



13.2.2024

NOTICE TO MEMBERS

Subject: Petition No 1466/2020 by Roxane Mitralias (Luxembourgish) on behalf of the Confédération paysanne and the Fédération Nationale de l’Agriculture Biologique, on alleged non-compliance by the French Government with the judgment of the Court of Justice of the European Union of 25 July 2018 in Case C-528/16

1. Summary of petition

Referring to the CJEU judgment of 25 July 2018 regarding the enforcement of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, the petitioner complains that it is still not being systematically applied in France to all crops concerned, thereby increasing the risk of irreversible contamination of traditional and organic crops by GM crops that are still being cultivated illegally. The petitioner refers to the Clearfield rapeseed mutagenesis case before the Council of State, indicating that the French Government, through its failure to promulgate a decree prohibiting the cultivation and marketing of this oilseed rape variety without authorisation, in line with the provisions of Directive 2001/18, is currently in breach of national and EU law.

2. Admissibility

Declared admissible on 31 March 2021. Information requested from Commission under Rule 227(6).

3. Commission reply, received on 23 July 2021

The petition

The petitioner claims that Clearfield rapeseed, which is produced by an *in vitro* random

mutagenesis technique, is subject to the requirements of Directive 2001/18/EC¹ on the deliberate release into the environment of genetically modified organisms (GMOs). Since this rapeseed variety has not been authorised in accordance with that Directive, the petitioner claims that its cultivation and placing on the market in France is against EU law. As a result, the petitioner claims that France is infringing EU law. To support these claims, the petitioner relies on the judgment of the Court of Justice of the European Union (CJEU) of 25 July 2018 in Case C-528/16, *Confédération paysanne and Others*.

The Commission's observations

The Commission considers that the petitioner's claim is unfounded. In accordance with Article 3(1) and Annex IB to Directive 2001/18/EC, genetically modified organisms (GMOs) produced by mutagenesis techniques/methods are excluded from the Directive under certain conditions². In that regard, the CJEU ruled, in its judgment in Case C-528/16, that '*only organisms obtained by means of techniques/methods of mutagenesis which have been conventionally used in a number of applications and have a long safety record are excluded from the scope of that Directive*'. The Court also ruled that new mutagenesis techniques/methods that have appeared or have been mostly developed since Directive 2001/18/EC was adopted are not excluded from the scope of the Directive.

Based on the Court ruling, the petitioner claims that the Clearfield rapeseed is a GMO subject to the requirements of the Directive. In the Commission's view, that interpretation is incorrect and not in accordance with the Court ruling. As the petitioner acknowledges, this rapeseed variety has been produced by *in vitro* random mutagenesis. Random mutagenesis techniques consist in subjecting plants, seeds, parts of plants or single cells to chemical or physical mutagens. Random mutagenesis techniques are conventional breeding techniques developed in the first half of the 20th century, first applied *in vivo*, and, progressively since the 1970s, *in vitro*. The information available at present shows that *in vitro* random mutagenesis had been developed and was a well-known technique for breeding plants well before the adoption of Directive in 2001/18/EC.

Further, neither the European Food Safety Authority, when referring to conventional mutation breeding techniques, nor the FAO/IAEA³ Mutant Variety Database, when defining mutant varieties, make a distinction between *in vivo* and *in vitro* application of physical or chemical mutagenesis. The CJEU did not make any differentiation either between these two types of applications when referring to '*conventional methods of random mutagenesis*' (Case C-528/16, para. 48).

The petitioner also refers to the notification by the French authorities on 6 May 2020 under Article 6(5) of the Single Market Transparency Directive (Directive (EU) 2015/1535)⁴ of three

¹ 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 - Commission Declaration, *OJ L 106, 17.4.2001, p. 1–39*.

² Organisms obtained through these techniques are exempted on 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 listed in Annex IB.

³ Food and Agriculture Organization/ International Atomic Energy Agency.

⁴ 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

draft measures to amend the national legislation as regards *in vitro* random mutagenesis and removing a number of plant varieties from the listing in the Official Catalogue of Species and Varieties of Cultivated Crops in France⁵. Those draft measures were proposed to comply with a judgment of the *Conseil d'Etat* of 7 February 2020 that ruled that plant varieties obtained through *in vitro* random mutagenesis should no longer be excluded from the scope of the GMO legislation.

As noted by the petitioner, the Commission issued a detailed opinion on the three draft measures. In its detailed opinion, the Commission pointed towards a breach of some provisions of Directive 2001/18/EC, as well as on some provisions of Council Directive 2002/53/EC⁶ and Council Directive 2002/55/EC⁷ on the registration of varieties of seeds of agricultural species and vegetable species respectively and their placing on the market in the EU. Five Member States also issued detailed opinions on at least one of the draft measures, and, among them, three issued comments on at least two. The French authorities have not yet responded to the Commission's detailed opinion and to the Commission's best knowledge France has not adopted these three notified draft measures yet.

Conclusion

In view of the above considerations, the petitioner's claim that the Clearfield rapeseed variety is a GMO subject to the authorisation and labelling requirements of Directive 2001/18/EC and therefore illegally placed on the market in France appears to be unfounded. Therefore, in the Commission's view, the French legislation allowing the cultivation and placing on the market of this rapeseed variety is in line with Directive 2001/18/EC and with the above-mentioned CJEU ruling.⁸

4. Commission reply (REV.), received on 29 August 2022

This petition was submitted on behalf of 'Confédération paysanne' and the 'Fédération nationale de l'agriculture biologique', alleging infringement by the French authorities of Directive 2001/18/EC⁸ on the deliberate release of GMOs into the environment and of the judgment of the Court of Justice of the European Union (CJEU) of 25 July 2018 in Case C-528/16 (*Confédération paysanne and Others*).

On 25 October 2021, a debate took place during the Committee on Petitions meeting on this petition. The Committee chair decided to keep the petition open for further evaluation. The chair asked the Commission to keep the Committee on Petitions informed about any reply by France to the Commission's detailed opinion on the three draft measures notified by France on

services (Text with EEA relevance), *OJL 241, 17.9.2015, p. 1–15*.

⁵ Notifications 2020/280/F, 2020/281/F and 2020/282/F.

⁶ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, *OJL 193, 20.7.2002, p. 1–11*.

⁷ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, *OJL 193, 20.7.2002, p. 33–59*.

⁸ 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 - Commission Declaration, *OJ L 106, 17.4.2001, p. 1–39*.

6 May 2020 under the Single Market Transparency Directive⁹.

The Commission has received no reply from the French authorities to its detailed opinion. However, on 8 November 2021 the French Conseil d'Etat referred two new questions to the CJEU concerning the interpretation of the mutagenesis exemption made by the Court in its 2018 judgment (Case C-688/21, *Confédération paysanne and Others*). Those questions were referred in the framework of new proceedings lodged before the Conseil d'Etat by 'Confédération paysanne' and eight other organisations, requesting the enforcement of the Conseil d'Etat decision of 7 February 2020, in which that court had ordered, amongst others, the exclusion of *in vitro* random mutagenesis from the list of mutagenesis techniques exempted from the genetically modified organisms (GMO) legislation.

In its 2018 judgment, the CJEU ruled 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. The new questions by the Conseil d'Etat to the Court refer to the interpretation of those conditions as regards techniques of *in vitro* random mutagenesis. The case is ongoing¹⁰.

In view of the above, and since the legal status of techniques of *in vitro* random mutagenesis under the GMO Directive is the object of this petition, any further considerations on this dossier should await the judgment of the CJEU.

The Commission takes this opportunity to inform the Committee on Petitions that, in an opinion published in November 2021, the European Food Safety Authority (EFSA) concluded that the distinction between plants obtained by *in vitro* or *in vivo* random mutagenesis is not scientifically justified¹¹. In particular, EFSA observed that the mutation process and the repair mechanisms act at cellular level and thus there is no difference between application of the mutagen *in vivo* or *in vitro*, and that the type of mutations induced by a specific mutagen are expected to be the same, regardless of whether such mutagen is applied *in vivo* or *in vitro*. EFSA's scientific conclusions support the Commission's position not to make a distinction between *in vivo* and *in vitro* mutagenesis when implementing the GMO legislation.

Conclusion

In view of the above, and since the legal status of techniques of *in vitro* random mutagenesis under the GMO Directive is the object of this petition, any further considerations on this dossier should await the judgment of the CJEU.

5. Commission reply (REV.), received on 13 February 2024

This petition was submitted on behalf of the entities *Confédération paysanne* and *Fédération nationale de l'agriculture biologique*, alleging infringement by the French

⁹ 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 (codification) (Text with EEA relevance), OJ L 241, 17.9.2015, p. 1–15.

¹⁰ The Advocate General's opinion will be delivered on 27 October 2022.

¹¹ EFSA GMO Panel, 2021. *In vivo* and *in vitro* random mutagenesis techniques in plants. EFSA Journal 2021;19(11):6611, 30 pp. <https://doi.org/10.2903/j.efsa.2021.6611>.

authorities of Directive 2001/18/EC¹² on the deliberate release of genetically modified organisms (GMOs) into the environment and of the judgment of the Court of Justice of the European Union (CJEU) of 25 July 2018 in Case C-528/16¹³.

On 25 October 2021, a debate took place during the meeting of the Committee on Petitions on this petition. The Committee chair decided to keep the petition open for further evaluation. The chair asked the Commission to keep the Committee on Petitions informed about any reply by France to the Commission's detailed opinion on the three draft measures notified by France on 6 May 2020 under the Single Market Transparency Directive¹⁴.

The Commission provided its observations on the petition on 29 August 2022, where it noted that, on 8 November 2021, the French *Conseil d'Etat* had referred two new questions to the CJEU¹⁵ concerning the interpretation of the mutagenesis exemption in Directive 2001/18/EC made by the Court in the above-mentioned 2018 judgment, in particular on whether that exemption covers organisms obtained by techniques of *in vitro* random mutagenesis. Since the legal status of such techniques is the object of this petition, the Commission concluded in its observations that any further considerations needed to await the judgment of the CJEU in the 2021 preliminary ruling case.

The CJEU delivered its judgment on Case C-688/21 on 7 February 2023¹⁶, and ruled that organisms obtained by the *in vitro* application of a random mutagenesis technique which has conventionally been used in a number of *in vivo* applications and has a long safety record with regard to those applications, are exempted from the GMO legislation, in accordance with Article 3(1) of Directive 2001/18/EC read in conjunction with point 1 of Annex IB thereto. Therefore, the Court has confirmed the Commission's interpretation, expressed in the above-mentioned Commission detailed opinion of 7 August 2020 on the French draft measures.

Conclusion

The interpretation given by the CJEU in Case C-688/21 is relevant for the proceedings before the French *Conseil d'Etat* concerning the matter raised in this petition. To date, the Commission has not received any new information about the status of those proceedings following the delivery of the CJEU judgment.

¹² 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 - Commission Declaration, OJ L 106, 17.4.2001, p. 1–39.

¹³ Case C-528/16, *Confédération paysanne and Others*, ECLI:EU:C:2018:583.

¹⁴ 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 (codification) (Text with EEA relevance), OJ L 241, 17.9.2015, p. 1–15.

¹⁵ Case C-688/21, *Confédération paysanne and Others*

¹⁶ ECLI:EU:C:2023:75