

USDA regulatory policy: Gene editing is not GM - what now for the EU ?

At the end of March the US Secretary of Agriculture, Sonny Perdue, issued a statement on the USDA's position on the regulation of plants produced through innovative new breeding techniques which includes gene editing techniques such as CRISPR-Cas9.

The statement said:

“Under its biotechnology regulations, USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests.” Secretary Perdue said: “With this approach, USDA seeks to allow innovation when there is no risk present.... At the same time, I want to be clear to consumers that we will not be stepping away from our regulatory responsibilities.”

However, the decision to leave these crops, and foods derived from them, unregulated may possibly not be final. The US Food and Drug Administration(FDA) may establish its own guidelines regarding any human health risk associated with them. In the case of CRISPR technologies applied to animals the FDA is known to consider them as genetically modified.

However, with plants it is anticipated that the USDA ruling will prevail as there are no extra health risks compared with food derived through conventional plant breeding. The USDA has yet to agree whether foods derived from gene edited crops will have to be disclosed through labelling. A review is underway, the outcome of which is expected to be released in July (page 5).

The consequences of the USDA decision are significant for the plant breeding industry in the US and potentially for the rest of the world. One factor already attracting the interest of investors is that the cost of developing new crop traits will be dramatically reduced compared with the cost of developing GM crops. It could, therefore, mean that the dominant position of the big four (shortly to become three) multinational biotechnology companies, Monsanto, Bayer, Syngenta and Corteva (DowDuPont) will be lessened. With the cost of development so much lower, start-up businesses can be expected to rapidly evolve.

Matthew Crisp, CEO of St Louis based biotechnology company Benson Hill Biosystems, has recently been quoted: “Genome editing holds immense potential to lower product development costs and level the playing field beyond those few companies with the largest research and development budgets.” It is reported that it can take 13 years and \$130 million to bring a GM crop to market.

A number of new businesses in the US have attracted Wall Street investors: Calyxt went public in July 2017. The company has used gene-editing to develop a potato variety that prevents the accumulation of certain sugars during cold storage, and so reduces the bitter taste that can be associated with storage. Another food biotechnology company that has gone public is Yield 10 which has developed a gene-edited camelina sativa or false flax, with enhanced omega 3 oil. The more established company Cibus has used gene-editing to develop a non-transgenic canola which is tolerant to sulfonylurea herbicides. The canola is already cleared for use in the US and Canada.

The multinational biotechnology companies are however alert to the threat, and opportunity, from the new technologies. In March Monsanto announced it was investing in a start-up gene-editing company, Pairwise Plants. It is reported that Monsanto will pay Pairwise \$100 million over the next five years to finance research exclusively for Monsanto in corn, soya beans, wheat, cotton and canola.

The USDA decision is now putting pressure on the EU regulators. Adding to the pressure it is also reported that regulatory authorities in Canada, Brazil and Argentina do not consider that gene-edited crops have to be treated in the same way as GM crops. In January, the European Court of Justice (ECJ) Advocate General Michal Bobek published his opinion saying that one example of a new plant breeding technology (mutagenesis) is, in principle, exempted from the obligations in the GMO directive (Crop Scene, January). However, it is not entirely clear whether this ruling will be extended to other new plant breeding techniques. The final ECJ ruling on the mutagenesis case is expected imminently.

There is clearly demand from the large sections of the European farming community to adopt a similar stance to that in the US. Thor Gunnar Kofoed from the EU farmers association Copa and Cogeca said at a recent conference “If we don’t act now, we will put ourselves in the hands of a few multinational American companies. EU farmers and their cooperatives will not accept it.” He commented that the EU has the largest number of plant breeders in the world. “They need to be encouraged to invest in new breeding technologies instead of being held back.”

However, EU organic farmers (IFOAM EU) firmly oppose gene editing and other New Plant Breeding Techniques, NPBTs. They believe they should clearly fall under the scope of GM crops, otherwise, the organic sector will be dealt a severe blow. A similar position is shared by the European Coordination Via Campesina (ECVC), a farmers’ organisation that defends farmers’ rights and sustainable farming, which says these new biotechnology-driven techniques were developed by the seed industry to counter consumers’ massive rejection of ‘old GMOs’.

Franziska Achterberg, food policy director at Greenpeace EU, said the court’s decision would not answer all the questions about what is in or out of the scope of the EU’s GMO law as it will only concern the scope of the mutagenesis exemption. He said: “In the end, it is up to the European Commission and EU national governments to properly apply the law.... But so far, the Commission has dragged its feet.”

EU Health Commissioner Vytenis Andriukaitis was reported to say that the future of NPBTs at the EU level lies in the ECJ’s interpretation of existing law. He said “The European Commission has no right to interpret the law.... We can present an opinion but not to say something is okay or not. It’s about law interpretation and this is in the hands of the ECJ.” He added that it’s not going to be a decision but a law interpretation, and then we can ‘move forward one way or another.’
