










# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2020/0320(COD) Awaiting Parliament's position in 1st reading
European Centre for Disease Prevention and Control Amending Regulation 2004/851 <a href="#">2003/0174(COD)</a>	
Subject 4.20.01 Medicine, diseases	
Legislative priorities <a href="#">Joint Declaration 2021</a>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 <a href="#">Environment, Public Health and Food Safety</a>	 <a href="#">KOPCIŃSKA Joanna</a> Shadow rapporteur	14/12/2020
		 <a href="#">KANEV Radan</a>  <a href="#">RÓNAI Sándor</a>  <a href="#">ȘTEFĂNUĂ Nicolae</a>  <a href="#">MÉLIN Joëlle</a>	
	Committee for opinion	Rapporteur for opinion	Appointed
	 <a href="#">Budgets</a>	 <a href="#">HERBST Niclas</a>	02/12/2020
Council of the European Union	Commission DG	Commissioner	
European Commission	<a href="#">Health and Food Safety</a>	KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events			
14/12/2020	Committee referral announced in Parliament, 1st reading		
29/06/2021	Vote in committee, 1st reading		
28/07/2021	Committee report tabled for plenary, 1st reading	<a href="#">A9-0253/2021</a>	
13/09/2021	Debate in Parliament		

14/09/2021	Decision by Parliament, 1st reading	<a href="#">T9-0376/2021</a>	Summary
14/09/2021	Matter referred back to the committee responsible		

### Technical information

Procedure reference	2020/0320(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2004/851 <a href="#">2003/0174(COD)</a>
Legal basis	Treaty on the Functioning of the EU TFEU 168-p5
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a> <a href="#">European Committee of the Regions</a>
Stage reached in procedure	Awaiting Parliament's position in 1st reading
Committee dossier	ENVI/9/04625

### Documentation gateway

Legislative proposal		<a href="#">COM(2020)0726</a>	11/11/2020	EC	Summary
Committee draft report		<a href="#">PE681.065</a>	25/02/2021	EP	
Amendments tabled in committee		<a href="#">PE691.216</a>	13/04/2021	EP	
Committee opinion	<b>BUDG</b>	<a href="#">PE663.222</a>	03/05/2021	EP	
Committee of the Regions: opinion		CDR5624/2020	07/05/2021	CofR	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A9-0253/2021</a>	28/07/2021	EP	
Text adopted by Parliament, partial vote at 1st reading/single reading		<a href="#">T9-0376/2021</a>	14/09/2021	EP	Summary

## European Centre for Disease Prevention and Control

**PURPOSE:** to reinforce the mandate of the European Centre for Disease Prevention and Control (ECDC) addressing surveillance, preparedness, early warning and response under a strengthened EU health security framework.

**PROPOSED ACT:** Regulation 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:** the EU is committed to protect and improve human health, in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health.

However, the COVID-19 pandemic has revealed shortcomings in the EUs mechanisms for managing health threats. The proposal builds on lessons learnt during the COVID-19 crisis, and proposes to strengthen the existing Union level structures and mechanisms for improved levels of protection, prevention, preparedness and response, against all health hazards across the EU.

The proposal is part of a package of closely associated measures that aim to reinforce the [crisis preparedness and response](#) and enhance the role of the [European Medicines Agency](#) (EMA). Together, they form part of the EUs overall health response to COVID-19 as well as an improved crisis management framework.

**CONTENT:** the proposal aims to amend the Centres founding regulation in order to reinforce its mandate so that it may support the Commission and Member States in the following areas:

- epidemiological surveillance via integrated systems enabling real-time surveillance preparedness and response planning, reporting and auditing situational awareness: rapid digitalisation of integrated surveillance systems;
- better preparedness in Member States: develop prevention and response plans against future epidemics and stronger capacities for integrated rapid epidemic and outbreak response;
- reinforced measures to control epidemics and outbreaks: provision of nonbinding recommendations for risk management;
- reinforced capacity and to identify population groups at risk and in need of targeted prevention and response measures;
- building up the key competences for health protection in Member States: the Centre will be tasked with coordinating a new network of Union reference laboratories for public health and a new network of national services supporting transfusion, transplantation and medically assisted reproduction;
- expanding work on the prevention of communicable diseases and specific health issues, e.g., antimicrobial resistance, vaccination and biosecurity;
- reinforcing the contribution to the EUs international cooperation and development and EU commitment to global health security preparedness.

#### Budgetary implications

The financial impact of this proposal on the EU budget should be part of the next Multiannual Financial Framework 2021-2027. The budgetary implications should relate mainly to:

- setting-up a new vaccine monitoring platform hosted jointly by the European Medicines Agency and the Centre;
- new networks on Union reference laboratories and on transfusion, transplantation and medically assisted reproduction;
- reinforcing surveillance systems and the Early Warning and Response System;
- monitoring and assessing health systems capacity and identifying population groups at risk and in need of targeted prevention and response measures;
- creating a EU Health Task Force to support countries with preparedness strengthening and quickly intervene in a health crisis;
- improving international collaboration and gathering of regional/national intelligence.

## European Centre for Disease Prevention and Control

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The European Parliament adopted by 598 votes to 84, with 13 abstentions, amendments to the 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 (ECDC).

The matter was referred back to the committee responsible for interinstitutional negotiations.

The main amendments adopted in plenary concern the following points:

#### ECDCs mandate

The regulation should aim to extend the Centre's mission and tasks to strengthen its capacity to provide the necessary scientific expertise and support actions against serious cross-border health threats in the EU to meet the need for a rapid, better coordinated and coherent response to new emerging health threats.

Members want to ensure that the ECDC's mandate is extended beyond communicable diseases to also cover major non-communicable diseases, such as cardiovascular and respiratory diseases, cancer, diabetes and mental illness.

EU Member States should develop national preparedness and response plans and provide timely, comparable and high-quality data so that the Centre can rapidly assess risks, including through epidemiological modelling and forecasting.

#### Mission and tasks

The Centres mission should be to:

- identify, assess, report and, where appropriate, ensure that information is presented in an easily accessible way on current and emerging threats to human health from communicable diseases and relevant major non-communicable diseases and health issues in collaboration with competent bodies of the Member States or on its own initiative, through the dedicated network;
- provide recommendations and support in coordinating the response at Union and national levels, as well as at interregional and regional level, where appropriate. In providing such recommendations, the Centre shall take into account existing national crisis management plans and the respective circumstances of each Member State.

The amending Regulation of the Centre should prioritise pragmatic solutions to improve transparent cooperation and exchange of information, expertise and best practice between Member State authorities and the Commission, the Health Security Committee and the Centre itself, and other EU institutions and agencies, such as the European Medicines Agency (EMA) and the future European Health Emergency Response and Preparedness Authority (HERA). This increased cooperation would allow for better preparedness and coordination of the response plans.

Specifically, the Centre should:

- monitor the capacity of health systems to manage communicable disease threats and other specific health problems on the basis of common indicators;
- organise regular visits to the Member States to assess health systems' capacity to manage health crises and ad hoc inspections to the Member States to verify preparedness and response plans;
- organise case-by-case source inspections in Member States to provide additional support and monitor progress in implementing and complying with the obligations set out in the Regulation, where necessary taking into account the results of stress tests;
- assist in monitoring the national response to the major communicable diseases in order to measure progress in the control of these diseases across the EU;

- inform the general public in an effective and transparent way about current and emerging health risks;
- create a public database of recognised national competent bodies and their public health experts operating within the Centre's remit;
- ensure that its processing operations comply with data protection principles.

In pursuing its mission, the Centre should take full account of the responsibilities and competences of the Member States, the Commission and other Union bodies or agencies, and of the responsibilities of international organisations active within the field of public health, in particular the WHO, to ensure coordination, comprehensiveness, coherence, consistency and complementarity of action.

#### Additional resources

The capacity of the Centre to implement new tasks will depend on the level of financial assistance available from the Union, as well as on the internal and external human resources available. In order to be able to fulfil the new tasks entrusted to it as a result of the COVID-19 pandemic, the Centre will need increased funding and more employees. Members therefore proposed to increase the Centres funding and staffing at the earliest opportunity.