Neutral Citation Number: [2026] EWHC 1306 (Admin)

Case No: AC-2025-LON-002733

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
PLANNING COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 4 June 2026

Before :

MR JUSTICE JOHNSON

- -

Between :

(1) Beyond GM
(2) Joseph Wookey
(3) Patrick Holden CBE
(4) Joanna Blythman **Claimants**

- and -

Secretary of State for Environment, Food and Rural Affairs **Defendant**

- -
- -

David Wolfe KC, James Robottom and Julianne Kerr Morrison (instructed by Leigh Day) for the Claimants
Charles Streeten and Jonathan Welch (instructed by Government Legal Department) for the Defendant

Hearing dates: 12 – 13 May 2026

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Approved Judgment

This judgment was handed down by release to The National Archives on 4 June 2026

Mr Justice Johnson:

1. This claim for judicial review concerns a new regulatory framework for precision bred organisms ("PBOs"). A PBO is, broadly, an organism that has a genome with a feature that resulted from the application of modern biotechnology, but where that feature is stable and could have resulted from traditional breeding processes. The law in the European Union, and in all parts of the United Kingdom apart from England, treats PBOs as genetically modified organisms ("GMOs") and regulates them accordingly. In England, PBOs are now subject to a lighter-touch regulatory regime, including in respect of transparency, traceability and environmental protection. That is a result of the Genetic Technology (Precision Breeding) Act 2023, read with the Genetic Technology (Precision Breeding) Regulations 2025.

2. The claimants seek judicial review of the Secretary of State's decision to make the 2025 Regulations. They say that it will no longer be possible (or at least will be much more difficult) for the organic sector to keep GMOs out of their supply chains, and for consumers to avoid GM food. The claimants contend that the 2025 Regulations threaten the organic sector, consumer confidence, and the protection of the environment. Allowing for an amendment to the original claim, and renumbering the grounds for convenience, the claimants submit that the decision to make the regulations was unlawful because:

   (1) It was incompatible with rights to respect for private life and peaceful enjoyment of possessions under the European Convention of Human Rights (ground 1).

   (2) It was irrational, including because there was a failure to undertake adequate enquiries (ground 2).

   (3) There was a failure to undertake an environmental assessment required by regulation 63(1) of the Conservation of Habitats and Species Regulations 2017 ("the Habitats Regulations") (ground 3).

   (4) Regulation 30(4)(b) is outside the scope of the power to make regulations conferred by the 2023 Act (ground 4).

3. Following directions given by Mould J, the claim was listed for a "rolled-up hearing" to determine whether the claimants should be granted permission to claim judicial review and, if so, to determine the substantive claim.

Outstanding procedural issues

4. The parties filed witness statements in accordance with the directions of Mould J. Additional statements were filed late. There are outstanding applications for them to be admitted. Helpfully, the parties presented their arguments on the basis that the court would consider the statements on a provisional basis so that any disputes as to admissibility could be determined in the light of the practical impact of the evidence on the overall case. None of the parties has been disadvantaged by this approach. I have considered the late evidence and also the reasons why it was not filed within the timetable set by the court. In each case, there is a good explanation for the evidence being submitted late. Neither party is materially disadvantaged by its late admission,

and, in each case, there are good reasons why an extension of time is required. I grant each of the applications.

5. There are also outstanding applications for extensions of time to comply with directions given by Mould J and to file extended skeleton arguments. Each application is meritorious, and there is no substantive opposition to any of them. I grant each of the applications.

6. In the written materials, reference is made to the passage of the 2023 Act through Parliament and to other matters that amount to proceedings in Parliament within the meaning of article 9 of the Bill of Rights 1689 and which raise issues of parliamentary privilege. The parties contacted the Speaker of the House of Commons in accordance with the Court of Appeal's guidance in *R (National Council for Civil Liberties) v Secretary of State for the Home Department* [2025] EWCA Civ 571; [2026] KB 39 *per* Underhill LJ at [56]. On 23 April 2026, Speaker's Counsel wrote a helpful letter to the Court in which she explained that proceedings of the Secondary Legislation Scrutiny Committee amounted to proceedings in Parliament. She also explained why the Speaker submitted that a draft Explanatory Memorandum that accompanied the 2025 Regulations also amounts to a proceeding in Parliament (albeit that issue has not been authoritatively determined by the courts). In the event, the parties did not make substantive reference to either the proceedings of the Secondary Legislation Scrutiny Committee or the draft Explanatory Memorandum. It is not therefore necessary to address any question of Parliamentary privilege or the application of article 9 of the Bill of Rights.

The witness evidence

Statements from the claimants and their witnesses

7. The claimants are an NGO, two organic farmers/food producers, and an ethical consumer. They are all concerned about the release of GMOs into the environment and the food chain.

8. The first claimant, Beyond GM, is a private company. It is described by its co-founder, Pat Thomas, as the United Kingdom's leading advocacy group in the field of agricultural and environmental genetic engineering. Its primary aims are to foster critical thinking, public awareness and engagement, influence policy and support sustainable agricultural practices. It participated in consultations connected with the 2023 Act and the 2025 Regulations. Ms Thomas says that the new regime does not make adequate provision for labelling and traceability. That makes it difficult for organic producers to keep GMOs out of the supply chain, jeopardising the interests of both organic businesses and consumers.

9. The second claimant, Joseph Wookey, along with his father, runs Rushall Organics, a 2,000-hectare family-owned farm in Wiltshire. It has been fully organic since the 1990s. Half of the farm's land is arable and is used to grow a variety of organic cereals. The other half is grassland, woodland, and biodiversity conservation areas which Rushall Organics maintains in furtherance of its conservation ethos. The farm lies in the area of Salisbury Plain which is a Special Protection Area, a Special Area of Conservation and a Site of Special Scientific Interest.

10. Mr Wookey explains that organic farming is integral to his family's farming model and his identity as a farmer. He says that organic certification depends on the exclusion of GMOs throughout the supply chain. Under the pre-existing regime, there was an obligation for public notification when GMOs were released into the environment, enabling local farmers that might be affected to know what was happening and to respond as necessary. The 2023 Act and 2025 Regulations do not contain any equivalent requirement for notification before PBOs are released. Also, the absence of a mandatory labelling requirement for PBOs makes it much more difficult to avoid PBOs in supply chains. There is thus both a risk of contamination from PBOs, and also inadvertent inclusion of PBOs, which would jeopardise the farm's organic certification. There is a consequential additional burden on the organic sector to maintain organic certification. There is also a risk to continued access to markets in Northern Ireland and the European Union. The latter risk applies not just to the organic sector, but also to any business exporting food which might contain PBOs.

11. The third claimant, Patrick Holden CBE, is the owner and operator of Holden Farm Dairy, an organic farm and food business in West Wales that produces a specialist cheddar-style cheese from its herd of pedigree Ayrshire cows. He exports to the European Union. It is essential for Holden Farm Dairy to maintain its organic certification to be able to continue to sell to its existing customers. The absence of a mandatory labelling regime will make it materially more difficult, or even impossible in practice, for organic operators to verify that seeds and animal feed are free from PBOs, and to reassure customers and certifiers. The divergence from the regulatory regime in other parts of the United Kingdom, and in the European Union, introduces uncertainties and compliance difficulties.

12. The fourth claimant, Joanna Blythman, is a multiple award-winning investigative food journalist and author. She chooses to buy, consume and feed her children food that is as natural as possible. She avoids consuming or purchasing food which has been subject to genetic modification, including precision breeding. She is reliant on organic certification because that guarantees that food is not genetically modified or produced from GMOs. She says that the 2025 Regulations make it materially more difficult for consumers to know whether food contains PBOs because there is no mandatory labelling requirement. Public registers are not a practical substitute for point-of-sale labelling and do not enable real-time consumer decision-making at the point of purchase in a shop. She also explains that the lack of a labelling requirement impedes monitoring and accountability (including her ability, as a journalist, to inform the public), and she expresses concern about the difficulty of detecting and responding to any adverse consequences if products are untraceable. The consequence is that the 2025 Regulations undermine consumer choice, and the consumer's right to choose not to eat GM food. The Secretary of State contends that there is no such right.

13. The claimants also rely on witness statements from David Wilson (a farmer and agriculturist who managed Duchy House Farm at Highgrove when it converted to organic agriculture), Christopher Stopes (an agricultural consultant and Chair of the English Organic Forum), Will Chester-Master (the co-owner of Abbey Home Farm which is committed to organic principles), Sarah Hathway (Head of Technical at the Soil Association Certification Ltd), Steven Jacobs (the Coordinator of the Organic Growers Alliance which represents growers and producers committed to organic and

agroecological food production) and Josiah Meldrum (the co-founder and director of a business that sells minimally processed whole foods).

14. This evidence identifies the concerns of organic farmers and producers about the impact of the 2025 Regulations on the organic sector, farmers and food producers generally, and the environment. Any business operating in the organic sector requires an organic certification. To retain an organic certification, the business must ensure PBOs do not enter the supply chain. That is most effectively achieved by ensuring the traceability of PBOs and the labelling of products that contain PBOs.

15. However, the 2025 Regulations permit the release of PBOs into the environment, and the food chain, without labelling or effective traceability. This means that organic businesses must avoid PBOs but do not have the practical means to do so. This puts a business' organic certification at risk, with a consequential impact on livelihoods and established markets (particularly in the European Union and other parts of the United Kingdom).

16. From the perspective of consumers, the witnesses emphasise that the absence of labelling prevents informed choice and risks eroding trust in organic and non-GMO products, thereby affecting demand and the credibility of certification schemes. The witnesses suggest that the framework was introduced without sufficient scientific testing, or economic assessment, or mechanisms for monitoring environmental or health effects once PBOs are released.

17. Julia Eriksen, the claimants' solicitor, has also made a statement. Ms Eriksen's evidence addresses a complaint made by the Secretary of State that the claim form was not filed promptly. Ms Eriksen also produces minutes of meetings of the Food Standards Authority that were referenced in evidence filed by the Secretary of State.

Secretary of State's evidence

18. The Secretary of State relies on witness statements from Lucy Foster and Rachel Bailey.

19. Ms Foster is the Interim Deputy Director for the Innovation, Productivity and Science Division in the Department for Environment, Food and Rural Affairs ("Defra"). She explains the impact of the delay in bringing these proceedings.

20. Ms Bailey is the Deputy Director for Agri-Growth, Trade and Technology at Defra. She explains the policy background to the 2023 Act and the 2025 Regulations. That includes scientific evidence that underpinned a deliberate legislative choice to move away from regulation based on the techniques used to produce a GMO and towards a "more proportionate" framework that depends on the characteristics of a GMO.

21. Ms Bailey says that although there is no compulsory labelling, the framework ensures that information about authorised PBOs is available through public registers, and that this is supplemented by existing registers established under the Plant Varieties and Seeds Act 1964. Those registers are intended to provide information at the start of the food supply chain (that is, in relation to seeds). Ms Bailey accepts that there may be a need for the organic sector to protect against contamination (including by cross-pollination), and that it may therefore need to take "coexistence measures" (such as planting buffer strips at the edge of an organic field), but she says that this can be done

by means of existing agricultural practices. Ms Bailey also explains the intended benefits of the 2025 Regulations: they support innovation, productivity and environmental benefits such as improved crop resilience.

The statutory framework

Plant Varieties and Seeds Act 1964

22. The 1964 Act enables the regulation of transactions in seeds, including the establishment of an index of names of varieties and the imposition of restrictions on the introduction of new varieties. Section 16(1)(a) of the 1964 Act allows the Minister to make regulations for the purpose of prescribing the information that is provided when seeds are sold. Regulation 17 of the Seed Marketing Regulations 2011, read with paragraph 3 of schedule 3 to the 2011 Regulations, requires that if a variety of seed has been genetically modified, this must be stated on the label.

23. Regulation 3 of the Seeds (National Lists of Varieties) Regulations 2001 requires the Secretary of State to publish lists of plant varieties of specified species. By regulation 3(5) if any plant variety is genetically modified, that must be indicated in the published list. For this purpose, "genetically modified" has the same meaning as that applied in EU Directive 2001/18: regulation 2(1). It therefore includes PBOs, notwithstanding their exclusion from the domestic GMO framework for other purposes by the 2023 Act.

Environmental Protection Act 1990

24. Part VI of the 1990 Act makes provision for the control of GMOs. It prohibits the release or marketing of any GMO unless a risk assessment has been conducted and the Secretary of State has been informed and (in prescribed cases) the Secretary of State has given consent. There is provision for enforcement and monitoring, and for a public register to ensure transparency. The Genetically Modified Organisms (Deliberate Release) Regulations 1992 required, with limited exceptions, the consent of the Secretary of State before the release or marketing of any GMO.

EU GMO Directive and Regulations

25. Article 2(2) of EU Directive 2001/18/EC ("the GMO Directive") defines a GMO as "an organism… in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." The GMO Directive is implemented in the United Kingdom by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (which revoked the 1992 Regulations). The 2002 Regulations amend section 106 of the 1990 Act to define a GMO in the same way as the GMO Directive. They regulate the release of GMOs into the environment.

26. Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003 regulate, among other things, the authorisation, traceability and labelling of food and feed that is produced from GMOs. They continue to take effect in the United Kingdom pursuant to section 3 of the European Union (Withdrawal) Act 2018 (subject, now, to statutory modifications in respect of England). They require that GMOs undergo a safety assessment before being placed on the market. There are traceability and labelling requirements for all food and feed that consists of, or is derived from, GMOs: articles 4 and 5 of Regulation

1830/2003. This enables farmers and producers to avoid using GMOs, including GM feed for animals, and enables consumers to avoid buying GM food.

27. The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 amended the 2002 Regulations (but for England only) by exempting from certain regulatory requirements PBOs that are "higher plants" (that is plants from the taxonomic group *Spermatophytae*, broadly plants that produce seeds). The 2022 Regulations permit the release of such qualifying higher plants other than in relation to marketing. It therefore permits research trials of qualifying higher plants.

The Genetic Technology (Precision Breeding) Act 2023

28. The Genetic Technology (Precision Breeding) Act 2023, in the words of its long title, makes "provision about the release and marketing of, and risk assessments relating to, precision bred plants and animals, and the marketing of food and feed produced from such plants and animals; and for connected purposes."

29. Section 1 of the 2023 Act defines a PBO:

> "**1 Precision bred organism**
>
> (1) In this Act "precision bred organism" means a precision bred plant or a precision bred animal.
>
> (2) For the purposes of this Act an organism is "precision bred" if—
>
> (a) any feature of its genome results from the application of modern biotechnology,
>
> (b) every feature of its genome that results from the application of modern biotechnology is stable,
>
> (c) every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone, and
>
> (d) its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology.
>
> …
>
> (4) A feature of an organism's genome is "stable" if it is capable of being propagated whenever the organism is reproduced, whether by sexual or asexual reproduction.
>
> …"

30. Section 41 introduces a new section 106A into the 1990 Act to provide that references to GMOs in the 1990 Act do not include references to PBOs. Section 106A applies only to England, and not to other parts of the United Kingdom. Thus, in England but not the rest of the United Kingdom, PBOs are exempted from the general framework that applies to GMOs more generally.

31. Before releasing or marketing a PBO, a person must first obtain a "precision bred confirmation" by sending a "release notice" or "marketing notice" to the Secretary of State: sections 4 and 6. Sections 6 - 8 enable the Secretary of State to issue a precision bred confirmation only after first securing a reasoned written report from the Advisory Committee on Releases to the Environment ("ACRE") confirming that the organism is a PBO.

32. Section 3 restricts the release of PBOs in England:

> "**3 Restrictions on release of precision bred organism in England**
>
> (1) A person who has a precision bred organism under their control must not release the organism in England unless—
>
> (a) the following apply—
>
> (i) the notification requirements are satisfied in relation to the release (see section 4),
>
> (ii) the person is a person specified in the release notice under section 4(2), and
>
> (iii) the release is carried out in accordance with the release notice, or
>
> (b) the organism is—
>
> (i) a marketable precision bred organism (see section 5(2))…
>
> (2) For the purposes of this Act an organism is under a person's "control" if the person keeps it contained by measures designed to—
>
> (a) limit its contact with humans and the environment, and
>
> (b) prevent or minimise the risk of adverse effects as regards the health of humans or the environment.
>
> (3) For the purposes of this section and section 4, a person "releases" an organism under their control by deliberately causing or permitting it to—
>
> (a) cease to be under their control or the control of anyone else, and
>
> (b) enter the environment."

33. Section 5 imposes restrictions on the marketing of PBOs.

34. Section 17 provides a power to make regulations to require an environmental risk assessment before PBOs are imported or acquired.

35. Section 18 requires the Secretary of State to maintain a freely accessible public register of all release notices and all marketing notices.

36. Part 3 of the Act makes provision in respect of food and feed that is produced from PBOs.

37. Section 26 provides a power to make regulations for the marketing of food and feed produced from PBOs. It states:

> "**Regulation of food and feed produced from precision bred organisms**
>
> (1) Regulations may make provision for regulating the placing on the market in England of food and feed produced from precision bred organisms.
>
> (2) Regulations under subsection (1) may, in particular—
>
> (a) prohibit any person from placing food or feed produced from a precision bred organism on the market in England except in accordance with a marketing authorisation issued by the Secretary of State under the regulations in relation to the organism, and
>
> (b) impose requirements for the purpose of securing traceability in relation to food or feed produced from precision bred organisms that is placed on the market in England.
>
> (3) Regulations made by virtue of subsection (2)(a) may, in particular, prescribe requirements that must be satisfied in order for the Secretary of State to issue a food and feed marketing authorisation in relation to a precision bred organism which may include requirements—
>
> (a) that the precision bred organism—
>
> (i) is a marketable precision bred organism,…
>
> (b) for securing that—
>
> (i) any food or feed produced from the organism and covered by the authorisation will not have adverse effects on human or animal health;
>
> (ii) the way in which any such food or feed will be placed on the market will not mislead consumers;

(iii) the production of any such food or feed will not have adverse effects on the environment;

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

(4) Regulations made by virtue of subsection (2)(a) may also make provision, in particular—

…

(e) about publication of information relating to applications for food and feed marketing authorisations.

…

(6) Provision that may be made by virtue of subsection (4) includes provision conferring functions on the Food Standards Agency, which may include provision—

(a) for requiring the Food Standards Agency, in carrying out a function conferred by the regulations—

(i) to obtain advice or information from, or consult, persons of prescribed descriptions;

(ii) to carry out risk assessments;

(b) relating to any risk assessment required by the regulations.

…

(9) Regulations under this section are subject to the affirmative procedure."

38. Thus, section 26(1) provides a general power to regulate the marketing of food and feed produced from PBOs. Section 26(2)(b) explicitly permits that power to be exercised to impose requirements to ensure such food or feed is traceable.

39. Section 27 provides a power to make regulations that require the Food Standards Agency to maintain a public register of food and feed marketing authorisations, which may include details of whether there is a precision bred confirmation in place in respect of an organism within the food or feed.

The Genetic Technology (Precision Breeding) Regulations 2025

40. The 2025 Regulations were made on 13 May 2025 and came into force on 13 November 2025. Regulation 3 makes provision for the notification requirements under section 4 of the 2023 Act (notification being necessary before a PBO may be released under section 3). Regulation 5 makes provision for a marketing notice (that being necessary to secure a precision bred confirmation, which in turn is necessary before a PBO may be marketed under section 5). The Regulations therefore provide a framework within which PBOs may lawfully be released and marketed. They do not impose any labelling

requirements: the Secretary of State did not exercise the power under section 26(2)(b) to impose requirements for the purpose of securing traceability. The claimants contend that the exercise of that power, whether by labelling or otherwise, would have addressed many of their concerns. Part of the claimants' case is that the Minister was wrongly briefed that there was no power under the 2023 Act to impose labelling requirements.

41. Part 7 of the 2025 Regulations makes provision in respect of food and feed produced from PBOs. Food or feed may not be placed on the market unless there is an authorisation issued by the Secretary of State and the conditions or limitations in the authorisation are met: regulation 19. An application for an authorisation must be referred to the Food Standards Agency, which must then make a report to the Secretary of State: regulations 20 - 28. The level of scrutiny applied by the Food Standards Agency depends on whether the applicant is able to demonstrate (among other matters) that the PBO belongs to a species that has a history of safe food use: regulation 20(1)(b) and regulation 22(1)(b).

42. The Secretary of State must then decide whether to issue an authorisation: regulation 30. That regulation states:

> "**30 Determination on authorisation by the Secretary of State**
>
> (1) Upon receipt of a report from the Food Standards Agency under regulation 21 or 28 the Secretary of State must decide whether to issue a food and feed marketing authorisation.
>
> (2) If the Secretary of State decides to issue a food and feed marketing authorisation, the Secretary of State must decide—
>
> (a) any conditions to which the authorisation must be subject;
>
> (b) any limitations to which the authorisation must be subject.
>
> (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.

(4) When considering whether the requirements in paragraph (3) are met, the Secretary of State must—

(a) have regard to any report which has been provided by the Food Standards Agency under regulation 21 or 28;

(b) 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.

(5) The Secretary of State must not issue a food and feed marketing authorisation if—

(a) the Secretary of State concludes from the assessment of the safety of the precision bred organism or having considered any other legitimate factors that a food and feed marketing authorisation cannot be issued;

(b) an application has been made under regulation 20 and the Secretary of State cannot reasonably conclude that the requirements of regulation 20(1) have been met.

(6) The Secretary of State must advise the Food Standards Agency of the decisions under paragraphs (1) and (2) (where applicable) as soon as reasonably practicable following receipt of the report from the Food Standards Agency.

(7) If the Secretary of State decides not to issue a food and feed marketing authorisation, the Secretary of State must give reasons for the decision to the Food Standards Agency."

43. Ground 4 of the claimants' claim is that regulation 30(4)(b) limits the tests that may be applied by the Secretary of State in a way that is not authorised by the 2023 Act.

44. Regulation 35 requires the Food Standards Agency to maintain a free electronic public register of all food and feed marketing authorisations. The register must contain the

name and unique reference number of each authorised PBO, the name and address of the authorisation-holder, any conditions or limitations of the authorisation, a summary of any risk assessment, and a link to the relevant entry in the register of confirmed PBOs.

45. Part 1 of Schedule 5 to the Regulations contains consequential amendments to assimilated direct legislation. Paragraphs 1 and 2 amend regulations 1829/2003 and 1830/2003 to exclude, in England, PBOs from their scope.

46. Paragraph 14 of Part 3 of Schedule 5 to the Regulations amends the Environmental Damage (Prevention and Remediation) (England) Regulations 2015 to exclude PBOs from the list of activities which cause environmental damage and which can give rise to liability under the 2015 Regulations.

The Habitats Directive and the Habitats Regulations

47. Article 6 of Council Directive 92/43/EEC ("the Habitats Directive") on the conservation of natural habitats and of wild fauna and flora states:

> "1. For special areas of conservation, Member States shall establish the necessary conservation measures involving, if need be, appropriate management plans specifically designed for the sites or integrated into other development plans, and appropriate statutory, administrative or contractual measures which correspond to the ecological requirements of the natural habitat types in Annex I and the species in Annex II present on the sites.
>
> 2. Member states shall take appropriate steps to avoid, in the special areas of conservation, the deterioration of natural habitats and the habitats of species as well as disturbance of the species for which the areas have been designated, in so far as such disturbance could be significant in relation to the objectives of this Directive.
>
> 3. Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives. In the light of the conclusions of the assessment of the implications for the site and subject to the provisions of paragraph 4, the competent national authorities shall agree to the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the general public."

48. Article 6(3) partly reflects (with slightly different language) one of the recitals of the Habitats Directive:

> "Whereas an appropriate assessment must be made of any plan or programme likely to have a significant effect on the conservation objectives of a site which has been designated or is designated in future".

49. The obligation under article 6(3) of the Habitats Directive was implemented in domestic law principally by regulation 63(1) of the Habitats Regulations. That states:

> "**63 Assessment of implications for European sites**
>
> (1) A competent authority, before deciding to undertake, or give any consent, permission or other authorisation for, a plan or project which—
>
> (a) is likely to have a significant effect on a European site… (either alone or in combination with other plans or projects), and
>
> (b) is not directly connected with or necessary to the management of that site,
>
> must make an appropriate assessment of the implications of the plan or project for that site in view of that site's conservation objectives."

50. The Secretary of State is a competent authority: regulation 7(1)(a). "European site" is an area in the United Kingdom that is designated for protection under certain specific provisions (and includes special areas of conservation): regulation 8. The Habitats Regulations are assimilated law: section 5 of the Retained EU Law (Revocation and Reform) Act 2023.

Organic certification

51. Assimilated Regulations 834/2007 and 889/2008 establish a legal framework for organic products which include the standards that are to be met by organic production. They were not amended by the 2023 Act or the 2025 Regulations. Recitals 9, 10 and 30 to regulation 834/2007 state:

> "9. Genetically modified organisms (GMOs) and products produced from or by GMOs are incompatible with the concept of organic production and consumers' perception of organic products. They should therefore not be used in organic farming or in the processing of organic products.
>
> 10. The aim is to have the lowest possible presence of GMOs in organic products. The existing labelling thresholds represent ceilings which are exclusively linked to the adventitious and technically unavoidable presence of GMOs.
>
> …
>
> 30. The use of GMOs in organic production is prohibited. For the sake of clarity and coherence, it should not be possible to

> label a product as organic where it has to be labelled as containing GMOs, consisting of GMOs or produced from GMOs."

52. Article 4(a)(iii) of regulation 834/2007 states that organic production must be based on principles that include adopting methods that exclude the use of GMOs and products produced from or by GMOs. Article 9(1) provides that GMOs and products produced from or by GMOs shall not be used as food or feed. Article 9(2) provides that operators may rely on product labels to ensure compliance with article 9(1).

53. Article 26(2)(a) and article 63(1)(c) of regulation 889/2008 impose obligations on organic operators to maintain precautionary measures to reduce the risk of contamination by unauthorised substances (so, including GMOs).

54. In the United Kingdom, the responsibility for certifying products as organic is delegated to accredited certification bodies, which include Soil Association Certification. That body publishes the standards that must be met by organic farmers and producers to obtain and retain organic certification. The standards reflect regulations 834/2007 and 889/2008. They state that a general principle of organic production is to exclude the use of GMOs and products produced from or by GMOs. None of the standards impose an absolute obligation to ensure that no GMO enters the producer's supply chain. They require practical measures to be taken. These include ensuring staff are adequately trained, that written procedures are in place, that adequate record keeping systems are in place, that organic products are separate and identified and that procedures are used to ensure that only permitted ingredients and inputs are used for organic production. Where a producer has been found not to comply with organic standards then a sanction may be imposed which is proportionate to the severity and extent of non-compliance. Producers are subject to an obligation proactively to report non-compliance, which includes where a producer has not been able to verify the organic status of goods that it has received.

55. The standards do not on their face require an absolute guarantee against any contamination. Rather, they require producers to identify any risks of contamination and to ensure that measures are in place to reduce that risk. That can include the risk of cross pollination or physical contamination from GM seeds and crops growing nearby.

56. The standards therefore distinguish between matters that are within a producer's control and those which are not. The former are subject to stringent obligations (for example, an absolute obligation not to purchase GM seed). The latter are subject to obligations that accommodate the producer's lack of complete control (for example, by requiring that measures are in place to reduce the risk of contamination, rather than imposing an absolute strict liability obligation to guarantee against any contamination).

Human Rights Act 1998

57. The Secretary of State is a public authority. It is unlawful for him to act (including by making regulations, or by deciding not to make regulations) in a way that is incompatible with Convention rights: section 6 of the Human Rights Act 1998. Article 8 of the Convention, and article 1 of the first protocol of the Convention, are each Convention rights: section 1(1)(a) and (b).

58. Article 8 is the right to respect for private and family life. By article 8(2), a public authority may not interfere with the exercise of that right save:

> "as is in accordance with the law and is necessary in a democratic society in the interests of… the economic well-being of the country, …or for the protection of the rights and freedoms of others."

59. Article 1 of the first protocol is the right to peaceful enjoyment of possessions. A public authority may not deprive any natural or legal person of their possessions:

> "except in the public interest and subject to the conditions provided for by law…"

60. This prohibition does not:

> "in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest…"

Factual and policy background

Assessment of risk posed by PBOs

61. The Explanatory Notes to the 2023 Act explain the policy background. Paragraph 1 states the Act is intended "to reduce the regulatory burden and financial barriers in place for researchers and commercial breeders using precision breeding technologies."

62. Paragraph 4 states that the regulatory regime for GMOs is over 30 years old and has not kept pace with scientific developments associated with PBOs. In September 2021, ACRE advised that the risk posed by an organism depends on its characteristics rather than how it is produced; a PBO (which, by definition, is an organism that could be the product of traditional breeding) does not pose any greater risk than a traditionally bred equivalent. Subsequently, the Advisory Committee on Novel Foods and Substances (which has responsibility for providing the Food Standards Agency with independent advice), reached the same conclusion.

63. Paragraph 5 of the Explanatory Notes says that other scientific groups also reached the same conclusion, specifically the Royal Society, the EU Commission's Scientific Advice Mechanism and the European Academies' Scientific Advisory Council. A public consultation did not produce any contrary scientific evidence. The claimants are critical of some aspects of ACRE's advice. They have not, however, adduced any expert scientific evidence to displace the general proposition that PBOs do not present any greater risk than traditionally bred organisms. Nor do they advance a free-standing challenge to that conclusion. Their principal complaint is directed to the design of the regulatory regime, including in respect of traceability, labelling, assessment and the practical consequences for organic and export supply chains.

64. The legislative response to the advice as to the risk of PBOs was the 2022 Amendment Regulations and the 2023 Act. The former permits the release into the environment of

qualifying higher plants; the latter exempts PBOs from the full regulatory regime that applies to (other) GMOs and applies a lighter-touch regime.

65. The Secretary of State's evidence is that other countries have adopted a similar approach, specifically Canada, the United States of America, Japan and Argentina. The European Union has not (yet) done so. In June 2024 the European Food Safety Authority said that PBOs could justifiably be treated as equivalent to conventional bred plants. However, the effect of the decision of the Court of Justice of the European Union in *Confédération paysanne and Others* case C-528/16 is that organisms produced by "New Genomic Techniques" ("NGTs") (which include PBOs) are not excluded from the regulatory regime imposed by the GMO Directive. The European Council requested the European Commission to submit a study and proposal in the light of that judgment. The resulting study concluded that the GMO Directive was not fit for the purpose of regulating NGTs, and that its requirements could be disproportionate or inadequate. It proposed a specific legal framework for plant NGTs, including that:

> "NGT plants that could also occur naturally or be produced by conventional breeding techniques and their progeny obtained by conventional breeding techniques… should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable, thereby derogating in full from the Union GMO legislation and GMO related requirements in sectoral legislation."

66. Ms Bailey anticipated that the European Parliament would consider this proposal in May 2026. That had not happened by the time of the hearing. I was told that it remained the Government's anticipation that this would happen over the coming weeks or months.

Decision to make the 2025 Regulations

67. Regulations were not made under section 26 at the time the 2023 Act came into force in March 2023. There followed a period of public consultation with stakeholders, including the organic sector and Beyond GM.

68. In addition to public consultation, both Defra and the Food Standards Agency undertook additional stakeholder engagement. There were nine workshops with stakeholders, including representatives of the organic sector, between 2022 and 2024. There were also round table discussions, public polling, and consumer research.

69. A new Government was formed on 5 July 2024. By this point, officials had prepared a draft statutory instrument "subject to final changes and checks." It had been shared with the Devolved Governments.

70. On 10 July 2024, Beyond GM wrote to the Minister of State for Food Security and Rural Affairs and said that although draft regulations had been prepared, the Minister should consider pausing their introduction. That was so that they could be revised to include (among other things) provisions for the mandatory labelling of all PBO food.

71. On 26 July 2024, a consortium of over 50 organisations wrote to the Secretary of State and said that the lack of visibility in the food system disempowered consumers and that there were opportunities for regulatory changes in respect of food labelling. It called for mandatory labelling of PBOs as a matter of urgency and pointed to research which showed that consumers wanted clear labelling of gene-edited products.

72. On 9 August 2024, a submission on "Regulatory Reform: A New Framework for Precision Breeding" was sent by Defra officials to the Secretary of State and the Minister. A section of the document was headed "key issues". The first key issue was "Provision of information":

> "We understand Ministers are interested in how we could go further on providing information about precision bred organisms. Within the Act, there are requirements to establish public registers to ensure information is available to the public. The previous Government and the FSA Board concluded that existing requirements for labelling and traceability under General Food Law and Food Information to Consumers regulations, were sufficient for the purposes of food safety. As such, powers to impose labelling requirements were not included in the Act.
>
> Industry across the supply chain have signalled that food labelling would deter investment, raise costs to consumers and result in a disadvantage internationally with many countries, including the EU, not proposing food labelling. Whilst we have not been considering food labelling, we are exploring ways to improve the provision of information on precision bred plant varieties and seeds." [Underlining added]

73. At a meeting on 20 August 2024 the Minister said that he thought "labelling is difficult".

74. A further submission dated 5 September 2024 referred to the potential for regulatory change in the European Union. It anticipated that this would take several years and would inhibit innovation in Europe:

> "We have an opportunity to create a competitive advantage for UK science and small businesses, drawing investment, expertise and innovation into the UK. As such, we recommend proceeding with the SI programme to implement the Act in the shorter term, putting UK science and industry on the front foot whilst the EU is developing their regulatory proposal.
>
> As the principles of the EU's NGT proposal are aligned, we can remain open to any potential dynamic alignment agreement with the EU in the longer-term, noting the opportunity to influence the EU's position on NGTs. There is also the potential to derogate from alignment in specific areas, should it be judged in the UK's and Devolved Governments interest (noting potential impacts on trade barriers for related products). EUIT (EU and

> International Trade) will provide advice on SPS alignment and the EU-UK re-set."

75. On 9 September 2024, it was recorded that the Minister agreed with the recommendation to proceed with the statutory instrument with the intention of laying it before Parliament towards the end of the year, so that, subject to Parliamentary time, it could come into force "mid-end 2025."

76. On 30 September 2024, the Secretary of State announced that secondary legislation would be presented to Parliament when Parliamentary time allowed.

77. On 16 October 2024, the Soil Association, Beyond GM, and others wrote to the Minister and said it was vital that the regulations ensured "transparency within the supply chain, with clear labelling, to reassure and protect consumer choice, secure the organic and GMO-Free sector and to protect regional and international trade."

78. On 29 October 2024, the Minister met Ms Thomas to discuss Beyond GM's concerns about the proposed regulations. A briefing from officials in advance of the meeting addressed the question of labelling:

> "The independent scientific advice is that precision bred plants and animals pose no greater risk than traditionally bred counterparts. Products of precision breeding will only contain genetic changes that could also occur through traditional breeding.
>
> We are committed to delivering informative food labelling and promoting robust food standards, to ensure that consumers can have confidence in the food that they buy.
>
> If pressed:
>
> The Precision Breeding Act did not include powers to mandate labelling of precision bred organisms or their food and feed. The statutory instrument we are presenting to Parliament will not include provisions for labelling of any precision bred plant or derived food and feed.
>
> We are reviewing options for providing information to consumers about plant breeding techniques. These options include voluntary industry standards and mandatory labelling."

79. It also addressed "Organics":

> "We do not expect the organic sector to be damaged by these regulations. There are established methods for enabling different supply chains to coexist in agriculture. We will continue to work with organic stakeholders to understand potential impacts to their businesses after legislation is in force."

80. On 31 October 2024, the Minister met with officials. The topic of "precision breeding and labelling" was discussed. A readout of the discussion is contained in an email from

the Minister's private secretary the following day (DZ is the Minister; JT, EM and OW are officials):

> "Precision breeding and labelling (JT)
>
> DZ opened by clarifying his familiarity with the issue. In opposition, he asked for more transparency.
>
> JT explained that currently, we don't require mandatory labelling because of the associated costs of separating associated supply channels. It would increase the cost and therefore the burden on breeders and manufacturers who won't take R&D projects forward due to cost. They have said this themselves.
>
> JT: We have looked at concerns of traceability through supply chain. One concern raised by organic organisations and devolved governments is that we can't have traceability through supply chain if seeds not labelled. Mandatory seed labelling would be relatively low-cost to manufacturers and wouldn't prohibit them from adding precision-bred products to market.
>
> DZ: There are strong arguments on both sides. Needing labelling due to testing limitations is a good argument. Consumer right to know is also a good argument and the public have an increasing appetite for information about their food. DZ sees merits to both sides and thinks that this issue needs to sit in the wider labelling debate. DZ highlighted the difficulties with devolved governments too and asked for their opinion.
>
> JT shared that there was a discussion last week and there has been a softening of their stance. Mandatory seed labelling would go a long way to meeting their requirements. They are concerned farmers could buy non-labelled seeds and inadvertently break the law.
>
> DZ asked if seed labelling would help the organic sector.
>
> JT confirmed that they think it would as do the organics team. She highlighted a possible requirement in future to change organic labelling as has been in the EU to allow for a small amount of PBO.
>
> DZ asked if we should push ahead with mandatory seed labelling.
>
> EM made the point that the SPS-agreement would have a large impact on this policy.
>
> She also asked to clarify the aim of a labelling policy. It's a good way to bring devolved governments with us, but do we

> have the capacity/resource to enforce this? An unenforced system may at least lead to increased traceability.
>
> DZ asked the for the difference between seeds available to public and seeds to available to growers.
>
> OW clarified that there are separate regulations for amateur vegetable growers and professional and that the regulations only cover certain varieties of vegetables (although most species in agricultural sector are covered).
>
> DZ asked for Actions/Decisions to be clarified.
>
> JT laid out the need for clarification around the mandatory seed-labelling choreography:
>
> > PBS are launching a consultation in November (that will last for 8 weeks).
> >
> > Then will be the response to consultation.
>
> DZ asked for the down sides of this policy. JT clarified that there aren't many but that it doesn't solve the whole problem.
>
> DZ asked if this could be done within the existing act?
>
> JT clarified that it could be done under new SI to be laid in June and asked if we bring forward all legislation or wait until response to consultation when we can commit to mandatory seed labelling.
>
> DZ gave the steer to press on.
>
> JT agreed to share proposals for working group."

81. A Departmental paper dated 1 November 2024 states "powers for labelling were not included in the Act" and therefore "labelling requirements will not be included in the secondary legislation."

82. On 25 November 2024, the Minister responded to concerns expressed by the Soil Association in respect of organic supply chains. He said:

> "Based on the scientific advice on risk, mandatory labelling focused on breeding technology was not considered to be appropriate for inclusion in the Precision Breeding Act. As such, there are no provisions in the Act to introduce mandatory labelling for precision bred foods. However, the forthcoming legislation will provide detailed requirements for public registers for information about precision bred plants and any approvals for use in food and feed."

83. On 5 December 2024, a further submission was put before the Minister. It referred to the discussion on 31 October 2024, the Minister's decision that the labelling of PBO food and feed would be considered within future work and the agreement of officials to provide further advice on the labelling of seed and other plant reproductive material. It recommended a consultation to collect evidence on mandatory seed labelling.

84. On 6 January 2025, the All-Party Parliamentary Group on Science and Technology in Agriculture wrote to the Minister and urged him to make the regulations, saying that there were prospective investors and innovators who were waiting for the regime to be put in place.

85. On 15 January 2025, a "De Minimis Assessment" in respect of the effect of the proposed Regulations was completed. This assessed that the Regulations would produce a net benefit to business (largely because of the reduced regulatory burden) of £8.26m per year. However, there was an assessed increased cost to the organic sector of £266,000 per year from 2033 (and this would increase thereafter). This cost arises because the organic sector would be required to check that the material they sourced did not include PBOs. There was considerable uncertainty as to precisely how this would be done, and thus as to the estimated financial impact on the organic sector. Thus, it was recognised that there would be a burden on the organic sector and there was uncertainty as to how the organic sector would exclude PBOs from their supply and food chains:

> "…stakeholders have acknowledged that existing mechanisms can enable segregation [of PBO crops from organic crops], but they have not reached a consensus on the details of these measures. This is exacerbated by uncertainty around what will be expected of organic producers to demonstrate how they have avoided Precision Bred crops. Therefore, it will be hard to establish quantitative costs at this stage.
>
> Nonetheless, despite this uncertainty, an attempt was made in the economic analysis to take account of potential impacts and the possible consequential cost implications that some organic producers might encounter. Organic farmers may adopt measures to minimise the likelihood of crops they are cultivating from mixing with Precision Bred material. These are likely to be based on measures used to maintain the separation of other agricultural supply chains, including those that maintain the purity of seed sold to farmers and enable organic production to coexist with non-organic production.
>
> As the future plans that might be applied in this respect are still emerging and are subject to ongoing discussions, it is difficult at this stage to determine either the exact level of the consequential costs or when they might be necessary. For example, only crops of the same or similar species would be affected by cross-pollination, and it is unlikely that there will be significant levels of production in arable crops during the assessment time period. However, to take account of the probable expense of putting in place counter measures, the costs associated with potential

> proxies to adopting protective buffers were provisionally assessed. The resultant estimates are recognised as being provisional, but they give a broad indication of approximate liabilities that some organic producers may experience depending on their circumstances."

86. On 7 February 2025, the Minister received an "advance pack" for the purpose of deciding whether to make the regulations. The "final pack" was provided on 19 February 2025. The pack included the De Minimis Assessment.

87. On 21 February 2025, the Minister, acting on behalf of the Secretary of State, confirmed that he was happy to proceed to make the regulations. This was therefore the decision to make the 2025 Regulations. They were laid before Parliament on 25 February 2025. Thereafter, they were approved by Parliament and were made on 13 May 2025. They came into force on 13 November 2025.

Plant Varieties and Seeds framework, and developments in the European Union framework

88. Agricultural and vegetable seed may not be marketed in England (or elsewhere in the United Kingdom) unless it is included in the statutory lists (see paragraph 22 above). Those lists (there are separate lists for Great Britain and Northern Ireland) are published in the Plant Varieties and Seeds Gazette.

89. Defra intends to update this regime to cater for PBOs. A consultation took place between 17 February 2025 and 14 April 2025 (so before the 2025 Regulations were made, but largely after the Minister had decided to make the 2025 Regulations). The consultation included:

    (1) A proposal for the introduction of a new, England-only, variety list which could include PBOs and would include information as to whether a seed on the list was a PBO. It was proposed that the organic sector could exclude PBOs by using this information, in conjunction with seed labels and the statutory register, when deciding what seed to purchase.

    (2) Seeking feedback on the potential impact of mandatory labelling for PBO seed.

90. Following that consultation, the Minister decided to mandate labelling of PB status for seeds, but subject to a proposed new "Sanitary and Phytosanitary" agreement with the European Union. That proposed agreement is intended to provide dynamic alignment between the regulatory regimes in England and the European Union. It seems likely that the prospects of an effective agreement of this nature may depend on whether the European Union adopts the proposal of the European Commission for a lighter touch regulatory regime in respect of NGTs/PBOs.

91. On the evidence, it appears likely that any such changes would be directed principally to seed labelling rather than to the labelling of resulting plants, or the produce of animals that have been fed PBOs.

Submissions

92. David Wolfe KC, for the claimants, submits that the 2025 Regulations permit PBOs to be released and to enter the food/supply chain in England without labelling and without an assessment of key impacts, thereby threatening the organic sector, consumer confidence, and environmental protection. He says that the Minister was materially and repeatedly misadvised about the scope of his powers to introduce mandatory labelling. The decision to make the 2025 Regulations was flawed under each of the 4 grounds advanced by the claimants, and they should be quashed. He submits that the claim was brought in time, and points to the successive requests for extensions of time that have been sought by the Secretary of State.

93. Charles Streeten, for the Secretary of State, submits that the claim form was not filed promptly and the claim is therefore out of time. He says that the organic sector can still maintain their organic status, and that there is still scope for mandatory labelling of seeds under powers conferred by the 1964 Act. He accepts that the Minister was wrongly advised about the scope of his powers, but contends that this error was later corrected, as is shown by the record of the discussion on 31 October 2024 (see paragraph 80 above). He submits that the court should be especially slow to second-guess the Minister's decision, because that involved predictive scientific and environmental risk assessment and economic policy. He also submits that the claim is (in substance) an "*ab ante*" challenge to legislation, rather than to the application of the legislation to the facts of an individual case. He says that this means that the claimants can only succeed if they can show that the legislation cannot be operated in a way that is compatible with Convention rights.

Ground 1: Human Rights

94. James Robottom, who argued this ground on behalf of the claimants, submits that the decision to make the 2025 Regulations was incompatible with article 8 and article 1 of the first protocol of the Convention. That is because they threaten the ability of organic businesses to retain organic certification. The absence of mandatory labelling means such businesses cannot determine whether products contain PBOs, jeopardising their ability to maintain PBO-free supply chains. The decision was not in accordance with the law because the Minister was misled as to his powers. It cannot be justified as proportionate because a less intrusive measure (that is, a requirement for labelling) could have been adopted.

95. Mr Streeten submits that the claimants have not shown that they are "victims" within the meaning of the 1998 Act and have not shown that there has been any interference with their Convention rights. He says that article 8 does not confer a right to pursue an occupation as an organic business and article 1 of the first protocol does not protect a business' future profitability. In any event, the 2025 Regulations will not prevent organic businesses from continuing to operate. If there is an interference with Convention rights, then the Regulations are justified as being in accordance with the law and pursuing legitimate aims and striking a proportionate fair balance.

Ground 2: Irrationality

96. Mr Wolfe submits that the Minister acted irrationally because he failed to consider key matters, including the likely impact on organic supply chains and on trade (including

exports to the European Union and the devolved jurisdictions in the United Kingdom, whether organic or not). The Minister ought to have made enquiries into measures to require labelling and traceability, but no such enquiries were undertaken because of the error as to the scope of the Minister's powers.

97. Mr Streeten responds that it is not for the court to substitute its view for that of the Minister. The court should only intervene if no reasonable decision-maker could have been sufficiently satisfied with the extent of the enquiries that had been undertaken. There had been extensive consultation. The various issues (including the impact on organic businesses and consumers) were all addressed in the De Minimis Assessment. The Minister was entitled to be satisfied that sufficient information had been obtained, and to make the 2025 Regulations.

Ground 3: Habitats Regulations

98. Mr Wolfe submits that the 2025 Regulations amount to a "plan or project" within the meaning of the Habitats Regulations, and there was a failure to conduct the environmental assessment that is required by those Regulations. Because PBOs are untraceable once they have been released, there is no later point at which an effective assessment can be conducted.

99. The defendant submits the 2025 Regulations are not a "plan or project" for the purposes of the Habitats Regulations. They do not have any link or nexus with any particular European site. They lack the precision necessary to qualify as a plan or project because future authorisations for the release/marketing of PBOs, and the locations in which they will take effect, are unknown. Further, there is no evidence that the integrity of any European site could conceivably be affected by plant PBOs: the evidence is that they do not give rise to any greater risk than traditionally bred organisms.

Ground 4: Regulation 30(4)(b) outside scope of power to make regulations

100. Mr Wolfe submits that the purpose of the Act was to secure the protection of human and animal health, and the environment, from risks associated with PBOs. Regulation 30(4)(b) of the 2025 Regulations falls outside the scope of the power to make regulations that is conferred by the 2023 Act because it limits the assessment and testing that may be conducted. Specifically, it prevents the Secretary of State from applying any test not otherwise applicable to traditionally bred organisms, thereby preventing testing to determine the safety or even the presence of a PBO during the authorisation process.

101. Mr Streeten contends that the 2025 Regulations are well within the ambit of the broad statutory power to create regulations in the 2023 Act. Regulation 30(4)(b) is consistent with the fact that PBOs are organisms that could be created by traditional techniques and the scientific evidence that they do not carry any greater risk.

Is the claim in time?

102. A claim form for judicial review must be filed promptly and, in any event, not later than 3 months after the grounds to make the claim first arose: CPR 54.5(1). The grounds to make the claim first arose when the Regulations were made on 13 May 2025 (it is not suggested that they arose at the earlier point when the Minister decided to make the

regulations). The claim form was filed on 12 August 2025. The claim form was therefore filed (just) within three months.

103. The time-period required by "promptly" depends on the context. It is highly fact sensitive. Part of the relevant context is that this was a challenge to legislation that impacted on third parties. Ms Foster describes the impact on Research Institutes, the Government funding of innovation, and Small and Medium-Sized Enterprises that market PBOs in England. A putative claimant is under a particular obligation to act timeously where delay is likely to impact on third parties, the more so where, as here, the proceedings are said to have been brought in the public interest: *R v Secretary of State for Trade and Industry ex parte Greenpeace Limited* [1998] Env LR 415 *per* Laws J at 424 - 425.

104. It is also relevant that the claimants knew, from the time the Act received Royal Assent on 23 March 2023, that it was likely that regulations would be made. The claimants closely followed the process leading to the 2025 Regulations. Beyond GM lobbied the Minister. The Secretary of State decided to make the regulations on 21 February 2025, almost 3 months before they were made. They were laid before Parliament on 25 February 2025, accompanied by a draft explanatory memorandum. The Secondary Legislation Scrutiny Committee published its report on the draft regulations on 20 March 2025. A revised version of the explanatory memorandum was published on 26 March 2025. It follows that the claimants did not proceed from a standing start on 13 May 2025 when the 2025 Regulations were made. That was the culmination of a 2-year process. This is all relevant to the question of whether the claimants acted "promptly".

105. As against that, the challenge that has been advanced is complex. Ground 2 is dependent on aspects of the decision-making process which were not in the public domain. The claimants complied with the pre-action protocol. That does not relieve the claimants of their obligation to file their claim promptly: *Finn-Kelcey v Milton Keynes Borough Council* [2008] EWCA Civ 1067; [2009] Env LR 17 *per* Keene J at [27], *R (British Gas Trading Ltd v Energy Security Secretary* [2025] EWCA Civ 209; [2025] 1 WLR 3342 *per* Zacaroli LJ at [38]. However, the pre-action conduct of the parties is part of the context which informs the assessment of whether the claimants acted promptly. The letter of claim was sent on 16 June 2025, just over a month after the regulations had been made. It was a highly detailed letter, running to almost 50 pages. It sought information and documents, at least some of which was important to the potential formulation of a claim, particularly in relation to ground 2. It asked the Secretary of State to reply within 14 days, so by 30 June 2025. The Secretary of State acknowledged the protocol letter on 27 June 2025 and said that further time was required to provide a response. No complaint was made about delay. There was no suggestion that the claimants were not acting promptly, or that any claim should now be brought urgently. On the contrary, the response said, "we trust that you will not seek to issue any claim until our client has had the opportunity to consider and respond to your pre-action protocol letter." It indicated that if the claimants did issue a claim before receiving the Secretary of State's pre-action response, then it would "bring this correspondence to the attention of the Court with respect to costs."

106. The Secretary of State's pre-action protocol response was sent on 21 July 2025. It ran to 22 pages. Documentation was provided with the letter. Nothing in the letter suggested that the claimants had not acted promptly, or that any claim for judicial review should

now be issued immediately. The claim was filed 3 weeks after the pre-action protocol response, and within the 3-month backstop.

107. The Secretary of State did not ask for the claim to be expedited. He filed the Summary Grounds of Resistance 14 days after the date on which they were due (and applied for an extension of time). On two occasions, the Secretary of State sought extensions of time to comply with the court's directions.

108. There is no specific evidence of any prejudice to anybody occasioned by the time taken to issue the claim form, and, particularly, the 3-week period after the pre-action response. The 2025 Regulations had not come into force at the time the claim form was filed. They did not do so until 3 months later. On analysis, the impact on third parties explained by Ms Foster relates to the delay in the 2025 Regulations coming into force rather than any delay in issuing these proceedings. These proceedings did not cause any delay to the 2025 Regulations coming into force. They came into force, in accordance with regulation 1(1), on 13 November 2025, six months after the date on which they were made.

109. In all the circumstances, but particularly in the light of the complexity of the case, the time taken to respond to the pre-action protocol, and the Secretary of State's general approach, it has not been shown that the claimants failed to act promptly. Even if that had been shown, the underlying claim raises issues that are of real importance to the whole organic sector; if necessary, I would grant an extension of time. That does not mean that the impact of these proceedings on third parties is left out of account. If the claim is otherwise well-founded then any prejudice to third parties, or detriment to good administration, may be considered when deciding what, if any, remedy to grant to the claimants.

The impact of the 2025 Regulations on the organic industry

110. The grounds of claim are formulated by reference to public law errors that the claimants allege the Secretary of State made. Put at its highest, the claimants' underlying complaint is that the 2025 Regulations make it practically impossible (or at the very least, much more difficult) for:

(1) the organic sector to prevent PBOs from entering their supply chains and hence to maintain their organic certification,

(2) consumers to exercise a free autonomous choice not to eat food that contains, or results from, the use of PBOs.

111. There are two features of the 2025 Regulations that fall to be considered for these purposes.

112. The first is the provision for the release of PBOs otherwise than by marketing, for example in field trials. That gives rise to a risk of contamination and cross-pollination. This is not a new issue. The 2022 Regulations permit the release of qualifying higher plants, which are themselves PBOs: see paragraph 26 above. That likewise gives rise to a risk of contamination and cross-pollination. Accordingly, the organic sector already had to deal with this challenge before the 2025 Regulations were made (albeit the scale of the problem is now greater). Moreover, the certification standards do not require

organic businesses to guarantee that no PBOs enter their products by way of contamination or cross-pollination. What is required is that reasonable steps are taken to mitigate the risk. These might include crop selection (so not using the same crop as a neighbouring non-organic field, thus reducing the risk of cross-contamination), or buffer planting (so maintaining a buffer strip at the edge of a field to reduce the risk of cross-contamination), or isolation distances, or physical barriers, or altering crop rotations, or staggered planting (so that the flowering periods of crops in adjacent fields do not overlap).

113. The second is the provision for marketing PBOs without any corresponding mandatory labelling requirement. This does make a material difference. Before the 2025 Regulations were introduced, any consumer or organic business purchasing food or feed could determine from the product label whether it contained a GMO (including a PBO). Now, for products purchased in England, that is not possible unless the supplier has decided voluntarily to provide the information on the label. It might be expected that the organic sector will choose to do so. Where the label is silent, a purchaser will have to make other enquiries to determine whether the product contains PBOs. The statutory public registers may assist with these enquiries: see paragraphs 34 and 43 above. Ms Bailey explains how those registers operate in practice:

> "Information relating to the release and marketing of precision bred organisms is publicly available on the GOV.UK website. The Department has a statutory duty to keep, update and maintain the precision breeding register.
>
> The register contains information relating to the environmental release of PBOs including a general description of the organism, intended use, the altered characteristics of the organism, identification of any unintended genetic changes, the technology used and ACRE reports. The register is publicly accessible and currently available.
>
> The FSA have also developed a public register for food and feed marketing authorisations. The information published is outlined in Section 35 of the 2025 Regulations..."

114. Accordingly, anybody can quickly and easily find out some information about the release and marketing of PBOs. This does not provide a complete answer to the concerns expressed by the claimants. That is because information about the release and marketing of PBOs will not necessarily inform a putative purchaser whether a particular product contains a PBO. It has not been shown that the information on a product's label is sufficiently detailed to enable reliable cross-reference to the statutory registers and thereby determine whether the product contains a PBO. Moreover, it does not assist at all with the question of whether PBOs have been used at an intermediate point in a food chain: for example, where feed derived from a PBO has been supplied to dairy cattle. Of course, a business or consumer could ask a supplier whether their product contains a PBO, and whether PBOs have been used in the food chain, but that is altogether more time-consuming and (from the point of view of the business or consumer) less satisfactory than simply being able to verify the position from the product's label.

115. The stakeholder dialogue that was conducted on behalf of Defra shows that there was concern within the organic sector about the steps that would need to be taken to avoid PBOs, and "the exact level of the consequential costs or when they might be necessary." However, there was no suggestion that it would be impossible to avoid PBOs; the issue was about the best mechanism for doing so.

116. Ms Hathway is critical of the process adopted for the stakeholder dialogue. She does not, however, suggest that it is impracticable for the organic sector to avoid purchasing PBO feed or food or to take reasonable steps to avoid PBO contamination. She does not go so far as to say that organic businesses will be unable to maintain certification, but her evidence does support the conclusion that the burden of doing so will become materially more difficult and more expensive.

117. It follows that the claimants have not shown that it is impracticable for the organic sector to maintain their organic certification. They have, however, shown that it will be significantly more difficult. It will also be more difficult for consumers: to avoid PBOs they will have to purchase food that is certified as organic, or else rely on voluntary labelling of products that do not contain PBOs. The position of non-organic farmers and food producers who wish to export to the European Union is analogous, though not identical: they too may face materially increased difficulty in demonstrating the absence of PBOs in products destined for markets that regulate such organisms as GMOs.

Did the Minister misunderstand his legal powers?

118. The claimants do not, in their Grounds of Claim, advance, as a separate ground of challenge, that the Minister made an error of law. However, as part of ground 2, the claimants say that the Minister was wrongly told that the 2023 Act did not enable him to introduce mandatory labelling, and this affected the enquiries (or lack of enquiries) that were made as to the benefits and detriments of labelling. It is convenient to address separately the question of whether the Minister correctly understood that he had a power under the 2023 Act to introduce mandatory labelling.

119. Nothing in the 2023 Act explicitly authorises, in terms, the Minister to introduce mandatory labelling of food and feed products that contain PBOs. However, section 26(1) and 26(2)(b) give the Minister the power to make regulations for the purpose of securing the traceability of food or feed produced from PBOs that is placed on the market in England. It is common ground that compulsory labelling of such food or feed would assist to secure its traceability. It is therefore also common ground that the 2023 Act gave the Minister a power to introduce mandatory labelling. The Minister did not exercise this power. If the reason was because he believed that he did not have the power to do so, then that was a public law error.

120. The claimants rely on:

(1) The Ministerial submission of 9 August 2024 which states powers to impose labelling requirements were not included in the Act (see paragraph 71 above).

(2) The briefing for the meeting with Ms Thomas on 29 October 2024 which said the Act "did not include powers to mandate labelling of precision bred organisms or their food and feed", as well as saying that it was not expected that the organic sector would be damaged by the Regulations (see paragraph 77 above).

(3) The paper of 1 November 2024 which said, "powers for labelling were not included in the Act" (see paragraph 80 above).

(4) The Minister's letter of 25 November 2024 which said, "there are no provisions in the Act to introduce mandatory labelling for precision bred foods" (see paragraph 81 above).

121. The last of these is, arguably and on one reading, strictly accurate: nothing in the Act introduces mandatory labelling (as opposed to providing a power to do so). The Secretary of State concedes, however, that the earlier briefing did wrongly state the law.

122. It follows that the Minister was given incorrect information as to his powers under the 2023 Act. That is not, by itself, enough to establish that the Minister acted on the basis of an erroneous understanding of the law. That would depend on whether the Minister, notwithstanding the briefing, correctly understood the law or, if he did not, whether that misunderstanding was material to his decision-making process.

123. It would have been open to the Secretary of State to file evidence on this issue. He chose not to do so. The Minister has not made a statement. Neither Ms Foster nor Ms Bailey address the issue in their witness statements.

124. Mr Streeten submits that the record of the meeting on 31 October 2024 (see paragraph 80 above) shows that notwithstanding the misleading briefing, the Minister correctly understood the law. I do not have a witness statement from anyone who was at the meeting. Nor do I have a transcript or a detailed note of the meeting. All that is available is the "readout" from the meeting.

125. According to that readout, the meeting concerned three topics, one of which was "[p]recision breeding and labelling." That in itself might indicate that there was a power to require labelling. It does not, however, indicate that there was power under the 2023 Act to do so. It is equally consistent with the power to require labelling (albeit only in respect of seeds) under section 16(1)(a) of the 1964 Act.

126. The Minister opened the topic by saying he was familiar with the issue and that in opposition (when he had been the shadow minister) he had asked for more transparency. That indicates that the Minister had some background knowledge about the issue and that he understood the merits of a labelling requirement, but it does not show that he was aware that the 2023 Act provided a power to impose mandatory labelling.

127. An official said that mandatory labelling would increase costs and thus the burden on breeders and manufacturers, who would not therefore embark on research and development projects. She also identified the concern raised by organic organisations that without labelling it would not be possible to ensure traceability through the supply chain. The Minister responded that there were good arguments on both sides. He referred to the need for labelling due to testing limitations, and also the importance of the consumer's right to know, and the "public's increasing appetite for information about their food." Again, that indicates that the Minister understood the benefits of labelling but does not show that he appreciated that there was power under the 2023 Act to introduce mandatory labelling.

128. The Minister then asked for advice as to whether to "push ahead with mandatory seed labelling". That implies that he may well have had in mind the power to require labelling under section 16(1)(a) of the 1964 Act (which applies only to seeds) rather than under section 26(2)(b) of the 2023 Act (which applies to PBOs generally).

129. The Minister also asked whether "that" could be done within the existing Act. Read in context, the "that" appears to be a reference to mandatory seed labelling (rather than mandatory labelling of all PBOs). The Minister was told that it could be done, but the record of the meeting does not show that the Minister was told that it could be done under the 2023 Act rather than the 1964 Act, and that labelling could be required for all PBOs that are placed on the market, not just seeds.

130. The Minister was told that the options were either to wait for the response to a consultation after which it would be possible to commit to mandatory seed labelling, or alternatively to press on with the draft Regulations (which did not require mandatory labelling). The Minister decided that they should "press on."

131. The short readout of the meeting has 8 references to seed labelling (in other words, labelling that can be imposed under the 1964 Act). That accounts for the majority of the references to labelling. There is no explicit reference to labelling of PBOs that are not seeds. To the extent that there are other references to labelling without explicit limitation to "seed labelling", those references are at least capable of being read as references to seed labelling.

132. Accordingly, the readout of the meeting is insufficient to show that notwithstanding the incorrect advice to the Minister as to his powers, he correctly understood that he could make regulations that would require mandatory labelling of all PBOs that are placed on the market. Nor is there, anywhere in the papers, any explicit correction of the erroneous advice that the Minister was given. If officials had realised the error, then it could be expected that they would have corrected the error and that there would be a record of that. Similarly, if the Minister had realised that the advice he was being given was wrong, then it is likely that there would be an indication of that in the documents.

133. Further, although the letter of 25 November 2024 is, on a generous view, consistent with the legal position, it is unlikely that it would have been written in this way if the Minister had correctly understood that he had the power under the 2023 Act to mandate labelling for PBOs.

134. On the totality of the evidence, therefore, the claimants have established that the Minister proceeded on the (erroneous) basis that he lacked powers under the 2023 Act to require mandatory labelling of all PBOs placed on the market.

Ground 1: Compatibility with Convention rights

135. This ground is pursued by Mr Wookey and Mr Holden, respectively an organic farmer and an organic food producer. They say that by deregulating PBOs and not introducing safeguards for the organic sector (such as mandatory labelling), the 2025 Regulations pose a real and genuine threat to their professional status. By making the 2025 Regulations, the Secretary of State acted incompatibly with Convention rights, and therefore unlawfully: section 6(1) of the 1998 Act. They are entitled to rely on

Convention rights, but only if they are (or would be) a victim of the decision to make the 2025 Regulations: section 7(1)(b) of the 1998 Act.

136. Mr Wookey and Mr Holden are directly affected by the 2025 Regulations. The absence of a mandatory labelling requirement makes it more difficult for them to maintain organic certification. The critical issue is whether that amounts to an interference with their Convention rights. They rely on article 8 and article 1 of the first protocol.

Article 8

137. Article 8 protects the right to respect for private life. It does not directly give rise to a right to work in any particular profession: *Thilimmenos v Greece* (2001) 31 EHRR 15 at [46]. However, there are circumstances in which measures which impact on a person's professional life may interfere with the right to respect for private life so as to engage the protection of article 8. That can be because the underlying reason for the impugned measure concerns the person's private life (for example, a disciplinary measure based on personal beliefs or lifestyle). It can also be because the measure has consequences for private life (for example, because it impacts on personal relationships). In the latter type of case, article 8 rights are only engaged where the consequences are "very serious" and affect private life to "a very significant degree". This "threshold of severity" has "critical importance", and it is for the applicant to show convincingly that the threshold is attained in their case: *Denisov v Ukraine* application 76639/11, judgment 25 September 2018 at [115] – [116].

138. The boundaries are illustrated by two cases that fall either side of the line, *Denisov* and *Platini v Switzerland* application 626/18, judgment 11 February 2020:

(1) In *Denisov*, the applicant was a judge who had been dismissed from his position as President of a court (but not from his role as a judge) for failing to perform his administrative duties properly. He said that his career, reputation and social and professional relationships had been irreparably damaged, and this amounted to an interference with his article 8 rights. The court found that the private life consequences of the dismissal did not meet the minimum threshold of severity to engage article 8 protection. The reduction in the judge's pay and pension did not materially impact his family life, he remained a judge at the same court, so relationship impacts were not substantial, and any reputational harm did not reach the required threshold (his judicial competence was not criticised, only his managerial skills).

(2) In *Platini v Switzerland* application 626/18, judgment 11 February 2020, the applicant (the world-renowned French footballer) was banned from any football-related activity for 6 years. The impact on his private life met the minimum threshold of severity needed to engage article 8. That was because the ban had very serious consequences for his private life: it prevented him from earning a living in football, which had been his sole profession and source of income, and the breadth of the ban affected his ability to maintain and develop social relationships. The sanction also carried a likely stigmatising reputational impact, given his public identification with football.

139. The status of the second and third claimants as an organic farmer and organic producer is, on their unchallenged evidence, important to them and is a part of their sense of self

and identity and a part of their personal reputation. That evidence also shows that it is the organic nature of their work that is important to them. If they lost their organic certification they would lose an important part of their personal identity, character and reputation. The fact that they would be able to continue as a (non-organic) farmer or producer is nothing to the point. I therefore accept that their retention of organic certification is relevant to their private lives. The question, however, is whether the consequences of the 2025 Regulations are sufficiently severe to amount to an interference with article 8.

140. The 2025 Regulations do not stop Mr Wookey or Mr Holden from continuing to operate in the organic sector. They do not impact on their reputations or character. They do not impact on their ability to maintain and develop professional and personal relationships with others who operate in the sector. The 2025 Regulations increase the burden on them to maintain their organic certification. Maintaining organic certification will require additional work, additional complexity and additional cost, and will result in reduced profits. This does not, however, come close to the minimum level of severity of impact on private life that is necessary to engage article 8.

141. In *R (Independent Workers' Union GB) v Mayor of London* [2019] EWHC 1997 (Admin); [2019] 4 WLR 118 the claimants (including two taxi drivers) challenged a decision that taxis would no longer be exempt from the London congestion charge. Lewis J held, at [92], that the fact that drivers would either lose income or else would have to work different or longer hours, or both, did not engage the protection of article 8. He said:

> "As with many legislative changes to a regulatory scheme, those affected by the changes may well have to adapt their behaviour in response to the changes. The fact that a person may have to work different or longer hours, or both, in order to earn enough to pay increased overheads because of a change in the regulatory scheme would not normally give rise to an interference with private or family life within the meaning of article 8.1 of the ECHR. Not all changes in a regulatory scheme, even those which have economic impacts for individuals, involve an interference within article 8.1 which has to be justified under article 8.2 of the ECHR. By way of example, where regulators approve increases in train or tube fares, that may well result in individuals having to adapt their working patterns to deal with the increase in fares. That would not, of itself, amount to an interference within the meaning of article 8.1 which has to be justified under article 8.2. Similarly, changes in transport costs as a result of increases in road or bridge tolls, or charges for road usage, such as the congestion charge, would not normally involve an interference with private or family life within the meaning of article 8.1 of the ECHR. There may be instances in which the consequences of particular changes have such an effect on an individual or his or her family as, potentially, to give rise to issues under article 8.1 of the ECHR."

142. The same reasoning applies to the present case. The practical and financial burdens imposed by the 2025 Regulations, substantial though they may be, do not attain the level of impact on private life that is required to engage article 8.

143. It follows that article 8 is not engaged. Mr Wookey and Mr Holden are not "victims" within the meaning of article 34 of the Convention. They are not therefore able to rely on article 8 in these proceedings: section 7(1)(b) of the 1998 Act.

Article 1 of the first protocol

144. Article 1 of the first protocol protects the peaceful enjoyment of possessions.

145. Mr Wookey and Mr Holden say that the Regulations amount to an interference with their right to peaceful enjoyment of their possessions. They identify, as relevant possessions, the marketable goodwill of their businesses, their reputation in the organic sector, their clientele, the organic certification of the business, their financial resources and any concluded contracts.

146. "Possession" (or "biens" in the French text of the Convention) has an autonomous meaning which is not dependent on legal definitions of property in domestic law. It covers a broad range of property rights. It is not limited to material goods. In the somewhat circular test that is applied by the Strasbourg authorities, it extends to any "substantive interest" that is protected by article 1 of the first protocol: *Brosset-Triboulet v France* application 34078/02, 29 March 2010 at [65]. As well as material goods, it covers shares, patents, leases and licences to occupy property, and welfare benefits.

147. The claimants' financial resources and interests under concluded contracts are protected by article 1 of the first protocol: *Breyer Group PLC v Department of Energy and Climate Change* [2015] EWCA Civ 408; [2015] 1 WLR 4559 *per* Lord Dyson MR at [47] – [49], *Axa General Insurance Ltd v Lord Advocate* [2011] UKSC 461; [2012] 1 AC 868 *per* Lord Reed at [114].

148. Conversely, anticipated future income which has not yet been earned and which could not be the subject of an enforceable claim, does not amount to a possession within the meaning of article 1 of the first protocol: *R (Countryside Alliance) v Attorney General* [2007] UKHL 52; [2008] 1 AC 719 *per* Lord Bingham at [20], *R (Nicholds) v Security Industry Authority* [2006] EWHC 1792 (Admin); [2007] 1 WLR 2067 *per* Kenneth Parker QC at [70] – [76]. Subject to that, the marketable goodwill of the claimants' businesses is a possession within the meaning of article 1 of the first protocol: *Solaria Energy UK Ltd v Department for Business, Energy and Industrial Strategy* [2020] EWCA Civ 1625; [2021] 1 WLR 2439 *per* Coulson LJ at [30].

149. Where the running of a business is dependent on a licence, then the withdrawal of the licence can amount to an interference with the peaceful enjoyment of property: *O'Sullivan McCarthy Mussel Development Ltd v Ireland* (2019) 68 EHRR 6 at [87] – [90]. The withdrawal of organic certification would prevent Mr Wookey and Mr Holden from continuing to run their organic businesses. It follows that a measure that resulted in the removal of their organic certification could engage the protection of article 1 of the first protocol.

150. Mr Wookey and Mr Holden have, therefore, identified possessions that are protected by article 1 of the first protocol.

151. They have not, however, shown that the 2025 Regulations deprive them of any of these possessions. The 2025 Regulations do not directly impact the marketable goodwill of their businesses (leaving aside future income streams which are not protected), their reputation in the organic sector, their clientele, the organic certification of their business or their financial resources. There is no evidence that the 2025 Regulations would deprive the claimants of their interests under concluded contracts. They do not prevent the claimants from being able to continue to maintain their organic certification and to operate in the organic sector. The practical effect of the Regulations is that it is likely to be more difficult and costly for the claimants to do so, impacting on future profitability. That is not sufficient to amount to an interference with possessions protected by article 1 of the first protocol, as distinct from an increased burden which may affect future profitability.

152. The Secretary of State raises a separate objection to the claim under article 1 of the first protocol based on the fact that Mr Wookey and Mr Holden each run their businesses as partnerships, and yet they have brought their claims as individuals rather than in the name of the partnership. It is not necessary to consider that argument. Even if it were well-founded, it would be an unsatisfactory basis on which to determine the claim. The issue could likely, if necessary, be cured by a simple amendment to the capacity in which Mr Wookey and Mr Holden bring the claim. Also, there are many other individuals who are sole-traders and who would have been able to advance the same claim.

153. Nor is it necessary separately to address the Secretary of State's objection that the claim fails because it is an *ab ante* challenge.

154. The Secretary of State submits that any interference with article 8 or article 1 protocol 1 rights is justified as being in accordance with the law and necessary for and proportionate to the legitimate aims that are pursued by the 2025 Regulations. It is not necessary to address that argument, and I do not consider it appropriate to do so. It is intensely fact-sensitive (particularly when it comes to assessing if a fair balance has been struck) and it is not straightforward to undertake that exercise on the counterfactual that the respective Convention rights are engaged; it would immediately be necessary to assess the degree of intrusion into the respective Convention rights, contrary to my finding that there is no interference.

Outcome of claim that the decision to make the regulations was incompatible with Convention rights

155. Mr Wookey and Mr Holden have not established that their Convention rights under article 8 or article 1 of the first protocol are engaged. This ground of claim is not arguable. I therefore refuse permission to claim judicial review on ground 1.

Ground 2: Irrationality (including breach of duty to make adequate enquiries)

156. The 2025 Regulations are highly controversial. The Secretary of State does not challenge the claimants' good faith or the genuineness of their concerns about the impact of the 2025 Regulations on the organic sector and the ability of consumers to

avoid PBOs. The 2025 Regulations put the regulatory regime in England out of kilter with the rest of the United Kingdom and the European Union. The decision not to introduce mandatory labelling was made at a meeting where the recorded discussion is somewhat perfunctory (see paragraph 80 above), even though (as the Minister was seemingly well-aware) the decision was going to be extremely unwelcome to the organic sector. The De Minimis Assessment shows that there remains considerable uncertainty about how the organic sector can best avoid the introduction of PBOs (whether by contamination or accidental introduction) into supply chains. There is also uncertainty about whether the European Union will amend its regulatory regime and, if so, in what way, and whether dynamic alignment of the regulatory regimes will be practical. Regulations to address the labelling of PBO seed in England have not yet been made.

157. For all these reasons there were strong arguments in favour of delaying making regulations and instead undertaking obvious further potential enquiries (such as what the real costs of a labelling requirement would be, or precisely how the organic sector could operate without a labelling requirement) and perhaps proceeding in tandem with the European Union.

158. It was, however, for the Minister to decide whether, and when, to make the 2025 Regulations. It is not for the court to substitute its view. It was also for the Minister to decide what enquiries to make, including the manner and intensity of any enquiries. Again, it is not for the court to substitute its view. The fact that there were sensible further enquiries that could be made does not mean that the Minister was bound to make them. There is no public law error unless the Minister acted irrationally in the sense explained in *Associated Provincial Picture Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223 *per* Lord Greene at 229.

159. The Minister's decision to "press on" rather than to direct further enquiries was irrational if it was a decision that no reasonable Minister, properly advised, would have made: *Secretary of State for Education and Science v Tameside Metropolitan Borough Council* [1977] AC 1014 *per* Lord Diplock at 1065B, *In re McAleenon* [2024] UKSC 31; [2025] AC 1362 *per* Lord Sales and Lord Stephens at [40], *R (Khatun) v Newham London Borough Council* [2004] EWCA Civ 55; [2005] QB 37 *per* Laws LJ at [35] – [36]. An example would be where the reason for not making further enquiries does not withstand logical scrutiny: *R (Law Society) v Lord Chancellor* [2018] EWHC 2094 (Admin); [2019] 1 WLR 1659 *per* Leggatt LJ and Carr J at [98]. Another example is where the process of reasoning involved a serious technical error (*Law Society* at [38]). Another example is where a decision-maker has not directed themself properly in law or has failed to have regard to a relevant matter, when deciding not to undertake further enquiries: *Wednesbury* at 229. That is because the sufficiency of inquiry is itself reviewed through the lens of *Wednesbury* rationality.

160. The Minister understood, and articulated, the arguments for and against introducing mandatory labelling. He recognised that the organic sector, and many consumers, were strongly in favour of mandatory labelling, and he understood why. He was aware that the 2025 Regulations would have a significant adverse impact on the organic sector. He was aware that the 2025 Regulations would mean that England would operate a different regime from other parts of the United Kingdom and from the European Union. He will have been aware that this would impact on trade. Although there was the potential for this to be mitigated by way of future regulations for the labelling of seed

in England, and a future agreement with the European Union, the detail of that was yet to be worked through.

161. Faced with all of that, the Minister's decision was to press on with making the 2025 Regulations without introducing mandatory labelling. He prioritised the interests of commercial innovators (and the consequential economic benefits of attracting investment into England) notwithstanding the concerns of, and impact on, the organic sector, consumers, and trade with the European Union and with other parts of the United Kingdom.

162. The De Minimis Assessment shows that there are considerable potential benefits in securing a "first mover competitive advantage" in terms of attracting innovators by a more attractive regulatory regime compared to the European Union. Although a number of questions were left unanswered, the Minister did address the relevant issues. There was a logical reason for proceeding more quickly and not making further enquires: the whole purpose was to secure a first mover competitive advantage. That militated in favour of the decision to "press on".

163. All of that may have been capable of withstanding a rationality challenge if the Minister had correctly understood his legal powers. But he did not. He was under the misapprehension that his powers to mandate labelling arose only under the 1964 Act and extended only to seeds. He did not know (because he had been wrongly advised) that he had powers under the 2023 Act to mandate labelling for all PBOs that are placed on the market. This inevitably constrained his thinking, and the range of enquiries that were appropriate. Given that the Minister thought the only power to mandate labelling was in the 1964 Act, and that was going to be considered later anyway, then it may be unsurprising that he decided to press on rather than to undertake further enquiries. If the Minister had understood that he had power under the 2023 Act to mandate labelling more broadly than seed-labelling, there was at least a real possibility that he would have considered a materially different range of options. There is a real possibility that he would have directed further enquiries into the costs, benefits and practical operation of such a requirement. It is not highly likely that the outcome would have been substantially the same if the Minister had correctly understood his legal powers (cf section 31(2A) of the Senior Courts Act 1981). It is unnecessary to find that the Minister would have taken a different course, or that there was only one rational option open to him. It is sufficient that his decision-making was materially constrained by a misunderstanding of his legal powers. That rendered the lack of further enquiry, and the decision itself, irrational. That is sufficient to vitiate the decision.

164. There is a more direct route to the same conclusion: the decision not to make regulations for traceability was vitiated by the Minister being misdirected that he did not have the power to do so. That argument was articulated in the Reply, but not in the Statement of Grounds. In a claim for judicial review, the grounds of challenge must be set out in the Statement of Grounds accompanying the claim form. A Reply is for responding to the defendant's acknowledgment of service and should only be filed where it is considered necessary to assist the court (for example to respond to a discrete point which was not addressed in the claim form): The Administrative Court Judicial Review Guide (2015) paragraph 8.5.1. It is not for introducing new grounds of claim. If a claimant wishes to rely on an additional ground of claim, then the correct course is to apply to amend the grounds: The Administrative Court Judicial Review Guide (2015) section 10.2. Permission is required to rely on an additional ground: CPR 54.15. Accordingly, if the

claimants had wished to advance this as a ground of challenge, then it would have been necessary to amend the Statement of Grounds.

165. Mr Wolfe indicated that he would, if necessary, make an application to amend the Statement of Grounds. Given my conclusion on Ground 2 it is unnecessary to consider such an application.

166. Accordingly, I grant permission to claim judicial review and give judgment for the claimants on the substance of this ground of claim.

Ground 3: Compatibility with the Habitats Regulations

167. The Habitats Regulations apply if the 2025 Regulations amount to a "plan or project". Those words are not defined in the Habitats Regulations. They derive from article 6(3) of the Habitats Directive, in which they likewise appear without definition. They must necessarily have an autonomous meaning, to be interpreted uniformly across the member states of the European Union. They must also be construed in the light of the purpose of article 6(3) to achieve a high level of environmental protection. That purpose reflects the precautionary principle, that measures should be taken to protect against harm even where there is scientific uncertainty as to the risk: *Landelijke Vereniging tot Behoud van de Waddenzee v Staatssecretaris van Landbouw, Natuurbeheer en Visserij (Case C-127/02)* [2005] 2 CMLR 31 at [44] and [58] – [61], *R (Wyatt) v Fareham Borough Council* [2022] EWCA Civ 983 [2023] Env LR 14 *per* Sir Keith Lindblom SPT at [9], *CG Fry & Son v Secretary of State for Housing, Communities and Local Government* [2025] UKSC 35 *per* Lord Sales at [26] – [28].

168. The concept of a "plan" or "project" is functional. It is not dependent on the form of the instrument which gives effect to the "plan" or "project". There is no principled basis for excluding a legislative instrument from the scope of article 6(3) solely because it has the force of law. Nor is there any reason the effect of a scheme should be limited to a single site for it to amount to a plan or project. Thus, in *R (Together against Sizewell C Ltd) v Secretary of State for Energy Security and Net Zero* [2023] EWCA Civ 1517; [2024] Env LR 22, it was common ground that a "national policy statement" designated under the Planning Act 2008 is a "plan" and that a "nationally significant infrastructure project" for which a development consent is applied for is a "project" (see at [12]). What matters is the nature and effect of the measure, not its legal characterisation.

169. There are, however, limits on what may properly be characterised as a "plan" or "project" within the meaning of the Habitats Regulations. Not every proposal or scheme or legislative instrument is a "plan" or "project" to which regulation 63 applies. The mere fact that a measure is likely to have a significant effect on a European site does not mean that the measure is a "plan" or "project".

170. The outer limits can be derived from the language of article 6(3) of the Habitats Directive. The obligation imposed by that provision is to conduct an appropriate assessment of the implications of the plan or project for a European site in view of its conservation objectives. It follows that the concept of a "plan" or "project" presupposes a measure whose implications for a European site are capable, in principle, of such assessment. Accordingly, although the concept is to be construed broadly and purposively, it does not extend to measures which lack sufficient precision, or any

discernible linkage to particular sites, such that their implications for those sites cannot meaningfully be assessed.

171. This conclusion is consistent with the jurisprudence of the Court of Justice, which indicates that a plan must go beyond "preliminary administrative reflection" and exhibit a degree of precision which is sufficient to enable an assessment of its environmental effect on specific sites: *Commission v Italy* (Case C-179/06) at [41]. It is also consistent with domestic authority emphasising the need for a sufficiently clear and direct connection between the measure in question and identifiable European sites: *R (Wildfish Conservation) v Secretary of State for Environment, Food and Rural Affairs* [2023] EWHC 2285 (Admin) [2024] Env LR 15 *per* Holgate J at [208].

172. Where a measure is expressed at such a level of generality that it neither authorises nor regulates activities by reference to particular sites, nor contains sufficiently concrete content to permit an evaluation of its effects on such sites, it falls outside the scope of article 6(3). Thus, in *R (Boggis) v Natural England* [2009] EWCA Civ 1061; [2010] 1 All ER 159 the introduction of a process for ensuring that activities likely to damage the environment are not authorised without prior assessment of their environmental impact was not a "plan" or "project" within the meaning of article 6(3). So too in *Wildfish*, an instrument that set national targets for storm flows generally, without authorising specific proposals which would affect specific European sites, did not amount to a "plan" or "project". At [208], Holgate J said:

> "I agree with the defendant's submission that the Plan is a statement of the "general political will" of the Secretary of State. It is a high-level, strategic document which does not identify where upgrades will be required in order to meet the policy targets because, in general, that remains to be assessed over a number of years running up to the target years. Accordingly, there is no link, let alone a clear and direct link, with any specific European site."

173. The Habitats Regulations are therefore not engaged merely by reason of a proposal to take steps that will have a significant effect on a European site: *Wildfish* at [204]. They are only engaged by a plan or project which is sufficiently precise and sufficiently linked to particular sites to enable the implications for those sites to be meaningfully assessed.

174. The 2025 Regulations establish a high-level and general policy and regulatory framework. They are of general application throughout England. They thereby necessarily apply to all European sites within England, but they do not have any nexus with any particular site. They do not identify, regulate or authorise any activity by reference to any particular European site. Rather, they establish a regulatory framework within which future decisions may be taken about the release and marketing of PBOs.

175. It follows that the Regulations lack any sufficiently tangible nexus with particular European sites. They also lack the degree of specificity necessary to permit an assessment of their implications for such sites in view of the sites' conservation objectives. The effects, if any, on individual sites will depend upon subsequent decisions on the application of the framework which the 2025 Regulations establish.

176. For these reasons, the 2025 Regulations do not constitute either a "plan" or a "project" within the meaning of article 6(3) of the Habitats Directive and regulation 63 of the Habitats Regulations.

177. The claimants further submit that, if the 2025 Regulations are not themselves a plan or project, the regime is nonetheless incompatible with regulation 63 of the Habitats Regulations because there is no later stage at which an effective assessment under the Habitats Regulations can take place. I do not accept that submission. Regulation 63 does not operate unless there is a plan or project. Here, there is no plan or project within the meaning of regulation 63.

178. It follows that the decision to make the 2025 Regulations did not involve a breach of regulation 63 of the Habitats Regulations and was not otherwise incompatible with the Habitats Regulations.

179. On a proper construction of regulation 63 of the Habitats Regulations, ground 3 is not properly arguable. I therefore refuse permission to claim judicial review on this ground.

Ground 4: Compatibility of regulation 30(4)(b) with the governing legislation

180. Section 26(2)(a) and (3)(b) of the 2023 Act empower the Secretary of State to make regulations that prescribe the requirements to be satisfied before issuing a food and feed marketing authorisation. Regulation 30(3) sets out the requirements to be satisfied before issuing a food and feed marketing authorisation. That regulation is therefore squarely within the scope of its governing provisions.

181. Section 26(2)(a) and (4) of the Act empower the Secretary of State to make regulations about the procedure for determining applications for food and feed marketing authorisations. By section 26(6), those procedural regulations may include the conferral of functions on the Food Standards Agency, including in respect of the conduct of risk assessments. Regulation 26 confers functions on the Food Standards Agency, including in respect of the conduct of risk assessments. In particular, by regulation 26(3) (read with regulation 26(1)), where the Food Standards Agency has not determined, on the basis of the information provided to it, that the PBO is safe for use in food and feed without further assessment, it must carry out an assessment of the PBO for use in food and feed. That regulation is therefore likewise squarely within the scope of its governing provision.

182. The effect of this framework is that it is for the Food Standards Agency to conduct any necessary risk assessment to determine the safety of PBOs that are used in food and feed. Regulation 30(4)(a) requires the Secretary of State to have regard to any report that is produced by the Food Standards Agency when considering whether the requirements for a marketing authorisation have been met. Regulation 30(4)(b) then limits the tests that may be applied by the Secretary of State when deciding whether the requirements for a marketing authorisation have been met. Regulation 30(4) is thus also part of the procedure for determining a marketing authorisation and is therefore squarely within the scope of the governing provision. The claimants rightly accept this.

183. The claimants submit that the governing statute is intended to promote safety and to provide a framework for an efficacious regulatory regime. I accept that submission. That statutory purpose is reflected in the Act's long title, the explanatory notes, and the

language of the statute including, most directly for this purpose, section 26(3)(b) and 26(6)(a)(ii) and 26(6)(b).

184. The claimants' point is that regulation 30(4)(b) "runs against the grain" of the purpose of the governing statute. They say it undermines rather than promotes safety, because it limits the tests that the Secretary of State may conduct: it would not even permit a test to determine whether the organism in question is in fact a PBO. It is therefore inconsistent with the underlying purpose of the governing legislation.

185. I do not accept this submission. It fails to take sufficient account of the overall effect of the 2025 Regulations, the context of regulation 30(4)(b), its limited role, and the advice that underpinned the governing statute and informed the policy intent.

186. PBOs are, by definition, organisms that could arise from traditional breeding methods. The advice that underpinned the governing statute was that they did not give rise to any greater risk than organisms that arise from traditional breeding methods. That is reflected in the limitation imposed by regulation 30(4)(b), limiting testing to that which would be applicable to traditionally bred organisms.

187. When the regulations are considered as a whole, they provide a regime that seeks to ensure the safety of food and feed that derives from PBOs. Thus, food or feed containing a PBO can only lawfully enter the market if:

(1) The organism is a plant (regulation 2).

(2) The organism could have resulted from traditional breeding processes alone (section 1(2) of the 2023 Act).

(3) The Secretary of State has issued a PBO confirmation (sections 6 – 8 and regulations 5 – 7).

(4) The marketing of the food or feed complies with any conditions or limitations imposed by the Secretary of State (regulation 30(2)).

(5) The food or feed would not adversely affect animal or human health (regulation 30(3)(a)).

(6) The food or feed would not mislead consumers (regulation 30(3)(b)).

(7) The production of the food or feed would not have adverse effects on the environment (regulation 30(3)(c)).

(8) The food or feed would not be nutritionally disadvantageous (regulation 30(3)(d)).

(9) The Secretary of State has not revoked the marketing authorisation (regulation 33(1)(a)(i)).

(10) The Secretary of State has not revoked the PBO confirmation (regulations 7 and 33).

188. The Food Standards Agency has an important role in the process. That is entirely appropriate: it is the statutory body responsible for protecting "public health from risks

which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise to protect the interests of consumers in relation to food": section 1(2) of the Food Standards Act 1999. There is no restriction on the testing that the Food Standards Agency may conduct when it assesses the safety of PBOs for use in food and feed under regulation 26(3), albeit the framework contemplates less intensive scrutiny by the Food Standards Agency in cases where the applicant demonstrates that the PBO belongs to a species that has a history of safe food use.

189. Regulation 30(4)(b) does not restrict the testing that may be conducted by the Food Standards Agency. It only applies at the point at which the Food Standards Agency has completed its assessments and provides a report to the Secretary of State: regulation 30(1). At that point, the Secretary of State must decide whether the requirements in regulation 30(3) are satisfied (that is, broadly, no adverse effect on health, no misleading of consumers, no adverse effects on the environment, and no nutritional disadvantage). In making that decision, the Secretary of State must have regard to the Food Standards Agency's report: regulation 30(4)(a).

190. The only effect of regulation 30(4)(b) is to limit the additional tests that may be conducted following receipt of the Food Standards Agency's report. On the assumption that the claimants are right that it prohibits testing of whether the food or feed has been produced from PBOs, then that is not objectionable: by this point the process proceeds on the footing that the organism is a PBO because a PB confirmation is already in force (and has not been revoked). That is because an application for an authorisation may only be made for a PBO in respect of which a PB confirmation is in force: regulation 20(1)(a). A PB confirmation can only be issued where the Secretary of State is satisfied that an organism is a PBO: section 8(1).

191. The restriction on the tests that can be conducted by the Secretary of State is also consistent with the advice that underpinned the introduction of the 2023 Act and informed its policy intent, namely that PBOs do not give rise to greater risks than traditionally bred organisms. For that reason, it cannot be said to be irrational: it runs with, rather than contrary to, the underlying policy of the 2023 Act.

192. For all these reasons, it is not arguable that regulation 30(4)(b) falls outside the scope of the power to make regulations that is conferred by the governing statute. I refuse permission to claim judicial review on ground 4.

Remedy

193. The parties agreed that if the claim succeeded on any individual ground (as it has, on ground 2), the court should not immediately determine what consequential remedy should follow and should instead provide the parties with an opportunity to make further submissions in the light of the court's judgment. That is what I will do.

Outcome

194. I refuse permission to claim judicial review on grounds 1, 3 and 4 (respectively, that the decision to make the Regulations was incompatible with Convention rights, incompatible with the Habitats Regulations, and (in respect of regulation 30(4)(b)) outside the scope of the power conferred by the 2023 Act).

195. I grant permission to claim judicial review on ground 2 (that the decision to make the Regulations was irrational) and allow the claim on that ground, subject to further submissions on the appropriate relief and consequential matters.