

# Legal and scientific briefing on the Genetic Technology (Precision Breeding) Bill

*ARROW Northwest*

## Summary

1. This is a briefing note on the provisions in the Genetic Technology (Precision Breeding) Bill (“the Bill”).<sup>1</sup> It has been produced with the assistance of our legal representatives Leigh Day and Co and leading and junior counsel on matters of law. The key points are as follows:
  - a) The Bill removes genetically modified plants and animals defined as “precision bred organisms” from the regulatory requirements currently applicable to most Genetically Modified Organisms (“GMOs”).
  - b) The definition of a “precision bred organism” (clause 1) is very wide. It is similar to that of a “Qualifying Higher Plant” (“QHP”) in the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022, although the definition in the Bill also includes animals.<sup>2</sup>
  - c) The Bill introduces two replacement regulatory systems: one for organisms produced for research purposes (for which there is only a notification requirement), the other for marketing purposes (for which the Secretary of State must be satisfied that the organism meets the wide definition in the Bill and, in the case of animals, certain animal welfare requirements).
  - d) The Bill also introduces powers to create a new authorisation procedure for food and feed products using these organisms via secondary legislation.
  - e) In our view, there are significant legal risks associated with the Bill, namely:
    - i. The very wide definition of a “precision bred organism”,
    - ii. The requirements of the new regulatory systems,
    - iii. The over-reliance on secondary legislation,
    - iv. The potential breach of the UK’s international legal obligations,

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<sup>1</sup> Available here: <https://bills.parliament.uk/bills/3167>

<sup>2</sup> Reg 2(2) provides that a QHP is “a higher plant which is a genetically modified organism but which has not been genetically modified other than to make modifications— (a) that could have occurred naturally, or (b) that could have been made using one or more of the techniques set out in regulation 5(2).”

v. Devolution issues.

2. We address each of these issues below in more detail.
3. In terms of our recommendations, we consider the Bill should be amended such that there is a requirement in primary legislation to (1) notify neighbouring farmers of the release of these organisms, and (2) to appropriately label food and feed containing these organisms. At the moment both of these matters are left in the Bill to the discretion of the Secretary of State via powers to create secondary legislation.

**Issue 1: the definition of a “precision bred organism”**

4. It appears to us that there are serious problems with the definition of a precision bred organism in the Bill.
5. Clause 1(2) of the Bill states that an organism is “precision bred” if a feature of its genome results from the application of modern biotechnology, every feature of its genome that does so is stable, and every feature of its genome “could have resulted from” traditional processes (whether or not in conjunction with selection techniques) or natural transformation.
6. This definition is very wide, and potentially misleading. A large number of genetic changes could, in theory, “have resulted from” either traditional processes or natural transformation: but it is somewhat artificial to say that this is the case if (for example) the mutation is a 1 in a million chance, or would only have occurred very slowly – say over the course of a million years. Nevertheless, the absence of appropriate qualifiers in the Bill means that genetic changes that fall within either of those two extreme examples would still meet the definition in the Bill.
7. The definition also provides that the copy number of a genome’s feature, its epigenetic status, its location in the genome, and genetic material that does not result in a functional protein should all be disregarded for the purposes of determining whether that feature could have resulted from traditional processes (clauses 1(5)-(6)). Each of these changes is a hallmark of genetic modification, and could not result from traditional processes (which is presumably why this exception is in place). But such changes can have a radical impact, as we demonstrate below.

**(i) Copy number**

8. For example, in the field of human medical genetics, the copy number of genes is acknowledged to be “pivotal in biological pathways” and to play an important role in susceptibility to major

common diseases.<sup>3</sup> In livestock animals, the copy number of genes is known to “alter the gene expression and change the phenotype of an individual”<sup>4</sup> – factors that could make the difference between health and severe disease, abnormalities, or premature death.

9. In plants, the copy number of specific genes has been linked to important traits such as flowering time, plant height and resistance to environmental stressors.<sup>5</sup> The copy number of genes has also been found to be linked to evolutionary adaptation in plants and to affect defences against diseases.<sup>6</sup>
10. In transgenic plants, the copy number of the transgene(s) can affect the stability of the desired GM trait.<sup>7</sup> Stability of the GM trait is one of the criteria named in the Bill for determining whether a GMO is a “precision bred organism”.<sup>8</sup>

**(ii) Epigenetic changes**

11. Human diseases such as Fragile X syndrome, Angelman’s syndrome, Prader-Willi syndrome, and various cancers are all caused by epigenetic changes.<sup>9</sup> It is therefore concerning that these kinds of changes are also disregarded for the purposes of determining whether a proposal is subject to the stricter GMO regulatory regime or not.
12. The importance of epigenetic status of gene-edited plants is illustrated by the findings of an experiment with Arabidopsis plants. The researchers used the CRISPR/Cas gene-editing tool to try to remove a section of DNA important for cold tolerance from the plants’ genome. The Crispr/Cas9 tool was used to simultaneously target and silence three genes in the genome. The three genes are similar in their structure and located close together in the genome. Three 'lines' of the same species were used; all had different origins. All three lines had the same gene sequences with regard to cold tolerance. However, the success rate of the intended gene manipulation in one line of Arabidopsis was 33%, whereas in another line it was only 3.7% – about a tenth of the former. According to the authors, epigenetic effects were likely to be responsible for the differences between the different lines.<sup>10</sup>

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<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920180/>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5960796/>

<sup>5</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544587/>

<sup>6</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5259951/>

<sup>7</sup> <https://pubmed.ncbi.nlm.nih.gov/26670088/>

<sup>8</sup> Part 1(2)(b).

<sup>9</sup> <https://www.nature.com/scitable/content/epigenetic-diseases-and-their-causes-and-symptoms-37397/>.

<sup>10</sup> <https://www.frontiersin.org/articles/10.3389/fpls.2017.01910/full>

13. These results show that gene editing outcomes do not solely depend on DNA sequence. Epigenetic status controlling global patterns of gene expression can also be a decisive factor and can therefore play a large role in determining the risk or safety of the GMO in question.

*(iii) Location of the genetic feature*

14. Position effects, or location of the genetic feature, are also crucial to the safety of the GMO for health and environment. A position effect is defined as a deleterious change in the level of gene expression brought about by a change in the position of the gene relative to its normal chromosomal environment, but not associated with a mutation or deletion of the gene.
15. Gene expression can be greatly influenced by its position in the genome, to the extent that in human genetics, gene position can make the difference between health and serious disease.<sup>11</sup>
16. In mammalian cells, transgene expression was found to vary more than 1,000-fold based on genomic location.<sup>12</sup> In transgenic animals, position effects can strongly influence the transcription of foreign genes, leading to complications such as low frequencies and levels of gene expression and abnormal patterns of expression. The seriousness of these effects has prompted scientists to spend years looking for ways to overcome them.<sup>13</sup>
17. Major problems caused by position effects negatively impacting gene function is one of the main reasons why GM crop developers must screen hundreds, if not thousands, of individually created transgenic plants to find a few suitable candidates to take forward. This is because each individually created transgenic plant contains the transgene inserted at different locations in the plant genome and thus is subject to different position effects. Only a few transgenic plants will harbour transgene integrations at locations that fortuitously permit a suitable level and stability of expression.
18. While gene editing aims to create targeted mutations and thus to overcome position effects, this has not been achieved. As a scientific review has pointed out, whilst the actual gene editing allows modifying the DNA at a target site, the claimed precision may not hold true for the delivery and integration of its tools. The common use of older-style first-generation genetic engineering techniques to integrate DNA encoding the CRISPR/Cas components results in insertion at a random location in the genome, often with multiple and flawed (e.g. partial) copies. Random integration of the transfer DNA (T-DNA) from Agrobacterium-mediated plant transformations

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<sup>11</sup> <https://academic.oup.com/hmg/article/7/10/1611/635945>

<sup>12</sup> <https://www.sciencedirect.com/science/article/pii/S0092867413008891>

<sup>13</sup> <https://pubmed.ncbi.nlm.nih.gov/7569038/>

(and fragments thereof) could have unwanted consequences for the resulting GMO, such as the disruption of genes important for plant growth or development.<sup>14</sup>

*(iv) Non-functional proteins*

19. It is also of note that clause 1(6) provides that in determining whether a feature of an organism's genome could have resulted from natural transformation, no account is to be taken of genetic material which does not result in a functional protein. There are two ways of interpreting this clause. First, the inserted genetic material could encode, either intentionally or unintentionally, for a protein that is not known to have any function. However, proteins that are assumed to be non-functional, in the absence of experimental evidence to support such an assumption, can still interact with other proteins (either enzymes, structural proteins, or signalling proteins) to change their form or otherwise modify their behaviour, which again can have a significant impact on the affected plant or animal. Second, genetic material introduced into an organism could be intentionally designed not to code for any protein. Examples of such genetic elements are those that innately possess gene regulatory properties (e.g. enhancers) and encode for RNA molecules involved in the process of RNA interference regulation of gene expression. Both these types of non-protein coding genetic elements can have wide-reaching unintended effects on multiple gene functions, which can lead to alterations in the organism's biochemistry and composition, with unknown consequences to animal and human health and the environment.
20. It is also crucial to understand that the four genetic features that the Bill asserts should be excluded from consideration in defining a precision bred organism are inter-dependent. For example, depending on the location of the genetic feature, it may or may not be more prone to epigenetic changes that influence its function. For example, it may be more or less prone to DNA methylation-mediated silencing.

*(v) Summary on definition*

21. In summary, therefore, the definition of precision bred organisms in the Bill is drafted very widely, without a precise focus on the cautionary science underpinning the existing law on genetic modification. The definition in the Bill would allow a large number of novel genetic changes to avoid the existing GMO regulations, with potentially serious consequences.

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<sup>14</sup> <https://doi.org/10.1146/annurev-genet-120215-035320> ; <https://doi.org/10.1023/a:1023929630687> ; <https://doi.org/10.1186/s12302-020-00361-2>

## Issue 2: the new regulatory regimes

22. The Bill introduces two new regimes: one for organisms produced for research purposes, the other for marketing purposes. It also creates a power to introduce a regime for food and feed created using these organisms (although, notably, there are no mandatory requirements in the Bill regarding what this regime should look like).
23. In summary, these proposals are very lax, afford maximum discretion to the Secretary of State to create a regulatory system of his own design, offer limited opportunities for Parliamentary scrutiny, and amount to a substantial reduction in environmental protection compared to the existing regulatory position.

### *(vi) Release of organisms*

24. Under the proposed new release regime, organisms which fall within the Bill's wide definition are subject only to a mandatory notification before they can be released into the environment (clauses 3 and 4).
25. The precise form of the notification is unclear, because the information requirements will be set out in secondary legislation. The Bill does not, however, impose any direct requirement for a risk assessment prior to release.
26. In our view, it is clear that neighbouring farmers have an important interest in knowing whether "precision bred" crops are being released near their farms. Their crops could be negatively affected by such organisms, and could for example have their organic certification jeopardised. **We suggest that the Bill is amended so that there is a hard requirement to notify neighbouring farms before these organisms are released into the environment, via scientific trials or otherwise.** This is not a matter that should be left to the discretion of the Secretary of State.

### *(vii) Marketing of organisms*

27. Clause 5 provides that precision bred organisms can also be marketed in England following confirmation from the Secretary of State. The precise requirements of obtaining confirmation are unclear, as they will be set out in secondary legislation.
28. However, before marketing is permitted, the application will be sent to an advisory committee, whose only purpose is to determine whether the organism falls within the Bill's wide definition of a precision bred organism (clause 7). If the Secretary of State is satisfied that the organism meets the definition, a confirmation of this will be issued, allowing the organism to be marketed (clause 8). A further authorisation is required in respect of marketing animals (clause 11), with a

requirement to provide a risk assessment in respect of the health or welfare of the animal (clause 11(4)) and a subsequent referral to a welfare advisory body (clause 11(6)), who will then produce a report (clause 12). The precise requirements of this assessment process are unclear, as they will be set out in secondary legislation.

*(viii) Food and feed from organisms*

29. Clause 26 provides that regulations may make provision for regulating the placing on the market in England of food and feed produced from precision bred organisms. There is no requirement for such regulations to be made, or any restrictions on the content of such regulations. The regulation can therefore be as “light touch” as the Secretary of State wishes, if indeed they are introduced at all.
30. In our view, it is deeply troubling that there is no requirement in primary legislation for food that includes “precision bred” organisms to be appropriately labelled. Consumers have a right to know what they are eating. Accordingly, **we suggest that the Bill should be amended to introduce a hard requirement on the packaging of any food and feed that contains “precision bred” organisms to clearly display to consumers that the products contain these organisms, before they enter the food chain.** This is not a matter that should be left to the discretion of the Secretary of State.
31. Overall, in our view the new systems set up by the Bill amount to substantial environmental deregulation. They are a serious rolling back of environmental protection compared to the pre-Brexit position.

### Issue 3: Reliance on secondary legislation

32. As is noted by the Memorandum from DEFRA to the Delegated Powers and Regulatory Reform Committee published alongside the Bill, the Bill contains 31 delegated powers provisions, including three ‘Henry VIII’ powers ( powers that enable ministers to amend or repeal provisions in an Act of Parliament using secondary legislation).<sup>15</sup> Clause 43(3)(i) also provides explicitly that a power to make regulations includes a power to make “different provision for different purposes.”

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<sup>15</sup> The expression is a reference to King Henry VIII's supposed preference for legislating directly by proclamation rather than through Parliament. The Henry VIII clauses in the Bill are clause 1(8) (definition of “modern biotechnology”), clause 10(2) (power to amend definitions), Part 5 (power to make consequential provision): see the Memorandum, p 4.

33. Given the amount of scientific uncertainty regarding the environmental impact of GMOs, it is surprising that so much of the detail of the regulatory systems provided for in the Bill is left to secondary legislation. In particular, as noted above, there is no fixed regime set out in the Bill regulating food and feed from precision bred organisms: the form of the regulations that may govern this area are entirely discretionary, if they are introduced at all.
34. It is also notable that Clause 1(8) allows the Secretary of State to widen the definition of a precision bred organism through regulations, via an amendment to the definition of “modern biotechnology.” Thus the already very wide definition in the Bill can be widened even further at the Secretary of State’s discretion.

#### **Issue 4: The UK’s international obligations**

35. In our view there is a serious risk that this Bill breaches the UK’s international legal obligations under the 2003 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (“the Cartagena Protocol” or “the Protocol”).

##### ***(ix) The requirements of the Cartagena Protocol***

36. The Cartagena Protocol is an international agreement on biosafety that supplements the 1993 Convention on Biological Diversity. It aims to protect biodiversity from the impact of genetically modified organisms. The Protocol has 173 parties including the UK.
37. The Cartagena Protocol uses the term “living modified organisms” (“LMOs”) rather than “genetically modified organisms”. It defines LMOs as “*any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology*” (Article 3(g)). Notably, the definition of modern biotechnology in the Protocol is broad, and includes techniques that “*overcome natural physiological reproductive or recombination barriers.*”<sup>16</sup>
38. Relevant provisions of the Cartagena Protocol include the following:
- a) Article 2(2) provides that parties to the Protocol “*shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity.*”

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<sup>16</sup> ‘Modern biotechnology’ is defined as the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.



- b) Article 11 provides that when placing LMOs on the domestic market for food or feed that may be subject to transboundary movement, a party must inform the other parties to the Protocol.
- c) Article 16(4) provides that *“each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.”*
- d) Article 18 imposes identification requirements such that exported LMOs are clearly identified as such.
- e) Article 23(2) imposes a requirement on parties to *“consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public.”*

***(x) Analysis of the Government’s position regarding the Protocol***

- 39. The Government’s position is that *“the Cartagena Protocol does not apply to organisms produced using modern biotechnologies if those organisms could have occurred naturally or been produced by traditional methods”* (Explanatory Notes to the GMO Bill, para 12).
- 40. We consider this position to be legally untenable.
- 41. Firstly, the definition in Article 3(g) of the Cartagena Protocol refers to *“any”* living organism. This wording is very broad and seems to us to be deliberately so.
- 42. Secondly, Article 3(g) provides that a living organism is a LMO if it possesses *“a novel combination of genetic material obtained through the use of modern biotechnology.”* The emphasis is firmly on how the LMO is made rather than whether it could have occurred naturally. Of course, novel combinations of genetic material can also be obtained through natural cross-breeding. It therefore seems to us that a *“precision bred organism”* clearly falls within the definition of an LMO as set out in the Protocol.
- 43. Thirdly, our analysis is in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, which is specifically referenced in both the preamble to the Protocol and Article 1.
- 44. Fourthly, our analysis is in accordance with the jurisprudence of the CJEU defining genetically modified organisms: *Case C-528/16 Confédération paysanne & others*. As is noted in the Bill’s

impact assessment at p 9, both international and CJEU jurisprudence contribute to the current definition of GMOs in UK law.

45. There is therefore, in our view, a serious and substantial risk that the provisions in this Bill are not in accordance with the UK's international law obligations to monitor, label and properly assess the risk of all exportable genetically modified plant and animal products.
46. A breach of an international obligation opens the UK to reputational risk and, potentially, an international legal challenge brought by another state.

## Issue 5: Devolution

47. The regulation of genetically modified organisms is a devolved matter and the provisions of the Bill generally extend to England and Wales only and apply in relation to England only. The Welsh Government has noted for example that it has "no plans to relax" the GMO rules in Wales.<sup>17</sup>
48. However, as a result of the changes proposed in the Bill, it will be possible to market precision bred plants and animals in England without the need for consent under Part 6 of the Environmental Protection Act 1990. 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 the Bill and the delegated legislation to be made under it.<sup>18</sup>
49. Thus, despite the regulation of genetically modified organisms being a devolved matter, the Scottish and Welsh Governments will have no control over the marketing of precision bred organisms in their respective nations.
50. Finally, there are also obvious potential cross-border issues regarding the contamination of Scottish and Welsh land by precision bred organisms grown in England.

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<sup>17</sup> <https://www.bbc.co.uk/news/science-environment-58737669>

<sup>18</sup> See the Explanatory Notes to the Bill, para 16. 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.