



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2023)6072590

Standing Committee on Plants, Animals, Food and Feed
Section *Regulatory Committee 2009/41/EC*
21 April 2023

CIRCABC Link: <https://circabc.europa.eu/ui/group/47075858-2b2d-4be4-b426-80fb29f081ac/library/56184262-abe3-4ffe-8a18-166fc6a3132a?p=1>

SUMMARY REPORT

A.01 Commission Report on the experience of Member States with Directive 2009/41 on the contained use of genetically modified micro-organisms for the period 2019-2021 –Commission presentation and discussion

The Commission presented the sixth Report on the experience of Member States with Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs) for the period 2019 – 2021 adopted on 15 February 2023.

A discussion followed where Member States highlighted some issues faced in the implementation of the Directive. Several Member States raised issues related to the assessment of alternative inactivation methods of GMMs. A few Member States noted difficulties interpreting GMO definition, particularly in relation to viral replicons. Some Member States highlighted the importance of raising awareness about the contained use of GMMs particularly in the context of “Do-It-Yourself” practices and shared their initiatives in this regard. Another Member State shared the difficulties in the approval process to phase out GMO strains containing antibiotic resistance marker genes and a few Member States showed their interest to further discuss this subject.

The Commission will consider these issues for the further discussion at Committee level.

A.02 GMO-related aspects of the revision of the pharmaceutical legislation – Update by the Commission

The Commission provided an overview of proposed changes to the pharmaceutical legislation related to investigational medicinal products containing or consisting of GMOs and addressed Member States questions.