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Press and Information

Advocate General's Opinion in Case C-528/16
Confédération paysanne and Others v Premier ministre et ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt

According to Advocate General Bobek, organisms obtained by mutagenesis are, in principle, exempted from the obligations in the Genetically Modified Organisms Directive

Member States are free to adopt measures regulating such organisms provided they respect overarching principles of EU law

The 'GMO Directive'[1] regulates the deliberate release into the environment of genetically modified organisms (GMOs) and their placing on the market within the EU. 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. The Directive does not, however, apply to organisms obtained through certain techniques of genetic modification, such as mutagenesis ('the mutagenesis exemption'). Unlike transgenesis, mutagenesis does not, in principle, entail the insertion of foreign DNA into a living organism. It does, however, involve an alteration of the genome of a living species. The mutagenesis techniques have made it possible to develop seed varieties with elements resistant to a selective herbicide.

Confédération paysanne is a French agricultural union defending 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 regulation transposing the GMO Directive[2]. They argue that mutagenesis techniques have evolved over time. Prior to the adoption of the GMO Directive in 2001, only conventional or random methods of mutagenesis were applied *in vivo* to entire plants. Subsequently, technical progress has led to the emergence of mutagenesis techniques like targeted mutagenesis methods which enable a precise mutation in a gene in order to obtain, for example, a product resistant to certain herbicides only. For Confédération paysanne and the other associations, 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.

In this context, the Court of Justice is invited by the French Conseil d'État to clarify the exact scope of the GMO Directive, specifically the ambit, rationale and effects of the mutagenesis exemption, and to assess its validity. The Court is also invited to indicate 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.

In today's Opinion, Advocate General Michal Bobek first considers that **an organism obtained by mutagenesis can be a GMO if it fulfils the substantive criteria laid down in the GMO Directive**[3]. He observes that that Directive does not require the insertion of foreign DNA in an organism in order for the latter to be characterised as a GMO, but merely says that the genetic material has been altered in such a way that does not occur naturally. The open-ended character

[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).
[2] This regulation excludes organisms obtained by mutagenesis from the obligations applying to GMOs.
[3] See Article 2(2) of the GMO Directive: this Article 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 an annex; (b) the techniques listed in another annex are not considered to result in genetic modification.

of that definition allows organisms obtained by methods other than transgenesis to fall under the notion of a GMO. Further, it would be illogical to exempt certain organisms obtained by mutagenesis from the application of the Directive if those organisms could not be characterised as GMOs in the first place.

The Advocate General then examines whether the mutagenesis exemption foreseen in the GMO Directive ought to mean *all* techniques of mutagenesis or only *some* techniques. According to him, the only relevant distinction that should be made in order to clarify the scope of the mutagenesis exemption is the caveat set out in Annex I B of the GMO Directive, namely whether the 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'. It follows that **mutagenesis techniques 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 one or more of the methods listed in Annex I B**.

The Advocate General points out that neither the historical context nor the internal logic of the GMO Directive support the contention that the EU legislature only intended to exempt *safe* mutagenesis techniques as they stood back in 2001. He considers that 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.

Next, the Advocate General examines 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. He is of the opinion that by inserting the mutagenesis exemption, the EU legislature did not wish to regulate that matter on the EU level. Accordingly, 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**.

As regards the **validity of the mutagenesis exemption**, the Advocate General recognises that the legislator is obliged to keep its regulation reasonably up to date. This duty becomes crucial in respect of those areas and issues covered by the precautionary principle so that the validity of an EU law measure like the GMO Directive is not only to be assessed with regard to the facts and knowledge as they stood at the time of the adoption of that measure, but also with regard to the duty to keep legislation reasonably up to date.

However, **the Advocate General does not see any grounds deriving from the general duty to update legislation (in this case enhanced by the precautionary principle) which could affect the validity of the mutagenesis exemption**.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

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 European Union 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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