EXPLANATORY MEMORANDUM TO

THE GENETIC TECHNOLOGY (PRECISION BREEDING) REGULATIONS 2025

2025 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs, in conjunction with the Food Standards Agency, and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Daniel Zeichner MP, Minister for Food Security and Rural Affairs at the Department for Environment, Food and Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

2.2 Sarah Evered, Deputy Director for Innovation, Productivity and Science at the Department for Environment, Food and Rural Affairs confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Oliver Watson and Louise Ball at the Department for Environment, Food and Rural Affairs (Defra) email: geneticstechnologies@defra.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation and Context of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument implements the Genetic Technology (Precision Breeding) Act 2023 ("the Act") for precision bred plants in England. The instrument contains the detailed regulations for meeting the requirements provided for in the Act, which include:

- Provisions for notifying the Secretary of State, through Defra, of the deliberate release of precision bred plants into the environment for non-marketing purposes, such as for field trials.
- Provisions for applying to the Secretary of State, through Defra, for a precision bred assessment and confirmation to enable precision bred plants to be marketed, such as for commercial cultivation.
- Provisions for applying to the Secretary of State, through the Food Standards Agency, for a food and feed marketing authorisation to allow food and feed produced from confirmed precision bred plants to be placed on the market.
- Provisions for two public registers: one of prescribed information associated with Defra's regulation of precision bred plants and one of precision bred plants authorised for food and feed use kept by the Food Standards Agency (FSA).
- An inspection and enforcement regime to secure compliance with the legislation, including civil sanctions by way of enforcement notices, namely compliance notices, stop notices and monetary penalty notices.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales. The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. Policy Context

What is being done and why?

5.1 Until recently, all plants produced by modern biotechnology were regulated as Genetically Modified Organisms (GMOs) in England. The marketing of food and feed derived from them was also regulated under GM legislation. This is because it was the techniques used to produce these plants, rather than their characteristics, that determined how they were regulated. However, this approach has become more of an issue in the last decade as modern biotechnology has been used to develop, more precisely and efficiently, organisms with genetic changes that could have occurred through traditional breeding.

5.2 The UK's Advisory Committee on Releases to the Environment, and other eminent scientific bodies such as the European Food Safety Authority, have advised that it is the characteristics of organisms that determine risk and not the technology used to produce them. They concluded that precision bred organisms present no greater risk to health or the environment than traditionally bred counterparts. The Advisory Committee on Novel Foods and Processes reached the same conclusion, stating that there is no evidence that precision bred organisms are intrinsically more hazardous than traditionally bred organisms. This advice is based on more than 30 years of intense scrutiny of GMOs. Applying GMO regulatory requirements to these organisms, when they do not pose a greater risk than their traditionally bred counterparts, is disproportionate.

5.3 Only one Genetically Modified (GM) crop is authorised for cultivation in England. GM food and animal feed has been authorised for use in England, but a limited number of companies submit these applications. The regulatory costs have resulted in applications for a low diversity of crop species and traits. The system therefore deters investment and innovation in a suite of technologies, which have great potential to introduce beneficial traits such as better resilience to pests, diseases, and climate change.

5.4 To address this, the Act established a new class of regulated product in England; "precision bred organisms". These are defined as plants and animals produced by the application of modern biotechnology, but which only contain genetic features that could have resulted from traditional processes. The Act establishes a new framework of regulatory requirements that apply to the environmental release and marketing of precision bred organisms and to their use as food and animal feed. It also includes provisions to introduce regulations that safeguard animal welfare, but these are not relevant to this instrument, which covers plants only.

What was the previous policy, how is this different?

5.5 The previous policy on GMO regulation was adopted before precision breeding techniques were developed. These GMO regulations would require precision bred plants to undergo a detailed comparative risk assessment with traditionally bred counterparts before they could be cultivated commercially or used as food and feed. There would also have to be a public consultation and surveillance plan for identifying unanticipated adverse effects on the environment. As above, this places a disproportionate regulatory burden on precision bred organisms.

5.6 The new policy is to regulate precision bred plants more like their traditionally bred counterparts rather than as GMOs. This means that the requirements above do not apply to precision bred organisms, but other requirements associated with transparency and oversight will. These new measures include a process for confirming that plants are precision bred, not GMOs, before they can be marketed. They also add detail on the content of public registers for precision bred organisms and for precision bred organisms authorised for use as food and feed.

5.7 The policy on field trials involving precision bred plants has not changed since the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations came into force in 2022 (The 2022 Regulations)[1]. These were introduced as a first step in regulatory reform. The 2022 Regulations reduced the burden on developers using GM plant lines in field trials if those plants could have been produced using traditional processes. As the environmental risks posed by these plants are no greater than their traditionally bred counterparts, they were exempted from requiring a risk assessment, from obtaining consent from the Secretary of State, from providing detailed information on the location of the trial site(s) and from carrying out a public consultation. Instead, the Regulations required developers to notify the Secretary of State before the trial began, providing information about the purpose of the trial, the characteristics of the plants involved in it and information about the person responsible for the trial. These Regulations will be replaced by the requirements in this instrument, which will have the same effect for research trials but go further to introduce the processes to allow a route to market outside the current GMO framework.

5.8 This instrument also sets out the requirements for a food and feed marketing authorisation to allow food and feed produced from precision bred plants to be placed on the market. There is a simpler assessment process for precision bred plants intended for food or feed which do not have any safety concerns; these will undergo a more streamlined route to authorisation by the Secretary of State. A fuller assessment will take place for any precision bred plants for use in food or feed which need scrutiny to ensure they are safe for consumption. Unlike GMOs, for both assessments, developers of precision bred plants will not be required to provide scientific detection methods as part of the authorisation process and once authorised, precision bred plants will not require authorisation renewals. Regulation (EU) 2015/2283 on novel foods applies in the UK to assess the safety of foods that do not have a significant history of consumption. However, regulation (EU) 2015/2283 will not apply to any precision bred food types as safety hazards normally captured under regulation (EU) 2015/2283 will be addressed in assessments under this instrument.

5.9 Policy on enforcement will change as this instrument will commence a proportionate enforcement regime that will encourage compliance.

6. Legislative and Legal Context

How has the law changed?

6.1 The regulation of GMOs in the UK is mainly based on EU law implemented in the UK through Part VI of the Environmental Protection Act 1990 (“the EPA 1990”) and subsequent secondary and assimilated direct legislation. Release and marketing of GMOs is mainly governed by the Genetically Modified Organisms (Deliberate Release)

[1] https://www.legislation.gov.uk/uksi/2022/347/pdfs/uksi_20220347_en.pdf

Regulations 2002,[2] while Regulation (EC) 1829/2003 on GM food and feed governs the use of GM food and animal feed. The introduction of a proportionate process for regulating certain categories of modified plants has been made in stages. The 2022 Regulations were introduced using powers in the EPA 1990 to reduce the regulatory requirements for research and development trials in England involving those GM plants which could have been developed using traditional processes.

6.2 The next step was to introduce, in England, a new class of regulated product, precision bred organisms. This was achieved through the Act which defined precision bred organisms and, by amending the EPA 1990 in relation to England, removed them from the existing regulatory requirements that apply to the deliberate release and marketing of GMOs and GM food and feed. The Act provides for a framework for a simpler procedure for authorising and regulating the environmental release and marketing of precision bred organisms and for precision bred organisms used as food and feed.

6.3 This instrument is made in exercise of the powers conferred by the Act and implements it in relation to precision bred plants and the food and feed produced from them. It does not implement the Act in relation to precision bred animals. It sets out the detailed processes and regulatory requirements that will apply to release notices, public registers, precision bred confirmations and food and feed marketing authorisations. This includes provisions for variation and revocation of confirmations and authorisations and for the review of decisions by the Secretary of State and appeal to the First-tier Tribunal where appropriate. It also includes provisions for inspection and enforcement, including civil sanctions by way of compliance notices, stop notices and monetary penalty notices. The instrument ensures that precision bred organisms imported or acquired for contained use will continue to be subject to an environmental risk assessment and makes the necessary consequential amendments to other domestic and assimilated EU legislation.

Why was this approach taken to change the law?

6.4 Existing domestic and assimilated EU law did not provide the powers to establish a new regulatory framework for precision bred organisms. Primary legislation was required through the Act to define precision bred organisms, remove them from the scope of the Environmental Protection Act 1990 and provide the powers to introduce the framework by which they would be authorised and regulated. This instrument is required to implement the Act in relation to precision bred plants.

7. Consultation

Summary of consultation outcome and methodology

7.1 Defra held a public consultation in 2021 prior to the Act and the 2022 Regulations.[3] This gathered evidence on whether organisms made using modern biotechnology, which could have been produced using traditional methods, should be regulated as GMOs. All responses were considered and used to inform decision making when developing the new regulatory system for these kinds of organisms. Key experts and stakeholder groups have continued to be engaged throughout the development of this instrument.

7.2 The FSA held a public consultation in 2023. This gathered evidence on policy proposals for a new framework for the regulation of precision bred food and animal feed in

[2] https://www.legislation.gov.uk/uksi/2002/2443/pdfs/uksi_20022443_en.pdf
[3] https://www.gov.uk/government/consultations/genetic-technologies-regulation/outcome/genetic-technologies-regulation-government-response

England. The draft proposals set out in the consultation were informed by the FSA Board's discussions in several public meetings in 2022 and 2023, culminating in the FSA Board Meeting on 20 September 2023.[4]

7.3 The FSA consultation sought views on four key areas: a pre-market authorisation process for precision breed plants intended for food and feed; a public register of authorised precision bred food and feed; proposals for traceability and enforcement provisions. Evaluation of the responses found no scientific evidence indicating that precision bred food or feed should be regulated in accordance with GM Food and Feed Regulations or that the proposed framework would not regulate this effectively.[5]

8. Applicable Guidance

8.1 Defra will publish four sets of technical guidance in draft ahead of parliamentary debates for public scrutiny. The final guidance will be published after the instrument is made and before the instrument comes into force.[6] These are:

- Guidance on the types of genetic changes introduced by modern biotechnology that could arise through traditional breeding processes. These will result in "precision bred" plants in accordance with Part 1 of the Act.
- Guidance on the information to be provided in a "release notice" to meet the requirements of Part 2 of, and Schedule 1 to, the instrument for those intending to carry out research and development trials involving precision bred plants.
- Guidance on the information to be provided in a "marketing notice" to meet the requirements of Part 3 of, and Schedule 2 to, the instrument for those seeking confirmation from Defra's Secretary of State that their plants are precision bred.
- Best practice guidance for those carrying out research and development trials.

8.2 The FSA will publish three sets of guidance after the instrument is made and before the instrument comes into force. Draft administrative and technical guidance will be published ahead of parliamentary debates for public scrutiny, whilst draft enforcement guidance will be shared directly with enforcement bodies. The three sets comprise of:

- Administrative guidance on the procedures involved in the submission and processing of applications for food and feed marketing authorisations under Part 7 of the instrument.
- Technical guidance on the requirements to be met for a food and feed marketing authorisation under Part 7 of, and Schedule 4 to, the instrument.
- Enforcement guidance for enforcement authorities and their officers involved in the enforcement of the instrument, e.g. local authorities and port health authorities in England. The FSA also plan to issue guidance to authorities in Wales and Northern Ireland in relation to the impact of the instrument on the UK internal market. This guidance will be shared with Food Standards Scotland.

[4] https://www.food.gov.uk/board-papers/fsa-board-meeting-september-2023-agenda-and-papers
[5] https://www.food.gov.uk/our-work/summary-of-stakeholder-responses-consultation-on-proposals-for-a-new-framework-in-england-for-the-regulation-of-precision-bred
[6] All guidance will be published on GOV.UK.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared as this instrument will have a low level of impact on businesses and will not introduce new costs or benefits above the threshold required for a full Impact Assessment. [7] We have chosen not to implement application fees in this instrument but reserve the right to review this.

Impact on businesses, charities and voluntary bodies

9.2 As above, this instrument will have a low level of impact on businesses, with low-cost implications and potential benefits and cost savings. There is no, or no significant, impact on charities or voluntary bodies because these groups have very limited involvement in the development of organisms using modern biotechnology.

9.3 Businesses with an interest in marketing precision bred organisms (estimated at around 75, many small or medium sized) will need to understand the new procedures and disseminate this information across their organisations at a one-off cost which is not believed to be onerous. Organic certification schemes will continue to regulate precision bred organisms as GMOs. As such, they will not be grown or used in organic production. The issue of ensuring precision bred material does not enter organic supply chains has been raised as a practical concern by some stakeholders and Defra is continuing to run a series of engagements with stakeholders to explore this further.

9.4 The regulatory requirements in the legislation are more proportionate and will result in significant regulatory cost savings for business, compared to the existing GMO regulatory framework. It is anticipated that the overall effect will be of benefit to business, including small or micro businesses.

9.5 Since this legislation is unlikely to result in higher costs to businesses, consumers would not have any direct costs being passed on to them. There may be consumers wishing to buy food that does not contain precision bred organisms who may have to research suitable products such as organic food. This may incur additional cost with less choice or availability. It was not raised as an issue in either Defra or Food Standards Agency consultations, however, and has not been quantified.

9.6 The impact on the public sector is limited. Administration resource in Defra and the Food Standards Agency is expected to grow to accommodate the demands of the application processes. There will also need to be a small amount of familiarisation cost for enforcement bodies which has been factored into costings. Ongoing monitoring and enforcement requirements have been agreed to be added to the existing GMO and food and feed frameworks with limited impact.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation will be by reviewing the number and content of applications made under it. This will be compared to baseline data collected as part of the GMO framework, under which all products of modern biotechnology were previously regulated.

[7] A de minimis assessment of the effect that this instrument will have on the cost of business has been prepared and is available from Defra, 2 Marsham Street, London, SW1P 4DF.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Daniel Zeichner MP, The Minister for Food Security and Rural Affairs has made the following statement: "In my view, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, the provisions of the Genetic Technology (Precision Breeding) Regulations 2025 are such that a statutory review clause would be inappropriate, for proportionality reasons, given the costs associated with such a review and the nature of the industry."

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 Daniel Zeichner MP, The Minister for Food Security and Rural Affairs has made the following statement regarding Human Rights:

"In my view the provisions of the Genetic Technology (Precision Breeding) Regulations 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").