Streamlined regulatory approach needed to unlock precision breeding potential

Professor Mario Caccamo

June 2023
Science for Sustainable Agriculture

NIAB chief executive Professor Mario Caccamo notes that since new, simplified arrangements were introduced in March last year for outdoor trials of gene edited plants, eight new field trial experiments have been notified in England, twice as many as for the whole of the EU over the same period. Without exception, the focus in each case is on using new precision breeding techniques to make our farming and food production systems healthier, safer, and more sustainable. But field experimentation is only part of the story. To realise their potential, these promising lines of research also need a clear route to market, he says, cautioning against unnecessary gold-plating of food and feed marketing requirements for precision bred products, without scientific evidence of additional risk compared to conventionally bred products.

In a recent correspondence article for Nature Biotechnology, I described the passing of the Genetic Technology (Precision Breeding) Act in England as a significant milestone, the first time in decades that regulations in Britain have sought to enable, rather than restrict, the use of genetic technologies in agriculture and food production.

The new law paves the way to unlock the potential of more precise breeding techniques such as gene editing, for example to accelerate the development of more nutritious, climate-ready crops, and to support more sustainable farming systems, less dependent on synthetic pesticides and fertiliser.

This is an opportunity for the UK Government to exercise new-found regulatory freedoms to implement a modern, fit-for-purpose legislation, and liberate ourselves from the anachronistic EU Court of Justice ruling in 2018 that all gene-edited crops should be considered as transgenics for regulatory purposes. It is an opportunity to incentivise innovation at a time we need it the most.

In relation to experimental research activity, that certainly appears to be happening. Since new, simplified arrangements were introduced in March last year for outdoor trials of gene edited plants, eight new field trial experiments have been notified in England. **That is twice as many as the whole of the EU over the same period.**

It is also worth considering the field trial research applications involved, which cover a range of different crops and traits. Without exception, the focus in each case is on using precision breeding techniques to make our farming and food production systems healthier, safer, and more sustainable.

So, for example, **high lipid barley**, gene edited to accumulate more oil in its stems and leaves, has the potential to reduce enteric methane emissions in ruminant livestock while also increasing productivity in milk and meat production.

Pod shatter resistance in oilseed rape can help minimise in-field seed losses pre-harvest, so increasing yields and also reducing the need for chemical use in subsequent crops to spray off volunteers (weeds).

Using gene editing to promote **cis-regulation of short vegetative phase (SVP) genes** in bread wheat may offer the potential to deliver a productivity-boosting increase in glume, grain size and specific weight.

The development of **ultra-low asparagine gene-edited wheat** can deliver benefits for food safety, by significantly reducing levels of the potential carcinogen acrylamide in baked products.

Tomato lines gene edited to accumulate provitamin D3 in the fruit could provide a new source of vitamin D, which plays a vital role in maintaining our health and immunity.

Camelina sativa, gene edited to accumulate omega-3 fish oils such as EPA and DHA, may offer a renewable, crop-based source of aquaculture feed and human supplements as an alternative to over-stretched marine resources.

Development of **gene edited barley lacking a functional GSK1 gene** may help reduce fertiliser inputs while maintaining current yields.

Investigating the field resistance of **Solanum americanum lines that have been edited to disable three immune receptor genes** may help pave the way to developing genetic resistance in potato to late blight, a major disease currently controlled using multiple chemical treatments.

The level and nature of research activity triggered by a more proportionate approach to field trial notification demonstrates the potential benefits on offer. In line with the Government's vision, the accelerated genetic improvements made possible through precision breeding can support the development of new crop varieties that require fewer chemical inputs, that are safer and healthier to eat, that allow more food to be produced from the same area of land, and that can help tackle climate change.

But field experimentation is only part of the story. To realise their potential, these promising lines of research also need a clear route to market.

The Precision Breeding Act itself provides a framework for subsequent implementing rules to be introduced through secondary legislation. Over the coming months, these will set out the details of any additional measures that would apply to precision bred plants and their derived products.

The underpinning rationale of the Act is that products confirmed by Defra as precision bred organisms (PBOs) have genetic changes similar to those that could equally have occurred naturally, or as a result of conventional breeding, and therefore pose no greater risks.

It is therefore paramount that the Food Standards Agency (FSA) does not burden the approval of precision bred products for food and feed marketing with unnecessary and disproportionate steps that may present an unwarranted barrier to investment and innovation.

Guiding regulatory principles of proportionality and non-discrimination dictate that products confirmed to have a similar risk profile should be regulated in the same way. And yet the FSA is currently proposing to establish an entirely separate regulatory process for precision bred food and feed products, potentially involving expert committee scrutiny, risk assessment, public consultation, Parliamentary approval and Secretary of State sign-off.

For plants, his would be in addition to the existing statutory requirements for the introduction of new crop varieties, a regulatory system which has operated effectively and with an impeccable track record of food and feed safety for many decades.

The Canadian authorities recently confirmed that gene editing technologies do not pose any unique risks to food or environmental safety compared with other plant breeding practices, and that gene-edited plant products should be regulated like all other plant products.

Indeed, guidance from Health Canada, the FSA's equivalent body, went so far as to emphasise that no additional safety assurances or knowledge would be gained through extra regulation of gene edited food crops or plants beyond existing plant variety and seeds regulations.

Beyond the findings of its own consumer research, which was largely framed around both leading and misleading questions, the Food Standards Agency and its scientific advisers must be required to explain and justify the basis for a differential approach to that taken by highly respected regulatory authorities such as Health Canada and the Canadian Food Inspection Agency.

But there is more.

According to a recently leaked version of draft regulations on new genomic techniques (NGTs) due to be unveiled by the European Commission, the EU may also propose that gene edited crops which could have occurred naturally or through conventional breeding should be treated similarly to conventionally bred varieties –

ie not requiring separate food or feed safety authorisation, risk assessment, traceability, labelling or coexistence.

If confirmed in the Commission's final proposals, this approach reflects the scientific opinion adopted by the European Food Safety Authority (EFSA) in November 2020, which states clearly that *"genome editing techniques that modify the DNA of plants do not pose more hazards than conventional breeding."*

There is much debate and discussion still to be had in Brussels, of course, but it would be the ultimate irony if the EU, from whose restrictive rules we originally sought to diverge, turned out to have more enabling and science-based rules than our own.

More importantly, unnecessary gold-plating of food and feed marketing requirements for precision bred products, without scientific evidence of additional risk compared to conventionally bred products, could deter investment and innovation in the promising areas of research described above.

This in turn could compromise the Food Standards Agency's own objectives to improve standards of safety, nutrition, affordability and sustainability in our food.

That's why I would urge the FSA to follow the science and adopt a more streamlined regulatory approach, similar to the Canadian model. A proportionate and science-led approach to the regulation of PBOs will help ensure that we can continue to feed the world within the boundaries of our planet.

Professor Mario Caccamo is chief executive of UK crop science organisation NIAB. A computer scientist, he has over 20 years' experience in life science research and big data, including specific projects to apply the latest DNA sequencing technologies and bioinformatics methods to advance scientific understanding of crop genetics and the interaction of agricultural crops with their environment.