

England's gene-editing rules could be far more restrictive than scientists hope

In proposals set out in a recent public [consultation document](#), the Food Standards Agency has confirmed its plans for implementing the food and feed marketing aspects of the Genetic Technology (Precision Breeding) Act, which received Royal Assent in March [2023]. In summer 2024, the Government intends to bring forward secondary legislation to enact these arrangements, which if passed by Parliament would then come into force at the beginning of 2025.

The Food Standards Agency (FSA) has certainly come a long way in its thinking since [summer 2022], when FSA chief scientist Professor Robin May warned that speed of development was a major risk factor with precision breeding techniques, since it meant less time and opportunity for developers to check the safety of their products. Or when the former FSA vice-chair Ruth Hussey suggested that post-market surveillance would be needed to track precision bred (PB) products, like new medicines, for unexpected health effects.

Indeed, until relatively recently, it appeared that the Agency was planning to apply a full regulated product approval process to the authorisation of all PB food and feed products, including separate food safety risk assessment, expert committee scrutiny, public consultation, approval by both Houses of Parliament and Secretary of State sign off.

Such an approach would be entirely disproportionate to the scientific evidence of risk associated with precision breeding, totally at odds with the underpinning rationale of the Act that PB products are no different from conventional, and out of line with the prevailing regulatory position in other countries around the world, including the EU.

A lengthy regulated products process would also become unworkable within a relatively short period, since precision breeding techniques are expected to be in routine commercial use within the next 5-10 years, with hundreds of new crop varieties likely to be released each year both here and around the world.

It would also be the ultimate irony if the European Union, from whose restrictive laws on GMOs and precision breeding we originally sought to diverge, ended up with more progressive and enabling arrangements than our own!

Indeed, a major turning point in the FSA's thinking appears to have been triggered by the [publication](#) in July of the European Commission's plans for regulating plants produced using gene editing, or new genomic techniques (NGT), in the EU.

The EU is proposing a simple notification process for Category 1 NGT plants (those which could also occur naturally or through conventional breeding), regulating them as conventionally bred, with no additional GMO-style requirements for risk assessment, traceability or labelling.

This approach is mirrored in the FSA's plans for a two-tier system, with developers required to self-determine tier status according to (yet to be published) technical guidance. Like the EU's Category 1 NGT products, Tier 1 would be equivalent to well-characterised, conventionally bred products, and would

require notification to FSA prior to marketing.

However, the information requirements set out in the FSA consultation document for Tier 1 products do give some cause for concern that the Agency has not entirely accepted the scientific advice that PB food and feed products introduce no new or additional food safety risks.

For example, the basic (Model 1) information requirements range from factual details of the nature and purpose of the genetic change, as well as the intended uses and history of safe consumption of the species, to much broader questions, such as a description of the measures taken to minimise 'off-target' effects, or to check for antinutritional factors.

Without clear technical guidance, these potentially 'open-ended' information requirements run the risk of mission creep towards a risk assessment-type approach. They could also attract widely differing responses from applicants in terms of the level of detail submitted, which in turn could set regulatory precedents or expectations which are disproportionate to any evidence of risk.

To have the confidence to invest in research, innovation and product development, developers need regulations that provide clarity, predictability and certainty. They will also be keen to ensure that regulatory requirements are future-proofed against the possibility of a change of Government, and the pressure a prospective Labour administration might come under to block or delay these technologies.

Given that Defra will have already assessed and confirmed these products as PBOs, and therefore equivalent to conventionally bred products, FSA must explain the value and purpose of this information, particularly in relation to so-called 'off-target effects': firstly because the primary objective of the breeding process is to remove unwanted characteristics, and existing statutory requirements check that new varieties are genetically uniform and stable; secondly because these are potentially open-ended questions (it is not possible to prove a negative); and thirdly because no off-target effects identified could possibly be attributed to the precision breeding process, since natural mutations are happening all the time.

Greater clarity is also required in relation to the scope and remit of the pre-approval audits FSA is proposing to carry out to verify the self-determination of Tier 1 PBOs in practice and to ensure the technical guidance is relevant and fit-for-purpose. This must not lead to disproportionate burdens for developers through potentially open-ended requests for information more usually associated with a risk assessment process, and not currently required for conventionally bred crops or products.

Similarly, in relation to plants, it is important that information requested by FSA does not duplicate or extend requirements which are already covered by the plant breeding and variety registration process, for example screening for known antinutritional factors such as glycoalkaloids in potatoes or glucosinolate levels in oilseed rape.

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Indeed, the FSA consultation document refers to existing General Food Law, but does not explicitly acknowledge the role of existing plant breeding and seeds regulations in providing an independent and transparent assurance of the quality and performance of each new agricultural crop variety.

Current regulations on plant variety registration and seeds marketing are proven over many years to support safer and more sustainable food production. Existing statutory arrangements – involving at least two years of field trials and performance, genetic stability and food quality tests – have an impeccable track record of food safety stretching back over many decades.

FSA must also be mindful of the potential impact its statutory information requirements might have on public and consumer perceptions of risk in relation to PBOs, particularly if the information is intended to be included on a public register. The Agency must avoid giving the impression that PB products may have a different risk profile, so need to be treated differently, however well-intentioned and keen it is to be seen to be providing reassurance to consumers.

The bottom line is that wheat is wheat, and barley is barley. If it is acceptable in food safety terms to induce literally hundreds of random and uncharacterised mutations in the genome, as plant breeders have been doing for decades, for example using chemicals or ionising radiation, then it is certainly acceptable to introduce a small number of targeted and well-characterised genetic changes using gene editing techniques.

At this stage it appears that virtually all PB products currently under development would be classified as Tier 1. But that does not mean the Tier 2 category, requiring additional bespoke risk assessment, would necessarily be redundant. The FSA consultation document includes encouraging signals that the Agency is also thinking strategically about future options to streamline the twelve regulated product regimes currently in operation. These include GMOs, whose development remains effectively blocked in Britain by the highly restrictive and burdensome regulatory system we inherited from the EU. Moving to a two-tier system for all regulated products would provide the opportunity for a more case-by-case, proportionate approach to food safety assessment, based on plausible hypothesis of risk rather than formulaic data requirements, such as the 90-day rat feeding studies which are presently required for all GMOs whether relevant to the trait involved or not.

So, a case of two steps forward, one step back for genetic technologies in the FSA's current approach.

One final point. It is hugely disappointing that the UK's much-vaunted precision breeding 'mission hub', a £13m research proposal led by the John Innes Centre and involving most of our leading research institutes and universities, has fallen at the first hurdle, not even short-listed for interview by UKRI.

Supported across the value chain, strongly endorsed by Defra and FSA, and touted by Government as an opportunity to establish the UK as a global leader in gene editing in food and agriculture, the cancelling of this project by UKRI must come as a major blow to Ministers who never hesitate to cite the Precision Breeding Act as an example of Britain flexing its post-Brexit regulatory freedoms to drive sustainable innovation and economic growth.

In view of new Defra Secretary Steve Barclay's [recent pledge](#) to 'tear down the barriers' to getting 'game changing innovation' from the lab onto farm, it suggests that thinking across Government may not be quite as joined up as Ministers would like to have us believe.

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