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Confédération paysanne case (C-528/16) : Legal Perspective on the GMO Judgment of the European Court of Justice

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I. – Background explanation

On 25 July 2018, in Case C-528/16, *Confédération paysanne a.o. against the French Minister for Agriculture, the Food Processing Industry and Forestry*, the European Court of Justice held that new plant breeding techniques based on mutagenesis fall under the current EU GMO legislative framework.

The main EU regulatory framework for genetically modified organisms is the so-called ‘GMO Release Directive’, i.e. Directive 2001/18/EC.¹ It regulates the *deliberate release* into the environment of GMOs and the *placing on the market* of GMOs as or in products. ‘Deliberate release’ is defined as any intentional introduction into the environment of a GMO for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment. In this, the Directive establishes a general definition of GMO, complemented by a non-exhaustive positive list of techniques that result in GMO (Annex 1A, part 1), and a negative list of techniques that are considered non-GMO (Annex 1A, part 2). In addition, the Directive establishes a list of exemptions (Annex 1 B), that is techniques that are not subject to the requirements of the Directive. Mutagenesis is listed as one of the exemptions.

Scientifically, mutagenesis refers to the creation of a genetic mutation. It can occur spontaneously in nature, but also through exposure to radiation or chemicals. However, a number of new technologies have emerged that also radically alter the potency of mutagenesis, for instance by creating precise and directed mutations. These new

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¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, *OJ* 2001 L 106, p. 1.

scientific developments gave rise to the issue in *Confédération paysanne*, namely whether also these new mutagenesis techniques should benefit from an exemption under the GMO Release Directive.

This case note briefly summarises the case and comments on the judgment from a legal perspective.

II. – Summary of the case

The case was brought by the French agricultural union *Confédération paysanne* and eight other similar associations against the French Agricultural Ministry. The associations had requested to revoke a French law that considered mutagenesis not to result in genetic modification; further they had requested to ban the cultivation of a herbicide-tolerant rape obtained by mutagenesis. The case was heard before the *Conseil d'État*, who triggered the preliminary reference procedure. The questions answered by the CJEU concerned the interpretation of Directive 2001/18/EC on the deliberate release into the environment of GMOs [paragraph 25, in paraphrased form]:

- Do organisms obtained by means of techniques/methods of mutagenesis constitute GMOs within the meaning of that provision, and are they exempted under the GMO Release Directive?
- Are genetically modified varieties obtained by means of techniques/methods of mutagenesis exempt from the obligations laid down in Directive 2002/53/EC² on the common catalogue of varieties of agricultural plant species?
- Does the GMO Release Directive deny Member States the option of subjecting the organisms obtained by means of techniques/methods of mutagenesis that are excluded from the scope of the directive to the obligations laid down in that directive or to other obligations?

The key findings of the case are that (1) organisms obtained by mutagenesis techniques are defined as GMOs, and that (2) the existing mutagenesis exemption from the applicability of the GMO Release Directive is valid only for ‘conventional’ mutagenesis techniques with a history of safe use and not new ones. Two less discussed outcomes of the case are that (3) the ‘conventional’ mutagenesis exemption is relevant in the context of Directive 2002/53 on the common catalogue of varieties of agricultural plant species and that (4) the GMO Release Directive does not have the effect of denying Member States the option of nevertheless subjecting GMOs, in compliance with EU law, to the obligations of that directive or to other obligations.

² Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, *OJ* 2002 L 193, p. 1.

III. – Argumentation

The European Court of Justice first considered whether an organism obtained by mutagenesis must be classified as a GMO, and subsequently, whether the GMO Release Directive would apply to new plant breeding techniques involving mutagenesis, despite the express exemption of mutagenesis from the applicability of the directive.

A. – DEFINITION OF A GMO

Much of the case revolves around the definition of genetically modified organisms (GMOs) in the European Union. Under Article 2 of the GMO Release Directive, a GMO is defined as

“an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”.

In EU law, therefore, the alteration of genetic material in a way that does not occur naturally is considered a GMO. The Court finds that the techniques at issue in the main proceedings involve alterations to the genetic material (i.e. to achieve herbicide-resistance): “certain of those techniques/methods involve the use of chemical or physical mutagenous agents, and others involve the use of genetic engineering, [therefore] those techniques/methods alter the genetic material of an organism in a way that does not occur naturally, within the meaning of that provision”.³

B. – THE MUTAGENESIS EXEMPTION IN EU GMO LAW

The controversy of the judgment stems from the fact that the GMO Release Directive expressly exempts mutagenesis from its applicability under Article 3(1) of the Directive, in conjunction with point 1 of Annex IB thereof.

While Annex IA (positive GMO list) lists techniques that result in a GMO,⁴ Annex IB lists techniques that are considered a GMO, but that benefit from an exemption from the legal framework of the Directive (list of exemption from the scope). The exempted techniques are mutagenesis, and cell fusion (including protoplast fusion) of plant cells of organisms that can exchange genetic material through traditional breeding methods. It is noteworthy, therefore, that the Directive is explicit about excluding mutagenesis tech-

³ Case C-528/16, *Confédération paysanne*, para. 29.

⁴ Recombinant nucleic acid techniques; techniques involving the direct introduction into an organism of heritable material prepared outside the organism; non-natural cell fusion (including protoplast fusion) or hybridisation techniques.

niques from its application. This begs the question of how the Court of Justice concluded that NPBT – ‘novel plant breeding techniques’ – are covered by the GMO regime.

In order to reach the conclusion that only conventional mutagenesis techniques are covered by the exemption, the CJEU relies heavily on recital 17 to legally anchor its argument. Recital 17 explains the reason for the list of exemptions in Annex IB. It states that the GMO Release Directive should not apply to certain techniques of genetic modification which have *conventionally been used in a number of applications* and *have a long safety record*. The CJEU therefore relies on the objective (teleologic) interpretation of the provision, and on the apparent will of the legislator to limit the exemptions to ‘conventionally used’ techniques in order to construe the scope of the exemption as covering only conventional mutagenesis techniques with a long safety record.

The main motive for this outcome appears to be that the Court was convinced that ‘new’ mutagenesis techniques enable modifications and consequently risks that are identical to transgenesis techniques to which the GMO Release Directive is consistently applicable. The CJEU, in thus characterizing the new plant breeding techniques, relies very heavily (and explicitly!) on the scientific characterisation of mutagenesis provided to it by the referring court and the parties. In this vein, the CJEU states: “As the referring court states in essence, ... the risks linked to the use of those new techniques/methods of mutagenesis might prove similar to those (...) from transgenesis. It thus follows from the material before the Court, ... direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that organism... those new techniques/methods make(...) it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis”.⁵ Put simply, based on the information at its disposal, the CJEU concluded that there is a qualitative difference between ‘conventional’ and ‘new’ mutagenesis techniques; and that the new mutagenesis techniques resemble in terms of effects and risks those that do fall under the GMO Release Directive obligations. It interprets these risks in light of the objective of the GMO Release Directive, i.e. to protect human health and the environment, in accordance with the precautionary principle.⁶

On this basis, the CJEU held that only organisms obtained by means of techniques of mutagenesis which “have conventionally been used in a number of applications and have a long safety record” are excluded from the scope of that directive”.⁷

In addition to these answers, the Court holds that the formulation of the mutagenesis exemption applies in the context of the Directive 2002/53 on the common catalogue

⁵ Case C-528/16, *Confédération paysanne*, para. 48.

⁶ Directive 2001/18/EC, Article 1.

⁷ Case C-528/16, *Confédération paysanne*, para. 6.

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of varieties of agricultural plant species.⁸ Lastly, it finds that the GMO Release Directive does not have the effect of denying Member States the option of subjecting GMOs obtained by mutagenesis, in compliance with EU law, to the obligations of that directive or to other obligations. This is the case, because the exemption of conventional mutagenesis from the GMO Release Directive applies “without specifying in any way the legal regime to which they may be subject”.⁹

IV. – Reflection points

The judgment has been vehemently criticised by practitioners and scientists;¹⁰ although the reception by legal scholars was more measured.¹¹

A. – LEGAL CONSEQUENCES OF THE JUDGMENT

In light of the criticism, it is necessary to comment on the legal consequences of the judgment, which has sometimes been characterised as amounting to a total ban for new plant breeding techniques on the EU market. From a legal technical point of view, the judgment results in a necessity to authorise; it is not a ‘ban’. For the cultivation of a GM plant, the regime is laid down in the GMO Release Directive, while for use in food the authorisation procedure is set out in Regulation (EC) No 1829/2003¹². Although not an outright ban, it is clear that authorisations are costly and time-consuming – the main reason why the judgment is so heavily criticised by stakeholders.¹³

Additionally, the interpretation of the exemption also unfolds widespread legal effects in other GMO relevant legislation. The CJEU clearly ruled that it applies in

⁸ Case C-528/16, *Confédération paysanne*, para. 60.

⁹ *Ibid.*, para. 80.

¹⁰ “This verdict has left scientists, breeders as well as officials from regulatory agencies perplex”, see for an extensive overview of reactions Martin WASMER, “Roads Forward for European GMO Policy-Uncertainties in Wake of ECJ Judgment Have to be Mitigated by Regulatory Reform” (2019) 7 *Frontiers in bioengineering and biotechnology* 132.

¹¹ For instance, Kai PURNHAGEN, “How to manage the Union’s diversity: The regulation of New Plant Breeding Technologies in *Confédération paysanne and Others*” (2019) 56(5) *Common Market Law Review*; Kathleen GARNETT, “Hold your pipettes: The European Court of Justice’s findings in *Confédération Paysanne & Others* stirs GMOTions” (2019) *Review of European, Comparative & International Environmental Law*; Bettina WANNER, Hervé MONCONDUIT, Andrea MERTENS, Jörg THOMAIER, “CJEU renders decision on the interpretation of the GMO Directive” (2019) 14(2) *Journal of Intellectual Property Law & Practice*, p. 90-92; Kai P. PURNHAGEN, Esther KOK, Gijs KLETER, Hanna SCHEBESTA, Richard G. F. VISSER & Justus WESSELER, “EU court casts new plant breeding techniques into regulatory limbo” (2018) 36(9) *Nature Biotechnology*, p. 799-800.

¹² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003, OJ 2003 L 268, p. 1.

¹³ Martin WASMER, “Roads Forward for European GMO Policy-Uncertainties in Wake of ECJ Judgment Have to be Mitigated by Regulatory Reform” (2019) 7 *Frontiers in bioengineering and biotechnology* 132.

the context of Directive 2002/53 on the common catalogue of varieties of agricultural plant species. Other legislation in the context of which it will become relevant are Regulation No 1829/2003 on GM food and feed authorisation, Regulation (EC) 1830/2003¹⁴ concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, Directive 2009/41/EC¹⁵ on contained use of genetically modified micro-organisms, Regulation (EC) 1946/2003¹⁶ on transboundary movements of GMOs, and Directive 2004/35/EC¹⁷ on environmental liability.¹⁸

In the face of disagreement among the Member States as to how to deal with GMOs, EU law has witnessed a trend of accommodating different Member States' positions on the topic. To this end, a new Member State derogation has been in place since 2015, concerning the cultivation authorisation requirements. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, Member States may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is excluded from cultivation (Article 26b(1) of Directive 2001/18). Authorisations, therefore, are not necessarily applicable EU wide; in total 19 Member States have made use of the opt-out mechanisms for (some) authorisations.¹⁹

It would be remiss to overlook the final part of the judgment as is often the case. Here, the Court held that Member States can continue to regulate GMOs obtained by conventional mutagenesis at national level, in compliance with general EU (free movement) law. Through this, the CJEU strengthened the Member States' ability to take individual measures further.

¹⁴ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, *OJ* 2003 L 268, p. 24.

¹⁵ Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms, *OJ* 2009 L 125, p. 75.

¹⁶ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, *OJ* 2003 L 287, p. 1.

¹⁷ Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, *OJ* 2004 L 143, p. 56.

¹⁸ Case C-528/16 *Confédération paysanne*, para. 60; see also Kai P. PURNHAGEN, Esther KOK, Gijs KLETER, Hanna SCHEBESTA, Richard G. F. VISSER & Justus WESSELER, "EU court casts new plant breeding techniques into regulatory limbo" (2018) 36(9) *Nature Biotechnology*, p. 799-800; Kai PURNHAGEN, Esther KOK, Gijs KLETER, Hanna SCHEBESTA, Richard VISSER, JUSTUS WESSELER, "The European Union court's advocate general's opinion and new plant breeding techniques" (2018) 36(7) *Nature Biotechnology*, p. 573-575.

¹⁹ European Commission, GMO authorisations for cultivation, Restrictions of geographical scope of GMO applications/authorisations: EU countries demands and outcomes, available at https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.

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Overall, the judgments' practical effect is the creation of a significant obstacle for the cultivation and marketing of organisms obtained by new mutagenic techniques and products derived thereof. It must be borne in mind, though, that the apparently significant burden of authorisation is a feature of the normal regulatory regime for GMOs. At least when it comes to authorisations for cultivation, a GMO is then subject to a very fragmented regulatory landscape that testifies the very cautious stance that most Member States take towards anything classified as GMO.

B. – THE DEFINITION OF GMOs

From a legal point of view, the principal classification of organisms created by mutagenesis techniques as GMOs is not surprising in light of the text of the GMO Release Directive. Both the general definition of GMO as alteration that does not occur naturally, as well as the formulation of the exemption list, leave little doubt that mutagenesis fulfils the legal definition for GMO creation. On this point, the judgment is therefore less striking when considering the actual legal EU GMO definition and bearing in mind that there is a diversity of GMO definitions across different global jurisdictions.²⁰

The authoritative international legal source for the definition of GMO is the Cartagena Protocol. Under the Protocol, a 'Living modified organism' (LMO, equivalent to GMO) is "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology",²¹ where modern biotechnology means the application of in vitro or direct injection nucleic acid techniques, or the fusion of cells beyond the taxonomic family. The question has been raised whether, particularly after the *Confédération paysanne* judgment, the EU GMO definition is in line with the Cartagena LMO definition.²² However, the Protocol stipulates under Article 2(4) that Parties can take actions that are more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol. For the European Commission this is the legal basis for assuming that the EU interpretation of GMOs, even after the judgment, is in compliance with the Protocol.²³

²⁰ Dennis ERIKSSON, Drew KERSHEN, Alexandre NEPOMUCENO, Barry J. POGSON, Humberto PRIETO, Kai PURNHAGEN, Stuart SMYTH, Justus WESSELER, Agustina WHELAN, "A comparison of the EU regulatory approach to directed mutagenesis with that of other jurisdictions, consequences for international trade and potential steps forward" (2019) 222(4) *New Phytol.*, p. 1673-1684.

²¹ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 3(g).

²² European Parliament, Parliamentary questions, 7 December 2018, Question for written answer to the Commission, Mark Demesmaeker (ECR), available at http://www.europarl.europa.eu/doceo/document/E-8-2018-006173_EN.html.

²³ European Parliament, Parliamentary questions, 11 February 2019, Answer given by Mr Andriukaitis on behalf of the European Commission, available at http://www.europarl.europa.eu/doceo/document/E-8-2018-006173-ASW_EN.html#def2.

New plant breeding techniques (NPBT) are problematic under process-based definitions of GMOs, such as the EU definition or the Cartagena Protocol (that is a combination of a product- and process-based definition). The reason is that the new techniques in some instances resemble ‘modern biotechnologic’ methods, but in some cases only introduce genetic modifications that cannot be distinguished from conventional breeding.²⁴ Certainly, the category of new plant breeding techniques does not have a strict scientific or legal meaning, and arguably has been created as a concept that avoids to be automatically considered as GMOs.²⁵

An international legal comparison shows that for these reasons, NPBT are a challenge in many GMO regulatory systems; and also that techniques that would commonly be considered an NPBT have already been classified as a GMO in some jurisdictions.²⁶

C. – THE EXTENT OF THE MUTAGENESIS EXEMPTION

From a legal point of view the Court of Justice’s interpretation of the mutagenesis exemption is much more interesting. Seemingly, mutagenesis was exempt from the scope of the GMO Release Directive, and the Court could have taken a literal interpretation to solve the case in line with the plain, literal and ordinary sense of the provision. Against this backdrop, the Court combined a purposive approach together with a construction of the provision based on the legislative intent.

As a starting point, it is important to bear in mind that exemptions are always to be interpreted narrowly, and it is certainly a relevant question to ask why mutagenesis techniques had been exempt from the GMO Release Directive in the first place. A study on the legislative history of the GMO Release Directive is highly instructive in this regard.²⁷ The GMO Release Directive had initially been proposed by the European Commission without mention of mutagenesis. A special treatment of mutagenesis was only suggested by the Economic and Social Committee, drawing attention to the fact that some kind of genetic modifications have been tested over “decades if not centuries”. In fact, mutagenesis techniques have found wide application in plant breeding since the 1930s and currently around 3.300 varieties are registered in the FAO-IAEA Mutant Variety Database. It is likely that the later inclusion of mutagenesis in the proposal leading to the Directive is due to reflect this societal fact.²⁸ Therefore,

²⁴ Agustina I. WHELAN and Martin A. LEMA, “Regulatory framework for gene editing and other new breeding techniques (NBTs) in Argentina” (2015) 6(4) *GM crops & food*, p. 253-65.

²⁵ *Ibid.*

²⁶ *Ibid.*

²⁷ Charlotte KRINKE, “GMO directive: the origins of the mutagenesis exemption”, INFOGM 16 mars 2018, available at <https://www.infogm.org/6509-gmo-directive-origins-mutagenesis-exemption?lang=fr>.

²⁸ See for a study of the legislative process on how the mutagenesis exemption was included in the Directive, <https://www.infogm.org/6509-gmo-directive-origins-mutagenesis-exemption?lang=fr>;

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when the Council amended the proposal text, it suggested the current exemption list, including an exemption for mutagenesis, together with the recital that the GMO Release Directive “should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record”.²⁹ In order to explain both the legislator’s intent, but also the purpose of the exemption, the recital therefore must indeed be regarded as authoritative, and not a merely incidental formulation.

When dealing with mutagenesis, the Court has been particularly attacked for its (lack of) science. In this sense, it is necessary to reflect on the fact that courts are limited in the legal process by material and evidence as it is made available to them by the referring court or parties.³⁰ The Court itself is not able to make scientific inquiries. Therefore, if it is presented with evidence that new mutagenesis techniques essentially pose the same risks as techniques that are currently subject to an authorisation, the Court will have to rely on this evidence.

From a legal point of view, therefore, the judgment is justifiable when taking together the facts that the Court (1) was apparently convinced that new mutagenesis techniques pose risks akin to those techniques that are regulated, (2) the insight that the legislator intended to exempt mutagenesis for being a conventional technique with a long safety record, and (3) the objective of the GMO Release Directive to protect human health and the environment, in accordance with the precautionary principle.

V. – Conclusions

The judgment has been regarded as a blow to the new plant breeding techniques, and many stakeholders are discontent with the outcome. However, something akin to a scientific consensus has emerged in recognizing that the problem was not necessarily the Court, but the underlying regulatory framework. In the current case, the CJEU was confronted with the interpretation of an almost twenty-year-old piece of legislation in a sector that has made rapid technological advances. Typically, the role of courts includes to take into account societal developments in the interpretation of law, and relay it to the will of the legislator and the objectives pursued by a piece of

see also Kathleen GARNETT, “Hold your pipettes: The European Court of Justice’s findings in *Confédération Paysanne & Others* stirs GMOtions” (2019) *Review of European, Comparative & International Environmental Law*.

²⁹ Directive 2001/18/EC, recital 17.

³⁰ Kai P. PURNHAGEN, Esther KOK, Gijis KLETER, Hanna SCHEBESTA, Richard G. F. VISSER & Justus WESSELER, “EU court casts new plant breeding techniques into regulatory limbo” (2018) 36 *Nature Biotechnology*, p. 799-800.

legislation. The scientific and societal deficiencies in the GMO definition and authorisation system are not for the court to change, or to solve. The case applies the EU GMO regime as it stands, and if the system is regarded as inadequate, it must be modified by the legislator. These institutional arguments are, in my view, those that weigh most in favour of the outcome of the judgment.