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Court of Justice of the European Union
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Judgment in Case C-528/16
Confédération paysanne and Others v Premier ministre and Ministre de
l'Agriculture, de l'Agroalimentaire et de la Forêt

Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive

However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the directive or to other obligations

Unlike transgenesis, mutagenesis is a set of techniques which make it possible to alter the genome of a living species without the insertion of foreign DNA. Mutagenesis techniques have made it possible to develop seed varieties which are resistant to selective herbicides.

Confédération paysanne is a French agricultural union which defends the interests of small-scale farming. Together with eight other associations, it has brought an action before the Conseil d'État (Council of State, France) in order to contest the French legislation which exempts organisms obtained by mutagenesis from the obligations imposed by the directive on genetically modified organisms (GMOs).¹ In particular, that directive provides that GMOs must be authorised following an assessment of the risks which they present for human health and the environment and also makes them subject to traceability, labelling and monitoring obligations.

Confédération paysanne and the other associations argue that mutagenesis techniques have evolved over time. Prior to the adoption of the GMO Directive, only conventional or random methods of mutagenesis were applied *in vivo* to entire plants. Subsequently, technical progress has led to the emergence of *in vitro* mutagenesis techniques which make it possible to target the mutations in order to obtain an organism resistant to certain herbicides. Confédération paysanne and the other associations take the view that the use of herbicide-resistant seed varieties carries a risk of significant harm to the environment and to human and animal health, in the same way as GMOs obtained by transgenesis.

It is in this context that the Court of Justice has been requested by the Conseil d'État to determine, in essence, whether organisms obtained by mutagenesis are GMOs and whether they are subject to the obligations laid down by the GMO Directive.

In today's judgment, the Court of Justice takes the view, first of all, that **organisms obtained by mutagenesis are GMOs** within the meaning of the GMO Directive, in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally. It follows that **those organisms come, in principle, within the scope of the GMO Directive and are subject to the obligations laid down by that directive.**

The Court states, however, that it is apparent from **the GMO Directive** that it **does not apply to organisms obtained by means of certain mutagenesis techniques, namely those which have conventionally been used in a number of applications and have a long safety record.** The Court nevertheless specifies that **the Member States are free to subject such organisms, in compliance with EU law (in particular the rules on the free movement of goods), to the obligations**

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 (OJ 2001 L 106, p. 1).

laid down by the GMO Directive or to other obligations. The fact that those organisms are excluded from the scope of the directive does not mean that the persons concerned may proceed freely with their deliberate release into the environment or with their placement on the market within the EU. The Member States are thus free to legislate in this area in compliance with EU law, in particular with the rules on the free movement of goods.

With regard to the question whether the GMO Directive may also be applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption, the Court considers that the risks linked to the use of these **new mutagenesis techniques** might prove to be similar to those that result from the production and release of a GMO through transgenesis, since the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into the organism (transgenesis) and those new techniques make it possible to produce genetically modified varieties at a rate out of all proportion to those resulting from the application of conventional methods of mutagenesis. In view of these shared risks, excluding organisms obtained by new mutagenesis techniques from the scope of the GMO Directive would compromise the objective pursued by that directive, which is to avoid adverse effects on human health and the environment, and would fail to respect the precautionary principle which that directive seeks to implement. It follows that **the GMO Directive is also applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption.**

Finally, the Court examines the question whether genetically modified varieties obtained by mutagenesis must fulfil a condition laid down by another EU directive,² according to which a genetically modified variety may be accepted for inclusion in the 'common catalogue of varieties of agricultural plant species the seed of which may be marketed' only if all appropriate measures have been taken to avoid risks to human health and the environment. The Court considers that the concept of 'genetically modified variety' must be construed as referring to the concept of a GMO in the GMO Directive, with the result that varieties obtained by mutagenesis which come under that directive must fulfil the condition mentioned above. By contrast, varieties obtained by means of mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from that obligation.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of EU law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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² Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ 2002 L 193, p. 1), as amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 (OJ 2003 L 268, p. 1).