



In the EU, gene-edited crops and food will be treated in the same way as genetically modified organisms.

GENE EDITING

EU law deals blow to CRISPR crops

Top court's ruling threatens research on gene-edited plants.

BY EWEN CALLAWAY

Gene-edited crops should be subject to the same stringent regulations that govern conventional genetically modified (GM) organisms, Europe's highest court ruled on 25 July.

The decision, handed down by the Court of Justice of the European Union (ECJ) in Luxembourg, is a major setback for proponents of gene-edited crops, including many scientists. They had hoped that organisms created using relatively new, precise gene-editing technologies such as CRISPR–Cas9 would be exempted from existing European law, which has limited the planting and sale of GM crops.

Instead, the ECJ ruled that crops created using these technologies are subject to a 2001 directive. That law was developed for older breeding techniques, and it puts high hurdles in the way of developing GM crops for food.

"It is an important judgment, and it's a very rigid judgment," says Kai Purnhagen, a legal scholar at Wageningen University and Research in the Netherlands who specializes in European and international law. "It means for all the new inventions, such as CRISPR–Cas9 food, you would need to go through the lengthy approval process of the European Union."

That is likely to hinder investment in crop research using these tools in the EU, says Purnhagen. "From a practical perspective, I don't think this will be at all of interest for business. So they will move somewhere else," he says.

The ruling is "tremendously disappointing," says Nigel Halford, a crop geneticist at Rothamsted Research in Harpenden, UK. "It's a real hit to the head," he says. Gene-editing techniques will still be used as a research tool for developing crops, he adds, but he doubts that companies in Europe will have much appetite to develop them. "They are not going to invest in a technology they see not having any commercial application," Halford says.

Environmental organization Friends of the Earth in Amsterdam, meanwhile, applauded the court's decision in a statement. It also called for all products made through gene editing to be regulated, assessed for their health and environmental impacts, and labelled.

DNA CHANGES

The 2001 EU directive behind the ECJ's decision concerns the intentional release of GM organisms into the environment — and was aimed at species into which entire genes, or long stretches of DNA, had been inserted. The law exempts organisms whose genomes were modified using 'mutagenesis' techniques,

such as irradiation, which introduce changes to an organism's DNA but don't add foreign genetic material.

In 2016, the French government asked the ECJ to interpret the directive in light of plant-breeding techniques that have since emerged.

Many plant breeders and scientists contend that gene-editing techniques such as CRISPR–Cas9 should be considered mutagenesis, just like irradiation, and thus be exempt from the directive, because they can involve changes to DNA and not the insertion of foreign genes. But people opposed to GM organisms contend that the deliberate nature of alterations made through gene editing means that they should fall under the directive.

In January, an advocate-general with the court, Michal Bobek, issued a 15,000-word opinion that both sides claimed was partly in their favour. He said that gene-edited crops do constitute GM organisms under the original directive, but also that species modified using technologies discovered since 2001 — such as those used for gene editing — could be exempted, as long as they don't contain DNA from other species, or artificial DNA.

But in its ruling, the ECJ determined that only mutagenesis techniques that have "conventionally been used in a number of applications and have a long safety record are exempt from those obligations". Organisms made using mutagenesis techniques developed after 2001 — including gene editing — are not exempt from the directive.

NO INCENTIVE

"This will have a chilling effect on research, in the same way that GMO legislation has had a chilling effect for 15 years now," says Stefan Jansson, a plant physiologist at Umeå University in Sweden. Gene-edited crops will not vanish from European research labs, but he worries that the funding to develop them could dry up. "If we cannot produce things that society finds helpful, then they will be less likely to fund us."

Jansson also has practical concerns about the ruling. He developed a 'CRISPR cabbage' that he has consumed, and which was growing in his home garden as he spoke to *Nature*. "I took a photo yesterday, and I took another after the ruling. It's still the same plant. Yesterday it wasn't a GMO, and now it's a GMO. I'm a bit curious what I have to do. Do I have to remove it?"

Purnhagen says that the ruling leaves open a possible loophole, whereby if scientists can prove that gene-editing techniques are as safe as mutagenesis methods already exempt from the law, such as irradiation, the new techniques, too, could earn an exemption.

But he doubts that researchers and businesses developing gene-edited crops will hold out hope. "I can't see CRISPR–Cas9 and all these new technologies will be profitable in the European Union. I can't see this happening. I think this research will move somewhere else." ■