BRIEFING

Beyond GM/A Bigger Conversation

Genetic Technology (Precision Breeding) Bill

The need for innovation that contributes to sustainable development goals is unarguable. The rapid development of agricultural genetic science and technologies means the time is right to review regulatory provisions for these technologies. The Government's Genetic Technology (Precision Breeding) Bill, therefore, should provide an opportunity for a comprehensive, society-wide discussion on how we should regulate genetic technologies in the UK. It should be a chance to avoid the ideology, arguments and impasses of the past.

Instead, we have been presented with proposals that are misleading in language and scientific fact; lack transparency and accountability; fail to protect consumers, farmers and animals; and ignore environmental protection. In our view, the bill fails on its own terms by generating confusion and mistrust and undermines the relationship between innovation, consumers, business and the market.

We urge parliamentarians to use the information in the sections that follow to raise questions and concerns and support amendments that will ensure gene editing benefits from clear, robust regulation.

WHAT BEYOND GM/A BIGGER CONVERSATION IS CALLING FOR

Innovation in agriculture, including genetic engineering, may have a role in responding to challenges such as feeding a growing world population, adapting to climate change and protecting natural resources. But based on what the Government has put forward, it is difficult to see how these poorly conceived proposals for regulatory reform will lead to either effective regulation or the kind of food, farmer, citizen and environment focused, socially-responsible innovation that we so desperately need in the 21st century.

Regulation and innovation need not be at odds. We believe that all products of agricultural genetic engineering (including newer gene editing techniques) should be regulated and that the bill would be immeasurable improved if the following changes were made to it:

- Remove/replace contentious and misleading language such as “precision breeding” and “natural transformation”;

- Limit scope of the bill to agricultural plants and animals;

- Ensure greater protection for animal welfare under the bill provisions;

- Ensure provisions for statutory labelling and traceability throughout the food chain;

- Broaden the assessment of all genetically engineered crops beyond narrow ‘scientific’ risk analysis to encompass social utility and proof of benefit. We propose the establishment of an Agricultural Genetic Technologies Advisory and Review Board comprised of representatives from research bodies, public interest bodies, civil society representatives and other relevant stakeholders to oversee, review and advise on the development and release of genetic technologies into food and farming.

For these provisions to be met the bill will require extensive revisions (and potentially deletions) some of which we detail in the next section of this brief. These changes would, nevertheless, ensure the bill is more balanced and equitable, that it serves the public good and that, in an area of technology that is rapidly evolving, it remains ‘future proof’.

PART 1 – QUICK TAKES

The bill and its accompanying documents are misleading

- It replaces the words gene editing and GMO with ‘Precision Breeding’. Yet, in scientific and legal terms (and buried in the bill’s text) precision breeding is genetic engineering and the new category of ‘Precision Bred Organisms’ (‘PBOs’) created for the purposes of the bill are GMOs.

- ‘Precision breeding’ is a marketing term, rather than a scientific one, which has been used to rebrand gene editing. However, as this joint statement by 100 international scientists and policy experts makes clear, this term is not commonly understood, poorly defined and its use obscures the full scope of the proposed deregulation.

- ‘Precision breeding’ has been promoted using a false narrative – specifically that the process is just a simple “cut” or “tweak” that might have occurred “naturally” and that it does not involve the insertion of transgenes (so-called ‘foreign’ DNA). These misperceptions affect the clarity and robustness of the Parliamentary debate. *See further context section below.*

The bill lacks transparency and accountability

- Almost every type of GMO, including those made using transgenes (foreign DNA) can come under the heading of precision breeding.

- Far too much in the bill depends on what the Government “may” (and therefore may not) do in the future. We are expected to trust it will make the right choices around *e.g.,* risk

assessment and environmental management. There are very few things the Government "must" do.

- The bill, for the most part, leaves further regulation to undebated secondary legislation.
- There is mention of various registers of 'precision-bred' organisms and products, but it is unclear how these will function and while there must be a register for crops, the FSA is under no obligation to make one for food and feed.
- For commercial products (plants and animals) careful assessment has been replaced with a notification system based on self-declaration by developers with no external risk (or benefit) assessment.
- Declarations will be "reviewed" not assessed by advisory panels/committees based on the ACRE model which has endemic, built-in conflicts of interest. The focus of these reviews will be narrowly science-based, excluding ethical and social impact assessments and citizen participation.

The bill fails to make a business case for deregulation

The Regulatory Policy Committee has twice rejected the impact assessment for the bill. Its 23 June 2022 report concludes that, overall, the government's analysis of the full impact of deregulating genome-edited plants and animals is "weak" and that the impact assessment:

- has not adequately considered and discussed the full range of potential impacts arising from the creation of a new category of genetically modified organisms;
- has not sufficiently considered and discussed the full range of impacts upon small and medium businesses;
- requires a detailed assessment of the competition, innovation, consumer and environmental impacts;
- needs to include greater discussion of the impacts arising from removing labelling and traceability requirements;
- needs to be improved by revisiting the assumption relating to the devolved administrations (DAs) and what impact this will have on the number of trials across the various scenarios.

It also notes that the quality of the Equivalent Annual Net Direct Cost to Business (EANDCB) and the Small and Micro Businesses Assessment (SaMBA) estimates provided by government are not based on validated evidence and "*Therefore, the RPC is unable to certify that the IA is fit for purpose*."

The bill fails to protect consumers, farmers and animals

- There are no provisions for labelling of genetically engineered/'precision-bred' food. This omission removes all consumer and farmer choice and transparency in the supply chain.
- There is no provision for mechanisms of coexistence between conventional/non-GM, organic/agroecological or local artisanal production systems and supply chains.

- There is no recognition of the considerable implications for animal welfare of this technology and no binding provision for delay or amendment in the deregulation of gene-edited animals.

The bill is for industry not for farming or the environment

- The single purpose of the bill is to remove regulations on the outdoor experimentation, planting and sale of genetically engineered crops and foods. The single beneficiary of the bill is the biotech industry.

- The bill makes no reference to 'farming' or 'agriculture'.

- There is, as the Impact Assessment says, no direct benefit to farming, to the environment or to consumers.

- Touted benefits for animal welfare, the environment and consumer health are described as "indirect" and "spillover" – and indeed no genome edited plants or animals currently exist that can deliver these benefits.

- Further, the Impact Assessment admits it is not feasible to track direct correlation between the uptake of genome edited crops and the touted outcomes.

The bill does not fulfil the obligations of the Environment Act

- The environmental statement on the front page of the bill, required by Section 20 of the Environment Act 2021 states that "the bill will not have the effect of reducing the level of environmental protection provided for by any existing environmental law".

- However, no environmental impact assessment has been performed, and the entire bill was drafted without reference to the environmental principles which the Environment Act says should inform the development of government policy going forward.

The bill generates confusion and mistrust in the market, thereby undermining its own aims

- It creates confusion and conflict within the UK internal market by failing to address the views of the devolved administrations;
- It runs counter to the "non-regression" terms of the Brexit agreement;
- It pays no attention to trade and regulation alignment with the EU and other parts of the world;
- The impact assessment fails to provide evidence of benefit to the diversity of SMEs throughout the UK farming and food supply chain;
- As drafted, the bill risks damaging the UK's reputation for sound and robust science and ethical regulation;
- Through its lack of transparency, it undermines citizen and consumer trust in scientific and technological innovation by putting corporate interests first and last.

PART 2 – FURTHER CONTEXT/CONSIDERATIONS

Poorly defined criteria

The criteria for reduced regulation – genetic changes that could have arisen through traditional breeding or "natural transformation" – is questionable.

There is no clear definition of these terms backed by convincing scientific evidence (actual or theoretical), nor is there clarity on how they can be consistently applied in robust regulation of genome-edited organisms in the environment or the marketplace.

In response to last year's public consultation, several learned organisations such as the FSA's Advisory Committee on Novel Foods and Processes, the Royal Society, the Microbiology Society, the Royal Society of Biology, the Institute of Food Science & Technology, Fera Science, Wildlife and Countryside Link and the Organic Research Centre challenged the Government's creation of a hypothetical class of GMOs that could have "occurred naturally" or could have been created using traditional breeding.

Their view was that this is a fundamentally flawed and unscientific basis for regulation. The Defra report on the consultation and the new bill ignore these concerns (see *Filling in the Blanks – What Defra Didn't Say*, A Bigger Conversation, 2022).

The implications of this are far-reaching:

- As there is no agreed international consensus on the scientific definition of the terms used in the proposed bill, any regulation based on them will not be aligned with those of the UK's trading partners.
- In addition, as it applies to England only, it will lead to confused and dysfunctional regulations and confused markets within the UK for both domestically grown crops and imported food and feed.

Lack of scientific coherence and clarity

In its title and text, the bill uses the term "precision breeding". However, "precision breeding" is not a specific technology nor a scientific discipline; it is a colloquialism for genome editing, and an umbrella term for a number of recently developed genetic engineering technologies which do not form a coherent group of methods and do not justify being called "precise". The scientific literature is full of reports of genetic technologies such as gene editing creating unexpected and unwanted mutations, genetic errors, altered proteins, and extensive deletions and complex rearrangements of DNA in plants (and in animals, see below).

Misleading about the nature of gene editing 1

Gene editing is not one technique, but many. The narrative around the bill is based on the simplest form of gene editing even though the process can be much more complex. Technologies like CRISPR do not, in themselves, create new organisms. In most instances, these genome editing tools, which are sometimes described as 'genetic scissors', are used to cut both strands of the DNA helix at a predetermined location. This cut then activates the cell's DNA repair mechanism. This combination

of events allows genetic engineers to introduce a genetic modification at a specific location on the genome.

Currently there are three types of procedures that can be used following the 'cut'. In the simplest possible terms these are:

- SDN-1 the cut is made and the organism's normal cellular repair mechanisms are left to make the repair;

- SDN-2 the cut is made and a template is provided to instruct the organism how to repair itself;

- SDN-3 the cut – and sometimes multiple cuts – are made and both a template for repair and the simultaneous insertion of transgenes ('foreign genes') are applied.

It is argued by proponents of genetic engineering that SDN-1 and possibly SDN-2, are close to what could happen in nature. Governments in the US, Australia and Japan have partially accepted this argument and have deregulated SDN-1 techniques. Nowhere in the world has deregulated SDN-3, but under ACRE's current advice it would, potentially, be deregulated here.

Misleading about the nature of gene editing 2

The popular narrative around gene editing is that it is different from genetic modification in that it does not insert foreign/exogenous genetic material into an organism. This is simply not the case. The majority of gene editing techniques (including CRISPR-Cas 9) are dependent on the insertion of exogenous genetic material from bacteria as a key element of the editing tool. This material may, or may not, be fully removed at some point in the organism's development.

Gene editing also can and does involve the deliberate insertion of foreign genes from a variety of different species in order to achieve a particular trait. In fact, the more complex the goal (such as drought or disease resistance) the greater the likelihood that foreign genes must be used to force the genetic change. Promoting the falsehood of no exogenous/foreign genes in the media makes an honest debate about gene editing impossible and fosters public mistrust.

Defra, and other government departments such as the Food Standards Agency, are also promoting the idea that the changes made by gene editing are undetectable. This is simply not true. When scientists develop gene-edited organisms, they must also develop the tools to trace and evaluate them. These tools help with research – they also help developers protect their valuable patent rights in the marketplace.

Detection tools are, at the moment, expensive. But as with most technologies, the more widely they are used the less expensive they will become. Gene-edited organisms can also be traced using standard audit trails already in place in the food system.

In addition, the Intelligence Advanced Research Projects Activity (IARPA), the research and development arm of the US Intelligence community, has just announced that it has developed new computational tools to help detect and identify when complex biological samples include genetically engineered organisms. This technology can be used at scale. If it can be done for genetically engineered organisms used in weaponry and biowarfare, it can be done for those used in the farming and food system.

Misleading about unsettled science

The core of the bill revolves around the contention, made by ACRE and others whom the Regulatory Policy Committee refer to as "interested parties", that it is "the final characteristics of an organism which determine whether it presents any safety risks, regardless of the method used to produce that organism".

Not all scientists agree, and the science is far from settled on this point.

Inexplicably, Defra has claimed that its consultation "received no new scientific evidence indicating that gene-edited organisms should be regulated as GMOs", when, in fact, there is a growing body of peer reviewed evidence and analysis which raises valid and credible questions about ACRE's opinion.

Two recent papers, from researchers in leading European research institutions are noteworthy; this paper by Kawall and this one by Eckerstorfer et al. However, there is an extensive and increasing body of evidence, for example the studies collected here and referenced here.

The omission of scientists representing these points of view means that Defra and by extension the MPs and Peers considering the bill are not benefitting from the opportunity to consider all the relevant scientific evidence.

A "science-based authorisation process" – means what?

The Government has said it wants a 'science based' authorisation process but without consideration of all the science this phrase has a hollow ring to it. Too often it is used as proxy language for trait or end-product assessment which is demonstrably inadequate in assessing complex genetic changes and for revealing unintended errors (see above). It is also shorthand for assessments made under controlled conditions, bound by confidentiality rules and undertaken by a narrow group of specialists, often with vested interests.

The notion of "science-based" regulation has become popular in government and amongst those with a narrow technological focus and vested interests. This is at odds with the socio-economic and values-based considerations which are integral to the Sustainable Development Goals to which the UK is signed up.

A recent investigation, for example, found that 100% of the scientists at ACRE – which has produced the current guidance on GMOs that" could have occurred naturally" – have conflicts of interest and none have any expertise in environmental toxicology. This kind of process is a major factor in continuing public mistrust over genetic technologies.

The impact of genetic technologies in agriculture cuts across multiple areas of concern. Therefore, robust and meaningful regulation must be based not just on evidence from laboratory science but also from the social sciences, environmental science, ecology, ethics, consumer preference and the concerns of farmers and food businesses.

Exaggerated promises of what gene editing can do

The Government has consistently said it wants to liberalise GMO regulations in order to fight climate change, feed the hungry and improve biodiversity. The urgency of these issues is being used to justify the haste with which this bill is being pushed through. However, the industry has been using this same justification for 25 years and still no genetically engineered crop can do these things.

The two recent approvals under new UK field trial rules are instructive. In the two months since the UK removed restrictions from field trials of GMOs that could have "occurred naturally" or been created through traditional breeding, researchers have put forward:

- A camelina (false flax) engineered to have an altered fatty acid profile. The camelina has been the subject of several trials in the UK already.

- A vitamin D-containing tomato. This trial seems very small and informal; the notification describes tomatoes "grown in pots on the research centre grounds". The variety being used, "Moneymaker", is popular with home gardeners.

Neither of these crops addresses pressing global issues. The camelina is intended for farmed fish feed and the nutraceutical industry. The vitamin D tomato also appears to be the subject of pharmaceutical rather than agricultural/environmental interest. Tomato fruits do not naturally contain vitamin D – a nutrient widely available in other foods and from exposure to sunshine.

Speeding genetically engineered animals into the marketplace

The Defra 'Lobby Pack' for the bill stated: "No changes will be made to the regulation of animals until animal welfare is safeguarded". This promise was open to wide interpretation and, indeed, the

Government's view of what is needed to safeguard animal welfare can be relatively undemanding.

It was also a tacit acknowledgement of the significant animal welfare implications of unintended and unexpected genetic errors (see here and here) which have been documented in genetically engineered animals.

On publication, it was clear the bill's provisions could be used to bring gene-edited animals into the marketplace at any time.

Not limited to agriculture

There is nothing in the bill that limits the gene editing of plants and animals to those used in agriculture. As written the bill greatly expands the definition of a plant from that in the Genetically Modified Organisms (Deliberate Release) Regulations 2002 from seeded and flowering plants.

In this bill, the definition of a plant (*Archaeplastida*) includes basically all plants. This means the usual agricultural crops but also trees, grass, shrubs, flowers, ornamentals and red and green algaes as well as brown algae (*Phaeophyceae*). The definition animal covers all vertebrates in the *Metazoa* family (except for humans) so mammals, birds, amphibians, reptiles and fish.

As with agricultural plants, developers will simply be able to self-certify that their plants and animals "could have occurred naturally" and these new organisms will not require further monitoring and assessment. We currently have no idea what harm genetically engineering wild species will do to ecosystems.

Ignoring public views

Last year the Government asked the public if it supported the planned changes in regulation of genetic technologies. The overwhelming majority said no; 85% expressed the view that genetic technologies used in farming should continue to be regulated in the same way as other GMOs.

This result was not unexpected. Recent public polls by the Economic and Social Research Council and UK Research and Innovation, the Lloyd's Register, the National Centre for Social Research, Food Standards Scotland and the Pew Research Center have all shown little public appetite for genetically engineered crops and foods.

A recent survey by the Food Standards Agency found that *"consumers wanted thorough regulation and transparent labelling if GE foods reach the UK market*".

The recent Nuffield Council on Bioethics public dialogues on genome-edited animals (here and here), found, amongst other things, that participants had a strong interest and desire to influence the way in which the food they consume is grown and reared and that they expressed significant concerns over the commercial drivers of genome editing in farmed animals, as well as the ability of governance and regulatory systems to control the technology in a way that meets public aspirations for the UK's future food system.

Nevertheless, citizens are major stakeholders in the food and farming discussion and their input on matters of how taxpayer money is spent, the needs for and appropriateness of specific genetically engineered crops and animals and on the roll out into the food chain and environment – including the necessity of labelling – is crucial. A failure to address these issues will result in a lack of trust and the collapse of both citizen and market "buy-in" to any new regulatory regime.

The proposal for a public register is welcome but…

…only if it is accessible, comprehensive and transparent enough in scope and detail to facilitate effective audit and provenance trails through the supply chain and, where necessary, post-release food safety and environmental monitoring. Since it is the stated intention of the Government to eventually deregulate all forms of agricultural genetic engineering, the public register should be forward looking and include all GMO 'events' used in plants and animals in the UK and not just those which are genome-edited.

All of this is necessary to ensure citizen and stakeholder trust and confidence in the regulatory process.

In addition, the bill, as currently drafted. does not require the FSA to make a register for gene-edited foods in our food system. This is an impediment to transparency and citizen choice.

Part 3 – SUGGESTED AMENDMENTS

The suggested amendments below cover more fully points made in our oral evidence to the Public Bill Committee 30 June 2022

PART 1 – Precision Breeding Definitions

Section 1 – replace 'Precision bred organism' with 'Genome-edited organism'

> **Explanation** (See also amendment to short title under Section 48, below). Genome editing is the scientifically correct term for the range of technologies referred to in the bill. In the interests are accuracy and transparency, in this section, definitions and throughout, all references to "precision breeding" and "precision bred organisms" – including in the long and short titles – should be amended to read "genome editing" and "genome-edited" and/or "GEOs".

Subsection (1) replace current text with

In this Act "genome-edited organism" means a plant or animal created using genome editing techniques.

> **Explanation**: as above

Subsection (2) replace current text with

For the purposes of this Act a plant is "genome-edited" if **–**

> **Explanation**: as above

Subsection (2)(c)(i) – Replace "traditional processes" with "conventional processes".

> **Explanation** The term "conventional breeding methods" is a more accurate and honest description of the methods set out in Part 1, (7a) of the bill and therefore at Part 1, (2)(c)(i). We suggest that these areas are amended accordingly. In addition, use of the term "traditional practices" is not consistent with international regulations and means something different from "traditional breeding" which is a whole system broader than the method used to make the initial genetic transformation. The Cartagena Protocol, for example, uses the term "traditional breeding" but doesn't define it. Other countries use the term "traditional breeding", and none use "traditional processes".

Subsection (2) (c)(ii) – Remove references to "natural transformation".

> **Explanation** This appears in Section 1 (2)(c)(ii) and (6) but nowhere else in the bill. It is unclear, for instance, whether this means "spontaneous mutation" (as in Part1 (7)(a)(ii)) or something else. Without definition or description of scope the term is meaningless and open to very wide interpretation. In addition, the use of the phrase natural transformation has

unexamined implications, elsewhere in the bill, for the potential inclusion or exclusion from the novel food regulation and for labelling.

Section 2 insert a new subsection

(d) if transgenic material is used or produced in the process it does not constitute a genome-edited organism even if that material has been subsequently removed.

Explanation Despite all the PR narrative about how gene editing does not involve the transgenes and transgenic transfer across species barriers. In fact, it involves both. This bill allows transgenesis to be used and then any resulting transgenic material to be removed from the final product. This is hidden deregulation of "old style GMOs". Irrespective of opinions about GMOs, this deceit should not be embedded in the bill.

Insert new section 3

For the purposes of this Act an animal is "genome-edited" if **–**

Explanation A clearer definition of genome-edited animals needs to be set out in this section. The definition of "modern biotechnology" set out in Section 1(3) references S.I. 2002/2443 is unclear in relation to animals. Definitions given in Section 1 (2, (2), (3), (4), (5), do not add clarity. The relationship of these to the "traditional processes" set out in Section 1 (7b) add to the confusion. For example, it is unclear whether cloning is allowed in the breeding process.

Sections (5) and (6) should be deleted.

Explanation Sections (5) and (6) remove all consideration of genetic changes which may occur in the breeding process which does not occur in the final product (except for "functional protein"). Other than the Canadian regulation no other regulatory body prohibits the possibility of such consideration. Different countries are developing various "trigger points" to allow and/or encourage such considerations on food safety and environmental grounds. They recognise that different gene editing methods involve different levels of genome disruptions and are also mindful of future technical developments. This bill does not allow any such consideration and thereby excludes the possibility of proportionate and tiered risk assessment. Further, it is unclear whether the Food Standards Agency will be limited by these sections in carrying out its food safety risk assessments under Part 3, Section 26(6). Consideration could also be given to a tiered risk assessment approach such as those developed in Australia, China and which will, almost certainly, be developed in the EU.

Section 2 – Meaning of "plant" and "animal"

Delete subsections (1) & (2)

Insert new subsections

(1) Sections 2, 3, 4 and 5 of this Act shall apply to agricultural plants and animals only.

(2) For the purposes of this Act, “agriculture” shall be taken to mean any activity which entails the commercial cultivation of plants or the breeding of animals to provide food, feed, drink, fibre, wool, skin, fuel or other products to sustain life.

(a) For the purposes of this Act, “agriculture” shall include **–**
(i) arable farming;
(ii) horticulture;
(iii) animal husbandry;

(b) For the purposes of this Act, “agriculture” shall not include **–**
(i) forestry;
(ii) allotments
(iii) aquaculture;

(3) For the purposes of this Act, an “agricultural plant or animal” means a plant or vertebrate animal, but not including **–**

(a) a fish, reptile or amphibian;
(b) an animal wholly or mainly for domestic purposes;
(c) an experimental or laboratory animal;
(d) an assistance or service animal;
(e) an animal or plant solely intended for use in, a competition, show or cultural or sporting event or activity;
(f) an animals and plants sold or kept for ornamental purposes;
(g) an animal or plant living in the wild.

Explanation The amendment aims to limit the scope of the bill to agricultural plants and animals only. As drafted, the bill allows a wide range of genome-edited plants and animals, including those that are free living, to be released into the environment without environmental assessment or monitoring. Research into the impact of free-living genome-edited organisms is in its infancy, no plans for monitoring free living gene-edited plants and animals are in place and the bill should be restricted to plants and animals in agriculture where there is at least some data (however incomplete).

PART 2 – Precision Bred Organisms: Release, Marketing and Risk Assessments

Insert a new section at the beginning of Part 2:

The Secretary of State will establish an “Agricultural genetic technologies advisory and review board” consisting of research bodies, public interest bodies, civil society representatives and other relevant stakeholders to oversee, review and advise on the development and release of genetic technologies into food and farming.

Explanation A scientific ‘risk assessment’ is inadequate to assess environmental, ethical and societal impacts of genome-edited crops and animals. The Board should ensure that ethical and social utility issues are considered alongside narrow based risk assessments. In order to ensure broad based societal engagement and assessment of risk and benefit in agricultural genetic technologies now and in the future, the composition of this board should ensure

public interest representation balances the interests of commercial and development stakeholders. The work of the advisory committees mentioned elsewhere in this bill should be overseen by this board which will have the power to veto or overturn recommendations in prescribed circumstances.

Insert a new section at the beginning of Part 2:

The Secretary of State will establish the requirements and a Code of Best Management Practice for management and notification procedures relating to the release of genome-edited organisms.

> **Explanation** In order to ensure equitable and clear co-existence between land use and different approaches to genetic technologies; and to prevent market and legal disputes.

Section 3 insert an additional subsection

(c) measures taken in (a) and (b) should be set out and described on a public register and are assessed by the "Advisory Committee" or ACRE and subject to inspection.

> **Explanation** To ensure that there is no release into the environment or the food chain before authorisation – as has happened previously in light touch regulatory regimes such as the US.

Marketing

Insert a new section under (5)

Before making regulations under this section, the Secretary of State must consult the "agricultural genetic technologies advisory and review board" (see above).

> **Explanation** To ensure ethical and social utility issues are given consideration alongside narrow based risk assessments before putting a product on the market.

Precision bred confirmation

Section 6(2)

Replace "may" with "must".

Section 6 (2)(b) details of ("required information") should include a comprehensive characterisation such required in the Chinese regulation (see here: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=MARA%20Issues%20First%20Ever%20Gene-Editing%20Guidelines_Beijing_China%20-%20People%27s%20Republic%20of_01-26-2022.pdf).

Section 7(2) insert new subsection

(c) The report by the advisory committee will include the information from 6(2) and this information will also be included on the Precision Breeding Register (Section 18) which should also stipulate that the advisory committee must refer its reports to the "Agricultural genetic technologies advisory and review board" (see above), as well as to the Secretary of State.

Explanation. The "Agricultural genetic technologies advisory and review board" can provide an ethical and social utility input, so it is not limited to narrow risk assessment. Ideally, these committees would be appointed not just by the Secretary of State but in conjunction with the Genetic Technologies Board and its views given parity with any scientific assessment.

Part 10 – Meaning of "relevant animal" amend (1)

(1) In this Act "relevant animal" means an agricultural animal (See new Section 2 above).

Explanation Limits the scope of the bill to agricultural animals only.

PART 3 – Food and feed produced from precision bred organisms

Section 26 – Regulation of food and feed produced from precision bred organisms

Subsections (1), (2), (3), (4) and (6) "may" should be amended to "must" and be part of the Act, not delegated powers.

Explanation More detail needs to be added here about the requirements of these regulations.

Subsection (2)(b) add

"Including labelling" after "impose requirements".

Explanation: Labelling provisions must be made within this Act and not left to regulations.

Subsection 6(a)(ii) should be amended

"to carry out risk assessments including those arising from the genetic modification process and not limited to the target trait."

Explanation to ensure any off-target effects are caught before marketing release.

Section 27 (1), (2) and (3) "may" should be amended to "must" and be part of the Act, not delegated powers.

Explanation to ensure FSA produces and maintains a publicly available register of genome-edited marketing releases in the food system.

Part 5 – General

Section 48 – Short title and commencement

The short title should be amended to read Agricultural Biotechnology (Genome Editing) Bill and that the words precision breeding and precision bred should be replaced throughout by the more widely understood and scientifically accurate terms genome editing and genome-edited.

> **Explanation:** Genome editing is the scientifically correct term for the range of technologies referred to in the bill. Precision breeding/bred is a colloquialism/euphemism/marketing slogan that has no place in serious and substantive legislation. In addition, it does not align with any terminology used by any regulators in the world, nor does it align with the Convention of Biodiversity and the Cartagena Protocol which many regulators are using as a "benchmark". See related amendments Section 1 (above).

The long title should then read:

"A bill to make provision about the release and marketing of, and risk assessments relating to, genome-edited plants and animals in agriculture, and the marketing of food and feed produced from such plants and animals."

> **Explanation:** this is consistent with proposed amendments to Section 2 (above)

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