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expert reaction to Court of Justice of the European Union ruling that GMO rules should cover plant genome editing techniques

The European Court of Justice has ruled that organisms obtained by mutagenesis – a set of techniques which make it possible to alter the genome of a living species without the insertion of foreign DNA – are GMOs and are, in principle, subject to the obligations laid down by the GMO directive.

Prof Cathie Martin, Group Leader, John Innes Centre, said:

“It is important to point out the wider implications of this ruling (wider than simply its impact on traits engineered using New Breeding Technologies). The important point is that this ruling ignores assessment of the safety of the trait developed, and rules only on the technology used. So introduction of higher yielding crops engineered by mutagenesis (traditional or by NBT) could be blocked by NGOs in the absence of an approved environmental impact evaluation!

“This is going to impact plant breeding in Europe hugely and negatively.”

Prof Wendy Harwood, Crop Transformation Group, Department of Crop Genetics, John Innes Centre, said:

“Every single plant on our planet is here because of mutations occurring during evolution. Human society as we know it, relies on the deliberate selection of mutations to improve food crops.

“The European Court of Justice opinion that organisms obtained by mutagenesis are GMOs and therefore subject to the obligations of the GMO directive is a disappointing setback for the use of valuable new technologies in crop improvement.

“Older mutagenesis techniques that have a long safety record are exempt from this obligation. The same outcomes can be achieved using newer, faster and more precise mutagenesis methods as using the older techniques. Treating the plants derived in different ways is not a logical approach based on the

scientific evidence. This decision could have major negative impacts on our ability to respond rapidly to the challenges of providing sufficient, nutritious food under increasingly challenging conditions.”

Dr Nicola Patron, Head of Synthetic Biology, Earlham Institute, said:

“The European Court of Justice has ruled that certain new techniques and methods used to induce precise mutations which alter the genetic material of organisms are GMOs and therefore subject to the obligations of the GMO directive. This is not an approach based on scientific evidence. Mutagenesis is a natural phenomenon responsible for the genetic diversity that can be seen in all living organisms. Humans have used different technologies to induce mutations in plants to increase genetic diversity and improve the agronomic qualities of crops for almost a century; the same outcomes can now be achieved using faster, more efficient and precise mutagenesis methods. In most cases, it will not be possible to determine which technique was used to induce the mutation. This decision may negatively impact our ability to respond to the challenge of securing sufficient food for our growing population in a changing climate. It may also hinder the competitiveness of the EU’s biotechnology sector.”

Prof Nick Talbot, Deputy Vice Chancellor, and Professor of Molecular Genetics, University of Exeter, said:

“This ruling by the CJEU is a mis-guided and retrograde step that is not based on any scientific evidence. Mutation occurs all the time in all organisms. Many modern crop varieties were generated over the last several decades by random mutagenesis in which there was no control on secondary effects. Precise modern gene editing technologies allow accurate, predictable changes to be made in a genome. To classify gene edited crops as GMOs and equivalent to transgenic crops is completely incorrect by any scientific definition. By adopting the precautionary principle in such a mis-guided and short-sighted way, Europe is again being denied the opportunity to innovate and lead in the development of beneficial, environmentally-friendly agriculture for the next century.”

Prof Denis Murphy, Professor of Biotechnology, University of South Wales, said:

“This ruling has potentially important implications for the regulation of the exciting new technique of genome editing both in the EU and elsewhere. Essentially the ruling, which is derived from a case involving plants, would appear to cause all new genome edited organisms to be regulated as if they were derived from classical ‘GM’ or transgenic methods as developed in the 1980s.

“This will potentially impose highly onerous burdens on the use of genome editing both in agriculture and even in medicine, where the method has recently shown great promise for improving human health and well being.

“It is of course important that, like any new biotechnology, genome editing is properly assessed and regulated according to evidence-based scientific criteria. However, by simply lumping together genome editing with the completely different GM/transgenic biotechnologies, the CJEU has missed a historic opportunity to create a new regulatory framework for this new biotechnology.

“In the rest of the world genome editing will continue to be used for human welfare, whether in curing hitherto intractable genetic diseases or in helping developing countries grow better crops. But sadly much of Europe might miss out on such opportunities if genome editing becomes effectively impossible to use in the EU.”

Prof Sophien Kamoun, Senior Group Leader and Professor, The Sainsbury Laboratory, said:

“This ruling ignores advances in plant bioediting that make this technology more precise than so-called ‘conventional mutagenesis’. Bioediting can also be used to recapitulate natural variations into cultivated varieties of crops.

“This ruling closes the door to many beneficial genetic modifications such as breeding of disease resistant plants that require much less pesticide input.

“A sad day for European plant science.”

Penny Maplestone, CEO of the British Society of Plant Breeders, which represents the agricultural plant breeding industry in the UK (a list of BSPB members is at <http://www.bspb.co.uk/members.php>), said:

“The Court has ruled that all plants derived from any type of mutagenesis are GMOs according to the legal definition in the Directive. It rules further that the exemption that the Directive gives to exclude mutants from the need to be regulated as GMOs applies only to well established types of mutagenesis and not to the latest plant breeding techniques of extremely precise targeted mutagenesis, even where these result in plants that could have been produced by traditional plant breeding methods and contain no foreign DNA. The outcome means that all plants derived by genome editing will be caught by the GMO regulations.

“This ignores the opinion of the Advocate General and is very bad news for plant breeding innovation in Europe. It seems likely that the potential of these innovative methods to deliver crop varieties with better disease resistance, enhanced nutrition, higher yields and resilience to extreme weather events such as the drought we are currently experiencing, will be lost to farmers and consumers in Europe. Other parts of the world have already given a green light to plant breeding innovation through exciting scientific developments like CRISPR Cas9 and are forging ahead. It is a deep disappointment to see Europe closing the door to plant breeding innovation at a time when we need it as we never have before to address the challenges of food production, climate change and environmental protection.”

Prof Jonathan Jones, Plant Scientist, The Sainsbury Laboratory, said:

“Commenting as a scientist not a lawyer, and relying on the text of the press release rather than the ruling, this outcome looks unhelpful for Europe, food security and international trade. Notably, it is framed around the idea that because these methods can be used to confer herbicide resistance, any application of these methods should be considered a GMO. This excludes a host of benign and beneficial applications for disease resistance and stress tolerance that are without conceivable harmful side effects. Other jurisdictions, notably US and China, are moving rapidly to facilitate exploiting new editing

methods for crop improvement, and one can anticipate that as a consequence of this ruling, investment in these technologies will depart the EU for more supportive countries.”

Prof Ottoline Leyser, Director, The Sainsbury Laboratory, University of Cambridge, said:

“This ruling has arisen because of an action brought to the Court arguing that herbicide-resistant seed varieties pose the same risks to the environment regardless of how they are produced. I agree with this argument. We need a future-proof risk-based regulatory framework based on the traits being introduced, not the way in which they were introduced. It should include all breeding techniques from conventional to whatever the latest approaches might be. The idea that things that could occur ‘naturally’ are distinct and somehow automatically safe for people and for the environment is untenable. The distinction between GMO and not GMO is contrived.”

Dr Sarah Schmidt, Institute for Molecular Physiology, Heinrich-Heine-Universität Düsseldorf, said:

“The ruling of the European Court of Justice to regulate new breeding techniques including gene editing techniques like CRISPR as GMOs is the deathblow for plant biotech in Europe. The costs of fulfilling regulatory science and administration to obtain approval for GMO crops are around \$35 million. Only the largest agribusinesses can afford these costs. With today’s court ruling, universities, start-ups and non-for-profits that might produce innovative solutions to tackle world hunger and crop adaption to climate change are excluded from the breeding process. Purely, because they cannot afford the legislative costs for approval of gene-edited crops as a GMO. So, Europe leaves it to big biotech companies to address the biggest humanitarian challenges of our time, hunger and climate change.

“I was shocked to read that the European Court of Justice fears that new breeding techniques could produce DNA changes in crops *“at a rate out of all proportion”*. New breeding techniques like gene editing enable scientists to make precise, directed changes to the existing crop’s genome. So precise that gene-edited crops could become indistinguishable from naturally occurring crop variants. Yet, the court considers these techniques not as safe, while it considers treatment with a carcinogenic chemical or ionic radiation (conventional breeding techniques) that induce hundreds and thousands of undirected changes in the DNA as safe.”

Prof Huw Jones, Professor of Translational Genomics for Plant Breeding, Aberystwyth University, said:

“I am shocked and saddened that the ECJ has ruled that crops bred using gene editing ARE GMOs and are NOT exempt from the regulations.

“What are the consequences?”

“1. This puts the EU at odds with the many countries that have already stated clearly that they do consider crops made using simple gene editing in the same way as other forms of mutagenesis and exclude them from their regulation / labelling requirements for conventional GMOs.

“2. The current expectations of EFSA and the JRC in terms of the information required for a conventional GMO application are impossible to fulfil for most simple gene edited crops where there is no inserted DNA, no new protein, no unique DNA identifier etc.

“3. It blurs the clear biological distinction between small, targeted edits in an organism’s existing genes and the insertion of very large sections of recombinant DNA from a non-sexual compatible species; this ruling means that both will be GMOs and subject to the same regulatory oversight.

“4. It will stifle crop genetic research and innovation in the EU, which will understandably see no route to market for gene edited crops if they are regulated as conventional GMOs. In fact it will encourage more use of older, less targeted mutagenesis methods!

“5. It places importers and port authorities in the impossible position of policing food and feed grown as conventional crops in the countries of origin but that become illegal GMOs when they arrive in EU!”

Prof Ian Crute, retired, Former Director of Rothamsted Research and Former Chief Scientist of the Agriculture and Horticulture Development Board, and Current Member of the Advisory Committee for Releases to the Environment, said:

“This ruling is not founded in science and will be an impediment to the introduction of new crop varieties with benefits to European farmers, consumers and the environment. In addition, it is likely to lead to yet more confusion and costly litigation since it will not be possible to determine if a new variety has resulted from the application of gene editing techniques or been produced using so-called ‘conventional’ mutagenesis (exempt from the GMO Directive). Most informed scientists agree that the only sensible way forward is to regulate the novelty of the trait and *not* the means by which it has been produced.”

Prof Achim Dobermann, Director and Chief Executive, Rothamsted Research, said:

“This is a disappointing judgement by the European Court of Justice. European farmers are already losing out, and now risk falling further behind the rest of the world with this decision. Let’s hope other regions, outside Europe, do not follow suit and that the UN’s Sustainable Development Goals can still be achieved so that there are many fewer hungry people in the world by 2030.”

Prof Johnathan Napier, Research Leader, Rothamsted Research, said:

“This is a very disappointing outcome, and one that will hinder European innovation, impact and scientific advance. The classification of genome-edited organisms as falling under the GMO Directive could slam the door shut on this revolutionary technology. This is a backward step, not progress.”

Prof Nigel Halford, Crop Scientist, Rothamsted Research, said:

“This is highly unusual in that the ruling appears to have ignored the opinion of the Advocate General and scientific advice and the pleas of multiple agricultural biotech organisations and taken a decision to keep the NGOs sweet. If adopted by the Council and Parliament the decision could set agbiotech in

Europe back another 20 years. We are already a generation behind. Young scientists interested in agbiotech are likely to move to places where common sense and scientific evidence prevail.”

* <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

<http://curia.europa.eu/juris/documents.jsf?num=C-528/16>

Declared interests

Prof Cathie Martin: “I am director of two spin-out companies aiming to improve the nutrient composition of foods and crops for use in cosmetics as well as holding my academic position in the Department of Metabolic Biology at the John Innes Centre.”

Prof Wendy Harwood: “Regarding conflicts of interest I have BBSRC funding to provide CRISPR based editing to the UK research community. I am also responsible for the BRAC platform that provides crop transformation and gene editing resources to the research community on a cost recovery basis.”

Dr Nicola Patron: “I can declare that I am employed at a non-profit institute as a researcher in plant biotechnology and have grant-funding from UKRI in this area of research.”

Prof Denis Murphy: “No relevant interests to declare.”

Prof Sophien Kamoun: “I consult for the biotech industry, notably BASF, and I’m a member of the Two Blades Foundation Science Advisory Board. My other professional activities and recent research funding are listed at http://kamounlab.dreamhosters.com/pdfs/SKamoun_CV.pdf.”

Prof Jonathan Jones: “Professor Jonathan Jones is a senior investigator at The Sainsbury Laboratory in Norwich, and uses molecular and genetic approaches to study disease resistance in plants. He received his Ph.D from the Plant Breeding Institute and Cambridge University in 1980, conducted postdoctoral work at Harvard, and then worked at an early agbiotech startup, AGS in California, from 1983-8. Since 1988, Jones worked at the Sainsbury Lab in Norwich (www.tsl.ac.uk), funded by David Sainsbury’s Gatsby Foundation. He was Head of Sainsbury Laboratory 1994-7, 2003- 2009, and Professor at University of East Anglia since 1997. He was elected to EMBO in 1998, FRS in 2003 and Foreign Associate of US National Academy of Sciences in 2015.

Jones is cofounder of and former science advisor to the biotech company Mendel Biotechnology, and also co-founded Norfolk Plant Sciences in 2007 with Prof Cathie Martin of JIC, with the goal of bringing flavonoid-enriched tomatoes to market (www.norfolkplantsciences.com).

He was on the Science advisory board of Nomad Biosciences in Halle, Germany, which aims to produce human pharmaceutical and other valuable proteins using plant viruses rather than GM plants, and was a science advisor to start-up Scottish biotech company Synpromics (<http://www.synpromics.com>).

Jones is on the board of www.isaaa.org and the science advisory board of the 2Blades foundation (www.2blades.org). He has contributed to advice to governments and international boards on GM crops (<https://royalsociety.org/policy/publications/2009/reaping-benefits/>), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/292174/cst-14-634a-gm-science-update.pdf http://www.sciencecouncil.cgiar.org/system/files_force/ISPC_StrategyTrends_Biotechnology.pdf).

In addition to his basic science programs, Jones has isolated and is isolating new resistance genes against potato late blight from wild relatives of potato, and conducting field trials to evaluate how well they work to protect the crop in the field. One blight resistance gene is being commercialized in the US by Simplot (www.simplot.com).

See also <http://www.tsl.ac.uk/groups/jones-group/>.”

Prof Ottoline Leyser: “My research is funded by the Gatsby Charitable Foundation, The BBSRC and the ERC. I am employed by the University of Cambridge, with ad hoc advisory roles for a number of organisations. Further details:

Employment and paid consultancies: Director, The Sainsbury Laboratory, University of Cambridge; Current Opinion in Plant Biology, Co-Editor in Chief; European Research Council, grants board member; Chair of the John Innes Centre Science and Innovation Advisory Board, and Governing Council Member; Gatsby Charitable Foundation, Plant Science Advisor; BBSRC Council Member; Ad hoc payments for one off consultancies for universities and research institutes, funders etc.; Netherlands Organisation For Scientific Research (NOW).

Other organisations (unpaid): Clare College (Fellow), Cambridge; The Royal Society (Fellow; Chair, Science Policy Advisory Group; Member, Audit Committee); Max Planck Institute for Developmental Biology, Tubingen (Advisory Board Member); European Molecular Biology Organisation (Member); Royal Society of Biology (Member); National Academy of Science, USA (Foreign Associate); Leopoldina (Member); Umea Plant Science Centre (Advisory Board Member); Genetics Society (Member); International Plant Molecular Biology (Past President); British Society for Developmental Biology (Chair); International Plant Growth Substances Association (Council member); Sense About Science (Plant science panel member); Science and Plants for Schools (Grant holder); Numerous academic Journals (Advisory Editorial Board member); Science Media Centre (Trustee); HEFCE (Forum for Responsible use of research metrics, member); Wellcome Trust (Open science expert advisory group, member); Prime Minister’s Council on Science and Technology (Member);

The Crick Institute Board of Directors (From September) (Trustee and Board Member).

Recent Research Funding: Gatsby Foundation; European Research Council; Biotechnology and Biological Sciences Research Council.”

Dr Sarah Schmidt: “None that I am aware of.”

Prof Huw Jones: “No interests to declare. I believe my doi is still on the EFSA website:
<https://ess.efsa.europa.eu/doi/doiweb/doisearch/panel/GMO/wg/681414>.”

Prof Ian Crute: “Trustee Director of the John Innes Foundation.”

Prof Achim Dobermann: “No conflicts.”

Prof Johnathan Napier: “I have no conflicts to declare. I am running the UK’s only field trial of genome-edited plants, but I had no role in the approval of that trial.”

Prof Nigel Halford: “I am using genome editing (CRISPR) to reduce the acrylamide-forming potential of wheat (in other words to improve food safety in foods produced from wheat). It is very much exploratory at the moment to see what can be done, but could potentially lead to a genotype that could be used in breeding programmes. It is being carried out by a PhD student supported by 5 wheat breeding companies and AHDB, as well as the BBSRC via the South-West Doctoral Training Programme.”

None others received.