

# THE EUROPEAN COURT TO RULE ON MILESTONE IN EUROPEAN GMO LEGISLATION: THE LEGAL CLASSIFICATION OF MUTAGENESIS IN PLANT BREEDING

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## Background

In recent years, scientific progress has led to the rapid development of new biotechnological applications in the plant breeding sector, commonly referred to as 'New Plant Breeding Techniques' ('NBTs').<sup>2</sup> Today, several NBTs are high on the agenda of the European plant breeding sector as they provide breeders with valuable tools to meet the sustainability challenges associated with the production of food, feed and other bio-based products. Indeed, genetic crop

improvement through NBTs has not only the potential to enhance agricultural resource use and increase efficiency gains (supporting sustainable farming methods that prevent soil erosion, water shortages and water pollution as well as limiting the use of pesticides), but also to improve the characteristics of the harvested plants such as their nutritional value, processing properties and storage performance. Needless to say, innovation in plant breeding techniques plays an integral part in addressing global challenges such as food security, environmentally sustainable farming and healthy diets.

However, the novel nature of some of these new biotechnological applications has also caused much debate over whether these techniques lead to organisms that could be deemed to be genetically modified organisms ('GMOs'), which are subject to specific regulatory requirements.

Indeed, for many years the EU has subjected the marketing of GMOs to a complex set of GMO legislation. The current comprehensive regulatory framework governing the marketing of GMOs in the EU consists of various directives and regulations, including the following main building blocks:

- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ('the GMO Directive');<sup>3</sup>
- Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed; and
- Regulation 1831/2003 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.

In December 2014, nine organisations initiated legal proceedings over Article D.531-2 of the French Environmental Code, which is a part of the French law transposing the GMO Directive.<sup>4</sup> In particular, they argued that herbicide tolerant

1) Both authors are lawyers working at Allen & Overy LLP. The views expressed in this article are those of the authors alone and do not represent the views of the firm or any third party.

2) Commonly, the following techniques are referred to as NBTs: (i) Oligonucleotide Directed Mutagenesis (ODM), (ii) Site Directed Nucleases (SDN), including SDN1, SDN2, SDN3, based on the use of TALEN, CRISPR-Cas and Zinc Fingers, (iii) Cisgenesis and Intragenesis, (iv) Grafting, (v) Agro-infiltration, (vi) RNA-dependent DNA methylation (RdDM), (vii) Reverse breeding, and (viii) Synthetic genomics.

3) The GMO Directive is the cornerstone of the GMO legislation, which subjects GMOs to stringent requirements such as a standard authorisation procedure, consultation obligations, an application for the renewal of consent and compulsory monitoring after GMOs have been put on the market.

4) The GMO Directive is implemented in France through Articles L.531-1, L.531-2, L. 531-2-1 and D.531-2 of the French Environmental Code. An English version of the French Environmental Code can be consulted at: [https://www.legifrance.gouv.fr/content/download/1963/13739/version/3/file/Code\\_40.pdf](https://www.legifrance.gouv.fr/content/download/1963/13739/version/3/file/Code_40.pdf).

varieties of rapeseed and sunflower resulting from new forms of mutagenesis constitute ‘new hidden GMOs’ and that, as such, they must be subject to the requirements imposed by the GMO Directive. Following these legal proceedings, the French Conseil d’Etat referred four preliminary questions<sup>5</sup> to the Court of Justice of the European Union (CJEU) on 3 October 2016, essentially to ascertain whether organisms resulting from new forms of mutagenesis should be subject to the GMO legislation.

The preliminary reference proceedings currently pending before the CJEU will undoubtedly constitute a milestone in the development of the EU’s GMO legislation. Indeed, it is expected that highly politicised arguments on GMOs and scientific and technical claims will play a significant role in this case. The importance of this preliminary reference should thus not be underestimated, as the decision of the CJEU could have far-reaching consequences on the further use of organisms obtained by these new mutagenesis techniques, which is a process already widely commercialised throughout the EU.

In this respect, it is important to also analyse this debate from a legal angle, and assess whether the current legal framework provides any guidance on how to classify NBTs. Therefore, we will first provide a short overview of the differences between the more traditional mutagenesis techniques and NBTs, after which we will review the current GMO legislative framework. Particular attention will be paid to the historical, systematic and teleological context of the legislation.

### **Setting the Stage: the Difference between Naturally Occurring Mutations, Crossing and Selection, Random and Targeted Mutagenesis**

Since the discovery of the Mendelian laws of genetics, breeders have tried to cross and select those plants and animals with the most desirable characteristics for the next

generations of food and feed.<sup>6</sup> For example, this was the case for plants with an increased resistance to environmental pressures or with an increased yield. In this respect, the basis for genetic diversity in nature is the occurrence of natural mutations which can lead to favourable plant traits. Indeed, mutations are the driving force of evolution and biodiversity in general. These spontaneous mutations, that are thus deviant types that are found in nature and not subject to deliberate intervention by man, have engendered the novel types. The loss or addition of certain characteristics in crops through spontaneous mutations is a principal driver for natural genetic diversity and similarly for plant breeding.<sup>7</sup> Notable examples of a heritable new genetic diversity based on naturally occurring mutants are the loss of bitterness, toxins or allergens in almonds, watermelons and potatoes.

Over the years, breeders have tried to boost this process of genetic mutation and subsequent crossing and selection to create the desired sets of altered or new useful traits (that is, mutant strains with useful properties or producing proteins with improved characteristics) and include them in commercial plant varieties.<sup>8</sup> Indeed, since as early as the first half of the 20th century, breeders have been able to produce a large numbers of plants with new genetic characteristics and variations by developing new varieties with useful traits through exposing organisms to mutagens (for example, certain chemicals) followed by the screening of mutation populations for the desirable traits.<sup>9</sup> This induced random mutagenesis (‘Random Mutagenesis’). However, Random Mutagenesis is intrinsically non-specific as either a large part of the genome is transferred by crossing instead of a single gene, or thousands of nucleotides are mutated instead of the desired single nucleotide. Random Mutagenesis is thus a rather random process with limited efficiency as it requires long processes of identifying useful traits, removing unwanted traits by back-crossing and finally introducing the desired traits into elite new plant varieties.<sup>10</sup> Today, Random Mutagenesis-derived varieties are planted and safely consumed every day in species such as

5) The reference for a preliminary ruling is a procedure exercised before the European Court of Justice. In contrast to other judicial proceedings, the reference of a preliminary ruling is not an action against a European or a national Act, but a question presented on the application of European law. Only the parties to the underlying national procedure may submit observations to the European Court of Justice as well as any Member State and EU institutions.

6) B.S. Ahloowalia, M. Maluszynski and K. Nichterlein, *Global Impact of Mutation-Derived Varieties* (Kluwer Academic Publishers 2004) at 187 to 204.

7) C. Mba, ‘Induced mutations unleash the potentials of plant genetic resources for food and agriculture’, *Agronomy* 2013, at 200 to 231.

8) Note 6 above.

9) F. Hartung and J. Schiemann, ‘Precise plant breeding using new genome editing techniques: opportunities, safety and regulation in the EU’, *The Plant Journal* 2014, at 742 to 752.

10) JRC Scientific and Technical Reports, *New plant breeding techniques. State-of-the-art and prospects for commercial development*, 2011, 1 to 99.

rice, maize, wheat, tomato, squash and soybean. Indeed, mutagenesis in plant breeding programmes throughout the world has generated thousands of novel crop varieties in hundreds of crop species.<sup>11</sup>

However, recently, a growing number of techniques have been developed to induce more precise genetic changes in plants for research and precision breeding. Indeed, with the realisation that genes are the underlying elements determining qualitative or quantitative traits desired by breeders, the intention arose to stimulate the mutation of *specific* genes.<sup>12</sup> Techniques such as Oligonucleotide Directed Mutagenesis ('ODM') or different types of Site Directed Mutagenesis (for example, SDN-1 and SDN-2) result in the precise editing of genes by targeted mutation ('Targeted Mutagenesis').

Targeted Mutagenesis enables scientists to employ only a short fragment of non-foreign DNA with a defined nuclear acid sequence into just one cell, so that they can bring about very precise mutations in the gene.<sup>13</sup> The genetic changes that can be obtained by using Targeted Mutagenesis include the introduction of a new mutation (reshuffling or replacement of one or a few base pairs), the reversal of an existing mutation or the induction of short deletions. Through the specific targeting of an identified useful trait in a suitable variety, the need for the time-consuming back-crossings to breed out a potential multitude of unwanted mutations is also significantly reduced.<sup>14</sup> Indeed, unlike Random Mutagenesis, Targeted Mutagenesis does not create multiple, unknown, unintended mutations throughout the genome; it enables precise and reliable changes to genomes in adding, removing or replacing DNA at specified locations.

Targeted Mutagenesis results in organisms that are nonetheless identical and indistinguishable from organisms that could be developed through Random Mutagenesis or that are the result of naturally occurring mutations.<sup>15</sup> Indeed,

all these mutagenesis techniques are processes developing traits and plants that (could) occur naturally, as no foreign, heritable recombinant DNA is contained in the end product. The essential difference between Random Mutagenesis and Targeted Mutagenesis is only that the latter consists of a targeted approach, whereby the genetic modification is induced in (a) specific gene(s) and hence a defined part of the DNA of the plants. In this respect, organisms resulting from both Random and Targeted Mutagenesis are fundamentally different from organisms where foreign heritable genes are introduced (GMOs).

## **Should Organisms Resulting from Targeted Mutagenesis be Subject to the GMO Legislation?**

### **Material Scope of Application of the GMO Directive**

In the first preliminary question submitted to the CJEU, the French Conseil d'Etat asked in essence whether all organisms resulting from mutagenesis are exempted from the scope of the GMO Directive or whether only those organisms resulting from Random Mutagenesis (and resulting from naturally occurring mutations) are exempted from the scope of the GMO Directive. In order to analyse whether organisms resulting from Targeted Mutagenesis are subject to GMO legislation, it is crucial to first review the material scope of the GMO Directive.

The GMO Directive applies to GMOs. Article (2)(2) of the GMO Directive contains the following benchmark definition of a GMO: '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'. This definition sets out the

11) See: <https://mvd.iaea.org/>. See also D. Eriksson and K.H. Ammann, 'A universally acceptable view on the adoption of improved plant breeding techniques', *Front. Plant Sci.*, 5 January 2017, available at <http://journal.frontiersin.org/article/10.3389/fpls.2016.01999/full>: 'Since the birth of the discipline of genetics and the advent of modern plant breeding though, breeders have used various scientific methods to (1) increase the available genetic variation, and (2) gain a higher level of control between deliberate genetic alterations and the resulting phenotypic traits. Mutations induced by radiation or chemicals enabled a revolution in the first mentioned, and has provided the world with at least 3240 improved varieties of all our major crops.'

12) Note 7 above.

13) The basis of ODM is a modified DNA or DNA/RNA oligonucleotide of 20 to 100 nucleotides that is delivered into the cell by suitable methods. The sequence of the modified oligonucleotide is homologous to a genomic sequence, but differs in one or a few nucleotides. Therefore, after binding of the homologous genomic sequence, a mismatch pairing is created that is corrected by the repair system of the host cell, leading to specific mutations.

14) Note 9 above.

15) *Ibid.*

constitutive elements of a GMO. It must be an ‘organism’ and it must be ‘genetically modified’, which means that it must be an inheritable alteration of genetic material that could not have occurred naturally by mating or natural recombination. Such alteration of genetic material consists of the introduction of foreign genes into the organism. Both a contextual and teleological interpretation of the GMO Directive indicate that it is the inability of the genetic material to alter naturally by mating and/or natural recombination, rather than the applied technique, that defines a GMO.<sup>16</sup>

Furthermore, the GMO Directive indicates that the alteration of the genetic material must be *inheritable*. This is first of all clear from Article 4(3) of the GMO Directive, which states that its purpose is to take measures against adverse effects ‘*through gene transfer from GMOs to other organisms*’. Since only an inheritable genetic modification can result in a gene transfer and potentially cause adverse effects, the inheritability of the foreign DNA is a necessary requirement for an organism to be considered a GMO. The *travaux préparatoires* also show that the alteration of the genetically modified material should be inheritable.<sup>17</sup> This is also apparent from the definition of an ‘organism’ (that is, ‘any biological entity capable of *replication or of transferring genetic material*’) and Annex I A, Part 1 (that is, ‘in which they are capable of *continued propagation*’, ‘*heritable material*’, and ‘*heritable genetic material*’). Finally, the CJEU also ruled in the *Bablok* case that the foreign genes should be capable of being transferred.<sup>18</sup> Only an alteration of the genetic material that is inheritable can thus be considered a genetic modification.

The annexes to the GMO Directive further define the techniques that (a) result in genetic modification (listed in Annex I A, Part 1); (b) are not considered to result in genetic modification (Annex I A, Part 2); and (c) result in genetic modification but yield organisms that are excluded from the scope of the GMO Directive (Article 3 and Annex I B). The latter

techniques, which are excluded under (c), are mutagenesis and specific forms of cell fusion, where the cells originate from organisms that can exchange genetic material through traditional breeding methods.

While the GMO Directive refers both to the organisms and the techniques used to create such organisms, the material scope of the Directive seem to be primarily determined by the organisms it seeks to regulate rather than by the techniques applied in the development of those organisms. This follows from Article 1 (the objective of the GMO Directive): ‘to protect human health and the environment *when*: – carrying out the deliberate *release* into the environment of genetically modified organisms ...’. Indeed, the aim of the GMO Directive is to avoid adverse effects on human health and environment that might arise from the deliberate release of GMOs or the placing of GMOs on the market. It is not the process itself that requires the specific protection of the environment by legislation but it is the organism that results from this process that must be examined to protect human health and the environment when releasing it.

This also demonstrates that the question whether or not an organism contains a genetic modification that could not have occurred naturally is to be assessed when the organism is released into the environment. The use of a genetic modification method consequently does not necessarily imply that the organism created by such method (process) automatically constitutes a GMO; this classification is rather assessed in view of the resulting characteristics of the modified organism.

It follows from the above that an organism that contains a genetic modification (that is, an inheritable alteration of genetic material where that alteration could not have occurred naturally by mating or recombination) on its release into the environment constitutes a GMO and is subject to the regulatory requirements of the GMO Directive.

16) From the *travaux préparatoires*, it is clear that the original proposal of Article 2(2) Directive 90/220 required that ‘the genetic material is altered in a way that *passes the natural barriers* of mating and recombination’ (European Commission, Proposal for a Council Directive on the Deliberate Release to the Environment of Genetically Modified Organisms, COM(88) 160 final, 4 May 1988, Brussels). This confirms that the legislator always intended to only cover alterations that could not occur naturally. Moreover, the Explanatory Memorandum of the Proposal Directive 90/220 indicates that it is directed at ‘the intentional release of organisms having a combination of traits that nature may have never produced’. Article 2(2) should therefore be interpreted so as to require that the alteration of the genetic material could not have occurred naturally.

17) This appears clearly from the reference to inheritable ability in the definitions of the 1986 OECD report on ‘Recombinant DNA safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques’, Paris, OECD, 1986 (‘the Blue Book’), Appendix A (‘in which they are capable of *continued propagation* in the UK definition of “genetic manipulation” “that can *replicate* in a living cell”’).

18) Judgment of 6 September 2011, *Bablok*, C-442/09, EU:C:2011:541, paragraphs 55 and 62.

Now that we have assessed what is to be understood by a GMO, we will analyse whether organisms resulting from Targeted Mutagenesis should be considered GMOs under the GMO Directive.

Firstly, the wording of the GMO Directive indicates that 'mutagenesis' is excluded from the scope of the GMO Directive:

Article 3: Exemptions of the Directive: 1. *'This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.'*

Annex I B: techniques referred to in Article 3: *'Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are: (1) mutagenesis'.*

The GMO Directive also states that it only applies to organisms that constitute GMOs. As indicated above, for an organism to constitute a GMO, the GMO Directive requires it to have genetic material which has been altered *'in a way that does not occur naturally by mating and/or natural recombination'*. However, Random Mutagenesis is essentially a process of induced mutations which could occur naturally. It follows from the definition of GMOs that Random Mutagenesis does not result in the creation of GMOs and is therefore not subject to the GMO Directive. This is also in line with the intention of the legislator to only cover organisms that, upon their deliberate release into the environment, contain an inheritable alteration of genetic material that could not have occurred naturally by mating or natural recombination. This approach should not be a surprise, as the legislator clearly considered it unfeasible and illogical to regulate 'nature' or 'natural processes' without having any possibility of influence, control or enforcement. The wording of the GMO Directive thus seems to indicate that Random Mutagenesis is exempted from its scope of application.

Since it was clearly the legislator's intention to only regulate gene combinations that cannot occur in nature, the term

'mutagenesis' in the GMO Directive should logically also include Targeted Mutagenesis. Indeed, it cannot be deduced from the GMO Directive that the term 'mutagenesis' would be restricted to certain specific types of mutagenesis and would exclude techniques such as Targeted Mutagenesis from its scope. So, it is important to assess the criterion the legislator used to delimit the scope of application of its GMO legislation, that is, whether or not the genetic material of an organism has been altered in a way which cannot occur naturally.<sup>19</sup> As indicated at page 2 above, like Random Mutagenesis, Targeted Mutagenesis is a technique that mimics the natural process of mutations and induces mutations, although in a more precise and targeted way. All the effects that could result from Targeted Mutagenesis can thus also occur naturally or by using breeding procedures such as Random Mutagenesis. Indeed, point mutations induced by means of Targeted Mutation cannot be differentiated from point mutations arising as a result of natural mutations or Random Mutagenesis. Contrary to the insertion of foreign heritable DNA into the organism, which by default leads to a GMO, the application of Targeted Mutagenesis results in a non-GMO and should thus not be subject to GMO legislation.

This is also confirmed by the requirements imposed by Annex I A, Part 1 and Annex I B of the GMO Directive, which clarify that techniques such as mutagenesis are only exempted from the Directive if they do not involve the use of recombinant nucleic acid molecules. This is also the case with Targeted Mutagenesis, where the oligonucleotides, as components of the mutagen that is used, are not recombinant nucleic acids. Although the term 'recombinant nucleic acid' is not defined in the Directive, the wording in Annex I A, Part 1, No 1 implies that 'recombinant nucleic acid techniques' must involve the formation of new combinations of genetic material. However, the oligonucleotides used in Targeted Mutagenesis are identical<sup>20</sup> to the corresponding site in the genome of the treated plant cells and therefore do not represent new combinations in the sense of new arrangements of genomic sequences. This can also be proven historically,<sup>21</sup> and was confirmed by the EFSA in its response to a request of the

19) Whereas the English transposition law ('does not occur naturally') and the French transposition law ('ne s'effectue pas') arguably leave some doubt as to whether it should be impossible for the alteration to occur naturally or should, in each particular case, not occur naturally, other linguistic versions make it abundantly clear that the 'does not' in the English version actually means 'cannot'. For example, the German version requires that 'genetisches Material so verändert worden ist, wie es auf natürliche Weise durch Kreuzen und/oder natürlichen Rekombination nicht möglich ist'.

20) See in this respect also Note 8 above.

21) The recombinant DNA produced by Paul Berg, who generated the first nucleic acid molecules in his laboratory at Stanford University in California, consisted of two DNA molecules of different origin which had been cut out with an enzyme and subsequently joined together using another enzyme. The result was a new combination of genetic material which could not be generated naturally.

European Commission: ‘... a recombinant nucleic acid molecule can be defined as a molecule that is generated by joining two or more nucleic acid molecules’.<sup>22</sup> In any case, according to Annex I A, Part 1, No 1, the new combinations of genetic material in the recipient organism must also be capable of continued propagation in order to fall within the scope of the Directive. This is not the case here either: the oligonucleotide used as the mutagen in Targeted Mutagenesis is not capable of propagation because it cannot replicate itself. Finally, Targeted Mutagenesis also does not fall under the scope of application of Annex I A, Part 1 as (i) it does not involve the use of nucleic acid molecules within the meaning of No 1 (ii) nor is heritable material introduced into an organism within the meaning of Annex I A, Part 2.

In addition, it seems that, even if Targeted Mutagenesis is not considered a technique that falls within the scope of the concept of ‘mutagenesis’ in Annex I B, the organisms resulting from Targeted Mutagenesis still do not constitute GMOs, and the GMO Directive will not apply to such organisms. Indeed, the criterion for determining whether an organism constitutes a GMO is whether at the moment of its deliberate release into the environment the organism contains a genetic modification (that is, an inheritable alteration of genetic material that could not have occurred naturally by mating or natural recombination). The material scope of the GMO Directive is thus primarily determined by the organisms it seeks to regulate, rather than by the techniques applied in the development of those organisms. This is illustrated by the fact that Article 2(2) and Annex I A, Part 1 only exemplify the techniques that in the opinion of the legislator automatically lead to such organisms, however, on the condition that the foreign genes are still present in the organism upon release into the environment, which is not the case here in the absence of inheritable foreign genes.

As indicated above, Targeted Mutagenesis produces organisms that are indistinguishable from organisms resulting from naturally occurring Mutagenesis or from Random Mutagenesis. The alteration of the organism’s genetic material (that is, the site-specific mutations in one or only a few base pairs, or short deletions or insertions) can

also occur naturally by mating or natural recombination. The introduced oligonucleotide is not inheritable and is only transiently present in the organism, and in any event is no longer present on the deliberate release of the organism into the environment. The introduced genetic sequences that acted as mutagens are consequently not present when the ‘end product’ (resulting from Targeted Mutagenesis) is replicated. This corresponds with the interpretation of the CJEU in the *Bablok* case as it also excludes organisms from the scope of the GMO legislation that cannot replicate the foreign genes previously introduced: ‘... the concept of a GMO ... is to be interpreted as meaning that a substance ... which has lost its ability to reproduce and is totally incapable of transferring the genetic material which it contains, no longer comes within the scope of that concept’.<sup>23</sup>

It follows from the above that even if Targeted Mutagenesis is not considered a technique under Annex I B, the resulting organisms are still not GMOs as they are identical to organisms that could have been traditionally bred or could have occurred naturally. The decisive regulating factor is, consequently, that the outcome of the process results in an organism with genetic alterations that differ from alterations that could arise through natural processes. This is clearly not the case for Targeted Mutagenesis, as the resulting organism can also be obtained through natural processes.

This conclusion is strengthened by the fact that the GMO Directive’s Recitals also do not indicate that Targeted Mutagenesis should not be exempt under the GMO Directive. Indeed, while Recital 17 states that organisms obtained through genetic modification techniques that have conventionally been applied and have a long safety record are exempted, it cannot be derived from this that the exemption in Annex I B is restricted to those mutagenesis techniques that had a history of safe use in 2001. First, this does not follow from the wording of the exemption criteria, as there is no reference that these are restricted to specific mutagenesis techniques. Such an interpretation would also mean that any new or improved mutagenesis techniques developed after the entry into force of the GMO Directive would be excluded from the scope of the exemption rule.

22) EFSA Response to Mandate M-2015-0183 (‘Request for EFSA to provide technical assistance with regard to issues related to the legal analysis of new plant breeding techniques’) Question 2, available at <http://registerof>

[questions.efsa.europa.eu/roqFrontend/wicket/page?6-1.lInkListener-mandateForm-documents-2-fileNameLnk](http://registerof.questions.efsa.europa.eu/roqFrontend/wicket/page?6-1.lInkListener-mandateForm-documents-2-fileNameLnk) (accessed 4 November 2015).

23) Note 18 above, at paragraph 62.

Such a broad interpretation cannot be derived from Recital 17. Finally, it would also contradict the wording of the GMO Directive, which in Annex I B, No 1 completely excludes mutagenesis from its scope. Nowhere in the extensive GMO legislative framework is reference made to a provision that suggests that Recital 17 must be interpreted in a specific or restricted manner. It is consequently our view that Recital 17 of the GMO Directive does not restrict the scope of the exemption rule to specific mutagenesis techniques.

Finally, the above reasoning is also confirmed in a more pragmatic and factual manner because subjecting organisms resulting from Targeted Mutagenesis to the GMO legislation would be discriminatory and unfeasible as (i) those organisms are indistinguishable from, and (ii) essentially have identical characteristics to, traditionally bred organisms resulting from naturally occurring mutagenesis or from Random Mutagenesis. Indeed, it is impossible to tell whether such type of modification has occurred naturally, was induced by Random Mutagenesis or triggered by Targeted Mutagenesis. Therefore, not only would it be very difficult, but also discriminatory, to subject identical organisms to different regulatory requirements. Regulating plants resulting from Targeted Mutagenesis under the GMO Directive would lead to large-scale requirements for the authorisation and use of these plants and subsequent food/feed products, while identical plants resulting from other forms of mutagenesis would be exempt from such requirements. Therefore, to avoid such blatant discrimination, organisms resulting from naturally occurring mutagenesis or other mutagenesis techniques (including Random Mutagenesis) would also have to be subject to the GMO legislation. As a very large part of all available varieties have today either been developed using naturally occurring mutants or result from the application of Random Mutagenesis (or have some mutagenesis ‘heritage’ in them as mutagenesis techniques have been used since the 1950s and genetic material resulting from such mutations is present in almost all breeding programmes for both conventional and

organic farming<sup>24</sup>), subjecting organisms resulting from all forms of mutagenesis to the GMO Directive is unfeasible.<sup>25</sup>

If the EU were to regulate all mutagenesis products in accordance with its GMO legislation for putting products on the market inside the EU, it would also have to consider the use of these same techniques by breeders and farmers *outside* the European Common Market.<sup>26</sup> Organisms produced in third countries resulting from naturally occurring mutations, Random Mutagenesis or Targeted Mutagenesis without the impediment of similar approval procedures are being – or may be – imported and widely used in Europe, possibly ever more so due to a potential competitive advantage and lack of distinguishability. As modifications produced by Targeted Mutagenesis are identical to those produced by other mutagenesis techniques or to mutations spontaneously occurring in nature, the detection and unambiguous identification of plants resulting from Targeted Mutagenesis would not be possible or enforceable for imports produced in third countries without specific requirements. Unilateral EU requirements would thus disadvantage EU plant breeding and variety development and result in a relocation of their activities outside of the EU to the detriment of the competitiveness of its Agrifood Chain.

In conclusion, a literal reading of the GMO Directive, as well as a historical, systematic and teleological interpretation, indicates that Targeted Mutagenesis, like Random Mutagenesis, is encompassed in the concept of ‘mutagenesis’ of Annex I B and is excluded from the scope of the GMO Directive.

### Is the Exemption of ‘Mutagenesis’ a Minimum or a Maximum Harmonisation Measure?

Now that we have come to the conclusion that Targeted Mutagenesis is excluded from the scope of the GMO Directive, it is necessary to consider the third question referred to the CJEU, namely whether Articles 2, 3 and Annex I B of the GMO Directive (exempting organisms resulting from ‘mutagenesis’

24) The main beneficiaries have not only been the developing countries (for example, India, China and Pakistan), but also North American and European countries have gained from the release of mutant cultivars. The emphasis in the developing countries has been on food crops such as rice, while North America and Europe have used mutants to improve crops for the processing industry (for example, edible oils from sunflower, rapeseed, juice quality of grapefruit, essential oil from mint).

25) B.S. Ahloowalia *et al.*, Note 6 above; D. Modrzejewski ‘Ergebnisse zur Befragung über Möglichkeiten und Grenzen von neuen

Pflanzenzüchtungstechniken im öko-Landbau’, available at <http://orgprints.org>.

26) Office parlementaire d’évaluation des choix scientifiques et technologies, ‘Rapport sur les enjeux économiques, environnementaux, sanitaires et éthiques des biotechnologies à la lumière des nouvelles pistes de recherche’, 30 March 2017, available at [http://www2.assemblee-nationale.fr/14/les-delegations-comite-et-office-parlementaire/office-parlementaire-d-evaluation-des-choix-scientifiques-et-technologiques/\(block\)/24975](http://www2.assemblee-nationale.fr/14/les-delegations-comite-et-office-parlementaire/office-parlementaire-d-evaluation-des-choix-scientifiques-et-technologiques/(block)/24975).

from the GMO legislation) constitute a measure of minimum or maximum harmonisation, and as such leave Member States (no) discretion to decide on the rules applicable to organisms resulting from mutagenesis.

In order to assess whether a specific legal instrument and, in particular, whether a specific clause in that legal instrument constitutes a measure of minimum harmonisation (EU law sets specific thresholds that national legislation must meet and may exceed) or maximum (full) harmonisation (EU law sets specific thresholds that national law may not exceed), we will consider the legal basis and the legislator's intention in adopting such legal instrument, which are determining factors.

The preamble of the GMO Directive indicates that the Directive is adopted on the basis of Article 114 (former Article 95) of the Treaty on the Functioning of the European Union (TFEU). This Article sets out the framework for the establishment and functioning of the internal market and its main objective is the harmonisation of this internal market. Full harmonisation is indeed frequently evident in environmental measures adopted on the basis of Article 114 TFEU.

The essential principle of a unified internal market is that once a certain product is authorised, it can move freely and be distributed within the EU without encountering any internal frontiers. This also implies that within the EU there should only be one interpretation of which organisms are subject to the provisions of the GMO Directive.

Moreover, since the scope of the GMO Directive (including Articles 2(2) and 3 and Annexes I A and B, which exclude mutagenesis) provides the cornerstone and the *ratione legis* for the whole GMO Directive, it is clear that these 'constitutional' aspects of the Directive do not leave any room for 'interpretation' and discretion to the European Member States, and consequently constitute measures of full harmonisation.

Indeed, if Member States were able to apply different interpretations and exempt identical organisms resulting

from the same mutation techniques from the scope of the GMO Directive, while others did not, this would create trade barriers between the Member States and prevent the free movement and distribution of these identical organisms. This would lead to a fragmented market instead of a common market in the EU where identical organisms would be subject to different legal regimes, which is contrary to the legal basis on which the GMO Directive was adopted.

In addition, the wording of the GMO Directive indicates that the Articles defining the scope of the GMO Directive are subject to full harmonisation and leave no room for discretion.

For example, Recital 2 highlights the legislator's intention to clarify the scope of the (previous) GMO Directive and the definitions therein.

Moreover, Recital 56 and Article 22 of the GMO Directive expressly confirm that it is prohibited to implement national measures that derogate from the GMO Directive:

*(56) When a product containing a GMO, as or in products, is placed on the market, and where such a product has been properly authorised under this Directive, a Member State may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive. A safeguard procedure should be provided in case of risk to human health or the environment.<sup>27</sup>*

*Article 22 – Free circulation: Without prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.*

The purpose of this 'free movement clause' is to restrict Member States from imposing their own deviating rules.<sup>28</sup>

From the above Articles and Recitals, it can thus be deduced that it was the legislator's intention to fully harmonise and

27) Even Article 23, the 'safeguard clause', which enables Member States to notify the European Commission when new or additional information is made available that affects the environmental risk assessment, stresses the harmonising character of the GMO Directive. Indeed, the safeguard clause is designed in a manner that assures full harmonisation across the EU if a Member State invokes the safeguard clause, as it is valid solely on the Member State's own territory and should be notified to the European Commission and the other Member States immediately. The notification is also subject to regulatory scrutiny by the European Commission and all the other Member

States according to a defined comitology procedure within a short timeframe of just a few months. All this underlines the principal objective of the GMO Directive to safeguard the common market even when the safeguard clause is invoked.

28) Judgment of 5 April 1979, *Ratti*, C-148/78, EU:C:1979:110, paragraph 26, where the court held that Member States were not allowed to maintain different rules for solvents for the domestic market that complied with the directive in question.

approximate the Member States' legislation in respect of GMOs. Articles 2, 3 and Annex I B of the GMO Directive constitute a full harmonisation measure, which prohibits European Member States from submitting organisms obtained by mutagenesis to the provisions of the GMO Directive. There is consequently no margin of discretion to subject organisms within the scope of the GMO Directive that have been specifically exempted under Article 3 *juncto* Annex I B of the GMO Directive.

## The Precautionary Principle and the GMO Directive

The French Conseil d'Etat also queries whether Articles 2 to 3 and Annexes I A and I B of the GMO Directive are still valid and consistent with the precautionary principle, in particular as they exclude 'new' organisms and varieties obtained by new techniques of mutagenesis from the scope of application of the GMO Directive.

This fourth preliminary 'question' essentially asks whether several Articles (that is, the Articles that define the scope of applicability) of the GMO Directive are still valid, and as such questions the whole scope (and exemption provisions) of the GMO Directive.

To answer this question, it should firstly be assessed whether the precautionary principle was sufficiently taken into account at the time of drafting the GMO Directive.

When comparing the former Directive 90/220/EEC with its later amendments, it is apparent that compliance with the precautionary principle was strengthened, for example by enacting more demanding comprehensive environmental risk assessment procedures (which allows for the review of possible risks connected to certain GMOs) throughout the GMO Directive.<sup>29</sup>

Furthermore, the language of the current GMO Directive demonstrates the critical role of the precautionary principle throughout the GMO Directive.<sup>30</sup> For example, Recitals 5, 6

and 8 of the GMO Directive all refer to the importance of the precautionary principle:

*(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs).*

*(6) Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken.*

*(8) The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.*

Recital 17 also reflects the protective purpose of the GMO Directive and the precautionary principle:

*(17) This 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.*

Moreover, the safeguard clause enshrined in Article 23 gives Member States the possibility of provisionally restricting or prohibiting the use of a GMO on its territory if, as a result of new or additional information or scientific knowledge, the Member States have valid grounds for considering that a GMO constitutes a risk to human health or the environment. This safeguard clause clearly reflects the European legislator's observance of the precautionary principle.

This is also confirmed by the CJEU, which stated the following in the case *Association Greenpeace France v Ministère de l'Agriculture et de la Pêche*:

*44. Next, observance of the precautionary principle is reflected in the notifier's obligation, laid down in Article 11(6) of Directive 90/220, immediately to notify the competent authority of new information regarding the risks of the product to human health or the environment and the competent authority's*

29) The European Commission was satisfied that the text of Directive 90/220/EEC as a whole already reflected the precautionary principle, but nevertheless strongly supported several amendments aimed at reinforcing the principle across the Directive: Amended proposal by the Commission for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, 26 March 1999, COM(1999)139 final, Explanatory Memorandum, at page 2.

30) 'Advanced genetic techniques for crop improvement: regulation, risk and precaution', House of Commons – Science and Technology Committee, Fifth Report of Session 2014–15, available at <http://www.publications.parliament.uk/pa/cm201415/cmselect/cmsctech/328/328.pdf>, at page 32.

*obligation, laid down in Article 12(4), immediately to inform the Commission and the other Member States about this information and, secondly, in the right of any Member State, provided for in Article 16 [now, Article 23] of the directive, provisionally to restrict or prohibit the use and/or sale on its territory of a product which has received consent where it has justifiable reasons to consider that it constitutes a risk to human health or the environment.*<sup>31</sup>

It follows from the above that the precautionary principle was sufficiently and expressly taken into account at the time of drafting and amending the GMO Directive. This also implies that possible uncertainties about the effects of mutagenesis, for example, were taken into account while applying the precautionary principle and establishing the scope of the GMO Directive.

Secondly, it should be assessed whether the scientific progress and development of new biotechnological applications such as Targeted Mutagenesis require a re-evaluation under the precautionary principle. Indeed, the precautionary principle allows Member States to adopt emergency measures such as, for example, imposing a ban on the cultivation of certain organisms in order to avert risks to human health that have not yet been fully identified or understood because of scientific uncertainty.<sup>32</sup>

In this respect, and as stated above, the organisms resulting from Targeted Mutagenesis are not new as they result in organisms that are identical and indistinguishable from organisms that could result from Random Mutagenesis or from naturally occurring mutations.

There is also a widespread consensus among scientists that targeted point mutations generated in plants through Targeted Mutagenesis allow breeders to maximise precision and minimise the unintended effects that often cannot be avoided with Random Mutagenesis, and this with the help of chemicals or ionising radiation.<sup>33</sup> There is no valid evidence that crops obtained by Targeted Mutagenesis have an impact

on health or the environment that is different from any other crops developed by conventional plant breeding technologies such as Random Mutagenesis or that are derived from naturally occurring mutations.

Indeed, Targeted Mutagenesis results in changes in an organism that can be obtained with other forms of mutagenesis or spontaneously occur in nature. Consequently, the mere fact that there is technological progress (in the form of new mutagenesis techniques) does not warrant a review of the exemption provisions of the GMO Directive except in the absence of any identification of any unintended changes or effects which would result from the use of these improved techniques. Consequently, the precautionary principle does not demand a general exclusion of new mutagenesis techniques, such as Targeted Mutagenesis, from the scope of Annex I B, No. 1.

It follows that the precautionary principle is enshrined in the GMO Directive and has been taken into account when establishing the scope of the GMO Directive. The mere fact that there is technological progress (in the form of new mutagenesis techniques) does not warrant a review of the exemption provisions of the GMO Directive, certainly in the absence of any identification of any unintended changes or effects which would result from the use of these improved techniques.

## **Advanced Mutagenesis in the Context of other Legislative Instruments**

The fact that organisms resulting from mutagenesis are excluded from the GMO Directive also raises the question whether organisms resulting from mutagenesis techniques are not only exempted from the GMO Directive but also from other legislation. In particular, do organisms resulting from mutagenesis constitute GMOs in the sense of Article 4 of Council Directive 2002/53/CE of 13 June 2002 on the common catalogue of varieties of agricultural plant species ('the Common Catalogue Directive'), and are they subject to

<sup>31</sup> Case C-6/99, *Association Greenpeace France v Ministère de l'Agriculture et de la Pêche*, Judgment of 21 March 2000, EU:C:2000:148, at paragraph 44.

<sup>32</sup> The Advocate General Bobek has recently indicated in Case C-111/16 that Member States may adopt emergency measures concerning genetically modified food and feed only if they can establish, in addition to urgency, the existence of a situation that is likely to constitute a *clear and serious risk* to

human health, animal health and the environment. Not any risk or uncertainty thus suffices to invoke the precautionary principle.

<sup>33</sup> F. Hartung and J. Schiemann, Note 9 above; European Academies Science Advisory Council, *New breeding techniques*, July 2015, 1-8; Office parlementaire d'évaluation des choix scientifiques et technologiques, Note 26 above.

the requirements for acceptance of GMO varieties under the Common Catalogue Directive or, alternatively, is the scope of the Common Catalogue Directive identical to the scope of the GMO Directive, thereby excluding organisms resulting from mutagenesis from the GMO Directive?

To answer this question, it is necessary to assess whether it was the legislator's intention to employ the same definition and scope of applicability of GMOs under the GMO Directive (and the GMO legislative framework) as under the Common Catalogue Directive (which forms a part of the European seed legislative framework).

The Common Catalogue Directive<sup>34</sup> is closely linked to the European legislation on seed marketing ('the Seed Directives'<sup>35</sup>) and together they form the European seed legislation. While the Common Catalogue Directive defines the criteria for accepting the inclusion of a plant variety in the common catalogue of varieties of agricultural plant species, the Seed Directives define the conditions for marketing the individual seed lots of those varieties (such as, for example, certain quality requirements). The goal of the Common Catalogue Directive is to first harmonise the recognition of plant varieties, not only nationally but throughout the EU after compiling national catalogues at Member State level into a European catalogue.<sup>36</sup> The European seed legislation is consequently designed to establish the common market for seed in the EU by harmonising the quality standards, control requirements and acceptance procedures. Only once a variety is included in the common catalogue, may a seed of that variety be marketed to farmers throughout the EU.

Certain varieties to be included in the common catalogue may inevitably be genetically modified and consequently constitute a GMO. For this special category of seed, the

Common Catalogue Directive introduces specific requirements comparable to those under the GMO legislation such as, for example, the obligation to carry out an environmental risk assessment (Article 4 Common Catalogue Directive) or to label the GMO variety accordingly (Article 9(5) Common Catalogue Directive), before that variety may be registered in the common catalogue.

The European variety registration legislation of the Common Catalogue Directive thus covers all varieties of both GMO and non-GMO seeds. As regards GMO varieties, it is clearly linked to the GMO legislative framework (in particular the GMO Directive) as it imposes the same requirements (impact assessment, labelling and so on) as the GMO legislative framework for those varieties that constitute GMOs.

Since identical obligations are imposed on GMO varieties as those under the GMO legislation, it should follow that the Common Catalogue Directive also uses the same definition and concept of GMOs (namely the benchmark definition of Article 2(2) which is supplemented by the exemptions under the Annexes of the GMO Directive) as under the GMO Directive (and the GMO legislative framework).<sup>37</sup> This follows first from the wording of the Common Catalogue Directive itself.

For example, Article 4(4) of the Common Catalogue Directive states:

*4. In the case of a genetically modified variety within the meaning of Article 2(1) and (2) of Directive 90/220/EEC the deliberate release into the environment of the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment. ...*

34) While the Common Catalogue Directive concerns agricultural plant species, the Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed concerns vegetable species. Both directives will hereafter be referred to as the Common Catalogue Directives.

35) The European Seed Directives consist of the Directives concerning the marketing of beet seed (2002/54/EC), fodder plant seed (66/401/EEC), cereal seed (66/402/EEC), seed potatoes (2002/56/EC) and oil and fibre plant seed (2002/57/EC).

36) This objective was also recognised in the former version of the Common Catalogue Directive, Directive 70/457/EEC of 29 September 1970, through recourse to former Article 100 of the Rome Treaty, now Article 114 of the TFEU, as legal basis for Directive 70/457/EEC.

37) Throughout the GMO legislative framework, the same definition and scope of application of GMOs is used: see for example Directive 2009/41/EC of 6 May 2009 on the contained use of genetically modified micro-organisms, which excludes mutagenesis from the definition of a GMO through its Article 2(b)(ii):

'(b) "genetically modified micro-organism" (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition: (i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A; (ii) the techniques listed in Annex I, Part B [amongst which, mutagenesis] are not considered to result in genetic modification'; Regulation No 1829/2003 of 22 September 2003 on genetically modified food and feed excludes mutagenesis from the definition of GMOs through its Article 2(5): '5. "genetically modified organism" or "GMO" means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC'; and Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products, Article 2(t): "the definition of "genetically modified organism (GMO)" is that given in 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 and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive'.

Moreover, Recital 16 of the Common Catalogue Directive stipulates:

*(16) In the light of scientific and technical developments, it is now possible to breed varieties through genetic modification. Therefore, when determining whether to accept genetically modified varieties within the meaning of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms Member States should have regard to any risk related to their deliberate release into the environment. Furthermore, conditions under which such genetically modified varieties are accepted should be established.*

The Common Catalogue Directive thus clearly relies on the scope and definition of GMOs as defined by the GMO Directive. This implies that whenever a certain variety constitutes a GMO under the GMO Directive, it will, in the case of registration, be subject to the specific registration requirements of the Common Catalogue Directive.

The fact that the same scope and benchmark definition of GMOs are used as under the GMO Directive to assess when the specific requirements under the Common Catalogue Directive apply is also apparent from the transposition of the Common Catalogue Directive into national law by the European Member States. For example:

- One of the Belgian implementation laws states: ‘3. Une variété génétiquement modifiée est admise uniquement si sa mise sur le marché a été autorisée conformément à la législation européenne en vigueur applicable aux organismes génétiquement modifiés et aux textes qui la transposent’;<sup>38</sup>
- One of the Italian implementation decrees states: ‘Una varietà geneticamente modificata può essere iscritta

nell'apposita sezione del registro nazionale delle varietà di cui all'articolo 17 previa verifica, effettuata con le procedure di cui all'articolo 19 della legge n. 1096 del 1971, che: (a) sia stata data attuazione a tutte le misure atte ad evitare effetti nocivi sulla salute umana, sull'ambiente e il sistema agrario del Paese, derivanti dall'emissione deliberata nell'ambiente o dall'immissione sul mercato di tale varietà, previste dalla normativa comunitaria e nazionale ...’.<sup>39</sup>

- One of the Dutch implementation measures states: ‘In het geval van *genetisch gemodificeerd materiaal* wordt alleen toestemming voor het in de handel brengen van teeltmateriaal voor beproevingsdoeleinden verleend indien het teeltmateriaal is toegelaten *overeenkomstig richtlijn (EG) 2001/18 of verordening (EG) 1829/2003*’.<sup>40</sup>
- The Maltese implementation Act states: ‘1. ... “genetically-modified seed” refers to seed that has its genetic material altered in a way that does not exist naturally within the meaning of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001. ... 21. The Director may authorise local producers or breeders to place on the market small but appropriate quantities of seeds for scientific purposes or selection work and for other test or trial purposes, provided that the seeds belong to varieties for which an application for entry in the national catalogues has been submitted and, in the case of vegetable seeds, specific technical information has been submitted. In case of *genetically-modified seeds*, such authorisation should be granted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment *in accordance with Directive 2001/18/EC* of the European Parliament and of the Council of 12 March 2001’.<sup>41</sup>

The above implementation Acts employ the same concept of GMOs as under the GMO Directive, and refer clearly to either the GMO Directive as such (and thus also the definition of

38) Article 6 §3 of the Arrêté du 24 avril 2014 du Gouvernement wallon relative aux catalogues des variétés des espèces de plantes agricoles et de légumes et abrogeant certaines dispositions en la matière, M.B. du 01/07/2014. Free translation: ‘§3. A genetically modified variety may only be admitted if its placing on the market has been authorised in accordance with the European legislation applicable to GMOs and with its implementing Acts’.

39) Article 15 of the Decreto del Presidente della Repubblica 8 ottobre 1973, n. 1065 (G.U. n. 95 del 10 aprile 1974). Free translation: ‘... A genetically modified variety may be included in the relevant section of the national catalogue of varieties referred to in article 17 subject to verification, pursuant to Article 19 of the Act no 1096 of 1971, that: (a) all appropriate measures have been taken to avoid adverse effects on human health, the environment and the Country's agricultural system arising from the deliberate release or the placing

on the market of such variety, as provided under Community and national legislation ...’.

40) Article 80 (13) of the Regeling van de Minister van Landbouw, Natuur en Voedselkwaliteit van 16 januari 2006, nr. TRCJZ/2006/98, houdende regels met betrekking tot het in de handel brengen van teeltmateriaal, Stcrt. 2006, nr. 15, 00016. Free translation: ‘In case of genetically modified material, authorisation for placing on the market of reproductive material for trial purposes may only be granted if the reproductive material has been authorised in accordance with Directive 2001/18/CE or Regulation 1829/2003’.

41) Article 1 and Article 21 of L.N. 485 of 2010 Environment Protection Act, Deliberate Release into the Environment of Genetically Modified Organisms Regulations, Govt. Gazette No 18674 of 16 November 2010.

GMOs under Articles 2 and 3 and its Annexes), Regulation No 1829/2003 on genetically modified food and feed (which uses the same definition of a GMO and its exclusions in its Article 2(5) as in the GMO Directive), or Directive 2009/41/EC of 6 May 2009 on the contained use of genetically modified micro-organisms (which excludes mutagenesis from the definition of a GMO through its Article 2(b)(ii)).

Thus, while the Common Catalogue Directive does not expressly refer to the Annexes of the GMO Directive (exempting organisms resulting from mutagenesis from the GMO legislation), it is clear that whether or not a certain organism is to be considered a GMO and whether or not the special requirements under the Common Catalogue Directive should apply is determined by the benchmark definition of GMOs under the GMO Directive *including* the exemptions in the Annexes of the GMO Directive. As the Annexes of the GMO Directive exclude organisms resulting from mutagenesis from the scope of the GMO Directive, those organisms will also not be subject to the GMO specific requirements of the Common Catalogue Directive.

However, whether or not the concept of GMOs under the Common Catalogue Directive should be determined by having regard to both the benchmark definition *and* the Annexes of the GMO Directive is irrelevant for the application of the special or general rules of the Common Catalogue Directive. Indeed, it follows from the above (page 11 above) that the defining criterion for the applicability of the GMO-specific requirements under the Common Catalogue Directive is the organism, rather than the technique used to 'create' such organism. Whether or not organisms are the result of certain techniques (such as mutagenesis) is in this respect irrelevant. If the organism constitutes a GMO, the GMO specific rules in the Common Catalogue Directive will apply, or, alternatively, if the organism does not constitute a GMO, the normal rules for registration under the Common Catalogue Directive will apply.

In this respect, and as indicated above, organisms resulting from mutagenesis (including Targeted Mutagenesis) fall outside the concept of a GMO as defined in Article 2(2) of the GMO Directive as they do not contain foreign inheritable genes upon their release into the environment. Varieties resulting from any form of mutagenesis are thus exempted

from the specific registration requirements for GMOs under the Common Catalogue Directive. However, this does not mean that organisms resulting from Targeted Mutagenesis are not subject to any registration requirements under the Common Catalogue Directive, as it subjects all those organisms (varieties) to all the variety registration requirements under the Common Catalogue Directive.

The above analysis indicates that the Common Catalogue Directive employs the same definition and concept of GMOs as the GMO Directive (that is, the same benchmark definition supplemented by the exemptions in the Annexes), as a result of which organisms resulting from any form of mutagenesis do not constitute GMOs and are not subject to the GMO specific requirements but to the general seed requirements under the Common Catalogue Directive.

## Conclusions and Future Perspectives

With the development of new plant breeding techniques, the European plant breeding sector is tackling the world's crucial challenge of feeding the 21st-century world. New plant breeding techniques indeed allow for much faster and more precise results than traditional plant breeding techniques, and allow for more food to be produced with fewer inputs. However, the novel nature of such techniques has recently raised the question as to whether or not these techniques lead to organisms that are GMOs and subject to stringent regulatory requirements.

The mostly theoretical legal uncertainty has recently become *incontournable* now that nine organisations have initiated legal proceedings (December 2014) against the French Environmental Code, arguing that organisms resulting from Targeted Mutagenesis constitute 'new hidden GMOs'. Indeed, the four preliminary questions referred by the French Conseil d'Etat to the CJEU serve to ascertain whether organisms resulting from new forms of mutagenesis should be subject to the GMO legislation.

The qualification of plant and seed as modified organisms has fuelled a primarily political debate within the EU. However, this article demonstrates that there are a plenty of legal arguments available within the current GMO framework that can provide guidance to the CJEU on how to resolve this issue.

In particular, a historical and teleological assessment of the GMO Directive indicates that it was the legislator's intention to only regulate gene combinations that could not occur naturally. The definition of GMOs is a clear example of this as it exempts organisms resulting from techniques such as Targeted Mutagenesis from the GMO Directive. It should also not be much of a surprise that the exemption constitutes a measure of maximum harmonisation and leaves Member States no discretion to decide on the applicable rules to organisms resulting from Targeted Mutagenesis. In the same vein, it follows from the text of the GMO Directive that the precautionary principle is enshrined in the GMO Directive and was taken into account when establishing the scope of the GMO Directive. The mere fact of technological progress does also not mandate a revision of the GMO Directive's exemption provisions. Finally, the Common Catalogue Directive employs the same definition and concept of GMOs as the GMO Directive, and organisms resulting from any form of mutagenesis do not constitute GMOs and are not subject to the GMO specific requirements. This is clear from the Articles and Recitals of the Common Catalogue Directive, as well as from the transposition of the Common Catalogue Directive into national law by the European Member States.

Arguing the opposite seems to be embarking on a journey full of obstacles, as the resulting plants and seed are indistinguishable from traditionally bred organisms. Even more intriguingly, there are no detection methods available to ascertain which plant or seed was produced by which technology. Furthermore, the resulting plant or seed will be more beneficial because no other side effects occur and only the gene of interest is recombined, leading to a precisely designed new variety. In this respect, GMO legislation should be focused on the potential hazards of the resulting end product rather than the process leading to it.

The importance of this preliminary ruling can thus hardly be underestimated as the qualification of plant breeding techniques such as Targeted Mutagenesis could have far-reaching consequences for the resulting organisms. Indeed, subjecting such organisms, which are already freely available on the European market, to the GMO legislation would make their commercialisation practically impossible. Needless to say, the EU will also face remarkable competitive disadvantages regarding the development and propagation of plants and seed resulting from NBTs, which will affect agricultural innovation within the EU.