



Statement of the International Society for Transgenic Technology on the recent decision of the ECJ to classify genome editing as GMO

The Board of Directors of the International Society for Transgenic Technology (ISTT) has the following comment on the ruling of the European Court of Justice (ECJ), which requires any that genome-edited organism shall be treated as GMO within the meaning of the European GMO Directive.

The ISTT, a scientific society representing the largest group of experts in the field of genome modification in animals, is surprised and disappointed that the court decided to focus on the method and not the product of genome editing and thus did not follow the recommendation of the court's Advocate General.

Insertion of foreign DNA has always been regarded as genetic engineering with or without the use of endonucleases and is not part of this court ruling.

However, the modification of the genome by chemical means or irradiation, a technology older than the term genetic engineering, has always been exempt from such regulation, as such genetic changes are indistinguishable from natural occurring mutation. This is also true for endonuclease-mediated genome editing.

The short press release from the court is scientifically inconsistent because the new genome-editing techniques are clearly more precise and predictable than classical mutagenesis methods. This increased precision means a significant improvement in technology, which could create numerous opportunities, including great potential for sustainable development and human therapeutics.

Nevertheless, while mentioning politically controversial herbicide resistant plants, other applications like drought or disease resistance are not mentioned. The latter could also be very relevant for animal welfare.

The new ECJ ruling will also greatly favor market concentration of the application of genome editing, because only the largest companies will be able to fulfill the requirements of the EU GMO directive and they will do so only for the most profitable projects.

The press release of the court leaves the impression that the ruling was influenced by political opinion rather than based on scientific evaluation. Particularly the focus on the process rather than the product is difficult to explain otherwise.

Altogether, the ECJ ruling helps to reinforce the already existing impression in general public opinion that genome-editing technologies are fundamentally dangerous. There is no evidence to support this.

The ISTT does not advocate unregulated genome editing. However, any legal regulation should focus on the product and the application rather than the method used to generate it.

It is one of the fundamental aims of the ISTT to provide expert information and guidance to the scientific community, policy makers and the general public regarding the benefits associated with the use and application of transgenic technologies. As one of our most important tasks, we will continue the scientific debate on the opportunities and risks of nuclease-mediated gene editing.