Genetic Technology (Precision Breeding) Bill
Written evidence submitted to the House of Commons Public Bill Committee

By email to scrutiny@parliament.uk
30 June 2022

1. Introduction

1.1. GM Freeze is the UK umbrella campaign for a responsible, fair and sustainable food system, focused on concerns around the use of genetic engineering in food and farming. Our member organisations include large NGOs, scientists, farmers, retailers and community groups.

1.2. We are aware of many misconceptions around the role of single-issue campaigns and would like to stress that we exist because we are needed. GM Freeze member organisations and the thousands of individuals who support and follow our work, tell us that they find it difficult to engage in political and policy discussion about the use of genetic engineering in food and farming. They ask us to follow the fine detail of technical and political developments on their behalf and help them to articulate their concerns. That is what we are seeking to do in submitting written evidence to the committee.

1.3. In summary our evidence covers:
2: Precision breeding is genetic modification (with further detail in Appendix 1).
3: Nature protects key parts of the genome.
4: All genetic material matters.
5: Businesses and the public have already rejected the measures included in the bill.
6: Key areas of concern in the bill.

2. Precision breeding is genetic modification

2.1. We appreciate that the majority of Members of Parliament have very limited scientific knowledge or training. Nonetheless, we have become increasingly concerned by the frequency with which inaccurate statements about the nature of gene editing techniques have been repeated during recent Parliamentary debates, including the Second Reading of the Genetic Technology Bill and the first day of oral evidence to the committee. It is simply not true to state that new genetic engineering techniques (variously described as gene editing, genome editing, new breeding techniques and, in the bill, precision breeding), do not involve the insertion of "foreign DNA". Indeed, this is the first step in ***all*** such applications and is carried out using exactly the same techniques that Katherine Fletcher MP described during the Second Reading as "pebble-dashing a target DNA area".

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2.2. Recognising the difficulty that non-scientists have in navigating this issue – and the conflicts of interest that the genetic engineering sector has in describing the nature of their work – we recently published a briefing entitled *Why Gene Editing is GM with Better PR*. This aims to explain the processes involved in the new generation of genetic engineering techniques in non-technical language and we hope that members of the committee will find it helpful. The briefing is available on our website[1] and is included as Appendix 1.

3. Nature protects key parts of the genome

3.1. Research increasingly shows that natural and induced mutations are not as random as had been previously assumed. For example, a study published in the peer-reviewed journal *Nature* in January of this year[2] found that genes that are involved in essential functions showed very low rates of natural mutation. Indeed, they seem to be protected by particularly effective DNA repair mechanisms. Genome editing techniques bypass this protection system, accessing the whole genome and overriding the cellular repair mechanism. This is one key reason why new genetic engineering techniques are not equivalent to natural variation or traditional breeding techniques.

3.2. The implications of the Nature study and others are well explained in a report by the German institute Testbiotech and the Canadian Biotechnology Action Network. *Unintended effects caused by techniques of new genetic engineering create a new quality of hazards and risks* is available online[3] and is attached to our email to the committee as Appendix 2.

4. All genetic material matters

4.1. The genome of any organism operates rather like a molecular ecosystem with complex interactions that are influenced by a range of internal and external factors. Some genes code for proteins, while others regulate when, where and how different coding genes are activated. Alterations to these regulatory genes is common in genetic engineering and can have profound and sometimes unpredictable effects. However, the bill instructs those assessing whether or not an organism qualifies as "precision bred" to ignore alterations to such regulatory genes when it states that "no account is to be taken of genetic material which does not result in a functional protein." [Part 1, 1, (6)]

4.2. We assume that this was the clause that led Gideon Henderson to assert, in oral evidence to the committee, that the insertion of exogenous genetic material is only of concern if it "has an outcome that matters".[4] We respectfully remind the committee that **all** genetic material matters and if we do not yet know what role it plays then that reflects the limits of human knowledge, not the significance of the material under consideration.

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[1] https://www.gmfreeze.org/publications/gm-with-better-pr/
[2] https://www.nature.com/articles/s41586-021-04269-6
[3] https://www.testbiotech.org/sites/default/files/New_GE_unintended_effects_2.pdf
[4] Oral evidence to the Genetic Technology Bill Committee, 28 June 2022

5. Businesses and the public have already rejected the measures included in the bill.

5.1. Defra's own *Consultation on the Regulation of Genetic Technologies* last year sought views on proposals broadly in line with those included in the bill and received in return a resounding **no.** The vast majority of responses rejected both the general direction of travel (deregulation of newer genetic engineering techniques) *and* the central proposition of the Genetic Technology Bill, ie that we can effectively regulate on the basis of whether or not a planned genetic change could, hypothetically, have been achieved in a different way.

5.2. Responses to the consultation were categorized in a way that privileged a tiny proportion of respondents and side-lined the views of members of the public who turn to organisations such as GM Freeze to help them articulate their concerns. Nonetheless, the results were unequivocal with 88% of individual responses and 64% of businesses saying that they wanted the genetic engineering techniques and outcomes covered by this bill to remain under the protection of GMO regulations.

6. Key areas of concern in the bill

Although we disagree fundamentally with the Government's policy regarding the regulation of genetic engineering in food and farming, GM Freeze remains willing to discuss ways in which the Genetic Technology Bill can be improved to safeguard our food, our farms and the environment. Key areas in which we would welcome the Committee's consideration include the following.

6.1. **Definitions. Several key terms used in the bill are not properly defined and the definitions that are included raise many questions.** In particular:

6.1.1. As noted in 4.1, above, a number of factors are expressly excluded from assessments to determine whether or not an organism is deemed "precision bred". One of these is the location on the genome at which a genetic change has been induced. As noted in section 3, above, gene editing techniques can access and change parts of the genome that are rarely altered by natural or induced mutation. As we do not know exactly how or why nature protects parts of the genome in this way it is reckless to discount the location of any genetic change in assessing whether or not a particular genetic change could (theoretically) have occurred in nature. The bill should be amended so that those tasked with assessing which organisms are to be deemed "precision bred" are compelled to consider a wide range of data.

6.1.2. No timescale is given for the comparison between what has been achieved through genetic engineering and what could, theoretically, have happened in nature or through traditional breeding techniques. The glorious variety of life on earth is testament to the potential for almost anything to evolve under the right circumstances. The bill should be amended to limit the timescale and number of generations over which any comparison with nature or traditional breeding techniques is considered.

6.1.3. All non-human animals are included in the deregulatory scope of the bill but only some animals are covered by the new protections which it will establish. This will leave significant groups of animal species completely without protection and must be amended.

6.2. **The bill mandates only very limited assessments of the impact of plants or animals deemed to be "precision bred".** The assessments that are set out in the bill focus on the genetic engineer's intentions rather than what has, in fact, occurred. Indeed, in his oral evidence to the committee on 28 June, Gideon Henderson stressed that the bill has been drafted to focus on intentionality, rather than outcomes. As we explain in the briefing included as Appendix 1, there are many ways in which gene editing can go wrong, including both unplanned genetic changes and unexpected outcomes of planned changes. The genetic engineers that have appeared before the committee as expert witnesses are, of course, drawn from long-established institutions with a good safety record. However, a stated purpose of the bill is to encourage growth in the genetic engineering sector, with a focus on independents and small enterprises that have no such pedigree. It is, therefore, vital that the bill is amended to require assessments that consider adequately the nature and impacts of the genetic changes actually made in each case.

6.3. **This bill does not provide adequate traceability or consumer labelling.** Research consistently shows high public demand for the labelling of all food products produced with genetic engineering methods. A 2021 consumer perceptions study commissioned by the Food Standards Agency found that, even when consumers felt it would be appropriate to regulate what the study described as "GE food" separately from GM food, "Most consumers felt labelling should always inform the consumer of the presence of GE ingredients".[5] The bill should be amended to provide consumers with the transparency that they have clearly and consistently requested and that can only be deilvered by compulsory labelling.

6.4. **The bill does not provide any measures to prevent contamination of the organic or conventional (non-GM) supply chain with "precision bred" organisms.** This is a matter of huge concern to food and farming businesses throughout the UK and is a significant factor in the Regulatory Policy Committee's Opinion that the Impact Assessment for this bill is "NOT FIT FOR PURPOSE (red-rated)"[6]. This opinion reflects our view that Defra has repeatedly failed to properly identify the business sectors impacted by this bill. Changes in the regulation of genetic engineering will, of course, impact the 80 or so seed breeders in the UK. However, this tiny sector is dwarfed by the range of businesses across the food and farming industries who will also be significantly impacted. The bill must be amended to ensure that "precision bred" organisms cannot be released without effective coexistence measures, supported by full traceability and clear allocation of liability.

6.5. **The bill confers a number of powers to regulate but very few obligations to do so.** Where use of regulations is specified, there are no minimum standards set to guide the quality of this secondary legislation, and there is an overuse of the negative scrutiny procedure which will hinder parliamentary oversight. These failures will not reassure concerned citizens and should be amended.

Liz O'Neill on behalf of GM Freeze, 30 June 2022

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[5] https://www.food.gov.uk/research/behaviour-and-perception/consumer-perceptions-of-genome-edited-food.

[6] https://www.gov.uk/government/publications/the-genetic-technologies-precision-breeding-techniques-bill-rpc-opinion

APPENDIX 1

Why Gene Editing is GM with Better PR
A simple briefing from GM Freeze

1. Introduction

GM Freeze is the UK umbrella campaign on the use of genetic engineering[i] in food and farming. We are clear that gene editing is GM with better PR (public relations) and these notes explain why in a way that we hope everyone will understand. Please note that many of the references we include as evidence are much more technical.

2. Genetics – the basics

2.1. Nucleotides are small molecules that act like a kind of biological information code. There are five different nucleotides, usually known by the letters A, C, G, T and U[ii].

2.2. Nucleotides are combined into more complex molecules known as DNA[iii] and RNA[iv]. Each organism's[v] DNA is unique, and the information it contains is sometimes referred to as its genome. RNA comes in many forms and plays a vital role in "decoding" genetic information. In this briefing we use the term genetic material to include both DNA and RNA as the two often work together, hand in hand.

2.3. Sections of DNA that have been identified as doing a particular job are usually known as genes. Coding genes help the organism's cells build a particular protein while regulatory genes are involved in controlling how, when and where different coding genes become active. Some genes have an impact on lots of different traits (characteristics). At the same time, most traits are controlled or influenced by more than one gene. The genome is far more complex than people used to believe, and many factors can influence how and when different genes are active.

2.4. Mutations are changes to an organism's genome, often caused by a genetic injury or an error when cells multiply. Mutations happen frequently and play a big part in evolution, but new research shows that some parts of the genome are protected and suffer very few mutations. This is probably because they are so important to the way that the organism works.[vi]

3. Genetic modification

The terms genetic modification (GM) and genetically modified organism (GMO) are defined in UK law.[vii] They mean that the genome of an organism has been changed in ways that don't involve breeding. The legal definition of a GMO does not say anything about whether or not a new gene (or other genetic material) is added to the organism.

4. How gene editing works

4.1. The term gene editing[viii] is not defined in law, but it generally means using laboratory techniques to change an organism by modifying its existing genome rather than deliberately adding a new gene.

4.2. The first step is to force genetic material into a target organism cell[ix] using the same techniques as with older GMOs.[x]

4.3. The genetic material that is added includes the editing tool and, usually, one or more "marker" genes that help the genetic engineer identify organisms that they have modified (for example genes for resistance to particular antibiotics). Sometimes extra genetic material is added to act as a guide or template (see 4.4 below). The genetic material used in the gene editing process usually comes from other species (including bacteria) but some of it is synthetic (made from scratch in the laboratory).

4.4. The gene editing tool seeks out a particular nucleotide sequence (a specific combination of A, C, G and T molecules). When it finds this sequence, it damages the target organism's DNA. The organism responds by trying to repair this damage. At this point a few different things can happen:

- The organism can make a perfect repair and there is no change to its genome.
- The organism can make an imperfect repair that changes its genome in ways that may – or may not – help the genetic engineer to achieve their aims.
- If the genetic engineer has included a template (see 4.3, above) this will force the organism to repair the damage in a way that makes a particular change to its genome.

4.5. Genetic engineers often plan to remove the genetic material they have added but they don't do this until late on in the process and it does not always work. Some of the gene-edited GMOs growing in UK field trials still contain the gene editing tool, in an active form.[xi] Also, gene-edited "hornless" cattle were found to contain genetic material that was supposed to have been removed, including genes for antibiotic resistance.[xii]

4.6. Gene editing is an invasive process that disrupts the way that an organism protects and repairs its genome. Gene editing can access – and change – all parts of an organism's genome, including the areas that are usually protected from mutations (see 2.4, above).

5. How gene editing can go wrong

5.1. Gene editing is often described as precise because it targets a particular nucleotide sequence (see 4.4, above). However, a very similar sequence can appear in many different parts of the genome, just like addresses can be so similar that our post gets delivered to the wrong house. Being precise is not the same thing as being accurate and gene editing can happen in the wrong place on the organism's genome. This kind of mistake is usually called an off-target error or effect.[xiii]

5.2. The genetic engineer may be successful in injuring the part of the genome that they intended but this may result in different genetic changes than were planned, either instead of or as well as the planned changes. This kind of mistake is usually called an on-target error.[xiv]

5.3. The gene editing process involves lots of complex stages that can put the target organism under stress. This can cause additional genetic injuries which are often called process-induced mutations.[xv]

5.4. The genetic changes can go as planned, but still create unexpected outcomes in the organism because the genome operates in very complex ways that scientists do not fully understand (see 2.3, above)[xvi]

5.5. Even if everything in the laboratory goes entirely as planned, releasing a gene edited organism into the environment can disrupt the ecosystem. This kind of problem is usually called an unintended consequence and can happen with any change (not just gene editing) but the more we interfere with nature the more we risk setting off chain reactions that we cannot stop.

5.6. Many people are concerned that, like with other forms of GM, gene editing will be used in ways that prioritise the interests of big business rather than animal welfare, human health or the environment.

6. **Don't believe the hype**

6.1. The genetic engineering industry does not like being regulated. They want the safety of the plants and animals that they create to be taken on trust and the development of new techniques gave them an opportunity to "re-brand" what they are doing. Lots of new names have been used including gene editing, genome editing, new breeding techniques and precision breeding. None of these terms is currently defined in law.[xvii]

6.2. Gene editing processes – and the organisms that are created with them – can be patented. This means that the law considers them to be inventions and not the same as organisms that occur in nature or that are developed through breeding.[xviii]

6.3. We often hear that gene editing makes small genetic changes. This is not always true as gene editing can be used to delete or add large sections of genetic material, and to make changes in lots of different parts of an organism's genome at once. More importantly, when it comes to genetics, even tiny changes can have huge impacts.[xix]

6.4. Those who want to remove safety checks and our GM labels don't want people to think of gene editing as a form of genetic modification but that is exactly what it is. There is much that can go wrong, and proper regulation is an essential safety net for our food, our farms and the environment.

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Notes and references to Appendix 1

[i] Genetic engineering is not defined in UK law but is generally understood to mean changing genetic material directly (rather than through breeding). We use this term when we need to be sure that everyone understands we mean both older GM techniques and the newer ones that are given various different names (including gene editing).

[ii] The five nucleotides are also known as bases and are adenine (A), cytosine (C), guanine (G) thymine (T) and uracil (U). DNA is made up of A, C, G and T in varying numbers and orders. RNA is made up of A, C, G and U, sometimes in very small sequences and sometimes in much longer ones.

[iii] Deoxyribonucleic acid.

[iv] Ribonucleic acid. There are lots of different types of RNA which you may see referred to with an extra initial letter, eg mRNA (messenger RNA).

[v] An organism is a living thing. It could be a plant, an animal or a microbe (tiny organisms such as bacteria).

[vi] Kawall K. New possibilities on the horizon: Genome editing makes the whole genome accessible for changes. Front Plant Sci. 2019;10. doi:10.3389/fpls.2019.00525

[vii] https://www.legislation.gov.uk/uksi/2002/2443/contents/made

[viii] Also known as genome editing

[ix] A cell is the basic unit of life as we know it. All organisms are made up of cells.

[x] For example, *Agrobacterium*-mediated transfer or microparticle bombardment.

[xi] https://www.gmfreeze.org/wp-content/uploads/2021/06/Multi-agency-response-to-GM-wheat-trial-application-ref-21_R08_01-UPDATED.pdf

[xii] https://www.gmwatch.org/en/news/archive/2019/19096-fda-finds-unexpected-antibiotic-resistance-genes-in-gene-edited-dehorned-cattle

[xiii] https://www.testbiotech.org/sites/default/files/Frequently_asked_questions_about_CRISPR_and_Co.pdf

[xiv] http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/genome-editing-techniques-fin.pdf

[xv] https://www.econexus.info/publication/transformation-induced-mutations-transgenic-plants. This paper focuses on older GM techniques but the problems it discusses are caused by the mechanisms used to insert genetic material, the use of tissue culture and other laboratory processes that are also used in gene editing.

[xvi] https://www.testbiotech.org/sites/default/files/New_GE_unintended_effects_2.pdf

[xvii] The Genetic Technology Bill aims to create a new legal status for “precision bred organisms”. This will set a legal precedent.

[xviii] In 2020, the European Patent Office Enlarged Board of Appeal confirmed that plants and animals exclusively obtained by essentially biological processes cannot be patented https://www.epo.org/law-practice/case-law-appeals/pdf/g190003ex1.pdf.

[xix] Consider, for example, that sickle cell disease, Tay-Sachs disease and colour blindness are all caused by a single point mutation, where only one nucleotide (the smallest unit of genetic material) is altered.