

Threat of significant loopholes in EU regulation of genetically engineered organisms

Advocate General of EU Court of Justice faces criticism

24 January 2018 / Last week, the Advocate General of the EU Court of Justice publically declared his position on whether new methods of genetic engineering, known as gene editing, should come under EU GMO regulation. In his statement he did not address these new techniques, their applications and risks in detail. Instead, his reasoning is largely based on very general, and in some cases, outdated categories, likely to lead to considerable legal uncertainty. In particular, the statement lacks a clear distinction between conventional breeding processes and the new techniques of gene editing which, for example, make use of the nuclease CRISPR-Cas. Consequently, Testbiotech is not expecting the forthcoming EU court ruling to put an end to the current debates on the regulation of new methods of genetic engineering.

The lack of clarity in his statement can be largely attributed to terminology coined by the seed industry: These stakeholders very often use terms such as “new breeding technologies” or “targeted mutagenesis” when discussing the new methods of genetic engineering. Indeed, throughout his statement, the Advocate General mostly uses the term “mutation” and only in one single footnote does he use the more precise and correct category of 'gene editing'. This wording is also found in the questions originally submitted to the Court, and is causing a great deal of confusion.

The way in which mutations in current in plant breeding are used is quite different from the new methods of gene editing: Mutations can occur spontaneously in nature or can be brought about by unspecific triggers, such as UV light or chemical compounds. These traditional methods of mutation breeding are used to promote a higher level of diversity in the genome of the plants. Due to their biological characteristics, these methods are difficult to be regulated. They are exempted from EU regulation also for historical reasons.

In contrast, methods of gene editing are used to make direct changes in the genome without aiming to increase genetic diversity; the preferred aim is to bring about specific changes. Even in those cases where no additional genomic information is inserted into the plants, the results and risks can be very different to those in conventional breeding.

This is evident in current research publications: In experiments using CRISPR-Cas on the plant species *Arabidopsis*, specific gene sequences that plant breeders have so far been unable to target were changed in their structure. Despite no additional genes being inserted, the results between the subgroups of the plants were surprisingly different. It is likely that epigenetic regulation influenced the outcome of the process. This shows the need for more scrutiny in risk assessment since epigenetic effects have so far been completely ignored.

Without going into any comprehensive detail, the Advocate General instead came to the conclusion that it does not come down to whether these new methods carry risks, or if they are used in traditional in plant breeding. Depending on the interpretation of his statement, even organisms that have undergone changes in their genome via the use of the DNA scissor, CRISPR-Cas, might be released without detailed risk assessment or labelling. According to the Advocate General, the individual EU member states would have to regulate the risks in their own national legislation.

If the EU Court of Justice follows this opinion, major loopholes in EU GMO regulation are likely to emerge. Consequently, in many cases it would be impossible to keep track of the respective organisms and there would also be no systematic risk assessment or adequate methods of identification.

According to Testbiotech, new methods of genetic engineering associated with risks and uncertainties must be assessed according to EU-wide standards. If the upcoming judgement of the EU Court of Justice does actually create substantial loopholes, Testbiotech will demand that political decision-makers take action to, for example, prevent uncontrolled imports or releases of genetically engineered organisms into the environment.

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Further information: [The statement of the Advocate General](#) [2]

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