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YOUR REF:

OUR REF: RWS/JEK/00741743/2

DATED: 16 June 2025

URGENT - LETTER BEFORE CLAIM

Dear Secretary of State for Environment Food and Rural Affairs

The Genetic Technology (Precision Breeding) Regulations 2025

INTRODUCTION

1. We write on behalf of Beyond GM Ltd (in discussion with other potential claimants including those people and organisations mentioned below) in relation to the decision by the Secretary of State for the Environment Food and Rural Affairs ("**SSEFRA**") to make the Genetic Technology (Precision Breeding) Regulations 2025 (the "**Regulations**") under powers in the Genetic Technology (Precision Breeding) Act 2023 (the "**Act**"), and the making of the Regulations on 13 May 2025.

2. This letter is a formal letter before claim, sent in accordance with the Pre-Action Protocol for Judicial Review. It sets out the factual (to the extent currently known to the claimants) and legal basis on which any claim would be pursued. Please be clear in your response in identifying any

areas of factual and/or legal dispute and the basis for them so that the issues in dispute can be identified and if possible narrowed.

3. We are aware that judicial review is a remedy of last resort and write in the hope that this matter can be resolved without recourse to legal proceedings. We therefore outline at the end of this letter the steps which we ask you to take to avoid proceedings.

4. If we do not receive a satisfactory response to this letter, we propose to advise our client to make an application for judicial review without further recourse to you.

INTRODUCTORY SUMMARY

5. As explained more fully below our clients consider the illegality to include and arise from the following:

    a. **Precision-bred GMOs will not be labelled as such:**

    The Regulations do not allow for (and indeed preclude) testing of whether something said to be a precision bred GMO in fact meets the criteria to be properly classified that way, and preclude safety testing beyond that which would be applied to traditionally bred plants thus exposing people and the environment to risks which have not and will not be assessed; and yet the Regulations unlawfully fail to provide for their labelling in a way which would allow for assessment of the risks to which people (including as regards economic/property interests) and the environment are being exposed (being risks which have not been and cannot properly be ruled out and which are indeed implicitly acknowledged by the creation of an exemption from the Environmental Damage Regulations);

b. **Testing of precision-bred GMOs is prohibited**

There is to be no testing to ensure that precision-bred GMOs indeed fit the definition and unjustifiable constraints are put on the testing of them including safety testing.

c. **Impact on organic and non-GMO farmers and food businesses:**

Unlawfully, there has been no proper assessment of the way in which, and extent to which, the failure to label precision bred seeds and other plant reproductive material as such will impact on organic and/or non-GMO farmers and food businesses (including in their ability therefore to state confidently that their crops/livestock/products do not contain and are not affected by precision bred GMOs directly or via use in the neighbourhood) both in terms of their regulatory status and consumer confidence (and thus their livelihoods);

d. **Impact on any farmer/food business wishing to export to the EU:**

Unlawfully, there has been no proper assessment of the way in which, and extent to which, the failure to label precision bred GMO seeds and other plant reproductive material as such will impact on *all* farmers and food businesses that wish or are required to maintain a non-GMO supply chain (that is , not merely organic ones, but also artisanal, traditional, natural, geographic indication farmers and indeed any farmer or food business which wants to export food items or products including meat and dairy items to the EU), including in their ability therefore to state confidently that their crops/livestock/products do not contain and are not affected by GMOs directly or via use in the neighbourhood, in relation to their ability to export to the EU and EU consumer confidence (and thus their livelihoods);

e. **Impact on protected sites:**

Unlawfully, there has been no assessment compliant with the requirements of the Habitats Regulations (let alone any lawful decision in the light of such an assessment) in relation to the potential impacts of precision-bred GMO plants (whether for use in farming or conservation or both) on the favourable conservation status of protected sites including, in particular, no assessment based on full information which (as there needed to be for a lawful decision) ruled out the possibility of such impacts, including in the light of the absence of testing to see whether a claimed precision-bred PBO in facts meets its criteria.

f. **Breach and misunderstanding of international law:**

The Regulations are based on a legal understanding of the Aarhus Convention which was simply not tenable such that the SSEFRA was wrong in law to conclude that the failure to ensure consultation prior to the release of a precision-bred GMO would meet the requirements of the Aarhus Convention and thus the law.

PARTY DETAILS

6. In accordance with the Pre-Action Protocol, we confirm the following details:

a. **Proposed claimants**:

i. Beyond GM Ltd c/o Leigh Day, Panagram, 27 Goswell Road, London, EC1M 7AJ: Beyond GM Ltd is a UK-based civil society organisation and private company limited by guarantee (company number: 9078147). It represents the interests of consumers, farmers, breeders, sustainable and artisanal food producers and other civil society groups on matters relating to genetic engineering in food, farming and

the natural environment. It has a long-standing record of public engagement, policy advocacy and expert input into regulatory debates, and acts to defend the public interest where transparency, environmental protection and democratic accountability are at risk.

ii. Any claim is also likely also to be brought by one or more other people or organisations who are consumers, farmers (including organic farmers), food businesses (including organic food businesses) and exporters of food (organic or other) to the EU. This letter has been supported by the following: Will Chester-Master (Abbey House Farm), Anita Atkins (Daylesford Organic), Patrick Holden (Holden Farm Dairy), Clare Marriage (Doves), Joanna Blythman, Josiah Meldrum (Hodmedods) and Renee Elliott (Planet Organic Ltd).

b. **Proposed defendant**: Secretary of State for Environment, Food and Rural Affairs, Seacole Building, 2 Marsham Street, London, SW1P 4DF. We understand that, in practice, some of the powers given by the Regulations will be exercised by the Secretary of State for Health and Social Care ("**SSHSC**").

c. **Proposed interested party**: We are not aware of any interested parties to this proposed claim. If you consider that there are any interested parties, who should be sent a copy of this letter, please provide their contact details.

d. **Our reference**: RWS/JEK/00741743/2

e. **Details of claimant's legal advisers**: Rowan Smith (rowans@leighday.co.uk), Julia Eriksen (jeriksen@leighday.co.uk) and Lily Hartley-Matthews (lhartleymatthews@leighday.co.uk) of Leigh Day, Panagram, 27 Goswell Road, London, EC1M 7AJ.

MATTER BEING CHALLENGED

7. This letter contemplates a judicial review challenge to the legality of the decision to make the Genetic Technology (Precision Breeding) Regulations 2025, including the Explanatory Memorandum published with the draft regulations (the "**EM**") under powers in the Genetic Technology (Precision Breeding) Act 2023.

8. Our clients are particularly concerned about the legality of the way in which the risks (including economic and business risks) associated with (and the impacts on farmers and others of) the release into the environment of a category of genetically modified organism ("**GMO**") plants known as "precision-bred organisms" (**"PBOs**") have been dealt with in the SSEFRA's decision to make the Regulations and in the Regulations themselves in circumstances where (among other problems) no proper risk assessment has been undertaken (and indeed proper risk assessment by regulators in future is outlawed) and yet – as below – the risk of wider harm (including economic and business harm including to any farmer or food business which wishes to export to the EU) cannot be excluded.

9. The Regulations implement in England the new regulatory framework for precision-bred GM plants, and any food and feed produced from them, that was introduced by the Act. To be clear though, the Regulations are not limited in scope to agricultural plants as generally understood. They would also, by virtue of the definition of "plants" in the Act, allow for the production and environmental release of a range of other non-agricultural land and aquatic plants including trees, grasses, seaweeds, algae and other plants being contemplated for other uses such as conservation.

10. For accuracy, we will refer to PBOs i.e. organisms where the genetic modifications are claimed to be only ones which could have occurred

naturally or in conventional plant breeding, as “precision bred GMOs” throughout this letter.

FACTUAL AND LEGAL BACKGROUND

Regulatory framework for GMOs

11. The regulation of GMOs in the UK was previously largely based on EU regulations passed in the 1990s and updated in the 2000s. They were implemented in the UK through Part VI of the Environmental Protection Act 1990 (the “**EPA**”) and subsequent secondary legislation and retained direct EU law.

12. Section 106 of the EPA (Part VI) and Regulation 5 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 ("**the Deliberate Release Regulations 2002**") use the EU definition of a GMO from Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, whereby GMO is defined as any organism whose genetic material has been altered in a way that does not occur naturally by mating or natural recombination. The EPA introduced the additional concept of ‘artificial modification’ which established that it is the techniques used to develop an organism that determine its GM status; whether the genetic changes could have occurred naturally or by traditional methods has no bearing. The techniques of artificial modification are set out in regulation 5 of the Deliberate Release Regulations 2002.

13. In July 2018, the CJEU case of *Confederation Paysanne* (C-528/16) confirmed that in EU law all organisms produced by modern biotechnology, so-called gene-editing techniques, or new techniques/new methods of mutagenesis (including but not limited to zinc finger nucleases, TALEN and CRISPR/Cas9), are GMOs and fall within the scope of the existing Directive 2001/18/EC. A subsequent

ruling in 2023 (C-688/21) clarified that historical methods of random mutation breeding, such as chemical and radiation induced mutations (rarely used today), are not a form of genetic modification and therefore can remain exempt from the GMO regulations. However, gene editing, which is a form of directed mutagenesis breeding, would continue to be regulated as GMO. Both judgements recognised the importance of methods of production (rather than end product) in determining a GMO.

14. Prior to the passing of the Act and the making of the Regulations, therefore, all plants produced by modern biotechnology were regulated as GMOs in England. The marketing of food and feed derived from them was also regulated under GM legislation. This is because it was the techniques used to produce these plants (the 'process'), rather than their characteristics (the 'product'), that determined how they were regulated.

15. However, the UK Government's position shifted post-Brexit to be that, where genetic alterations and combinations are of the type that could be selected for in traditional breeding, the environmental release of these plants should not be regulated in the same way as the environmental release of other GMOs (on the basis that it is the characteristics of the end-product that determines its risk to human health and the environment – not how they were made).[1]

16. In 2022, the previous Government introduced the Genetically Modified Organisms (Deliberate Release) Regulations 2022 which amended the Deliberate Release Regulations 2002 and introduced a de-regulated notification system for research and development trials involving certain genetically modified plants in England. These regulations removed what were termed "qualifying higher plants" (QHPs) – genetically modified

[1] Explanatory Memorandum to Genetically Modified Organisms (Deliberate Release) Regulations 2022

organisms that could have occurred naturally or through traditional breeding methods, intended for all non-marketing purposes – from the scope of the 2002 regulations. They replaced a comprehensive risk assessment and explicit consent from the SSEFRA for these environmental releases with a simplified notification system.

The Act

17. The Introductory Text to the Act states it is an "Act to make 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." The purpose, as set out in the explanatory notes, was to reduce the regulatory burden and financial barriers in place for researchers and commercial breeders using precision breeding techniques. However, it was also to do so in a safe way that does not pose (or minimises to the greatest extent possible) risks to the environment and human (and animal) health, as well as to businesses and consumers affected by it. That is clear from the emphasis on risk assessment in the Introductory Text, as well as the content of the powers provided to the Minister under the Act to create a new regulatory framework for precision bred GMOs.

18. The Act established 'precision-bred organisms' as a new class of regulated products which have been produced by the application of modern biotechnology, such as gene editing. PBOs are, thus, a type of GMO – defined in the Act as a precision-bred plant or animal.

19. The Act removed precision-bred GMOs, and the food and feed derived from them, from existing GMO regulation where those organisms could have been produced by "traditional processes" including "sexual fertilisation".

20. In order for a genetically modified organism to be considered to be precision bred for the purposes of the Act, the genome of the organism

must have been altered using modern biotechnology, the alterations must be stable, and all of the features of the genome that have been made using modern biotechnology must also be capable of having arisen by traditional process (with or without selection techniques) alone. A genetically modified organism cannot be precision-bred where it contains any genetic features which have been made by artificial modification techniques, other than modern biotechnology. The definition of modern biotechnology under the Act aligns with the techniques listed in Regulation 5 of the Deliberate Release Regulations 2002.

21. We understand SSEFRA to take the view that genetically modified precision bred organisms present no greater risk to health or the environment than organisms produced through traditional breeding.[2] However, no greater risk is not equivalent to no risk. Traditional breeding, while imperfect, operates over multiple generations through sexual reproduction, allowing for extended observation, selection, and elimination of undesirable traits across time. However, first contrast, gene editing bypasses sexual recombination and compresses what would otherwise be a gradual, multi-generational process into a single, directed genetic intervention, raising concerns about scalability, unintended effects, and regulatory oversight. Second, while developers may subsequently select among edited organisms, this is not breeding in the conventional biological or agricultural sense. Even with sexually compatible species the process of gene editing can induce unintended effects or unanticipated adverse interactions with other organisms or ecosystems that need to be assessed on a case-by-case basis. Moreover, third, evidence shows that genome editing makes the whole genome, including parts that would normally be protected from mutation, accessible for changes, illustrating that the types of changes

[2] As set out here: ACRE advice concerning Defra's consultation on the regulation of genetic technologies - GOV.UK

possible from gene editing are different from, and can go far beyond, those occurring through natural breeding or chemical/radiation-induced mutagenesis breeding. Fourth, the regulatory presumption of equivalence between PBOs and traditionally bred organisms therefore fails to account for the systemic and procedural risks introduced by the technological process itself, and risks placing untested organisms into the environment and food system without sufficient precaution.

22. For consumers the 'right to know' what they are consuming is greater with genetically modified precision bred organisms, given that, unlike their 'GMO' predecessors, the food products being developed now (strawberries, bananas, tomatoes, rice and eventually animal products and microorganisms etc) are intended to be sold and eaten as whole foods rather than highly processed, highly diluted ingredients such as corn syrup or refined oils. Many GMOs – including precision-bred GMOs – have not been studied across multiple generations, making it impossible to fully assess their long-term health impacts on human metabolism, gut microbiota and immune responses. However, the Regulations do not require and/or remove any requirements for traceability and labelling.

23. Moreover, the 'no greater risk' proposition itself assumes that the outcome of the genetic modification process is indeed something which could have occurred (eventually and over many cycles of breeding) in nature or by traditional breeding, and that additional genetic changes have not crept into the result (for which no proper testing is to be undertaken). In the context of releases into the environment (whether related to agriculture, conservation or any other purpose) we note that once released, all living organisms reproduce and spread and, in some cases, can quickly become dominant and invasive. Their interactions with existing ecosystems are complex and unpredictable. Unlike

chemical pollutants that (may) eventually break down, genetic modifications may persist and propagate through successive generations.

24. In any event, according to the Explanatory Notes to the Act [3], it includes provisions to:

- Bring in two mandatory notification systems for PBOs: one for non-marketing purposes (research and development); and one for marketing purposes.
- Allow for new powers to introduce on-going obligations to report information relating to the health and welfare of precision-bred vertebrate animals, and to prescribe the processes and powers the Secretary of State can use to take the necessary action in response to this post-marketing animal welfare information.
- Create a duty on the Secretary of State to create and maintain a new public register of notified information. The register is to be kept in electronic form and accessible on gov.uk.
- Grant powers to create a new regulatory framework for food and feed derived from PBOs, ensuring that appropriate regulation is in place before placing these products on the market. These powers include the power to make regulations that will outline the procedure for issuing a precision bred food and feed marketing authorisation, and the power to make regulations that will require the FSA to carry out risk assessments. Regulations will also set out the requirements within the resultant framework that must be satisfied before the Secretary of State can issue a food and feed marketing authorisation.
- Grant powers for the FSA (and in practice, so we understand the SSHSC) to establish, publish and update a public register for PBOs

authorised for food and feed use. An entry on this register would indicate that the SSHSC has made a determination to authorise the PBO, and products derived from it to enter the market for food and feed uses based on the recommendation of the FSA.

- Grant powers to create an inspection and enforcement regime, including civil sanctions, in order to secure compliance with the obligations under the Act.

25. Importantly, however, the Act did not specify how those processes were to operate (including, for example, in relation to any requirements for notification to consumers, farmers, landowners, etc as to any releases or their potential impacts, including health, environmental, regulatory or economic). Those matters were left to be dealt with through regulations, such as those in issue here.
26. Of further importance is that section 42(2) of the Act provides a power to make supplementary incidental or consequential provision by subsequent regulations, including by ones which modify primary legislation and retained direct EU legislation (commonly known as a "Henry VIII power"). Section 43(1) further provides a wide power to make regulations other than commencement regulations. Thus, both the definition of PBOs and the regulatory system for the release and marketing of them, could be subject to very significant future changes which, without needing any further amendment of the Regulations in issue here, could thus nonetheless significantly alter the nature of the issues arising from their operation, as considered in this letter. The breadth of such powers makes it all the more important that a close level of scrutiny is applied to the lawfulness of the Regulations as currently made.
27. Section 17 of the Act provided powers for the SSEFRA to make Regulations to require persons to carry out environmental risk assessments before

importing precision bred GMOs into England; and before acquiring precision bred GMOs which are already in England. We note, therefore, that the Act explicitly recognised the risks to the environment which may arise from the release of precision bred GMOs. We further, note, however, that no Regulations have yet been made under section 17, thus watering down the regulatory intentions of Parliament in passing the Act.

28. Part 3 of the Act provided the SSEFRA with the powers to create the regulatory framework in relation to food and feed produced from precision bred GMOs. Section 26, in particular, provided powers for the SEFFRA to make regulations in relation to the placing on the market of such food and feed, including in relation to requirements that must be satisfied in order for the SEFFRA to issue a food and feed marketing authorisation (which would enable the precision bred GMO to be placed on the market lawfully).

29. The Act received royal assent on 23 March 2023, despite being subject to significant criticism from Labour (the then opposition government)[3] and various parliamentary committees[4] and in spite of analysis, quoted widely in the parliamentary debates, that respondents to the Defra public consultation, including those who were more favourably inclined towards deregulation, found the government's consultation and framing of organisms that could have been created using traditional methods or occurred naturally to have been variously: "overly simplistic", "purely philosophical", "exceptionally challenging", "fundamentally flawed"

[3] See, for example, proposed amendments seeking introduction of comprehensive oversight in the form a Genetic Technology Authority (here) and requiring gene-edited organisms to be developed in line with specific sustainability criteria (here).

[4] See, for example: Regulatory Policy Committee Report, p.8 (here); Delegated Powers and Regulatory Reform Committee Report (here); Select Committee on the Constitution (here); and European Scrutiny Committee (here).

"misleading, poorly defined and likely driven by industry" and "problematic".[5]

The Regulations

30. On 25 February 2025, SSEFRA laid the draft Regulations[6] and an Explanatory Memorandum (the "**EM**")[7] before the House of Commons and House of Lords. The Regulations span over 40 pages with 55 regulations across 11 parts, including amendments to 14 different pieces of legislation. It was accompanied by a 7-page explanatory memorandum, a 37-page de minimis assessment ("**DMA**"), 32 pages of the guidance produced by independent scientific committee - the Advisory Committee on Releases to the Environment ("**ACRE**") and 135 pages of FSA guidance (with further promised FSA enforcement guidance still unpublished).

31. A full impact assessment was not produced for the Regulations (EM, para 9.1). Critical aspects (such as technical criteria, public register content and procedures for notification) were deferred to be dealt with in guidance documents. This guidance will, in any event, have to operate within the constraints of the Regulations and thus cannot cure the inherent defects in those Regulations such as those we describe here. That lack of assessment at the time of making the regulations is significant here because – as explained further below – it meant that the SSEFRA made the regulations without any proper understanding of their impact for farmers and food businesses.

32. The Regulations implement the Act in respect of precision-bred GMO plants in England and contain new processes for meeting the

[5] Responses submitted by the Institute of Food Science & Technology, the Microbiology Society, the Roslin Institute, The British Veterinary Association: See parliamentary debates referring to these on the following dates: 15 June 2022 (here); 14 March 2022 (here); and 2 March 2022 (here).
[6] The Genetic Technology (Precision Breeding) Regulations 2025
[7] Explanatory Memorandum to The Genetic Technology (Precision Breeding) Regulations 2025

requirements provided for in the Act, according to the Explanatory Memorandum [1][8]:

a. Notifying the SSEFRA of the deliberate release of precision bred plants into the environment for non-marketing purposes, such as for field trials.

b. Applying to the SSEFRA for a precision bred assessment and confirmation to enable precision bred plants to be marketed, such as for commercial cultivation.

c. Applying to the SSHSC through the Food Standards Agency, for a food and feed marketing authorisation to allow food and feed produced from confirmed precision bred plants to be placed on the market.

d. Establishing two public registers: one of prescribed information associated with SSEFRA regulation of precision bred plants; and one of precision bred plants authorised for food and feed use kept by the Food Standards Agency (FSA).

e. Establishing a local authority led inspection and enforcement regime to secure compliance with the legislation, including civil sanctions by way of enforcement notices, namely compliance notices, stop notices and monetary penalty notices.

33. Importantly, however, the Regulations do not provide for, let alone require, any specific technical or scientific assessment within any of those processes as to whether an organism claimed to be a precision-bred GMO is in fact one which could (among other of the qualifying requirements) have been created by traditional breeding (so as to test for any additional genetic changes). Moreover the Regulations specifically prevent the

[8] Notwithstanding the summary included, Beyond GM submits that the EM does not accurately summarise the notification processes introduced by the Regulations.

SSEFRA (or, we understand in practice, SSHSC) in deciding whether to authorise the release of a precision-bred GMO from applying "any test … 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" (Regulation 30(4)(b)), thus specifically precluding (among other things) any future evaluation of whether the 'no greater risk' assumption as above turns out to be correct generally or in relation to any specific new organism, and action if that turns out not to be correct.

34. The Regulations on environmental release will thus replace the Genetically Modified Organisms (Deliberate Release) Regulations 2022 and go further to allow a route to market for experimental precision bred GMO plants outside the current GMO framework.

35. However, the guidance that accompanies the 2025 Regulations differs in important ways from the 2022 guidance for QHPs. Whilst it addresses the same category of gene-edited organisms, and also relies on the criteria that genetic changes must be of a kind that could occur naturally or through traditional breeding, the QHP advice took a more rigorous and risk-aware stance - highlighting, for example, the potential risks of multiplex editing and the need for careful molecular characterisation. By contrast, the newer PBO guidance downplays such concerns, adopts a more permissive tone, and is explicitly framed to facilitate streamlined approval process and support innovation and facilitate market access. This shift reflects a significant weakening of oversight and precaution, despite referring to the same type of organism, and gives rise to legitimate concerns about the adequacy and legality of the current regulatory regime.

36. It is noted that Part 3 of the Regulations amend the Environmental Damage (Prevention and Remediation) (England) Regulations 2015 ("**2015 Regulations**") to exclude precision-bred GMOs from being capable of being treated as a "activity causing damage" for the purposes

of the EDRs. As per para 9(2), Schedule 2 of the 2015 Regulations, the "deliberate release into the environment, transport and placing on the market of [GMOs] as defined by Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of [GMOs]" is an activity causing damage. However, part 3 Reg 14 of the Regulations will now exclude precision bred GMO plants within the meaning of section 1, as read with section 2(1) of the Act from that description and thus preclude claims arising under the 2015 Regulations for what would otherwise be damage caused by them within the meaning of those Regulations. That decision to make that exclusion itself recognises that the possibility of damage to the environment from PBOs cannot be excluded: if PBOs were inherently safe and/or risk free then the exclusion would not have been needed.

37. Regulation 30 was made under section 26(3) of the Act. It provides the SSEFRA with powers to grant food and feed marketing authorisations. In particular, having received a report from the FSA in relation to the relevant precision bred GMO, it provides a wide discretion to the SSEFRA (or, we understand in practice, the SSHSC) provided he is satisfied certain conditions relating to safety and risk are met (Regulation 30(3)). However, it specifically precludes the SSEFRA/SSHSC, in making his decision from applying "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" (Regulation 30(4)(b).

38. On 20 March 2025, concerns were raised by the Secondary Legislation Scrutiny Committee ("**SLSC**") in its 20th Report, following submissions sent to the SLSC on the draft Regulations and EM by a series of campaign organisations, namely GMWatch, Beyond GM and GM Freeze. These submissions and the response of Defra were published concurrent with the Report by the SLSC.

39. Beyond GM submitted general comments and recommendations to the SLSC relating to the draft instrument and EM, including: (i) the regulatory approach taken; (ii) ambiguities in the definitions and criteria relied on to define the boundary of the regulatory system; (iii) transparency and public accountability; (iv) compliance with the UK's legal obligations and (v) administrative complexity and enforcement challenges.

40. In respect of legal concerns, Beyond GM submitted that the regulatory approach taken in the draft instrument raised serious questions about compliance with the UK's legal obligations under the Aarhus Convention and Human Rights Act. In response to the concerns raised in Beyond GM's consultation response regarding the UK's legal obligations, Defra stated[9]:

> *Defra Response:*
>
> *• The Genetic Technologies (Precision Breeding) Act 2023 carves precision bred organisms out of GMO legislation. We therefore consider that the Aarhus Convention on GMOs does not apply to precision bred organisms.*
>
> *• The Government considers that the regulations and Act are compatible with the European Convention on Human Rights. The registers provided for in both the regulations and the Act and published by Defra and the FSA will contain publicly available information about precision bred plants, including those approved for use in food and feed." [underlining added]*

Traceability and Organic produce

41. In Defra's response to the concerns raised to the SLSC regarding the traceability of PBOs once they have entered the market, Defra stated "[*to] our knowledge, there are currently no scientific methods that provide unequivocal identification of genetic changes associated with precision*

[9] committees.parliament.uk/publications/47173/documents/244335/default/

bred plants without prior knowledge of the altered genome and suitable reference materials. If these data were available, there would be no way of knowing whether the genetic change resulted from the application of precision breeding technology or traditional breeding practices" [8-9]. Defra officials maintained in relation to a concern that, unlike GMOs, under the Regulations PBOs no longer require a unique identifier which may assist with traceability through the food system, but that the SSEFRA would ensure marketing information is available and establish a Precision-Bred Plant Variety List.

42. In response to the same concerns, the FSA agreed that "The consensus is that currently there are no methods that provide unequivocal detection of PBOs." [10] The FSA noted that under general food/feed legal traceability requirements, business operators are only required to be able to able to identify their immediate suppliers, and the immediate person they are supplied to (known as "one-up-one-down"). There is no requirement for identification further down the food chain.
43. Because PBOs cannot be definitely traced, and there is no requirement for mandatory labelling in the Regulations, as the SLSC noted, people and organisations (including consumers, farmers, businesses and others) will not be able to know whether products in the food chain have or have not been made with or contain precision-bred GMOs (and thus, in EU and Aarhus Convention terms, GMOs).
44. As the SLSC further noted, that has particular significance in the organic sector. For consumers, it means the only source of public information available as to the identity of precision-bred GMOs will be the public register, but that does not assist in respect of traceability, which is intended for professionals. As the Regulations stand, there will be no marking of the produce.
45. As to farmers and growers, as the DMA noted, under the assimilated organic regulations in the UK, it is unlawful to use GMOs (including

PBOs), or products produced by them, in organic production. The production of PBOs under the Regulations (and without there being any information as to whether a seed or plant is a PBO or not) therefore places organic farmers directly at risk of breaching the conditions of their licences. The Regulations contain no provisions or system for maintaining segregation of organic produce in the supply chain. The DMA [18] recognises the potential economic impact of this issue on organic farmers, but states merely that an organisation has been contracted to facilitate discussions on coexistence measures require for segregation of production systems. There is no evidence SSEFRA or the FSA have conducted or considered risk assessments with regard to the contamination of organic supply chains, and there is no system in the regulations to ensure segregation. Nor has there been any provision made setting out how organic producers are to demonstrate their products are free from PBOs (whether through them or their neighbours using precision-bred GM seed or produce). As a result, the DMA concedes it is "hard to establish quantitative costs at this stage." We note with further concern that SSEFRA responded to the SLSC stating that as the Act "does not contain powers to legislate for coexistence measures between PB and non-PB crops. As such, coexistence measures will be developed and implemented by industry." It follows that, in making the Regulations, the Secretary of State did not properly consider their impact on organic farmers and businesses.

46. SSEFRA thus apparently recognised that there was no system in place at the time of the making of the Regulations and yet went ahead with them anyway, thus recklessly exposing organic farmers and food businesses to the risks (economic and regulatory) in question.

47. Still more concerning was the SSEFRA's reminder that "There are no obligations on growers with marketable precision-bred plants to put in place containment measures or restrictions." It should be noted that

there are also no requirements in the Regulations for containment measures or restrictions on experimental, non-marketable, environmental releases.

Labelling

48. The decision to exempt precision bred GMOs from labelling requirements applicable to other GMOs is not a neutral or technical adjustment; it is a substantive and material departure from previously applicable regulatory safeguards under retained EU law, where all GMOs in food and feed were subject to mandatory labelling and traceability. This change was neither consulted upon nor justified by evidence. Neither the 2021 Defra consultation nor the 2023 FSA consultation asked about labelling. The FSA consultation specifically stated it did not feel it was appropriate given government had no safety concerns about PBOs.
49. Polling in the UK (by FSA and BGM) however, has shown that 8 in 10 citizens polled want labelling. The Government has argued that the creation of two public registers (for environmental releases and marketed food/feed) provides sufficient transparency. We do not accept that view. Registers are not a functional substitute for on-product labelling. They are not accessible at the point of purchase or use, denying citizens the ability to make informed choices in real time. They therefore require disproportionate effort from consumers and supply chain actors to search, interpret and cross-reference products.

Trade with Scotland and Wales, and Northern Ireland and the EU

50. The Scottish and Welsh devolved Governments have explicitly rejected (via parliamentary process) the Genetic Technology Act, opposing the cultivation and sale of genome-edited organisms within their borders. Neither has proposals to permit PBOs onto their markets without them being identified as GMOs. As recognised in the DMA, that raises

concerns as to how businesses in Scotland and Wales will be able to comply with requirements concerning GMO identification given that the mutual recognition principle under section 2 of the United Kingdom Internal Market Act 2020 dictates any food produce which is produced saleable in England can be sold without restriction elsewhere in the UK.

51. Further, as noted by the SLSC [48] PBOs are not recognised as a separate legal entity under EU law and remain defined as GMOs for those purposes. Under EU law, GMOs (including therefore any product authorised for release under the Regulations) require mandatory labelling, but the Regulations provide for no system of mandatory labelling, and SSEFRA confirmed to the SLSC that it does not consider mandatory labelling appropriate. Farmers and food businesses (including meat and dairy producers whose livestock may have been fed on PBO feed) will therefore have to label their products as GMO in order to trade with NI or the EU. However, for the reasons related to traceability set out above, it is questionable whether producers further down the supply chain would even be aware that their produce had been produced with GMOs. As Slow Food observed to the SLSC, this raises "fundamental concerns about this country's ability to trade with its EU neighbours."

52. The SLSC noted the risks to trade inherent in making the Regulations in their current format. The DMA recognises that in its summary where it states "*Internal Market Concerns & UK exports to EU (Risk) – The main risks associated with this SIs are related to trade and the potential complications that may arise from legislative differences."* The Impact Assessment which accompanied the Act recognised the potential significant impact on trade [143-147; 151-152]. It stated with regard to the potential impact of non-tariff measures on UK crop related food exporters that:

This would have a relatively significant impact on UK producers, UK crop-related food exporters are heavily dependent on EU consumers' demand. Approximately 55% of all crop related food exports from the UK are to the EU68. And so, it would be difficult to replace EU demand. Therefore, there is a possibility for a portion of the £8.56 billion worth of crop related exports to the EU to decrease, potentially outweighing the scale of direct benefits to business. Nonetheless, this represents only 2.5% of our annual total value of exported goods and 5.4% of our annual value of exported goods to the EU. And so, even if UK crop-related food exports are maximally impacted, the overall impact on the UK balance of trade is minimal.

53. These are very significant financial impacts including for all and any farmers and related businesses including food producers and exporters who might with to access the EU market. However, the DMA made no attempt to assess or quantify the negative economic impact of the Regulations on trade either internally or with the EU. The reason given in the DMA for avoiding a Full Impact Assessment (which is required for all regulatory provisions where the impact is greater than plus or minus £10 million annual net direct costs on businesses[10]) is ***"A full Impact Assessment has not been prepared as this instrument will have a low level of impact on businesses and will not introduce new costs or benefits above the threshold required for a full Impact Assessment."*** Given the known significance of the risks to trade for all farmers and food businesses wishing to export to the EU from the measures implemented in the Regulations (namely that their export produce will simply be rejected by the EU and/or EU consumers given that it cannot be ruled out as GM), it was simply not sustainable to assert that the Regulations will

[10] DFT, Better Regulation Framework Guidance, September 2023 6.9-6.11.,

only have a low impact on businesses. There was no evidence for the claim in question.

54. Further, that was a different reason from that given by SSEFRA when the SLSC queried why the impact on trade was not dealt with more comprehensively in the DMA, which was that "*detailed economic analysis on this issue was not amenable to include in the DMA.*" That reason would, again, have amounted to the reckless exposure of the affected businesses to an impact which the SSEFRA had not even properly taken into account.

55. It should further be noted that the original Impact Assessment which accompanied the Genetic Technology (Precision Breeding) Bill prior to Parliament passing the Act was deemed "not fit for purpose" by the Regulatory Policy Committee[11]. Its cost-benefit analysis and analysis of the wider impacts of the Bill (including impact on trade, investment and environmental impacts) were determined to be "weak" by the RPC. That, in turn, compounded the lack of analysis of the likely impact of the Regulations. In a letter dated 6 October 2022 to Adrian Steele and Christopher Stopes of the English Organic Forum, farming minister Mark Spencer had promised "*Defra has agreed to work with the RPC and its secretariat to address the comments raised and we are currently working closely with stakeholders and economists to update the IA to address these concerns*." However, this update of the IA never occurred.

The Cartagena Protocol on Biosafety

56. The UK is a signatory of the Cartagena Protocol on Biosafety. The Cartagena Protocol on Biosafety is an international treaty governing the movements of GMOs from one country to another. This is implemented

[11] RPC-DEFRA-5170(1).

by retained EU Regulation 1946/2003, which establishes a system for notifying and providing information for the transboundary movements of GMOs. The Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 provide for enforcement of this Regulation in England. As set out in the Explanatory Notes to the Act, the UK Government considers that the Cartagena Protocol does not apply to organisms produced using modern biotechnologies if those organisms could have occurred naturally or been produced by traditional methods.

The Almaty (or "GMO") Amendment to the Aarhus Convention

57. The GMO Aarhus Amendment[12], to which the UK is a signatory, came into force on 20 April 2025 following Ukraine's ratification in January 2025 which triggered the entry into force of the amendment. Pursuant to the amendment, parties are required to establish arrangements for public participation prior to decisions on whether to permit the deliberate release or market placement of genetically modified organisms.

58. The GMO Aarhus Amendment specifically requires the UK to:

    a. Provide for early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of genetically modified organisms (Article 6 bis (1)).

    b. Ensure the requirements made in accordance with that obligation are " complementary and mutually supportive to the provisions of their national biosafety framework, consistent with the objectives of the Cartagena Protocol on Biosafety." (Article 6 bis (2)).

    c. The ways in which Parties should provide for early and effective information and public participation include (under Annex I bis):

[12] https://unece.org/DAM/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.2.e.pdf

i. Providing reasonable time frame, in order to give the public an adequate opportunity to express an opinion on such proposed decisions.

ii. Ensuring transparency of decision-making procedures and provide access to the relevant procedural information to the public. This information could include for example:

iii. Publication of information relating to proposed releases including environmental risk assessments;

iv. Ensure that when decisions are taken on whether to permit the deliberate release of GMOs into the environment, including placing them on the market, due account is taken of the outcome of the public participation procedure.

v. Publishing decisions with regard to the release of GMOs along with the reasons on which it is based.

59. Defra's response to the SLSC was to assert that the Aarhus Convention on GMOs does not apply to precision-bred GMOs because: "The Genetic Technologies (Precision Breeding) Act 2023 carves precision bred organisms out of GMO legislation" is simply misconceived and wrong in law.

60. The amendment of domestic legislation to ensure PBOs are not within the definition of GMOs plainly cannot affect the definition of a GMO in international law so as to somehow take them out of scope of the Aarhus Convention. PBOs, as defined in the Act, remain GMOs both under the Arhus Convention and in EU law (indeed, they also remain GMOs under domestic legislation governing the organic sector).

European Convention on Human Rights ("ECHR")

Article 8 ECHR

61. Article 8 of ECHR protects the right to private and home life, including the right to health.

Organic farmers

62. Article 8 applies to professional activities. The notion of private life under Article 8 may include professional and business activities. Restrictions on an individual's professional life may fall within Article 8 where they have repercussions on the manner in which he or she constructs his or her social identity by developing relationships with others – *Fernandez Martinez v Spain* (GC) (2015) 60 EHRR 3. It is, after all, in the course of their working lives that the majority of people have a significant opportunity to develop relationships with the outside world. Private life is often intricately linked to professional life - the link to Article 8 will be particularly strong where the requirements of a profession directly relate to factors relating to private life – *Fernandez* [110-111]

Applicability as an environmental risk

63. As regards environmental pollution and harmful activities, harm must attain a certain minimum level if the complaints are to fall within the scope of Article 8. The assessment of that minimum is relative and depends on all the circumstances of the case, such as the intensity and duration of the nuisance and its physical or mental effects. The general context of the environment should also be taken into account - *Hardy and Maile v UK* (2012) 55 E.H.R.R. 28 [188]. In such cases *potential* environmental risks from state projects are capable of engaging Article 8 prospectively. The actual risk need not have materialised for Article 8 to be engaged, it is sufficient that the possibility of the event occurring

and the consequences and risks associated with such an event have not been properly assessed - *Hardy and Maile* [190].

Negative obligations

Interference not in accordance with the law

64. There may be a justiciable interference with Article 8 rights where a person is likely to be exposed (but has not yet been so exposed) by the state measure in question – *Hardy* see also e.g. noise, vibrations and pollution that would emanate from a planned railway line *Maatschap Smits and Others v. Netherlands (dec.), 2001);* (at 1).

65. Any interference by a public authority with an individual's Article 8 rights must be in accordance with the law. The national law must be clear, foreseeable, and adequately accessible. It must be sufficiently clear in its terms to give citizens an adequate indication of the conditions and circumstances in which the relevant interference will take place. Domestic law must indicate with reasonable clarity the scope and manner of exercise of the relevant discretion conferred on the public authorities so as to ensure to individuals the minimum degree of protection to which they are entitled under the rule of law in a democratic society - *Fernandez Martinez v Spain* (GC) at [117].

66. Provided it meets the requirement of lawfulness, a measure constituting an interference with a claimant's Article 8 rights must satisfy the proportionality test as set out by the Supreme Court in *Bank Mellat v HM Treasury* [2013] UKSC 38, [2014] AC 700.

Positive obligations

67. In *Verein Klimasenriorinnen Schweiz v Switzerland* (**"VKS"**) (GC) (2024) 79 EHRR 1 at [538], the Grand Chamber summarised the principles arising from its case law regarding the content of the positive obligations under Article 8 as they apply to the environment. States have a positive

obligation under Article 8 to put in place a legislative and administrative framework designed to provide effective protection of human health and life from activities which pose environmental risks. In particular, States have an obligation to put in place regulations geared to the specific features of the activity in question, particularly with regard to the level of risk potentially involved. They must govern the licensing, setting-up, operation, security and supervision of the activity and must make it compulsory for all those concerned to take practical measures to ensure the effective protection of the citizens whose lives might be endangered by the inherent risks. In particular, the State has a positive obligation to provide access to essential information enabling individuals to assess risks to their health and lives (*VKS* [538(f)].

68. Moreover, states have a positive duty to apply that framework effectively in practice. Convention is intended to protect effective rights, not illusory ones. The relevant measures must be applied in a timely and effective manner. Although in cases involving environmental issues, the State is allowed a wide margin of appreciation and an impossible or disproportionate burden must not be imposed on the authorities, the court can assess whether the authorities approached the matter with due diligence and gave consideration to all competing interests.

69. The ECtHR has frequently reviewed the domestic decision-making process, taking into account that the procedural safeguards available to the individual will be especially material in determining whether the respondent State has remained within its margin of appreciation – *VKS* [539]. The Court must therefore first examine whether the decision-making process was adequate. It is required to consider all the procedural aspects, including the type of policy or decision involved, the extent to which the views of individuals were taken into account throughout the decision-making procedure, and the procedural

safeguards available (see *Hatton and Others v UK* [GC] (2003) 37 EHRR 28 [104]). A governmental decision-making process concerning complex issues such as those in respect of environmental and economic policy must necessarily involve appropriate investigations and studies in order to allow the authorities to strike a fair balance between the various conflicting interests at stake. This does not mean that decisions can only be taken if comprehensive and measurable data are available in relation to each and every aspect of the matter to be decided. What is important is that the effects of activities that might harm the environment and thus infringe the rights of individuals under the Convention may be predicted and evaluated in advance - *Hardy and Maile* at [220]. Moreover, the public must have access to the conclusions of the relevant studies, allowing them to assess the risk to which they are exposed.

70. It is a well-established principle of interpretation of the Convention that it should be construed in line with and in the light of relevant specialist international instruments and other rules of international law (see *VKS* at [455]). This has been especially the case in environmental cases, where the ECtHR has relied directly on the obligation under Article 5(1) of the Arhus Convention in emphasising that Article 8 ECHR attaches particular importance to public access to information that enables them to assess the risks to which they are exposed - *Di Sarno and Others* [107].

The Arhus Convention:

71. Public participation in environmental decision-making is an important procedural safeguard for ensuring the rights protected by Article 8 of the Convention. On this basis, adopting its normal approach to the interpretation of the Convention, the ECtHR has read the provisions of the Aarhus Convention into the obligations under Article 8 –

Grimkovskaya v Ukraine, 38182/03, 21 July 2011; *Di Sarno and Others v Italy*. Article 2(3) of the Arhus Convention provides that the definition of "Environmental information" includes "any information in written, visual, aural, electronic or any other material form on: (a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, **including genetically modified organisms,** and the interaction among these elements." (bold added).

Article 1 Protocol 1 ECHR

72. Article 1 Protocol 1 ("A1P1") protects the peaceful enjoyment of possessions, and their deprivation except where in the public interest and subject to the conditions provided by law. "Possessions" is an autonomous concept which encompasses licences to use property in a particular way and to run a business – *O'Sullivan McCarthy Development v Ireland* App. No.44460, 7 June 2018. The question is whether in the circumstances of the case, the applicant was conferred a substantive interest protected by A1P1. The economic value of a company and its assets are possessions under A1P1. Professional business practices whereby an applicant has built up an established clientele constitute possessions. The applicability of Article 1 of Protocol No. 1 extends, among others, to professional practices, their clientele and their goodwill – *Könyv-Tár Kft and Others v. Hungary*, App. No.21623/13, 16 October 2018.

73. An interference with A1P1 rights will be established where the state has taken measures to control the use of an applicant's A1P1 property interest, including the revocation or change of conditions of licences which affect or determine the running of a business – *Centro Europe 7 SRL and di Stefano v Italy* (GC) app. No.38433/09, 7 June 2012; and the imposition of positive obligations on land owners arising from the business on their land - *Denev v Sweden*, App. No.12570/86, 18 January

1989. Further, there is a general rule which covers state interference with possessions, which includes, for example the imposition of town-planning policy, and the approval of land use - *Katte Klitsche de la Grange v. Italy*, App. No.12539/86, 27 October 1994.

74. In order to satisfy A1P1, any interference must meet a requirement of lawfulness. That duty imposes an obligation against arbitrariness. The applicable provisions of domestic law must be sufficiently accessible, precise and foreseeable in their application. The law must be formulated with sufficient precision to enable citizens to regulate their conduct by foreseeing to a reasonable degree the consequences an action may entail - *Centro Europe 7 SRL and di Stefano v Italy (GC)* at [141]. A legal norm is foreseeable when it provides a measure of protection against arbitrary interferences by the public authorities. Any interference with the peaceful enjoyment of possessions must, therefore, be accompanied by procedural guarantees affording to the individual or entity concerned a reasonable opportunity of presenting their case to the public authorities for the purpose of effectively challenging the measure - *Lekić v. Slovenia* (GC), App.36480/07/, 11 December 2018.

75. As with Article 8 ECHR, provided it meets the requirement of lawfulness, a measure constituting an interference with a claimant's A1P1 rights must satisfy the proportionality test.

76. A1P1, like Article 8, also places positive obligations on states to take measures to protect claimants' property interests. The "effective exercise of the right protected by [A1P1] does not depend merely on the State's duty not to interfere, but may require positive measures of protection, particularly where there is a direct link between the measures an applicant may legitimately expect from the authorities and his effective enjoyment of his possessions" - *Öneryıldız v. Turkey* (GC), (2005) 41 EHRR 20 at [134].

The Human Rights Act 1998

77. Both Article 8 and A1P1 are rights scheduled to the Human Rights Act 1998 and public authorities are therefore under an obligation to act compatibly with them in accordance with s.6 HRA. Proceedings may be brought by a victim of such an act under sections 7 and 8 HRA.

The Habitats Directive and the Habitats Regulations

78. As noted above, the Regulations will also allow for the production and release into the environment of plants for purposes other than food including conservation and other purposes. All or any of those plants (including trees, grasses, flowers, lichens and algae) may be released or grown in a way which could impact on protected areas designated by reference to the EU Habitats Directive.

79. Such releases potentially amount to a plan or project falling within the scope of Article 6(3) of the Directive and Regulation 63 of the Habitats Regulations which now give it domestic effect. The requirements flowing from that were summarised by (among others) Lindblom SPT in *R (Wyatt) v Fareham Borough Council* [2022] EWCA Civ 983 at [9]. We have seen no evidence that the SSEFRA considered whether adverse impacts on protected sites could be precluded so as to obviate the need for any appropriate assessment, let alone any sustainable conclusions on those points.

80. Regulation 9(1)/(3) of the Habitats Regulations also required compliance with Article 6(2) of the Directive so as to promote (and certainly not undermine) the conservation status of protected sites which might be impacted by the release of precision-bred GMOs. Again, we have not seen evidence of the SSEFRA even considering those matters in the context of the making of the Regulations, let alone any sustainable conclusions that would secure compliance with those obligations.

81. We note in this context that even if the view had been taken (and were sustainable on the basis of assessment and evidence, rather than assertion and assumption) that precision-bred GMOs created no greater risk to protected sites than plants which could have occurred in nature or through traditional breeding (and we see no evidence of any such view being taken), then that would be no answer in relation to protected sites, since plants which occur in nature or which could arise through traditional breeding clearly can have harmful effect on such sites and their conservation status (such that release of them would be contrary to the requirements of the Habitats Directive and Habitats Regulations).

PROPOSED GROUNDS OF CHALLENGE

82. The potential claimants consider SSEFRA to have acted unlawfully on the following grounds.

GROUND 1: BREACH OF ARTICLE 8 AND THE ARHUS CONVENTION

83. The positive obligations under Article 8 ECHR must be construed in the light of the provisions of the Arhus Convention, including the GMO Arhus Amendment. The Regulations breach the GMO Arhus Amendment, and therefore Article 8 EHCR, on the basis that there is no provision for early and effective information or public participation, as required by Article 6 bis (1), prior to PBOs placed on the market and released into the environment.

84. Neither the notification process under Regulation 5, or the application process for precision-bred confirmation under Regulation 5 provide for participation or the provision of information to the public regarding the release/PBO. There is no obligation on the SSEFRA to publish the reasons that a release of a PBO is to be made. There is no provision in the marketing process, or the process of authorisation for food and feed produced from PBOs, for public participation prior to decisions being made. The public will only be notified of inclusion on the precision

breading register (Regulation 10) and the food and feed register (Regulation 35) after the event. The Regulations themselves constitute a breach Article 6 bis read with Annex I bis because they breach the duty to lay down a regulatory framework providing for arrangements for effective information and public participation.

85. That plainly adversely impacts among others consumers, farmers and people running food businesses, who will be denied effective information in relation to PBOs which are likely to have very significant impacts on their consumer choices, professional lives, and environmental rights, at the same time as being denied any opportunity to participate in decision making in relation to the PBOs release.

86. To the extent that the SSEFRA relies in response on the proposition that PBOs are somehow not within the scope of the Aarhus Convention that is based on an untenable construction and understanding of the provisions of that Convention. We note in this context that the Attorney General has emphasised the Government's intention to uphold the rule of law including through the UK 'clearly, and without question, honouring our obligations under international law' (Attorney General's 2024 Bingham Lecture on the rule of law, published 15.10.24.). That has clearly not happened here.

GROUND 2: BREACH OF ARTICLE 8 AND/OR A1P1

Article 8 ECHR

87. The Regulations engage the potential claimants' Article 8 rights, firstly, by way of their profession as farmers and owners of food businesses including organic farmers and food businesses. The particular identification of a farmer or food business owner as organic is a professional one, but also one which is integral to their personal social identity. It its fundamental to the way they construct their social and professional identity.

88. Furthermore, the identification of a farmer (or food producer) as organic is intrinsically linked to the assurance that their food that does not present environmental and/or health risks, in contrast to non-organic food, and in particular GMOs. The Regulations, of course, imperils their regulatory authorisation and public certification as being 'organic'.
89. But the point also goes further than that because their operation and livelihood as organic farmers or food producers relies in part on consumer choices which are made on the basis of people's concerns and perceptions as to the nature of the food they are purchasing and eating (even where – which we do not accept is the case here– those concerns and perceptions may be misplaced). In practice, (for lack of labelling or notification, as is allowed for by the Regulations) such farmers and businesses will thus be adversely affected by consumer choices made by people not prepared to take the risk that the produce in question, though proclaimed as organic, nonetheless in fact contains or is contaminated by precision-bred GMOs.
90. Further or in the alternative, Article 8 applies here by reason of the risks of harm created by the Regulations and the roll-out of PBOs without sufficient regulatory oversight or public consultation.
91. The Regulations constitute an interference with the potential claimants' Article 8 rights.
92. That interference is not in accordance with the law. No system has been set down to provide for how organic farmers or food producers can or should regulate their business and farming so as to avoid or even mitigate those risks. They do not set out requirements for labelling and do not set out requirements or standards for segregation of supply chains. The upshot is that organic farmers/producers cannot foresee how to regulate their conduct so as to comply with the Regulations and protect their Article 8 rights (if indeed that is possible at all). The key guidance setting out the types of genetic changes introduced by

biotechnology that will determine a plant to be a PBO under Part 1 of the Act has not been published.

Article 1 Protocol 1

93. As above, the production of untraceable PBOs under the Regulations places organic farmers and food businesses directly at risk of breaching the conditions of their professional/regulatory licences (which require their produce to be PB GMO free).

94. Such releases also pose direct risks to organic farmer's land and possessions (including livestock) through environmental and food-chain contamination.

95. The DMA recognised (although makes no effort to quantify) the economic impact this will have on organic farmers and food businesses.

96. Such contamination also poses a direct threat to established business clientele built up by such farmers and food businesses, who are likely to exercise their choice to purchase from sources which are not subject to untraceable contamination risk.

97. The Regulations therefore constitute an interference with the potential claimants' A1P1 rights. Furthermore, that interference is not in accordance with the law, for the reasons set out above.

Proportionality

98. Further or in the alternative, the Regulations do not satisfy the proportionality test. The objective of the Regulations, as per the Act (as discussed below) is to permit the release of PBOs safely, in a way which does not pose risks to the environment or human health.

99. Whilst it is accepted in principle that is a legitimate aim, the Regulations come nowhere close to being rationally connected with it. They preclude the labelling as PBO of PBO seeds and food products without explanation or justification; they provide no mechanism for ensuring

that something which is claimed to be a precision-bred GMO in fact contains no other genetic changes without explanation or justification ; and in circumstances where the possibility even of testing for (or taking into account the results of any third party testing for) risks which go beyond those associated with plants produced by traditional breeding has been specifically outlawed without explanation or justification.

100. They have been made subject to the failures of inquiry set out in relation to Ground 3 below; the failures to provide for effective participation and information in Ground 1 above; and the failures of inquiry set out in relation the Habitats Regulations below.

101. Given those failures, it cannot sensibly be argued that less intrusive measures to the Claimant's Article 8 and A1P1 rights could not have been used to achieve the Regulations' objective, or that having regard to the measures' consequences, a fair balance has been struck between the rights of the individual and the rights of the community.

Positive Obligation

102. Further or in the alternative, the Regulations constitute a breach of the Defendant's positive obligations under Article 8 ECHR and/or A1P1.

103. As above, there has been a breach of the obligation to provide sufficient information to the public, and to make arrangements for effective information and public participation.

104. The decision-making process in respect of the Regulations was flawed. It did not take any or adequate account of the impact of the non-traceability of PBOs on organic producers, nor did it take adequate account of the trade risks internally within the UK and in trade with Northern Ireland and the EU. The Regulations make no, or insufficient provision for consumer information about precision-bred GMOs when placed on the market; information enabling food producers to reassure

consumers about their products; and protection of property rights to enable farmers and landowners to prevent contamination of their land and crops by precision-bred GMOs grown nearby.

105. Indeed, the problem is not limited to organic farmers/food producers. It will impact any farmer/producer who wishes to export their produce (including meat and dairy arising from animals which might have been fed on precision-bred GMOs) to the EU. We anticipate that, as above, such producers – unable as will be the case to ensure that their produce is not free of GMOs – will be adversely affected in their access to the EU market.

GROUND 3: BREACH OF TAMESIDE DUTY/LACK OF LOGIC

106. The common law *Tameside* duty required the Defendant, in making the regulations, to have "[asked] himself the right question and take reasonable steps to acquaint himself with the relevant information to enable him to answer it correctly" - *Secretary of State for Education and Science v Tameside MBC* [1977] AC 1014. It imposes a substantive duty of sufficient inquiry. - *R (Plantaganet Alliance Ltd) v Secretary of State for Justice* [2014] EWHC 1662 (Admin) at paras [137]–[139]. The duty requires the decision maker to call his own attention to considerations relevant to his decision, which in practice may require him to consult outside bodies with a particular knowledge or involvement in the case – *R (Balajigari) Secretary of State for the Home Department* [2019] 1 WLR 4647 at [70]. The wider the discretion conferred on the Secretary of State, the more important it must be that he has all relevant material to enable him properly to exercise it - R (Venables) v Secretary of State for the Home Department [1998] AC 407 at [466G].

107. It is clear from the DMA and the Defendant's responses to the concerns raised to the SLSC that it has conducted insufficient inquiry

into the potential effects of crucial aspects of the Regulations. Those include:

a. The risk of the contamination of organic supply chains.

b. Prohibiting the SSEFRA from using any test on authorisation under Regulation 30 which could not be used on any food or feed not produced with modern biotechnology as set out in Ground 5.

c. The adverse effect on businesses which rely on consumer choices around the integrity of such food chains.

d. The feasibility of co-existence and segregation measures for organic produce.

e. The financial impact on the organic sector.

f. The failure to assess or quantify the negative economic impact of the Regulations on trade either internally within the UK or with the EU.

g. The corresponding failure to conduct a full economic impact assessment. This was a breach of the Better Regulation policy Guidance. The department plainly has not demonstrated that the Regulations' economic impact will be less than plus or minus £10 million. The SSEFRA simply ignored the very significant impact on trade internally within the UK and between the UK and EU when determining whether or not to conduct a full impact assessment.

h. The failures to provide for effective participation and information in Ground 1 above, which breach the duty to consult with bodies with particular knowledge, expertise or experience of the case; and the failures of inquiry set out in relation the Habitats Regulations as below.

108. Insofar as there was consideration by the SSEFRA (for the purpose of making the Regulations) of those matters, then it appears to us to

have been based on assertion and assumption, rather than any actual evidence; insofar as it relied on any expert evaluation, then of course the SSEFRA will need (per *R (Mott) v Environment Agency* [2016] 1 WLR 4338 at [64]) to explain the basis for that to the court.

GROUND 4: BREACH OF HABITATS REGULATIONS

109. As explained above, there is no evidence that the SSEFRA even considered the discharge of obligations under the Habitats Regulations (including Regulation 63 and, for the purposes of Article 6(2) of the Directive, Regulation 9) let alone has lawfully done so to reach lawful conclusions about the impact on protected sites of the release generally or specifically of precision-bred GMOs.

110. As above, we note the necessary implication of the removal of such releases from the provisions of the Environmental Damage Regulations (something which would not have been required if such releases were not capable of creating any environmental damage).

GROUND 5: ULTRA VIRES

111. The interpretation of a statutory provision conferring a power to make secondary legislation is to be effected in accordance with normal principles of statutory construction. The content of Regulation 30 of the Regulations is outwith the scope of the enabling power under s.26 of the Act in two respects.

112. First, Section 26(3), is clear that "Regulations... 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—

..

(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."

113. Section 26(3) thus requires that any requirements imposed under Regulations for the securing the safety related factors under s.26(3)(b) are "**requirements that must be satisfied** in order for the Secretary of State to issue a food and feed marketing authorisation" (emphasis added). "Requirements" indicates, on an orthodox construction, objective determinable tests which the SSEFRA must be satisfied of in order to issue an authorisation.

114. However, Regulation 30(3) goes well beyond the scope of that enabling power. Rather than imposing objective determinable requirements that must be satisfied for an authorisation to be granted, it simply gives the SSEFRA a subjective discretion to determine for himself whether the safety factors in section 26(3)(b) of the Act are satisfied, as follows:

(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.

115. That plainly goes beyond Parliament's intention in enacting the enabling power. Section 26 could have said "Regulations may be made prescribing factors the Secretary of State must be satisfied of in order to grant an authorisation…" - but it did not. The intention of Parliament was that the Regulations would include objective requirements in relation to the requisite safety factors. Any such Regulations would have enabled the general public, as well as those with specific interests such as the potential claimants, to see the relevant safety requirements set down in Regulations.

116. Second, subordinate legislation may be ultra vires if it is outside not just the words, but also *the purpose* of the enabling power – *R (Public Law Project) v Lord Chancellor* [2016] AC 1531. Regulation 30(4). The purpose of the Act was, as above, to ensure that any precision bred GMOs would be released in a safe way that does not pose (or minimises to the greatest extent possible) risks to the environment and human (and animal) health, as well as to businesses and consumers affected by it. Regulation 30(4)(b), which precludes the SSEFRA, in determining for himself whether the safety factors in section 26(3) of the Act are met, from using "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" is incompatible with the Act's safety related purpose. It prevents (with no rational foundation) any test which may determine the safety or presence of a precision-bred GMO (but which is not already used in relation non precision-bred GMO food and feed) from ever being deployed during the authorisation process, in circumstances where the Government accepts that such food and feed is currently untraceable. It thus prevents safety related tests in relation to precision bred GMOs which may already be available, which or may become available in the future, from being used in order to determine safety. In the alternative to Regulation 30(4) being ultra vires section 26 of the Act, for the reasons set out above, it is irrational.

DETAILS OF THE ACTION THE DEFENDANT IS EXPECTED TO TAKE

117. Please confirm the Defendant will:

a. Take the necessary steps to bring about revocation of the Regulations urgently and in any event before they take effect;

b. Commit to undertaking and publishing before enacting further regulations a comprehensive impact assessment of the Act and Regulations including on farmers and food producers including those who are organic and/or who wish to export to the EU.

118. If SSEFRA refuses to take the above steps, then the Claimant intends to bring a claim for judicial review in which it will seek: (i) a quashing order revoking the Regulations 2025; (ii) a declaration that Regulations were unlawful; and (iii) its costs.

ALTERNATIVE DISPUTE RESOLUTION

119. We do not currently consider that this issue is suitable for alternative dispute resolution but would be pleased to consider any proposals you have for this.

AARHUS COSTS PROTECTION

120. The proposed claim is plainly an environmental claim that falls within the scope of the Aarhus Convention. Please confirm in response that you do not contest the application of the Aarhus Convention and that any claim will benefit from the costs capping provisions under CPR 46.24.

INFORMATION AND DOCUMENTS SOUGHT

121. Please provide the following under SSEFRA's duty of candour:

a. What was the SSEFRA's understanding and what information was considered by the SSEFRA personally[13] for the purposes of making the Regulations on the following matters:

i. The absence of risk of harm to human health;

ii. The potential adverse impact on farmers and food businesses which are organic (or which grow/produce/market with a view to being, and being seen to be, GM free), including how such businesses will be able to demonstrate to trading partners, regulators and consumers that their produce has not been directly or indirectly contaminated by precision bred GMOs;

iii. The potential adverse impact on licensing arrangements for organic farmers and food businesses;

[13] To be clear: that does not include information which might have been considered by civil servants or others which was not then personally also considered by the person who personally decided to make the regulations.

iv. The feasibility of co-existence and segregation measures for organic produce.

v. The potential adverse impact on EU exports, including:

    1. how farmers and food businesses (including meat and dairy farmers/businesses) which wish to export to the EU (whether organic or 'conventional') will (or will not) in practice be able to satisfy trading partners and/or EU regulatory authorities that their produce has not been directly or indirectly contaminated by GMOs (within the meaning of EU law); and

    2. The impact on their EU exports of not being able to do so.

vi. The potential adverse impact on trade with Scotland, Wales, and Northern Ireland;

vii. The potential adverse impact on protected sites;

viii. The potential impact on the safety and traceability of precision bred PBO releases of prohibiting the SSEFRA from using any test on authorisation under Regulation 30 which could not be used on any food or feed not produced with modern bio-technology;

ix. The adverse effect on farmers and food businesses which rely on consumer choices around the integrity of their production and food chains;

x. Any justification for not requiring precision-bred GM seeds and items derives from them not to be clearly labelled as such;

xi. Any justification for not allowing for or requiring the testing of materials claimed to be precision-bred GM to ensure that they are that;

xii. Any justification for restricting the nature or range of the testing to be undertaken on precision-bred materials as part of the assessment of their safety;

xiii. The balancing and evaluation of any such justifications against those adverse impacts.

b. All and any documents or other materials which evidence the SSEFRA's understanding or consideration for the purposes of making the Regulations of the matters in subparagraph a above.

122. This material should be disclosed now, at pre-action stage. The Treasury Solicitor's own Guidance on Discharging the Duty of Candour and Disclosure in Judicial Review confirms the duty of candour applies to every stage of proceedings, including letters of response under the pre-action protocol. Similarly, the Administrative Court Judicial Review Guide provides at [15.3.2] that "[t]he duty of candour has been recognised as applying at, or even before, the permission stage as well as at the substantive stage."

123. If the Defendant fails to disclose a document or other item now, which it later relies on in defence of this claim, then we reserve the right to bring this to the Court's attention when it comes to the matter of costs. Moreover, as a matter of law, a claimant in a judicial review cannot be prejudiced at the permission stage due to an absence of documents, and the existence of such further material (which may be critical to the arguability of the claim) is capable of being a good reason in and of itself to grant permission to bring a claim for judicial review: *R (Blue Sky Sports & Leisure Ltd v Coventry City Council* [2013] EWHC 3366 (Admin) at [25].

124. As is clear, the court must be supplied with all the information necessary, including through pre-action disclosure, in order to determine any permission stage on an accurate footing: *R (HM & others) v Secretary of State for the Home Department* [2022] EWHC 2729 (Admin) at [15-16, 39].

ADDRESS FOR REPLY AND SERVICE OF DOCUMENTS

125. The address for your reply is: Leigh Day, Panagram, 27 Goswell Road, London, EC1M 7AJ. Please send by email to the addresses given in our letterhead.

126. In your response, please provide confirmation that you are willing to accept service of the claim form and supporting documents by email and, if so, please confirm the correct email address for service.

PROPOSED REPLY DATE

127. Please provide a substantive reply to this letter within 14 days (i.e. by 6pm on 30 June 2025).

Yours faithfully

Leigh Day.

LEIGH DAY