POSITION PAPER ON THE OPINION OF ADVOCATE GENERAL BOBEK DELIVERED ON 18 JANUARY 2018 IN CASE C-528/16

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BACKGROUND

Scientific progress has in recent years led to the continuous development of new innovations in the plant breeding sector, commonly referred to as "new plant breeding techniques" (**NBTs**).[1] However, the novel nature of some of such breeding applications has also raised the question as to whether or not these tools lead to genetically modified organisms (**GMOs**), which have since their creation been subject to specific regulatory requirements.

In December 2014, 9 organizations initiated legal proceedings against Article D.531-2 of the French Environmental Code, which is a part of the French law implementing the GMO Directive. They argued that herbicide tolerant varieties in rapeseed and sunflower resulting from new forms of mutagenesis constitute 'new hidden GMOs' and as such need to be subject to the requirements imposed by Directive 2001/18/EC of 12 March 2001 (the **GMO Directive**). The French *Conseil d'Etat* referred on 3 October 2016 four preliminary questions to the European Court of Justice (**ECJ**), essentially to ascertain whether organisms resulting from traditional and new forms of mutagenesis techniques should be subject to the GMO legislation. One year later, on 3 October 2017, the ECJ convened in a grand chamber public hearing, and on 18 January 2018 Advocate General Bobek delivered his Opinion in this case.

ANALYSIS OF THE ADVOCATE GENERAL'S REASONING

FIRST PRELIMINARY QUESTION

The first preliminary question reads as follows: "*Do organisms obtained by mutagenesis constitute genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of 12 March 2001, although they are exempt under Article 3 of and Annex IB to the directive from the obligations laid down for release and placing on the market of genetically modified organisms? In particular, may mutagenesis techniques, in particular new directed mutagenesis techniques implementing genetic engineering processes, be regarded as techniques listed in Annex IA, to which Article 2 refers? Consequently, must Articles 2 and 3 of and Annexes IA and IB to the GMO Directive 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?*"

In answering the first question, the Advocate General starts by distinguishing two sub-questions, i.e. (i) whether organisms resulting from mutagenesis fall under the definition of a GMO within the meaning of Article 2(2) of the GMO Directive, and (ii) whether such organisms are exempted from the scope (and thus the obligations) of the GMO Directive. The Advocate General indicates that first it needs to be assessed whether a certain organism constitutes a GMO, after which it needs to be reviewed whether such GMO could be exempted from the obligations of the GMO Directive.

[1] Commonly, the following techniques are referred to as NBTs: (i) Oligonucleotide Directed Mutagenesis (**ODM**), (ii) Site Directed Nucleases (**SDN**), incl. 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.

Combining both sub-questions, according to the Advocate General, three categories of organisms resulting from different mutagenesis techniques exist (para. 66):

(i) Organisms resulting from mutagenesis techniques which don't constitute GMOs according to the definition of Article 2(2) (**Category One Organisms**);

(ii) Organisms resulting from mutagenesis techniques which constitute GMOs (according to the definition of Article 2(2)), but which are exempted from the obligations of the GMO Directive (**Category Two Organisms**); and

(iii) Organisms resulting from mutagenesis techniques which constitute GMOs (according to the definition of Article 2(2)) and which are not exempted from the obligations of the GMO Directive (**Category Three Organisms**).

As will be indicated in further detail below, this threefold distinction between the categories of mutagenesis organisms is the linchpin of the Advocate General's reasoning in his Opinion.

The definition of a GMO

The Advocate General states that an organism resulting from mutagenesis can constitute a GMO under Article 2(2) if it fulfils the substantive criteria laid down in that provision.[2] Therefore, the Advocate General first establishes the criteria in order for an organism to be considered a GMO.

In this respect, the Advocate General distinguishes the technique of transgenesis from the technique of mutagenesis. While neither of these terms are defined in the GMO Directive, the Advocate General considers that transgenesis leads to the insertion of foreign genes into the recipient organisms, while this is not the case with mutagenesis (paras 43-44). The Advocate General continues to argue that in order to fall within the scope of Article 2(2), the genetic material of an organism should have "a genetic modification that does not occur naturally". As this concept is not specified in the GMO Directive, he interprets such criterion rather broadly and indicates that such genetic modification is not to be understood as solely to include an insertion of foreign genes (paras. 61-62). According to the Advocate General, a genetic modification that does not occur naturally could happen with or without the insertion of foreign genes. Therefore, the Advocate General concludes that also mutagenesis techniques (in addition to transgenesis) could lead to organisms which are considered GMOs under the definition of Article 2(2) (i.e. Category Two and Category Three Organisms). Such reasoning is moreover true as, according to the Advocate General, it would be illogical to exempt certain organisms from the application of the GMO Directive if those organisms could not be characterised as GMOs in the first place. He also argues that if the European legislator would have wanted to avoid that organisms resulting from mutagenesis constitute GMOs, the legislator would have indicated this at the level of the definition of GMOs itself.

From such definition, it is already clear that the Advocate General, in answering the preliminary questions, adheres first and foremost to a legal, theoretical and also literal interpretation of the GMO Directive. Indeed, the Advocate General first derives a definition of mutagenesis and applies such definition to the criterion of GMOs. He concludes from the fact that the definition of GMOs is not very explicit (and e.g. does not specify that the introduction of foreign DNA is a necessary requirement), that certain techniques of mutagenesis could result in organisms which constitute GMOs (i.e. Category Two and Category Three Organisms).

[2] 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 are coming from organisms which can exchange genetic material through traditional breeding methods.

With such reasoning, the Advocate General seems to apply both a product (i.e. does the end product contain a genetic modification which could not occur naturally?) as well as a process based (i.e. does the process consist of a process of genetic modification?) interpretation of the GMO Directive in considering whether a certain organism constitutes a GMO. This is exemplified by the fact that the Advocate General stresses that Category One Organisms can exist. Indeed, Category One Organisms consists of organisms which result from a technique of genetic modification (such as for example mutagenesis) – which by definition is not a natural process – but which do not constitute GMOs as their genetic modification could also occur naturally. Consequently, even if the technique does mimic a natural process, but by itself is technically induced like the traditional and new mutagenesis methods, only if also the final product was modified in a way which could not occur naturally would such organism be considered to constitute a GMO. The GMO Directive indeed is somewhat in two minds with respect to the question whether the defining criterion is a process based rather than a product based approach. While it suffices according to the definition to involve a genetic modification which does not occur naturally (this mainly refers to the process of genetically modifying a product), Article 1 of the GMO Directive (the objective) stipulates: *"to protect human health and the environment when: - carrying out the deliberate release into the environment of genetically modified organisms"*. The aims of the GMO Directive thus seem to be 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, which indicates that it is not the process itself which requires the specific protection, but rather 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 latter aspect is however not put forward by the Advocate General. Nor does he refer to the requirement of inheritability.

It follows from the above that the prime criterion to assess whether an organism constitutes a GMO is to assess whether the genetic material of such organism has a genetic modification which could have occurred naturally (even though a technique of genetic modification was used). Thus, only to the extent that organisms have been obtained through a technique of genetic modification and their final product consist of a genetic modification which could not have occurred naturally, such organisms should be considered to constitute GMOs. As will be demonstrated below, the GMO Directive however explicitly exempts certain of such GMOs from the GMO Directive.

The scope of the mutagenesis exemption

After having elaborated on the definition of GMOs, the Advocate General continues to review the scope of the exemptions of the GMO Directive. In particular, he argues that organisms resulting from both new as well as old mutagenesis techniques can be exempted from the obligations of the GMO Directive, depending on the specific process used in such techniques. Indeed, the only assessment criterion for such exemption lies according to the Advocate General in the question whether or not the mutagenesis techniques involve the use of (i) 'recombinant nucleic acid molecules' or (ii) 'non-exempted GMOs' (para.77).

To support his thesis, the Advocate General refers to the fact that the requirement of 'the use of recombinant nucleic acid molecules' was introduced when adopting the GMO Directive, while its predecessor, Directive 90/220/EEC of 23 April 1990, did not include such caveat. The inclusion of such caveat demonstrates that to determine the scope of the mutagenesis exemption, the European legislator did not wish to distinguish between mutagenesis techniques which existed at the time of the adoption of the GMO Directive and which would be developed later on, but rather narrowed down the exemption by adding the caveat. Such caveat was consequently considered by the Advocate General to sufficiently take into account the emergence of new mutagenesis techniques (paras. 81-82).

With such strictly legal and literal reasoning, the Advocate General has shifted the debate from 'are new mutagenesis techniques excluded?' to the question 'does a particular mutagenesis technique involve the use

of recombinant nucleic acid molecules?'. The concept of recombinant nucleic acid molecules however is not defined by the GMO Directive. As the Advocate General does not clarify several key concepts, it is essential to interpret such concepts in their broader context.

First, the most authoritative definition of the term recombinant nucleic acid molecule stems from the European Food and Safety Authority (**EFSA**), which defined recombinant nucleic acids in October 2015 as: *"molecules which are generated by joining nucleic acid molecules and which can replicate in a living cell."*[3] This definition is confirmed and specified by the European Social and Economic Committee, which put forward a similar definition already in 1979: *"the coupling of nucleic acid molecules outside a living organism to form a new molecule not occurring in nature and the introduction of this new molecule into a host organism where it is propagated and passed on to future generations of the host organism."*[4]

Those definitions indicate that the recombinant nucleic acid molecule should be capable of propagation to future generations (and thus should be inheritable) in order not to be exempted from the GMO Directive. This requirement of inheritability implies that it is not relevant whether at some point during the process recombinant nucleic acid molecules were used in the organism, but that the recombinant nucleic acid needs to be present and inheritable in the organism that is supposed to be released into the environment. When we apply such definition to the term "involve the use of", it is thus clear that the recombinant nucleic acid molecule should be present in the final product. Reference should here be made to Article 4(3) of the GMO Directive, which indicates that its purpose is to take measures against advance affects "*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 resulting from such gene transfer, 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.[5] This also tells from the definition of an 'organism' (i.e. *"*any biological entity capable of *replication or of transferring genetic material"*) and Annex I A, Part 1 (i.e. "in which they are capable of *continued propagation"*, "*heritable material"*, and *"heritable genetic material"*). The ECJ finally also indicated in the *Bablok* case that the foreign genes should be capable of being transferred.[6] Thus, only an alteration of the genetic material that is inheritable can be considered a genetic modification. The Advocate General nonetheless does not mention this requirement in his Opinion.

Annex IB further specifies that such organisms cannot involve the use of recombinant nucleic acid molecules or GMOs "*other than those produced by one or more of the techniques/methods listed*", referring thereby to mutagenesis and cell fusion. This means that any mutagenesis organisms, even though they involve the use of recombinant nucleic acid molecules, which themselves were produced by mutagenesis or cell fusion techniques, are still excluded from the scope of the GMO Directive. Consequently, a nucleic acid which originates from sexually compatible plant speci will not be regarded as recombinant, as well as a nucleic acid being a mutant of another nucleic acid which originates from the organism itself.

It should consequently not cause surprise that the Advocate General also strongly rejects the allegation of the 9 organisations which opposed the herbicide tolerant varieties resulting from new forms of mutagenesis that such mutagenesis techniques should be distinguished according to their degree of safety, and that only those techniques that were tried and tested (and thus safe) in 2001, can be exempted. The Advocate General points out that neither the text, nor the historical context, or the internal logic of the GMO Directive indicate that the EU legislator only intended to exempt "safe" mutagenesis techniques (paras. 90-91). It is indeed correct that it is unfeasible to use such distinction as the correct yardstick to assess whether a certain technique is

[3] See EFSA Response to Mandate M_2015-0183, "Question 1: Definition of the term "recombinant nucleic acid molecule", 15 October 2015, available at http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?1.

[4] Annex to the opinion of the Economic and Social Committee, No C 247/3, 1.10.79, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51979AC0851&from=EN.

[5] 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*"; "*than can replicate in a living cell*").

[6] Judgment of 6 September 2011, *Bablok*, C-442/09, EU:C:2011:541, paras. 55 and 62.

safe as any of such techniques could at the time only have been used in laboratories, could have been modified later on, or only later would have been found safe. The Advocate General also correctly indicates that recital 17 of the GMO Directive, which refers to the long safety record of certain techniques, was drafted and inserted in the text of the directive before the mutagenesis exemption was even discussed. The caveat of mutagenesis techniques which involve the use of recombinant nucleic acid molecules however does show a certain willingness of the European legislator to legislate such matter at EU level. Indeed, as shall be demonstrated below, the choice of the European legislator to include this caveat should be seen as an explicit choice to legislate specific mutagenesis techniques in which use is made of recombinant nucleic acid molecules.

Finally, as an ancillary point, the Advocate General also mentions that France incorrectly implemented the GMO Directive in French law, as it did not correctly include the caveat with respect to the use of recombinant nucleic acid molecules. This implies that an action for annulment could be instigated against the French Environmental Code, as the French Government wrongly implemented the GMO Directive.

In conclusion, it follows from the above that the Advocate General considers that first it needs to be assessed whether a certain organism constitutes a GMO, after which it needs to be reviewed whether such GMO could be exempted from the obligations under the GMO Directive. The GMO Directive intends to regulate organisms which have been genetically modified, though exempts certain of such genetically modified organisms to the extent they involve the use of nucleic acid molecules which don't consist themselves of an outright genetic modification. While organisms resulting from mutagenesis could in certain instances constitute GMOs (i.e. because their genetic modification happened in a way that does not occur naturally), they could be exempted from the obligations of the GMO Directive (subject to other conditions). Consequently, three possible types of organisms resulting from mutagenesis techniques exist (para. 66): (i) Category One Organisms, (ii) Category Two Organisms, and (iii) Category Three Organisms.

THIRD PRELIMINARY QUESTION

After having replied to the first question, the Advocate General goes on to discuss the third question in which it is asked whether Member States may adopt national rules regarding Category One and Category Two Organisms: *"Do Articles 2 and 3 of and Annex IB to the GMO Directive constitute, insofar as they exclude mutagenesis from the scope of the obligations laid down in the directive, a full harmonisation measure prohibiting Member States from subjecting organisms obtained by mutagenesis to all or some of the obligations laid down in the directive or to any other obligation, or do the Member States, when transposing those provisions, have a discretion to define the regime to be applied to organisms obtained by mutagenesis?"*

– This question essentially boils down to question of the legislative choice of the European legislator with respect to mutagenesis. In other words, whether the exemption of mutagenesis constitutes a measure of full or rather partial harmonisation and whether Member States have a margin of discretion to impose national measures beyond what is left to them by the harmonising measure (para. 113). The Advocate General first of all states that there are two possible ways of understanding the intention of the European legislator with respect to the mutagenesis exemption:

(i) The European legislator made a legislative choice and came to conclusion that all mutagenesis techniques are to be excluded from the scope of the GMO Directive because they are safe. Consequently, Member States cannot regulate organisms resulting from mutagenesis; or

(ii) The European legislator did not make any statements about the safety of mutagenesis techniques, but just didn't want to regulate this matter at the European level. Member States can consequently enact national rules with regard to organisms resulting from mutagenesis.

The Advocate General indicates that he considers the second interpretation to be correct, and invokes four reasons for this (paras. 118-122). First, he states that he finds no support in the wording of the GMO Directive that the mutagenesis exemption was introduced specifically because the European legislator came to the conclusion that all organisms resulting from mutagenesis techniques were safe. Second, he argues that a reasonable legislator would never state that something (such as a technique of mutagenesis) is safe to the degree that it does not need regulating at all, at any level. In addition, the Advocate General refers to the fact that the Council would have confirmed that there was no intention of stating that all organisms resulting from mutagenesis techniques were safe. Finally, according to the Advocate General, Directive 2015/412 grants Member States far-reaching competences, which would indicate a certain "renationalisation" of competences in the field of GMOs.

The Advocate General concludes from this that Member States have the competence to regulate organisms obtained through mutagenesis provided that they comply with their overall EU law obligations. Such reasoning is predominantly based on the fact that the European legislator would not have excluded mutagenesis techniques from the obligations included in the GMO Directive because such mutagenesis techniques are considered 'safe'. While it is certainly applaudable not to make a distinction between organisms resulting from old and mutagenesis techniques in terms of their alleged safety (see point 12 above), it is remarkable that the Advocate General assumes that the inclusion of the caveat 'use of nucleic acid molecules' was not included for specific (safety) reasons. Indeed, the caveat was introduced in the GMO Directive in 2001, which as the Advocate General stresses himself, was done in order "*to take into account the emergence of new mutagenesis techniques*". This at least implies that, out of certain health and safety reasons, it was deemed necessary to subject organisms resulting from mutagenesis techniques which involve the use of recombinant nucleic acid molecules, to the same obligations as other techniques such as transgenesis, which without a doubt lead to outright genetic modification.

It would indeed only be logical that the European legislator regulates a certain issue at European level because such issue is for certain reasons less aptly regulated at national level. The European legislator is moreover obliged to do so in accordance with the principles of proportionality and subsidiarity: the European legislator can (in areas of shared competences) only legislate in circumstances in which it is preferable for action to be taken by the European Union, rather than by the Member States. Indeed, the GMO Directive is exactly built on the premise that organisms resulting from certain techniques need to be regulated (i.e. mutagenesis techniques which involve the use of recombinant nucleic acid molecules) and need to be subject to the obligations imposed by the GMO Directive, while others either (i) do not fall within the scope of application (because they do not lead to GMOs), or (ii) are exempt. The Advocate General also seems to confirm this himself in his Opinion, as he stresses that the latter two categories "benefit from the exemption" included in the GMO Directive (para. 77). Consequently, it would be illogical to subject certain organisms to GMO obligations (because it is scientifically proven that they have to be subjected to such strict requirements), while the other organisms (not considered necessary to be subject to such obligations) could be regulated at the national level (and subject to even stricter measures).

Such reasoning is even more true with respect to mutagenesis organisms which don't even constitute GMOs. Indeed, it would be perverse to subject such organisms (not considered GMOs) to national requirements similar or equivalent to the obligations included in the GMO Directive.

In addition, it is also not correct to state that the European legislator did not wish to regulate the mutagenesis organisms (exempt from the GMO Directive) at all at EU level, as they are in fact already regulated at EU level. Indeed, while such organisms might be exempt from the GMO Directive, they are subject to several other European obligations. In particular, all plant varieties also need to comply with the requirements of EU law on the marketing of seed and plant propagating material, as set out in particular in Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC and 98/56/EC (the **Seed Directives**). The Advocate General moreover seems to confirm this himself in para. 166 of his Opinion.

In this respect, it should also be questioned to what extent Member States can enact their own rules with respect to organisms resulting from mutagenesis without violating their overall EU law obligations, whether

of primary or secondary law origins, such as Articles 34 and 36 TFEU (para. 123). Indeed, when establishing national rules, Member States should comply first and foremost with the rules of the internal market, and not subject organisms resulting from mutagenesis (and which are not covered by or exempt from the GMO Directive) to legislation which impedes the internal market.[7] This was explicitly confirmed by Directive 2015/412 itself, which states that *"Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products."*, and which puts clear emphasis on the fact that while cultivation of Category Three Organisms could be regulated by the Member States, the placing on the market and importation is still (only) to be decided at EU level.

This restriction however also means that Member States should have regard to secondary EU legislation, including (but not limited to) the GMO Directive and the Seed Directives. For example, Member States should comply with the legislative choice embedded within the GMO Directive, i.e. to subject GMOs resulting from mutagenesis techniques which involve the use of recombinant nucleic acids to a stringent regime of requirements. It would in this respect consequently be in contradiction with the GMO Directive should Member States impose similar or equivalent requirements to the organisms resulting from mutagenesis which are not covered by or exempted from the GMO Directive, as this would violate the legislative choice with respect to such GMO Directive (i.e. to subject certain organisms to strict requirements, while exempting others from such requirements). As will be indicated below (see para. 33), this would moreover lead to the odd outcome whereby certain obligations of the GMO Directive would apply indirectly (through the imposition of national measures) to organisms that are exempted from any obligation derived from that Directive. Consequently, while Member States could impose certain national measures (such as for example certain notification obligations), such measures can however not go beyond (depending on the specific organisms, i.e. Category One or Two Organisms) those included in the Seed Directives or the GMO Directive.

Consequently, it appears from the Advocate General's reply to the first and the third preliminary question that there are, in his view, three different categories of mutagenesis organisms, with a varying possibility for Member States to enact national measures for each category:

(i) with respect to the Category One Organisms: Member States could enact certain national measures (such as for example a notification duty) which however can't be more restrictive as the obligations included in the Seed Directives (such as for example the Common Catalogue Directive). Indeed, as the Category One Organisms don't constitute GMOs, they will be considered to be conventional plant varieties and as such be subject to the European legislation on plant varieties. Any national measures consequently can't go beyond the obligations imposed on conventional varieties (Category One Organisms) by European law.

(ii) with respect to the Category Two Organisms: Member States could enact certain national measures, though such measures cannot be as restrictive as the obligations included in the GMO Directive; and

(iii) with respect to the Category Three Organisms: Member States are not allowed to regulate such organisms as they are subject to the GMO Directive.

Finally, while the Advocate General claims that Directive 2015/412 (which amends and updates the GMO Directive) *"effectively allows Member States to ban the release and placing on the market of products covered by the GMO Directive",* and "*that would seem to indicate certain renationalisation of competences in the field of GMOs*", such overly broad statement needs to be nuanced. First, Directive 2015/412 only

[7] See also Commission of the European Union v. Kingdom of Spain (C-12/00, 16 January 2003), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62000CJ0012&rid=2, in which it is stated that secondary legislation such as the GMO Directive could not be interpreted as leading to restrictions on the free movement of goods: *"The Court has consistently held that a rule of secondary legislation, such as Article 8 of Directive 2000/36, cannot be interpreted as authorising the Member States to impose or to maintain conditions contrary to the Treaty rules on the free movement of goods (Case C-47/90 Delhaize et Le Lion [1992] ECR I-3669, paragraph 26; Case C-315/92 Verband Sozialer Wettbewerb [1994] ECR I-317,'Clinique' paragraph 12; and Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others [1996] ECR I-3457, paragraph 27).*

applies to GMOs subject to GMO obligations (as defined under the GMO Directive), i.e. organisms which constitute GMOs and are not exempted (Category Three Organisms). Member states consequently cannot introduce similar obligations vis-à-vis non- regulated products such as Category One Organisms and Category Two Organisms. Secondly, while it is correct indeed that this directive allows Member States to (partially) ban cultivation on their territory based on certain grounds, it does not allow Member States to ban the placing on the markets of such products.

From this third question, it thus seems that the Advocate General concludes to partial rather than full harmonisation with respect to the scope of the mutagenesis exemption. However, it is important to stress that any national measures adopted by Member States should comply with EU law, which in fact means that any such measures are rather limited in scope and consequently have little far-reaching implications for organisms resulting from mutagenesis.

FOURTH PRELIMINARY QUESTION

The fourth preliminary question reads: *"May the validity of Articles 2 and 3 of and Annexes IA and IB to the GMO Directive with regard to the precautionary principle guaranteed by Article 191(2) of the Treaty on the Functioning of the European Union, in that those provisions do not subject genetically modified organisms obtained by mutagenesis to precautionary, impact assessment and traceability measures, be called in question, taking account of the development of genetic engineering processes, the appearance of new plant varieties obtained by means of those techniques and the current scientific uncertainty as to their impacts and the potential risks they represent for the environment and human and animal health?"*

Third, the Advocate General tackles the fourth preliminary question, in which it is suggested that the European legislator failed to react after the adoption of the GMO Directive to new technical and scientific evolutions through amendments or other adjustments. Indeed, due to the alleged absence of any assessment and surveillance mechanisms of organisms resulting from mutagenesis, there would be a danger of a risk that ought to trigger the precautionary principle. Consequently, the scope of the mutagenesis exemption of the GMO Directive would not be valid.

The Advocate General strongly rejects this alleged invalidity and states that there is no factor of any kind which indicates that the validity of Articles 2 and 3 of the GMO Directive and its Annexes is affected (para. 152). The Advocate General stresses the importance of the ex-post review of legislation, and the obligation of the European legislator to keep its legislation reasonably up to date.

In particular, the Advocate General points out that, contrary to the generally accepted understanding that a legislator is to assess the context of a situation at the time of the adoption of certain legislation, the legislator also has a constitutional duty for its legislation to be relevant and consequently if need be, to regularly update its legislation. Such duty to update the legislation is moreover stronger in case of sensitive areas where the precautionary principle applies and in which extra caution and vigilance is called for. At the same time, the Advocate General stresses the exceptional nature of this duty for the legislator: it can only be asked from the legislator in cases of clear and paramount dissonance between changed reality and effectively obsolete legislation (paras. 139-140).

When applying this theoretical framework to the case at hand, the Advocate General stresses that the duty to update the legislation has been complied with. This is true mainly because of three reasons.

First, the GMO Directive has been regularly discussed and updated. The Advocate General refers in this respect to (i) the preceding Directive 90/220, (ii) the amendment of the GMO Directive in 2008 and (iii) the amendment of the GMO Directive in 2015 (which made it possible for Member States to ban the cultivation of GMOs on several grounds). The GMO Directive moreover also foresees today in its own adaptation mechanism due to Article 27, which requires the adjustment of a number of the annexes of the GMO

Directive depending to the technological progress. The Advocate General refers in this respect also to the caveat modification of Annex I B (mutagenesis is only exempted from the GMO Directive if does not involve the use of recombinant nucleic acid molecules or GMOs), which indicates that the legislator updated the legislation in order to accommodate the concerns with respect to the recombinant nucleic acid molecules.

Secondly, the Advocate General points out that there is limited knowledge of any concrete risks for the health or environment which are connected to mutagenesis. As protective measures are only allowed if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, and which would indicate that those measures are necessary, this is not the case with respect to mutagenesis. The Advocate General refers in this respect also to the ECJ's case law with respect to the precautionary principle, which states that 'general doubts' do not equal an unambiguous uncertainty or risk.

Third, the Advocate General refers to his answer in the third question and stresses that while the obligations of the GMO Directive only apply to certain types of organisms resulting from mutagenesis, Member States could adopt national measures with respect to the organisms which are not subject to the GMO Directive. The Advocate General states: *"Conversely, the same duty will be much weaker, or even non-existent, when any party that considers itself to be concerned can do it for themselves."* (para. 151).

In conclusion, while the Advocate General imposes a strong duty and strict yardstick on the EU legislator to update its GMO legislation (such duty to update is particularly relevant as the GMO legislation is considered to be a 'sensitive' topic which could easily mandate for extra protective measures to protect health and environment), the Advocate General at the same time points out that the EU legislator in this case did comply with the strict yardstick, and did assess and update its legislation. The Advocate General thus does not make a distinction between 'old' and 'new' mutagenesis techniques, which is in line with his previous argumentation, but rather makes a distinction between 'which measures pose a potential health problem and which don't'.

SECOND PRELIMINARY QUESTION

The second preliminary question reads as follows: "*Do varieties obtained by mutagenesis constitute genetically modified varieties within the meaning of Article 4 of Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, which would not be exempt from the obligations laid down in that directive? Or, on the contrary, is the scope of that directive the same as that which under Articles 2 and 3 of and Annex IB to the GMO Directive, and does it also exempt varieties obtained by mutagenesis from the obligations laid down for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species by the Directive of 13 June 2002?*"

Finally, the Advocate General ends with answering the second, and arguably also the least contentious, preliminary question. This question, which relates to the interpretation of the GMO Directive in relation to other European law instruments primarily stems from the sloppy drafting of certain provisions of Directive 2002/53 EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (the **Common Catalogue Directive**). Indeed, the Common Catalogue Directive contains several provisions which apply to GMOs, but does not specify that the scope of such provisions is identical to the scope of the provisions (and thus the mutagenesis exemption) of the GMO Directive, as a consequence of which the claimants have argued that scope of both directives would not be identical.

The Advocate General strongly rejects such approach and states that the Common Catalogue Directive should be interpreted as exempting varieties obtained by mutagenesis techniques from the specific obligations laid down in such Directive. In other words, the Advocate General holds that the scope of the clauses with respect to GMO organisms should be interpreted in the light of the mutagenesis exemption contained in the GMO Directive, in order to exclude an indirect application of the GMO Directive to varieties of agricultural plant species obtained by mutagenesis (para. 154).

The arguments for this are twofold. First, there should be an internal consistency between the Common Catalogue Directive itself. As such, Article 4(4) – which refers explicitly to the definition of GMOs contained in Article 2(2) GMO Directive – should be read in conjunction with Article 7(4), which refers to Article 4(4) of the same directive as well as the obligations imposed on GMOs in the GMO Directive.

Consequently, as the Advocate General points out correctly, even though textually it not explicitly stated that the mutagenesis exemption of the GMO Directive also applies to the Common Catalogue Directive, it would be hardly acceptable to accept two different scope of applications, as it would lead to the odd outcome whereby certain obligations of the GMO Directive would apply indirectly to organisms that are exempted from any obligation deriving from that Directive.

In addition, there should also be an external consistency between the Common Catalogue Directive and EU secondary legislation which regulates GMOs. The Common Catalogue Directive does not primarily concern GMOs, but regulates more generally varieties of agricultural plant (and vegetable) species. The Advocate General consequently concludes that the Common Catalogue Directive is to be seen as a *lex generalis*, while the GMO Directive is considered the *lex specialis*. Indeed, *"it would hardly be conceivable that products exempted from the obligations laid down in the specialised GMO specific legislation would have to comply with equivalent substantive obligations on the basis of a piece of EU legislation that primarily legislates in a different field and only accidentally touches upon GMOs."* (para. 163). Thus, 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 Directive.

The Advocate General concludes by indicating that organisms resulting from mutagenesis do not fall short of any control or supervision, as they may be subject to obligations derived from other EU secondary law measures. Such statement is correct, as for example European legislation on food and feed subjects such organisms to several obligations.

The Advocate General's approach constitutes a sound legal reasoning. It is indeed most likely that the European legislator forgot to include or did not clarify explicitly the scope of the exemptions under the Common Catalogue Directive. As the Advocate General rightfully indicates, it could only have been the legislator's intention to employ the same definition and scope of applicability of GMOs under the two directives.

CONCLUDING OBSERVATIONS

To formulate a reply to the key question in this debate, – "are (and which) organisms resulting from mutagenesis techniques excluded from the obligations imposed by the GMO Directive?" – the Advocate General interprets several key concepts and aspects of this GMO Directive, including *inter alia* the definition of a GMO, the scope of the exemptions, the intention of the European legislator, and the concept of mutagenesis. The main findings underlying the interpretation of these concepts are that (i) both the process as well as the end result are important criteria in order to conclude an organism to be a GMO, and (ii) mutagenesis techniques are not to be understood as 'frozen in time', but are an evolving concept, allowing both older as well as newer mutagenesis techniques to be covered by the exemption (provided they meet the statutory language).

When we apply these findings to the key question, it becomes clear that the Advocate General considers that organisms resulting from mutagenesis techniques are exempt from the GMO obligations if (i) such organisms do not constitute GMOs (because their genetic modification could occur naturally), or (ii) such organisms constitute GMOs but do not involve the use of recombinant nucleic acid molecules which themselves are built of anything other than mutagenesis or natural processes. The Advocate General thus makes a distinction between three categories of mutagenesis organism, in this paper called (i) Category One

Organisms (i.e. organisms which don't constitute GMOs), (ii) Category Two Organisms (i.e. organisms which constitute GMOs but are exempt) and (iii) Category Three Organisms (i.e. organisms which constitute GMOs and are not exempt).

It needs to be stressed that such distinction is first and foremost theoretical and does not necessarily reflect the reality of mutagenesis organisms. Indeed, while theoretically three different categories of mutagenesis organisms are possible, we understand that in practice the majority of organisms resulting from mutagenesis constitute Category One Organisms as they do not, even though obtained by a technique of genetic modification, represent a genetic modification which could not have occurred naturally and thus are not considered to be GMOs.

In addition, it is certainly positive that the Advocate General considers the mutagenesis exemption not to be frozen in time and does not limit it to techniques that were available when the GMO Directive was enacted in 2001. Although he gives no further clarification with respect to the concept of recombinant nucleic acid molecule, which is not defined by the GMO Directive, we believe that such concept should be interpreted by looking at the existing interpretations given by EFSA and by the Economic and Social Committee. A lack of clarity also remains with respect to the question on the intention of the EU legislator. While the Category One Organisms and Category Two Organisms are exempt from the GMO Directive, they could, as the Advocate General surprisingly suggests, still be subject to national measures as long as they comply with European Union law. We believe that when reviewing the obligations imposed by EU law, this statement can only be understood as follows: in order to respect the legislative choice of the European legislator, Member States cannot impose national measures which are more far-reaching than those imposed by EU law.