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EU Court Extends GMO Directive to New Plant Breeding Techniques

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Report Highlights:
On July 25, 2018, the Court of Justice of the European Union issued its judgment that organisms created through many newer genome editing techniques are to be regulated as genetically modified organisms (GMOs) in the EU. This decision subjects such organisms, and food and feed products containing these organisms, to expensive and lengthy approval processes as well as traceability, labelling, and monitoring obligations. In addition to affecting global agricultural trade, this judgment has significant consequences for EU innovation.

General Information:

Surprising many, the Court issued a judgment for "Case C-528/16 Confederation Paysanne and Others" taking a very restrictive view of how the EU's main GMO legislation from 2001, "Directive 2001/18/EC," applies to organisms created by new plant breeding techniques such as CRISPR/Cas or Talen. Many scientists, breeders, and agri-food industry stakeholders had anticipated that the Court would categorize organisms derived from these newer mutagenic techniques as GMOs, but exempt them from the regulatory obligations in the Directive [1].

Instead, the Court found that organisms produced with newer mutagenesis methods are subject to the regulatory obligations of the EU's GMO Directive. As such, they will be subject to risk assessment and review requirements as they are applied to the cultivation and imports of transgenic varieties (incorporating foreign genes into the organism). For context, products approved for importation in 2017 under the GMO Directive took an average of six years to complete—five years for the risk assessment by the European Food Safety Authority and a year to garner Commission approval through the risk management process. Cultivation approvals, as well as new applications, for transgenic varietals have languished [2].

Under the EU's GMO Directive 2001/18/EC, the EU focuses on the process of genetic alternation to determine what agricultural products are regulated. However, the EU's GMO Directive exempts certain genetic modification techniques— notably for this case, "the mutagenesis exemption." In plant breeding, mutagenesis is a long-established technique that uses chemical, radiation, or other physical stimuli to induce mutations. Plant breeders then evaluate whether the genetic alternations have yielded beneficial properties. If so, these plants are selected for use in breeding programs. With the Directive's exemption, plants developed through these common breeding techniques can enter the EU marketplace without additional GMO-related regulation [3]. The EU's GMO Directive does not have a legislative definition for mutagenesis. Although most new genome editing methods use mutagenesis in a more targeted manner than older techniques, the Court found that newer techniques are not covered by the "mutagenesis exemption."

In its ruling, the Court stressed that "the number of applications" (i.e. frequency of use) and "the long safety record" are essential components of the mutagenesis exemption. Organisms produced with the newer mutagenesis techniques are therefore not exempt from the obligations of the GMO Directive. The judgment neither defined the threshold for the "number of applications," nor what constitutes a "long safety record." Also of note, the Court stressed that risks associated with newer mutagenesis techniques "might prove to be similar to the risks associated with transgenesis due to the direct modification of the genetic material."

In these regards, the Court's judgment very much differed from the advisory opinion from the Court's Advocate General (AG) Michal Bobak in January 2018 [4]. For the Court of Justice of the European Union, the AG's opinion is wholly advisory, but as conventional wisdom and legal studies note [5], the Court follows the AG's opinion around 70 percent of the time. The AG had opined that some newer applications of genome editing techniques are exempt from the GMO Directive and that it did not matter that these techniques were popularized or invented after the GMO Directive was established in 2001. Rather the determinants for exemption were the technique—mutagenesis and the other techniques listed

as exempt in the Directive, and that the organism does not involve the use of recombinant DNA or the use of organisms other than those produced by one or more of the exempted techniques.

The court also found that EU Member States have the authority to regulate organisms produced by conventional mutagenesis that are exempt from the GMO Directive, so long as the actions are in compliance with the overarching obligations of EU law, particularly the free movement of goods.

With the Court of Justice of the European Union's judgment, the length of time that a new mutagenesis technique has been used is now a primary consideration determining if costly and lengthy product assessments are required [6]. The potential risk of the technique or the product itself is not considered. This case is significant because by not basing regulatory oversight on potential risk, agricultural breeding techniques and products that pose little or no risk will be overregulated, which will significantly discourage innovation. This is especially true for small companies and public research institutions, who lack the ability to surmount the EU's multiyear, multistep approval process. Finally, the commercialization of these technologies globally will increase the occurrence of trade disruptions within the EU.

The Commission has yet to react to the judgment. Follow on actions will likely have to wait until after the elections, as the European Commission and Parliament's terms are coming to a close. The Commission's election recess starts in October 2018, and the European Parliament's recess usually starts by March with elections following in May of 2019.

[1] See: Purnhagen, K.P., et al. "The European Union Court's Advocate General's Opinion and New Plant Breeding Techniques." *Nature Biotechnology* 36.7 (2018): 573 or Michalopoulos, Sarantis. "Industry shocked by EU Court decision to put gene editing technique under GM law." 07/25/2018. Euractiv.com, accessed: 07/25/2018

[2] For an overview of issues related to implementation of the GMO Directive, see: "EU Food and Feed Chain Coalition Position paper for a functioning evidence-based EU policy on GMOs." Food and Feed Chain Coalition. 05/28/2015, accessed 07/27/2018.

[3] As required through Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species and complementary directives and associated Seed Directives

[4] See FAS GAIN Report: European Court Examines Whether Some NBTs Are Exempted from GMO Law and the Opinion of Advocate General Bobek delivered on 18 January 2018

[5] See Arrebola, Carlos, Ana Julia Mauricio, and Héctor Jiménez Portilla. "An Econometric Analysis of the Influence of the Advocate General on the Court of Justice of the European Union." Cambridge J. Int'l & Comp. L. 5 (2016): 82.

[6] A 2009 publication from The Netherlands Commission on Genetic Modification (COGEM) puts the applicant's costs of obtaining a GE approval in the EU at estimated 7-10 million Euros. COGEM. "Should EU legislation be updated? Scientific developments throw new light on the process and product approaches" 06/26/2009, citing: Schenkelaars (2008). Dossierkosten markttoelating genetisch gemodificeerde gewassen in de Verenigde Staten en de Europese Unie. COGEM onderzoeksrapport 2008-05