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**Interinstitutional File:
2025/0405 (COD)**

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AGRI 316
AGRILEG 101
ENV 417
CODEC 776
BIOTECH 43**

COVER NOTE

From: Secretary-General of the European Committee of the Regions
date of receipt: 27 April 2026
To: Ms Thérèse BLANCHET, Secretary-General of the Council of the
European Union

Subject: Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL amending Directives 2001/18/EC and 2010/53/EU
as regards the placing on the market of genetically modified micro-
organisms and the processing of organs
- *Renunciation letter from the Committee of the Regions (CoR)*

Delegations will find attached a renunciation letter from the Committee of the Regions (CoR) regarding the consultation on file 2025/0405 (COD).

E-MAIL

IM 3185 2026
27-04-2026

Ref. Ares(2026)4313730 - 27/04/2026



**European Committee
of the Regions**

The Secretary-General

Brussels, *date of official registration*

Thérèse Blanchet
Secretary-General
Council of the European Union

Dear Secretary-General,

On behalf of the President of the European Committee of the Regions (CoR), Kata Tüttö, I would like to thank you for your referral request to the CoR, dated 18 February 2026, regarding the following dossier:

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs.

The CoR's Commission for Natural Resources (NAT) decided at its meeting on 4 February 2026 not to issue an opinion on this proposal and not to include the dossier into the ongoing work of the CoR.

This legislative initiative is a component of the European Biotechnology Act, aimed to modernise and simplify the regulatory landscape for biotechnology in the EU. The proposal targets two primary areas by amending existing legislation:

- Genetically Modified Micro-organisms (GMMs): It amends Directive 2001/18/EC to create a tailored regulatory framework for the placing on the market of GMMs (such as bacteria, algae, and fungi) in products other than food or feed (e.g., fertilisers, biocontrol, and wastewater treatment).
- Processing of organs: It amends Directive 2010/53/EU to explicitly recognise and clarify the regulatory treatment of advanced organ processing technologies, ensuring high quality and safety standards for human organs intended for transplantation.

Proposed measures are of technical nature and authorisations largely national or EU competence, cities and regions are not routinely involved in setting these procedures.


Should you require any further information, please do not hesitate to contact the NAT secretariat (nat@cor.europa.eu).

Yours sincerely,

Petr Blížkovský

Cc: Kata Tüttö, President of the European Committee of the Regions
Didier Seeuws, Director-General, General and Institutional policy, Council of the European Union

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 Electronically signed on 27/04/2026 11:04 (UTC+02)