COMMISSIE COGEM GENETISCHE MODIFICATIE

ZKBS The Central Committee on Biological Safety

Advice of European Advisory Committees on Biosafety

Dear Ms Chantal Bruetschy,

European Advisory Committees on Biosafety are calling on the European governments to amend the regulation on genetically modified organisms, in order to account for scientific developments and experience gathered. On 6 and 7 November, the 9th Meeting of the European Advisory Committees on Biosafety (MEACB) took place in Berlin. Participants discussed current topics in risk assessment of genetic engineering and related biosafety aspects. The European committees provide advice to their respective governments on matters of contained use, deliberate release and placing on the market of genetically modified organisms (GMO). Having thus closely followed the evolution of modern biotechnology during the last 30 years, they have compiled a sound body of knowledge on risk assessment, risk management strategies and continuous monitoring of GMOs.

During the meeting, the opportunity was taken to exchange views on the European Court of Justice ruling of July 2018 on genome editing. The Genome editing as referred to in this text can lead to site-specific small mutations in the genome of organisms which are identical in size to natural mutations or mutations induced by mutagenesis using chemical or radiation mutagens. The ruling stated that the application of genome editing techniques always leads to the creation of GMO as defined in Directive 2001/18/EC on the deliberate release of genetically modified organisms into the environment, and that organisms created by genome editing techniques are not exempted from the obligations defined in this directive in contrast to organisms resulting from chemical or radiation mutagenesis.

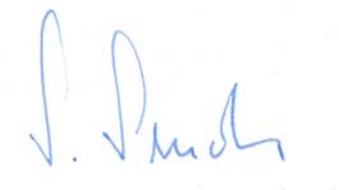
The members of the advisory committees concordantly agreed that the current regulation of genetically modified organisms in the EU is outdated. Although scientific progress is enormous, especially in the ability to induce targeted and precise genetic changes in living organisms, the definition of a GMO has not been updated since 1990. The current regulation does not take into account the experience in safety assessment of genetic engineering gathered during the past decades, thus not allowing the handling of organisms according to the specific risks they might or might not pose to humans and the environment. The advisory committees agreed that products created with genome editing techniques, which cannot be distinguished from products with natural mutations or from products of chemical or radiation mutagenesis, should not be regulated based only on the process of inducing the genetic changes alone.

The best method for detecting genetic alterations is sequence analysis. This method does not allow to distinguish products of genome editing from products derived from mutagenesis using chemicals or radiation. As a consequence, the obligation to handle products of genome editing identically to products of conventional transgenesis will very likely prove infeasible.

It was agreed that an improved regulation is needed which focuses more on the result of the genetic modification than on the way this modification has been achieved. An adaptation should take into account the decades-long national and international experience with genetic engineering gained so far, the similarity of products derived from natural, classical and targeted mutagenesis, and the practical availability of tools for law enforcement and control.

This recommendation is in concordance with a multitude of reports of research organisations and advisory bodies which have been published in the past all recommending a much-needed revision of the regulation of genome-edited organisms, among them a joint statement of scientists of 127 European research organisations and universities, the European Plant Science Organisation (EPSO), the Group of Chief Scientific Advisors (part of Scientific Advice Mechanism - SAM), the Bioeconomy Council of the Federal Republic of Germany, the German Academies of Sciences and the German Research Foundation and the Netherlands Commission on Genetic Modification Engineering (COGEM), and the Swiss Expert Committee for Biosafety.

on behalf of SECB, COGEM and ZKBS



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