

Gene Editing

Gene editing ranks among the major methodological innovations in molecular biology for over 20 years. This is a collective term for a number of different methods with which DNA building blocks of microorganisms, plants and mammals can be edited in a more precise and pinpointed manner than ever before: Genes can be turned on and off, repaired, inserted, removed, replaced or regulated. Compared with conventional methods, these techniques are uncomplicated, time-saving and cost-effective. They are used worldwide in basic research, medicine, biotechnological production and agriculture. The said techniques have a fundamental role not only in plant biotechnology but also in the production of bio-based products and, in particular, in medicine. Gene editing opens up new possibilities to decode diseases and to decisively improve their prevention, therapy and cure – or to enable them in the first place.

Court ruling puts innovation at risk

The European Court of Justice (ECJ) dealt until July 2018 with the question whether gene editing falls under the EU legislation on GMOs or whether the mutagenesis exemption – as laid down in this legislation – applies. Gene editing is also called "targeted mutagenesis". For example, in crop breeding it can bring about the same changes as traditional breeding methods or natural

mutations. Its products are at least as safe for humans, animals and environment as crops bred with conventional methods. All the same, the judges held that gene editing results in genetically modified organisms (GMOs) that require approval under the GMO legislation.

This ruling is problematic, because it is based on an EU directive dating back to 2001 which, in turn, relies on the state of science of the 1980s. No consideration was given to recent natural science assessments and new scientific findings. With its interpretation of the European GMO Directive, the court ruling blocks the enormous innovative potential of gene editing for agriculture and impairs urgently needed progress in medicine and bio-economy. Germany and Europe are bound to fall behind countries like China and the USA in all areas of biotechnology, both scientifically and economically.

It is important for research-intensive products and processes to be not only developed in Germany and to be allowed to show their benefits fast. General and scientifically unfounded rejection of certain methods adversely affects medical, industrial and agricultural biotechnology.

The public and legal environment for gene editing in Germany and the EU is in need of improvement. Large and small businesses of the life science industry should be able to use gene editing.

THE VCI IS CALLING FOR THE FOLLOWING

● Science-based, case-by-case assessment of gene editing

The European GMO legislation should be adapted to the current state of development and knowledge in technology and natural science, and it should be open for new developments. Future laws should be oriented primarily to the hazard potential of organisms and not to the production method.

● Use the chances of gene editing in all fields of biotechnology

The NanoDialog of the German federal government decisively contributed to examining the chances and risks of nanotechnology in an open and fair manner, supporting a responsible handling of nanomaterials. The same should be done for gene editing: In a BioDialog of the federal government, politicians and society could discuss ethical questions and potential risks.