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Advisory Legal Opinion Expected for New Plant Breeding Techniques

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SP2 - Prevent or Resolve Barriers to Trade that Hinder
U.S. Food and Agricultural Exports

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Report Highlights:

On January 18, 2018, an Advocate General of the Court of Justice of the EU (ECJ) is expected to publish his legal opinion clarifying how certain innovative plant breeding techniques should be regulated under EU law (Case C-528/16 Confederation Paysanne and Others). This advisory opinion will set out to answer whether and to what extent organisms developed through certain classical and innovative plant breeding techniques, in particular directed mutagenesis, are to be regulated either through the same framework as conventional plant breeding or as genetically modified organisms (GMOs). Presently, organisms developed through classical mutagenesis breeding techniques are regulated as conventional and are exempt from the EU's main GMO regulation, Directive 2001/18/EC.

[1]

This ECJ interpretation of the law will have major implications for the future of seed breeding and innovation in Europe, as well as impacts on European agricultural production and global trade. In the ECJ, an Advocate General's legal opinion is non-binding and advisory for the panel of judges who decide the case, but is nonetheless viewed as important in shaping the final determination. The ECJ's Grand Chamber of Judges is expected to issue their findings in summer of 2018.

^[i] "Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms."

General Information:

Background

For nearly a decade, EU legislators have been grappling with whether and how to regulate a variety of newer genome editing and modification techniques—referred to in EU as New Plant Breeding Techniques (NBTs); these include genome editing techniques such as CRISPR. These genome editing techniques can produce specific genetic variations that are indistinguishable from conventionally bred plants as well as plants bred through classical mutagenesis and cell fusion, which are exempted from the EU’s main GMO regulation. Plant breeders and researchers can also use certain NBTs to introduce specific variations that include gene sequences foreign to the organism—such as those developed through transgenic breeding techniques regulated through the EU’s GMO directive. In 2015, at the behest of scientists, plant breeders, the seed industry and Member States, the European Commission committed to issuing a non-binding legal interpretation by that year’s end on which of these NBTs—if any—should be covered by the European GMO legislation, Directive 2001/18/EC. This is now delayed due to questions raised in the ECJ Case C-528/16 Confederation Paysanne and Others, described below.

Also in 2015, nine French anti-biotech NGOs, “Confederation Paysanne and Others,” submitted a complaint with the highest court in France, the French Council of State. They called on France to regulate all mutagenesis as GMOs, claiming this interpretation was consistent with the EU’s GMO directive. In adjudicating the case, the French court posed four questions on EU law to the ECJ, seeking clarification on the applicability of the EU’s GMO legislation to classical and NBT mutagenesis breeding techniques. The main thrust is whether the newer mutagenesis breeding techniques—commercialized and/or invented after the EU’s 2001 main GMO legislation—are considered to be and regulated as GMOs. For background information see the [2017 France Agricultural Biotechnology Annual](#) report.

The ECJ accepted the case with a Grand Chamber—comprised of 15 judges and presided over by the President of the Court. Most ECJ cases are staffed by three or five judges, and the engagement of the Grand Chamber suggests the court views the case as particularly important and/or complex.

^[i] Advocates General are assigned to most cases before the ECJ to serve as an advisor to the court on how the case should be resolved. Their opinions are given considerable weight, and often are followed by the court, but are non-binding in all cases. The court can decline to follow them or follow them in part, as it so decides. Reviews of ECJ case law find that the majority of ECJ judgements complement the opinions of the advocate general.^[iii] The Advocate General Michal Bobek is expected to publish his opinion on January 18, 2018 and the full ECJ judgement is expected to follow in summer 2018.

As a result of the pending ECJ case on mutagenesis plant breeding techniques, the European Commission significantly delayed its nonbinding legal interpretation on the full suite of NBTs and their applications as they relate to the GMO legislation until the ECJ issues its legal interpretations on the subset of NBTs under review by the French Council of State and the ECJ.

Plant breeding with NBTs remains in legal limbo and will only be partially clarified by the ECJ decision this year.

The ECJ Case and What Is at Stake

The EU authorization process for research field testing, production, and import of products that are considered genetically modified and/or not exempt from Directive 2001/18/EC is incredibly lengthy and expensive. In fact, most EU and international seed companies have essentially stopped seeking regulatory approval for production in the EU. A key critique of the EU's approval process is that the time^[iii] and expense of the regulatory review stymies innovation and research and restricts these activities to large companies, who can afford to navigate that system.

The ECJ's Advocate General's legal opinion will respond to four interlocutory questions on the scope of the EU's GMO legislation that boil down to: do classical and/or newer site-directed mutagenesis plant breeding techniques produce GMOs and do EU Member States retain any discretion in transposing these EU Directives to their national laws? For the complete text of the French Council of the State's questions see [The Official Journal of the European Union C 14/24](#); a summary is presented below.

1. Do organisms developed by mutagenesis— classical and/or site-directed NBTs— constitute GMOs as defined in the GMO Directive 2001/18/EC? This EU Directive expressly exempts organisms created through several plant breeding techniques, including classical mutagenesis, from the precautionary, impact assessment and traceability measures required of GMOs—so are the newer site-directed mutagenesis breeding techniques exempted, too?
2. For the regulatory requirements for “genetically modified varieties” set forth in the EU's Directive 2002/53/EC governing how seeds are produced and marketed in the EU, do these apply to organisms derived from classical and/or NBT mutagenesis—that is to say, are the definitions and exemptions from the EU's GMO Directive 2001/18/EC determining what is considered a “genetically modified variety” defining what is a genetically modified variety in 2002/53/EC?
3. Do Member States have any national discretion in interpreting the GMO Directive 2001/18/EC or is this a fully EU harmonized directive?
4. Is the exclusion of mutagenesis from the EU's GMO Directive 2001/18/EC consistent with the precautionary principle guaranteed in the Treaty of the Functioning of the EU?

The ECJ Grand Chamber will consider the Advocate General's opinion and is expected to issue a judgement this summer. The court has a mixed record tackling complex biotech issues.^[iv] In 2011, the Court delivered a very controversial ruling on the status of pollen in honey [C-442/09 Karl Heinz Bablok and others v Freistaat Bayern](#). Pollen is a natural component of honey, introduced by bees through foraging. However, in 2011 the ECJ ruled that pollen is an ingredient in honey. This interpretation set off a cascade of regulatory assessments and authorizations for beekeepers and agribusinesses, who might have to demonstrate their honey and food products containing honey did not have trace pollen from genetically engineered plants. The ECJ decision introduced great confusion into the EU and international honey markets on labeling and testing requirements. The EU then passed legislation to re-assert that pollen is a natural component of honey.

The NBT judgement has the potential to alter the regulatory fate and public perception of a large swath of food and agricultural products. Some of the technologies being reviewed have been in common

commercial use for decades, both in the EU and by trading partners globally. The judgement could also lead to the fracturing or the closing off of the EU's single market for plant breeding research, production, and/or trade for organisms developed with these newer breeding techniques. However, the judgement could also take a major step in clearing the path for researchers, breeders and seed companies to pursue academic research and commercialization of food and agricultural products that address food and agricultural challenges in Europe and in the world.

The regulatory fate of NBTs and the full suite of their applications in the EU will be far from decided by summer 2018, but this ECJ case is very important in shaping its future.

^[i] Statute of the Court of Justice of the European Union; Article 16.

^[ii] Carrubba, Clifford J., Matthew Gabel, and Charles Hankla. "Judicial behavior under political constraints: Evidence from the European Court of Justice." *American Political Science Review* 102.4 (2008): p.448-449

^[iii] Although the legally prescribed approval time is 12 months, the 2017 approvals of applications for GE plant varieties took an average of over six years (industry estimate)

^[iv] See: Editorial "Gene editing in legal limbo in Europe: Nature News & Comment" *Nature* 542,393 (2017): 2 doi:10.1038/542392a