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COVER NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a regulation of the European Parliament and of the Council on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Critical Medicines Act) - Opinion of the European Committee of the Regions

Delegations will find attached the opinion[1] adopted by the European Committee of the Regions on the above-mentioned proposal.

Encl: Opinion of the European Committee of the Regions – The Critical Medicines Act
Ref: NAT-VII/010

[1] Other language versions, if needed, will soon be available on the following website: https://dmsearch.cor.europa.eu/search/opinion

European Committee of the Regions

NAT-VIII/010

169th plenary session, 10-11 December 2025

OPINION

The Critical Medicines Act

THE EUROPEAN COMMITTEE OF THE REGIONS

- underlines that medicine security should be integrated into the EU's defence strategy and funding, enabling accelerated investments in local production, increased preparedness for future health crises, and stable access to medicines across Member States; is convinced that maintaining uninterrupted production of medicines has a direct impact on regional, national and European security and calls for clear recognition of the importance of health security within the European Defence Industrial Strategy;
- calls on the co-legislators to explicitly recognise the role of regional authorities and include them in the evaluation of strategic projects to properly capture regional expertise, priorities and needs in project evaluations;
- calls on the Member States to guarantee that designated authorities take into account local and regional environmental land use restrictions and rules;
- calls on the regions to develop, upskill, and re-skill a dedicated workforce in pharmaceutical production and medicine shortage management; urges regions, universities, vocational centres, hospitals, pharmacists' organisations, and industry to create innovative apprenticeships and fund scholarships, fostering collaboration between academia and stakeholders; and invites the EU Commission to support these efforts through funding, cross-border coordination, and promotion of applied research in pharmaceutical production;
- calls for a decrease in the minimum number of Member States that can jointly request that the Commission procure on their behalf or in their name;
- supports the creation of an independent Critical Medicines Coordination Group involving consumers, patients, healthcare professionals and regional representatives from decentralised health systems.

Rue Belliard/Belliardstraat 101 | 1040 Bruxelles/Brussel | BELGIQUE/BELGIË | Tel. +32 22822211
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Rapporteur:

Erika VON KALBEN (DE/Greens+PRO), Member of the State Parliament of Schleswig-Holstein

Reference document:

Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (COM(2025) 102 final)

Opinion of the European Committee of the Regions –
The Critical Medicines Act
COM(2025) 102 final

I. RECOMMENDATIONS FOR AMENDMENTS

Amendment 1
Article 5

Text proposed by the Commission	*CoR amendment*
Article 5 *Strategic Projects*	*Article 5* *Strategic Projects*
A project located in the Union and related to creating or increasing manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria: (a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances; (b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency; (c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances; (d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.	A project located in the Union and related to creating or increasing manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria ***and contributes to the security of supply and availability of the medicinal product(s) in the Union:*** (a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances; (b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency; (c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances; (d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs***;*** (e) ***it creates or enhances strategic capacity for the storage, preservation, and distribution of critical medicinal products, their active substances, or key inputs, while also reducing external dependencies, improving strategic autonomy, and ensuring greater territorial coherence in supply chains, thereby strengthening the overall security of supply within the Union***.

Reason
To make sure that greater manufacturing capacity leads to benefits for health systems and consumers, the entity requesting that its project be considered strategic should demonstrate how this investment will contribute to the continued supply and availability of products from the Union list of critical medicines. Connection to strategic autonomy.

Amendment 2
Article 6

Text proposed by the Commission	*CoR amendment*
Article 6 *Recognition of Strategic Projects*	*Article 6* *Recognition of Strategic Projects*
1. Each Member State shall designate an authority (‘the designated authority’) that shall assess and verify whether or not a project meets at least one of the criteria set out in Article 5 and therefore constitutes a strategic project.	1. Each Member State shall designate an authority (‘the designated authority’) that shall assess and verify whether or not a project meets at least one of the criteria set out in Article 5 and therefore constitutes a strategic project.
A promoter may request the designated authority to assess whether a project is a strategic project.	***Where appropriate, Member States shall designate ‘regional designated authorities’ to assess and confirm strategic projects on their territory.***
Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.	A promoter may request the designated authority to assess whether a project is a strategic project.
2. Member States shall communicate to the Commission what ***is*** the designated ***authority*** for the purposes of paragraph 1.	Any Member State authority may request the designated authority to verify its determination of whether a project is a strategic project.
3. The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the Member States’ designated authorities shall be clearly listed.	2. Member States shall communicate to the Commission what the designated for the purposes of paragraph 1.
4. Any other Member State authority that receives a request from a promoter concerning Articles 8 to 14 shall assess whether that given project meets the criteria to be considered a strategic project as provided for in Article 5 and where necessary, request the verification of its determination from the designated authority.	3. The Commission shall provide a simple, accessible webpage on which the contact details and other relevant information on the Member States’ designated authorities shall be clearly listed.
5. Where the verification whether a project is a strategic project has been performed by an authority in accordance with this Article, any other authority shall rely on that verification.	4. Any other Member State authority that receives a request from a promoter concerning Articles 8 to 14 shall assess whether that given project meets the criteria to be considered a strategic project as provided for in Article 5 and where necessary, request the verification of its determination from the designated authority.
	5. Where the verification whether a project is a strategic project has been performed by an authority in accordance with this Article, any

	other authority shall rely on that verification.

Reason
Such an explicit inclusion of regional authorities, especially those vested with legislative powers, in the recognition of strategic projects would ensure that regional expertise, priorities and needs are properly considered in project evaluations.

Amendment 3

Article 8

Text proposed by the Commission	***CoR amendment***
Article 8 *Administrative support*	*Article 8* *Administrative support*
1. Upon request of a project promoter, a Member State shall provide to a strategic project located on its territory all the administrative support necessary to facilitate its timely and effective implementation, including assistance:	1. Upon request of a project promoter, a Member State shall provide to a strategic project located on its territory all the administrative support necessary to facilitate its timely and effective implementation, including assistance:
(a) with regard to compliance with applicable administrative and reporting obligations;	(a) with regard to compliance with applicable administrative and reporting obligations;
(b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project;	(b) with regard to informing the public, with the aim of increasing public acceptance of the strategic project;
(c) along the permit-granting process.	(c) along the permit-granting process.
2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium EN 31 EN size enterprises (SMEs) and, where appropriate, establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.	2. When providing the administrative support and the assistance referred to in paragraph 1, the Member State shall pay particular attention to small and medium EN 31 EN size enterprises (SMEs) and, where appropriate, establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of this Regulation.
	3. Member States shall provide technical and financial support to regional authorities for implementing strategic projects on their territories.
	4. The technical and financial support provided to regional authorities shall include specific mechanisms targeting regions with less industrial development or less administrative capacity, to ensure equal opportunities in the implementation of strategic projects and in attracting investments linked to the production

	of critical medicines. ***5. Funding should prioritise projects with either demonstrable ecological innovation, including carbon footprint reduction, waste management and responsible resource use, or an impact on employment, including the creation of quality jobs, skills development and the territorial resilience of production systems.***

Reason
To support regional authorities and increase their capacity to assist promoters and to best align regional development strategies and the Union's strategic objectives, including sustainable goals, and to ensure equal opportunities for regions with less industrial capacity.

Amendment 4

Article 12

Text proposed by the Commission	***CoR amendment***
Article 12 *Environmental assessments and authorisation* (2) Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information.	*Article 12* *Environmental assessments and authorisation* (2) Member States shall ensure that the competent authorities issue the reasoned conclusion referred to in Article 1(2), point (g)(iv), of Directive 2011/92/EU on the environmental impact assessment within 45 days of receiving all necessary information. ***Member States shall ensure that designated authorities have taken into account local and regional environmental land use restrictions and rules.***

Reason
To ensure that local and regional authorities are involved in the environmental assessment and that their collaboration enables better incorporation of local and regional preferences and needs.

Amendment 5

Article 13

Text proposed by the Commission	***CoR amendment***
Article 13 *Planning* 1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data is available.	*Article 13* *Planning* 1. National, regional and local authorities responsible for preparing plans, including zoning, spatial plans and land use plans, shall consider including in such plans, where appropriate, provisions for the development of Strategic Projects, as well as the necessary infrastructure. To facilitate the development of strategic projects, Member States shall ensure that all relevant spatial planning data is available. ***Regional and local authorities shall consider the possibility of such strategic projects in their regional development plans and shall be included in nationally-led planning and delivery phases to ensure alignment with local strategies and needs.***

Reason
To recognise that local and regional authorities have competence in zoning, spatial and land use decisions and that their territorial knowledge, as well as their policy orientations and regional development choices should be taken into account. This amendment also seeks to improve alignment between the Union's strategic objectives and regions' plans and preferences.

Amendment 6

Article 21

Text proposed by the Commission	***CoR amendment***
Article 21 *Commission facilitated Member States' cross-border procurement* 1. Upon a reasoned request of three or more Member States ('the request'), the Commission may act as facilitator for the requesting Member States' cross-border procurement as laid down in Article 39 of Directive of the European Parliament and of the Council 2014/24/EC28 for medicinal products of common interest.	*Article 21* *Commission facilitated Member States' cross-border procurement* ***or price negotiations.*** 1. Upon a reasoned request of three or more Member States ('the request'), the Commission may act as facilitator for the requesting Member States' cross-border procurement ***or price negotiations*** as laid down in Article 39 of Directive of the European Parliament and of the Council 2014/24/EC28 for medicinal products of common interest.

Reason
To give Member States the possibility to benefit from a collectively negotiated price while keeping

the possibility to procure separately.

Explanation of proposed changes
Price negotiations are part of the procurement procedure and do not need to be specifically mentioned in the legal text. Procurement, pricing and subsidies fall within the Member States' competence, and the Member States have different regulatory frameworks governing these processes.

Amendment 7

Article 25

Text proposed by the Commission	***CoR amendment***
Article 25 *Establishment of Critical Medicines Coordination Group*	*Article 25* *Establishment of Critical Medicines Coordination Group*
2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status.	2. The Member States and the Commission are Members of the Critical Medicines Group. Each Member State shall appoint a maximum of two high-level permanent representatives, with the expertise relevant for implementing all the different measures set out in this Regulation. ***Member States with decentralised health system management shall appoint at least one regional level representative as part of their quota.*** Where relevant as regards the function and expertise, Member States may appoint different representatives in relation to different tasks of the Critical Medicines Group. Appointed permanent representatives shall ensure the necessary coordination within their respective Member State. The Agency shall have an observer status. ***In Member States with highly decentralised health systems, regions shall be represented in the Critical Medicines Coordination Group based on a rotation system among regions, or multiple regions may be represented, ensuring that the circumstances of different regions are adequately reflected.***

Reason
Health systems are decentralised in the majority of Member States, and the expertise of territorial entities should be incorporated into the working of the group. This will also better reflect the concerns and realities of regions where strategic projects are located. Moreover, a rotation system or multi-regional representation will avoid excluding small regions.

II. POLICY RECOMMENDATIONS

THE EUROPEAN COMMITTEE OF THE REGIONS (CoR)

1. welcomes the European Commission's efforts to address the growing problem of medicine shortages in the EU, its commitment to ensuring the availability of critical medicines for all patients and the efforts made towards the proposed revision of the EU's general pharmaceutical legislation;

2. points out that medicine shortages have steadily increased at a very rapid pace in Europe over the past 10 years, and welcomes the fact that this issue has been on the EU's political agenda since 2017;

3. emphasises that shortages of medicinal products present substantial risks to patients and public health and undermine the functioning of healthcare systems as they can lead to treatment delays or interruptions, patients suffering side effects from alternative treatments, and increased co-payments;

4. considers that the general objective of this Regulation is to strengthen the security of supply and availability of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting the security and autonomy of the Union. Other specific medicines also need to be made available and accessible for when the market cannot ensure their availability and accessibility for patients, while also giving due consideration to ensuring their affordability, including essential medicines related to contraception, mental health, antiviral treatments, vaccines and substitution therapies;

5. stresses that medicine shortages are caused by multiple factors, including insufficient diversification (e.g. geographical, number of production sites) and market concentration[2]. It is clear that efforts need to be made to increase the number of production sites, following sustainable requirements, while also incentivising regions with scarce pharmaceutical industry to create a climate favourable to establishing such sites; stresses that ensuring the availability of critical medicines requires improved distribution logistics, particularly in island and outermost regions; calls on authorisation holders and distributors to establish fully operational depots in these areas to prevent supply disruptions and ensure equal access for all;

6. regrets that the publication of the Critical Medicines Act proposal was not preceded by an impact assessment; considers it is essential to evaluate the cost of the measures proposed by the European Commission in light of their expected effectiveness;

7. calls for this regulation to therefore establish a balanced and coherent regulatory framework. A data-driven approach should be promoted to enable environmental policies to be fine-tuned in a manner that preserves the availability of medicines without compromising environmental and sustainability standards;

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2 Strategic Report of the Critical Medicines Alliance, European Commission, February 2025.

8. agrees that the medicines included in the Union list of critical medicines deserve special attention; points out, however, that the Union list published in December 2024 does not include a number of medicines that are on national lists of critical medicines and that several therapeutic areas are still missing, as the current list only reflects the review of 75% of authorised medicines for human use in the EU/EEA.[3] The list should be revised *ex officio* every year, and any updates published. Advocates for the consultation with regional and local authorities to identify gaps and emerging needs;

9. strongly supports the Commission's proposal to add the availability and accessibility of medicines that present specific access challenges for patients ('medicines of common interest') to the Regulation's specific objectives, using collaborative procurement tools; underlines that a unified management system would be desirable to integrate both terms, ensuring clarity and consistency in the legislation;

10. further supports the reference to the affordability of medicines in Article 1, but considers that the Regulation should refer to the need to ensure the affordability and quality of both 'medicines of common interest' and 'critical medicine', as all medicines should be affordable to guarantee patients' access;

11. considers that ensuring a high level of transparency in the implementation of the Regulation is necessary for public accountability and public trust and that this principle should be mainstreamed across the text potentially supported by AI, data analysis, and other digital tools where relevant;

On European security

12. warns that Europe must prioritise the production of critical medicines and APIs, as reliance on third countries amid rising geopolitical tensions and increasing tariffs could undermine European pharmaceutical security; reminds that 80–90% of the global antibiotic supply and up to 80% of APIs used in Europe come from Asia, notably India and China;

13. asks the co-legislators to specify in Article 5 of the Regulation that a project is 'strategic' if it also 'contributes to the security of supply and availability of the medicinal product(s) in the Union';

14. reinforces the fact that the production of critical medicines within the European Union is essential for ensuring that medicines meet the highest health and safety standards expected by European citizens. Relocating production to within the Union allows for more direct oversight, quality assurance and rapid response to safety concerns, beyond existing regulatory frameworks for imported medicinal products. Strengthening local production capacity reduces risks associated with external manufacturing, including supply disruptions, inconsistent standards and limited transparency;

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3 https://www.ema.europa.eu/en/documents/other/questions-answers-union-list-critical-medicines_en.pdf.

15. highlights the United States' Defense Production Act, which designates pharmaceutical supply chains as a national security issue; is convinced that maintaining uninterrupted production of medicines has a direct impact on regional, national and European security;

16. underlines that medicine security should be integrated into the EU's defence strategy and funding, enabling accelerated investments in local production, increased preparedness for future health crises, and stable access to medicines across Member States; emphasises that uninterrupted treatments and medicines such as antibiotics and anaesthetics are vital for both civilian healthcare and military or emergency scenarios; and calls for clear recognition of the importance of health security within the European Defence Industrial Strategy;

On funding and strategic projects

17. agrees to consider as 'strategic projects' those initiatives that create or increase manufacturing capacity in the EU for critical medicines, with a special focus on small and medium-sized enterprises (SMEs), which should be given the possibility to launch strategic projects;

18. calls for dedicated, sustainable, and long-term funding for the implementation of the Critical Medicines Act to support its objectives; considers that the proposed redeployment of current programmes is insufficient and that resources should be increased and mobilised where possible, while ensuring that existing programmes, such as EU4HEALTH, continue to fully support their important public health objectives;

19. calls on the European Commission to create strong incentives to develop biotechnology, which is a key area for medical innovation. The upcoming Biotech Act should support both research and industry capacity to boost Europe's pharmaceutical sovereignty and safety, industrial competitiveness, citizens' wellbeing and economic growth;

20. stresses that national and European budgets are very constrained and that public funding should be granted to projects with high added value for patients and society including those proposed by SMEs, which can equally deliver significant impact;

21. recommends that the Member States and the Commission concentrate financial support, provided in the framework of the present Regulation, on critical medicinal products addressing vulnerabilities in the supply chain to maximise the public funding impact.

22. argues that any public funding for pharmaceutical companies must be accompanied by obligations including supply guarantees, full transparency in the use of public funds;

23. calls on Member States and the European Commission to lay down rules on effective, dissuasive and proportionate penalties applicable to infringements of the obligations set out in the Regulation;

24. requires that an undertaking that has received financial support does everything at hand to ensure that the medicine also becomes available in Member States where it is not on the market yet, upon request from their national competent authorities;

25. calls for financial incentives to be inclusive, catering to producers of all sizes, ensuring fair access to funds among regions and avoiding disparities influenced by national fiscal capacities;

26. encourages Member States and the European Commission to set up and prioritise financial support lines or programmes for public or not-for-profit production facilities aimed at developing sustainable not-for-profit local production of critical medicines;

27. is convinced that a thriving European research and innovation ecosystem would contribute to consolidate and secure the pharmaceutical supply chain; calls for a strong, stand-alone 10th Framework Programme for Research and Innovation; calls for dedicated funding for research and development of cleaner, greener and more efficient alternatives to traditional manufacturing; strongly believes that Europe's competitive edge should stem from innovative and sustainable production solutions;

28. recommends exploring the use of regional development funds to support the capacity of public hospitals, and where appropriate other medical organisations, in mitigating medicine shortages, preparing critical medicines and thus contributing to Europe's health security;

On the role of regional authorities

29. calls on the co-legislators to explicitly recognise the role of regional authorities and include them in the evaluation of strategic projects to properly capture regional expertise, priorities and needs in project evaluations;

30. calls on the Member States to provide technical and financial support to local and regional authorities to increase their capacity to co-design and implement strategic projects on their territories, ensuring that support is accessible to projects of varying scale that demonstrate clear added value for patients and society;

31. calls on the Member States to guarantee that designated authorities take into account local and regional environmental land use restrictions and rules; calls on the European Commission to verify whether this has been the case when evaluating strategic project proposals;

32. calls on regional authorities managing health systems to evaluate how their public hospitals' pharmacies are and could be more involved in the preparation of critical medicines;

33. recommends that regional authorities managing health systems include, in strategies aimed at promoting the proper use of medicines, appropriate references to the correct use of critical medicines, in order to support their proper prescription and consumption, without conflating this with broader supply chain measures.

34. calls on the regions to develop, upskill, and re-skill a dedicated workforce in pharmaceutical production and medicine shortage management; urges regions, universities, vocational centres, hospitals, pharmacists' organisations, and industry to create innovative apprenticeships and fund scholarships, fostering collaboration between academia and stakeholders; and invites the EU

Commission to support these efforts through funding, cross-border coordination, and promotion of applied research in pharmaceutical production;

On collaborative procurement and price negotiations

35. acknowledges that by teaming up at the European level in joint procurements, Member States increase their bargaining power and their chances to secure more affordable prices; highlights that for smaller Member States, getting together is also an opportunity to ensure that companies will launch their products in their countries;

36. calls, going forward and within the framework of the treaties, for the possibility for the European Commission to negotiate the price of medicines on behalf of the Member States without resorting to cross-border procurement in case they prefer to conduct separate procurement procedures;

37. calls for a decrease in the minimum number of Member States that can jointly request that the Commission procure on their behalf or in their name, as nine is one third of all Member States and this very high proportion may limit the use of this form of collaborative procurement;

38. recognises that minimum contingency stock levels imposed on pharmaceutical companies by Member States are an important and legitimate instrument to reinforce the security of supply and prevent medicine shortages in the interest of patients and public health;

39. calls for more solidarity and coordination in the management of national stockpiles, encouraging Member States to share the national stocks resulting from stockpiling obligations, when other countries face critical shortages, based on the Voluntary Solidarity Mechanism managed by the EMA;

40. calls for closer international cooperation with reliable partners, especially in wider Europe and closest neighbourhood;

41. supports the creation of an independent Critical Medicines Coordination Group involving consumers, patients, healthcare professionals and regional representatives from decentralised health systems to ensure inclusive and effective implementation, to consult on the list of critical medicines, and to follow dialogues with industries;

42. underscores that strategies for ensuring the security of supply of critical medicines need to take account of the specific needs of island and outermost regions, whose dependence on maritime and air transport and whose remoteness, in the case of the latter, increase the risk of logistical disruptions. The CoR believes that the regulation must include stronger monitoring mechanisms and specific contingency plans for these regions to ensure sufficient restocking time, minimum supplies tailored to circumstances in island regions, and direct coordination with EU early-warning systems;

43. stresses that smaller Member States face particular challenges due to limited market size and must not be disadvantaged in EU-level procurement or price negotiations;

44. calls on the Commission to ensure that EU solidarity mechanisms guarantee equitable access to critical medicines across all Member States, regardless of population size or geographical location

Brussels, 10 December 2025.

The President
of the European Committee of the Regions

Kata TÜTTŐ

The Secretary-General
of the European Committee of the Regions

Petr BLÍŽKOVSKÝ

III. PROCEDURE

Title	The Critical Medicines Act
Reference(s)	COM(2025) 102 - COD
Legal basis	Own-initiative opinion (Article 307(4) TFEU)
Procedural basis	Rule 41(a)
Date of Council/EP referral/Date of Commission letter	
Date of Bureau/President's decision	
Commission responsible	Commission for Natural Resources
Rapporteur	Erika Von Kalben (DE/Greens)
Discussed in commission	23 September 2025
Date adopted by commission	23 September 2025
Result of the vote in commission (majority, unanimity)	Majority
Date adopted in plenary	10 December 2025
Previous Committee opinions	
Subsidiarity reference	