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Date: Thursday, April 2, 2026, 11:38 AM
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CC: EK-postbus <postbus@eerstekamer.nl>
Subject: FW: To the attention of Speakers and Presidents of EU Parliaments – information about a reasoned opinion from the Swedish Parliament

Attachments:

Courtesy translation of Reasoned Opinion COM(2025) 1031 2025_26_SoU37.pdf

Van: <5.1.2.e <5.1.2.e @riksdagen.se>

Verzonden: donderdag 2 april 2026 11:33

Onderwerp: To the attention of Speakers and Presidents of EU Parliaments – information about a reasoned opinion from the Swedish Parliament

Reasoned opinion from the Swedish Parliament

Dear Speaker, dear Colleague,

On 1 April, the Riksdag adopted a reasoned opinion on the Commission Proposal for a Directive dealing with genetically modified micro-organisms and the processing of organs. In the reasoned opinion, the Riksdag considers that the parts relating to Directive 2001/18/EC are compatible with the principle of subsidiarity. However, regarding certain parts of the proposal that concern amendments to Directive 2010/53/EU, the Riksdag considers that these, in their current form, are not compatible with the principle of subsidiarity. Please find a link to the reasoned opinion [here \(COM\(2025\) 1031\)](#).

Please find a courtesy translation of the reasoned opinion attached to this email.

I would also like to take this opportunity to inform you of a recent online meeting between the Swedish Committee on Industry and Trade and the EU Policies Committee in the Italian Chamber of Deputies. In the online meeting, the two committees discussed the finding in the Riksdag's reasoned opinion on two proposals of the European Grids Package ([COM\(2025\) 1006](#)) and [COM\(2025\) 1007](#) - courtesy translation available).

During the online exchange the members from both committees emphasised the importance of an early exchange of information between national parliaments on matters relating to the principle of subsidiarity. The committees also stressed that national parliaments should make a reference to one another's reasoned opinions when the assessments align, in order to strengthen the collective position of national parliaments.

The Riksdag's reasoned opinion was proposed by the Committee on Industry and Trade in statement [2025/26:NU26](#). Following the adoption of the statement, the Chair of the Committee on Industry and Trade, Mr Tobias Andersson (The Sweden Democrats - ECR), sent a letter to his counterparts in the national parliaments in the EU to inform them of the committee's findings, which in turn drew the attention of the EU Policies Committee of the Italian Chamber of Deputies to the two proposals' possible breach of the principle of subsidiarity.

This is an excellent initiative and the first of its kind, as far as I am aware. I believe that this is an underutilised opportunity and a way to deepen our interparliamentary cooperation, especially in relation to our responsibilities related to the subsidiarity control mechanism.

Please read more about the online meeting on [lpex](#).

I look forward to your scrutiny results of this proposal, preferably on IPEX or in a way you deem appropriate.

Wishing you a happy and peaceful Easter a little in advance!

Yours sincerely,

5.1.2.e

Speaker Swedish Riksdag

Statement by the Committee on Health and Welfare 2025/26:SoU37

Subsidiarity check of the Commission's Proposal for a Directive dealing with genetically modified micro-organisms and the processing of organs

Summary

The Committee has conducted a subsidiarity check of the Commission's Proposal for a Directive dealing with genetically modified micro-organisms and the processing of organs (COM(2025) 1031). The Committee considers that the Commission's proposal in the parts relating to Directive 2001/18/EC is compatible with the principle of subsidiarity. However, regarding certain parts of the proposal that concern amendments to Directive 2010/53/EU, the Committee considers that these, in their current form, are not compatible with the principle of subsidiarity.

The examined proposal

The Commission's 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 (COM(2025) 1031).

APPENDIX 2

Reasoned opinion from the Riksdag

The Riksdag has examined the Commission's 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 (COM(2025) 1031).

The Riksdag is positive to the general ambitions of the proposal and welcomes the Commission's efforts to strengthen competitiveness within the sector of medical biotechnology. Furthermore, the Riksdag understands that updates to previous legislative acts may be required for the proposal for a regulation on biotechnology to work effectively within the existing regulatory framework. However, the Riksdag would like to emphasise that it is important that a full impact assessment is carried out to clarify the consequences of the proposals and to determine to what extent a measure at EU level would entail advantages compared to the current system or measures at member state level.

Given that the Commission is presenting the proposal for a directive in direct connection with the proposal for a regulation on biotechnology, it would have been an advantage, in the opinion of the Riksdag, if the two proposals could have been examined for subsidiarity in the same context.

The Riksdag considers that the proposal in the parts relating to Directive 2001/18/EC is compatible with the principle.

In the case of the parts of the proposal that concern the processing of organs for transplantation and which result in amendments to Directive 2010/53/EU, the Riksdag considers that it is unclear what obligations it would entail for the member states, as well as what added value there is to be gained in adopting new rules at EU level. The Riksdag has identified a number of uncertainties, particularly regarding the requirement for prior approval before processed organs are used on a recipient. In the opinion of the Riksdag, it is unclear whether the requirement relates to the approval of the processing technology used or whether it entails a requirement for prior approval before each individual transplant. Furthermore, the Riksdag sees a risk that the proposal may lead to additional administrative burdens without the added benefit being clearly expressed. The Riksdag considers that, with reference to the principle of subsidiarity, it would be problematic if a regulation at EU level were to affect how health and medical care services in the member states make decisions on care for individual patients. Such standards should instead be determined at national level, taking into account the responsibility of member states to organise and make decisions regarding health and medical care policy.

In the light of this, the Riksdag considers that the proposal in its current form is not compliant in all its parts with the principle of subsidiarity.