provides for existing requirements placed on Genetically Modified Organisms and Precision Bred plants and animals in contained use conditions (such as laboratories) to be maintained. In the majority of cases, a mixture of Genetically Modified and Precision Bred organisms will be present in laboratories and other contained use facilities and this subsection will provide for the current regulations on environmental risk assessment to continue to apply. These are proportionate and science based.

Regulations made under this section are subject to the negative procedure.

Precision breeding register

Clause 18 refers to the Precision Breeding Register which the Secretary of State must establish and maintain. The register must be accessible to the public for free, in electronic form (18(5)). Subsections provide for the Secretary of State not to include information in the register if they determine it to be commercially confidential (subject to 18 (4)). Clause 18 (3) explains the circumstances applicable when the information is determined by the Secretary of State to be no longer commercially confidential.

Regulations made under this section are subject to the negative procedure.

Clause 19 refers to monitoring and inspection powers. The Secretary of State may appoint inspectors for the purposes of Part 2 of the Bill and this clause sets out various provisions on their appointment.

Clause 20 provides for monitoring and inspection of Part 2 obligations, including powers for the Secretary of State to make regulations regarding the appointment of inspectors and their functions.

Regulations made under this section are subject to the draft affirmative procedure.

Clause 21 defines the meaning of a part 2 obligation.

Release and marketing: general provisions

Clause 22 concerns the advisory bodies referred to in Part 2 of the Bill. Clause 22 (1) specifies that the advisory committee is the same committee established under section 124 (1) of the Environmental Protection Act 1990. Subsections provide further details on the duties of the advisory committee to give advice to the Secretary of State on precision breeding applications, confirmation issuing and revocations.

They also define 'welfare advisory body' as the body designated by regulations. 22 (4) allows this body to be either appointed specifically by the Secretary of State or to be one previously established under another Act or which "exercises functions of a public nature".

Further subsections set out details on committee membership terms, remuneration and allowances.

Regulations made under Clause 22 (3) are subject to the negative procedure.

Clause 23 sets out additional provisions for the advisory bodies.

Regulations made under this section are subject to the negative procedure.

Clause 24 establishes the meaning of a "qualifying progeny" of a marketable precision bred organism.

Precision bred animal marketing authorisation: adverse effects

Clause 25 (1) enables the Secretary of State to set out by regulations any thresholds for assessing risk or any exceptions which may need to be considered when determining if a relevant animal or its qualifying progeny is adversely affected by any precision bred trait, as part of the decision to issue, suspend, or revoke a precision bred animal marketing authorisation.

Regulations made under this section are subject to the draft affirmative procedure.

7.3 Part 3: Clauses 26-30: Food and feed produced from precision bred organisms

Regulation of food and feed produced from precision bred organisms

Clause 26 sets out powers for the regulation of food and feed derived from precision bred organisms. Clause 26 (1) will grant a general power to introduce a regulatory framework governing the placing on the market of food and feed from precision bred organisms. Further subsections make specific provisions including:

- Clause 26 (3) provides that regulations which prohibit any person from placing food or feed from precision bred organisms on the market except in accordance with a marketing authorisation issued by the Secretary of State may include the criteria that must be met in order for the Secretary of State to grant such an authorisation.
- Clause 26 (4) and (5) provide powers for establishing an application procedure to be followed for food and feed marking authorisations and provision that such authorisations be issued subject to conditions and limitations and to be varied or cancelled.
- Clause 26 (6) grants powers to make regulations that confer functions on the Food Standards Agency (FSA).

Regulations made under this section are subject to the draft affirmative procedure.

Food and feed marketing authorisations: register

Clause 27 sets the associated marketing authorisation of such products and how the limitations of these authorisations can be varied or cancelled. Under 27 (1) powers are given to make regulations requiring the FSA to establish a register of precision bred products that have been granted marketing authorisation for uses in food and feed. Further subsections set out further details on the register.

Regulations made under this section are subject to the draft affirmative procedure.

Monitoring and inspection of Part 3 obligations

Clause 28 makes provisions for monitoring and inspection of Part 3 obligations, including powers to make regulations for designating enforcement bodies with various functions.

Clause 29 defines the meaning of an obligation under Part 3.

Regulations made under this section are subject to the draft affirmative procedure.

Clause 30 sets out definitions and clarifications used in association with Part 3. Definitions of key terms including 'food' and 'feed' are aligned with the definitions in retained Regulation (EC) 178/2002, which is the main piece of retained direct principal EU legislation governing the regulation of food in England.

Clause 30 (3) outlines that 'placing on the market' means the holding of food or feed for the purpose of sale-including offering for sale or any other form of transfer whether free of charge or not- and the sale, distribution, and other forms of transfer themselves, in line with Article 3 (8) of retained Regulation (EC) 178/2002.The term "placing on the market" is defined broadly in retained EU food law to extend to the holding of the food and feed for the purpose of the sale.

7.4 Part 4: Clauses 31-38: Enforcement

Clause 31 relates to "relevant breach". Clause 31 (3) grants powers to create regulations that may outline certain circumstances where a failure to comply with a Part 3 obligation will not be deemed to constitute a relevant breach. Examples included where the breach was someone else's fault or where a person can demonstrate that they took all reasonable precautions and exercised due diligence to avoid the breach in question. It also provides a power for regulations to enable the transfer of liability to another person in circumstances where the commission of the relevant breach was due to the fault of that other person.

Regulations relating to this subsection are subject to the draft affirmative procedure.

Clause 32 enables the Secretary of State to make regulations on the issuing of compliance notices, stop notices, and monetary penalty notices, as well as on legal enforcement in the courts by way of an application for an injunction by the Secretary of State.

Regulations relating to this subsection are subject to the draft affirmative procedure.

Clause 33 sets out provisions on compliance notices. Clause 34 sets out provisions regarding stop notices.

Clause 35 section sets out provisions regarding monetary penalty notices. Subsections provide for the Secretary of State to make provisions in various respects, such as manner and period in which payments must be made and the consequences of late payment.

Content of enforcement notices: further provision

Clause 36 sets out further provisions on enforcement notices.

Clause 37 section sets out provisions on reviews and appeals of enforcement notices, including rights to review and appeal against notices, make appeals to the First-tier tribunal, and provides for further regulations to be made in relation to the notice pending the outcome of the appeal.

Clause 38 sets out provisions regarding costs. Clause 38 (1) grants powers to create regulations that may allow the appropriate authority, by a "cost notice", to recover costs incurred by them in relation to the issuance of an enforcement notice. Subsections provide further details on matters related to costs.

7.5 Part 5: Clauses 39-48: General

Clause 39 sets out provisions on fees, including the desirability of, as far as possible, setting fees that are equal to the cost of providing the function. Regulations made under this Clause will subject to the draft affirmative procedure.

Clause 40 provides for the Secretary of State to make regulations in respect of how a notice or other document is issued or confirmed as being received under this part. Regulations brought forward under this clause will be subject to the negative procedure.

Clause 41 makes consequential amendments to the Environmental Protection Act 1990. Clause 41 (2) inserts a new clause 106A in the Environmental Protection Act 1990 in order to exclude precision bred organisms from Part VI of the Act and describes what is meant by Part 6 "applying in England".[103]

Clause 41 (3) establishes that the advisory committee under this Bill is the same advisory committee established under section 124 (1) of the Environmental Protection Act 1990.

[103] S106 of the Environmental Protection Act 1990 covers the definition of a genetically modified organism.

Powers to make consequential provisions

Clause 42 sets out further powers for consequential provisions in connection with any provision of or made under this Bill. Subsection (1) gives powers to make supplementary, incidental and consequential provisions by regulations, which could be used to modify primary legislation, retained direct EU legislation or subordinate legislation. Regulations made under these powers will be subject to the draft affirmative procedure if they contain provision modifying primary legislation. Other regulations made under these powers will be subject to the negative procedure.

Regulations

Clause 43 provides that regulations made under this Bill are to be made by statutory instrument and may make transitional, transitory or saving provisions; and that different provision may be made for different purposes or areas. Clause 43 (4) provides for regulations made under the draft affirmative procedure to be laid before and approved by a resolution of each House before they are made. 43 (5) provides what is meant by "the negative resolution procedure" in relation to regulations made under this Bill. 43 (6) provides that regulations made under the negative procedure may be made subject to the draft affirmative procedure.

Final provisions

Clauses 44 – 48 are final provisions including definition of terms, financial provisions to provide that expenditure by the Secretary of State of by the Food Standards Agency may be out of money provided by Parliament, and to set out the Extent and application and commencement provisions for the Bill.

8 Second Reading

The Bill received its Second Reading in the House of Commons on 15 June 2022.[104] A Programme Motion was agreed committing the Bill to a Public Bill Committee to be concluded by 12 July 2022.[105]

8.1 Government position

Opening the debate, Defra Secretary of State George Eustice, outlined the key objectives of the Bill. He said that precision breeding techniques such as gene editing were a "natural evolution of conventional approaches to plant breeding". They were:

> simply a modern way of creating more targeted and predictable changes to DNA within a species than would have been possible using induced mutagenesis or natural breeding. They result in nothing that could not occur through natural breeding processes. In that sense, precision breeding techniques are distinct from genetic modification, which can involve moving genes across species boundaries. It is the recognition of this difference that is the reason for this Bill today.[106]

He said that the UK Government disagreed with the 2018 European Court of Justice judgment [pdf] that all gene edited (GE) organisms should be regulated as genetically modified (GM) organisms. This had "hampered" the UK's ability to use GE technologies and outside the European Union, the UK was "free to consider what a consistent, coherent and science-based policy looks like". He said the aim should be to achieve "a fusion of the traditional principles of good farm husbandry with some of the best technology available to us in the 21st century.[107]

The Secretary of State gave reassurances that the Bill's provisions presented "no compromise whatever on food safety and that there will be a comprehensive assessment of the safety of any products placed on the market that result from precision-bred organisms".[108]

A number of backbench MPs spoke in support of the Bill, citing advantages for disease control and food security from a change to the regulatory framework for GE organisms. For example, Conservative MP,

104 HC Deb 15 June 2022, vol 716, c374 onwards
105 The Committee concluded scrutiny of the Bill and reported it to the House on 7 July 2022
106 As above, c374
107 As above, c374
108 As above, c378

Dr Neil Hudson, supported the Government position, citing benefits for agriculture, animals and the environment:

> From developing disease resistant crops to bird flu resistance in poultry to PRRS—porcine reproductive and respiratory syndrome —resistance in pigs, there are significant benefits, including: for food security; for the environment; and importantly, for animal health and welfare. Ultimately, there are also significant benefits for public health, as we are reducing medicines and therefore tackling things such as antimicrobial resistance.[109]

8.2 Opposition views

Shadow Secretary of State for Environment, Food and Rural Affairs, Ruth Jones, said that Labour would not be calling for a vote on Second Reading as this was a "much -needed Bill, given the need for agri-innovation and scientific development, and of course the Opposition welcome the concept". However, she called on the Government to develop "strong and robust regulation" based on "clear scientific evidence and strong protections to safeguard animal welfare". In addition, "clear and transparent labelling to protect and inform consumers" was needed.[110]

Defra Shadow Minister, Daniel Zeichner, said that the Government had taken a narrow approach and had "failed to grasp the opportunity in its wider policy approaches to ask the bigger questions" posed by bodies including the Nuffield Council on bioethics and by Henry Dimbleby's food strategy review - on issues such as food systems, animal welfare, and approaches to novel food. He also cited criticisms by the Royal Society that the approach focused narrowly on just one technology rather than using an outcomes-based approach. He said that the proposals risked having the opposite effect from that intended since "unless public and investor confidence is maintained, research will stall and opportunities will be squandered". Although Labour would support the Bill's progress at Second Reading, it wanted its provisions to be "significantly strengthened". He said that Labour would propose an array of amendments in Committee.[111] [See Committee Stage below]

Key areas for Labour amendments would include:

- putting more detail on the face of the Bill. Mr Zeichner said that "far too much" was being left to secondary legislation.
- removing animals produced by GE technologies from the scope of the Bill. Mr Zeichner said that although notes accompanying the Bill said new measures for animals would only be introduced after extensive consultation to establish the right regulatory framework

109 HC Deb 15 June 2022, vol 716, c374
110 As above, c399
111 As above, c380

> for animals, there was nothing in the Bill to make that happen. He said that the preferred regulatory framework should be set up first, then put into law.[112]

Helen Morgan, for the Liberal Democrats, said that she supported "a science-based approach to technologies such as genetic editing for precision breeding". She added that such methods had potential for tackling climate change and excessive antibiotic or pesticide use in farming. She welcomed the advice from the Advisory Committee on Releases to the Environment and the European Food Safety Authority that "no more risk is attached to precision-bred foods than to those from traditional breeding methods".[113]

She asked for clarification on regulatory aspects of the Bill where the detail was "light" including:

> how can consumers be reassured that the Bill is not a back-door route to reducing animal welfare and environmental standards, in which our farmers have led the world? It certainly makes no provision for food labelling, that would allow consumers to decide whether or not they prefer a precision-bred product. Those concerns are a direct consequence of the fact that it is not at all clear how the precautionary principle outlined in the Environment Act 2021 and the Government's environmental principles policy statement of 12 May will be applied in this area.[114]

The SNP opposed the Bill because of its impact on Scotland. Spokesperson Deirdre Brock noted that, if the Scottish Parliament refused to allow gene edited crops to be planted in Scotland, under the Internal Market Act 2020 it still could not stop GMO food produced elsewhere in the UK from being sold in Scottish shops.[115]

8.3 Key issues debated

The debate focussed on key concerns about the Bill's provisions. These included: animal welfare; definitions of precision bred organisms; labelling of GE products; and the non-alignment of UK Government and devolved administrations' positions on regulation.

Animal Welfare

Some members, such as Conservative MP Tracey Crouch, cited concerns from animal welfare organisations about the potential for GE to "drive animals to faster growth and higher yields" which could "exacerbate the

112 HC Deb 15 June 2022, vol 716, c381
113 As above, c395
114 As above, c395
115 As above, c384

severe welfare problems that have arisen through selective breeding for increased productivity".[116]

However, other Members, such as Julian Sturdy (Conservative), considered it would be going against animal welfare not to use GE technology. He said he wanted to refute misconceptions that gene editing was "bad for animals and animal welfare". It was right, in his view, to "proceed with careful additional safeguards for animal precision breeding," as the Bill proposed, but he said that:

> precision breeding could provide animal welfare benefits so huge that to my mind it is actually unethical not to allow it. Stopping diseases such as PRRS in pigs, bird flu, swine flu and mastitis is obviously a huge advance for animal welfare, not a threat to it. Put simply, regulation should follow the science. It should be based on the evidence, not on superstition or political agendas.[117]

Labour Member Kerry McCarthy questioned the inclusion of animals within the scope of the Bill, accepting there were "some positives, such as helping to reduce our reliance on antibiotics". However, she said that there were other ways to do that: if animals were not "crammed together in unsanitary conditions in industrialised conditions then farming would not have to rely on the routine use of antibiotics".[118]

Defra Secretary of State, George Eustice, gave assurances that concerns of animal welfare bodies such as Compassion in World Farming had been listened to and the Bill would not compromise animal welfare standards. He said that the Bill establishes a regulatory system to safeguard the welfare of precision-bred animals:

> This system is described in clauses 10 to 15. Clause 10 establishes that precision-bred animals will need to be authorised before they can be marketed. Clause 11 describes the application process. Clause 12 describes the involvement of an animal welfare advisory body. Clause 14 makes provision for regulations requiring information on the health and welfare of these animals once they have been placed on the market.[119]

Labour spokesperson Daniel Zeichner said that if the system were regulated "in the right way" then most people could be reassured about their animal welfare concerns.[120]

Definitions of precision breeding

A key issue debated during the Bill's Second Reading was how the measures defined the concept of a 'precision bred' organism.

116 HC Deb 15 June 2022, vol 716, c375
117 As above, c388
118 As above, c392
119 As above, c378
120 As above, c381

Green MP Caroline Lucas disputed the basic definition, stating that precision breeding was "neither a specific technology nor a scientific principle. It relies on the creation of a hypothetical class of GMOs that could have occurred naturally".[121] Some Members referred to the concerns of expert bodies such as the British Veterinary Association and the Royal Society. For example, Daniel Zeichner, referred to the Royal Society's preference for an "outcomes based approach" rather than the narrow focus on just one technology.[122]

In response, the Secretary of State reiterated that the Government's view that the "overwhelming view of scientists are that these precision-breeding techniques, which do not achieve or do anything that could not be achieved through natural breeding processes, are not in fact GMOs".[123]

A key concern on definitions was the potential for exogenous DNA (ie DNA from another species) to be introduced into a precision bred organism. Daniel Zeichner said that Labour had concerns about the Bill's GE definitions in this respect. [124] [These technical issues were explored in more detail during Committee Stage – see section 9 below].

Labelling and transparency

Members raised concerns that products made using GE technology would not require to be labelled as such under the Government's proposals. Sir Roger Gale, Conservative, said that "people should at least have the right to know what they are buying". In response, Mr Eustice said that:

> There will be transparency in the sense that any authorised product will be listed. No marketing authorisation will be granted for the sale of any food unless it has been properly assessed. However, it is not currently our intention to have some kind of labelling requirement specifically for food, because a loaf of bread might have some of these crops going into it and others produced through other techniques. We do not currently, for instance, require people to label that a crop has been produced using an F1 hybrid technique such as an open pollination.[125]

For Labour, Daniel Zeichner said that whilst consumers supported for GE foods a different regulatory system to the GM framework, Food Safety Agency research showed that they wanted clearer labelling of such products.[126]

Devolved matters

Deirdre Brock for the SNP emphasised that the regulation of genetically modified foods was a devolved issue. She said that "although the

121 HC Deb 15 June 2022, vol 716 c374
122 As above, c380
123 As above, c374
124 As above, c381
125 As above, c378
126 As above, c382

intended scope of the Bill may be England only, it is explicit that it will have significant impacts on devolved areas". Ms Brock noted that, if the Scottish Parliament refused to allow gene edited crops to be planted in Scotland, it would still be prevented from stopping GMO products from being sold in Scottish shops under the Internal Market Act 2020. She was critical that the Devolved Administrations were only informed of this on the day before the Bill's introduction, in a letter from the Environment Secretary encouraging them to adopt the Bill's principles. She said that:

> A UK-wide approach can, of course, sometimes be desirable, but this invite creates an illusion of collaboration and choice when in fact DEFRA is acting unilaterally once again. Frankly, it smacks of contempt for our democratically elected Government.[127]

Ms Brock added that:

> The SNP is committed to ensuring that Scotland operates to the highest environmental standards, […] diverging standards with the EU could cause further damage to our sales, risking damage to Scotland's reputation for high-quality food and drink.[128]

She suggested that the UK Government should monitor the EU and its ongoing public consultation to ensure that the UK's GE policy was aligned and avoided divergence which could "further threaten trade with our largest trading partner". She said that as the European Commission's formal policy announcement was expected in the first half of 2023, the wait "would not greatly undermine the UK's competitive edge but would ensure minimal trade disruption".[129]

She added that the EU's 2021 study into gene editing and new genetic technologies highlighted that research into animals and micro-organisms was "still limited or lacking". The UK Government should return to the precautionary principle in the deployment of GE, especially in developing produce for human consumption. Ms Brock said that the SNP did not oppose further research in this area and acknowledged the work of the James Hutton Institute, the Roslin Institute and other Scottish scientists and researchers:

> The more empirical data available in this area, the better we can understand exactly the effects in crops and animals, and in genetically modified organisms. However, the SNP will always listen to the concerns of the public and producers and take them into consideration in agricultural matters or in scientific development. Indeed, DEFRA's own consultation last year found that 88% of individuals and 64% of businesses supported continuing to regulate such organisms as GMOs. The strength and range of opposition to the use of gene editing should give us pause to reflect.[130]

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127 HC Deb 15 June 2022, vol 716, c384

128 As above, c383

129 As above, c384

130 As above, c385

Labour spokesperson Daniel Zeichner said that a potentially difficult issue was the "legitimately held views of different Administrations within the United Kingdom. [….] the devolved Administrations are not happy with the way this has been handled so far". He said that clearer labelling of GE products was therefore "a sensible way forward".[131]

The Secretary of State said that the Scottish Government had stated that "that if the European Union changed its law, Scotland would change its law at that time, but not before, and it would appear that the Scottish Government do not want to move early on that". He noted that many of the leading international research institutes, such as the Roslin Institute and James Hutton, were world leaders in these technologies. He added that these Institutions would "probably be acutely disappointed if the Scottish Government do not take this opportunity to lead the world, rather than waiting and following the European Union".[132]

131 HC Deb 15 June 2022, Vol 716, c382

132 As above, c379

9 Committee Stage

9.1 Overview

The Bill had its committee stage from 28 June to 7 July 2022. The bill committee issued a call for written evidence and held four oral evidence sessions on 28 and 30 June 2022. At these sessions it took evidence from witnesses representing a range of farming, food sector, and scientific bodies as well as environmental, animal welfare and GM advocacy groups.[133]

The committee considered the Bill line by line in a further four committee sessions held on 5 and 7 July 2022.[134]

Three substantive new clauses were tabled by the Opposition. New Clause 1 aimed to require gene edited (GE) organisms to be labelled. New Clause 2 would delay the release of precision bred animals for at least 12 months after the Animal Sentience Committee established under the Animal Welfare (Sentience) Act 2022 has been established and at least 6 months after the Committee has reported on the impact of the Act on animal welfare. New Clause 3 would set up a new regulatory body – the Genetic Technology Authority. All were negatived on division.[135]

The Committee considered a number of Opposition amendments and divided on 17 of these.[136] No amendments were successful and the Bill completed its Committee Stage unamended.

A date for Report Stage in the House of Commons is awaited.

9.2 Proposed amendments: key issues

Inclusion of animals in the scope of the Bill

The Labour Party moved amendments aimed at removing animals from the scope of the Bill. Amendment 29 would delete "or a precision bred

133 Public Bill Committee (Bill 11), 2022-23, 5 July 2022 [pdf]
134 As above
135 Committee Stage Decisions [pdf]
136 Eight amendments were withdrawn after debate but without a division or a decision being recorded.

animal" from Clause 1 which defined the scope of the Bill. This was negatived on division after debate (summarised below).[137]

Separately, Labour proposed amendment (33) to Clause 10 which would give 'animal' the meaning given by section 5 of the Animal Welfare (Sentience) Act 2022 rather than the definition of animal from the Animal Welfare Act 2006. This was also negatived on division.[138]

Key points raised in debate

Moving amendment 29 to Clause 1, Defra Opposition spokesperson Daniel Zeichner said that the Party was "particularly concerned about the place of animals in the Bill".[139] He said that the Government's previous secondary legislation on genetic editing was about plants, not animals. He said that furthermore, while Defra's consultation on GE regulation referenced them, animals "did not seem to be the main focus of attention". He highlighted that many Members and stakeholder and advocacy groups were therefore surprised that the Government had included animals in the Bill:

> When we look at the Bill, there is some evidence of the lack of really concrete provisions in the vague and non-committal timeframes offered by the Government, and the admission that much of the preparation necessary for a regulatory framework for animals has not yet been done.[140]

Mr Zeichner said the Government was aware of the risks of including animals in the Bill's scope. He noted that page 41 of the Bill's Impact Assessment [pdf] said that "despite the potential benefits accrued by applying changes to the GMO regulations in animals, there is currently high risk of considerable consumer backlash in altering their regulations".[141]

Defra Minister, Jo Churchill, said that those proposing the amendments "rightly want to protect animal welfare". She said the Government shared this view and wanted to "utilise precision breeding to improve the health and welfare of animals". She said it was "vital that animals are covered by the Bill because the science is clear as to the benefits".[142]

The Minister added that the Bill laid down a framework for the regulatory system and the Government would work with expert groups, industry and non-governmental organisations on "enabling the right regulations to ensure that the system is effective, safe and workable". She noted that the Animal Welfare Act 2006 provided "comprehensive and robust legislation" to protect all animals and made it an offence to cause any captive animal unnecessary suffering and to not provide for

137 Committee Stage Decisions [pdf]
138 As above
139 Public Bill Committee (Bill11) 2022-23, 5 July 2022, c158 [pdf]
140 As above, c158
141 As above
142 As above, c163

their welfare needs. The Bill's system to protect animal health and welfare would work with this legislation and with the Welfare of Farmed Animals (England) Regulations 2007 which prohibit breeding procedures that cause or are likely to cause suffering or injury.[143]

The Minister also noted that the Animals (Scientific Procedures) Act 1986 protected animals used in scientific research projects, which "would be the first stage of developing a breeding line using precision breeding for animals". She noted that the Act ensured that animals were only used in science where "the potential harm to animals is limited, there are no alternatives, and where the number of animals is the minimum needed to achieve a scientific benefits, and that includes a harm-benefit analysis".[144]

The Minister said that the Bill supported this existing legislation the regulations by requiring an animal welfare declaration and independent scrutiny by an expert group before an animal could be marketed. She added that:

> We are ensuring that the health and welfare of the animal and its offspring will not be adversely affected by any trait resulting from precision breeding. If we want to drive innovation and investment in this area while continuing to be at the forefront of animal welfare, we need to move forward and show how the best regulatory systems can work. The Bill provides a clear signal that the UK is the best place to conduct the research and bring products to market.[145]

Amendment 29 was negatived on division.[146]

Separately, Labour proposed amendment (33) to Clause 10 which would give 'animal' the meaning given by section 5 of the Animal Welfare (Sentience) Act 2022 rather than the definition of animal from the Animal Welfare Act 2006. The definition would be "any vertebrate other than homo sapiens…any cephalopod mollusc,[147] and…any decapod crustacean".[148] Labour spokesperson, Daniel Zeichner, said this would align definitions across legislation as well as allowing for inclusion of invertebrates if the Animal Welfare Act definitions changed.[149]

Defra Minister, Jo Churchill, said that this change was not necessary as:

> Clause 10 defines relevant animal as a vertebrate for the purpose of welfare protection measures in clauses 11 to 15. That is line with the definition of animal in the 2006 Act—the core legislation that establishes the practical rules for individuals and businesses that handle, keep and

143 Public Bill Committee (Bill11) 2022-23, 5 July, c163 [pdf]
144 As above, c164
145 As above
146 Committee Stage Decisions [pdf]
147 A cephalopod is any member of the molluscan class Cephalopoda such as a squid, octopus, cuttlefish, or nautilus.
148 Decapods ("ten-footed") are an order of crustaceans within the class Malacostraca, including groups such as crabs, lobsters, crayfish, shrimp and prawns.
149 Public Bill Committee (Bill11) 2022-23, 5 July, c193 [pdf]

> care for animals in this country. For that reason, it is the right definition to apply.[150]

Amendment 33 was negatived on division.[151]

Release of precision bred animals

Labour moved New Clause 2. This would delay the release of precision bred animals for at least 12 months after the Animal Sentience Committee established under the Animal Welfare (Sentience) Act 2022 had been established and at least 6 months after the Committee had reported on the impact of the Act on animal welfare.

Mr Zeichner asked why the Government had not waited to introduce the Bill until that committee had been established and had reported on the implications for animal welfare of the proposed legislation.[152] Defra Minister, Victoria Prentis, said that work was underway to establish the Animal Sentience Committee by the end of 2022. As it would be some years before precision bred animals were anticipated to be released or brought to market, she said that delaying the provisions for 12 months from the date on which the Animal Sentience Committee was established was, , unnecessary. She added that the Government were clear during the passage of the sentience legislation that it would be for that Committee to decide which policy decisions it wanted to scrutinise:

> its expert members will be best placed to know where they can add value to the animal welfare debate. It would be contrary to that important principle if this Bill was used to mandate the committee to produce a report before the provisions in the Bill can be commenced.[153]

New Clause 2 was negatived on division.[154]

Definitions of precision bred organisms

The Opposition moved a number of amendments in relation to the Bill's definition of what constitutes a precision bred organism. Labour spokesperson, Daniel Zeichner, said that the Bill's definition was weak and the amendments would tighten this up. Amendment 1 to Clause 1 would insert that an organism was not 'precision bred' if "any feature of its genome results from any technique or process which involves transgenesis".[155] [156]

150 Public Bill Committee (Bill11) 2022-23, 5 July, c194 [pdf]
151 As above, c195
152 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c260 [pdf]
153 As above, c261 & c262
154 Committee Stage Decisions [pdf]
155 Transgenesis is meant here as the introduction of genetic material (DNA or RNA) into an organism from another species
156 Public Bill Committee (Bill11) 2022-23, 5 July 2022 c167 [pdf]

Mr Zeichner said that the intention of the Bill was clearly stated to relate to organisms that could have been created by traditional breeding processes, in contrast to genetically modified organisms, which could not. He said that gene editing, unlike genetic modification, meant that material was not transferred from another species: the problem was that this distinction was not in the Bill:

> nowhere is it stated that precision breeding technologies are technologies that edit a single organism. Indeed, clause 1(7) mentions "somatic hybridisation or cell fusion of plant cells of organisms which are capable of exchanging genetic material". To me and to others, that sounds as though it opens to door to transgenic exchange. The only distinction made in the Bill is between processes that could have occurred naturally or through traditional breeding techniques and those that could not. That is where things start to get difficult. As the Labour party, scientific societies and stakeholder groups have said a number of times, that is a weak definition, which could feasibly include just about anything".[157]

Amendment 1 was negatived on division. Amendment 2 (to exclude the introduction of exogenous genetic material from the definition of modern biotechnology) was withdrawn.[158]

Animal welfare

Labour considered that the Bill did not include sufficient detail about how the welfare advisory body to be established by the Bill would make decisions relating to animal welfare. It proposed a number of amendments, none of which were successful.

Key amendments included:

- amendment 4 to Clause 12 which would require the welfare advisory body to carry out an assessment of the likely impact of any precision bred trait on the health and welfare of the relevant animal and its qualifying progeny;
- amendment 5 to Clause 12 which would require the welfare advisory body to report, where the "purpose of a precision bred trait includes achieving fast growth, high yields or any other increase in productivity", on whether animals or their progeny with similar traits resulting from selective breeding or traditional processes have experienced "pain, suffering or lasting harm arising from or connected with fast growth, high yields or any other increase in productivity"; and
- Amendment 35 to Clause 12 which would require the welfare advisory body to report on the likely effects of a precision bred trait on breeding stock.[159]

157 Public Bill Committee (Bill11) 2022-23, 5 July 2022 c167 [pdf]
158 Committee Stage Decisions [pdf]
159 As above

Labour spokesperson, Daniel Zeichner said that the amendments aimed to set out:

> some of the processes and frameworks that we think the Government should have set out […] without knowing much about what this body will be and what resources will be available to it, there is a concern that all it is doing is taking a proposal, written by an applicant, and making a judgment on the basis of what it has been told. It may well be that it would need to check some of the evidence presented to it".[160]

Jo Churchill gave assurances that technical details about how the Bill's provisions would work would be developed collaboratively. She said that:

> The purpose of this part of the Bill is to create the regulatory framework for the approval of marketing authorisations for precision bred animals. I assure all Members that we propose to work closely with the industry, expert groups, scientific advisers, non-governmental organisations and all other stakeholders on the development of that technical detail. I think the hon. Gentleman would agree that it is important that all those voices are heard, and that we work on that technical detail with everyone.[161]

The Minister also said that the amendments were unnecessary because:

> Clause 12 already requires the advisory body to report to the Secretary of State on whether the notifier, when making their animal welfare declaration, has had regard to health and welfare risks to the animal or its progeny that could reasonably be expected to result from its precision bred traits. The advisory body's report must consider whether the notifier has taken reasonable steps to identify the animal's precision bred traits and any related risks, and has made an appropriate assessment of those risks.[162]

Amendment 4, amendment 5, and amendment 35 were negatived on division.[163]

Labelling

The Opposition tabled New Clause 1 on labelling. New Clause 1 would prevent a person from marketing a precision bred organisms (PBO) or placing food and feed produced from a PBO on the market unless it is labelled in accordance with regulations made by the Secretary of State. The labelling requirements are set out in more detail in the New Clause. New Clause 1 was negatived on division after debate (summarised below). [164]

160 Public Bill Committee (Bill11) 2022-23, 5 July 2022 c199 [pdf]
161 As above, c200
162 As above, c203
163 Committee Stage Decisions [pdf]
164 As above

Key points raised in debate

Labour spokesperson, Daniel Zeichner said that consumers wanted more information about their food. The Bill would create a new type of food product on supermarket shelves and New Clause 1 would require the Government to introduce regulations to ensure that the products were labelled to provide "sufficient information to support informed consumer choice". Information would cover in particular (a) nutritional content, (b) the potential presence of allergens or other substances which may cause adverse human health impacts, and (c) the environmental impact of the product. Mr Zeichner noted that it would be important to consult the organic sector so that "whatever labelling regime the Government introduces, it allows for different types of food production to co-exist".[165]

Mr Zeichner said that the Government had set out its opposition to labelling based on the costs it could incur for businesses, but the Impact Assessment (IA) did not include cost and benefit calculations for labelling. The Regulatory Policy Committee had asked Defra to provide quantification on traceability and labelling regulatory options set out in the IA.[166] Mr Zeichner also noted that paragraph 114 of the IA said that "maintaining a labelling and tracing system could also have wider benefits, most notably, improved consumer confidence in food products potentially adding value across the food supply chain".[167]

Mr Zeichner quoted written evidence to the Bill Committee from the Nuffield Council on Bioethics which stated that the Government's present stance on labelling "runs contrary to the findings of many public engagement initiatives that have broached this question... in this context, not labelling amounts to the withholding of information about consumer preferences". Mr Zeichner said that he recognised the challenges of labelling but considered that:

> the significant benefit it would bring in terms of public trust and supporting consumer choice may well be worth having. Our view is that the Government have not given sufficient thought to the matter nor evaluated it sufficiently, as is admitted in the impact assessment. Our new clause 1 would require them to undertake further consultation on labelling and then introduce an appropriate system.[168]

In response, Defra Minister, Victoria Prentis said that:

> The Bill is based on the science, and the science tells us that precision bred organisms are equivalent to, and pose no greater risk than, their traditionally bred counterparts. We have received advice from independent scientific experts and heard from many witnesses who considered labelling to be unnecessary in the case of precision breeding. Dr Helen Ferrier of the NFU agreed that it would be "misleading" to consumers to require a compulsory label, as there is no scientific

165 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c257 [pdf]

166 Regulatory Policy Committee, Opinion on the Genetic Technologies (Precision Breeding Techniques) Bill, June 2022

167 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c257 [pdf]

168 As above, c258

> difference. Dr Richard Harrison said, "I do not think there is any scientific rationale to have additional labelling criteria for gene-edited products, because they are fundamentally indistinguishable from nature".[169]

She added that much of the proposed New Clause was covered by existing legislation:

> Regulations on the provision of food information to consumers already adequately cover nutritional and allergen labelling, and that does not change because the product is derived from a precision bred organism. We therefore do not think it is necessary to include additional provisions in the Bill. We will respond to the further information that the [Regulatory Policy Committee] RPC requests [..] towards the end of the Bill's passage through Parliament.[170]

For the SNP, Deirdre Brock said that having no requirement to label obstructed the "enforcement of Scotland's devolved powers to regulate produce and impedes our intention to align, wherever possible, with the EU". She added that not requiring labelling made it harder to filter products for sale to markets such as Europe. Furthermore, labelling was important for transparency and consumer choice:

> a recent survey showed that 84% of the public consider it important that all GE products introduced for sale in the UK be labelled as such and 63% of people consider it very important. A mere 8% do not consider it important. The public have a right to know how their food is produced, even if the changes in GE foods that come down the line could have occurred in crops naturally. It is my belief and that of the Scottish Government that labelling is vital".[171]

Deirdre Brock said that she would revisit the issue at Report Stage.[172]

Devolved Administrations

Deirdre Brock for the SNP moved amendment 37 to Clause 48 to the Bill to amend the Internal Market Act 2020 . She said her aim was to "ensure that the Scottish Parliament's authority to legislate in the marketing of precision bred organisms is respected, and seek to prevent the operative parts of the Bill from coming into force until a common framework agreement on precision breeding has been agreed between the UK Government and the Scottish and Welsh Government".[173] The amendment was withdrawn after debate (summarised below).

Key points raised in debate

Deirdre Brock said amendment 37 would prevent the "operative parts" of the Bill coming into force until a common framework had been agreed between the UK, Welsh and Scottish Governments relating the release

169 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c258 [pdf]
170 As above, c259
171 As above, c272
172 As above
173 Public Bill Committee, (Bill 11) 2022-23, 5 July 2022, c161 [pdf]

and marketing of precision bred plants and animals (and the marketing of food and feed from them)

Ms Brock said that the Scottish Government was clear in its opposition to the UK approach and did not "presently intend to amend the GMO regulatory regime in Scotland to remove categories of products currently regulated as GMOs while they sensibly await the outcome of the EU's consultation on whether some gene-edited organisms will be excluded from the GM definition". She said that the Impact Assessment showed "clear implications" that more trade barriers were a "very likely outcome" of having different approaches. She added that the EU was currently considering (changes to regulation of) "only plant-based GEOs, not animals".

In terms of the outcome for Scotland, she said that the potential impact of the Bill was that, through the United Kingdom Internal Market Act 2020:

> If the Scottish Parliament did not ultimately decide to allow gene edited organisms to be sold, Scotland would still be prevented under the Act from stopping those products being sold in our shops. That, of course, is exactly the kind of scenario that the Scottish National party warned against when the legislation was forced through this place. As the UK Government's own impact assessment for the Bill acknowledges, removing gene edited products from England's regulatory regime for GMOs would mean divergence from the current EU approach. As such, it would have implications for compliance, costs and future trade. New trade barriers could also come in the form of checks and certification requirements on UK food exports entering the EU's single market, which could affect not only products exported to the EU that contain precision bred plant material, but those in the same product categories that do not—something that, again, emphasises the importance of labelling and traceability,
>
> .[…]We do not want to erect further barriers to our largest market, so we are waiting to see the position as the EU progresses its review, including its consultation. If the EU retains its current opposition to gene editing, there are concerns about, for example, the export of Scottish salmon—a huge export product to Europe, and particularly to France. It has been suggested that products might be considered on a product-by-product basis, but there is little detail for us to scrutinise that and to examine potential costs and logistics challenges. In the meantime, the SNP Scottish Government, and indeed the Welsh Government, simply insist that the devolution settlement is respected.[174]

Labour spokesperson, Daniel Zeichner, criticised the UK Government's late consultation with the Welsh and Scottish Governments, noting that both Governments had raised concerns:

> that the mutual recognition principle of the United Kingdom Internal Market Act 2020 will mean that it will be possible to legally place precision bred food on the Welsh and Scottish markets even if the Welsh and Scottish Governments choose not to adopt the changes contained in the Bill, which obviously presents a challenge. It is for the Government to resolve that challenge, but I would have certainly liked to have seen them

[174] Public Bill Committee (Bill11) 2022-23, 7 July 2022 c252 &c253 [pdf]

> consult the devolved Administrations earlier and in a more constructive manner. [175]

Referring to Clause 27, Mr Zeichner said the provision for a delegated power for the Government to require the Food Standards Agency to establish a public register of food and feed marketing authorisations for GE products, could not only give consumers confidence, but also be helpful in tackling some of the devolution issues that witnesses had raised in oral evidence sessions. He said that:

> some supermarkets and shops may decide that they want to operate within the spirit of Scottish and Welsh legislation and not stock precision bred products on their shelves, as is their right. The register of foods authorised for sale may help companies address that conundrum—certainly, without it, it is hard to see how they could do so without setting up very expensive parallel production systems, which might simply not be practical in many cases. In other words, a chain of unintended consequences might follow, which I do not think anyone would wish to see.[176]

Responding for the Government, Defra Minister, Victoria Prentis said that under the UK Internal Market Act, market access principles would apply to precision-bred products produced in or imported into England that can lawfully by sold in England:

> That will allow those goods to be sold on the Scottish and Welsh markets. This clause will grant the power required to allow the FSA to establish a register that will give the required transparency.[177]

The Minister also said that the regulation of GMOs is a devolved matter and the Government had invited the Scottish and Welsh Governments to join in bringing forward the Bill so as to give confidence to investors in Scottish and Welsh precision breeding research. On the issue of common frameworks, she said that, while a GMO framework was within the scope of the frameworks programme, all four Administrations agreed that a common framework was not required "because the administration and co-ordination of this policy area was provided for through existing inter-governmental arrangements under the GMO concordat".[178] Ms Prentis said that If the Devolved Administrations were in agreement the Government would be willing to look again at the concordat and whether the intergovernmental arrangements for which it provides were "sufficient for intergovernmental working, and, where relevant, to

175 As above, c237 & 238

176 Public Bill Committee (Bill11) 2022-23, 7 July 2022, c237 &c238 [pdf]

177 As above, c240

178 The GMO concordat [pdf] sets out the framework for co-operation between the DAERA in Northern Ireland, Defra, the Welsh Government and the Scottish Government, on the administration and coordination of the regulatory frameworks established under: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs); and Regulation (EC) No.1946/2003 on trans-boundary movements of GMOs.

manage divergence in the regulation of genetic technologies".[179] She noted that:

> […] it will be at least five years before products come on to the markets for farmers and growers. We hope that consumers across the whole of the UK will be able to benefit from the research into precision bred plants and animals that the Bill will enable.[180]

Ms Brock withdrew the amendment as there was "likely to be some movement in discussions on the GMO concordat" and would speak further to Ministers before the Bill returned to the House for its Report Stage.[181]

Ms Brock also tabled New Clause 9, which was not called, to provide a power of the Scottish Parliament to legislate on the marketing of precision bred organisms. This would amend Schedule 1 of the United Kingdom Internal Market Act 2020 (UKIM) to disapply the UK market access principles to precision bred organisms, or food or feed produced from them.[182] Minister Victoria Prentis said that

> There is an established process for considering exclusions to the application of the UKIM market access principles in the common framework areas. That process has been agreed by the UK Government, the Scottish Government, the Welsh Government and the Northern Ireland Executive. The UK Government are fully committed to common frameworks and to taking forward discussions with the Governments of Scotland, Wales and Northern Ireland on the interaction between the proposals in the Bill and UKIM.[183]

Public benefit

Labour moved amendment 32 to Clause 3 which would require that any precision bred organism that is to be released into the environment must have been developed to provide a public benefit (such as to produce food that protects biodiversity or improves the health or welfare or animals. Defra Minister, Jo Churchill said that the Government was aligned with the intentions behind the amendment and was "already undertaking a range of work across Government that delivers public good".[184] Daniel Zeichner for Labour disagreed with the Government position stating that the Bill was "highly deregulatory". He questioned whether the market would deliver "the right societal return in environmental benefits" and the Opposition sought to include a public benefit in the Bill because it was "not convinced that the proposed framework will always work for the public good".[185]

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179 Public Bill Committee (Bill11) 2022-23, 7 July 2022, c254 [pdf]
180 As above, c255
181 As above
182 Committee Stage Decisions [pdf]
183 Public Bill Committee (Bill11) 2022-23, 7 July 2022, c255 [pdf]
184 As above, c181
185 As above, c183& c184

The amendment was withdrawn after debate.[186]

The Opposition also moved an amendment (32) to Clause 4 on the release of genetically edited organisms. This would require that the regulations setting out the details of a release notice for precision-bred organisms would be scrutinised under the affirmative rather than the negative procedure for secondary instruments. This was negatived on division.[187]

Environmental principles

Labour tabled two key amendments on environmental principles. Neither were successful – amendment 26 was withdrawn after debate and amendment 27 was negatived on division.[188]

Opposition spokesperson, Daniel Zeichner, said that the two amendments would insert subsections into Clause 43 to ensure that regulations are made in accordance with firstly, the environmental principles of the Environment Act 2021; and secondly the non-regression principle laid out in the 2020 trade and co-operation agreement between the United Kingdom of Great Britain and Northern Ireland and the European Union. He said that the Government is required under the 2021 Act to prepare a policy statement on environmental principles to be interpreted and applied in the making of Government policies, but:

> The problem is that the Government have yet to finalise the statement. A draft was published in May 2022, but we are yet to have a response from the Secretary of State, or the final version of the policy statement.[189]

Mr Zeichner added that:

> Amendment 26 would ensure that regulations under the Bill are made in accordance with the environmental principles set out in section 17(5) of the Environment Act.
>
> Amendment 27 would ensure that no regulations may be made under the Bill unless the policy statement has been finalised and laid before Parliament, and Ministers are under an obligation to pay due regard to it. […]
>
> Amendment 26 concerns article 391 of the trade and co-operation agreement [TCA] between the UK and the EU, which was agreed in December 2020. Chapter 7 of the TCA covers environment and climate, and defines environmental levels of protection as "the levels of protection provided overall in a Party's law […] which have the purpose of protecting the environment including the prevention of a danger to human life or health from environmental impacts". The TCA then lists some specific examples, some of which would concern this Bill. Those include: "the protection and preservation of the aquatic environment" and "the

186 Committee Stage Decisions [pdf]
187 Public Bill Committee (Bill11) 2022-23, 7 July 2022, c170 [pdf]
188 Committee Stage Decisions [pdf]
189 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c245 [pdf]

> management of impacts on the environment from agricultural or food production". Each party in the agreement—the EU and the UK—committed to "the principle that environmental protection should be integrated into the making of policies", as well as to "the precautionary approach" and "the principle that environmental damage should as a priority be rectified at source".[190]

Mr Zeichner also noted that the TCA aimed to prevent weakening environmental legislation or climate protection "in a manner affecting trade or investment" between the UK and EU, below levels in place at the end of the transition period after the UK's departure from the EU.[191]

Defra Minister, Victoria Prentis responded that

> The scientific advice is clear that precision breeding poses no greater risk to the environment than traditional breeding. Section 19 of the Environment Act 2021 provides that Ministers must have due regard to the policy statement on environmental principles. DEFRA has already published and laid that statement before Parliament for debate. I understand that that is the draft version, but we have made it clear that our intention is to publish the final version in autumn this year. Therefore, by the time regulations are made under this Bill, the final version of the policy statement will have been laid before Parliament, and section 19 will be in force. It is therefore unnecessary to make a provision that will be meaningless by the time the Bill comes into force.[192]

The Minister said that the Bill was precautionary and, in line with Section 20 of the Environment Act, the Government had reviewed whether the Bill would reduce existing environmental protections:

> Based on the scientific advice from the independent scientific committee ACRE, our assessment is that the provisions do not have the effect of weakening environmental protections. We published that statement when the Bill was introduced. I listened carefully to what the hon. Member for Cambridge said about the TCA. The scientific advice is clear that precision breeding poses no greater risk to the environment than traditional breeding, and we therefore believe that the Bill is consistent with our non-regression commitment to the EU. Indeed, the EU is consulting on its own new regulatory framework for precision bred plants.[193]

Establishment of Genetic Technology Authority

The Opposition tabled New Clause 3 which would establish a Genetic Technology Authority. It also tabled New Clauses 4 to 8 which set out further details of how the Authority would be constituted and operate. This body, modelled on the Human Fertilisation and Embryology Authority would, in Labour spokesperson Daniel Zeichner's words, establish a "a proper regulatory body that can look at [these] issues of consumer confidence, proportionality, environmental safety and the

190 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c245 [pdf]
191 As above, c246
192 As above c247
193 As above, c247 & c248

implementation of the legislation could address these issues and make the new system better for everyone".[194]

Mr Zeichner said that establishing an authority would give researchers, businesses and consumers confidence in the regulatory system and its public acceptance. It would also be:

> better for the country as a whole, with the benefits of the Bill being realised while any potential environmental issues and risks are safeguarded against. New clause 3 would establish such a body. […] This seems to us to be a sensible, proportionate approach that strengthens the Bill.[195]

Defra Minister, Victoria Prentis, responded that the Government had committed to consider wider regulatory reform of genetic technologies as part of a "stepwise approach to developing a more proportionate governance framework in this area". She said this was the "more appropriate context for discussions on an over-arching body, such as a genetic technologies authority, and it is consistent with a recommendation made by the Regulatory Horizons Council in its recent report". Under the Bill's provision, the Secretary of State would be required to make decisions based on the advice of expert committees. The Advisory Committee on Releases to the Environment (ACRE) would provide Minister with advice as to whether they should confirm the status of a precision bred organism. She added that:

> This is a complex and controversial area, as the hon. Gentleman acknowledges, and we can expect ACRE to be put under considerable scrutiny, rightly. However, I can assure the hon. Gentleman that the committee operates to the highest standards of impartiality and has the expertise to deal with the task in hand. I thank the hon. Gentleman for his detailed considerations on this topic but establishing a new independent body is not necessary at this point and does not provide value for money when we have an established committee with a superb track record in this area. However, I acknowledge this is a topic that we are likely to come back to when we consider wider GM regulatory reform in the future.[196]

New Clause 3 was negatived on division after debate (with New Clauses 4 -8 falling as they were consequential on New Clause 3).[197]

Scrutiny provisions

The Opposition tabled a number of amendments to various clauses that would strengthen the Parliamentary scrutiny process. In particular, these included: amendment 11 to Clause 6; amendment 15 to Clause 16; amendment 16 to Clause 17; and amendment 17 to Clause 22. These would require the affirmative procedure to be used rather than the

194 Public Bill Committee (Bill11) 2022-23, 7 July 2022 c269 [pdf]
194 As above, c269

196 As above, c269 & c270
197 Committee Stage Decisions [pdf]

negative procedure for scrutinising secondary legislation made under the regulation-making powers in the Bill. These amendments were negatived on division.[198]

Separately, the Opposition tabled several amendments to change a requirement from "may" to "must" in respect of various clauses in the Bill; for example, on environmental reporting (Clause 17), and on regulating the placing on the market in England of food and feed produced from precision bred organisms (Clause 26). See Amendments 19, 20, 21, 23 to Clauses 17, 25, 26 and 27 respectively. These amendments were all negatived on division.[199]

Clause 42 is a Henry XVIII clause – it allows primary legislation to be amended using secondary legislation. Questioned about the effect of this Clause by Labour spokesperson Daniel Zeichner, Defra Minister Victoria Prentis said that the Clause would lead to mainly "very technical amendments" as precision bred organisms are currently regulated by many GM legislative instruments that will need amending to reflect the changes made by the Bill. In the Government's view "the power in clause 42 enables the Government to make reasonable, proportionate and technical amendments".[200]

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198 Committee Stage Decisions [pdf]
199 As above
200 Public Bill Committee, (Bill 11) 2022-23, 7 July 2022, c243 [pdf]

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