

Euroseeds' opinion over the ECJ ruling clarifying the non-GMO status of in-vitro mutagenesis

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[European Court of Justice Ruling in case C-688-21](#)

"Euroseeds welcomes the clarification by the European Court of Justice on in-vitro mutagenesis methods. This ruling provides the long-awaited legal clarity that is needed by breeders and seed producers for the marketing of plant varieties that have been on the EU market since years", says Garlich von Essen, Secretary General of Euroseeds.

The ruling¹ confirms that in-vitro mutagenesis falls under the exemption of Annex IB of the GMO Directive. With this, plant varieties resulting from in vitro mutagenesis are exempted from the obligations of Directive 2001/18.

The ECJ highlights that the exemption under Annex IB must be read in conjunction with Recital 17 which elaborates on the history of safe use of a method in several applications. Taking this into account the ECJ reasonably considers not only the mutagenesis method but also the resulting genetic modification to be decisive elements for an exemption from the GMO Directive.

This is a much more science-based approach compared to the pure process-based judgement from 2018. The Court states that those mutagenesis methods can be exempted that lead to genetic modifications of an organism which do not differ by their nature or by the rate at which they occur, from those obtained by a technique of mutagenesis which has conventionally been used in several applications and has a long safety record.

"It needs further careful assessment of the ruling to get a better understanding of the exemption requirements and in how far they might also be applicable to other mutagenesis methods", concludes von Essen.

¹ ECJ press release n. 22/23: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2023-02/cp230022en.pdf>



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