

## Development of regulatory framework for genome-edited organisms in the European Union

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Genome editing is a set of techniques to make highly specific targeted changes in genomes. Unlike established methods of genome modification, genome editing may achieve desired plant traits without introducing any exogenous DNA in target genomes. These techniques have been hailed worldwide as a solution for targeted crop improvement, especially for tackling the challenges of climate change. However, the European Court of Justice indicated that the genome-edited organisms may be subject to the EU GMO Directive potentially facing extensive regulation for authorization. Since EU is a major importer of agricultural goods, such regulation may have broad implications for international trade. Per request of the Council of the European Union, the European Commission initiated and recently concluded a study involving input from the Member States and different stakeholders regarding the status of novel genomic techniques including genome editing. In this talk, I will outline the major conclusions of the EC study. In particular, I will discuss current European Food Safety Authority scientific opinions on the site-directed nucleases 1 and 2 (SDN-1, SDN-2), synthetic biology plants and gene drive organisms which formed part of the EC study. The EFSA opinion will provide a temporary solution for scientific risk assessment of SDN-1 and SDN-2 plants; however, it is hoped that current stakeholder initiatives will result in updates to the EU GMO legislation that better reflect the benefits of modern agricultural biotechnology and the needs of society.