Placing on the market of genetically modified micro-organisms and the processing of organs

2025/0405(COD) - 16/12/2025 - Legislative proposal

PURPOSE: to update and clarify EU rules on the placing on the market of genetically modified micro-organisms (GMMs) and on the processing of human organs.

PROPOSED ACT: Directive of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Directive 2010/53/EU on quality and safety of human organs intended for transplantation necessitate targeted amendments in order to enhance legal certainty, ensure coherence between existing Union acts, and take account of scientific and technical developments.

The proposal accompanies the European Biotech Act, which establishes a framework to strengthen the competitiveness of the EU health biotechnology sector across the full innovation cycle, from research to market placement and production, while ensuring high standards of health, safety, environmental protection, ethics, and biosecurity. Health biotechnology is broadly defined in line with the EU's public-health objectives under Article 168 TFEU. To ensure the effective functioning of this new framework within existing EU law, the proposal introduces targeted amendments to **two sectoral legislative acts**.

CONTENT: the proposal for a Directive amends Directives 2001/18/EC and 2010/53/EU to **update and clarify** EU rules on the placing on the market of genetically modified micro-organisms (GMMs) and on the processing of human organs.

The amendments aim to modernise and harmonise regulatory requirements applicable to:

- **genetically modified micro-organisms** (GMMs), the adjustments proposed here have the aim of creating a tailored, more efficient and streamlined regulatory framework for GMMs. They relate to the risk assessment, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs, as well as to the introduction of the concept of low-risk GMMs, including scientific criteria confirming this status, and set a framework for a streamlined authorisation procedure for eligible low-risk GMMs;

- **processing of organs**, the scope of Directive 2010/53/EU is amended to expressly include processing alongside donation, testing, characterisation, procurement, transport and transplantation, and to clarify that where organs are used for research purposes, the Directive applies only where they are intended for transplantation into the human body. The proposal requires *inter alia*:

- transplantation centres to obtain **prior authorisation** from the competent authority before applying a processed organ to a recipient;

- transplantation centres to perform a **benefit–risk assessment** of the processing, including the intended clinical indication;

- the Commission to publish a **list of authorised organ processing operations**.