The legal status of genome editing and other new forms of directed mutagenesis after the ECJ judgment of 25 July 2018, C-528/16

Hubert Bocken,
Prof. em. UGent Faculty of Law and Criminology

I. Introduction

1. The scientific community has passionately debated the judgment of the ECJ of 25 July 2018 in case C-528/16[1] and its impact on the legal status of genome editing for plants and other new directed mutagenesis techniques[2].
Interesting issues covered are, a.o., whether the interpretation of the GMO definition and of the concept mutagenesis by the Court is correct, whether the scientific data referred to by the court are accurate, whether the decision of the Court corresponds to the intention of the legislator as experts have witnessed it develop during the preparation of the Directive, whether the court could or should have decided otherwise,…
To establish the present legal status of genome editing, however, the relevant question is: what has the court decided? This must be the starting point for evaluating that legal status and for adapting it in view of scientific developments of the last two decades.
Although summaries of the Court's decision on the legal status of genome editing have been published by institutions with a considerable degree of authority such as the ECJ itself[3], the EU

[1] http://curia.europa.eu/juris/document/document.jsf;jsessionid=B00E1542AD9104C5C6EE05FBE717F4DB?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=19904769.

[2] The Court does not use the term "genome editing" but examines the status of the broader category of "new directed mutagenesis techniques implementing genetic engineering processes" (par. 25, 1). "New" techniques are those "which have appeared or have been mostly developed since Directive 2001/18 was adopted" (par 47). As the focus in the ALLEA statement on genome editing for crop improvement is on genome editing rather than on the broader category of newly developed plant breeding techniques, in this note reference is also made to genome editing as part of the more general category of new directed mutagenesis techniques to which the judgment applies (see ALLEA (2020) lead authors: Dima, O.; Bocken H.; Custers, R.; Inze, D.; Puigdomenech, P.; Genome Editing for Crop Improvement. Symposium summary. Berlin. DOI: 10.26356/gen-editing-crop.)

[3] A summary of the decision is available on the website of the Court itself: http://curia.europa.eu/juris/document/document.jsf;jsessionid=53A56A22D464786A7F2234A8C1964A49?text=&docid=207002&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=16993821. The main elements of the summary with respect to the legal status of genome editing are: 1. Article 2(2) of Directive 2001/18/EC … must be interpreted as meaning that *organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms* within the meaning of that provision. 2. Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B … and in the light of recital 17 …, must be interpreted as meaning that only organisms obtained by means of techniques/methods 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. In those circumstances, *Article 3(1)* of Directive 2001/18, read in conjunction with point 1 of Annex I B to that Directive, *cannot be interpreted as excluding, from the scope of the Directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18*

Commission [4] and the French Conseil d'Etat and government[5], there remain differing views on the meaning of the judgment in the biotech community (more so than among legal scholars). As one knows, not all opinions on the safety of genome editing are equally based on scientific facts. Similarly, not all interpretations of the ECJ judgment in case C-528/16, are equally based on legal facts. This note intends to present an overview of relevant legal facts with respect to the meaning of the judgment under consideration.

2. If the legal status of directed mutagenesis and genome editing, as determined by the ECJ, requires to be amended to reflect the scientific developments of the last two decades, an appeal should be made to the legislator. Courts have as function to interpret and apply the law. In so doing, they contribute to the development of legal concepts. Their function, however, is not to formulate a set of nuanced technical rules on complex scientific issues not yet regulated by the legislator. This is the more so when these issues are intertwined with social and political issues on which substantially diverging opinions prevail.

II The preliminary ruling procedure under EU law.

3. To correctly evaluate the Court's decision, it is important to consider that it was rendered on *request for a preliminary ruling* from the French Conseil d'Etat, in *grand chamber* (composed of 15, rather than 3 or 6 judges, presided over by the president of the Court) and after a substantially *contradictory opinion of advocate general* Bobek. In other words, it clearly was not a decision lightly taken.

4. Especially the fact that it was a *preliminary ruling* is essential to understand the decision. A procedure for a preliminary ruling by the ECJ differs substantially from traditional litigation at national level in which a court establishes the facts, determines the relevant legal rules and applies these rules to the facts.
It is the duty of national courts and administrative bodies to apply EU regulations and (domestic law implementing) EU Directives in the same manner as domestic law. However, if a court of a Member State in a case governed by EU law, finds the meaning of a provision thereof to be unclear, it may and in certain cases must, before disposing of the case, seek a preliminary ruling[6]

---

was adopted." (Italics or emphasis in this and other citations from court decisions or legislative documents have been added by the author).

[4] COUNCIL DECISION (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019D1904&from=EN): "By its judgment in Case C-528/16 (2), the Court of Justice, after considering the overall objectives of Directive 2001/18/EC, ruled that *new mutagenesis techniques fall within the scope of that Directive* and are subject to the obligations laid down therein". (Italics added)

[5] When implementing the judgment of the ECJ. See further nr. 16 and 17.

[6] Article 267 Treaty on the Functioning of the European Union (TFEU): "The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:
(a) the interpretation of the Treaties;
(b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union; Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a

from the highest judicial authority of the EU, the ECJ, on the interpretation of that provision. The role of the ECJ in the preliminary ruling procedure consists of and is limited to answering the questions on the interpretation of EU law raised by the national court. The ECJ does not establish the facts, but generally proceeds on the basis of the statement thereof by the referring court. It does not determine which rules are relevant for disposing of the case. It is for the referring national court to determine which issues of EU law are to be examined by the ECJ and to render judgment on the case, in accordance with the ECJ's ruling. Preliminary rulings are binding for the referring court but are also authoritative for other judicial and administrative authorities in the Member States. Consequently, national judges, whenever they apply EU law directly or indirectly, follow earlier interpretations of that law given by the ECJ. In exceptional cases, a national court might ask the ECJ to provide further clarification on the interpretation of a preliminary ruling[7].

5. When interpreting EU law[8], the ECJ does not only consider the specific wording of a provision (textual interpretation[9]). As is the case in the judgment under consideration[10], the Court generally attaches great importance to other parts of the text in which the provision to be interpreted occurs (contextual interpretation), as well as to the aims and purposes of the legislation - which often are clarified in the recitals in the preamble of the document - (teleological interpretation) The Court may also consider published preparatory documents which clarify the common intention of the parties involved in the legislative process. An additional rule of interpretation, relevant especially when legislation establishes a comprehensive regulatory scheme, is that exceptions are to be interpreted restrictively[11].

6. The questions submitted by the referring national court to the ECJ are restated - and often also rephrased- in the preliminary ruling itself. To fully understand the judgment, it may also be useful to consider more closely the underlying litigation and the referral decision of the national court, in this case judgment n°388649 of the French Conseil d' Etat (CE) of 3 October 2016, *Confédération paysanne e.a.*[12] To assess the practical impact of the ECJ's decision, one may also want to look at the final decision of the referring court and the consequences thereof in the domestic legal system.

---

decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon. Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court" For further information, see https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:12016E267

[7] As the judgment was rendered after careful deliberation in grand chamber and rejection of the opinion of the advocate general it is most unlikely that the Court would change its opinion if a new preliminary question were submitted on the same issue.

[8] On the methods of interpretation of the ECJ, see especially K. Lenaerts and José A. Gutierrez-Fons, *Les méthodes d'interprétation de la Cour de justice de l'Union européenne*, Bruylant, 2020, 214 p; K. Lenaerts and P. Van Nuffel, *European Union law*, 3rd edition, Sweet & Maxwell, 2017, 813-815.

[9] Which is often complicated by the fact that all linguistic versions of EU law have equal legal force.

[10] See esp. par. 41 and 43.

[11] See par. 41 of decision under consideration and the reference to earlier case law.

[12] See https://www.legifrance.gouv.fr/ceta/id/CETATEXT000033191647/.

Hereafter we briefly examine the litigation before the referring French court (III), the relevant parts of the ECJ judgment itself (IV) and the implementation thereof in French GMO law (V).

III. The litigation in France leading to the ECJ judgment. The questions submitted to the ECJ.

7. In 2014, Conféderation paysanne and a number of other NGO's, requested the French prime minister to abrogate art. D 531-2 of the French Environmental Code as this provision excludes from the application of GMO legislation plant varieties obtained by mutagenesis. The article in question reads as follows: "The techniques referred to in Article L. 531-2, which are not considered to give rise to genetic modification, are the following: …. 2) On condition that they do not involve the use of genetically modified organisms as recipient or parental organisms: (a) mutagenesis; …". The petitioners also asked a moratorium to be imposed on the culture and commercialization of herbicide tolerant plants, in particular canola varieties, developed by mutagenesis, because, among other reasons, their cultivation leads to an increased use of herbicides. The Prime Minister did not respond to the request, which under French law amounts to an implicit rejection.
On 12 March 2015, Confédération paysanne thus started a procedure before the Conseil d'Etat (CE) in order to obtain the annulment of the implicit refusal to abrogate the provision in question and to enjoin the government to suspend the use of a number of herbicide tolerant varieties.

8. Among the variety of legal issues debated before the CE, the main ones are:
-Is art. D.531-2, which defines mutagenesis as not giving rise to genetic modification, contrary to art. 2 of the EU Directive according to which organisms obtained by mutagenesis constitute genetically modified organisms, although they are exempted by art. 3 and Annex IB?
-Do modern techniques of directed mutagenesis constitute techniques of genetic modification as referred to in art 2, 2, (a) of the Directive?
-Are all types of mutagenesis, including the modern forms of genome editing covered by the mutagenesis exemption of Annex IB of the Directive?
It is interesting to note that the CE in its decision made a number of findings of law and fact[13]

[13] Par. 23: « La mutagénèse conventionnelle ou aléatoire, qui est visée par l'annexe I B de la Directive du 12 mars 2001 et qui est exemptée du respect des obligations prévues par celle-ci, consiste en revanche à susciter des mutations aléatoires dans une séquence d'ADN par l'action d'agents mutagènes chimiques ou physiques (rayonnements ionisants). Cette technique était appliquée in vivo sur des plantes entières ou parties de plantes, qui faisaient ensuite l'objet de procédés de sélection et de croisement afin de sélectionner les mutations intéressantes d'un point de vue agronomique. Postérieurement à l'adoption de la Directive du 12 mars 2001, de nouvelles méthodes de modification génétique ont été développées. Celles-ci ont tout d'abord consisté à appliquer les procédés de mutagénèse aléatoire in vitro, en soumettant des cellules de plantes à des agents mutagènes chimiques ou physiques. De nouvelles techniques, dites de mutagénèse dirigée ou d'édition du génome, consistent aujourd'hui, grâce au génie génétique, à provoquer une mutation précise dans un gène cible sans introduction de gène étranger. On distingue ainsi, notamment, la mutagénèse dirigée par oligonucléotide (ODM), qui consiste à introduire dans des cellules une courte séquence d'ADN qui provoquera dans la cellule une mutation identique à celle que porte l'oligonucléotide, et la mutagénèse par nucléase dirigée (SDN1), qui utilise différents types de protéines (nucléases à doigts de zinc, TALEN, CRISPR-Cas9) capables de couper ou d'éditer l'ADN. Les cellules ainsi modifiées font ensuite l'objet de techniques de culture in vitro afin de régénérer des plantes entières. »
https://www.legifrance.gouv.fr/ceta/id/CETATEXT000033191647/

which were not submitted to the ECJ. The most relevant ones are: (a) Directed mutagenesis is to be distinguished from traditional random mutagenesis. The latter may be considered exempt from the application of the Directive, the former not. (b) Random mutagenesis in vivo is to be distinguished from random mutagenesis in vitro. The former, having been applied prior to the 2001 Directive may be considered exempt. The latter, having been developed only after 2001 is not covered by the exception.

In view of the divergent possible interpretations of art. 2 and 3 and annex IB of the GMO Directive, the CE decides to submit a number of questions to the ECJ. The main question is stated in par. 25 of the ECJ's judgment: "*Do organisms obtained by mutagenesis constitute GMOs* within the meaning of Article 2 of Directive 2001/18, although they are exempt under Article 3 of and Annex I B to the Directive from the obligations laid down for release and placing on the market of GMOs? In particular, *may* mutagenesis techniques, in particular *new directed mutagenesis techniques* implementing genetic engineering processes, *be regarded as techniques listed in Annex I A*, to which Article 2 refers? Consequently, *must Articles 2 and 3 of and Annexes I A and I B* to Directive 2001/18 *be interpreted as meaning that they exempt* from precautionary, impact-assessment and traceability measures *all organisms and seeds obtained by mutagenesis*, *or only organisms obtained by* conventional random *mutagenesis methods* by ionising radiation or exposure to mutagenic chemical agents *existing before those measures were adopted*".

IV. The decision of the ECJ on the legal status of genome editing and other new directed mutagenesis techniques[14]

[14] In most comments on the judgment, the focus has been on the legal status of directed mutagenesis and genome editing. It, however, also illustrates the limits of the of harmonizing effect of the GMO Directive which, although it aims at approximating the laws of the member states, it is not a measure of full harmonization.
The question whether national legislation could regulate organisms developed by methods of mutagenesis which are exempt under the GMO Directive was also submitted to the Court by the French CE. (par. 25 of the judgment). The answer of the ECJ is clear: member states have the right to regulate organisms exempt from the Directive and in doing so, can also submit them to the rules of the Directive (par. 82, par. 86, 3). The Court's conclusion is mainly based on a contextual argument: the absence in the Directive of any specification of the legal regime to which the exempted organisms have to be submitted (par. 79-81). The position of the Court corresponds to that taken by the Commission in its submissions to the Court: member states can regulate products not covered by the GMO Directive, provided that other rules arising from EU law, such as, in particular, those relating to the free movement of goods, are respected (par. 71). Amending the mutagenesis exception thus will not guarantee that organisms which are exempt under the GMO Directive are not submitted to regulation by individual member states.
Member States also have an option of imposing stricter rules for organisms that do qualify as GMOs under the Directive. The legal basis for this restrictive national legislation was originally very limited, but has substantially been broadened in 2015, be it only for the cultivation of GMO's.
In the first place, art 114 of the Treaty on the functioning of the European Union (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A12008E114) which entrusts the EU institutions with the approximation of the laws of the member states in view of the establishment of the single market, provides a safeguard clause under which a member state can impose restrictive measures to deal with issues relating to the protection of the environment or the working environment which are specific to that member state. A comparable clause is provided in art. 23 of the GMO Directive itself for the event the sale or cultivation of an organism authorized under the GMO Directive constitutes a risk to human health or the environment. In both cases, restrictive measures are only possible on condition that they are justified by new scientific evidence available after the adoption of the harmonisation

9. In fact, the above question submitted by the CE consists of two sub-questions: (1) Is any product of mutagenesis a GMO? (2) Are all organisms obtained by mutagenesis exempt under the GMO Directive or only those obtained by conventional random methods of mutagenesis developed prior to the 2001 Directive?
The exact scope of the mutagenesis exception not being specified in the Directive, the interpretation methods referred to above come into play, especially for the second sub-question.

a. Are organisms obtained by mutagenesis GMO's?

10. The first sub-question, rephrased by the ECJ (par. 26) as "…whether Article 2 (2) of Directive 2001/18 must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute GMO's within the meaning of that provision" receives a clearly positive answer: "Article 2(2) of Directive 2001/1 must be interpreted as

---

measure and that other rules of EU law, notably with respect to the single market and the free movement of goods, are respected. The national legislation based on the safeguard clause has to be approved by the Commission. In the event the member state does not comply with the objections of the Commission, an infringement procedure leading ultimately to the ECJ is possible. Article 34 of Regulation 1829/2003 on genetically modified food and feed and art. 16 (2) of Directive 2002/53 of 13 June 2002 on the common catalogue of varieties of agricultural plant species contain comparable clauses. In the past, a fairly large number of countries, among which Austria, France, Hungary, Germany, Greece, Italy, Luxemburg and Poland, have, on the basis of a variety of arguments, invoked these safeguard clauses to express their reluctance to cultivation of genetically modified crops. As they depart from the principle of the free movement of goods, these clauses have been narrowly interpreted by the Commission as well as the ECJ, although the Commission is said not always to have enforced them.
The discretion for the member states to impose restrictions on the *cultivation* (not the commercialization in or as a product) of GMO's authorized under the Directive was substantially increased by Directive 2015/412 of 11 March 2015 (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32015L0412) which amends Directive 2001/18/EC by inserting an art. 26b. In line with the principle of subsidiarity this new provision authorises member states to ban or restrict the cultivation of GMO's in their territory on a wide range of "compelling grounds *such as* those related to environmental policy objectives; town and country planning; land use; socioeconomic impacts, avoidance of GMO presence in other products, agricultural policy objectives, public policy". Not only risks for health or the environment, but also e.g. economic considerations can come into play. Demonstration of new scientific evidence that the GMO concerned poses a risk to human health or to the environment is not required. A procedure is provided for the information of the other member states and the Commission. The restrictive national legislation is however not subject to approval by the commission which, however, can reject it if it is not "otherwise in conformity with Union law, reasoned, proportional and non-discriminatory". (See extensively: Zanna Vanrentergem, *Regulating biotechnology in the European Union. Towards more possibilities for member states to regulate GMO cultivation*, masterpaper 2013-14, UGent Faculty of Law and Criminology, https://lib.ugent.be/en/catalog/rug01:002163198?i=0&q=002163198; Nicolas de Sadeleer, "Marketing and Cultivation of GMOs in the EU: An Uncertain Balance between Centrifugal and Centripetal Forces", *European Journal of Risk Regulation*, 2015, Vol. 6, No. 4 (2015), pp. 532-558; N. de Sadeleer, "National control of GMO cultivation in the EU. The path to reconciliation of opposed interests", *Nordic environmental law Journal*, 2018: 1, www.nordiskmiljoratt.se; Louise Verstraete, "*The European decision-making under scientific uncertainty: between law, politics and expertise*", masterpaper 2017-2018, UGent Faculty of Law and Criminology, https://lib.ugent.be/fulltxt/RUG01/002/508/481/RUG01-002508481_2018_0001_AC.pdf, esp. p. 93 ff.; N. De Sadeleer, *Environmental Principles, From political slogans to legal rules*, Oxford University Press, 241-242).
The conclusion seems to be that, short of a fairly fundamental revision of the EU GMO legislation, uniformity of the GMO legislation cannot be guaranteed within the EU.

meaning that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of 8" (par. 30, 38, 54 and 86).
The Court's positive answer is based on a simple logical syllogism in which the process-oriented character of the GMO definition is a premise. .
- A GMO is defined "as an organism, … in which the genetic material has been *altered in a way that does not occur naturally* by mating and/or natural recombination" (par. 27).
- "Account being taken by the information provided by the referring court, … the *mutations brought about by techniques/methods of mutagenesis* such as those at issue in the main proceedings, the implementation of which is intended to produce herbicide-resistant varieties of plant species, *constitute alterations made to the genetic material of an organism* for the purposes of Article 2(2) of Directive 2001/18" (par. 28).
-"…s*ince*, as is apparent from the order for reference, certain of those *techniques*/methods involve the use of chemical or physical mutageneous agents, and others involve the *use of genetic engineering*, *those techniques*/methods *alter the genetic material of an organism in a way that does not occur naturally, within the meaning of that provision*,
- "It follows that *organisms obtained by means of techniques/methods of mutagenesis must be considered to be GMOs* within the meaning of Article 2(2) of Directive 2001/18" (par. 29).
A number of contextual arguments support this logical conclusion:
-The list of techniques which constitute genetic modification in part 1 of Annex 1 A is not exhaustive: "inter alia" (par. 34, 35).
-The *exhaustive* list of techniques not resulting in genetic modification (art. 2(2)(b) read in conjunction with part 2 of Annex IA. does not mention mutagenesis (par. 36).
-Mutagenesis is explicitly cited in Annex IB as one of the techniques/methods of genetic modification referred to in art. 3(1) relating to organisms excluded from the scope of the Directive (par. 37)

b. Are all organisms obtained by mutagenesis exempt under the GMO Directive or only those obtained by conventional random methods of mutagenesis developed prior to the 2001 Directive?

11. The second sub-question is answered by the Court in two steps.
1. (Must) "… Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to the Directive and in the light of recital 17 thereof, … be interpreted as meaning that such organisms are excluded from the scope of the Directive *only* if they have been obtained through mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record ?" (par. 26). 2. This question having been answered in a positive manner, the Court addresses the specific issue which the CE is called upon to rule, of the status of "the techniques/methods of directed mutagenesis involving the use of genetic engineering which have appeared or have been mostly developed since Directive 2001/18 was adopted and in respect of which the risks for the environment or for human health have not thus far been established with certainty" (par. 47). Do also these new techniques constitute mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record and thus satisfy the conditions for exemption (par. 47).

12. Before giving its response to the questions, the Court recalls its rules of interpretation.
"As a provision derogating from the requirement to subject GMOs to the obligations laid down in Directive 2001/18, Article 3(1) thereof, read in conjunction with point 1 of Annex I B to that Directive, must be interpreted strictly" (par. 41). It further "is necessary to consider not only the wording of the provision of EU law, but also the context in which it occurs, and the objectives pursued by the rules of which it is part" (par. 42). As it is clear that the reference to mutagenesis in the annex IB, does not, on its own, "provide conclusive guidance as to the types of techniques/methods that the EU legislature intended specifically to exclude from the scope of the Directive" (par. 43), recourse is to be had to the context of the provision and the purpose of the legislation.

13. *Only organisms obtained by mutagenesis techniques which have a long safety record are exempt.*
*"*Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B … and in the light of recital 17 thereof, must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded" (par 86).
The main argument for this conclusion is a contextual one. "Recital 17 states that Directive 2001/18 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" (par. 45).
The Court also invokes the objectives of the GMO Directive: Recital 4 and 5 of Directive 2001/18 "state that the protection of human health and the environment requires that due attention be given to controlling risks" from the release of living organisms on the environment (par. 49). Recital 8 holds "that the precautionary principle was taken into account in the drafting of the Directive and must also be taken into account in its implementation" (par. 50).

14. O*rganisms obtained by techniques of directed mutagenesis which appeared or were developed since 2001 are not exempt.*
Next a more concrete application of the conclusion that only mutagenesis techniques that have a long safety record are exempt is addressed: " … it should be pointed out that the referring court is called upon to rule, in particular, on the techniques/methods of directed mutagenesis involving the use of genetic engineering which have appeared or have been mostly developed since Directive 2001/18 was adopted and in respect of which the risks for the environment or for human health have not thus far been established with certainty" (par. 47). Here also, the answer of the Court is clear: "Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B … *cannot be interpreted as excluding* … organisms obtained by means of new *techniques*/methods of mutagenesis *which have appeared or have been mostly developed since Directive 2001/18 was adopted*" (par. 51).
The Court's conclusion is mainly based on arguments of a teleological nature.
-Such interpretation would fail "to have regard to the *intention* of the EU legislature, reflected in *recital 17* of the Directive, to exclude from the scope of the Directive *only* organisms obtained by means of techniques/methods which have conventionally been used in a number of applications and have a long safety record" (par. 51).

- "That finding is supported by *the objective of the Directive* in accordance with the precautionary principle to protect human health and the environment" (par. 52).
- "An interpretation of the exemption … which excludes organisms obtained by means of techniques/methods of mutagenesis from the scope of that Directive, without any distinctions, would compromise the *objective of protection* pursued by the Directive and would fail to respect the *precautionary principle* which it seeks to implement" (par. 53).

c. Conclusion: A "frozen" interpretation of the mutagenesis exception.

15. The reading of the judgment proposed in the preceding paragraphs corresponds to the summary available on the Court's website, the EU Commission and the French government. Plants developed by mutagenesis are GMO's. Plants resulting from the application of mutagenesis methods or techniques developed before the adoption of the GMO Directive and having a long safety record (random mutagenesis by treatment with chemicals or radiation) are exempt under the Directive. Plants bred with new mutagenesis methods or techniques developed thereafter (directed mutagenesis or genome editing) remain subject to the provisions of the Directive.
The long safety record which justifies the exemption must have been established at the moment of enactment of the Directive. The ECJ thus adopts a static, "frozen"[15] interpretation of the mutagenesis exception which strongly contrasts with the dynamic interpretation of scientific concepts proposed by the advocate general[16].

16. In two parts of the world, the legislator has, up to now, refrained from accommodating the application of new genome editing techniques for plants: the EU and New Zealand. It is striking that the judicial approach to the issue has in both jurisdictions been largely comparable.
The New Zealand Hazardous Substances and new Organism Act of 1996[17], art. 2, in essence defines as genetically modified an organism in which any of the genes or other genetic material (a) have been modified by in vitro techniques; or (b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques. A regulation of 1998[18] excludes however "organisms that result from mutagenesis that uses chemical or radiation treatments that were in use on or before 29 July 1998". In April 2013, the NZ Environmental Protection Agency decided that non-transgenic genome editing was sufficiently similar to the techniques listed in the exemption and should be similarly excluded from the application of the GMO regime. This decision was appealed in the High Court of New Zealand in Wellington[19], which on May 20, 2014 decided that the 1998 list of

[15] Opinion of Advocate General Bobek delivered on 18 January 2018 (par 98 and ff). See https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1590472234905&uri=CELEX:62016CC0528
[16] See previous note.
[17] New Zealand Hazardous Substances and new Organism Act of 1996. http://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html
[18] Regulation of 1998. Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998, Art. 3,1 (ba). http://www.legislation.govt.nz/regulation/public/1998/0219/latest/whole.html
[19] High Court of New Zealand (2014) [2014] NZHC 1067 [20 May 2014] The Sustainability Council of New Zealand Trust v The Environmental Protection Authority (https://forms.justice.govt.nz/search/Documents/pdf/jdo/76/alfresco/service/api/node/content/workspace/Space

exceptions was a closed one and that adding to the list is a political and not an administrative decision. The judgment has given rise to a similar criticism and call for amendment of the prevalent regulations as the ECJ decision of 25 July 2018 in Europe.
The reluctance of both the ECJ and the Wellington High Court to accommodate new plant breeding techniques no doubt reflects not only the specifics of the applicable legislation, but also the nature of the judicial process. As indicated above, courts are not the appropriate institutions to develop detailed rules on complex scientific matters not yet regulated by the legislator, especially when these issues are intertwined with social and political issues on which there is no consensus in society.[20]

V. Implementation of the ECJ ruling in France

17. The French CE, applying the provisions of the GMO Directive as interpreted by the ECJ, disposes of the claim of Confédération paysanne on 7 February 2020[21].
The CE summarizes the ECJ's ruling along the same lines as described above[22]. It concludes that the mutagenesis exception in art. D 531-2 of the Code de l' environment is too large as it exempts all forms of mutagenesis.
As already indicated[23], the CE made in its decision of 2016 the finding (not submitted to the ECJ) that in vitro random mutagenesis techniques subjecting plant cells to chemical or physical mutagens have developed only after the adoption of the GMO Directive. It thus also concludes in its decision of 2020 on the merits of the case that "both so-called "directed" or "genome editing" techniques or methods and in vitro random mutagenesis techniques subjecting plant cells to chemical or physical mutagens, must be regarded as being subject to the obligations imposed on genetically modified organisms … as they both appeared after the date of adoption of Directive 2001/18 / EC or have mainly developed since that date"[24].

---

sStore/1594ff52-8c2c-4bf5-8f15-29dbcecc6fa9/1594ff52-8c2c-4bf5-8f15-29dbcecc6fa9.pdf)

[20] See nr. 2 above.

[21] CE 7/2/2020, nr 388649, *Conféderation paysanne*, https://www.legifrance.gouv.fr/ceta/id/CETATEXT000041569364

[22] Par. 4: « Par l'arrêt du 25 juillet 2018 …, la Cour de justice de l'Union européenne a dit pour droit, … que : " l'article 2, point 2, de la Directive 2001/18/CE … doit être interprété en ce sens que les organismes obtenus au moyen de techniques/méthodes de mutagenèse constituent des organismes génétiquement modifiés au sens de cette disposition " et que " l'article 3, paragraphe 1, de la Directive 2001/18, lu conjointement avec l'annexe I B, point 1, de cette Directive et à la lumière du considérant 17 de celle-ci, doit être interprété en ce sens que ne sont exclus du champ d'application de ladite Directive que les organismes obtenus au moyen de techniques/méthodes de mutagenèse qui ont été traditionnellement utilisées pour diverses applications et dont la sécurité est avérée depuis longtemps ". La Cour de justice a, en outre, précisé au point 51 de son arrêt que " l'article 3, paragraphe 1, de la Directive 2001/18, lu conjointement avec l'annexe I B, point 1, de celle-ci, ne saurait être interprété comme excluant du champ d'application de cette Directive des organismes obtenus au moyen de techniques/méthodes nouvelles de mutagenèse qui sont apparues ou se sont principalement développées depuis l'adoption de ladite Directive ".

[23] Nr. 10 above

[24] Par.6: «En second lieu, il résulte de l'arrêt de la Cour de justice du 25 juillet 2018, en particulier des motifs de son point 51, que doivent être inclus dans le champ d'application de la Directive 2001/18/CE les organismes obtenus au moyen de techniques ou méthodes de mutagénèse qui sont apparues ou se sont principalement développées depuis l'adoption de la Directive le 12 mars 2001. A cet égard, il ressort des pièces du dossier que tant les techniques ou méthodes dites " dirigées " ou " d'édition du génome " que les techniques de mutagénèse aléatoire

The practical consequences of the judgment of the Conseil d'Etat are: (1) The implicit decision by which the Prime Minister rejected the request of Confédération paysanne is canceled. (2) The prime minister is ordered, within six months and after consultation of the Haut Conseil des Biotechnologies, to modify article D. 531-2 of the environment code by fixing by decree the exhaustive list of techniques or methods of mutagenesis traditionally used for various applications and whose safety has been proven for a long time. (3) The competent authorities are directed to identify, within nine months, within the common catalog of varieties of agricultural plant species, the varieties, in particular among the varieties made tolerant to herbicides, which have been listed without the evaluation to which they should have been subjected, and to assess the necessary measures to be taken on the basis of the applicable legislation.

18. In implementation of the CE's decision, the French government, after consultation of the Haut Conseil des biotechnologies[25], establishes a *draft*[26] revising art D. 531-2 of the Code de l' environnement[27] which reads as follows: "The techniques referred to in art. L. 531-2, which are not considered as giving rise to a genetic modification *or which have been traditionally used without any noted drawbacks to public health or the environment are the following: …* 2) On condition that they do not involve the use of genetically modified organisms as recipient or parental organisms: a) *random* mutagenesis, *with the exception of in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents…*" It follows from this draft that plants developed not only by new directed mutagenesis methods but also by in vitro random mutagenesis will fall within the scope of the GMO regulations. Next, the minister of agriculture drafts orders (1) laying down the list of varieties mentioned in Article 2 of the decree[28] and (2) amending the official catalogue of species and varieties of plants cultivated in France (rapes seed and other cruciferous plants)[29]. The cultivation and sale of the varieties concerned will be prohibited in France, as they have not been evaluated and authorized under the regulations on GMOs. Crops sown or planted before the registration on that list can be brought to term.

---

in vitro soumettant des cellules de plantes à des agents mutagènes chimiques ou physiques, telles que mentionnées au point 23 de la décision du Conseil d'Etat du 3 octobre 2016, sont apparues postérieurement à la date d'adoption de la Directive 2001/18/CE ou se sont principalement développées depuis cette date. Il résulte de ce qui précède que ces techniques ou méthodes doivent être regardées comme étant soumises aux obligations imposées aux organismes génétiquement modifiés par cette Directive »

[25] Which provided an elaborate and interesting opinion: http://www.hautconseildesbiotechnologies.fr/sites/www.hautconseildesbiotechnologies.fr/files/file_fields/2020/07/15/200707-recommandation-cees-hcb-projet-decret-modifiant-code-environnement.pdf

[26] On January 5, 2021, the original text quoted in nr. 7 was still in force.

[27] The original text of the draft decree is annexed in the opinion of the Haut conseil des biotechnologies (p. 10) An English translation is attached to the notification 2020/280/F to the EU Commission of the draft https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.results

[28] Notification 2020/281/F https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2020&num=281

[29] Notification 2020/282/F: https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2020&num=282

19. The draft regulations were notified by the French government to the EU Commission, in application of the Single market transparency Directive 2015/1535[30] which aims to prevent the creation of new trade barriers and requires national authorities to inform the European Commission of any draft technical regulations on products and information society services before they are adopted in national law.
The reaction of the EU Commission of 11 September 2020 to all three notifications however is critical[31], especially with respect to the distinction made between in vitro and in vivo random mutagenesis techniques. The draft amendment of the Environmental code is considered to violate article 3(1) and Annex IB of Directive 2001/18: "based on the lack of distinction between in vitro and in vivo random mutagenesis and given the evidence of long safety record of the use of these techniques before 2001, their exclusion from the list of techniques yielding organisms exempted from the application of Directive 2001/18/EC does not appear justified." The draft amending the official catalogue of plants cultivated in France notified under 2020/282/F would not be compatible with article 14 of Directive 2002/53/EC nor with article 14 of Directive 2002/55/EC.
The Commission threatens with an infringement procedure: ". … should the text of the draft technical regulation under consideration be adopted without account being taken of the above-mentioned objections or be otherwise in breach of European Union law, the Commission may commence proceedings pursuant to Article 258 of the Treaty on the Functioning of the European Union".[32]
The legal status of genome editing may thus again be brought before the ECJ, to challenge not the rule that organisms produced by directed mutagenesis or genome editing developed after 2001 are subject to the GMO Directive, but the fact that the French government, in application of the decision of the CE, would also submit organisms developed by random in vitro mutagenesis to the GMO regime.

[30] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32015L1535. Summary: https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32015L1535

[31] Communication from the commission of august 24 2020: https://cdn.website-editor.net/ed25e686182040aeb41d3b3d05cc2cd2/files/uploaded/20.0422%25202020_280_F%2520COM%2520en.pdf

[32] "If the Commission considers that a Member State has failed to fulfil an obligation under the Treaties, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations. If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice of the European Union".