

Scientific critique of the Genetic Technology (Precision Breeding) Act 2023, the Genetic Technology (Precision Breeding) Regulations 2025, and the corresponding ACRE and FSA guidance documents

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This document provides a scientific commentary and critique of:

- The Genetic Technology (Precision Breeding) Act 2023, the primary legislation on which the secondary legislation, the Genetic Technology (Precision Breeding) Regulations 2025 and the relevant guidance documents are based
- “ACRE [Advisory Committee on Releases to the Environment] guidance on producing precision bred plants” of 13 November 2025 (hereinafter called the “ACRE guidance document”),¹ which relates to the Genetic Technology (Precision Breeding) Act 2023 and the Genetic Technology (Precision Breeding) Regulations 2025.
- The UK Food Standards Agency’s (FSA’s) “Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed”, of December 2025.²
- The Genetic Technology (Precision Breeding) Regulations 2025 (hereinafter called “the 2025 Regulations”.

I. Problems with the Genetic Technology (Precision Breeding) Act 2023

The Act unscientifically dismisses crucial genetic elements that could make the difference between safety or risk from the GM-PB organism

In determining whether a feature of a genetically modified “precision bred” (GM-PB) organism’s genome could have resulted from traditional processes, the Act states that the following will **not** be considered:

- The gene copy number of the feature
- Its epigenetic status, or
- Its location in the genome.³

¹ ACRE (2025). ACRE guidance on producing precision bred plants. 13 Nov.

<https://www.gov.uk/government/publications/acre-guidance-on-producing-precision-bred-plants/acre-guidance-on-producing-precision-bred-plants>

² UK Food Standards Agency (2025). Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed. December.

<https://www.food.gov.uk/sites/default/files/media/document/FSA%20PB%20Technical%20Guidance%20for%20applicants%2011.2025.pdf>

³ Part 1, 1(5).

Contemporary understanding of gene function, especially across an organism's whole genome, as well as experience of outcomes from GM processes stretching back decades, shows that there is no scientific justification for dismissing these elements. All these elements will not only impact the function of the newly introduced genetic feature, but also the modified organism's host genes. Thus, ignoring or dismissing these effects of the elements puts public health and the environment at risk.

Copy number of genes: In the field of human medical genetics, which appears to be far more safety-conscious than the field of agricultural genetic engineering, 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.⁴

In livestock animals, the copy number of genes is known to “alter the gene expression and change the phenotype of an individual”⁵ – factors that could make the difference between health and severe disease, abnormalities, or premature death.

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.⁶ The copy number of genes has also been found to be linked to evolutionary adaptation in plants and to affect defences against diseases.⁷

In transgenic plants, the copy number of the transgene(s) can affect the stability of the desired GM trait.⁸ Stability of the GM trait is one of the criteria named in the Act for determining whether a GMO is a “precision bred organism”.⁹

While the Act may assume that GMO applicants will ensure the stability and phenotypic normality of their product, this is likely to be restricted to aspects such as whether the plant or animal looks normal and grows acceptably. Less obvious aspects at the level of the organism's biochemistry, including unexpected toxicity or allergenicity, or altered nutritional value, will easily pass unidentified into our fields and onto our dinner plates, without strict regulatory requirements for testing and independent assessment.

Given all the above, it seems extraordinary, as well as determinedly at odds with the science underpinning gene editing, that the Act would dismiss taking account of gene copy number in the consideration of whether a GMO could have arisen from “traditional processes” or “natural transformation” and therefore be exempted from in-depth risk assessments.

⁴ Smith AJ de (2009). Human genes involved in copy number variation: mechanisms of origin, functional effects and implications for disease. *Cytogenet Genome Res* 123(1-4): 17–26. doi: 10.1159/000184688. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920180/>

⁵ Bhanuprakash V et al (2018). Copy number variation in livestock: A mini review. *Vet World* 11(4): 535–541. doi: 10.14202/vetworld.2018.535-541. <https://pmc.ncbi.nlm.nih.gov/articles/PMC5960796/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5960796/>

⁶ Żmieńko A et al (2013). Copy number polymorphism in plant genomes. *Theor Appl Genet* 127(1): 1–18. doi: 10.1007/s00122-013-2177-7 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544587/>

⁷ Suryawanshi V et al (2016). Between-species differences in gene copy number are enriched among functions critical for adaptive evolution in *Arabidopsis halleri*. *BMC Genomics* 17(Suppl 13):1034. doi: 10.1186/s12864-016-3319-5 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5259951/>

⁸ Głowacka K et al (2016). An evaluation of new and established methods to determine T-DNA copy number and homozygosity in transgenic plants. *Plant Cell Environ* 39(4):908-17. doi: 10.1111/pce.12693. <https://pubmed.ncbi.nlm.nih.gov/26670088/>

⁹ Part 1(2)(b).

Epigenetic status: Epigenetics means “above genetics” and refers to molecular structures that are associated with DNA and which regulate the function (expression) of genes in the organism. Therefore epigenetic status in any given part of an organism is crucial in controlling overall global patterns of gene function and thus health or disease status. Importantly, epigenetic status is dynamic and can change not only in response to internal cues within the organism, but just as crucially, to changes in the environmental (weather, soil condition, application of agrochemicals), leading to dramatic alterations in global patterns of gene function and the performance and composition of the organism.

Under current UK and EU law, differences in gene regulation in a GMO compared with the non-GMO parent are not taken into account in GMO risk assessments. However, such differences can become a risk if, for example, environmental conditions change (such as climate changes, pest attacks, or pesticide applications). Such environmental stresses can alter the functioning of the genetically manipulated genes. This could trigger adverse effects on the biochemistry of the plant, affecting its performance in the field or its safety for consumption or the environment, even if no such effects were observed in the laboratory or in field trials. For example, altered plant biochemistry can include the production of novel toxins or allergens, or altered levels of existing toxins or allergens.

While the Act requires that the GM traits in “precision bred organisms” are stable, it does not specify that their stability must be tested under different environmental conditions.

The influence of the environment on epigenetic status and thus gene regulation will be markedly amplified if the genes whose products (DNA methyltransferases, histone protein modifiers, miRNAs) are at the basis of building the layers of epigenetic control are either intentionally or unintentionally altered by GM, including gene-editing, procedures.

The importance of epigenetic status of gene-edited plants is illustrated by the findings of an experiment with *Arabidopsis* plants. The researchers used 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.¹⁰

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.

Location in the genome: Position effects, or location of the genetic feature, are 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.

¹⁰ Cho S et al (2017). Accession-dependent CBF gene deletion by CRISPR/Cas system in *Arabidopsis*. *Front. Plant Sci., Sec. Plant Abiotic Stress* 8. <https://doi.org/10.3389/fpls.2017.01910>
<https://www.frontiersin.org/articles/10.3389/fpls.2017.01910/full>

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.¹¹

In mammalian cells, transgene expression was found to vary more than 1,000-fold based on genomic location.¹² 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.¹³

Major problems caused by position effects negatively impacting gene function is one of the main reasons why GM crop applicants 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.

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

In addition, in gene editing, off-target cuts, deletions, insertions and rearrangements of DNA, including insertions of foreign DNA and foreign genes, are common and a major concern.¹⁵

¹¹ Kleinjan D-J, van Heyningen V (1998). Position effect in human genetic disease. *Human Molecular Genetics* 7(10): 1611–1618. <https://doi.org/10.1093/hmg/7.10.1611>.
<https://academic.oup.com/hmg/article/7/10/1611/635945>

¹² Akhtar W et al (2013). Chromatin position effects assayed by thousands of reporters integrated in parallel. *Cell* 154(4): 914-927. <https://www.sciencedirect.com/science/article/pii/S0092867413008891>

¹³ Clark AJ et al (1994). Chromosomal position effects and the modulation of transgene expression. *Reprod Fertil Dev* 6(5):589-98. doi: 10.1071/rd9940589. <https://pubmed.ncbi.nlm.nih.gov/7569038/>

¹⁴ Gelvin SB (2017). Integration of *Agrobacterium* T-DNA into the plant genome. *Annual Review of Genetics* 51(2017). <https://doi.org/10.1146/annurev-genet-120215-035320> ; Forsbach A et al (2003). A comprehensive characterization of single-copy T-DNA insertions in the *Arabidopsis thaliana* genome. *Plant Molecular Biology* 52: 161–176. <https://doi.org/10.1023/a:1023929630687> ; Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environmental Sciences Europe* 32, article no 106. <https://doi.org/10.1186/s12302-020-00361-2>

¹⁵ Zhang X-H et al (2015). Off-target effects in CRISPR/Cas9-mediated genome engineering. *Molecular Therapy Nucleic Acids* 4, e264. <https://www.sciencedirect.com/science/article/pii/S216225311630049X> ; Kosicki M et al (2018). Repair of double-strand breaks induced by CRISPR–Cas9 leads to large deletions and complex rearrangements. *Nature Biotechnology* 36: 765–771. <https://www.nature.com/articles/nbt.4192> ; <https://www.nature.com/articles/s42003-019-0705-y> ; Sansbury BM et al (2019). Understanding the diversity of genetic outcomes from CRISPR-Cas generated homology-directed repair. *Communications Biology* 2, article no: 458. <https://www.jbc.org/content/early/2020/03/11/jbc.RA120.012933> ; Wolt JD et al (2016). Achieving plant CRISPR targeting that limits off-target effects. *Plant Genome* 9(3). doi: 10.3835/plantgenome2016.05.0047. <https://www.ncbi.nlm.nih.gov/pubmed/27902801> ; Biswas S et al (2020).

In one study, the DNA template encoding CRISPR/Cas9 was not only detected at the target location in soybeans as intended, but also at other multiple, apparently random, genomic locations.¹⁶ In another study, CRISPR/Cas sequences were found at multiple genomic sites that were similar to the transgene integration sites, indicating that the integration of CRISPR/Cas sequences might not be completely random.¹⁷

A 2019 study on CRISPR/Cas-mediated gene editing of rice plants begins by noting that “gene targeting in plants is still very inefficient” and that variability in position of the guide RNAs used to target the editing tool to a specific site in the genome can result in “dramatic developmental phenotypes” (abnormal characteristics) when the target genes overexpress. The researchers achieved a partial success by designing guide RNAs specifically for the rice plants studied, in that they no longer observed “strong detrimental effects”, but they concluded that the topic requires further study to refine approaches.¹⁸

Given the generally acknowledged importance of position effects and the difficulties that scientists experience in overcoming them, it is not comprehensible that the Act allows them to be ignored in determining whether or not a GMO is a “precision bred organism” that can be subjected to a weaker form of regulation than other GMOs.

The Act includes “induced mutagenesis” as a “traditional process”

The Act lists “induced mutagenesis” as one of the “traditional processes” that provide the crucial comparators that will enable the applicant to claim that a GM-PBO is conventional-like and therefore can evade risk assessment, traceability, and labelling.¹⁹

However, outcomes of chemical- and radiation-induced mutagenesis are not suitable comparators because in contrast to selective breeding, they are technologies intended to magnify mutations and variations at the genome level. These tools frequently result in extreme outcomes, including killed plant cells and surviving plants that are deformed, unhealthy, and/or infertile.²⁰ Such outcomes likely explains why induced mutagenesis has largely fallen out of use since the mid-2000s.²¹ These outcomes are not indicative of the frequency or probability of harm from the “traditional processes” of selective breeding or spontaneous mutations in nature.

Investigation of CRISPR/Cas9-induced SD1 rice mutants highlights the importance of molecular characterization in plant molecular breeding. *Journal of Genetics and Genomics* 47(5): 273-280. <https://www.sciencedirect.com/science/article/pii/S1673852720300916> ; Ono R et al (2019). Exosome-mediated horizontal gene transfer occurs in double-strand break repair during genome editing. *Communications Biology* 2(57). <https://www.nature.com/articles/s42003-019-0300-2.pdf?origin=ppub>

¹⁶ Li Z et al (2015). Cas9-Guide RNA directed genome editing in soybean. *Plant Physiology* 169(2): 960–970. <https://doi.org/10.1104/pp.15.00783>

¹⁷ Michno J-M et al (2020). Integration, abundance, and transmission of mutations and transgenes in a series of CRISPR/Cas9 soybean lines. *BMC Biotechnology* 20, article no 10. <https://doi.org/10.1186/s12896-020-00604-3>

¹⁸ Gong X et al (2020). Positional effects on efficiency of CRISPR/Cas9-based transcriptional activation in rice plants. *aBIOTECH* 1(1): 1-5. <https://doi.org/10.1007/s42994-019-00007-9>

¹⁹ Part 1, 6.a.vii

²⁰ Acquaaah G (2007). *Principles of Plant Genetics and Breeding*. Oxford, UK: Wiley Blackwell ; Van Harten AM (1998). *Mutation Breeding: Theory and Practical Applications*. London: Cambridge University Press ; GM Science Review Panel (2003). *First Report: An Open Review of the Science Relevant to GM Crops and Foods Based on Interests and Concerns of the Public*.

²¹ Beyond GM (2023). *Mutation breeding and gene editing*. https://beyond-gm.org/wp-content/uploads/2023/10/Beyond-GM_GE_Mutation-Breeding-Brief-Sept-2022.pdf

Using induced mutagenesis as a comparator for GM-PBOs artificially widens the range of variation that enables a GMO applicant to declare that their GM-PBO could have arisen through conventional breeding or in nature, even though the GM-PBO may contain extreme genetic elements that make it dangerous to health or the environment.

II. Problems with the Genetic Technology (Precision Breeding) Regulations 2025

According to the 2025 Regulations:

- (1) A person may apply for a food and feed marketing authorisation under this regulation if – ...
 - (c) the person is able to demonstrate that the application of modern biotechnology to the precision bred organism does not introduce genetic changes that are expected to –
 - (i) significantly alter the nutritional quality of the organism as it is being consumed as food or feed at the date of the application in a way that is likely to be disadvantageous to the consumer;
 - (ii) significantly elevate the toxicity of any food or feed produced from the precision bred organism;
 - (iii) alter the allergenicity of any food or feed produced from the precision bred organism;
 - (iv) introduce any additional features that may affect the safety of any food or feed produced from the precision bred organism.²²

This language can be interpreted as helpful to the aim of ensuring the safety of a genetically modified (GM) “precision bred” (GM-PB) plant for health and the environment. It correctly identifies the areas of risk posed by such a GM plant. However, the corresponding November 2025 ACRE guidance document is so flawed that it significantly weakens the aim of the 2025 Regulations, in the following ways.

Natural variation is inadequately defined and characterised

The November 2025 ACRE guidance document (section 1) states that evidence shows that natural variation exists, even within individuals of the same species, and that “precision bred plants contain these types of genetic changes”.

It is not scientifically valid or even logical to draw an equivalence between “natural” plants and GM-PB plants on the basis that certain types of genetic changes caused by gene editing are of a similar type to certain genetic changes that can happen in nature. The problem with this assumption is that it ignores how infrequently such changes may occur in nature and what their consequences might be. Those consequences potentially include damaging ones that, in nature, would affect the viability and composition of the plant, that would be rare in occurrence, and that would be selected out of the reproducing population over evolutionary time.

²² UK Government. Genetic Technology (Precision Breeding) Regulations 2025. <https://www.legislation.gov.uk/ukdsi/2025/9780348269123/regulation/20>

In addition, the guidance document only considers each individual change in the GM-PB plant and concludes that it could happen in nature or through traditional processes, without considering the sum total of all the intended and unintended changes brought about by the gene editing processes, and without asking whether the totality of these changes taken together would be likely to arise through traditional processes.

The ACRE guidance document enables the applicant for approval of a claimed GM-PB plant to self-declare that it could have arisen naturally or through traditional processes when in fact this is only one – idealised – potential outcome of gene editing, among many potential outcomes that go far beyond anything that could arise in nature or conventional breeding. And it's correct to specify "potential", because no one has ever proved, via long-read whole genome sequencing and "omics" (molecular characterisation) analyses, that any given gene-edited plant is identical genetically to a plant produced naturally or through traditional processes. A declaration that any given gene-edited plant could have arisen naturally or through traditional processes remains a hypothesis that needs to be proven via detailed analysis.

Notably, the ACRE guidance document ignores evidence that gene editing, using tools such as CRISPR/Cas, can give rise to biological outcomes that are frequently very different from, and go far beyond, those that could arise in nature, or in conventional breeding, or in chemical- or radiation-induced random mutagenesis breeding, and that they pose different and potentially higher risks.²³ This is because the processes of altering the DNA in each of these methods are different, causing different types of intended and unintended changes, which in turn lead to different risks. ACRE fails to acknowledge or address any of the many studies and reviews that document these different outcomes and risks – a significant oversight.

In this context it must also be borne in mind that GM-PB plant developers intend to apply gene editing to either simultaneously or sequentially target multiple genes (multiplexing).²⁴ This type of application of gene editing can result in changes that, taken together, would not be found in nature or would be highly unlikely to be found in nature. The US Dept of Agriculture Animal and Plant Health Inspection Service (APHIS) notes that uses of SDN1 (gene disruption), SDN2 (gene modification using an introduced repair template), and each or both in multiplex or sequential reactions, can create outcomes with no known equivalent in conventional breeding.²⁵

²³ Examples of scientific publications presenting such evidence include: Koller F (2025). The potential of NGTs to overcome constraints in plant breeding and their regulatory implications. *Int. J. Mol. Sci.* 2025, 26(23), 11391; <https://doi.org/10.3390/ijms262311391> ; Mundorf J et al (2025). The European Commission's regulatory proposal on new genomic techniques in plants: a focus on equivalence, complexity, and artificial intelligence. *Environmental Sciences Europe* 37, article number 143. <https://link.springer.com/article/10.1186/s12302-025-01199-2> ; Kawall K (2019). New possibilities on the horizon: Genome editing makes the whole genome accessible for changes. *Frontiers in Plant Science* 10. <https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full> ; Chu P, Agapito-Tenfen S (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants (Basel)* 11(21):2997. doi: 10.3390/plants11212997. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9655061/> ; Koller F, Cieslak M (2023). A perspective from the EU: unintended genetic changes in plants caused by NGT – their relevance for a comprehensive molecular characterisation and risk assessment. *Front. Bioeng. Biotechnol, Sec. Biosafety and Biosecurity* 11. <https://doi.org/10.3389/fbioe.2023.1276226>.

²⁴ Kawall K (2021). The generic risks and the potential of SDN-1 applications in crop plants. *Plants* 10, 2259. <https://doi.org/10.3390/plants10112259>

²⁵ USDA (APHIS) (2024). Movement of organisms modified or produced through genetic engineering; Notice of additional modifications exempt plants can contain. A notice by the Animal and Plant Health Inspection Service on 11/13/2024. [Docket No. APHIS-2023-0022]. <https://www.federalregister.gov/documents/2024/11/13/2024-26232/movement-of-organisms-modified-or-produced-through-genetic-engineering-notice-of-additional> : "We have not yet identified any literature

In contrast, in the section of the ACRE document titled “Multiplexing”, ACRE selectively chooses to mention only those outcomes that may have an equivalent in conventional breeding: “Developers may also use SDN1 to target multiple sites at once, to generate lesions at 2 or more spatially separated locations within a chromosome. In this way, larger stretches of DNA can be deleted or inverted, potentially removing one or more whole genes or non-coding regions. This approach can result in significant rearrangements, deletions or duplications of translocations of genetic material. These are events that also occur and can be selected for when using traditional breeding techniques, where they may be mediated by agents such as transposons or other mutagens.”

This is disingenuous and scientifically invalid, as it is generalising an idealised outcome of multiplex gene editing (natural/traditional-like) without considering that certain outcomes have, in the words of USDA-APHIS, “no known equivalent in conventional breeding”. In addition, large deletions, inversions and rearrangements of DNA, as well as the catastrophic ‘shattering of the chromosome’ event known as chromothripsis, are recognised by the scientific community as frequent unintended outcomes of gene editing,²⁶ with potential consequences that are not conventional-like in terms of type, frequency, or effects of the organism on health or the environment.²⁷ The ACRE guidance document permits all such genetic modifications to be included under the umbrella of natural variation, however rare they may be in traditional processes such as conventional breeding, and whatever their unintended effects and consequences. ACRE therefore allows organisms with these modifications to escape risk assessment, traceability requirements, and labelling, without considering their unintended consequences.

Notably, a landmark study shows that the genetic variation that occurs in conventional breeding is not random, and that certain areas of the genome are protected from mutations. The researchers also found that the occurrence and frequency of mutations in populations does not only depend on the evolutionary mechanism of random mutation and natural selection as it has traditionally been understood. The study found that mutation in plants is not random and directionless, but biased in a direction that benefits the plant.

demonstrating that identical indel or deletion modifications can be achieved across subgenomes using conventional breeding methods. For this reason, we are restricting the application of AM2 in combination with AM1, when a repair template is used, to allow modification to one pair of homologous chromosomes.” According to US §340.1, AM1 is a combination of SDN1 and SDN2 categories and AM2 is multiplex or sequential modification: see USDA (APHIS) (2024). Guide for requesting a confirmation of exemption from Regulations under 7 CFR part 340. 12 Nov. <https://www.aphis.usda.gov/sites/default/files/confirmation-guide.pdf>

²⁶ Chu P, Agapito-Tenfen S (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants (Basel)* 11(21):2997. doi: 10.3390/plants11212997 ; Kosicki M et al (2018). Repair of double-strand breaks induced by CRISPR–Cas9 leads to large deletions and complex rearrangements. *Nature Biotechnology* 36:765–771. <https://www.nature.com/articles/nbt.4192> ; Shin HY et al. (2017). CRISPR/Cas9 targeting events cause complex deletions and insertions at 17 sites in the mouse genome. *Nature Communications* 8, Article number: 15464. doi:10.1038/ncomms15464. <https://www.ncbi.nlm.nih.gov/pubmed/28561021>

²⁷ Chu P, Agapito-Tenfen S (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants (Basel)* 11(21):2997. doi: 10.3390/plants11212997 ; Kawall K (2021). The generic risks and the potential of SDN-1 applications in crop plants. *Plants* 10, 2259. <https://doi.org/10.3390/plants10112259> ; Koller F et al (2023). The need for assessment of risks arising from interactions between NGT organisms from an EU perspective. *Environmental Sciences Europe* 35, Article number 27. <https://enveurope.springeropen.com/articles/10.1186/s12302-023-00734-3> ; Koller F and Cieslak M (2023). A perspective from the EU: unintended genetic changes in plants caused by NGT — their relevance for a comprehensive molecular characterisation and risk assessment. *Front. Bioeng. Biotechnol.* 11. 27 October. Sec. Biosafety and Biosecurity. <https://doi.org/10.3389/fbioe.2023.1276226>

The study does not mention gene editing, but it has clear implications for the notion that gene-editing techniques like those used in so-called “precision breeding” primarily make changes that could occur naturally or via traditional processes. In reality, gene editing is specifically designed to override natural protections against mutations, in ways that do not happen in conventional breeding or are very unlikely to happen. Also, the unintended changes to the genome that occur during gene editing and associated processes are random, occurring throughout the genome and bypassing the natural protections against mutations.²⁸

In sum, considering all the above evidence, outcomes indistinguishable from conventional breeding are only true when they are proven to be. And they must be proven if there is to be a ‘reasonable’ expectation or anticipation that they will not harm health or the environment, as required by both the ACRE and FSA²⁹ guidance documents.

ACRE ignores likelihood and scale of genetic changes in gene editing vs nature

In evaluating a claim that a GM-PB plant could have been produced via traditional processes, the likelihood and frequency with which gene editing-induced changes (both intended and unintended) might occur in nature and in traditional processes needs to be considered, as well as the scale. While some types of changes caused by gene editing may also occur in nature, or conventional breeding, or mutagenesis breeding, the ACRE guidance document fails to take into account the likelihood, frequency, spatial scale, and timescales with which such changes might occur in the different breeding systems.

Upscaling mutations (DNA damage), as occurs in gene editing, also means upscaling risk. In this regard, scientists at New Zealand’s Centre for Integrated Research in Biosafety have compiled a table, based on peer-reviewed evidence in plants, showing that gene editing – including in SDN1 (gene disruption) applications, the simplest type – is a far more powerful mutagen than is found in nature, conventional breeding, or chemical- and radiation-induced mutagenesis breeding.³⁰ Mutagens are strictly regulated in our society, with good reason. Plants developed using the powerful mutagen of gene editing should not be exempted from robust regulation, especially at this nascent stage of the technology’s application.

The tests needed to establish nature-equivalence are not required

As noted above, the 2025 Regulations stipulate that in order to qualify as a GM-PB plant and thus escape risk assessment, monitoring and labelling, the gene editing process must not alter the plant’s toxicity, allergenicity and nutritional content in a way that would affect its safety. Yet in order for an applicant for approval of a GM-PB plant to demonstrate that this is the case, they would have to consider the full spectrum of both intended and unintended changes caused by the entire process of gene editing (including the obligatory

²⁸ Grey Monroe JG et al (2022). Mutation bias reflects natural selection in *Arabidopsis thaliana*. *Nature* 602: 101–105. <https://www.nature.com/articles/s41586-021-04269-6>

²⁹ UK Food Standards Agency (2025). Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed. December. <https://www.food.gov.uk/sites/default/files/media/document/FSA%20PB%20Technical%20Guidance%20for%20applicants%2011.2025.pdf>

³⁰ Centre for Integrated Research in Biosafety (2024). Submission to the Parliament Health Committee on the Gene Technology Bill 2024, p.16. <https://ir.canterbury.ac.nz/server/api/core/bitstreams/0e1aa118-5e68-4b43-b395-2a4487d90aa4/content>

and highly mutagenic tissue culture and Agrobacterium/bioliistic-mediated transformation³¹ stages). These changes would have to be analysed using the only adequate methods – long-read whole genome sequencing, followed by “omics” analysis – transcriptomics (to analyse gene expression changes), proteomics (to analyse protein profile), and metabolomics (to analyse metabolites).

However, the ACRE guidance does not specify the utility of such analyses or require them to be carried out. So the declared status of a GM-PB plant as something that could have been produced via traditional processes would be nothing more than a ‘wish’, as opposed to a verifiable fact.

The words “expected to” may not let applicants off the hook in the event of harm occurring

The 2025 Regulations state that a person may apply for a food and feed marketing authorisation under this regulation if they are able to demonstrate the gene editing process does not introduce genetic changes that are “*expected to*” alter the toxicity, allergenicity, or nutritional content in a way that could affect the food safety of the GM-PB organism.

In similar vein, the UK Food Standards Agency’s (FSA’s) guidance states: “During the Tier 1 safety assessment [Tier 1 avoids ‘independent of the applicant’ risk assessment], applicants must consider whether genetic changes may be reasonably anticipated to alter levels of substances other than those targeted (including potentially harmful substances), or change nutritional quality (Nutrition).”³²

Does this weak wording – “expected to” and “reasonably anticipated to” – let the applicant off the legal hook if in fact a GM-PB plant does turn out to be toxic, allergenic, or otherwise detrimental to health?

Arguably, it does not. This is because a large and ever-growing body of scientific evidence shows that gene editing processes can induce unintended DNA damage (mutations), which could change patterns of gene function and thus the biochemistry of gene-edited plants. In addition, the intended changes can also have unintended results. Consequences could include unexpected toxicity or allergenicity, altered nutritional value, and impaired crop performance. Therefore, these changes could pose risks to the consumer and/or to the environment.³³

³¹ Latham JR et al (2006). The mutational consequences of plant transformation. J Biomed Biotechnol 2006. Doi 10.1155/JBB/2006/25376. <http://www.ncbi.nlm.nih.gov/pubmed/16883050> ; Wilson AK et al (2006). Transformation-induced mutations in transgenic plants: Analysis and biosafety implications. Biotechnol Genet Eng Rev 23. <http://www.ncbi.nlm.nih.gov/pubmed/22530509>

³² UK Food Standards Agency (2025). Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed. December. <https://www.food.gov.uk/sites/default/files/media/document/FSA%20PB%20Technical%20Guidance%20for%20applicants%2011.2025.pdf>

³³ A limited selection of relevant scientific papers includes: Chu P and Agapito-Tenfen SZ (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. Plants 2022, 11, 2997. <https://pubmed.ncbi.nlm.nih.gov/36365450/> ; Koller F (2025). The Potential of NGTs to overcome constraints in plant breeding and their regulatory implications. Int. J. Mol. Sci. 2025, 26(23), 11391; <https://doi.org/10.3390/ijms262311391> ; Koller F et al (2023). The need for assessment of risks arising from interactions between NGT organisms from an EU perspective. Environmental Sciences Europe 35, Article number 27. <https://enveurope.springeropen.com/articles/10.1186/s12302-023-00734-3> ; Koller F and Cieslak M (2023). A perspective from the EU: unintended genetic changes in plants caused by NGT — their relevance for a comprehensive molecular characterisation and risk assessment. Front. Bioeng. Biotechnol. 11. 27 October. Sec. Biosafety and Biosecurity. <https://doi.org/10.3389/fbioe.2023.1276226> ; Kawall K

Many of these scientific papers emphasise the need for long-read whole genome sequencing and/or “omics” analysis to confirm that the gene editing process has not caused changes that could have adverse effects on end users, consumers, or the environment.³⁴

Given the extent of this evidence and its accumulation over many years, it is inconceivable that any applicant of a GM-PB plant would be unaware of its existence, even if ACRE fails to address it. Under the law, therefore, in the event that harm is caused by a GM-PB, it would not be reasonable for ACRE or the applicant to rely for their defence on their “expectation” or reasonable “anticipation” that harm will occur. This remains the case even given the failure of the 2025 Regulations to mandate adequate analyses to check for unintended and potentially harmful changes.

Absence of transgenes not required to be confirmed

While the ACRE guidance document specifies that a GM-PB plant must not contain transgenes, it fails to mandate that the applicant conduct the correct analysis (long-read whole genome sequencing) to identify such transgenes. In the absence of such an analysis confirming transgene absence, it must be assumed that the GM-PB plant does contain transgenes. As the Centre for Integrated Research in Biosafety states: “Transgene insertion through the routine use of gene technology is unavoidable. The use of genome editing techniques is unlike conventional or mutation breeding because they always involve exogenous sources of contaminating genetic material. DNA/RNA contaminants are used by cells to repair the damage caused by the site-directed nucleases regardless of whether or not the genetic engineer wants them to be.”³⁵

(2021). The generic risks and the potential of SDN-1 applications in crop plants. *Plants* 10(11). 10.3390/plants10112259

<https://www.mdpi.com/2223-7747/10/11/2259/htm> ; Eckerstorfer MF et al (2021). Biosafety of genome editing applications in plant breeding: Considerations for a focused case-specific risk assessment in the EU. *BioTech* 2021, 10(3), 10; <https://doi.org/10.3390/biotech10030010> ; Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environmental Sciences Europe* volume 32, Article number: 106 (2020) <https://enveurope.springeropen.com/articles/10.1186/s12302-020-00361-2> ; Eckerstorfer MF et al (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). *Front. Bioeng. Biotechnol.* <https://doi.org/10.3389/fbioe.2019.00031> ; Kawall K (2019). New possibilities on the horizon: Genome editing makes the whole genome accessible for changes. *Frontiers in Plant Science*, 10:525. doi: 10.3389/fpls.2019.00525. <https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full> ; Biswas S et al (2020). Investigation of CRISPR/Cas9-induced SD1 rice mutants highlights the importance of molecular characterization in plant molecular breeding. *Journal of Genetics and Genomics*. May 21. doi:10.1016/j.jgg.2020.04.004. <https://www.sciencedirect.com/science/article/pii/S1673852720300916> ; Kawall K. (2021) Genome-edited *Camelina sativa* with a unique fatty acid content and its potential impact on ecosystems. *Environ Sci Eur*, 33(1), 1-12. <https://doi.org/10.1186/s12302-021-00482-2>

³⁴ For example: Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* volume 34, pages 1014–1015. <https://www.nature.com/articles/nbt.3680> ; Chu P and Agapito-Tenfen SZ (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants* 2022, 11, 2997. <https://pubmed.ncbi.nlm.nih.gov/36365450/> ; Park SH et al (2023). Detection and quantification of unintended large on-target gene modifications due to CRISPR/Cas9 editing. *Current Opinion in Biomedical Engineering* 28, 100478.

<https://www.sciencedirect.com/science/article/abs/pii/S246845112300034X> ; Kawall K (2021). The generic risks and the potential of SDN-1 applications in crop plants. *Plants* 10, 2259.

<https://doi.org/10.3390/plants10112259>

³⁵ Centre for Integrated Research in Biosafety (2024). Submission to the Parliament Health Committee on the Gene Technology Bill 2024, p.16. <https://ir.canterbury.ac.nz/server/api/core/bitstreams/0e1aa118-5e68-4b43-b395-2a4487d90aa4/content>

Most developers of gene-edited organisms do not conduct such analyses, leading to a failure to identify the presence of transgenes and/or foreign DNA.³⁶ An example from the area of gene-edited animals is the case of the gene-edited cattle, developed by Recombinetics using an SDN1 (gene disruption) procedure. Recombinetics then claimed that they were confident that there were no unintended changes in the cattle genome.³⁷ As described by the then director of the FDA Center for Veterinary Medicine, which later conducted its own analysis and found multiple transgenes:³⁸

“This edit was designed by [Recombinetics] to produce an alteration mimicking a sequence ‘found in nature’. This characterization of the alteration is significant because some policymakers and scientists have argued that using genome-editing techniques to replicate a ‘natural’ mutation should not be of regulatory concern because it is equivalent to existing, naturally occurring alleles. FDA’s (our, we) analysis illustrates, however, why it is necessary for there to be regulatory oversight of intentional genomic alterations in animals, even when the intended modification seeks to replicate a naturally occurring mutation...The unintended alteration in this case resulted in the integration of a bacterial plasmid containing various sequences designed for use in molecular biology, including antibiotic resistance markers [genes].”³⁹

Recombinetics simply had not conducted the correct analysis to spot the unwanted foreign DNA and transgenes. While this example applies to gene-edited animals, the principle applies also to gene-edited plants. Accordingly, scientists recommend that whole genome sequencing should be carried out to make sure that gene-edited crops and/or other gene-edited organisms do not contain foreign DNA or transgenes⁴⁰ – not only to protect the consumer and the environment, but also to protect the gene-edited GMO applicant from legal challenges regarding the regulatory status of their gene-edited product in the event that foreign DNA and transgenes are found to be present.⁴¹

UK government promises industry it will never find out if a GM-PBO harms health or environment

³⁶ Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* 34: 1014–1015. <https://www.nature.com/articles/nbt.3680> ; Chu P and Agapito-Tenfen SZ (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants* 11, 2997. <https://pubmed.ncbi.nlm.nih.gov/36365450/>

³⁷ Carlson DF et al (2016). Production of hornless dairy cattle from genome-edited cell lines. *Nature Biotechnology* 34. <https://www.nature.com/articles/nbt.3560>

³⁸ Norris AL et al (2020). Template plasmid integration in germline genome-edited cattle. *Nature Biotechnology* 38(2). <https://www.nature.com/articles/s41587-019-0394-6>

³⁹ Solomon SM (2020) Genome editing in animals: Why FDA regulation matters. *Nat Biotech* 38, 142-143. <https://pubmed.ncbi.nlm.nih.gov/32034392/>

⁴⁰ Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* volume 34, pages 1014–1015. <https://www.nature.com/articles/nbt.3680> ; Chu P and Agapito-Tenfen SZ (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants* 2022, 11, 2997. <https://pubmed.ncbi.nlm.nih.gov/36365450/> ; Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environmental Sciences Europe* 32(1). <https://doi.org/10.1186/s12302-020-00361-2> ; Murugan K et al (2020). CRISPR-Cas12a has widespread off-target and dsDNA-nicking effects. *Journal of Biological Chemistry* March 11, 2020 doi: 10.1074/jbc.RA120.012933. <https://www.jbc.org/content/early/2020/03/11/jbc.RA120.012933> ; Shin HY et al. (2017). CRISPR/Cas9 targeting events cause complex deletions and insertions at 17 sites in the mouse genome. *Nature Communications* 8, Article number: 15464. doi:10.1038/ncomms15464. <https://www.ncbi.nlm.nih.gov/pubmed/28561021>

⁴¹ Kim J, Kim J-S (2016). Bypassing GMO regulations with CRISPR gene editing. *Nature Biotechnology* volume 34, pages 1014–1015. <https://www.nature.com/articles/nbt.3680>

The Genetic Technology (Precision Breeding) Regulations 2025 state:

30. (3) The Secretary of State may issue a food and feed marketing authorisation if it appears to the Secretary of State that—

(a) any food or feed produced from the organism to which the food and feed marketing authorisation would apply would not have adverse effects on animal or human health;

(b) the way in which any such food or feed would be placed on the market would not mislead consumers;

(c) the production of any such food or feed in place of other food or feed that it might reasonably be expected to replace would not have adverse effects on the environment;

(d) consuming any such food or feed in place of other food or feed that it might reasonably be expected to replace would not be nutritionally disadvantageous to humans or animals.

This language is unacceptably weak – even weaker than that applying to the applicant, whose responsibility for ensuring safety goes no further than their own subjective ‘expectation’ or ‘anticipation’ (see above). The clause states that the Secretary of State may issue a marketing authorisation “if it appears” to them that these conditions are in place. If these conditions “appear” to them to be in place, but in reality are not, then GM-PBOs that can damage human or animal health or the environment or which are nutritionally harmful can be marketed without restriction.

In an extreme but possible scenario, all the scientific advisory bodies in the UK could be convinced that a GM-PBO is dangerous and should be removed from the market, but unless and until the Secretary of State shares that conviction, the GM-PBO in question could remain on the market. The language of this clause is unacceptably subjective for a law that is supposed to protect health and the environment. “If it appears...” should be replaced by a term such as “if the applicant is able to demonstrate...”

Regulators banned from tracing harms to GM-PBOs

What is even more unacceptable is that when considering whether the above conditions are in place, according to the secondary legislation, the Secretary of State “must... not apply any test in connection with these requirements which would not otherwise be applicable in relation to any food or feed produced from organisms which are not produced from the application of modern biotechnology” (30.4(b)).

This is an extraordinary stipulation. It assumes, without requiring confirmatory testing, that GM-PBOs are equivalent to traditionally bred organisms. And worryingly, it bars the regulator from ever finding out that the genetic engineering processes used to create the GM-PBO have caused unintended changes that could endanger human or animal health or the environment. Among the tests that could begin to identify risks of GM-PBOs are long-read whole genome sequencing, “omics” analyses (transcriptomics, proteomics, and metabolomics), and long-term animal feeding studies.

Yet not only will these tests not be required by the regulator, but the government, in passing this secondary legislation, is banning them from ever being required, on the grounds that they are not applied to traditionally bred foods. The government regulator is in effect telling the industry, “Not only do I not see any risks from PB-GMOs at the moment (because the right tests have not been done), but I promise I will never see any risks or identify any actual harms in the future (because those tests will never be done).”

As the process of gene editing is completely different from traditional breeding, it leads to very different risks, as many scientists have pointed out. The government's move in banning regulatory agencies from requiring any tests that could reveal risks arising from these gene-edited GMOs goes against every scientific principle. Any scientist worthy of the name would be horrified that a government that is elected to serve and protect the people could impose such a law, which blocks the execution of appropriate scientific analysis.

Regulatory agencies at present may believe that there is no need for such tests to be done. However, given the fact that this technology is in its infancy, no one can predict what problems may arise in future. Hence the need for future-proofing legislation to take account of these uncertainties.

No traceability ensures that any harms will not be traced to a GM-PBO

As for the clause in the Genetic Technology (Precision Breeding) Act 2023 saying that future regulations may “impose requirements for securing traceability in relation to food or feed produced from PBOs that is placed on the market in England” (26.2(b)), the Genetic Technology (Precision Breeding) Regulations 2025 only mention traceability to say that the EU law requiring that GMOs are traceable and labelled does not apply to GM-PBOs in England (Schedule 5, Part 1; 2).

A complete ban on government safety testing combined with a complete lack of traceability means that it is virtually certain that any problems caused by a GM-PBO will never be traced.

No mandatory analytical process that could confirm PBO status

The Genetic Technology (Precision Breeding) Regulations 2025 and the FSA's guidance document⁴² lack mandatory analytical processes, namely long-read whole genome sequencing and untargeted “omics” analyses, that would help to establish whether any given GMO qualifies as precision bred. Without the mandatory application of these scientific methods, the system relies on self-declaration by applicants, creating significant regulatory uncertainty about whether genetic changes in supposed PBOs truly “could arise from traditional processes”, as required by the Regulations.

These scientific gaps have far-reaching implications across multiple sectors. The absence of mandatory detection methods prevents conventional and organic breeders from verifying and maintaining their non-GMO status, while also leaving them vulnerable to potential patent infringement claims. Meanwhile, the regulatory framework's assumption that PBOs present no greater risk to health or the environment than their traditionally bred counterparts lacks an empirical evidence base, contradicting scientific perspectives that emphasise the need for robust case-by-case analysis. Yet these scientific considerations ultimately determine whether the Regulations can achieve their intended balance between innovation and safety, transparency and practicality.

FSA's “hypothesis-driven safety assessment” has no scientific basis

⁴² UK Food Standards Agency (2025). Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed. December.
<https://www.food.gov.uk/sites/default/files/media/document/FSA%20PB%20Technical%20Guidance%20for%20applicants%2011.2025.pdf>

FSA relies on the applicant generating their own “initial hypothesis-driven safety assessment to determine whether a PBO may present potential safety concerns”. For this ‘do-it-yourself’ safety assessment, the applicant need focus only on the intended genetic change and intended trait, ignoring all unintended genetic changes and traits, even though the latter may render the PBO dangerous.

They then “identify the ‘substances of interest’; these are substances with levels or activity altered as a result of the genetic change, including those changes which can be reasonably anticipated, and which can impact nutrition, toxicology or allergenicity... Where applicants have sufficient evidence to conclude, using any of these parameters, that a substance is not relevant for the safety or quality of food/feed, the Tier 1 safety assessment is concluded by completing the descriptive statement required in the relevant section(s) of the application form for this substance.”

In cases “Where there are no substances of interest identified by the applicant... or where the body of scientific evidence does not provide a hypothesis for a credible impact of a substance of interest on nutrition, toxicity or allergenicity, no further information is required on the substance.”

The FSA adds, “Where information is not available, it must be clearly specified, and brief reasoning for why the applicant considers that it does not raise concerns must be provided. Applicants are not expected to conduct non-hypothesis-based searches or assays to identify new changes.”

Inviting applicants to come up with their own hypotheses to define specific risks and then enabling them to dismiss them does not achieve the Regulations’ stipulation that the applicant must “demonstrate that the application of modern biotechnology to the precision bred organism does not introduce genetic changes that are expected to” heighten toxicity or allergenicity, or negatively impact nutritional quality. Focusing only on the intended genetic changes ignores unintended changes, which could, from a public health perspective, reasonably be “expected” or “anticipated” to cause harm to the consumer.

It is also unacceptable to imply that an absence of relevant safety data (“Where information is not available...”) – otherwise known as a “data gap” – is no barrier to authorisation. Absence of evidence concerning risk is not the same as evidence of absence of risk.

The FSA fails to address the risk of unintended changes from gene editing processes

The FSA guidance document does address a situation in which “An unintended genetic alteration... occurs at the targeted genomic location” and stipulates that “When it can be reasonably attributed to the genetic technology/methodology used, the impact on food nutritional quality/safety of any unintended on-target alteration must be assessed in the same manner as intended alteration”.

However, the FSA fails to address risks from unintended effects at other genomic locations than the targeted one (off-target effects), which can be extensive in number and type, and which could affect food safety.⁴³ The FSA gives a sound definition of an unintended effect as “A change that was not the objective of the breeding and was not predicted to occur but

⁴³ Chu P, Agapito-Tenfen S (2022). Unintended genomic outcomes in current and next generation GM techniques: A systematic review. *Plants (Basel)* 11(21):2997. doi: 10.3390/plants11212997.

has occurred and may have consequences for food safety in addition to the intended effect,” but then merely concludes that “Unintended effects are inevitable, and also occur in traditional breeding.”

This is unsatisfactory because empirical investigations (long-read whole genome sequencing and “omics” molecular analyses, as a minimum) are needed to confirm that the unintended effects are comparable to those that occur in traditional breeding and do not pose any additional risk.

Both ACRE’s and the FSA’s guidance documents make the fundamental mistake of allowing applicants to self-declare their GM-PBO as conventional-like without requiring adequate empirical proof. The FSA also relies on the applicant to define any hypothetical risk that their GM-PBO might pose and enables them to argue that there is no risk, again, without proving that this is so.

According to Google’s AI, a hypothesis is a tentative, testable, and falsifiable explanation for a specific phenomenon, based on existing knowledge, observation, or reasoning... [it] must be capable of being supported or refuted through experimentation or observation.”

Yet the FSA does not require the types of experimentation or observation that could begin to test the hypothesis, such as long-read whole genome sequencing and “omics” molecular analyses. Instead, the FSA only requires applicants to focus on expected effects of the genetic modifications performed, such as those included in the peer-reviewed literature or genomic databases (which are limited, incomplete, and focus only on a few well known crops).

Conclusion

The fundamental problem with the primary and secondary legislation and accompanying guidance documents on GM-PBOs is that they *assume* equivalence of the GM-PBO with what could arise from traditional processes, without requiring *evidence* of that equivalence. This is in spite of the fact that tests that could largely establish such equivalence are widely available and can be readily undertaken, and which could help to justify a reduced risk assessment for claimed GM-PBOs.

Among the tests that could begin to identify any risks of GM-PBOs are long-read whole genome sequencing and “omics” molecular profiling analyses. These would be followed up by long-term animal feeding studies, especially if the omics analyses revealed compositional changes that raise concerns.

Yet not only will these tests not be required by the regulator, but the government, in its secondary legislation, is banning them from ever being required, on the grounds that they are not applied to traditionally bred foods. The government regulator is wilfully blinding itself to any risks or harms arising from GM-PBOs – not only for the present, but for the indefinite future. For a nascent technology, the risks or safety of which are still an active topic of discussion among scientists, this is an extraordinarily irresponsible move.

The legislative system and accompanying guidance rely on self-certification by the applicant that the GM-PBO is equivalent to what could arise from traditional processes, without independent confirmation based on experimental data. It is again extraordinary

that the FSA believes it is acceptable for the applicant to form their own “hypothesis” of which risks the GM-PBO might pose, and then to argue that it does not pose such risks – again, without providing any actual experimental data that could help to provide proof.

The entire process only focuses on the intended genetic changes and completely ignores unintended changes from the gene-editing and associated processes (e.g. tissue culture and Agrobacterium/biolistic-mediated transformation), even though the unintended changes, or the full spectrum of intended and unintended changes taken together, could make the difference between safety and risk.

The potential for risk is increased by the 2023 Act’s listing of “induced mutagenesis” as one of the “traditional processes” that provide the comparators that enable the applicant to claim that a GM-PBO could have arisen through traditional methods and therefore can evade risk assessment, traceability, and labelling. Using induced mutagenesis as a comparator for GM-PBOs artificially widens the range of variation that enables a GMO applicant to declare that their GM-PBO could have arisen through traditional processes, even though the GM-PBO may contain extreme genetic elements that make it dangerous to health or the environment.

Neither ACRE’s nor the FSA’s guidance documents provide any indication that their experts have read or engaged with the large and increasing body of peer-reviewed scientific evidence that shows that gene editing processes, including those with outcomes that would qualify the product as a GM-PBO, can produce changes that would be difficult or impossible to produce via traditional processes (including random mutagenesis techniques) and that they can pose greater or unique risks. In GM-PB plants, these risks include unexpected toxicity and allergenicity or altered nutritional value.

In sum, the legislation and accompanying guidance fail to protect public health and the environment from the still poorly understood risks of gene-editing technologies.