ECLI:EU:C:2023:75

Provisional text

JUDGMENT OF THE COURT (Grand Chamber)

7 February 2023 (*)

(Reference for a preliminary ruling – Environment – Deliberate release of genetically modified organisms – Directive 2001/18/EC – Article 3(1) – Point 1 of Annex I B – Scope – Exemptions – Techniques/methods of genetic modification which have conventionally been used and have a long safety record – In vitro random mutagenesis)

In Case C-688/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (Council of State, France), made by decision of 8 November 2021, received at the Court on 17 November 2021, in the proceedings

Confédération paysanne,

Réseau Semences Paysannes,

Les Amis de la Terre France,

Collective Vigilance GMO et Pesticides 16,

Vigilance OG2M,

CSFV 49,

OGM : dangers,

Vigilance OGM 33,

Fédération Nature et Progrès

v

Premier ministre,

Ministre de l'Agriculture et de l'Alimentation,

intervening party:

Fédération française des producteurs d'oléagineux et de protéagineux,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, L. Bay Larsen (Rapporteur), Vice-President, A. Arabadjiev, A. Prechal, E. Regan and L.S. Rossi, Presidents of Chambers, M. Ilešič, S. Rodin, N. Piçarra, I. Jarukaitis, A. Kumin, I. Ziemele, M. Gavalec, Z. Csehi and O. Spineanu-Matei, Judges,

Advocate General: M. Szpunar,

Registrar: R. Stefanova-Kamisheva, Administrator,

having regard to the written procedure and further to the hearing on 20 June 2022,

after considering the observations submitted on behalf of:

– 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 and Fédération Nature et Progrès, by G. Tumerelle, avocat,

– Fédération française des producteurs d'oléagineux et de protéagineux, by M.-A. de Chillaz and B. Le Bret, avocats,

– the French Government, by G. Bain and J.-L. Carré, acting as Agents,

– the European Commission, by F. Castilla Contreras, B. Eggers, I. Galindo Martín and C. Valero, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 27 October 2022,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3(1) of and point 1 of Annex I B to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1).

2 The reference has been made in proceedings between, on the one hand, Confédération paysanne, Réseau Semences Paysannes, Les Amis de la Terre France, Collectif Vigilance OGM et Pesticides 16, Vigilance OG2M, CFSV 49, OGM : dangers, Vigilance OGM 33 and Fédération Nature et Progrès, and, on the other hand, the Premier minister (French Prime Minister) and the

Ministre de l'Agriculture et de l'Alimentation (French Minister for Agriculture and Food) concerning the implementation of a judicial order to adopt measures aimed, in particular, at establishing the list of techniques/methods of mutagenesis, which have conventionally been used in a number of applications and have a long safety record, to be excluded from the scope of the French legislation designed to transpose Directive 2001/18.

Legal context

European Union law

3 Recital 17 of Directive 2001/18 is worded as follows:

'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.'

4 Under Article 1 of that directive:

'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 [European Union],

– placing on the market genetically modified organisms as or in products within the [European Union].'

5 Article 2 of Directive 2001/18 provides:

'For the purpose of this Directive:

…

(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;

…'

6 Pursuant to Article 3(1) of the directive:

‘This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.’

7 Under the heading ‘Techniques referred to in Article 2(2)’, Annex I A to Directive 2001/18 provides:

‘PART 1

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 …;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism …;

(3) cell fusion (including protoplast fusion) or hybridisation techniques …

PART 2

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.’

8 Under the heading ‘Techniques referred to in Article 3’, Annex I B to Directive 2001/18 provides:

‘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 of organisms which can exchange genetic material through traditional breeding methods.’

French law

9 Article L. 531-2 of the Code de l’environnement (Environmental Code) provides:

‘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.'

10 Article D. 531-2 of that code provides:

'The techniques referred to in Article L. 531-2, which are not considered to give rise to genetic modification, are the following:

…

2 On condition that they do not involve the use of genetically modified organisms as recipient or parental organisms:

(a) mutagenesis,

…'

The dispute in the main proceedings and the questions referred for a preliminary ruling

11 By application of 12 March 2015, the applicants in the main proceedings, which are a French agricultural union and eight associations concerned with the protection of the environment and the dissemination of information on the dangers of GMOs, asked the referring court, the Conseil d'État (Council of State, France), in the first place, to annul the implied decision of the Prime Minister refusing their request that, inter alia, first, he revoke Article D. 531-2 of the Environmental Code, transposing Directive 2001/18, which excludes mutagenesis from the definition of techniques giving rise to genetic modification within the meaning of that code, and, secondly, ban the cultivation and marketing of herbicide-tolerant rape varieties obtained by mutagenesis, and, in the second place, to order the Prime Minister, subject to a periodic penalty, to take all steps to introduce a moratorium on herbicide-tolerant plant varieties obtained by mutagenesis.

12 By decision of 3 October 2016, the Conseil d'État (Council of State) made a request to the Court for a preliminary ruling, which gave rise to the judgment of 25 July 2018, *Confédération paysanne and Others* (C-528/16, EU:C:2018:583).

13 Following that judgment, the referring court, by decision of 7 February 2020 ('the decision of 7 February 2020'), annulled the implied decision referred to in paragraph 11 of the present judgment and ordered the Prime Minister, inter alia, to draw up, within six months of notification of that decision, the exhaustive list of techniques/methods of mutagenesis which have traditionally been used in a number of applications and have a long safety record.

14 In the decision of 7 February 2020, the referring court found that it follows from the judgment of 25 July 2018, *Confédération paysanne and Others* (C-528/16, EU:C:2018:583), that organisms obtained by means of techniques/methods which appeared or were mainly developed after the date that Directive 2001/18 was adopted must be included in the scope of that directive. In that regard, that court held that both techniques/methods known as 'directed' or 'genome editing' and the techniques of '*in vitro* random mutagenesis' appeared after or were principally developed after that date and that, therefore, those techniques/methods must be regarded as being subject to the obligations imposed by that directive.

15 With a view to implementing the order issued by the same court, the French Government drew up, inter alia, a draft decree amending the list of techniques for obtaining GMOs which had

been traditionally used without proven harm for public health or the environment within the meaning of Article L. 531-2 of the Environmental Code. That draft decree provided that random mutagenesis, with the exception of *in vitro* random mutagenesis, had to be regarded as coming under such a use.

16 Following notification of that draft decree, pursuant to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ 2015 L 241, p. 1), the European Commission delivered a detailed opinion. In that opinion, it stated, in particular, that it was not justified, having regard to EU law and in the light of scientific advances, to make a distinction between *in vivo* random mutagenesis and *in vitro* random mutagenesis.

17 Since the same draft decree had not been adopted by the French authorities within the period prescribed by the decision of 7 February 2020, the applicants in the main proceedings requested the Conseil d'État (Council of State), by application of 12 October 2020, to ensure the implementation of that decision.

18 The referring court notes that it is apparent from an opinion issued by the Haut Conseil des biotechnologies (High Council for Biotechnology) that the mechanisms for the repair of deoxyribonucleic acid (DNA) activated by changes caused by a mutagenic agent are identical, irrespective of whether the cells are cultivated *in vitro* or *in vivo*. However, *in vitro* cultivation involves genetic and epigenetic variations, referred to as 'somaclonal variations', the frequency of which is higher than that of spontaneous mutations.

19 In that context, that court takes the view that, in order to determine which techniques of mutagenesis constitute techniques/methods which have conventionally been used and have a long safety record to be outside the control scheme laid down by Directive 2001/18, there are two opposing approaches. According to the first approach, account should be taken, for that purpose, only of the process by which the genetic material is modified. According to the second approach, account should be taken of all the effects on the organism of the process used, since they may affect human health or the environment, including those which may produce somaclonal variations.

20 In addition, the referring court takes the view that, if that second approach were to be followed, it would be necessary to clarify the factors which are relevant for the purpose of assessing whether a technique/method has a long safety record. In the light of the uses of *in vitro* random mutagenesis prior to the adoption of Directive 2001/18, it is necessary to determine whether it is necessary, in that regard, to have sufficient data relating to open-field cultivation of organisms obtained using that technique/method or whether, on the contrary, that safety may also be established on the basis of research work and publications which do not relate to such cultivation.

21 In those circumstances, the Conseil d'État (Council of State) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 3(1) of Directive [2001/18], read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 of the directive, to be interpreted as meaning that, in order to distinguish from amongst techniques/methods of mutagenesis those techniques/methods which have conventionally been used in a number of applications and have a long safety record, within the meaning of the judgment [of 25 July 2018, *Confédération paysanne and Others* (C-528/16, EU:C:2018:583)], consideration need be given only to the methods by which the [mutagenic] agent modifies the genetic material of the organism, or must account be taken of all the variations in the

organism induced by the process used, including somaclonal variations, which may affect human health and the environment?

(2) Is Article 3(1) of Directive [2001/18], read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 of the directive, to be interpreted as meaning that, in order to determine whether a technique/method of mutagenesis has conventionally been used in a number of applications and has a long safety record, within the meaning of the judgment [of 25 July 2018, *Confédération paysanne and Others* (C-528/16, EU:C:2018:583)], account need be taken only of open-field cultivation of … organisms obtained using that method/technique, or may account also be taken of research work and publications that do not relate to such cultivation and, in relation to that work and those publications, is consideration to be given only to work and publications relating to risks for human health or the environment?'

Procedure before the Court

22 The referring court requested that the Court deal with the present reference for a preliminary ruling under the expedited procedure pursuant to Article 105 of the Rules of Procedure of the Court of Justice.

23 In support of that request, the referring court states that it must, in accordance with the French rules of procedure, rule on the case in the main proceedings as a matter of urgency, that this case involves particular risks to human health and the environment and that it raises a controversy involving the Commission and a significant number of Member States.

24 Article 105(1) of the Rules of Procedure provides that, at the request of the referring court or tribunal or, exceptionally, of his or her own motion, the President of the Court may, where the nature of the case requires that it be dealt with within a short time, after hearing the Judge-Rapporteur and the Advocate General, decide that a reference for a preliminary ruling is to be determined pursuant to an expedited procedure derogating from the provisions of those rules.

25 In the present case, the President of the Court decided, on 10 December 2021, after hearing the Judge-Rapporteur and the Advocate General, that there was no need to grant the request referred to in paragraph 22 above.

26 It is important, in the first place, to point out that the requirement that proceedings pending before the Court be dealt with within a short time cannot arise solely from the fact that the request for a preliminary ruling was made in the context of proceedings which, under the national system, are urgent and that the referring court is required to ensure that the dispute is resolved rapidly (order of the President of the Court of 7 October 2013, *Rabal Cañas*, C-392/13, not published, EU:C:2013:877, paragraph 15 and the case-law cited).

27 In the second place, whether the application of the expedited procedure can be justified where there is a high risk of irremediable consequences for the environment pending the Court's decision (see, to that effect, order of the President of the Court of 13 April 2016, *Pesce and Others*, C-78/16 and C-79/16, not published, EU:C:2016:251, paragraph 10), it is not apparent from the order for reference that such a risk is clear in the case in the main proceedings, which has been pending since 2015 and in which the referring court must rule on a potential revision of a national regulation which has been in force for several years.

28 In the third place, as regards the fact that this case has given rise to a controversy involving the Commission and a significant number of Member States, it should be borne in mind that, while

there is, in principle, no correlation between the degree of difficulty of a case and the urgency with which it should be dealt with, the fact that a case raises, as in the present case, sensitive and complex legal problems is liable to preclude the application of the expedited procedure (see, to that effect, judgment of 29 March 2022, *Getin Noble Bank*, C-132/20, EU:C:2022:235, paragraph 53 and the case-law cited).

Admissibility of the request for a preliminary ruling

29 The Fédération française des producteurs d'oléagineux et de protéagineux maintains that an answer from the Court to the request for a preliminary ruling is not necessary in order to resolve the dispute in the main proceedings and that that request is therefore inadmissible.

30 First, according to the Fédération française des producteurs d'oléagineux et de protéagineux, the referring court already has, on the basis of the judgment of 25 July 2018, *Confédération paysanne and Others* (C-528/16, EU:C:2018:583), and the national file, sufficient information to resolve the dispute in the main proceedings in finding that, as the *in vitro* random mutagenesis has been conventionally used in a number of applications and has a long safety record, that technique/method does not come within the scope of Directive 2001/18.

31 Second, in the view of the Fédération française des producteurs d'oléagineux et de protéagineux, the referring court cannot reasonably harbour doubts as to the merits of that assessment, in so far as it is apparent from the detailed opinion adopted by the Commission, referred to in paragraph 16 of the present judgment, that the decision of 7 February 2020, the implementation of which is at issue in the case in the main proceedings, is contrary to EU law in so far as it distinguishes between the respective regimes of *in vivo* random mutagenesis and *in vitro* random mutagenesis.

32 In that regard, it should be recalled that, according to settled case-law, in the context of the cooperation between the Court and the national courts provided for in Article 267 TFEU, it is solely for the national court before which a dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine, in the light of the particular circumstances of the case, both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted by the national court concern the interpretation of EU law, the Court of Justice is, in principle, bound to give a ruling (judgment of 15 July 2021, *The Department for Communities in Northern Ireland*, C-709/20, EU:C:2021:602, paragraph 54 and the case-law cited).

33 The Court may refuse to rule on a question referred by a national court for a preliminary ruling only where it is quite obvious that the interpretation of EU law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment of 15 July 2021, *The Department for Communities in Northern Ireland*, C-709/20, EU:C:2021:602, paragraph 55 and the case-law cited).

34 In the present case, the questions referred seek to obtain, from the Court, clarifications to enable the Conseil d'Etat (Council of State) to determine whether, having regard to the factors stated by it concerning the characteristics and uses of *in vitro* random mutagenesis and the factors which arise from the Commission's detailed opinion referred to in paragraph 16 of the present judgment, it is necessary to consider that that technique/method comes within the scope of Directive 2001/18. Accordingly, the substance of the argument, put forward by the Federation française des producteurs d'oléagineux et de protéagineux, according to which those factors are sufficient to rule

that that is not the case depends on the response given to those questions and that argument cannot therefore, in any event, enable those questions to be regarded as being inadmissible.

35 Moreover, even if, as the Fédération française des producteurs d'oléagineux et de protéagineux puts forward, the solution to the dispute in the main proceedings can been inferred from the judgment of 25 July 2018, *Confédération paysanne and Others* (C-528/16, EU:C:2018:583), and does not give room for any reasonable doubt, those circumstances are not such as to show the inadmissibility of the request for a preliminary ruling. Those circumstances are, at best, capable of exempting the referring court from its obligation under the third paragraph of Article 267 TFEU to make a reference.

36 First, even when there is case-law of the Court resolving the point of law at issue, national courts and tribunals retain the broadest power to bring a matter before the Court if they consider it appropriate to do so, and the fact that the provisions whose interpretation is sought have already been interpreted by the Court does not deprive the Court of jurisdiction to give a further ruling (see, to that effect, judgments of 27 March 1963, *Da Costa and Others*, 28/62 to 30/62, EU:C:1963:6, paragraphs 75 and 76; of 6 October 1982, *Cilfit and Others*, 283/81, EU:C:1982:335, paragraphs 13 and 15; and of 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19, EU:C:2021:799, paragraphs 36 and 37). Second, a national court is in no way prohibited from referring questions to the Court for a preliminary ruling which, in the opinion of one of the parties to the main proceedings, leaves no room for reasonable doubt (see, to that effect, judgments of 1 December 2011, *Painer*, C-145/10, EU:C:2011:798, paragraphs 64 and 65, and of 24 February 2022, *Viva Telecom Bulgaria*, C-257/20, EU:C:2022:125, paragraph 42).

37 In the light of the foregoing, the reference for a preliminary ruling must be declared admissible.

Consideration of the questions referred

The first question

38 By its first question, the referring court asks, in essence, whether Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning that organisms obtained through the application of a technique/method of mutagenesis which is based on the same processes of modification, by the mutagenesis agent, of the genetic material of the organism concerned as a technique/method of mutagenesis which has conventionally been used in a number of applications and has a long safety record, but which differs from that second technique/method of mutagenesis by virtue of other characteristics, including by the use of *in vitro* cultures, are excluded from the exemption laid down in that provision.

39 In accordance with settled case-law of the Court, Article 3(1) of Directive 2001/18 must be interpreted as taking account not only of its wording, but also the context in which it occurs and the objectives pursued by the rules of which it is part (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 42).

40 Whilst it follows from Article 2(2) of Directive 2001/18 that organisms obtained by means of techniques/methods of mutagenesis constitute GMOs within the meaning of that directive, subject to the obligations laid down by that directive (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 38), it follows from

Article 3(1) of that directive, relating to derogations, that the directive does not apply to organisms obtained by means of techniques of genetic modifications listed in Annex 1 B to that directive.

41 That Annex 1 B lists techniques/methods of genetic modification yielding organisms which are to be excluded from the scope of that directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by one or more of the techniques/methods listed in that annex. Among those techniques/methods, point 1 of that annex refers to mutagenesis.

42 In those circumstances, the wording of Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, does not in itself provide a conclusive indication as to the organisms which the EU legislature intended to exclude from the scope of that directive.

43 That said, recital 17 of Directive 2001/18 clarifies the relevant criteria for considering that an organism is not subject to the obligations laid down by that directive, by stating that that directive should not apply to organisms obtained by means of certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraphs 44 to 46).

44 In addition, the interpretation of Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, must be made in the light of the objective of that directive, as set out in Article 1 thereof, namely, in accordance with the precautionary principle, to protect human health and the environment when, first, GMOs are deliberately released into the environment for any purpose other than placing on the market within the European Union, and, secondly, when GMOs are placed on the market within the European Union as or in products (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 52).

45 An interpretation of Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, according to which organisms obtained by means of techniques/methods of mutagenesis would be excluded from the scope of that directive, without any distinctions, would compromise the objective of the protection of human health and the environment pursued by that directive and would fail to respect the precautionary principle which it seeks to implement (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 53).

46 In the light, in particular, of the foregoing considerations, the Court has held that Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 54).

47 It is important to point out, in that regard, that the limitation of the scope of the exemption provided for in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, by reference to the dual criterion of conventional use in a number of applications and with a long safety record, is closely linked to the very objective of that directive, set out in paragraph 44 of the present judgment.

48 The application of that dual criterion thus makes it possible to ensure that, because of age and the variety of uses of a technique/method of mutagenesis and the information available as to its safety, organisms obtained by that technique/method may be released into the environment or placed on the market within the European Union, without it being necessary, in order to avoid adverse effects on human health and the environment, to subject those organisms to the risk assessment procedures laid down in Part B and Part C respectively of Directive 2001/18.

49 That application also addresses the requirement of strict interpretation of Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex 1 B thereof, arising from the derogating nature of that provision from the requirement of GMOs to be subject to the obligations laid down in that directive (see, to that effect, judgment of 25 July 2018, *Confédération paysanne and Others*, C-528/16, EU:C:2018:583, paragraph 41).

50 In the present case, the referring court seeks, in essence, to ascertain whether, in order to determine whether a technique/method of mutagenesis must be treated in the same way as a technique/method of mutagenesis meeting the dual criterion of conventional use and the long safety record, it is sufficient to examine the processes of modification, by the mutagenic agent, of the genetic material of the organism concerned.

51 In that regard, it must be stated that a general extension of the benefit of the exemption provided for in Article 3(1) of Directive 2001/18 to organisms obtained by the application of a technique/method of mutagenesis which is based on the same processes of modification, by the mutagenic agent, of the genetic material of the organism concerned as a technique/method of mutagenesis which has been conventionally used in a number of applications and which has a long safety record, but which combines those processes of modification with other characteristics, distinct from those of that second technique/method of mutagenesis, would not respect the intention of the EU legislature set out in paragraph 48 of the present judgment.

52 It cannot be ruled out that the application of a technique/method with such characteristics may lead to genetic modifications of the organism concerned which differ, by their nature or by the rate at which they occur, from those obtained by the application of that second technique/method of mutagenesis.

53 It follows that the limitation of the examination carried out for the purposes of applying the exemption provided for in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, solely to the processes of modification, by the mutagenic agent, of the genetic material of the organism concerned, would present the risk that, under cover of the application of a technique/method of mutagenesis conventionally used in a number of applications and with a long safety record, organisms may ultimately be obtained whose genetic material is different from those obtained by the application of that technique/method of mutagenesis, whereas it is precisely the experience gained as regards the latter organisms which enables establishing that the dual criterion resulting from that provision is satisfied.

54 Consequently, the release into the environment or the placing on the market, without having carried out a risk assessment procedure, of organisms obtained by means of a technique/method of mutagenesis with characteristics distinct from those of a technique/method of mutagenesis which has been conventionally used in a number of applications and has a long safety record is likely, in certain cases, to entail negative effects, possibly irreversible and affecting several Member States, on human health and the environment, even where those characteristics do not relate to the processes of modification, by the mutagenic agent, of the genetic material of the organism concerned.

55 Nonetheless, to take the view that organisms obtained through the application of a technique/method of mutagenesis which has conventionally been used in a number of applications and with a long safety record is shown necessarily to fall within the scope of Directive 2001/18 where that technique/method has undergone any modification would be liable to render largely redundant the exemption provided for in Article 3(1) of that directive, read in conjunction with point 1 of Annex I B thereto, since such an interpretation could make all forms of adaptation of techniques/methods of mutagenesis excessively difficult, even though that interpretation is not necessary to achieve the objective of protecting the environment and human health pursued by that directive, in accordance with the precautionary principle.

56 Therefore, it must be held that the fact that a technique/method of mutagenesis includes one or more characteristics distinct from those of a technique/method of mutagenesis conventionally used in a number of applications and which has a long safety record justifies the exclusion of the exemption provided for in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, only in so far as it is established that those characteristics are liable to result in modifications of the genetic material of the organism concerned that differ, by their nature or by the rate at which they occur, from those obtained by the application of that second technique/method of mutagenesis.

57 However, in the case in the main proceedings, the referring court is specifically called upon to determine whether the application *in vitro* of a technique/method of mutagenesis initially used *in vivo* may fall within that exemption. It is therefore necessary to ascertain whether the EU legislature considered that the fact that a technique/method involves *in vitro* cultures is decisive for determining whether or not such an application falls within the scope of Directive 2001/18.

58 In that regard, the EU legislature did not consider that the genetic modifications inherent in the *in vitro* cultures, to which the referring court makes reference, justified the fact that the organisms affected by such modifications necessarily constituted 'GMO's subject to the risk assessment procedures referred to in Part B and Part C respectively of Directive 2001/18.

59 In the first place, *in vitro* culture is not included in the illustrative list of techniques which, pursuant to Article 2(2)(a) of Directive 2001/18, read in conjunction with Part 1 of Annex I A thereto, must be regarded as producing a genetic modification enabling an organism to be regarded as a 'GMO' within the meaning of that directive.

60 In the second place, it is apparent from Article 2(2)(b) of Directive 2001/18, read in conjunction with Part 2 of Annex I A thereto, that *in vitro* fertilisation is not considered, for the purposes of the application of that directive, to be a technique entailing genetic modification, except where it involves the use of recombinant nucleic acid molecules or GMOs obtained by other techniques/methods. Thus, the fact that the application of that technique presupposes an *in vitro* culture was not, as such, regarded by the EU legislature to be an obstacle to its exclusion from the scope of that directive.

61 Similarly, it follows from Article 3(1) of Directive 2001/18, read in conjunction with point 2 of Annex I B thereto, that the cell fusion of plant cells of organisms which may exchange genetic material by traditional selection methods falls outside the scope of that directive even though, as the French Government and the Commission have observed in their written observations, without being contradicted, that cell fusion is necessarily applied *in vitro* to isolated cells.

62 In the third place, it follows from Article 2(2)(b) of Directive 2001/18, read in conjunction with point 3 of Part 2 of Annex I A thereto, that the EU legislature chose not to make the regime

applicable to polyploidy induction dependent on whether or not it is applied *in vitro*. The Commission pointed out in that regard in its written observations, without being contradicted, that the *in vitro* application of that technique was already known for a long time when that directive was adopted.

63 In that context, as the French Government and the Commission submit, in essence, to consider that, because of the effects inherent in *in vitro* cultures, an organism obtained by the application *in vitro* of a technique/method of mutagenesis initially used *in vivo* is excluded from the exemption provided for in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, would be to disregard the fact that the EU legislature did not consider that those effects were inherent in the definition of the scope of that directive.

64 In the light of the foregoing, the answer to the first question is that Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning that organisms obtained through the application of a technique/method of mutagenesis which is based on the same processes of modification, by the mutagenic agent, of the genetic material of the organism concerned as a technique/method of mutagenesis which has conventionally been used in a number of applications and has a long safety record, but which differs from that second technique/method of mutagenesis by virtue of other characteristics, shall, in principle, be excluded from the exemption laid down in that provision, provided that it is established that those characteristics are likely to lead to modifications of the genetic material of that organism which differ, by their nature or by the rate at which they occur, from those obtained by the application of that second technique/method of mutagenesis. However, the effects inherent in *in vitro* cultures do not, as such, justify the exclusion from that exemption of organisms obtained by the *in vitro* application of a technique/method of mutagenesis which has conventionally been used in a number of *in vivo* applications and has a long safety record with regard to those applications.

The second question

65 It is apparent from the order for reference that an answer to the second question is necessary for the purposes of resolving the dispute in the main proceedings only if it follows from the answer to the first question that, in order to determine whether a technique/method of mutagenesis falls within the exemption laid down in Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B thereto, account must be taken of the effects inherent in techniques/methods involving *in vitro* culture.

66 Therefore, having regard to the answer given to the first question, there is no need to examine the second question.

Costs

67 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

Article 3(1) 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, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 of that directive,

must be interpreted as meaning that organisms obtained through the application of a technique/method of mutagenesis which is based on the same processes of modification, by the mutagenic agent, of the genetic material of the organism concerned as a technique/method of mutagenesis which has conventionally been used in a number of applications and has a long safety record, but which differs from that second technique/method of mutagenesis by virtue of other characteristics, shall, in principle, be excluded from the exemption laid down in that provision, provided that it is established that those characteristics are likely to lead to modifications of the genetic material of that organism which differ, by their nature or by the rate at which they occur, from those obtained by the application of that second technique/method of mutagenesis. However, the effects inherent in *in vitro* cultures do not, as such, justify the exclusion from that exemption of organisms obtained by the *in vitro* application of a technique/method of mutagenesis which has conventionally been used in a number of *in vivo* applications and has a long safety record with regard to those applications.

[Signatures]

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* Language of the case: French.