New plant breeding techniques: Stuck in the lab or market potential?

It is estimated we will need to produce 60% more food by 2050 to feed a rapidly growing global population. At the same time we need to reduce our environmental footprint. Agriculture faces major difficulties in delivering food security worldwide due to climate change, economic instability and the continuing imperative to avoid further losses in biodiversity and raw materials. The development of gene-editing methods – the so-called new plant breeding techniques (NBTs) – is touted as a great opportunity to provide sustainable solutions for agricultural production. But regulatory uncertainty in Europe may be limiting their potential.

What are new plant breeding techniques?

NBTs are new biotechnology methods that achieve desired characteristics in plants by adding, removing or replacing DNA at specified locations. Unlike genetic modification, the end product does not contain foreign DNA from unrelated species and in most cases is indistinguishable from plants obtained through conventional breeding. NBTs allow seed breeders to develop new plant varieties in a similar manner to conventional breeding, but more quickly and precisely.

Among the benefits cited of NBTs are that they can enhance plant disease resistance and resilience to climate extremes, provide improved nutritional value, allow for better storage and processing performance, and can lessen the impact of agriculture on the environment by decreasing the required amount of water and other agricultural inputs. They are hailed as a cheap and fast way to improve crops, but also to increase plant diversity.

> *With the momentum picking up on the use of new plant breeding techniques, regulatory uncertainty in the EU's approach to defining these methods may be harming the nascent industry in Europe.*

Science is one step ahead of regulation

While the potential of NBTs is recognised by scientists and industry alike, they are already being opposed in certain quarters. Opponents of biotechnology are quick to label these techniques as genetic modification. The EU defined GMOs in the 1990s as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

However, most of the products obtained by NBTs cannot be distinguished from conventional plants, as concluded by several European and national scientific bodies such as the European Academies Science Advisory Council, the EU's Joint Research Centre (JRC) and the German Federal Office of Consumer Protection and Food Safety.

But there are also voices claiming that some NBTs, if not all, are GMOs. The European Commission therefore – helped by the Court of Justice of the EU (CJEU) that is in charge of interpretation of the GMO law – needs to closely examine each technique to decide which ones should be considered as resulting in genetic modification. The task will be complicated by the fact that while some NBTs use genetic modification temporarily as an intermediary step in the process, for most of the techniques the final product is not a GMO. It is unclear whether the Commission will focus on the process or the final product in establishing its definitions.

The European Commission is discussing eight key technologies: Zinc finger nuclease (ZFN); oligonucleotide directed mutagenesis (ODM); cisgenesis and intragenesis; RNA-dependent DNA methylation (RdDM); grafting; reverse breeding; agro-infiltration; and synthetic genomics. Currently there is no formal EU position on NBTs. The Commission is expected to publish a guidance document but no legislative proposals: the topic is very technical, which may be why it is being dealt with from a judicial and not political perspective. It will be up to the Court of Justice to interpret the EU GMO law.

The jargon explained

- Cisgenesis & intragenesis transfer a gene from the same or a cross-compatible species.
- ZFN and ODM are methods that achieve targeted mutations in a gene. Unlike chemical- or radiation-induced mutations, often used in traditional crop improvement, ZFN and ODM induce precise and predefined mutations of a gene. Other similar techniques include TALEN and CRISPR/Cas.
- RdDM changes the expression of a gene through gene silencing methods without the need of stable incorporation of foreign DNA.
- Agro-infiltration and reversed breeding are different methods that use genetic modification in the intermediary product but the final plant has no foreign DNA. Agro-infiltration is used to infiltrate plant tissue (mostly leaves) with the desired genes. Reverse breeding inverses the order of events leading to the production of a hybrid plant variety.
- Grafting is used to attach a non-GM plant on GM rootstock to get improved cultivation characteristics. The DNA of the resulting leaves, stems, flowers, seeds and fruits remains unchanged.
- Synthetic genomics has the ability to create new biological systems and components. Although the Commission refers to it as one of the NBTs, there is no research on synthetic genomics in plant breeding under way.

The commercial potential for NBTs

This is creating uncertainty for European business, who want to be reassured that the seeds they produce will not be subject to the same costly and long regulatory burden that applies to GMOs. Companies will be reluctant to invest in these new technologies until they have clarity from the Commission on its definition of them.

The benefits would not only be for the big seed producers. Greater certainty on the future of NBTs would allow start-ups and SMEs to develop innovative methods to arrive at new plant varieties. Allowing such small business to thrive in this sector is wholly consistent with the EU's vision for growth: the EU's Entrepreneurship Action Plan strives to remove barriers to entry across a range of industries for Europe's SMEs, which have been responsible for 85% of all new jobs created in Europe in the last five years.

It is clear that regulatory uncertainty has already had a deleterious effect for Europe: in 2014 the JRC reported that only 37.6% of patents linked to NBTs originated in the EU, compared to 50.3% from the US. The US's lead has been supported by its decision not to automatically include NBTs under blanket GMO legislation but to rather evaluate each technique on a case-by-case basis. This approach has produced new crops such as potatoes that do not accumulate reducing sugars when cold-stored, gluten-reduced wheat and lower trans-fat soya bean & canola oils – the latter demonstrating a clear commercial benefit in light of the EU's likely ban of trans-fatty acids.

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Urgent need for proper communications

The environmental and demographic challenges of agriculture cannot be ignored, and NBTs can provide a useful tool in helping address these. They therefore offer promising perspectives for commercial development, but for successful commercialisation to be realised policymakers need to be provided with timely, clear and sound arguments about their benefits. By 2014 over three-quarters (77%) of all scientific publications on NBTs came from the public sector, and only 13% from industry (JRC 2014). That would suggest a clear gap in input from industry, and it is critical that those who will be at the forefront in bringing this new technology to market be involved from the outset in open and constructive dialogue that addresses the key questions around NBTs. It is also incumbent upon the industry to proactively tackle upfront any potential myths and misconceptions regarding NBTs before these potentially become widespread. Industry and policymakers need to work together to ensure that the potential of NBTs is unlocked.

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