

# Genetic Technologies (Precision Breeding) Bill

Commentary by Dr Pete Mills, Assistant Director, Nuffield Council on Bioethics

15 June 2022

The [Genetic Technologies \(Precision Breeding\) Bill](#), promised in the Queen's speech in May, is now before Parliament. Its aim is to facilitate agricultural and aquacultural innovations that involve the use of molecular techniques to make alterations in the genomes of plants and animals.<sup>1</sup> Taking advantage of the greater legislative freedom obtained by the UK's departure from the European Union, the Bill sets out a new governance framework that is intended to replace the retained scheme, which has existed for three decades under EU law, for certain classes of genetically altered organism. Almost no one – including EU lawmakers – thinks that this existing regime is fit for purpose, but it has become a strategic 'no-man's land' in the trench warfare over competing visions of agricultural food production. The idea is that while the EU moves glacially towards legislative review, the UK will set off an avalanche of innovation.

In our 2021 report, [Genome editing and farmed animal breeding: social and ethical issues](#), we argued that the distinctive ethical issues relating to the genetic alteration of farmed animals required more careful consideration than they had hitherto received. Our report offered a contribution to this. We concluded that, if new genetic technologies were to be introduced in livestock breeding and aquaculture, this should not be done until a revised governance system with clear standards and aims was in place. We set out a number of recommendations on governance, which may be summarised in three points: (1) the establishment of transparent and meaningful standards for farmed animal breeding, (2) improved collection and reporting of data to demonstrate these standards were being met, and (3) the empowerment of an appropriate body to ensure compliance with those standards, in the light of those data. More importantly, however, this should function as part of a system of appropriate incentives and controls that would shape the food and farming system to respond to the profound societal challenges it faces, and it should do so in a way that does justice to those whose capacity to thrive and flourish depends upon that system.

## *The Bill*

The precision breeding Bill is a kind of promissory note. Most of the detail remains to be determined, at some time in the future, through Regulations. What is on offer is really a framework for the governance of 'precision bred organisms' (the preferred rubric for a certain subset of genome edited organisms, those that are indistinguishable from organisms that might have come about through more established breeding methods). While Defra have indicated their intention to review the governance of all products of 'modern biotechnologies', the long title and

---

<sup>1</sup> This includes some photosynthesizing microorganisms.

provisions of this Bill do not allow its extension to transgenic GMOs – those containing DNA sequences derived from other species – or more creatively edited organisms. It is no doubt a prudent tactic to focus on securing more modest aims, though this may turn out to be at the expense of reinforcing the moral distinctness of the different classes of technology. This could be counterproductive: the different techniques generally have different ranges of potential application while, for some purposes, different techniques might need to be used in conjunction. Quick wins for genome editing may come at the cost of a prolonging the path for transgenic technologies rather than drawing them along in their slipstream. This is difficult to predict.

So what does the framework offer? The Bill covers precision bred plants and animals, though not fungi and microorganisms (either single cells or colonies). Firstly, to move beyond experimental, contained use, a ‘release notice’ must be obtained (cl.3). (This subsumes the provisions of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, made earlier this year to enable plant research.) Further information requirements for the submission of release notices may be specified in Regulations (cl.4).

Next, to place a precision bred organism, its progeny or products (including gametes) on the market in England a ‘precision bred confirmation’ is required. The ‘precision bred confirmation’ requires a ‘marketing notice’ to be submitted, containing information that may be further specified in Regulations (cl.4). Endorsement of the notice by the Secretary of State will be subject to advice from the Advisory Committee on Releases to the Environment (cl.22). The scope of this advice is limited, however, to whether or not the product in question is, indeed, a precision bred organism and implicitly, therefore, one that could have come about through either ‘traditional processes’ (something of a *faux ami*) or natural transformation (cl.1(2)(c)). We know already, from ACRE’s advice, cited in [Defra’s response](#) to the findings of their own 2021 consultation, that ACRE does not see a problem with releases of many genome edited organisms as they ‘would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism.’ And ACRE is formally concerned with little beyond this narrow conception of risk (Part VI of the EPA 1990 and the GMO Deliberate Release Regulations 2002). In the case of food and feed deriving from precision bred organisms, requirements may be imposed by Regulations to ensure traceability, safety, nutrition (that eating precision bred products, rather than conventionally bred ones, will not be ‘nutritionally disadvantageous’) and that marketing ‘will not mislead consumers’ – although there is no requirement (and apparently no intention) that precision bred products should be labelled as such (cl.26). This is despite the clear findings of an [FSA public dialogue](#) last year that consumers want the opportunity to exercise choice in accordance with their values and preferences. This is troubling in light of the general approach to allow the uses of biotechnology to be shaped by industry and the market: in this context, not labelling amounts to a kind of epistemic erasure, whereby the preferences that many people would wish to inform the system of agricultural production are simply removed from the signals that are fed back through the market. But there are more fundamental problems with this approach itself, as we shall see.

The provisions described so far apply equally to precision bred plants and animals. To place a precision bred animal, its progeny or products on the English market, a 'precision bred animal marketing authorisation' is also required (cl.5 and cl.11).<sup>2</sup> This additional step requires the notifier to submit a declaration that they do not expect the health or welfare of the relevant animal (or its progeny) to be adversely affected by its precision bred traits (cl.11(3)).<sup>3</sup> The declaration must contain the evidence and methodology supporting this conclusion and further information requirements may be specified, once again, in Regulations (cl.11(5)(b)). This declaration must then, in effect, be quality assured by a 'welfare advisory body'. That body remains to be specified by Regulations (cl.12) but is most likely to be a revamped version of the Animal Welfare Committee (supported by a secretariat shared with related bodies – see my previous post ['Animals as sentient beings'](#)). Release notices, confirmations and marketing authorisations, and supporting information, will be included in a statutory register, accessible to the public (cl.18).

In the Bill as currently drafted it is unclear whether declarations and authorisations apply to a type or token when they refer to 'the relevant animal', that is, whether they operate case-by-case or class-by-class. For example, clause 11(3) provides that an application for a precision bred animal marketing authorisation 'must include a declaration that the notifier does not expect the health or welfare of the relevant animal or its qualifying progeny to be adversely affected...by the precision bred trait.' Ignoring, for the moment, some rather abstruse philosophical problems with this, the implication is that we must reach for a normative criterion for these notions of 'health' and 'welfare' when applied to animals of that kind. (This is, to some extent, what the 'breeding indices' used by commercial breeders purport to offer; we address the challenges of composition and periodic rebasing of breeding indices in our 2021 report.) It is important, here, to distinguish between the health of the next animal, and the health effects of a breeding practice on breeds over time, which may scarcely be detectable from one generation to the next. That the latter effects potentially lack any clear purchase in the proposed scheme is a problem, given that the applicable standards are, in effect, established by industry and moved along by successive applications, rather than set prospectively and publicly.<sup>4</sup>

The detail of many of the important elements of the governance system remain to be determined through future Regulations. (Those which impose regulatory burdens on the sector will be affirmative Regulations, the content of which will be debated in Parliament; the information requirements will generally be established through

---

<sup>2</sup> The requirement does not apply to invertebrates, for example, of the sort covered by the Animal Welfare (Sentience) Act 2022, some of which are farmed and some of which are eaten by humans.

<sup>3</sup> 'Precision bred traits' are the ostensible characteristics resulting from a 'feature' of the animal's genome that is brought about by the intervention. This seems to imply a rather neat correspondence between the molecular change and the resulting characteristic and potentially to disregard the more potential pleiotropic effects. See also the comments on cl.1(6) in the footnote below.

<sup>4</sup> The problem of longitudinal drift, to the point where animals may become constitutionally incapable of living a life of adequate quality, was found not to be justiciable – see: *R. (Compassion in World Farming Ltd) v. The Secretary of State for the Environment, Food and Rural Affairs* [2004] EWCA Civ. 1009 per Sedley L.J. at para.57.

negative Regulations). In particular, clause 25 of the Bill creates a power to prescribe when animal health or welfare has been adversely affected by precision breeding. In effect, this is a power to set certain breeding standards and could, potentially, be used to give effect to the kind of ‘traffic light’ system we proposed in our 2021 report (albeit only in respect of ‘precision bred traits’). There is also a power to impose reporting requirements that may involve the submission of – potentially longitudinal – information (cl.14). However, such information need not be placed on the public register if it is determined to be commercially confidential (cl.18(2)). And we have already heard, in the course of our Nuffield inquiry, that commercial confidentiality is the main obstacle to sharing information relevant to judgements about animal welfare, so such information may well remain unavailable for public or academic scrutiny.

Nonetheless, the apparent teasing apart of health and welfare in the Bill is important (as in the disjunctive formulation ‘health or welfare’): there is a tendency among some contributors to the discourse surrounding the effects of animal breeding implicitly to elide the concepts of health and welfare, and even to reduce the concept of welfare to that of health, closing down discussions of animal experience and psychology. Teasing them apart admits the possibility that by breeding animals to be more robust, and therefore better able to endure conditions of poor welfare without manifesting adverse health effects, there is a possibility that improvements in health may lead to reduction in welfare. Consequently, the importance of developing and deploying separate measures of health and of welfare should be recognised when these standards are elaborated.

A further power exists to appoint inspectors to monitor and investigate compliance with obligations under the Act (those relating to submission of the prescribed notices and applications under Part 2 or compliance with directions issued). This could include a power to enter premises and seize documents (cl.20), which is likely to fall to the existing Animal and Plant Health Agency. Enforcement is to be achieved by issuing compliance notices, stop notices or monetary penalties, but stops short of criminal justice measures (cl.32). All of the confirmations and authorisations issued by the Secretary of State are, naturally, subject to suspension or revocation, and determinations and directions may be appealed (cII.9, 15 and 16).

From this brief summary, it should be clear that the Bill could offer responses to a number of the recommendations contained in our 2021 Nuffield Council report. For example, we recommended that specific attention should be given to the potential impact of breeding technologies on animal welfare (rec. 12). The Bill contains provision for scrutiny by a welfare advisory body and an authorisation requirement in relation to this (cl.11). We recommended that there was a need for better collection, recording, reporting and monitoring of data to determine the effects of breeding interventions (rec. 7 supported by recs 4 and 5). There are powers in the Bill to create such requirements (cl.14). We recommended the development of detailed, explicit and enforceable standards for farmed animal breeding (rec.2). As noted, the Bill contains powers to establish and impose these, too (cl.25). But before we allow optimism to carry us away, there are some more general observations that should be made.

## *Language and discourse*

Let's begin with the language. Advocates of genetic technologies have consistently sought to shift the rubric from 'genetic modification' to something less invasive and more clinical sounding: 'precision breeding'. The conventional gloss is that this is about enabling techniques described as genome editing (sometimes more casually as 'gene editing'), by implication a more subtle intervention than first generation 'genetic engineering'. These are molecular techniques capable of making precise, targeted alterations to sequences of DNA in living cells. They are continually undergoing development and refinement in the laboratory but there is little dispute that they have revolutionised recent biological research, particularly since the description of the CRISPR-Cas9 system in 2012.<sup>5</sup>

Though there is a persistent debate about undetected off-target effects or undesirable on-target effects of genome editing, these are technical questions that can, in principle, be addressed, in each case, through continuing technical refinement.<sup>6</sup> What is important is that we use the genomic techniques available to us to detect errors and ensure that they are not used until they can be used with confidence. A bigger difficulty lies, perhaps, in the insidious translation of the idea of 'precision' from the molecular level of the genome to the industrial practice of 'breeding'. However sharp the molecular scissors may be, their use does not translate directly into herds, flocks and shoals of healthy, nutritious, affordable and humanely reared animals. The outcome depends on their incorporation into complex, multilevel interacting systems, running from the laboratory to the dinner table, around which knowledge, money, interests and influence circulate. Why is this relation between the molecular and the industrial scales important in the context of the present Bill?

This observation about the language used leads on to a consideration of the discourse in which it operates. The case for introducing new breeding technologies is, as yet, promissory, orchestrated by a legitimating vision of the future that they will bring about (a 'sociotechnical imaginary'). The most strident enthusiasts for genetic breeding innovations mount arguments that they (or innovations of this sort) are somehow 'necessary' in order to feed the growing global population – that our dependence on agricultural technologies has brought us to a point where we have no choice but to

---

<sup>5</sup> The narrative that GE is about deleting (or disabling) genes while GM is about adding them is inaccurate, though. It is unclear what significance this is supposed to convey be in any case: why would missing a functional gene be better than having an extra one, or a more advantageous version of an existing one? This can only be determined case by case.

<sup>6</sup> The need for such refinement should not be overlooked, however. Clause 1(6) says that "In determining whether a feature of an organism's genome could have resulted from natural transformation, no account is to be taken of genetic material which does not result in a functional protein". Though it's not clear what the drafters have in mind here, this could be taken to imply that off-target events (such as the inclusion of the plasmid with the genome edited calf Buri, and the duplication of the repair template in his progeny) can be ignored so long as they do not affect gene function, although events in this class might very well affect gene function without resulting in a functional protein. For Buri see: Young AE, Mansour TA, McNabb BR et al. (2020) Genomic and phenotypic analyses of six offspring of a genome-edited hornless bull *Nature Biotechnology* 38(2): 225-32.

‘double down’ on what (in an earlier report) we have called the ‘biotechnology wager’.<sup>7</sup> But there is always a choice and, implied in this choice, there are ethical questions. Argument that this or that biotechnology is necessary appear disingenuous when the benefits are made out as a justification for pressing forward with innovation, while managing the potential mischiefs are someone else’s problem. Genome editing is not ‘just a tool’ – its adoption into agriculture implies a complex pathway of connected, industry-shaping decisions and their social implications. If one is going to engage in justificatory discourse in terms of promissory benefits one cannot, in good faith, avoid engaging, symmetrically, with questions of responsible innovation. You can’t have it both ways.

This is an argument for anticipatory governance. It entails at least two things: it means broadening the consideration of relevant factors from the technical conditions of innovation to the social, economic and political conditions of innovation, diffusion and normalisation of biotechnologies, and it means ceding the presumed authority of technical knowledge to public and political debate around common challenges and competing interests and values.<sup>8</sup> It is when considering these more general questions that the promissory discourses of biotechnology encounter other discourses, other imaginaries, in a mutual interrogation of the uncertainties, ambiguities and assumptions of each.

### *Broader themes*

That is not the approach taken here, which is driven by applications from innovators and industry, without an articulated vision of what the aims of breeding should be, and without a transparent regulatory function with delegated powers.<sup>9</sup> (Most of the crucial powers to approve new applications are to be exercised formally by the Secretary of State, in the light of advice from a range of sources.) What is missing is a strategy for food and farming that identifies and addresses the challenges that the system is already facing and sets out realistically what role biotechnologies may play in responding to these (considering also, their potential to aggravate them, and how this may be controlled). Such an approach would avoid the exceptionalism that attaches to genome editing and other genetic technologies. (It is notable that the outcomes that make the current system unsustainable, as well as damaging to many of the animals implicated in it, have resulted from ‘traditional breeding’. This is probably why

---

<sup>7</sup> See Nuffield Council on Bioethics (2012) [Emerging biotechnologies: technology, choice and the public good](#) (London: NCOB), esp. chapter 1.

<sup>8</sup> Many of the originators of the technologies in question have, to their credit, done this. See, for example, Doudna, Jennifer and Samuel Sternberg (2017) *A Crack in Creation, the new power to control evolution* (London: The Bodley Head).

<sup>9</sup> Arguments have been made, particularly in veterinary circles, for a kind of ‘Fertilisation and Embryology Authority’ for animal breeding (similar to the widely respected Human Fertilisation and Embryology Authority). The closest analogy would perhaps be to the HFEA’s authorisation of preimplantation genetic testing. The use of PGT advances according to applications from clinics, driven ultimately by the interests of patients and the potential offered by genetic science. In this case, new tests are approved by an independent body (the HFEA) with delegated powers in accordance with clearly established purposes (to avoid a significant risk of a serious genetic condition), which are determined (following the enactment of the framework legislation) to be in the public interest. These features (delegated powers, independent professional regulation and, crucially, orientation by the public interest) are absent from the scheme established in the Bill.

the argument, which was heard a lot in 2021, that genome editing was ‘just conventional breeding speeded up’ backfired with sceptical publics. And research suggests that there is considerable latency in public views about genetic technologies, which might or might not be reawakened by the passage of the present Bill.)

Addressing the challenges facing food and farming will require a clearly articulated vision of the way ahead, the coordination of a wide range of science, technology and industrial policy areas that bear on this, and a governance function that is architecturally appropriate and operationally effective. There is clearly some work in progress here, for example, with the establishment of the animal welfare centre of expertise in Defra (consolidating the ‘back end’ of a constellation of advisory and regulatory bodies), the empanelling of the Animal Sentience Committee and a refreshed membership of the Animal Welfare Committee, but this clearly has some way still to run. This is, perhaps, why so much of what might have been included in Schedules, to be debated alongside the Bill, has been left to future Regulations, with the result that Parliamentarians and the public are left uncertain about what kind of new governance system might emerge. For the time being, what we have is a Bill for science and innovation, one that might well promote post-Brexit Britain as an international service provider for agricultural biotechnology, so long as it can capture the early mover advantage; however, it leaves the consequences for the food and farming system troublingly unclear. We are told that there is still plenty of time to address these issues but we should be wary, now, of how the legislative process can create path dependencies that might later be difficult to escape.