Regulating Innovation: The Future of New Genomic Techniques in Europe

Potentials and Challenges for European Innovation and Competitiveness

Description of the conference's main theme

The emergence and rapid advancement of new genomic techniques (NGTs) have sparked intense legal and policy debates in both health and agricultural biotechnology. NGTs allow for precise and efficient genetic modifications. In the health sector, the first CRISPR-based therapeutics are currently in development and testing, with broad global consensus around their transformative potential. In the agricultural sector, NGTs hold significant promise for enabling higher crop yields, greater varietal diversity, improved climate resilience, and reduced pesticide use.

Regulators have taken different stances towards NGTs. With respect to NGT plants, the United States and several other countries have adopted permissive frameworks that exempt NGT plants with minor genetic changes from strict GMO oversight. In contrast, the European Union, ruled in 2018 that all NGT plants fall under the 2001 GMO Directive - effectively treating them the same as traditional GMOs, subjecting NGT plants to a prohibitively costly and lengthy market authorization process. This stricter regulation of NGT plants has important implications for scientific innovation, investment, and the competitiveness of the EU. In response, the EU has initiated steps toward deregulation. In March 2025, the Council of the European Union agreed on a negotiating mandate for a revised regulatory framework on NGT plants.

Against this background, we will discuss the future of NGT regulation in Europe in two panels. The first panel will examine the scope and implications of the proposed EU deregulation compared to the current regime, with a focus on its impact on public and private sector research. The second panel will discuss one of the most contentious issues in ongoing negotiations: should NGT plants be eligible for patent protection? Across both panels, we will explore the broader consequences of regulatory choices for innovation, competition, and the future of biotechnology in Europe

Panel I: Market Access and the New Regulatory Divide: Implications for R&D

In this panel we will examine the implications of the current EU regulatory framework for the European science and innovation system: Does the existing restrictive regulatory environment measurably constrain the scope and ambition of plant science research compared to the United States and the United Kingdom? Are research institutions and talents (re-)locating or orienting their work toward jurisdictions with more permissive regulatory environments? To what extent

do these divergent approaches shape public funding priorities, academic-industry collaboration, and the ability to participate in international scientific networks?

In a second step, we will discuss the potential impact of the new EU deregulation proposal on market access and commercialization. The panel will assess how the proposed classification of NGT plants into two categories – Category 1 plants (those considered equivalent to conventional varieties and exempted from the GMO Directive) and Category 2 plants (those subject to GMO legislation) – could reshape regulatory pathways. Questions may include whether exempting Category 1 plants from pre-market authorization requirements can accelerate product development and reduce costs for developers? Does the continued application of GMO rules to Category 2 plants disincentivize the development of more complex or novel edits? To what extent do the proposed traceability measures for Category 2 plants and mandatory labeling for Category 1 plant seeds, despite their regulatory exemption, influence supply chain logistics and in turn innovation incentives?

Panel II: Access, Competition, and Incentives: Rethinking Intellectual Property for NGTs

The second panel will discuss how to govern patenting and licensing for plants developed through new genomic techniques (NGTs). While the European Commission's original proposal for a new Regulation on plants produced by NGTs of 5 July 2023 (COM(2023) 411 final) intended to leave the existing intellectual property framework unchanged, the European Parliament raised concerns about market concentration, legal uncertainty for breeders, and barriers to access. Against this background, the EU Parliament on 2 February 2024 adopted a position to exclude Category 1 NGT plants from patentability and grant protection only under plant variety rights. The negotiating mandate adopted in March 2025 did not endorse a full patent exclusion but proposed alternative measures to address issues of transparency and access. These include the establishment of a public patent database for NGTs, voluntary FRAND-like licensing commitments, the creation of an expert group to assess the impact of patents on the sector, and a commitment to publish a comprehensive study on the effects of patenting within a year of the regulation's entry into force.

This panel will explore whether and how patents on NGT-related inventions impact (follow-on) innovation in the agricultural sector. Specifically, it will ask: could a centralized clearinghouse improve transparency and reduce the problem of overlapping patents, or "patent thickets"? What are the advantages and drawbacks of such a mechanism? What should be expected from the proposed voluntary FRAND-like licensing system, and is it likely to meaningfully lower access barriers for smaller breeders? Ultimately, is the current EU proposal sufficient to address concerns about market concentration and access barriers while still preserving incentives for corporate R&D?