ECJ ruling on gene editing – four months on

In July the European Court of Justice (ECJ) ruled that organisms obtained by a mutagenesis plant breeding technique are GMOs and should, in principle, fall under the GMO Directive. There was an immediate response from scientists who described it as a "setback for cutting-edge science and innovation in the EU" (*Crop Scene, September*).

Since then more considered reaction from many quarters has come forth which emphasises the potential impact on the scientific community and the competitiveness of European agriculture.

It is reported that the European Commission has been analysing the ECJ ruling and has also been discussing the issue with member states. The subject was raised with member states at the Plant Animal Food and Feed Standing Committee in late October and a further discussion was planned for the November meeting. Whether or not the outcome will be a complete review of the whole GMO regulatory process it is early to say.

Support for a complete re-think on how Europe should legislate for GMOs came from a surprising source. In mid-October, speaking at a Citizens' Dialogue in Modena, Italy EU Health Commissioner Vytenis Andriukaitis said: "I don't understand why in Europe we are so aggressive against GMO and innovation. I eat GMO food and I am still alive…. If we don't invest in new technologies we will lose competitiveness and young people who will go abroad to work on GMOs."

He suggested that there should be open discussion on how biotechnology products are regulated and that ways should be found to change the legal framework covering mutagenesis and cisgenesis.

Commissioner Andriukaitis went even further by saying: "Let's collect one million signatures and launch a Citizens initiative in order to ask the European Commission to rethink the regulatory framework."

The ruling is already having an impact on academic and commercial developments in Europe and further afield. Dirk Inzé, science director at the VIB-U Ghent Centre for Plant Systems Biology in Ghent, Belgium, reported how ongoing trials have been effected. "A maize field trial we've been conducting in Belgium for over a year and a half was suddenly considered a GM field." He described how, as a result of the ruling, local authorities have insisted on extra precautionary measures, such as placing a fence around the researchers' plot and completing extensive documentation. Also in Belgium, a start-up company was planning to use CRISPR technology to help Africa's banana industry by developing an edible banana that is resistant to Panama disease and black Sigatoka. The company now reports that it has lost its source of funding.

According to a feature in *Nature* (www.nature.com/articles/d41586-018-07166-7) there is also a risk to overseas businesses which supply the European market. The Brazilian plant-breeding company, Tropical Melhoramento & Genética, had been expanding partnerships and investing in several research initiatives in soya bean gene editing but now needs to factor in the extra compliance work needed to meet the EU rules. Head of soya bean R&D, Alexandre Garcia, said: "For at least the past six years the EU has been the second biggest market for Brazilian soya beans, so if any farmer plans to plant soya beans on Brazilian land they need to worry about EU rules." He said that research partnerships and investments that are valued at millions of dollars are now on hold while their viability is evaluated.

What may yet influence the regulatory policy adopted by the European Commission (EC) on gene editing as well as genetic modification is a letter published in mid November by seven advisors appointed to the EC. They are calling for a revision of the existing GMO directive 2001/18/EC because the recent ruling of the ECJ has revealed that 'it is not abreast with science.' The advisors said: "There is a need to improve EU GMO legislation to be clear, evidence-based, implementable, proportionate and flexible enough to cope with future advances in science and technology in this area."

The advisors challenge the logic of differentiating crops created by modern gene editing methods from crops created by naturally occurring mutations or by random mutagenesis crops as they will be indistinguishable. The ECJ ruling stated that crops that have been created by chemically and radiation-induced mutagenesis need not be considered as GMOs due to their long safety record.

The advisors also addressed the issue of the 'unintended effects' that can occur from gene editing. They observed that unintended effects will occur less frequently in gene edited products and that such products are potentially safer than the products of random mutagenesis. But more significantly the advisors argue that to assess the risk to human health or the environment the regulators need to 'examine the features of the final products regardless of the underlying technique used to generate that product.'

In order to initiate a broad social dialogue 'on how we want our food to be produced in Europe' and to provide 'the highest possible protection of health and the environment' the advisors recommend that the EC should seek public opinion before changing any legislation.

It is not the first time that the argument in favour of assessing the crop variety rather than the method by which it was bred has been promoted. The European Commission will need to decide one way or the other. However, with European Parliament elections coming up in May 2019 it is likely that politics rather than science will dominate in the short term.

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