## 'Quantum shift': UK regulators replacing science-strangling ultra-precautionary crop biotech regulations to accelerate adoption of CRISPR and other precise breeding technologies

quantum shift' by the Food Standards Agency in its planned approach to regulating gene edited food and feet products puts England on course to adopt one of the most progressive and enabling regulatory systems in the world. This could unlock significant new investment and economic activity by plant breeders and, combined with the UK's world-leading science base in crop genetics, could establish Britain as a global hub for gene editing research and innovation, writes Robin Wood, chairman of the British Society of Plant Breeders and deputy chairman of independent UK plant breeding company, Elsoms Seeds.

On 20 September, the UK Food Standards Agency (FSA) presented its recommendations to the FSA Board for a simplified approach to regulating the placing on the market of food and feed products developed using precision breeding techniques such as gene editing, under the terms of the Genetic Technology (Precision Breeding) Act 2023.

If adopted in this form, the FSA's proposals could put England on course to adopt one of the most progressive and enabling regulatory systems in the world, and combined with the UK's world-leading science base in crop genetics, could establish Britain as a global hub for gene editing research and innovation.

By accelerating the development of improved crop varieties, more precise breeding technologies such as CRISPR/Cas gene editing will help plant breeders keep pace with demands for increased agricultural productivity, resource-use efficiency, more durable pest and disease resistance, improved nutrition and resilience to climate change.

Mirroring the regulatory process already adopted in Canada, and the approach recently proposed in the European Union, the FSA is planning a move away from the lengthy regulated products process currently applied to GMOs, novel foods and irradiated foods, opting instead for a more streamlined process for Precision Bred Organisms (PBOs), more proportionate to the scientific evidence of risk.

This is in line with expert scientific advice from the Advisory Committee on Novel Foods and Processes (ACNFP) that there is 'no evidence that PBOs are intrinsically more hazardous than traditionally bred organisms (TBOs)', and is consistent with the definition set out in the Precision Breeding Act that PBOs contain genetic changes which could have occurred in nature or through conventional breeding.

As such, the proposed approach represents a quantum shift by the FSA, confirming the adoption of a more proportionate, science-based approach to approving precision bred products for marketing as food and feed.

Until very recently, there were serious concerns among plant breeders, farmers and scientists that the FSA was planning to require separate risk assessment, expert committee scrutiny, public consultation, approval by both Houses of Parliament and Secretary of State sign off for each and every precision bred product.

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This would have been entirely disproportionate to the scientific evidence of risk, and out of line with the underpinning rationale of the Act that precision bred products are no different from conventionally bred.

Within a relatively short period of time, as gene editing techniques are expected to become commonplace in modern breeding programmes, the lengthy regulated products process previously considered by the FSA would also have become unmanageable, with literally hundreds of new crop varieties coming forward each year.

Over recent months, many people within the plant breeding and scientific community have worked hard to present evidence to FSA officials and scientists regarding the overwhelming scientific consensus that the products of precision breeding pose no greater risks than products obtained through conventional breeding methods. It is encouraging that this is reflected in the simplified process proposed to the FSA Board.

A more streamlined approach is likely to encourage interest and investment from plant breeding businesses of all sizes, across a wide range of crops and traits, which is fantastic news.

Under arrangements set to be presented to the UK Parliament in summer 2024, and entering into force at the end of 2024, the simplified FSA approach would give applicants responsibility for undertaking initial triage and determining whether a PBO should be regulated as Tier 1 or Tier 2, subject to technical guidance.

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Tier 1 products are defined by FSA as very similar to traditionally bred products, which consumers are familiar with and for which potential safety risks are understood. Tier 2 products are defined by FSA as novel foods or PBOs with compositional changes which could affect toxicity or allergenicity, or other potential safety concerns. Under the FSA's revised proposals, these PBO products would be subject to case-by-case risk assessment.

The vast majority of PBOs are expected to be classified as Tier 1. For these PBOs, applicants would be required to notify FSA of the Tier 1 determination, alongside information such as a description of the nature and purpose of the genetic change(s) introduced using precision breeding. A public register would be maintained by FSA providing information about notified PBOs.

Importantly, the FSA process complements the existing, proven systems of statutory plant variety registration, seed certification and seed marketing, which already deliver an assurance of quality, sustainability and traceability, and which will continue to apply equally to all precision bred crop varieties.

Alongside the FSA register, the plant breeding industry has also made a commitment to transparency in relation to precision bred varieties.

Plant breeders fully support transparency. Last year, BSPB wrote to the Defra Minister responsible, Rt Hon Mark Spencer MP, to reiterate the Society's commitment to maintain a <u>public register</u> of all precisionbred plant varieties approved for sale in the UK, so enabling choice and openness of information within the supply chain. We recognise that this will be an important resource for farmers who do not wish to grow precision bred varieties, such as registered organic farmers who are currently prohibited by law from doing so.

Finally, for these new arrangements to realise their full potential, there is an urgent need for clarity from the devolved administrations in Scotland and Wales over UK-wide regulation of precision bred products.

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The FSA Board's decision confirms that regulatory arrangements in England will be very similar those proposed in the EU, with no separate requirements for food and feed marketing of precision bred products considered to be equivalent to their conventionally bred counterparts.

While the Scottish and Welsh governments have previously opposed the Precision Breeding Act, indicating their preference to remain aligned with the EU, they have remained tight-lipped over their plans since the EU's deregulatory proposals were published in July.

To deliver a harmonised UK-wide approach, I would urge both devolved administrations to provide clarity sooner rather than later on how they plan to move forward on this issue.

Robin Wood is deputy chairman of Elsoms Seeds, an independent, family-owned plant breeding and seeds business based in Spalding, Lincolnshire which was established in 1844. Robin is also chairman of the British Society of Plant Breeders (BSPB), which represents the interests of the UK plant breeding industry. Find Robin on X @RobinLauriewoo1

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