Misleading statements made by Emma Hardy MP in the Delegated Legislation Committee meeting on the Draft Genetic Technology (Precision Breeding) Regulations 2025

On 31 March 2025, the Delegated Legislation Committee considered the Draft Genetic Technology (Precision Breeding) Regulations 2025.[1] In this session, Parliamentary Under-Secretary for the Department of Environment, Food and Rural Affairs, Emma Hardy MP, leading for the government, made a number of significantly misleading statements regarding the Act and its impact.

These statements formed the basis of much of her contribution to the session and we believe their misleading nature is serious enough to warrant scrutiny and a correction of the Parliamentary record. These are:

1. Mischaracterisation that PBOs are not GMOs

> *"It is incredibly important that we make that distinction because the methods are very different. Gene editing is different from genetic modification."*— Dr Neil Hudson

> *"It is incredibly important that we make clear the distinction between genetic modification and what we are talking about here, and that we note how different the two things are."*— Emma Hardy

In response to prompting from Dr Neil Hudson, Emma Hardy repeated, and therefore validated, the claim that precision-bred organisms (PBOs) are not genetically modified organisms (GMOs).

The persistence of this claim, which contradicts both the general recognition in the scientific community [2] and the law itself, is more than a presentational point. It is a deliberate strategy of obfuscating the fact that, according to the scientific consensus,

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[1] Draft Genetic Technology (Precision Breeding) Regulations 2025, https://hansard.parliament.uk/Commons/2025-03-31/debates/22611a77-81c0-4e1c-a248-d6bf750b0cc4/DraftGeneticTechnology(PrecisionBreeding)Regulations2025

[2] Future of Human Reproduction, What is Genome Editing?, https://wp.lancs.ac.uk/futureofhumanreproduction/genome-editing; Technology Networks, 4 January 2024, Gene editing vs genetic engineering, https://www.technologynetworks.com/genomics/articles/genetic-modification-techniques-and-applications-382001#D2

legal frameworks in many jurisdictions and major international definitions, gene editing is a form of genetic modification.

The Genetic Technology Act 2023 defines PBOs as the products of "modern biotechnology". It then defines "modern biotechnology" according to the definitions of the "techniques of genetic modification" in the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

The Act treats "precision-bred organisms" (PBOs) as a subclass of GMOs which can be regulated differently. Indeed, its essential purpose is to create regulatory exemptions around the environmental release and marketing of these precision-bred GMOs. This does not, however, alter the fact that PBOs are GMOs.

The techniques used in so-called "precision breeding" (such as CRISPR) might – under circumstances left undefined in the Act – generate changes that resemble those arising from traditional breeding. However, the persistent claim that they are not GMOs are incorrect and serve to cloud and suppress other issues such as true economic impact, supply chain integrity and consumer choice.

2. Claims of "no foreign DNA" are misleading

> *"Gene editing is different from genetic modification, in which genetic material from an exogenous, or unrelated, species can be introduced. That does not happen in gene editing, a process in which any changes must be equivalent to those that could have been made using traditional plant or animal breeding methods."* — Dr Neil Hudson
>
> *"I echo the comments made by the hon. Member for Epping Forest: we are not talking about the same things"*— Emma Hardy

Ms Hardy had an opportunity to correct the declaration made by Neil Hudson. Instead she chose to validate the factually incorrect claim that gene editing (PBOs) does not use DNA from exogenous or unrelated species ("foreign DNA").

This claim misrepresented the legislation being discussed by the Committee, as well as the science and the complexity of biotechnology techniques.

While the Genetic Technology Act requires that the final organism does not contain "foreign", or exogenous, DNA, it does not prohibit the use of foreign DNA during the editing process (e.g. via plasmids or templates).

The gene editing ("precision breeding") process typically involves the introduction of foreign DNA into cells using plasmids or bacterial vectors such as *E. coli* and *Agrobacterium tumefaciens*.

These vectors deliver the editing tools which are then used in a range of ways from so-called simple 'snips' to more disruptive insertion of foreign DNA. As a result, gene-edited plants and animals may contain unintended foreign DNA, making them transgenic in nature.[3, 4]

During the passage of the Genetic Technology Bill through Parliament, evidence to this effect was presented.

Lord Benyon, who led on this issue in the Lords, stated for instance:

> "*Therefore, we are allowing for foreign DNA to be present in precision-bred organisms only so long as this DNA does not serve any function and is within the range achievable through natural processes*."[5]

Lord Winston, a scientist and medical doctor by profession who "*has been practising genetics for over 40 years and doing modification of genes in various animal species*"[6] tabled numerous scientific papers on this and noted:

> "*Once you have taken the double-stranded break – which is what happens during CRISPR – the DNA is vulnerable to the introduction of foreign DNA that you do not expect or want and might express*."[7]

In its 2021 advice on the environmental release of ultra-low asparagine, low acrylamide, gene-edited wheat[8], the government's chosen advisor, the Advisory Committee on Releases to the Environment (ACRE), acknowledges:

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[3] Kim J and Kim J-S (2016), Bypassing GMO regulations with CRISPR gene editing, Nature Biotechnology 34:1014-015, https://www.nature.com/articles/nbt.3680; See also Ülker B et al (2008), Nature Biotechnology, 26:1015-17, T-DNA–mediated transfer of *Agrobacterium tumefaciens* chromosomal DNA into plants, https://www.nature.com/articles/nbt.1491

[4] Independent Science News, 23 September 2019, Gene-editing unintentionally adds bovine DNA, goat DNA, and bacterial DNA, mouse researchers find https://www.independentsciencenews.org/health/gene-editing-unintentionally-adds-bovine-dna-goat-dna-and-bacterial-dna-mouse-researchers-find

[5] Hansard, 21 November 2022, https://hansard.parliament.uk/lords/2022-11-21/debates/243A3CA0-6AAA-404C-AA70-1193916D0177/GeneticTechnology(PrecisionBreeding)Bill#contribution-F7CC63E5-5B05-47DF-9078-22292021C32A

[6] Hansard, 14 December 2022 https://hansard.parliament.uk/lords/2022-12-14/debates/318A724E-A72B-402F-A144-9989FA6B087B/GeneticTechnology(PrecisionBreeding)Bill#contribution-5BFE4FE7-66C8-4DCA-AC78-AA27CBE137EB

[7] Hansard, 14 December 2022 https://hansard.parliament.uk/lords/2022-12-14/debates/318A724E-A72B-402F-A144-9989FA6B087B/GeneticTechnology(PrecisionBreeding)Bill#contribution-77AE696C-4631-48EB-87B4-84022BB12BCB

[8] ACRE, July 2021, Advice on an application for deliberate release of a GMO for research and development purposes https://assets.publishing.service.gov.uk/media/614862f2e90e07043e85e0d2/Advice_on_an_application_for_deliberate_release_of_a_GMO_for_research_and_development_purposes.pdf

> "*The production of these gene-edited plant lines required genetic modification to introduce 3 transgenes, these genes were carried on 3 separate plasmid vectors and were cotransformed into cultivar (cv.) Cadenza wheat embryos*."

Fragments of exogenous DNA can inadvertently integrate into the genome of the edited organism and research has shown that some of this foreign DNA introduced into gene-edited organisms may remain functional, potentially producing novel proteins with unknown effects on health, including allergenicity or toxicity. These unintended insertions are often missed or ignored by developers, who rely on inadequate screening methods that cannot reliably detect them. [9, 10]

In passing the Act, and in refusing to make provisions requiring long-read, deep whole genome sequencing [11] which could detect the presence of exogenous DNA, the government has chosen to set aside the scientific reality of gene editing.

Nonetheless, the fact that gene editing ("precision breeding") does involve the use of "foreign", exogenous DNA from unrelated species cannot be denied.

Emma Hardy (and Neil Hudson) misled the Committee in this matter and the Parliamentary record should be corrected to avoid it becoming part of the ongoing parliamentary and public discourse.

3. Failure to address concerns from Parliamentary oversight committees

In her comments, Emma Hardy recognised that:

> *"concerns have been raised in the Secondary Legislation Scrutiny Committee's report, most notably around traceability and labelling, the impact on the organic sector, the UK internal market and trade with the EU... our work to understand and mitigate implications is ongoing."*

However, she notably omitted to mention the SLSC's references to the Regulatory Policy Committee's criticisms of Defra's Impact Assessment for the Genetic Technology Act as "not fit for purpose"[12] and the SLSC's regret that a comprehensive IA has still not been undertaken for this legislation.

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[9] Kim J and Kim J-S (2016), Bypassing GMO regulations with CRISPR gene editing, Nature Biotechnology, 34: 1014–1015, https://www.nature.com/articles/nbt.3680

[10] Chu P and Agapito-Tenfen SZ (2022), Unintended genomic outcomes in current and next generation GM techniques: A systematic review, Plants (Basel), 11(21): 2997, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9655061/

[11] López-Girona et al, (2020) CRISPR-Cas9 enrichment and long read sequencing for fine mapping in plants, https://plantmethods.biomedcentral.com/articles/10.1186/s13007-020-00661-x See also Kim & Kim, 2016 *op cit* and Chu & Agapito-Tenfen, 2022 *ibid*

[12] Regulatory Policy Committee, 16 June 2022, https://assets.publishing.service.gov.uk/media/63401c08e90e0709dd89bd5f/2022-06-16-RPC-DEFRA-5170_1_-_Genetic_Technologies__Precision_Breeding_Techniques__Bill.pdf

This omission allows Defra – and Ms Hardy in her comments to the DLC – to make misleading claims about the purported benefits of PBOs as regulated in the Act without any balanced information on costs or potential adverse impacts.

4. Unsubstantiated and misleading claims

When creating a regulatory framework for innovation and growth, accurate figures on economic impact are crucial and, in the absence of such figures, transparency around reasonable projection and promotional speculation seems sensible.

Gene editing technology is not widely in use in agriculture and where it is being used its application is limited. As a consequence, no accurate figures exist and caution and transparency should be exercised when making projections.

We acknowledge that the Act has had a significant level of Parliamentary support. However, in the absence of a thorough impact assessment, this support has been based on, and consistently been stoked by, the use of unsubstantiated and exaggerated claims for economic (and other benefits) for which no concrete evidence exists, and which mislead Parliament as well as the media and the general public.

Ms Hardy made some of these misleading claims in the DLC meeting:

> *"The existing legislation carries a significant burden, adding a stifling 74% to the cost of marketing for businesses."*

No source is cited for this precise-sounding but unsubstantiated figure. It appears to derive from industry feedback but no peer-reviewed or publicly available data appears to support it.

In fact, it is generally accepted that regulation accounts for only around 25% of the cost involved in the development and commercial release of gene-edited crops.[13]

In addition, Ms Hardy claimed:

> *"Precision breeding... will increase food production, reduce the need for pesticides and fertilisers, lower emissions and reduce costs for farmers."*

These claims lack grounding in available empirical evidence and rely on a narrative of 'inevitable benefit' rather than realistic timelines or proven outcomes.

There are few commercialised gene-edited ("precision-bred") crops anywhere in the world and those that have been brought to market have only limited distribution. Some companies like Calyxt, the first to market gene-edited soybeans in 2019 have, in just a

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[13] Lassoued R et al, (2019) Estimating the cost of regulating genome edited crops: expert judgment and overconfidence, GM Crops & Food, 10(1): 44–62, https://www.tandfonline.com/doi/full/10.1080/21645698.2019.1612689#d1e417

few years, failed to thrive in the US, the most lenient regulatory environment in the world. Others like Cibus, creators of a failed gene-edited herbicide-tolerant canola[14], and now merged with Calyxt[15], continue to see their share prices fall.[16]

Defra has undertaken no credible comprehensive economic analysis, nor produced any evidence to suggest that agricultural biotechnology companies in the UK will fare any differently.

The following figures were quoted twice by Ms Hardy during the session:

> *"A report by the Breakthrough Institute and Alliance for Science estimates that the EU's current regulations on gene editing could result in an annual opportunity cost of $182 billion to $356 billion."*

This figure relates to the EU and is not specifically related to gene editing ("precision breeding"). No reliable figures for an annual opportunity cost exist for the UK.

Instead, the figure quoted is for all types of and uses for genetic technologies, however speculative, and is not specifically related to use in the food and farming system. It is, likewise, based on economic projections from the global McKinsey Institute and does not factor in environmental or public health risks, regulatory lag or public resistance. It also assumes full adoption and perfect implementation without acknowledging the piecemeal and uneven nature of the regulatory landscape which is developing globally.

5. Conclusion

The statements made by Emma Hardy MP during the Delegated Legislation Committee session on the Draft Genetic Technology (Precision Breeding) Regulations 2025 demonstrate a pattern within government of strategic misrepresentation and overstatement:

- PBOs are framed as non-GMOs, despite legal and scientific evidence to the contrary.
- Hypothetical benefits are presented as facts.
- Cost/benefit figures are uncited or unverifiable.

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[14] GMWatch, 16 December 2022, Has another gene-edited pioneer crop disappeared from the market? https://www.gmwatch.org/en/106-news/latest-news/20142-has-another-gene-edited-pioneer-crop-disappeared-from-the-market

[15] Cibus, 1 June 2023, Cibus Announces Closing of Merger with Calyxt to Create Industry Leading Precision Gene Editing and Trait Development Company, https://investor.cibus.com/news-releases/news-release-details/cibus-announces-closing-merger-calyxt-create-industry-leading

[16] Investing.com, 4 January 2025, Cibus stock plunges to 52-week low, hits $1.8 amid sharp decline https://uk.investing.com/news/company-news/cibus-stock-plunges-to-52week-low-hits-18-amid-sharp-decline-93CH-4008662

- Legitimate regulatory concerns are acknowledged but not addressed.
- Economic modelling from industry-linked sources is used as primary justification.

The net result is a misleading discourse that marginalises transparency and public accountability around a crucial food system issue.

It is in the interests of parliamentary oversight and UK citizens that all these errors and misleading statements made during this Committee hearing are corrected on the Parliamentary record.

Further Information
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