LEGAL REASONING
THE GENETIC TECHNOLOGY (PRECISION BREEDING) BILL

Prepared for Beyond GM/A Bigger Conversation by
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The proposed Genetic Technology (Precision Breeding) Bill defines a "precision bred" organism in Part 1, (2) (c) (i) & (ii), as a product of modern biotechnology which, in addition is the same as what could be achieved through a "traditional breeding process"[2] and/or as the product of a "natural transformation".

Use of these words is:

1. Factually, legally and scientifically problematic.
2. Is unlikely to improve the natural environment in a manner capable of being objectively measured.
3. Probably poses an inherent, endemic risk to the environment.
4. Is likely to mislead consumers and the wider public that use thereof is common, traditional, natural, conventional, and therefore safe.

1. Factually, legally and scientifically problematic

1.1 The legal basis of the proposed Bill is environmental law.[3]

1.2 To establish whether there is any merit under environmental law to define genetic precision bred plant biotechnology as "traditional" and/or "natural" the novelty,[4] inventiveness[5] and industrial criteria[6] in patent law can be used as an objective scientific and legal baseline to stress-test this proposition.

1.3 Where a genetic technology (precision engineered) plant/animal breeding process for a living organism (including plants) has been granted a patent[7] and/or a related genetic *sui generis* right such as a Plant Variety Right (PVR)[8] under either national or international law we know they cannot be the result of a traditional process or a natural transformation.[9]

1.4 It is a long-standing condition of national and international patent law and related *sui generis* rights that to be granted monopolistic rights the engineered technology must be novel[10] or new[11], invented by man not by nature,[12] be a cultivar[13] nor a wild species created through natural mutation[14] and capable of industrialisation.[15]

1.5 Any invented processes and/or transformations found to be either traditional or natural could - as a matter of long-standing legal principle in IPR law - be denied or revoked.[16]

1.6 Plant breeders in possession of a national, European, or international patent or related *sui generis* right for a genetic precision bred technology must be made aware that their monopoly rights can be revoked if the Bill becomes law and describes their technology as either a) "traditional breeding process" or b) "natural transformation".

2. Is unlikely to improve the natural environment in a manner capable of being objectively measured.

The proposed Bill is based on environmental law – the Environment Act 2021 - the stated intention of which is 'Improving the Natural Environment'.[17] Improving the natural environment is to be realised through a standard, 'which must be capable of being objectively measured'[18]. Targets to be prioritised under the EA 2021 includes, *inter alia* the 'natural environment', [19] and 'biodiversity'.[20]

2.1 It is impossible to measure, objectively, how genetic precision bred engineering biotechnology standards can improve (i) the natural environment and (ii) biodiversity.

2.2 The legally and technologically objective baseline of absolute novelty in patent law and related *sui generis* rights offers environmental law insights into the limits of measuring future outcomes objectively.

2.3 It has already been established in early environmental case law that where novel technologies (including novel biotechnologies) are operating on the frontiers of science it is deductively logical and self-evidently true there is no history of use and limited to no data on which to make any objective measurement.[21]

2.4 As a result, it is impossible for regulators to create measurable or objective standards that can improve the natural environment for biodiversity.

3. Probably pose an inherent, endemic risk to the environment.

3.1 What a number of case studies[22] based on empirical data[23] prove is that on the balance of probabilities the environment *is at risk* from the introduction of novel, anthropogenic and industrial activities which have been commercialised in the absence of data.

3.2 The introduction of reconstituted protein meal from sheep infected with scrappies, by way of example, led to scrappies spreading for the first time to cattle and from there to the human population.[24] This was not foreseen by anyone in DEFRA or scientists when the *novel practice* of feeding reconstituted protein pellets to cattle was first marketed and sold to British farmers and from there to the wider public. It left a big reputational stain on British agriculture and closed off international markets (not just the EU market) to British farmers for decades.

3.3 The removal of risk assessment, as proposed in the Bill, ignores the uncertain and potentially negative effects, radical novel, untested, manmade and industrialised activities have on the environment, and which can often take years to materialise.

4. Is likely to mislead consumers and the wider public that use thereof is common, traditional, natural, conventional, and therefore safe.

4.1 There is a lot of common knowledge on the safe consumption of traditional, conventional, and natural foodstuffs and food processes. As a result, there is widespread societal and consumer confidence in traditional, conventional, and natural food processes and products.

4.2 As a matter of legal and scientific fact it is possible to establish that a precision bred technology (both process & end product) [25] which has been awarded either a modern biotechnology[26] patent and/or related genetic *sui generis* right cannot be traditional, cannot be natural and cannot be conventional. Were they to be either conventional, traditional and or natural their monopoly rights are at risk of being revoked by the patent authorities.

4.3 It is therefore misleading to state in law that these products and processes are traditional and natural and as result require reduced safety oversight and no risk assessment.

4.4 Plant breeders in possession of either a modern biotechnology patent and or related *sui generis* right based on genetic precision breeding are fully aware that their invention is neither traditional, nor conventional nor natural.[27]

4.5 As a result, any legal or natural person in possession of a modern biotechnology patent or related genetic, biotechnology precision bred *sui generis* right seeking to release, market and commercialise through direct sale or licensing of either the process or the end product as traditional, natural, is knowingly, intentionally, and possibly fraudulently misleading English consumers.

4.6 Some may choose to take the risk anyway, however, there is little doubt that such misleading claims will leave patentees~~,~~ food manufacturers, farmers, and retailers highly vulnerable to legal action and significant reputational damage.

4.7 It also leaves patentees vulnerable to having their monopoly rights revoked by public patent authorities.

5. Conclusion

5.1 If passed as it stands there is high level of probability that the 'traditional' and 'natural' definitions will be contested. It could lead to existing precision bred genetic biotechnology patents and related genetic *sui generis* rights being revoked.

5.2 The lack of measurable, objective data for safety standards to improve the natural environment as required under EA 2021, s.1.4.(a). could be challenged on health and environmental safety grounds.

5.3 It is highly possible that it will cause friction in trade with the UK's international trading partners in the EU and elsewhere.

5.4 At the very least, and in order to be fully aligned with existing national and international IPR law, genetic engineering technology regulation and UK environmental law as expressed in the EA 2021, the proposed Bill should be amended to state that any marketing and commercialising of genetic technology (precision bred) processes and end products should be clearly defined, sold, labelled and marketed as:

- novel,
- untested,
- probably unsafe,
- manmade,

- anthropogenic, and
- industrial.

Anything short of this is legally and scientifically untrue, misleading, potentially fraudulent to end users and vulnerable to legal action under patent revocation law and consumer law.

References

[1] The views and opinions in this briefing are solely those of the author and not those of Wageningen University Law Group.
[2] The list of proposed technologies defined as a "traditional process" includes, under proposed s.1(1)7 includes technologies such as *in vitro* fertilisation, polyploidy induction, embryo rescue, induced mutagenesis, or somatic hybridisation or cell fusion of plant cells of organisms which are capable of exchanging genetic material, recovery and transfer of primordial germ cells.
[3] See Environmental Statements to the Proposed Bill made by Lord Benyon, "under section 20(2)(a) and (3) of the Environment Act 2021. "In my view (a) the Genetic Technology (Precision Breeding) Bill contains provision which, if enacted, would be environmental law, and (b) the Bill will not have the effect of reducing the level of environmental protection provided for by any existing environmental law."
[4] Patents Act 1977 s. 1(1) A Patent may be granted only for an invention on condition (a) the invention is new.
[5] Patents Act 1977 s. 1(1) A Patent may be granted only for an invention on condition (b) it involves an inventive step. (Interpreted to mean manmade transformation not a natural transformation).
[6] Patents Act 1977 s. 1(1) A Patent may be granted only for an invention on condition (c) it is capable of *industrial* application.
[7] Patents on living organisms including genetic precision bred biotechnology plants has been available in Europe since the early 1990's. For an evolution of European case law on the patenting of living organisms see M. Llewelyn & M. Adcock. For a statistical analysis on the growth in biotechnology patent globally see J. Martin-Laffon et al, 'CRISPR patent landscape shows strong geographical biases' *Nat Biotechnol* 37**,** 613– 620 (2019).
[8] International Convention for the Protection of New Varieties of Plants (UPOV Convention) (emphasis authors); Regulation 2100/94/EC on Community Plant Variety Rights, 27 July 1994. (CPVR Regulation), Article 6 'Protectable Varieties' (d) 'new'.
[9] Patents Act, 1977 s1.2 amended by Patents Act 2004, European Patent Convention (EPC) 2000, Article 52 (2) 'Non-patentable Subject Matter' (a) discoveries. This includes, "To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable." EPO Guidelines, Part G-II, para 3.1. For US case law see *Mayo Collaborative Sevs v Prometheus Labs. Inc* 132 S Ct 1289 [2012] and *Myriad v Association of Molecular Pathology*, 569, US Supreme Court [2013].
[10] Patents Act 1977 s. 1(1) (a), "A Patent may be granted only for an invention on condition the invention is new"; European Patent Convention (EPC) 2000, Articles 52 'Conditions for Patentability', "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, …" Article 54 'Novelty' (1) "An invention shall be considered to be new if it does not form part of the state of the art. (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application."; U.S. Code s 101 "Inventions Patentable", "Whoever invents or discovers any new and useful process machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

[11] UPOV Convention, Article 5 'Conditions of Protection' (1) (i) Plant Breeders can be granted a right if the plant variety is "new"; and CPVR Regulation, Community plant variety rights shale be granted if the variety under Article 6 'Protectable Varieties' (d) is 'new',

[12] Patents Act 1977 s. 1(1) (b) "A Patent may be granted only for an invention on condition it involves an inventive step"; European Patent Convention (EPC) 2000, Articles 52 'Conditions for Patentability', "European patents shall be granted for any inventions, in all fields of technology, provided that they … involve an inventive step..," U.S. Code s 101 "Inventions Patentable", "Whoever invents or discovers any new and useful process machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." In the case of biotechnology patents "inventive step" is interpreted, inter alia, to mean it must have a technical effect, be engineered and created by man not by nature. See, T741/91 HOWARD/FLOREY/Relaxin [1995] EPOR; EPO Guidelines, Part G-II, 3.1 "a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy." Part G-II, 'Patentable Biotechnological Inventions' 5.2 (i) 'Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature' and 5.2 (ii) "…techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself."; EPO Guidelines, Part G-II, 3.1 'Discoveries'. "If a new property of a known material or article is found, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable." For US case law on manmade inventiveness see *Mayo Collaborative Sevs v Prometheus Labs. Inc* 132 S Ct 1289 [2012] and *Myriad v Association of Molecular Pathology*, 569, US, Held, 'A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but synthetic complementary DNA ("cDNA") is patent eligible because it is not naturally occurring."

[13] CPVR Regulation, Article 11, rights awarded to "the person" as in "the breeder" who "developed" the variety. It is generally recognised in plant breeding that only a person can breed or develop a cultivar in order to distinguish them from natural mutation where new traits are created through nature not by man. See also, International Society for Horticultural Science, (ISHS) International Code of Nomenclature for Cultivated Plants, 9th ed. a, Cultivars are describes as a "taxa of plants whose origin or selection is primarily due to intentional human activity.", Preamble 8, "These are deliberately selected plants that may have arisen by intentional or accidental hybridisation in cultivation, by selection from existing cultivated stock, or from variants within wild populations or from genetically modified crops." (emphasis added). https://www.ishs.org/sites/default/files/static/ScriptaHorticulturae_18.pdf Last accessed 2 December 2022.

[14] As catalogued by the International Botanical Congress (IBC) in 'Nomenclature for algae, fungi and plants (ICN)' [2018], Shenzen, China. A botanic is generally considered a wild plant discovered in nature as opposed a cultivated plant intentionally and deliberately selected to be bred by mankind for horticultural, agricultural or forestry purposes. New botanical varieties come about through natural mutation not induced manmade mutations. https://www.iapt-taxon.org/nomen/main.php last accessed 2 December 2022.

[15] Patents Act 1977 s. 1(1) (c) A Patent may be granted only for an invention on condition it is capable of industrial application; (EPC) 2000, Articles 52 'Conditions for Patentability', "European patents shall be granted for any inventions, in all fields of technology, provided that they…are susceptible of industrial application." U.S. Code s 101 "Inventions Patentable" see 'utility' requirements; EPO Guidelines for Examination, 4.9 'Industrial Application', '...in relation to certain biotechnological inventions, i.e. sequences and partial sequences of genes, the industrial application is not self-evident. The industrial application of such sequences must be disclosed in the patent application." And "In general it is required that the description of a European patent application must, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. The invention claimed must have such a sound and concrete technical basis that the skilled person can recognise that its contribution to the art could lead to practical exploitation in industry." See T898/05, "For the purpose of Article 57 EPC and Rules 23e(3) and 27(1)(f) EPC, none of these levels is more fundamental than the other ones insofar as at least from one of these levels a practical application (a profitable use in a wider sense) is derivable in a straightforward manner (cf. points 29 and 30 of the Reasons).

[16] Patents Act, 1977 s. 71 (1), EPC 2000, Article 138.
[17] EA 2021, Chapter 1.
[18] EA 2021, s.1.4.(a). Emphasis added.
[19] EA 2021, s. 1. (1) (a).
[20] EA 2021, s. 1. (3). (c).
[21] For early US judicial insights into the link between novelty and insufficient data to determine safety see, *Industrial Union Department, AFL-CIO v Hodgson*, 499 F2D 467 (DC Cir 1974). (Hodgson) "[S]ome of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination"474; *The Society of the Plastics Industry, Inc v OSHA*, 509 F2d 1301, 1308 (2d Cir 1975). (Society of Plastics) "[T]he ultimate facts here in dispute are 'on the frontiers of scientific knowledge', the factual finger points, it does not conclude", 137; *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1 (D.C. Cir. 1976) "[H]ow can the Administrator determine that a risk is a significant risk if he cannot assess risks?", 21.
[22] European Environment Agency (2001): Late Lessons from Early Warnings: The precautionary principle 1896-2000 (2001 Copenhagen) and European Environment Agency (2013): Late Lessons from Early Warnings: Science, Precaution and Innovation (ed) (2013 Copenhagen)
[23] Hansen and Tickner, 'The precautionary principle and false alarms — lessons learned', (EEA 2013), 17-37.
[24] Patrick van Zwanenberg and Erik Millstone, 'Mad cow disease' 1980s–2000: how reassurances undermined precaution', (EEA 2001), 157- 166.
[25] This includes processes and methods such as (but not limited to) *in vitro* fertilisation, polyploidy induction, embryo rescue, induced mutagenesis, or somatic hybridisation or cell fusion of plant cells of organisms which are capable of exchanging genetic material
[26] Patents Act 1977, s 1 (1) (a); European Patent Convention 2000, Articles 54 & 55; 35 U.S. Code s 101 "Inventions Patentable".
[27] See by way of example how the CRISPR Cas-9 pioneers fought bitter battles to claim novelty for their patents in J. Cohen, 'How the battlelines over CRISPR were drawn' *Science Magazine*, 17 February 2017 https://www.science.org/content/article/how-battle-lines-over-crispr-were-drawn ; and J. Cohen 'The birth of CRISPR' *Science Magazine*, 17 February 2017 https://www.science.org/doi/10.1126/science.355.6326.680