Council of the European Union

Brussels, 21 May 2021
(OR. en)

8965/21

Interinstitutional Files:
2020/0320(COD)
2020/0322(COD)

SAN 311
PHARM 93
COVID-19 214
PROCIV 60
CODEC 735

COVER NOTE

From:	European Committee of the Regions
date of receipt:	19 May 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU - Opinion of the European Committee of the Regions

Delegations will find attached the opinion adopted by the European Committee of the Regions on the above.

Other language versions, if needed, soon available on the following website:

https://dmsearch.cor.europa.eu/search/opinion

European Committee of the Regions

NAT-VII/014

144th plenary session, 5-7 May 2021

OPINION

Commission for Natural Resources (NAT)

Cross-border health threats and the mandate of the European Centre for Disease Prevention and Control

THE EUROPEAN COMMITTEE OF THE REGIONS

- insists that representatives of the European Committee of the Regions should be involved in the work of teams, committees and task forces set up at EU level to deal with public health emergencies, particularly the Advisory Committee on Public Health Emergencies;
- requires that Regions should be fully involved at political level in drawing up and implementing pandemic preparedness plans;
- finds it necessary to launch a reflection on EU competences in the field of health during the debate on the future of Europe;
- calls for the swift adoption of appropriate legal solutions (…) to prepare and coordinate actions in the regions on both sides of the border in the event of a health threat emerging;
- suggests promoting the conclusion of permanent health cooperation agreements between the competent authorities of the appropriate levels in various countries in order to ensure the exchange of patients in crisis situations;
- recommends that, as part of its new mandate, the ECDC collect data at subnational level and improve cooperation between border regions and transit hubs in situations involving cross-border health threats.

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Rapporteur:
Olgierd GEBLEWICZ (PL/EPP), Marshal of the Zachodniopomorskie Region

Opinion of the European Committee of the Regions – Cross-border health threats and the mandate of the European Centre for Disease Prevention and Control

Introductory remarks

THE EUROPEAN COMMITTEE OF THE REGIONS

– supports the European Commission's plans for a stronger and more comprehensive legal framework within which the Union, with due consideration for the subsidiarity principle and Member States' primary responsibility for healthcare and crisis preparedness, can react rapidly and trigger the implementation of preparedness and response measures to cross-border threats to health across the EU;

– points out that in 19 countries of the European Union, responsibility for public health is not exclusively a national matter, but is largely decentralised, with local and regional authorities having significant competences in the national health system; therefore insists that a stronger subnational component be introduced;

– underlines that the COVID-19 pandemic has become a real stress test, highlighting serious shortcomings in preparedness and cross-border communication and cooperation between Member States and border regions when it comes to tackling health threats. The epidemiological approaches taken by individual Member States, but also individual regions, have been very different, with negative consequences not only for health but in the social and economic fields too;

– believes that representatives of the European Committee of the Regions, as the institution representing local and regional authorities from all the countries of the European Union, should be involved as observers in the work of teams, committees and task forces set up at EU level to deal with public health emergencies, particularly the Advisory Committee on Public Health Emergencies;

– calls for the introduction of effective instruments for coordination between border regions, including those on the EU's external borders, and proposes that interregional, cross-border contact groups be set up;

– notes that, although health policy remains a primary competence of the Member States in accordance with the subsidiarity principle, it is necessary to launch a reflection to deepen EU competences in the field of health (Article 168 of TFEU) during the debate on the future of Europe in order to address – in solidarity – serious cross-border health threats across the European Union, taking into account the different subnational structures in the field of health and the different competences of the health authorities in individual Member States. These new competences should, among others, enable the Commission to formally recognise a public health emergency at Union level;

– reminds that the COVID-pandemic has been accompanied by important restrictions to the freedom of movement inside the European Union;

I. RECOMMENDATIONS FOR AMENDMENTS

A. Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU

Amendment 1

Article 5

Text proposed by the European Commission	*CoR amendment*
1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.	1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.
2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.	2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.
3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:	3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:
(a) the timely cooperation between the Commission, the Member States and the Union agencies;	(a) the timely cooperation between the Commission, the Member States***, their regions and local authorities*** and the Union agencies;
(b) the secure exchange of information between the Commission, Union agencies and the Member States;	(b) the secure exchange of information between the Commission, Union agencies and the Member States;
(c) the epidemiological surveillance and monitoring;	(c) the epidemiological surveillance and monitoring;
(d) the early warning and risk assessment;	(d) the early warning and risk assessment;
(e) the risk and crisis communication;	(e) the risk and crisis communication;
(f) the health preparedness and response and intersectoral collaboration;	(f) the health preparedness and response and intersectoral collaboration;
(g) the management of the plan.	(g) the management of the plan.
4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.	4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. ***Regions shall be fully involved at political level in drawing up and implementing these plans.*** The plans shall include preparedness and

5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.	response means to address the situation of those citizens with higher risks. 5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.

Reason

Amendment 2

Article 6

National preparedness and response plans

Text proposed by the European Commission	***CoR amendment***
1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.	1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan. ***If applicable, where local and regional authorities have significant public health responsibilities in the national health system, national plans should include subnational preparedness and response plans.*** ***2. National preparedness and response plans should specify that inter-regional, cross-border contact groups can or should be set up in border areas to prepare and coordinate actions in regions on both sides of the border in the event of a health threat emerging.***

Reason
When competences at regional level are concerned, the involvement of regions is not an option.
Explanation of proposed changes
Self-explanatory.

Amendment 3

Article 7

Reporting on preparedness and response planning

Text proposed by the European Commission	*CoR amendment*
(c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, healthcare associated infection, and other specific issues. The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions. 2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years. The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national level.	(c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, healthcare associated infection, ***territorial statistics*** and other specific issues. The report shall include, whenever relevant, interregional ***and cross-border*** preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions. ***Regional and local authorities should be involved in preparing reports on matters relating to their area of responsibility, particularly those mentioned in subpoint (c) above.*** 2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years. The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national ***or subnational*** level.

Reason

Amendment 4

Article 9

Commission report on preparedness planning

Text proposed by the European Commission	*CoR amendment*
1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European	1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European

Parliament ***and to*** the Council a report on the state of play and progress on preparedness and response planning at Union level.	Parliament***,*** the Council ***and the European Committee of the Regions*** a report on the state of play and progress on preparedness and response planning at Union level.

Reason

Amendment 5

Article 10

Coordination of preparedness and response planning in the HSC

Insert subpoint.

Text proposed by the European Commission	***CoR amendment***
	(f) supporting regional cross-border cooperation on health in regions potentially or already at risk and coordinating the activities of inter-regional, cross-border contact groups.

Reason
A regional territorial component in the work of the HSC will allow for seamless integration of border regions in the crisis response and prevent the lack of communication experienced on many occasions during the COVID-19 outbreak in 2020.

Amendment 6

Article 11

Training of healthcare staff and public health staff

Text proposed by the European Commission	***CoR amendment***
2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools. [...] 5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other.	2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools. ***Training activities shall also be targeted towards local and regional authorities with competences in healthcare in order to support capacity-building at subnational level.*** [...] 5. The Commission may support organising programmes, in cooperation with the Member

	States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. ***Such actions should be carried out particularly in border regions where regional and local authorities have significant competences in the field of healthcare, not least through the training of people who work for interregional, cross-border contact groups.***

Reason
While the division of powers may vary in different Member States, local and regional authorities are often involved both in the management of municipal hospitals and civil protection, but lack specific training or capacity. Targeted training is very much needed for often understaffed municipal services and would allow faster response times and more efficient action.

Amendment 7

Article 13(8)

Epidemiological surveillance

Text proposed by the European Commission	***CoR amendment***
8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1	8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1. ***This monitoring shall be developed also territorially, notably through regional statistics.***

Reason
Self-explanatory.

Amendment 8

Article 19(3)

Alert notification

Text proposed by the European Commission	***CoR amendment***
When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as: (a) the type and origin of the agent; (b) the date and place of the incident or outbreak; (c)means of transmission or dissemination; (***d***) toxicological data;	When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as: (a) the type and origin of the agent; (b) the date and place of the incident or outbreak; (c) ***the territorial areas concerned;*** ***(d)*** means of transmission or dissemination;

(***e***) detection and confirmation methods; (***f***) public health risks; (***g***) public health measures implemented or intended to be taken at national level; (***h***) measures other than public health measures; (***i***) urgent need or shortage of medical countermeasures; (***j***) requests and offers for cross-border emergency assistance; (***k***) personal data necessary for the purpose of contact tracing in accordance with Article 26; (***l***) any other information relevant to the serious cross-border threat to health in question.	(***e***) toxicological data; (***f***) detection and confirmation methods; (***g***) public health risks; (***h***) public health measures implemented or intended to be taken at national level; (***i***) measures other than public health measures; (***j***) urgent need or shortage of medical countermeasures; (***k***) requests and offers for cross-border emergency assistance; (***l***) personal data necessary for the purpose of contact tracing in accordance with Article 26; (***m***) any other information relevant to the serious cross-border threat to health in question.

Reason
Self-explanatory.

B. **Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control**

Amendment 9

Article 3

Missions and tasks of the Centre

Text proposed by the European Commission	***CoR amendment***
2. (g) provide, upon request of the Commission or the HSC, or its own initiative, guidelines for treatment and case management of communicable diseases and other special health issues relevant for public health, in cooperation with relevant societies;	2. (g) provide, upon request of the Commission or the HSC, or its own initiative, guidelines for treatment and case management of communicable diseases and other special health issues relevant for public health, in cooperation with relevant societies***, including guidance for border regions and transit hubs in cases of cross-border health threats***;

Reason
In the case of COVID-19, border regions and transport hubs remained without guidance for certain periods before national measures were rolled out. Initial guidance from the ECDC, even of an informal and non-binding nature, would facilitate a common early response at the local and regional level across the EU, before targeted national measures enter into force.

Amendment 10

Article 5

Operation of dedicated networks and networking activities

Text proposed by the European Commission	*CoR amendment*
	2. (h) ensure, where possible, the collection of data at subnational level.

Reason
The request for the ECDC to collect data at subnational level is based on the experience gained from the COVID-19 pandemic; in some regions, the epidemiological picture has differed from the national average or the conditions in neighbouring regions.

Amendment 11

Article 5b

Preparedness and response planning

Text proposed by the European Commission	*CoR amendment*
1. (c) facilitate self-assessments and external evaluation of Member States' preparedness and response planning, and contribute to reporting and auditing on preparedness and response planning under Articles 7 and 8 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];	1. (c) facilitate self-assessments and external evaluation of Member States' preparedness and response planning***, including preparedness and response plans at subnational level applicable to border regions and transport hubs***, and contribute to reporting and auditing on preparedness and response planning under Articles 7 and 8 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];

Reason
Regions with substantial powers in the field of health have reacted to the COVID-19 pandemic with their own planning and measures. Independent guidance and auditing would have helped with the exchange of information and improved the quality of the initial response.

Amendment 12

Article 5b

Preparedness and response planning

Text proposed by the European Commission	*CoR amendment*
	1. (l) produce recommendations for cross-border coordination and compatibility of regional responses to heath threats;

Reason
Regions with substantial powers in the field of health have reacted to the COVID-19 pandemic with their own planning and measures. Independent guidance and auditing would have helped with the exchange of information and improved the quality of the initial response.

Amendment 13

Article 8

Operation of the Early Warning and Response System

Text proposed by the European Commission	*CoR amendment*
	6. The Centre shall coordinate closely, where possible, with regional cross-border contact groups on health.

Reason
The lack of possibilities for exchange hampered adequate responses in cross-border regions during the crisis. Joint cross-border contact groups sharing information with the ECDC and authorities at all levels would allow the competent authorities to take informed decisions.

II. POLICY RECOMMENDATIONS

A. Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU

THE EUROPEAN COMMITTEE OF THE REGIONS

1. stresses that according to Article 168 of the Treaty on the Functioning of the EU (TFEU), "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities", as well as Article 196 thereof which states that "The Union shall encourage cooperation between Member States in order to improve the effectiveness of systems for preventing and protecting against natural or man-made disasters";

2. refers to its commitment, set out in its opinion on the EU4Health programme to prioritise "health at European level and to support regional and local authorities in the fight against cancer and epidemics of diseases in cross-border health cooperation and in the modernisation of health systems";

3. recalls the principle "one health", which means that health is a horizontal topic which must be mainstreamed throughout policy fields and actions of the European Union;

4. takes into consideration the European Commission Work Programme published on 29 January 2020, which states that the European way of life "is about finding common solutions to shared challenges and equipping people with the skills they need, and investing in their health and wellbeing";

5. points out that pursuant to Article 1 of Directive 2011/24, measures should be taken to facilitate access to safe and high-quality cross-border healthcare and promote cooperation on health between Member States, in full respect of national competencies in organising and delivering healthcare;

6. stresses that, according to Eurobarometer data from 2017, over 70% of Europeans expect greater EU involvement in the field of health. Health is – now more than ever – a key concern for EU citizens, who rightfully expect the EU to take a more active role in this area;

7. highlights that the lessons learned from the COVID-19 crisis provide an opportunity for the EU to establish a better interregional framework for monitoring and fighting cross-border health threats for its citizens;

8. points out that, in addition to fighting the pandemic, the EU is faced with the serious problem of health system inequalities and permanent shortage of medical personnel in some parts, which require also our attention;

9. is concerned that the local and regional level is not properly taken into account in the proposal, and that cross-border issues are treated from the perspective of national borders rather than the specific needs of border regions;

Strengthening the role of local and regional authorities in planning and preparing responses

10. points out that 19 of the 27 Member States have chosen to allocate primary responsibility for health, care and public health to the local and regional authorities, and therefore calls for local and regional authorities to be fully involved in the development of national preparedness and response plans, their evaluation and the preparation of responses;

11. points to the need to develop implementation mechanisms at regional level. Effective implementation of national preparedness and response plans depends on the extent to which national governments involve the regional level;

12. welcomes the proposal of the European Commission to organise stress-tests of the health systems in Member States in order to ensure the functioning of the Union preparedness and response plan. Recalls that these stress-tests should fully involve, depending on their competences, regions and cities in the Member States concerned;

13. welcomes the Commission's idea of organising training for healthcare staff in the development and implementation of national preparedness plans, with a view to boosting crisis preparedness, including through the use of digital tools; at the same time, considers that this training should cover the staff of local and regional authorities responsible for health, when these authorities have significant public health responsibilities;

14. highlights the need for flexibility in combining top-down activities with local and regional knowledge and actions;

15. stresses that the involvement of citizens and local authorities would allow for more effective resilience to threats. This process should also involve practitioners, who may have a different perspective to legislators;

16. draws attention to the subject of education and promoting awareness of public health-related issues among the general public. Local and regional authorities play a key role in this area;

17. insists on support for digital connectivity and training in regional health facilities as well as the promotion of telemedicine, with a view to providing more effective care through smart centres and mobile multidisciplinary teams;

Border regions

18. draws attention to the particular role and challenges facing regions along the EU's internal and external borders, whose models of health cooperation between border regions have been developed over many years, and to the benefits that these arrangements bring to local populations;

19. suggests strengthening measures to protect regional and local authorities' health technology systems against potential cyberattacks that could jeopardise the functioning of Member States' healthcare systems. Coordinated planning and centralised guidance is needed to shore up systems that are critical in normal situations but even more so during pandemics;

20. points out that the current crisis has revealed the existing threats to the cross-border healthcare system and has created additional barriers to cooperation between regions. Differences in competences and administrative difficulties arising from different legal provisions have become major challenges in achieving more effective and improved healthcare management in border regions;

21. calls for the swift adoption of appropriate legal solutions, a system of incentives and the promotion of good practices to secure lasting improvements to healthcare cooperation between border regions, in particular by taking into account the possibility or necessity of setting up, within the framework of national preparedness and response plans, interregional, cross-border contact groups, which would prepare and coordinate actions in the regions on both sides of the border in the event of a health threat emerging;

22. stresses that patients seeking care abroad mainly do so in the neighbouring region, making border region cooperation a key element for success;

23. suggests creating the "status" of cross-border healthcare professional in order to facilitate the mobility of medical staff; thinks that to facilitate the mobility of medical staff within Europe it would make sense to enhance the system of mutual recognition of professional qualifications and promote uniform training structures;

24. calls, therefore, on the Commission to put forward a proposal to ensure a minimum level of permeability of borders and related cross-border cooperation in the field of health in order to

maintain or, where necessary, improve the provision of services in this area, including in crisis situations, as has been the case with the COVID-19 pandemic;

25. suggests promoting the conclusion of permanent health cooperation agreements between the competent authorities of the appropriate levels in various countries in order to ensure the exchange of patients in crisis situations. These agreements must also take account of the fact that the EU has common borders with third countries;

B. Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control

THE EUROPEAN COMMITTEE OF THE REGIONS

26. welcomes the proposal for a consolidated mandate for the European Centre for Disease Prevention and Control (ECDC), as requested in the opinion on the Health Emergency Mechanism;

27. believes that the expansion of the ECDC's remit is crucial in order to develop common EU strategies for dealing with cross-border health threats;

28. recommends that, as part of its new mandate, the ECDC collect data at subnational level and improve cooperation between border regions and transit hubs in situations involving cross-border health threats;

29. highlights that close cooperation with the ECDC will contribute to better preparedness and response planning, reporting and auditing within local and regional authorities, especially in border regions, and calls for the adoption of suitable provisions allowing regional authorities to arrange cross-border responses and coordination more quickly in the event of pandemics;

30. hopes that the ECDC will issue non-binding recommendations and suggestions on risk management, especially with regard to border regions;

31. underlines the importance of capacity to mobilise and deploy the EU Health Task Force to assist local response in Member States;

32. points out that close cooperation between the operational contact points in the Member States and the competent authorities overseeing healthcare units at local and regional level will significantly increase the effectiveness of epidemiological surveillance;

33. stresses that healthcare facilities have the most up-to-date knowledge, including databases on the epidemiological situation; urges, therefore, that the local and regional authorities overseeing them become involved in the preparation and implementation of harmonised systems for the provision of this information;

34. insists on the need for the Member States to agree on a common statistical protocol to allow for comparability of the data on the impact of the COVID-19 crisis and future pandemics. This protocol, to be developed under the joint authority of the ECDC and Eurostat, could rely on data provided at NUTS 2 level to facilitate a policy response integrating the use of European Structural and Investment Funds;

35. believes that the ECDC can ensure epidemiological surveillance via integrated systems enabling real-time surveillance by deploying modern technologies and available artificial intelligence modelling applications.

Brussels, 7 May 2021

The President
of the European Committee of the Regions

Apostolos Tzitzikostas

The Secretary-General
of the European Committee of the Regions

Petr Blížkovský

III. PROCEDURE

Title	Opinion on *Cross-border health threats and the mandate of the European Centre for Disease Prevention and Control*
Reference document	COM(2020) 726 final COM(2020) 727 final
Legal basis	Article 307(1) TFEU
Procedural basis	
Date of Council/EP referral/ Date of Commission letter	11 November 2020
Date of Bureau/President's decision	
Commission responsible	Commission for Natural Resources (NAT)
Rapporteur	Olgierd Geblewicz (PL/EPP), Marshal of the Zachodniopomorskie region
Analysis	15 December 2020
Discussed in commission	29 January 2021
Date adopted by commission	22 March 2021
Result of the vote in commission (majority, unanimity)	majority
Date adopted in plenary	7 May 2021
Previous Committee opinions	
Date of subsidiarity monitoring consultation	