## Basic information

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|---|---|
| **2020/0320(COD)**<br>COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | Procedure completed |
| European Centre for Disease Prevention and Control<br>Amending Regulation 2004/851 2003/0174(COD)<br>**Subject**<br>4.20.01 Medicine, diseases<br>**Legislative priorities**<br>Joint Declaration 2021 | |

## Key players

### European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | KOPCIŃSKA Joanna (ECR) | 14/12/2020 |
| | Shadow rapporteur<br>KANEV Radan (EPP)<br>RÓNAI Sándor (S&D)<br>ȘTEFĂNUȚĂ Nicolae (Renew)<br>MÉLIN Joëlle (ID) | |

| Committee for opinion | Rapporteur for opinion | Appointed |
|---|---|---|
| BUDG Budgets | HERBST Niclas (EPP) | 02/12/2020 |

### Council of the European Union

### European Commission

| Commission DG | Commissioner |
|---|---|
| Health and Food Safety | KYRIAKIDES Stella |

European Economic and Social Committee

European Committee of the Regions

## Key events

| Date | Event | Reference | Summary |
|---|---|---|---|
| 11/11/2020 | Legislative proposal published | COM(2020)0726 | Summary |
| 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 | A9-0253/2021 | |
| 13/09/2021 | Debate in Parliament | | |
| 14/09/2021 | Decision by Parliament, 1st reading | T9-0376/2021 | Summary |
| 14/09/2021 | Matter referred back to the committee responsible for interinstitutional negotiations | | |
| 13/01/2022 | Approval in committee of the text agreed at 1st reading interinstitutional negotiations | | |
| 03/10/2022 | Debate in Parliament | | |
| 04/10/2022 | Decision by Parliament, 1st reading | T9-0332/2022 | Summary |
| 04/10/2022 | Results of vote in Parliament | | |
| 24/10/2022 | Act adopted by Council after Parliament's 1st reading | | |
| 23/11/2022 | Final act signed | | |
| 06/12/2022 | Final act published in Official Journal | | |

## Technical information

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| **Procedure reference** | 2020/0320(COD) |
| **Procedure type** | COD - Ordinary legislative procedure (ex-codecision procedure) |
| **Procedure subtype** | Legislation |
| **Legislative instrument** | Regulation |
| **Amendments and repeals** | Amending Regulation 2004/851 2003/0174(COD) |
| **Legal basis** | Treaty on the Functioning of the European Union TFEU 168-p5 |
| **Other legal basis** | Rules of Procedure EP 165 |
| **Mandatory consultation of other institutions** | European Economic and Social Committee<br>European Committee of the Regions |
| **Stage reached in procedure** | Procedure completed |
| **Committee dossier** | ENVI/9/04625 |

## Documentation gateway

**European Parliament**

| Document type | Committee | Reference | Date | Summary |
|---|---|---|---|---|
| Committee draft report | | PE681.065 | 25/02/2021 | |
| Amendments tabled in committee | | PE691.216 | 13/04/2021 | |

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|---|---|---|---|---|
| Committee opinion | BUDG | PE663.222 | 03/05/2021 | |
| Committee report tabled for plenary, 1st reading/single reading | | A9-0253/2021 | 28/07/2021 | |
| Text adopted by Parliament, partial vote at 1st reading /single reading | | T9-0376/2021 | 14/09/2021 | Summary |
| Text adopted by Parliament, 1st reading/single reading | | T9-0332/2022 | 04/10/2022 | Summary |

**Council of the EU**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Draft final act | 00082/2021/LEX | 23/11/2022 | |

**European Commission**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Legislative proposal | COM(2020)0726 | 11/11/2020 | Summary |
| Commission response to text adopted in plenary | SP(2022)623 | 07/12/2022 | |

**National parliaments**

| Document type | Parliament /Chamber | Reference | Date | Summary |
|---|---|---|---|---|
| Contribution | PT_PARLIAMENT | COM(2020)0726 | 15/02/2021 | |
| Contribution | CZ_SENATE | COM(2020)0726 | 24/03/2021 | |
| Contribution | IT_SENATE | COM(2020)0726 | 19/05/2021 | |

**Other institutions and bodies**

| Institution/body | Document type | Reference | Date | Summary |
|---|---|---|---|---|
| EESC | Economic and Social Committee: opinion, report | CES5933/2020 | 27/04/2021 | |
| CofR | Committee of the Regions: opinion | CDR5624/2020 | 07/05/2021 | |

**Additional information**

| Source | Document | Date |
|---|---|---|
| European Commission | EUR-Lex | |

**Final act**

Regulation 2022/2370
OJ L 314 06.12.2022, p. 0001 

# European Centre for Disease Prevention and Control

2020/0320(COD) - 14/09/2021 - Text adopted by Parliament, partial vote at 1st reading/single reading

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:

***ECDC's 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 Centre’s 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 Centre's funding and staffing at the earliest opportunity.

# European Centre for Disease Prevention and Control

2020/0320(COD) - 11/11/2020 - Legislative proposal

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 EU's 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 EU's overall health response to COVID-19 as well as an improved crisis management framework.

CONTENT: the proposal aims to amend the Centre's 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 EU's 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

2020/0320(COD) - 04/10/2022 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 542 votes to 43, with 9 abstentions, a legislative resolution on 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 European Parliament's position at first reading under the ordinary legislative procedure amends the Commission proposal as follows:

***Expanded mandate***

The Regulation aims to expand the mission and tasks of the **European Centre for Disease Prevention and Control** (ECDC) to enhance the Centre's capacity to provide the required scientific expertise and to support actions which combat serious cross-border threats to health in the Union. The

Centre's actions should be consistent with the '**One Health**' approach, recognising the interconnections between human and animal health and the environment, as many outbreaks of communicable diseases are of zoonotic origin.

*Mission and work of the Centre*

The mission of the Centre will be to:

- **identify and assess current and emerging threats** to human health from communicable diseases and related special health issues, to report thereon and, where appropriate, to ensure that information thereon is presented in an easily accessible way. The Centre will act in collaboration with competent bodies of the Member States or on its own initiative, through a dedicated network;

- **provide science-based recommendations** and support in coordinating the response at Union and national levels, as well as at cross-border interregional and regional level, to such threats, where appropriate. In providing such recommendations, the Centre shall, where necessary, cooperate with Member States and take into account existing national crisis management plans and the respective circumstances of each Member State.

The Centre will perform the following tasks:

- search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, using the most effective technologies, such as, where relevant, artificial intelligence, respecting European standards regarding ethical aspects;

- coordinate **standardisation of data collection procedures**, and validation, analysis and dissemination of data at Union level;

- monitor, in close cooperation with Member States, their health system capacity and support the collection of data on their health system capacity;

- organise **on-site visits** in Member States, on a case-by-case basis, in close collaboration with the Member States concerned;

- monitor the capacity of Member States' health systems to **detect, prevent, respond to and recover from outbreaks** of communicable diseases;

- provide scientific and technical assistance to help Member States **develop their detection and sequencing capacities**, in particular those Member States that do not have sufficient capacities;

- ensure **interoperability** of automated applications and other digital tools that support cross-border public health activities;

- **mitigate the risks**, such as those related to biased datasets, flawed system design, lack of quality data and overdependence on automated decision-making.

The Centre will cooperate with the European Commission, national authorities, EU bodies and international organisations, in particular the WHO, to ensure effective coherence and synergies between their respective activities.

*Obligations of Member States*

Member States should coordinate and collaborate with the Centre in relation to the mission and tasks set out in the Regulation, by:

- reporting regularly to the Centre, in accordance with agreed timetables, data on the surveillance of communicable diseases (such as HIV, viral hepatitis B and C and tuberculosis), specific related health issues (i.e. antimicrobial resistance and health care associated infections) and other serious transboundary health threats;

- preparing national prevention, preparedness and response plans;

- facilitating the digitalisation of the data collection and the data communication process between national and European surveillance systems to provide the necessary information in a timely manner.

*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. To be able to fulfil the new tasks entrusted to it as a result of the COVID19 pandemic, the Centre will need sufficient funding and staffing. Project-oriented funds, such as those allocated under the EU4Health Programme are **not sufficient** to respond to the Centre's needs in the future.

# European Centre for Disease Prevention and Control

2020/0320(COD) - 06/12/2022 - Final act

PURPOSE: to extend the mission and tasks of the European Centre for Disease Prevention and Control (ECDC) to strengthen its capacity to provide the necessary scientific expertise and to support actions against serious cross-border health threats in the Union.

LEGISLATIVE ACT: Regulation (EU) 2022/2370 of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control.

CONTENT: this Regulation amending Regulation (EC) No 851/2004 **expands the mission and tasks of the European Centre for Disease Prevention and Control** (ECDC) in order to strengthen the Centre's capacity to provide the required robust and independent scientific expertise and to support

actions relevant to the planning of prevention, preparedness and response to serious cross-border health threats in the Union. The updated mandate of the ECDC is part of the broader package on a European Health Union.

*Mission and work of the Centre*

To strengthen the capacity of the EU and the Member States to protect human health through the prevention and control of communicable human diseases and related special health issues, the Centre will:

- **identify, assess and communicate on current and emerging threats** to human health from communicable diseases and related special health issues and, where appropriate, to ensure that information on them is presented in a readily accessible manner. The Centre will act in collaboration with the competent bodies in the Member States or on its own initiative through a dedicated network;

- **make science-based recommendations and help coordinate responses to such threats** at EU and national level, as well as at inter-regional and regional cross-border level where appropriate. In making such recommendations, the Centre will cooperate, as appropriate, with Member States and take into account existing national crisis management plans and the individual situation of each Member State.

The Centre will respect the responsibilities of the Member States, the Commission and other Union bodies or agencies, and the responsibilities of third countries and international organisations active within the field of public health, in particular the WHO, in order to ensure that there is comprehensiveness, coherence and complementarity of action and that actions are coordinated. It will also support the work of the Health Security Committee (HSC), established by Council Regulation (EU) 2022/2371 on serious transboundary health threats.

*Expanded mandate*

The Regulation strengthens the mandate of the ECDC so that it can better support the Commission and the Member States, in particular in the following areas:

- providing epidemiological information and analysis, modelling, epidemiological forecasting and anticipation, as well as timely **risk assessments and recommendations**, based on scientific evidence, which provide options for the prevention and control of communicable diseases;

- monitor, in close cooperation with the Member States, **the capacity of Member States' health systems to detect, prevent, respond to and recover from outbreaks of communicable diseases**, identify gaps and make science-based recommendations to strengthen health systems;

- develop secure and interoperable digital platforms and applications to support epidemiological surveillance at EU level and provide Member States with scientific and technical advice to set up integrated epidemiological surveillance systems;

- identify **emerging health threats** and monitor and report on trends in communicable diseases;

- contribute to strengthening the capacity within the EU to diagnose, detect, identify and characterise infectious agents that may threaten public health, by ensuring the operation of a specialised network of EU public health reference laboratories;

- cooperate with Member States to safeguard patients in need of treatment using a substance of human origin from the transmission of such a communicable disease. The Centre should therefore establish and operate a network of services supporting the use of substances of human origin;

- enhance preparedness and response capacity at EU and national level by providing scientific and technical expertise to Member States and the Commission;

- mobilise and deploy outbreak assistance teams, known as the **EU Health Task Force**, to assist in local responses to disease outbreaks and collect field data;

- **inform the general public** in an effective and transparent manner about current and emerging health risks.

*Obligations of the Member States*

Member States will coordinate and cooperate with the Centre in all its missions and tasks by:

- communicating regularly to the Centre data on the surveillance of communicable diseases, related special health issues and other serious cross-border threats to health;

- preventing, responding to and recovering from outbreaks of communicable diseases;

- notifying the Centre of any serious cross-border threats to health, as soon as detected, through the Early Warning and Response System (EWRS);

- identifying, within the scope of the mission of the Centre, competent bodies and public health experts and organisations that could be available to assist in the Union response to serious cross-border threats to health;

- preparing national prevention, preparedness and response plans;

- facilitating the digitalisation of data collection and the data communication process between national and European surveillance systems.

As **personal data** concerning health are considered sensitive data, any processing of personal data under the Regulation by Member States or the Centre will be subject to the General Data Protection Regulation (GDPR).

ENTRY INTO FORCE: 26.12.2022.