Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 18 January 2018 [1]

Case C-528/16

Confédération paysanne
Réseau Semences Paysannes
Les Amis de la Terre France
Collectif vigilance OGM et Pesticides 16
Vigilance OG2M
CSFV 49
OGM dangers
Vigilance OGM 33
Fédération Nature & Progrès
v
Premier ministre
Ministre de l'agriculture, de l'agroalimentaire et de la forêt

(Request for a preliminary ruling from the Conseil d'État (Council of State, France))

(Reference for a preliminary ruling — Environment — Agriculture — Directives 2001/18/EC and 2002/53/EC — Interpretation and assessment of validity — Notion of 'genetically modified organism' — Common catalogue of varieties of agricultural plant species — New techniques of mutagenesis implementing genetic engineering processes — Random and directed mutagenesis — Scope of the exemption — Degree of harmonisation — Precautionary principle)

I. Introduction

1. The 'GMO Directive', Directive 2001/18/EC regulates the deliberate release into the environment of genetically modified organisms ('GMOs') and their placing on the market within the Union. [2] In particular, the organisms covered by that directive must be authorised after an environmental risk assessment. They are also subject to traceability, labelling and monitoring obligations.

2. Article 3(1), read in conjunction with Annex I B, states that the GMO Directive shall not apply to organisms obtained through certain techniques of genetic modification, such as mutagenesis ('the mutagenesis exemption').

1 Original language: English.

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

3. Mutagenesis involves an alteration of the genome of a living species. Unlike transgenesis, it does not, in principle, entail the insertion of foreign DNA into a living organism. Techniques of mutagenesis have evolved over time as the result of scientific progress in biotechnology. For Confédération paysanne and others, some of the most recently developed techniques present risks for health and the environment. They therefore brought judicial proceedings before the referring court, seeking the annulment of a national provision that exempts organisms obtained by mutagenesis from the obligations applying to GMOs.

4. It is in this context that the Court is invited to clarify the exact scope of the GMO Directive, more specifically the ambit, rationale and effects of the mutagenesis exemption — and potentially assess its validity. More broadly, the Court is invited to ponder the question of time, more precisely on what role the passing of time and evolving technical and scientific knowledge should play with regard to both legal interpretation and the assessment of the validity of EU legislation, carried out with the precautionary principle in mind.

II. Legal framework

A. EU law

1. Primary law

5. Article 191(2) TFEU provides that:

'Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union.'

2. Secondary law

(a) The GMO Directive

6. Recital 8 of the GMO Directive emphasises that the 'precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it'.

7. Recital 17 states that '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'.

8. The directive's objective is presented in Article 1:

'In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

– carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,

– placing on the market genetically modified organisms as or in products within the Community.'

9. Definitions are found in Article 2(2):

'"genetically modified organism (GMO)" means 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;

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification.'

10. Article 3 lays down exemptions. Its first paragraph states that the GMO Directive 'shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B'.

11. Article 4 sets out general obligations for the Member States. In particular, paragraph (1) states that: 'Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs …'

12. Pursuant to Article 27, 'the adaptation to technical progress of Sections C and D of Annex II, Annexes III to VI, and Section C of Annex VII, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 30(3)'.

13. Annex I A sets out the techniques referred to in Article 2(2). Part 1 of Annex I A provides that:

'Techniques of genetic modification referred to in Article 2(2)(a) are *inter alia*:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.'

14. Part 2 of Annex I A sets out the techniques referred to in Article 2(2)(b), which are 'not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) *in vitro* fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.'

15. Finally, Annex I B enumerates the techniques referred to in Article 3(1):

'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,

(2) cell fusion (including protoplast fusion) of plant cells or organisms which can exchange genetic material through traditional breeding methods.'

(b) Directive 2002/53

16. Recital 16 of Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species [3] reads: '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 [4] … 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.'

17. Article 4(4) provides that, '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'.

18. According to Article 7(4) of that directive:

'(a) In the case of a genetically modified variety referred to in Article 4(4), an environmental risk assessment equivalent to that laid down in Directive 90/220/EEC shall be carried out.

(b) The procedures ensuring that the environmental risk assessment and other relevant elements shall be equivalent to those laid down in Directive 90/220/EEC shall be introduced on a proposal from the Commission, in a Council Regulation based on the appropriate legal basis in the Treaty. Until this Regulation enters into force genetically modified varieties shall only be accepted for inclusion in a national catalogue after having been accepted for marketing in accordance with Directive 90/220/EEC.

3 Council Directive of 13 June 2002 (OJ 2002 L 193, p. 1).

4 Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15).

(c) Articles 11 to 18 of Directive 90/220/EEC shall no longer apply to genetically modified varieties once the Regulation referred to in point (b) above has entered into force.'

19. In accordance with Article 9(5) of the GMO Directive: 'Member States shall ensure that genetically modified varieties which have been accepted are clearly indicated as such in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in his sales catalogue that the variety is genetically modified.'

B. French law

20. Article L. 531-1 of the Code de l'environnement (Environmental Code) defines a genetically modified organism as an 'organism whose genetic material has been modified other than by natural mating or recombination'.

21. Article L. 531-2 of the code provides that 'the provisions of this Title and of Articles L. 125-3 and L. 515-13 shall not apply to genetically modified organisms obtained by the use of techniques which, by reason of being natural, are not considered to involve genetic modification or by those which have been traditionally used without proven harm for public health or the environment. The list of those techniques shall be determined by decree after the Haut Conseil des biotechnologies (High Council for Biotechnology) has given its opinion'.

22. Article D. 531-2 of the code states: 'The techniques referred to in Article L. 531-2, which are not considered to give rise to genetic modification, are the following: … 2. On condition that they do not involve the use of genetically modified organisms as recipient or parental organisms: (a) mutagenesis.'

23. Article D. 531-3 of the code adds that: 'The techniques and definitions referred to in Articles D. 531-1 and D. 531-2 shall be interpreted and implemented in accordance with the development of scientific knowledge in the field of genetic engineering, molecular genetics and cell biology.'

III. Facts, proceedings and questions referred

24. Confédération paysanne is a French agricultural union defending the interests of small-scale farming. For the purposes of this case, it is joined by eight other associations [5] whose objective is the protection of the environment and/or the dissemination of information concerning the dangers relating to GMOs (together, 'the Applicants').

25. As follows from the referring court's order, herbicide resistant seed varieties are the result of transgenesis or mutagenesis. Varieties resistant to a non-selective herbicide (such as glyphosate) are to that extent the result of transgenesis. Those varieties obtained by mutagenesis however have also made it possible to develop elements of resistance to a selective herbicide. The only herbicide resistant seeds registered in the common catalogue of varieties of agricultural plant species are the result of *in vitro* random mutagenesis. Thus, 46 varieties of herbicide resistant sunflower and six varieties of herbicide resistant rape are included in the common catalogue. However, no variety of herbicide resistant seed resulting from the directed mutagenesis techniques has yet been included in the common catalogue.

26. The Applicants contest the fact that organisms obtained by mutagenesis are exempt from the obligations laid down by the provisions of the Environmental Code concerning GMOs. The Applicants are of the opinion that mutagenesis techniques have evolved over time. Before the adoption of the GMO Directive in 2001, only conventional mutagenesis techniques and *in vivo*

5 Réseau Semences Paysannes; les Amis de la Terre France; Collectif Vigilance OGM et Pesticides 16; Vigilance OG2M; CSFV 49; OGM dangers; Vigilance OGM 33; and Fédération Nature & Progrès.

random techniques that involve ionising radiations or exposing plants to chemical agents were used as a matter of routine. Subsequently, technical progress has led to the emergence of mutagenesis techniques that can be carried out by different means (*in vitro* random mutagenesis and directed mutagenesis — referred to as 'the new mutagenesis techniques'). Through these techniques, it is possible to target the mutations in order to obtain a product which will be resistant to certain herbicides only.

27. For the Applicants, the use of herbicide resistant seed varieties obtained by mutagenesis carries a risk of significant harm to the environment and to human and animal health. It leads to an accumulation of carcinogenic molecules or endocrine disruptors in cultivated plants intended for human or animal consumption. The Applicants refer, moreover, to the risks of unintentional effects, such as undesired or off-target mutations on other parts of the genome. They consider that this is the result of the techniques employed when modification of the genome takes place *in vitro* and for the regeneration of plants from the cells thus modified.

28. On the basis of those arguments the Applicants asked the Premier ministre (Prime Minister) to revoke Article D. 531-2 of the Environmental Code[6] and to ban the cultivation and marketing of herbicide tolerant rape varieties.

29. The Prime Minister did not reply to the Applicants' request. Under national law, he is thus considered to have rejected it.

30. In an application of 12 March 2015 made to the Conseil d'État (Council of State, France) (the referring court), the Applicants sought the annulment of that implied, negative decision of the Prime Minister. They also requested that the Prime Minister be ordered to take all steps to introduce a moratorium on herbicide tolerant varieties within one month.

31. The Applicants raised a number of arguments before the referring court concerning the compatibility of Article D. 531-2 of the Environmental Code with the GMO Directive, with Directive 2002/53, and the precautionary principle which is also provided for under the French Constitution.

32. First, they maintain that Article D. 531-2 of the Environmental Code is inconsistent with Article 2 of the GMO Directive. They claim that organisms obtained by mutagenesis are GMOs within the meaning of that latter provision, although, pursuant to Article 3 and Annex I B, they are exempt from the obligations laid down for the release and placing on the market of GMOs.

33. Second, the Applicants claim that Article D. 531-2 of the Environmental Code is at odds with Article 4 of Directive 2002/53. They argue that that latter provision does not exempt varieties obtained by mutagenesis from the obligations laid down in that directive for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species.

34. Third, the Applicants allege that Article D. 531-2 of the Environmental Code breaches the precautionary principle as guaranteed by Article 5 of the Charter for the Environment, which has constitutional status in France. Article D. 531-2 does not sufficiently take into account the adverse effects for the environment and for human and animal health: these are linked to the release into the environment of seeds resulting from genetic modifications obtained by mutagenesis, and the placing on the market of the products resulting from those cultures. Owing to the exclusion of mutagenesis from the rules applicable to GMOs, those seeds are not the subject of preventive measures or prior assessment or surveillance after they have been put on the market.

6 Reproduced above at point 22 of this Opinion.

35. As a contextual point, it might be noted that it would appear that the Applicants' third argument had initially been put before the referring court as a question of national law: is Article D. 531-2 of the Environmental Code, which exempts mutagenesis from the national rules applying to GMOs, in line with the precautionary principle, which is found in the French Constitution?

36. In its order for reference, the referring court has termed the question as being one of potential (in)compatibility of the EU law mutagenesis exemption with the EU law precautionary principle.[7] As implied by the referring court, the content of Article D. 531-2 of the Environmental Code, which is the national measure of transposition, necessarily derives from the obligations laid down in the GMO Directive and is thus meant to mirror it in terms of substance. Challenging the validity of the former therefore amounts to indirectly challenging the validity of the latter.[8] Accordingly, the referring court wishes to ascertain whether the directive at issue is itself valid with regard to the precautionary principle as protected under EU law.[9]

37. In this factual and legal context, the Conseil d'État (Council of State) decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Do organisms obtained by mutagenesis constitute genetically modified organisms within the meaning of Article 2 of Directive [2001/18], although they are exempt under Article 3 of and Annex I B to the directive from the obligations laid down for release and placing on the market of 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 I A, to which Article 2 refers? Consequently, must Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] be interpreted as meaning that they exempt from precautionary, impact assessment and traceability measures all organisms and seeds obtained by mutagenesis, or only organisms obtained by conventional random mutagenesis methods by ionising radiation or exposure to mutagenic chemical agents existing before those measures were adopted?

(2) Do varieties obtained by mutagenesis constitute genetically modified varieties within the meaning of Article 4 of Directive [2002/53] 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 […] under Articles 2 and 3 of and Annex I B to [Directive 2001/18], 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 [Directive 2002/53]?

(3) Do Articles 2 and 3 of and Annex I B to Directive [2001/18] 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?

(4) May the validity of Articles 2 and 3 of and Annexes I A and I B to Directive [2001/18] 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

7 For a previous example regarding other principles in the French context, see judgment of 16 December 2008, *Arcelor Atlantique et Lorraine and Others* (C-127/07, EU:C:2008:728).

8 Thus apparently falling under the situation contemplated by the Court in the judgment of 22 June 2010, *Melki and Abdeli* (C-188/10 and C-189/10, EU:C:2010:363, paragraphs 54 to 56).

9 In this regard, the referring court states that 'the precautionary principle guaranteed by the provisions of Article 191(2) TFEU has a scope that ensures the effectiveness of the respect for the constitutional principle the breach of which is alleged by the Applicants'.

into 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?'

38. Written submissions were made by the Applicants, the Greek, French, Netherlands, Austrian, Swedish and United Kingdom Governments, the European Parliament, the Council, and the European Commission. With the exception of the Netherlands and Austrian Governments, these parties presented oral argument at the hearing that took place on 3 October 2017.

IV. Assessment

39. This Opinion is structured as follows. I will start by examining the first question concerning the interpretation of the scope of application of the GMO Directive and of the mutagenesis exemption contained therein (A). Next, I will turn to the third question on the degree of harmonisation reached by the GMO Directive with regard to mutagenesis and the correlating issue of Member States' regulatory competence (B). Then I will address the fourth question, concerning the compatibility of the mutagenesis exemption with the precautionary principle (C). I will conclude with the second question relating to the relationship between the scope of application of the GMO Directive and that of Directive 2002/53 as far as the mutagenesis exemption is concerned (D).

A. First question

40. The first question enquires in essence about the interpretation of the notion of 'mutagenesis' contained in Annex I B of the GMO Directive in general, and then specifically to the passing of time and the emergence of new technologies, particularly in the light of safety considerations and/or the precautionary principle.

41. Before addressing that question (2), I offer some introductory remarks (1) on the terminology used (a) and the general understanding of the precautionary principle in EU law (b).

1. Preliminary clarifications

(a) Basic notions: mutagenesis and transgenesis

42. There are a number of methods that can be used in order to modify the genetic heritage of a living organism. There is also no shortage of potential definitions of the generic notions used in this context. The GMO Directive itself does not provide any general definition of these notions. It is furthermore not the role of this Court to start drawing up such (thoroughly scientific and factual) definitions in the context of a reference for a preliminary ruling. For the purpose of this Opinion, I shall thus simply use the working definitions helpfully provided by the referring court.

43. *Transgenesis* is a genetic engineering technique that consists in inserting one or more genes from other species into the genome of another species. The GMO Directive does not explicitly refer to the notion of transgenesis. However, substantively that directive covers various techniques which could normally be described as such. [10]

10 Part 1 of Annex I A enumerates, in a non-exhaustive manner, three different techniques that all somehow involve the artificial insertion, by means of methods that do not occur naturally, of heritable material into a host organism.

44. *Mutagenesis* does not entail the insertion of foreign DNA into a living organism. It nonetheless involves an alteration of the genome of a living species.

45. Mutagenesis techniques have changed over time. According to the referring court, prior to the adoption of the GMO Directive, there were only conventional or random methods of mutagenesis that were applied *in vivo* to entire plants. These techniques were used for decades without apparently creating any identifiable risks for the environment or health.

46. Gradually, new techniques have appeared. As further explained by the referring court, not only have random mutagenesis techniques been applied *in vitro* to plant cells, but targeted mutagenesis methods applying new genetic engineering techniques have been devised, such as oligonucleotide-directed mutagenesis (ODM) [11] or directed nuclease mutagenesis (SDN1). [12] Whereas conventional mutagenesis involves random mutations, some of the new techniques cause a precise mutation in a gene.

(b) The precautionary principle in EU law

47. Beauty is in the eye of the beholder. That also appears to be the case for the content, scope and potential use of the precautionary principle. Over the years, a number of propositions about what the precautionary principle is and how it ought to be used have been made, in particular by the legal scholarship and in the political discourse.

48. The judicial approach to and the understanding of the precautionary principle has been, quite understandably, much more circumscribed, perhaps even (pre)cautious. [13] In the case-law of the Court, the precautionary principle is primarily understood as allowing different actors, such as the Member States, the Commission or the undertakings, to adopt *provisional* risk management *measures* without having to wait until the reality and gravity of the alleged risks become fully apparent. [14] In areas harmonised under EU law, those measures are to be taken on the basis of secondary law provisions giving specific expression to that principle, for instance safeguard clauses [15] or other provisions dedicated to the handling of new information with regard to risks to health or the environment presented by a certain product. [16] In the absence of harmonisation, the precautionary principle may also be relied on autonomously, to justify the adoption of restrictive measures. The latter must nonetheless respect the overarching EU law obligations of the Member States, notably those stemming from Articles 34 and 36 TFEU. [17]

11 It would appear that ODM consists in introducing into cells a short DNA sequence which will cause a mutation in the cell identical to the cell carrying the oligonucleotide.

12 SDN1 uses different types of proteins (zinc finger nucleases, TALEN, CRISPR/Cas9) capable of cutting or editing the DNA.

13 For a detailed discussion of the case-law of Union Courts, see, for instance, Da Cruz Vilaça, J.L., 'The Precautionary Principle in EC Law', in *EU Law and Integration: Twenty Years of Judicial Application of EU Law*, Hart Publishing, 2014, pp. 321 to 354.

14 See, in the context of a BSE (Bovine spongiform encephalopathy) outbreak, judgment of 5 May 1998, *National Farmers' Union and Others* (C-157/96, EU:C:1998:191, paragraph 63).

15 See, for instance, Article 23 of the GMO Directive and Article 12 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1). As regards the characterisation of the latter as giving specific expression to the precautionary principle, see notably judgment of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 110).

16 See, for instance, Articles 8 and 20 of the GMO Directive (and, with regard to its predecessor, judgment of 21 March 2000, *Greenpeace France and Others* (C-6/99, EU:C:2000:148, paragraph 44)); or Article 16(3) of Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ 2000 L 169, p. 1). In connection with the latter, see judgment of 9 June 2016, *Pesce and Others* (C-78/16 and C-79/16, EU:C:2016:428).

17 See, for instance, judgments of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraphs 42 to 54); of 28 January 2010, *Commission* v *France* (C-333/08, EU:C:2010:44, paragraphs 85 to 93); and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraphs 45 to 47).

49. However, such provisional risk management measures may be taken only if a number of conditions are fulfilled. It is established case-law that 'a correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the substances or foods concerned, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research'. [18] In other words, these two requirements entail that protective measures 'cannot validly be based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified. On the contrary, such protective measures, notwithstanding their temporary character and even if they are preventive in nature, may be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary'. [19]

50. Furthermore, 'where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures'. [20]

51. If those conditions are satisfied, non-discriminatory, objective and proportionate protective measures may be taken.

52. It is true that in reality, the precise threshold for triggering preventive or temporal measures under the precautionary principle may vary, in particular depending on the exact wording of the specific secondary law instrument in question. [21]

53. The bottom line in all those cases is that there must be at least some discernible risks based on science. [22] In contrast to permanent measures, the threshold for triggering the application of the precautionary principle with regard to provisional measures is lower. But there must still be some clear data on the alleged risk(s), which must be buttressed by a minimum set of scientific data, coming from a minimum number of different reliable national or international independent sources. A mere fear of a risk induced by something new, or a vaguely and generally asserted risk of a risk where it cannot be conclusively stated that the new thing is safe, is an insufficient trigger for the precautionary principle.

54. With these clarifications in mind, I now turn to the first question submitted by the referring court: the scope of the GMO Directive and of the mutagenesis exemption.

18 See, for instance, judgments of 2 December 2004, *Commission* v *Netherlands* (C-41/02, EU:C:2004:762, paragraph 53); of 28 January 2010, *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 92); and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 56).

19 See, for instance, judgments of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraph 77), and of 13 September 2017, *Fidenato and Others* (C-111/16, EU:C:2017:676, paragraph 51).

20 See, for instance, judgments of 2 December 2004, *Commission* v *Netherlands* (C-41/02, EU:C:2004:762, paragraph 54); of 28 January 2010, *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 93); and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 57).

21 For a comparative examination of Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) and Article 34 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1), see, for example, my Opinion in *Fidenato* (C-111/16, EU:C:2017:248).

22 See also my Opinion in *Queisser Pharma* (C-282/15, EU:C:2016:589, points 53 to 54).

2. The scope of the GMO Directive and of the mutagenesis exemption

55. In my view, the first question effectively contains two sub-questions. First, the referring court seeks to ascertain the scope of application of the GMO Directive: what organisms fall under the definition of a GMO within the meaning of Article 2(2)? Second, it enquires as to the scope of the mutagenesis exemption itself, contained in Article 3(1) of, read in conjunction with Annex I B to the GMO Directive: does that exemption encompass all organisms obtained by mutagenesis, including those obtained by new mutagenesis techniques applied after the adoption of the GMO Directive? Or only that subset of organisms obtained by certain techniques, namely those existing before the GMO Directive was adopted?

56. In my view, provided that they meet the substantive conditions of Article 2(2) of the GMO Directive, organisms obtained by mutagenesis are GMOs within the meaning of the GMO Directive (a). However, as long as the process of mutagenesis does not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by one or more of the techniques listed in Annex I B, those organisms are exempt from the obligations laid down by the GMO Directive by virtue of Article 3(1) of the GMO Directive, read in conjunction with its Annex I B (b).

(a) Mutagenesis and GMOs

57. Article 2(2) of the GMO Directive defines a GMO as 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'. That provision further adds that 'within the terms of this definition: (a) genetic modification occurs at least through the use of the techniques listed in Annex I A, Part 1; (b) the techniques listed in Annex I A, Part 2, are not considered to result in genetic modification'.

58. Thus, in addition to the general requirement, two lists refining that basic definition are added: a 'positive' list in Annex I A, Part 1, and a 'negative' list in Annex I A, Part 2.

59. The 'positive list' refers to techniques that, in a way or another, concern insertion of foreign genetic material into the recipient organism. It would thus appear that organisms obtained by *transgenesis* as defined above,[23] are likely to be covered by that list.

60. *Mutagenesis* is less clear cut. Judging from the definition in Article 2(2) alone however, I see no reason why organisms obtained by that method, provided that they meet the substantive criteria of Article 2(2) of the GMO Directive, should not also be seen as falling under that definition. Such a conclusion follows from the text, internal logic, and broader context of the GMO Directive.

61. First, Article 2(2) clearly does not require the insertion of foreign DNA in an organism in order for the latter to be characterised as a GMO. It merely says that the genetic material has been altered in a way that does not occur naturally. Its open-ended character allows organisms obtained by methods other than transgenesis to be included within the definition of a GMO. As regards mutagenesis in particular, it is implied in the wording of Article 3 of and Annex I B to the GMO Directive that mutagenesis can also be characterised in principle as 'a technique of genetic modification'.

62. Second, the fact that mutagenesis is exempt from the obligations laid down in the GMO Directive suggests that the organisms obtained by that method can be GMOs. I therefore agree with the Commission that it would be illogical to exempt certain organisms from the application of the directive if those organisms could not be characterised as GMOs in the first place. Organisms that are excluded do not need to be exempted.

23 See above in point 43 of this Opinion.

63. Third, as an element of broader legislative context, if the EU legislature wanted to exclude organisms obtained by mutagenesis from the definition of GMOs under the GMO Directive, it could have expressly foreseen such an exclusion *at the level of the definition itself*, as it did in other secondary law acts on GMOs. [24]

64. Thus, in my opinion, an organism obtained by mutagenesis can be a GMO under Article 2(2) if it fulfils the substantive criteria laid down in that provision.

65. Without seeking to provide any definitions that are not set out in the GMO Directive itself, but to clearly articulate the logical relationship between the notions contained in the GMO Directive, there are essentially, as helpfully outlined by the United Kingdom Government at the hearing, three variables. These are the concept of mutagenesis; the definition of a GMO under Article 2(2); and the exemption under Article 3(1) and Annex I B. These can generate three logical sets of possible scenarios, dependent on the exact technique used for the creation of the organism in question.

66. First, there can be organisms obtained by mutagenesis that are not GMOs within the meaning of the GMO Directive, because they do not fulfil the criteria of Article 2(2). Second, there can be organisms obtained by mutagenesis that do fulfil the criteria. They would therefore be GMOs within the meaning of the directive, but provided that they fall under the exemption of Article 3(1) and Annex I B, they will be exempted from the obligations laid down in that directive. Third, there can be organisms obtained by mutagenesis, fulfilling the criteria of Article 2(2), but falling short of the exemption under Annex I B. The third type of organism would then be fully caught by the GMO Directive.

67. In sum therefore, the characterisation as a GMO derives only from the (lack of) fulfilment of the criteria laid down in Article 2(2) of the GMO Directive. The fact that that organism might later be exempted by virtue of Article 3(1) of the GMO Directive read in conjunction with its Annex I B has no impact on the legal characterisation as a GMO: such organisms remain GMOs under the directive.

(b) The scope of the mutagenesis exemption

68. Article 3(1) of the GMO Directive states that the directive shall not apply to organisms obtained through the techniques listed in Annex I B. Annex I B lists, in its first point, 'mutagenesis'. As there is no legislative definition of mutagenesis in the directive, the second part of the first question referred by the national court essentially enquires whether 'mutagenesis' ought to mean *all* techniques of mutagenesis or only *some* techniques? If only some, then which ones?

69. Divergent views regarding the scope of the mutagenesis exemption were expressed in the submissions made to this Court.

70. At one end of the spectrum, the Applicants consider that the mutagenesis exemption should be interpreted in the light of the conditions in place in 2001 when the GMO Directive was adopted. Therefore, only those mutagenesis techniques that were used as a matter of routine at the time of the adoption of the GMO Directive fall under the mutagenesis exemption, namely, *in vivo* random mutagenesis, as opposed to any other techniques, whether it is random *in vitro* or, a fortiori, directed mutagenesis.

24 See notably Article 2(5) of Regulation No 1829/2003 and Article 3(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ 2003 L 287, p. 1).

71. At the other end of the spectrum, the Greek and United Kingdom Governments contend that no distinction should be made within mutagenesis. All technological developments subsequent to the adoption of the GMO Directive should fall within the scope of the mutagenesis exemption, as it was clearly foreseeable in 2001 that scientific progress related to mutagenesis would not stop there.

72. The other interested parties who submitted observations to the Court find themselves between these positions, although perhaps closer to those of the Greek and United Kingdom Governments.

73. The Austrian Government suggests that all mutagenesis techniques that were traditionally used when the GMO Directive was adopted are exempt. New techniques should be examined on a case-by-case basis to determine whether they can fall within the mutagenesis exemption.

74. The French and Netherlands Governments endorse a similar approach while focusing in particular on safety. They contend that only organisms obtained by techniques that are equally safe as the traditional techniques should be exempted. The French Government argues in particular that the scope of the mutagenesis exemption should be determined in the light of the precautionary principle.

75. The Swedish Government also underlines the safety dimension, which leads it, however, to conclusions that oppose those of the French and Netherlands Governments. Even if it considers that directed mutagenesis does not lead to GMOs within the meaning of Article 2(2) of the GMO Directive, it takes the view that such a technique is still exempt because it presents even fewer risks than conventional mutagenesis and is similar to naturally occurring, spontaneous mutations. Organisms obtained by introducing foreign DNA (involving the use of recombinant nucleic acid molecules) however fall within the scope of the directive because they do not amount to mutagenesis.

76. The Commission [25] observes that no particular problems connected with conventional mutagenesis have been reported since the 1960s, when it was first used. There is no real difference between *in vitro* and *in vivo* mutagenesis. *In vitro* mutagenesis would even have predated the adoption of the GMO Directive and, to a lesser extent, that of its predecessor. [26]

77. By using the generic term of mutagenesis in Annex I B, Article 3(1) of the GMO Directive may also exempt the new techniques. In 2001, the EU legislature could not ignore technological progress. It must be inferred that it was its intention to include all mutagenesis techniques within the exemption. Thus, the EU legislature deliberately kept the generic name but added the prohibition on the use of recombinant nucleic acid molecules in order to narrow down the range of techniques benefiting from the exemption.

78. According to the Commission, a case-by-case analysis should be carried out to determine whether organisms obtained by mutagenesis can be exempted by looking at the different processes used to modify the genetic material, including the possible use of recombinant nucleic acid molecules or non-exempted GMOs. Organisms obtained by conventional mutagenesis (including *in vitro*) and by new techniques are exempted provided that they fulfil the conditions laid down in Annex I B.

79. Like the Commission, I am of the opinion, that there is only one relevant distinction that should be made in order to clarify the scope of the mutagenesis exemption: the caveat set out in Annex I B, namely whether the mutagenesis technique involves 'the use of recombinant nucleic acid molecules or [GMOs] other than those produced by … mutagenesis [or] cell fusion … of plant cells of organisms which can exchange genetic material through traditional breeding methods' ('the Annex I B caveat') (1). No further distinctions should — or even could — be made judicially (2).

25 The European Parliament and the Council have submitted observations with respect to the issue of validity of the GMO Directive only.
26 Directive 90/220.

(1) The Annex I B caveat

80. The Annex I B caveat was introduced in 2001. Prior to that, its predecessor, Directive 90/220, exempted organisms obtained by mutagenesis on the sole condition that 'they do not involve the use of GMOs as recipient or parental organisms'. [27]

81. As observed by the Commission, the EU legislature intentionally decided not to distinguish between the techniques to determine the scope of the mutagenesis exemption. At the same time, it effectively narrowed down the exemption in order to take account of ongoing technological developments by adding the caveat deriving from the use of recombinant nucleic acid molecules. That caveat was considered to sufficiently take into account the emergence of new mutagenesis techniques.

82. Thus, on the textual level alone, it is already quite clear that it is incorrect to state that under the GMO Directive, there would be a straightforward and unqualified exemption for any and all mutagenesis techniques. On the contrary: the Annex I B caveat provides a significant qualification.

83. A contextual reading of the GMO Directive confirms the importance of this 2001 addition. The use of recombinant nucleic acid molecules is indeed expressly mentioned in Part 1 of Annex I A as a technique of genetic modification referred to in Article 2(2)(a) — the positive list. The use of such molecules may even lead to the rebuttal of the presumption that the techniques enumerated in Part 2 of Annex I A (namely *in vitro* fertilisation, natural processes and polyploidy induction) are not considered to result in genetic modification.

84. Accordingly, it follows that mutagenesis techniques that meet the criteria laid down in Article 2(2) are exempt from the obligations of the GMO Directive *provided* that they do not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by mutagenesis or cell fusion of plant cells of organisms, which can exchange genetic material through traditional breeding methods. If that latter condition contained in Annex I B is not satisfied, all the obligations laid down by the directive will apply.

85. In conclusion, it might be useful to mention one ancillary point. It is common ground that Member States are obliged to correctly transpose all provisions of a directive, including its annexes. [28] Although it is not directly the subject matter of this case, it would appear that Article D. 531-2 of the Environmental Code (contested at national level) is still drafted in the same terms as was the predecessor of Annex I B in the Directive 90/220. That national measure of transposition does not seem to reflect the post-2001 Annex I B caveat. It nonetheless remains solely for the referring court to verify whether this is indeed the case and if so what conclusions may be drawn from such a finding in terms of correct transposition of the GMO Directive into national law.

(2) Further distinctions?

86. Apart from the one deriving from Annex I B, should further distinctions be made among mutagenesis techniques?

27 Annex I B of Directive 90/220.

28 To that effect, see, for instance, judgments of 23 April 2009, *Commission* v *Belgium* (C-287/07, not published, EU:C:2009:245, paragraphs 71 to 80), and of 27 October 2011, *Commission* v *Poland* (C-311/10, not published, EU:C:2011:702, paragraphs 64 and 69).

87. The Applicants, the French and Netherlands Governments and, in a way also the Swedish Government essentially argue that mutagenesis techniques should be distinguished according to their degree of safety. In particular, the Applicants together with the French Government suggest interpreting the scope of the mutagenesis exemption in the light of recital 17 of the GMO Directive and of the precautionary principle. From their point of view, that ought to lead to the interpretative narrowing down of the mutagenesis exemption to only those techniques that were 'tried and tested' and thus safe, in 2001.

88. There are two temporal layers to this argument. For ease of presentation, they ought to be kept separate: first, it is suggested that, in spite of what it put in writing, the EU legislature meant to exempt only safe techniques back in 2001. Second, even if that was not the case at that time, safety considerations that emerged after that date should lead, some 17 years later, to the same de facto result today, that is, limiting, in 2018, the mutagenesis exemption to the techniques that were known and used in 2001.

89. I disagree with both propositions. It appears to me that the legislature in 2001 clearly meant what it said in writing (i). For a number of reasons, constitutional and also practical, it is certainly not the role of this Court to start judicially rewriting definitions and categories contained in a highly technical and complex piece of secondary law (ii).

(i) Intent of the legislature

90. The Applicants and several other interested parties have, to a great extent, relied on recital 17 to reach the conclusion that the EU legislature only intended to exempt safe *mutagenesis* techniques.

91. I cannot agree. Neither the text, nor the historical context, nor the internal logic of the GMO Directive supports that proposition.

92. First, looking at the wording, recital 17 states that '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'. There is no explicit mention of *mutagenesis* in the recital. Certainly, depending on the exact scope of the definition adopted for the notion of 'genetic modification', at least some types of mutagenesis are likely to be included in that broader notion. However, recital 17 clearly does not aim *specifically* at mutagenesis, thus it does not warrant the suggestion that the specific exemption was introduced in the light of recital 17.

93. In addition, neither Article 3 nor Annex I B (which set out the mutagenesis exemption) refers in any way to recital 17, such as mirroring its wording or using its categories. None of those provisions subjects or justifies the exemption on the basis of the 'long safety record' of exempted organisms. Thus, the text of recital 17 finds no clear reflection in the categories and definitions provided by the GMO Directive.

94. Second, and perhaps even more importantly, the legislative history of that recital and the mutagenesis exemption clearly shows that recital 17 simply cannot be used for the interpretation of Article 3(1) and Annex I B. When looking at the legislative history of Directive 90/220, which preceded the GMO Directive, recital 17 was drafted and inserted by the Commission *before* the mutagenesis exemption was even discussed in subsequent stages of the legislative process.[29] In other words, the mutagenesis exemption was inserted only later and independently of recital 17.

29 The content of recital 17 was already to be found, albeit in slightly different terms, in the seventh recital of the Commission's initial proposal that eventually led to Directive 90/220 (COM(88) 160 final). Yet, as far as can be ascertained, the mutagenesis exemption was only inserted into the final version of that directive by the Council, possibly also under the influence of the Economic Social Committee, which for the first time brought up the notion of mutagenesis and the need for an exemption (see the ECOSOC Opinion 89/C 23/15, OJ C 23/45 of 30 January 1989, paragraph 2.2.2).

95. Third, it derives from the general scheme of the GMO Directive that the EU legislature did not seem to intend to divide the category of mutagenesis based on the precise technique used and its supposed degree of safety. At the hearing, the Commission stated that recital 17 was a mere statement, while the Council confirmed that the EU legislature had no intention to regulate mutagenesis techniques, irrespective of their safety.

96. Moreover, within the GMO Directive, the EU legislature already made a number of distinctions amongst various methods in Annexes I A and I B. Thus, it is fair to assume that the distinctions the EU legislature wished to make were indeed expressly stated. Within such a context, it is difficult to maintain that apart from those clear distinctions, the EU legislature also intended to add a new layer of complexity to the entire structure by providing for further implicit distinction between the different mutagenesis techniques based on a legislatively non-stated criterion of safety.

97. Thus, I have no doubt that in 2001, what the legislature drafted is what the legislature intended to draft: that organisms obtained by mutagenesis techniques are exempt from the obligations laid down in the GMO Directive unless they fall under the Annex I B caveat.

(ii) 'Frozen' or dynamic interpretation?

98. Further to their argument as to what the EU legislature meant in 2001, the Applicants essentially claim that in 2018, the mutagenesis exemption should be interpreted in the light of the factual conditions that existed in 2001. Therefore, only those safe techniques that were routinely used at the time of the adoption of the GMO Directive fall under the mutagenesis exemption. The stated reason for such an interpretation is the precautionary principle.

99. I disagree.

100. Generally speaking, interpretation of the law, and in particular of indeterminate notions contained in the law, must be dynamic. It must react to the societal evolution, both technical and social. Moral categories evolve over time: 'degrading treatment' in 1818 likely meant something quite different to what it means in 2018. The same goes for the more technical definitions, such as that of a 'vehicle' or 'means of communication'. The suggestion that the interpretation of such notions ought to be 'frozen' in the factual or societal circumstances that prevailed when those notions were passed into law would represent a singularly *originalist* approach to legal interpretation, not frequently encountered on this side of the Atlantic.

101. More specifically, in the present case, a generic category labelled 'mutagenesis' should logically encompass all those techniques that are, at the given moment relevant for the case in question, understood as forming part of that category, including any new ones.

102. Against this background, the precautionary principle invoked by the Applicants is apparently seen as an internal exception to the overall principle of dynamic interpretation of the law. Presumably, a snapshot of the areas or issues covered by that principle should be taken which would freeze them in time.

103. Leaving aside for a moment the question of whether or not the precautionary principle could, in fact, be triggered in the case at hand on the basis of the documents and materials provided to this Court,[30] it would appear to me that if one wishes to remain in the realm of legal *interpretation*, the precautionary principle is likely to play a different role. As in other cases of legal interpretation, that

30 See generally above, points 48 to 53 of this Opinion and further in points 146 to 148 below.

principle can be used to interpret *uncertain* notions or categories, where there is doubt about their meaning within reasonably acceptable semantic limits of the written text — where there are several (equally plausible) options on the table. It cannot lead, however, to rewriting[31] the provisions of the legal text against their wording, that is, *contra legem*.[32]

104. This, in a nutshell, is the *constitutional* problem with the propositions advanced by the Applicants. What the Applicants are effectively asking for is not an interpretation of the GMO Directive but a judicial redrafting of it, more specifically the redrawing of the scope of the exemption of Article 3(1) and Annex I B, against the wording of the legislation, seeking an insertion through a judicial medium of categories which are clearly not provided for in the legislation itself.

105. This in turn reveals a number of *practical* problems flowing from the Applicant's proposition, which only further underline why any such assessment has to be carried out by the expert legislator, and not by courts. To mention but one in lieu of a conclusion: the criterion proposed by the Applicants for such judicial redrafting of the current rules was to include into the remodelled Annex I B *only techniques which were safe and had already been routinely used in 2001*. However, how exactly would such techniques be defined? Could they in fact be identified? What about techniques which existed, were safe, but used only in selected laboratories (not routinely) in 2001? What if a technique which existed in 2001 was slightly modified in 2005, but the research foreshadowing that modification or extension had already been there since the 1980s? What about a technique which existed and was routinely used in 2001, was believed to be safe back then, but only later was found not to be entirely safe? Incidentally, could such later developments even be taken into account in a world where it is only the knowledge that existed at the time of the adoption of the law that ought to be relevant for its interpretation?

106. It is sometimes said, perhaps not entirely as a compliment, that putting two lawyers in a room means having to deal with three different legal opinions. It might, however, be safe to assume that if faced with criteria drafted in such a way, the same could easily be the case for (bio)scientists, not to mention national regulators that would be asked to apply such criteria.

107. Consequently, I would suggest that the Court answer the first question as follows:

– provided that they meet the substantive criteria of Article 2(2) of Directive 2001/18, organisms obtained by mutagenesis are genetically modified organisms within the meaning of that directive;

– the exemption laid down in Article 3(1) of Directive 2001/18 read in conjunction with its Annex I B covers all organisms obtained by any technique of mutagenesis, irrespective of their use at the date of the adoption of that 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 methods listed in Annex I B.

31 Whether and to what extent, however, the issues of interpretation (and the impossibility of reaching a satisfactory interpretation within the textual limits of the provision in question) can spill over into the question of validity will be addressed below with regard to question four (points 130 to 141 of this Opinion).

32 See, for instance, by analogy to the limits of conform interpretation, judgments of 15 April 2008, *Impact* (C-268/06, EU:C:2008:223, paragraph 100), or of 15 January 2014, *Association de médiation sociale* (C-176/12, EU:C:2014:2, paragraph 39).

B. Third question

108. By its third question, the referring court asks the Court to determine whether the GMO Directive is a complete or partial harmonisation measure with regard to organisms obtained by mutagenesis. The specific aim of that question is to ascertain whether Member States may either adopt (national) rules regarding mutagenesis despite the fact that it is exempted from the obligations laid down by the directive, and/or whether in the process of transposition of the GMO Directive, they could also apply the obligations set out in the directive to mutagenesis.

109. The Commission argued in their written submissions that that question is inadmissible. I disagree, and shall first explain why I find that question to be admissible, and then why Member States are in principle free to regulate organisms obtained through mutagenesis.

110. As regards admissibility, the Commission deems the third question hypothetical. The application lodged before the referring court challenges the legality of Article D. 531-2 of the Environmental Code to the extent that that provision exempts organisms obtained by mutagenesis from the obligations laid down by the national measures transposing the GMO Directive. According to the Commission, the Applicants do not aim to have that national provision declared invalid in so far as the latter would go beyond the requirements of the directive by imposing obligations that are not foreseen therein. In this context, the issue of whether Member States have leeway to regulate mutagenesis would be hypothetical.

111. I do not agree. In line with the established case-law of this Court, references made by the national courts enjoy a presumption of relevance.[33] In the present case, it is certainly not apparent to me that that presumption has been rebutted: quite to the contrary.

112. In the main proceedings, the Applicants have requested the referring court to impose a moratorium on herbicide tolerant varieties obtained by mutagenesis. Although it is not for this Court to determine whether the referring court has the necessary powers to adopt such measures, the third question asked by the referring court seems relevant for the purposes of determining whether Member States could actually go further than the GMO Directive and decide to subject organisms obtained by mutagenesis either to the obligations laid down by the directive or to purely national rules.

113. The existence and extent of the leeway that Member States enjoy is dependent on the degree of harmonisation of a certain field, as ensured by a directive. In the case of full harmonisation of an area of law, Member States are precluded from regulating that area as EU action has fully pre-empted it. Member States no longer have substantive autonomy and discretion to adopt general measures.[34] Their margin of discretion does not go beyond what is left to them by the harmonising measure. On the other hand, in the case of partial harmonisation, Member States are still free to adopt general measures as long as they generally comply with EU primary law commitments.[35]

114. From this point of view, and of course while in no way pre-empting the internal division of competence within the Member State, I can understand why a national court would ask such a question. The third question is therefore admissible.

33 See, for instance, judgments of 6 October 2015, *Târşia* (C-69/14, EU:C:2015:662, paragraph 12), and of 27 June 2017, *Congregación de Escuelas Pías Provincia Betania* (C-74/16, EU:C:2017:496, paragraph 25).

34 To that effect, see, for instance, judgments of 25 March 1999, *Commission* v *Italy* (C-112/97, EU:C:1999:168, paragraphs 55 to 58); and of 8 May 2003, *ATRAL* (C-14/02, EU:C:2003:265, paragraphs 44 to 45).

35 See, for instance, judgment of 16 December 2008, *Gysbrechts and Santurel Inter* (C-205/07, EU:C:2008:730, paragraph 34 et seq.). More implicitly, see also judgment of 30 May 2013, *F.* (C-168/13 PPU, EU:C:2013:358).

115. As far as the merits of that question are concerned, it boils down to the issue of what legislative choice the EU legislature made with regard to mutagenesis. There are two ways in which the mutagenesis exemption of Article 3(1) of the GMO Directive and its Annex I B could be construed.

116. On the one hand, it could be suggested that with regard to mutagenesis, the EU legislature made a legislative choice. It carried out an evaluation, and on the basis of that evaluation came to the conclusion that all the mutagenesis techniques are to be excluded because they are safe. If this were the case, the EU legislature would not only have exempted mutagenesis from the obligations laid down in the directive, but would have also logically precluded Member States from regulating organisms obtained through that method at national level. In such a case, the EU legislator would be like an architect that decided to have a room called 'mutagenesis' in his house, but who also decided to keep that room empty.

117. On the other hand, it could also be argued that by inserting the mutagenesis exemption, the EU legislature did not make any statement about its safety. The exclusion simply meant that the EU legislature did not wish to regulate that matter at EU level. That would then mean that that space remains unoccupied and, provided that the Member States respect their overall EU law obligations, they can legislate with regard to organisms obtained by mutagenesis. In such a case, the architect effectively decided to leave that space called 'mutagenesis' outside his house.

118. I am of the view that the second understanding of the mutagenesis exemption is correct.

119. First, as already explained, there is no clear textual or historical support in the wording of the GMO Directive for the proposition that the mutagenesis exemption was introduced *specifically* because the EU legislature came to a firm conclusion that all the mutagenesis techniques were safe.[36] Thus, there is no trace of any explicit legislative assessment made in that regard.

120. Second, on a more abstract plane, as pertinently noted by the European Parliament at the hearing, one could hardly assume that a reasonable legislator could ever wish to state, *en bloc* and for the future, that something is safe to such a degree that it does not need regulating at all, whether at EU level or at Member State level.

121. Third, at the hearing, the Council confirmed that as far as it could be ascertained in view of the sporadic written documentation available from that period, the Council (the body in the legislative process that actually inserted the mutagenesis exemption into the text[37]) had no intention of stating that all mutagenesis techniques were safe.

122. Finally, on a rather ancillary note, but fully in line with the outlined dynamic approach to legal interpretation,[38] it might also be added that precluding Member States from legislating on the basis of an irrefutable presumption of the safety of mutagenesis would sit somewhat uncomfortably with the latest developments regarding GMO legislation in the European Union. Today, Directive (EU) 2015/412[39] effectively allows Member States to ban the release and placing on the market of products covered by the GMO Directive. That seems to indicate certain renationalisation of competences in the field of GMOs. In such a context, excluding mutagenesis from a trend applicable to GMOs in general would be rather surprising.

36 See above, points 90 to 97. For the sake of clarity, I wish to underline that this statement in no way implies that the EU legislature did not take safety or science into account when drawing up the GMO Directive as such. The claim made here is much more precise and narrow, namely that there is no specific and explicit link in that regard between recital 17 and Article 3(1) and Annex I B.

37 See above, footnote 29.

38 See above, point 100.

39 Directive of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18 as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ 2015 L 68, p. 1).

123. Against this background, I am of the opinion that Member States have the competence to regulate organisms obtained through mutagenesis provided that they comply with their overall EU law obligations, whether of secondary law origins or the rules of primary law, such as Articles 34 and 36 TFEU.

124. I therefore suggest that the third question be answered as follows: Directive 2001/18 does not preclude Member States from adopting measures governing mutagenesis provided that, in so doing, they respect the overarching obligations arising from EU law.

C. Fourth question

125. The fourth question concerns the validity of the mutagenesis exemption of the GMO Directive. It is based on the premiss that, if the precautionary principle cannot be effectively employed in order to interpret the mutagenesis exemption in a way that is arguably compatible with the precautionary principle, the same principle could then be relied on to challenge the validity of the directive regarding the scope of the exemption.

126. In its order for reference, the national court distinguishes between mutagenesis techniques depending on whether they predate or postdate the adoption of the GMO Directive. For the predating techniques, the referring court considers that the plea alleging that the GMO Directive disregarded the precautionary principle *on the date of its adoption* could be rejected because conventional random mutagenesis methods have been used for several decades without creating identified risks for the environment or health. For the postdating techniques, the referring court notes that, since the adoption of the directive, new herbicide resistant varieties have been obtained as a result of the *in vitro* random mutagenesis techniques and of directed mutagenesis techniques. The development of new techniques permits the production of modifications of the genetic heritage to increase at a rate out of all proportion to the modifications likely to occur naturally or randomly.

127. According to the referring court, there is currently scientific uncertainty concerning the impact of the new techniques and the potential risks that may result for the environment and human and animal health. There was no risk assessment prior to the marketing of the non-transgenic varieties, nor post-market surveillance and traceability. The only assessments as regards the herbicide tolerant varieties have been performed in the context of the marketing authorisation procedure.

128. The referring court also stated that, given the absence of assessment and surveillance, there can be risks arising from the unintended effects on the genome of the genetic modification technique used or from the characteristics of the plant likely to be obtained. Those risks are related to the impact on the environment and human and animal health of the cultivation of herbicide resistant genetically modified varieties. They are in part similar to those that might result from seeds produced by transgenesis. In so far as direct modification of the genome makes it possible to obtain the same effects as the introduction of a foreign gene, risk of harm might result from the properties of the plant thus obtained.

129. Thus, in view of the appearance of new plant varieties obtained by new mutagenesis techniques, and the fact that it is impossible to determine with certainty the existence and the extent of the ensuing risks, the validity of the GMO Directive could be called into question on the basis of the precautionary principle — in so far as the likelihood of actual harm continues to exist if the risks mentioned materialise.

130. I emphasise at the outset that although one may harbour some doubts as to some of the assertions made by the referring court, it is not the role of the Court to engage in factual debate. However, I wish to outline one key element that seems to permeate the order for reference (as well as, for that matter, the Applicants' submissions). It is suggested that given the absence of assessment

and surveillance of the organisms obtained by mutagenesis, there is a danger of a risk that ought to trigger the precautionary principle. In other words, it is the absence of surveillance, together with the absence of conclusive scientific data proving that organisms obtained by mutagenesis are safe, that is said to amount to a breach of the precautionary principle, potentially justifying the annulment of Articles 2 and 3 of the GMO Directive and its Annexes I A and I B.

1. Yardstick for validity review: 'Frozen No 2'?

131. Before turning to the actual assessment of validity in the present case, the temporal element pertaining to that assessment ought to be clarified. The Court is being asked to assess the validity of Articles 2 and 3 of the GMO Directive, together with its Annexes I A and I B in the *current* conditions, that is, in the light of the latest developments regarding mutagenesis.

132. It is established case-law however that the assessment of validity of a secondary law act is carried out, in principle, in the light of the facts and circumstances that prevailed at the time when that act was adopted. An assessment in the light of the facts and circumstances that prevailed at a later point in time is exceptional. [40]

133. I think that this statement, relied on by the Commission and the Council in the present proceedings, is in need of refinements relating to the *type* of measure challenged and the *grounds* of the challenge made.

134. Considering the *type* of EU measure challenged, a difference in approach is likely to be present with regard to the assessment of individual measures (administrative decisions) and legislative measures. The former are by nature rather *retrospective*: they fix the rights and obligations of a given set of persons with regard to a certain point in time. Fixing rights and obligations in this way will certainly also be relevant in the future. But decisive for that decision were indeed the facts and the law at the time of its adoption. By contrast, truly legislative measures are by their nature rather *prospective*: they aim to regulate an indefinite number of situations arising in the future. For legislative measures, subsequent evolution in social and factual reality is more important. [41]

135. That connects to the *grounds* of challenge, which is particularly relevant with regard to legislative measures. As is clearly evident in the present case, those grounds might relate to: (i) facts or reasons that the EU legislature ought to have taken into account at the time of the adoption of the act; and/or (ii) those that arose after that moment in time.

136. The present challenge is primarily of the latter sort. In this type of challenge, it is not of course suggested that the EU legislature should have been clairvoyant and have predicted the future back in 2001. With regard to the legislative choices made in 2001, the facts and the law of 2001 naturally remain as the review yardstick.

40 'As regards the possibility of invoking new factors which have arisen after the adoption of a Community measure in order to challenge the legality of that measure, it should be recalled that, in any event, the legality of a measure must be assessed on the basis of the factual and legal situation which existed at the time when it was adopted' — see judgments of 7 February 1979, *France* v *Commission* (15/76 and 16/76, EU:C:1979:29, paragraph 7), and of 22 October 2002, *National Farmers' Union* (C-241/01, EU:C:2002:604, paragraph 37). However, 'the validity of a measure might, in certain cases, be assessed by reference to new factors which arose after its adoption' — see judgments of 17 July 1997, *SAM Schiffahrt and Stapf* (C-248/95 and C-249/95, EU:C:1997:377, paragraph 47), and of 1 October 2009, *Gaz de France — Berliner Investissement* (C-247/08, EU:C:2009:600, paragraph 50).

41 In its judgment of 22 October 2002, *National Farmers' Union* (C-241/01, EU:C:2002:604, paragraph 38), the Court only accepted the possibility to file an action for failure to act in a situation concerning the failure of the Commission to adopt a fresh administrative decision, in the context of the emergency measures taken during the BSE crisis. However, the lack of (potentially necessary) update of general *legislation* is quite a different situation.

137. The ground of challenge is of a slightly different quality: it is effectively suggested that the EU legislature failed to react *after* the adoption of the measure to *new* important technical and scientific evolution through amendments or other adjustments. However, if in view of such a claim, the standard formula that the assessment of validity of a 'secondary law act is carried out, in principle,in the light of the facts and circumstances that prevailed at the time when that act was adopted' is reaffirmed, any later evolution would become irrelevant for the question of validity of the EU law act.

138. I do not think that such an approach would be correct. Logically, dynamism in law must cut both ways: if technical or social evolution is allowed to fuel the interpretation of indeterminate notions and categories,[42] then the same factors must also be relevant in the context of subsequent judicial review of validity.

139. In my view, there is a constitutional duty for legislation to be relevant, in the sense of being technically and socially responsive, and, provided that it is necessary in view of later evolution, to be updated. As already lucidly put by Advocate General Mischo[43] and also echoed in a different context elsewhere:[44] the legislature is obliged to keep its regulation reasonably up to date. This does not necessarily mean, in a legal order of attributed competence, that there is a duty to legislate, a duty to cover new ground. But there is certainly a duty to nurture the ground already covered.[45]

140. Thus, the exact content of such a challenge to validity is not 'failure to take something into account at the moment of adopting the original instrument', but effectively the 'failure to keep that instrument up to date after that'. Failing to meet such a duty could result, in *extreme* cases of technical or social lack of responsiveness, in a potential declaration of invalidity of the specific legislative provisions because of inactivity, namely, because of the failure to amend. I wish to underline the very *exceptional* nature of such a step, which could only be contemplated in cases of clear and paramount dissonance between changed reality and effectively obsolete legislation.

141. The legislative duty to update is, in my view, general. It is not however of equal *strength* in all potential areas of regulation. The specific role and value of the precautionary principle is that in those areas and issues covered by that principle, that duty becomes crucial. In the sensitive areas covered by that principle, extra caution and vigilance is called for, which translates into the need for regular updates and review by the legislature.

142. Therefore, in response to the views expressed by the Council and the Commission, I do not agree with the proposition that the validity of an EU law measure, certainly with regard to prospectively applicable legislation of a general nature, is to be assessed *exclusively* with regard to the facts and knowledge as they stood at the time of the adoption of that legislation. If the grounds for a challenge to validity is the failure to take into account facts or circumstance already known at the time of the adoption of that legislation, a snapshot of that assessment naturally 'freezes' in that way. There is,

42 See above, point 100.

43 Opinion of Advocate General Mischo in *National Farmers' Union* (C-241/01, EU:C:2002:415, point 51) stating that 'in the legal field, nothing is unchangeable and that, in particular, what is justified today will perhaps no longer be so tomorrow, with the result that the duty of every legislature is, first, to check, if not constantly at least periodically, that the rules which it has imposed still meet the needs of society and, second, to amend or even repeal the rules which have ceased to have any justification and are thus no longer appropriate in the new context in which they must produce their effects'.

44 In my Opinion in *Lidl* (C-134/15, EU:C:2016:169, point 90), I suggested that 'the broad discretion enjoyed by the Union institutions in certain areas cannot be understood, in my view, as being a temporally unlimited "blank cheque", whereby past regulatory choices concerning market organisation ought to be perceived as permanent and sufficient justification for their ongoing application to considerably changed market and social contexts. Put metaphorically, a legislator, much like a forester, must regularly take care of the state of the legislative forest. He must not only keep planting new trees, but also, at regular intervals, thin the forest and cut out the deadwood. Failing to do so, he cannot be surprised that somebody else might be obliged to step in'.

45 See, to that effect, also judgment of 12 January 2006, *Agrarproduktion Staebelow* (C-504/04, EU:C:2006:30, paragraph 40).

however, another ground for a potential challenge of validity, which I outlined in this section. The focus of it by definition moves to present conditions: judicial review of the respect for the duty to keep legislation reasonably up to date, with a particular focus on the precautionary principle, which inevitably means that such a review takes place *ex post*.

2. The present case

143. In the present case, I see no grounds deriving from the general duty to update legislation, *in casu* enhanced by the precautionary principle, which could affect the validity of the mutagenesis exemption laid down in both Article 3(1) of the GMO Directive and its Annex I B.

144. First, the EU legislature certainly cannot be reproached for not having exercised its discretion in the GMO area, whether in general or specifically with regard to the mutagenesis exemption. The GMO Directive and the regulation in this area have indeed been regularly discussed and updated. The GMO Directive of 2001 is itself not only the result of an amendment to the preceding Directive 90/220 — it was amended again in 2008.[46] By 2015, the system had again been modified by allowing Member States to ban the cultivation of GMOs on their territory on several different grounds.[47] In addition, the GMO Directive foresees its own adaptation by requiring the adjustment of a number of annexes to Article 27 as a result of technical progress, albeit not Annexes I A or I B.

145. The mutagenesis exemption has also been changed regularly, such as in 2001 when the Annex I B caveat was narrowed down, adding the condition that mutagenesis shall be exempted only if it does not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by one or more of the techniques listed in Annex I B.[48] Thus, it certainly cannot be argued that the EU legislature failed to update the relevant legislation.

146. Second, as far as the triggering of the precautionary principle is concerned, on the elements presented to this Court, there appears to be rather limited knowledge of the concrete risks for health or the environment in the case at hand.

147. It might be recalled[49] that the Court has already clearly stated that protective measures 'cannot validly be based on a purely hypothetical approach to the risk, founded *on mere assumptions which have not yet been scientifically verified*. On the contrary, such protective measures, notwithstanding their temporary character and even if they are preventive in nature, may be adopted only if they are based on *a risk assessment which is as complete as possible* in the particular circumstances of an individual case, which indicate that those measures are necessary'.[50]

148. It follows from the Court's case-law that under the precautionary principle, 'risk uncertainty' does not mean mere general doubts. Concrete risks for human health or the environment must be identified, supported by a minimum amount of serious and independent scientific research. A fear of a risk, or risk of a risk, is not enough.

46 Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission (OJ 2008 L 81, p. 45).

47 Directive 2015/412.

48 See above, points 81 to 82.

49 As outlined above at points 48 to 53.

50 See, for instance, judgments of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraph 77), and of 13 September 2017, *Fidenato and Others* (C-111/16, EU:C:2017:676, paragraph 51). Emphasis added.

149. In this respect, the Court's role is inherently limited. It is certainly not for it to compare and consider scientific arguments. That is the task of the EU legislature or the executive. Whilst acknowledging and respecting the different sensitivities and concerns raised by the broader issue of GMOs, the documents that have been presented to this Court are, in my view, far from demonstrating any clear dissonance between the applicable legislation and scientific knowledge that could, in the extreme scenarios outlined above, cause this Court to intervene.[51]

150. Third, as follows from the answer to the third question,[52] the obligations flowing from the GMO Directive do not apply to (some types of) mutagenesis. The mutagenesis exemption nonetheless does not preclude Member States from adopting measures regulating that sub-field. A fortiori, provisional protective measures may be adopted by the Member States on the basis of the precautionary principle or of rules to that effect under national law.

151. This third element is quite important: a different degree of responsibility in the duty to provide for relevant legislative updates will naturally exist in areas in which the European Union exercises its competence as opposed to those where Member States themselves are also entitled to legislate. It is in the former scenario that the duty will clearly exist: if one claims exclusivity for a certain activity, one must then actually exercise that activity, provided that it is needed. 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.

152. For these reasons, I would suggest to the Court to give as an answer that consideration of the fourth question referred has not disclosed any factor of such a kind as to affect the validity of Articles 2 and 3 of the GMO Directive and its Annexes I A and I B.

D. Second question

153. By its second question, the referring court seeks, in essence, to know whether the exemption laid down in Article 3(1) of the GMO Directive and its Annex I B also applies in the context of Directive 2002/53. The reason for the question is the fact that in its Article 4(4), Directive 2002/53 makes a cross-reference to definitions of GMOs contained only in Article 2(1) and (2) of Directive 90/220 (the predecessor of the current GMO Directive), without making reference to the mutagenesis exemption in Article 3(1). Furthermore, Directive 2002/53 does not contain any exemption regarding mutagenesis itself.

154. I am of the opinion that Directive 2002/53 must be interpreted in the light of the mutagenesis exemption contained in the GMO Directive so as to exclude an indirect application of the GMO Directive to varieties of agricultural plant species obtained by mutagenesis. I shall first present the results that would follow from a purely textual reading of Directive 2002/53 before explaining why Directive 2002/53 must be interpreted consistently with the GMO Directive.

155. Directive 2002/53 lays down *general* obligations applying to varieties of agricultural plant species: they must notably go through an official examination before being accepted for inclusion in the common catalogue of agricultural plant species. At the same time, as results from Article 4(4) of Directive 2002/53, that directive contains *specific* obligations for those varieties of agricultural plant species that are genetically modified within the meaning of Article 2(1) and (2) of the previous Directive 90/220. In particular, Article 7(4)(a) of Directive 2002/53 requires that the environmental risk assessment be *equivalent* to that laid down in Directive 90/220.

51 See also above, points 139 to 142.

52 See above, points 108 to 124.

156. There is, however, no mention in Directive 2002/53 of any exemption that would apply to organisms obtained by mutagenesis. The Applicants therefore claim that varieties obtained by mutagenesis are genetically modified varieties under Directive 2002/53 and that they should be subject, under Article 7(4)(a), to 'an environmental risk assessment equivalent' to that provided for in the GMO Directive.

157. Prima facie, the conclusion drawn by the Applicants on the basis of the text is correct. It was established above[53] that organisms obtained by mutagenesis may constitute GMOs within the meaning of Article 2(2) of the GMO Directive, provided that they meet the substantive criteria announced in that provision. As such, those organisms should therefore also go through the more stringent risk assessment required by Article 7(4) of Directive 2002/53.

158. However, such purely textual reading of Directive 2002/53 is hardly acceptable. It would lead to a systematically odd outcome whereby certain obligations of the GMO Directive (a similar kind of environmental risk assessment) would apply indirectly to organisms that are exempted from any obligation deriving from that latter directive.

159. As a consequence, it is my view that Directive 2002/53 must be interpreted in the light of the GMO Directive so that, despite them being genetically modified varieties, organisms obtained by mutagenesis are exempted from the *specific* obligations laid down in Directive 2002/53.

160. Two systemic arguments plead in favour of such an interpretation of Directive 2002/53 consistent with the GMO Directive.

161. First, there should be *internal consistency* within Directive 2002/53. Thus, Article 4(4) must be read in conjunction with Article 7(4)(a) of the same directive. As notably submitted by the French Government, it would be inconsistent to impose the same kind of obligations, with regard to the environmental risk assessment, on genetically modified varieties under Directive 2002/53 whereas they are explicitly exempted therefrom under the GMO Directive. Therefore, the mutagenesis exemption should also apply in the context of Directive 2002/53.

162. Second, there should also be *external consistency* between Directive 2002/53 and secondary law instruments regulating GMOs. Unlike the GMO Directive and other secondary law instruments which *do* expressly exclude mutagenesis from their scope,[54] Directive 2002/53 does not primarily concern GMOs. It regulates varieties of agricultural plant species generally. It certainly does not aim at governing GMOs in the first place, but merely touches upon them incidentally, in order to emphasise their specificity and the fact that they are regulated by specific rules that shall prevail over general ones.

163. It follows that Directive 2002/53 cannot be seen as *lex specialis* with regard to the GMO Directive. It is rather the other way around. Directive 2002/53 is the *lex generalis* applying to a whole set of varieties of agricultural plant species, *including* genetically modified varieties. 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 incidentally touches upon GMOs.

53 See above, points 57 to 67.

54 See Article 2(5) of Regulation No 1829/2003 and Article 3(2) of Regulation No 1946/2003.

164. It is for that same reason that one should not draw too radical a conclusion from the fact that, unlike the abovementioned secondary law instruments regulating GMOs, Directive 2002/53 does not *expressly* exclude organisms obtained by mutagenesis from the definition of genetically modified varieties under its Article 4(4). Again, that directive does not primarily govern GMOs. It primarily contains general obligations of examination that also apply to organisms obtained by mutagenesis, not as genetically modified varieties, but as one subset of varieties of agricultural plant species.

165. In the light of the foregoing, I am of the view that it is necessary to interpret Directive 2002/53 taking into account the scope of the GMO Directive and to conclude that the exemption laid down in the GMO Directive also applies to Directive 2002/53. Thus, organisms created by mutagenesis are subject to the general obligations laid down in Directive 2002/53 that apply to all kind of varieties of agricultural plant species to be put in the common catalogue. They are not, however, subject to the specific obligations laid down for genetically modified varieties.

166. One concluding remark is perhaps called for, in particular in the view of the assertions repetitively made in these proceedings that organisms obtained by mutagenesis fall short of any control and supervision. It might be recalled that, as noted by the Commission, organisms obtained by mutagenesis, even those not caught by the Annex I B caveat and thus not regulated by the GMO Directive, may be subject, where applicable, to the obligations derived from other EU secondary law measures, such as the EU legislation on seeds [55] or legislation on pesticides. [56] Thus, it is clear that obligations deriving from several other EU secondary law instruments may also apply to organisms obtained by mutagenesis, in addition to those resulting from Directive 2002/53.

167. Accordingly, I suggest that the Court answer the second question referred as follows: Directive 2002/53 is to be interpreted as exempting varieties obtained by mutagenesis from the specific obligations laid down therein for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species.

V. Conclusion

168. In the light of the foregoing considerations, I recommend that the Court answer the questions referred to it by the Conseil d'État (Council of State, France) as follows:

(1) Provided that they meet the substantive criteria of Article 2(2) of 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, organisms obtained by mutagenesis are genetically modified organisms within the meaning of that directive;

The exemption laid down in Article 3(1) of Directive 2001/18, read in conjunction with its Annex I B covers all organisms obtained by any technique of mutagenesis, irrespective of their use at the date of the adoption of that 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 methods listed in Annex I B.

55 Council Directive 98/95/EC of 14 December 1998 amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species (OJ 1999 L 25, p. 1).

56 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ 2005 L 70, p. 1); Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).

(2) Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species is to be interpreted as exempting varieties obtained by mutagenesis from the specific obligations laid down therein for the inclusion of genetically modified varieties in the common catalogue of agricultural plant species.

(3) Directive 2001/18 does not preclude Member States from adopting measures governing mutagenesis provided that, in so doing, they respect the overarching obligations arising from EU law.

(4) Consideration of the fourth question referred has not disclosed any factor of such a kind as to affect the validity of Articles 2 and 3 of Directive 2001/18 and its Annexes I A and I B.