COURT OF JUSTICE
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Judgment of the Court in Case C-688/21 | Confédération paysanne and Others (*in vitro* random mutagenesis)

Techniques of genetic modification: the Court specifies the status of *in vitro* random mutagenesis having regard to the GMO Directive

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 are excluded from the scope of that directive

Directive 2001/18/EC [1] defines a common methodology to evaluate, on a case-by-case basis, the risks for the environment associated with the release of genetically modified organisms (GMOs), and the common objectives for monitoring GMOs after their voluntary release or their placing on the market. Those rules provide, inter alia, for an evaluation prior to placing on the market, an authorisation, labelling or monitoring after marketing. That directive however includes an exemption meaning that certain techniques/methods of mutagenesis fall outside its scope ('the exemption').

Random mutagenesis comprises increasing the frequency of spontaneous genetic mutations of living organisms.

This technique of mutagenesis can be applied *in vitro* (the mutagenic agents are applied to plant cells, the whole plant is then artificially reconstituted) or *in vivo* (the mutagenic agents are applied to the whole plant or plant parts).

In 2015, a French agricultural trade union (the Confédération paysanne) and eight associations whose purpose is to protect the environment brought an action before the Conseil d'État (Council of State, France) concerning the exclusion of certain techniques or methods of mutagenesis from the scope of the French law transposing Directive 2001/18, on the deliberate release of GMOs into the environment.

In a judgment delivered on 25 July 2018, [2] the Court ruled, in particular, that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used for various applications and with a long safety record benefit from the exemption provided for by Directive 2001/18.

In a decision of 2020, the Conseil d'État inferred from that judgment that the organisms obtained by means of techniques or methods which appeared or were mainly developed after the date that Directive 2001/18 was adopted, in particular by means of *in vitro* random mutagenesis techniques, must be included in the scope of Directive 2001/18 and are therefore subject to the obligations imposed by that directive.

The French authorities have not, however, adopted any measures aimed at ensuring the implementation of the decision of the Conseil d'État, in particular because of the Commission's opposition to the application of separate

[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] See press release 111/18.

regimes to *in vivo* random mutagenesis and *in vitro* random mutagenesis.

The Confédération paysanne and the 8 aforementioned associations then brought another case before the Conseil d'État to obtain the ruling of a penalty payment intended to ensure the implementation of its 2020 decision.

The Conseil d'État seeks that the Court specifies whether *in vitro* random mutagenesis can be treated in the same way as a technique/method of mutagenesis meeting the dual criterion of conventional use and of the long safety record, thus benefiting from the exemption provided for by Directive 2001/18, or whether, on the contrary, it should fall within the scope of that legislation.

The Court, sitting as the Grand Chamber, rules that it is, in principle, justified to exclude the application of the exemption provided for by Directive 2001/18 to 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 differ from that second technique/method of mutagenesis by virtue of other characteristics, provided 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 through the application of a technique/method of mutagenesis which has conventionally been used in a number of applications and has a long safety record.**

In support of this solution, the Court states that the limitation of the scope of the exemption provided for by the directive in question, by reference to the dual criterion of (i) conventional use in a number of applications and (ii) with a long safety record, is closely linked to the very objective of that legislation, namely, in accordance with the precautionary principle laid down by EU law, to **protect human health and the environment**.

It states that a general extension of the benefit of the exemption to organisms obtained by the application of a technique/method of mutagenesis based on the same processes 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.**

The Court considers that 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 **could have negative effects on human health and the environment**, affecting several Member States **in a sometimes irreversible manner**. That could be the case even where those characteristics do not relate to the process of modification, by the mutagenic agent, of the genetic material of the organism concerned.

Nevertheless, it states that **the exemption would be rendered redundant** if it were considered 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 the directive where that technique/method has undergone **any modification.**

Therefore, 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 where 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.**

However, the effects inherent in *in vitro* cultures **do not justify the exclusion from the 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 Court analyses various aspects of Directive 2001/18 to determine whether the EU legislature considered that the fact that a technique/method involves *in vitro* cultures is decisive in determining whether it falls within the scope of that directive. It infers from this analysis that that is not the case, in particular with regard to the fact that other techniques are not subject to the GMO monitoring regime provided for by Directive 2001/18 even though they involve or may involve the use of *in vitro* cultures.

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.

The full text and the résumé of the judgment is published on the CURIA website on the day of delivery.

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