



2020/0320(COD)

29.4.2021

OPINION

of the Committee on Budgets

for the Committee on the Environment, Public Health and Food Safety

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 (COM(2020)0726 – C9-0366/2020 – 2020/0320(COD))

Rapporteur for opinion: Niclas Herbst

PA_Legam

SHORT JUSTIFICATION

The proposed changes to Regulation (EC) No 851/2004 of the European Parliament and of the Council¹, can be summarized in 3 parts:

1. A reinforced mandate for the European Centre for Disease Prevention and Control (ECDC) addressing surveillance, preparedness, early warning and response under a strengthened EU health security framework.
2. Consistency of the ECDC founding regulation with other Union instruments and with the proposal for an amending Regulation on serious cross-border threats to health.²
3. Compliance with the ‘common approach’ for decentralised agencies, as laid down in the ‘Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralized agencies’³.

Your BUDG standing rapporteur for agencies, has concentrated the analysis on point 3 of the proposed changes, in particular the proposed changes on governance, financial procedures, accountability and transparency. In addition, the budgetary implications of this enlarged mandate have been assessed. The assessment is based in particular on the following reference documents:

- The Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council⁴
- Joint statement of the European Parliament, the Council and the Commission on decentralised agencies of 19 July 2012 and the Common Approach
- European Parliament resolution of 14 February 2019 on the implementation of the legal provisions and the Joint Statement ensuring parliamentary scrutiny over decentralised agencies (Schoepflin report)⁵
- ECA Special Report - Future of EU agencies⁶
- Policy department C study - EU agencies and conflict of interest⁷

¹ OJ L 142, 30.4.2004, p. 1

² COM(2020) 727 final

³ https://europa.eu/europeanunion/sites/europa.eu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R0715>

⁵ https://www.europarl.europa.eu/doceo/document/TA-8-2019-0134_EN.html

⁶

https://www.eca.europa.eu/Lists/ECADocuments/SR20_22/SR_Future_of_EU_Agencies_EN.pdf

⁷

[https://www.europarl.europa.eu/RegData/etudes/STUD/2020/621934/IPOL_STU\(2020\)621934_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2020/621934/IPOL_STU(2020)621934_EN.pdf)

- MFF agreement

Overall, your rapporteur welcomes the proposed changes as there are largely in line with the common approach developed on agencies and the requests made by Parliament since the founding regulation of the ECDC has been established in 2004. In particular, the proposed changes in Article 14 (Management Board) introducing of draft single programming documents and multiannual work programmes are in line with the requests made in the EP Schoepflin report. These tools will, also according to the ECA finding, allow to further develop a performance-oriented management and monitoring framework. The proposed amendments to the Commission proposal are therefore mainly only to clarify some points further.

Uncertainty on the budget

Should the co-legislator decide on a reinforced mandate of ECDC, it will obviously have a financial impact on the Union budget 2021-2027. According to the Commission's proposal, the budgetary implications are mainly related to the following objectives:

- setting-up a new vaccine monitoring platform hosted jointly by the European Medicines Agency and the Centre;
- preparedness and response planning activities including modelling, anticipation, monitoring and assessment;
- 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.

According to the legislative financial statement, the Commission intends to address this with a reprogramming of the relevant heading in the multiannual financial framework. The proposed additional budget for ECDC may be financed by a reduction of EU4Health budget in future years. Furthermore, given the on-going reflection on the creation of an European Health Emergency preparedness and Response Authority (HERA)⁸, a proposal planned for the 4th quarter of 2021, the Commission mentions that it retains the right to adjust the proposed resources and staff allocation when a precise proposal for HERA is tabled.

Your rapporteur estimates that in the coming months, it will be important to deepen the understanding of the interplays between EU4Health, EMA, ECDC and the new HERA in order to assess if the limited financial resources within Heading 2 are sufficient to meet the ambition and how the resources could be used in the most efficient ways.

⁸ <https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-biomedical-research-and-development-agency>

AMENDMENTS

The Committee on Budgets calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) On 11 March 2020, the World Health Organization (WHO) declared the novel coronavirus COVID-19 outbreak a global pandemic. From the challenges experienced in responding to the pandemic it became clear that the Centre's role in the Union's framework for health crisis preparedness and response should be strengthened.

Amendment

(3) On 11 March 2020, the World Health Organization (WHO) declared the novel coronavirus COVID-19 outbreak a global pandemic. From the challenges experienced in responding to the pandemic it became clear that the Centre's role in the Union's framework for health crisis preparedness and response should be strengthened ***in order to better use the potential of the Union's and the Member States' capacities to respond to future pandemics.***

Amendment 2

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Action taken at Union level is targeted at delivering added value, in support of and respect for the Member States' competences. Strengthening the existing Union level structures and expertise, ensuring that coherence and synergies are achieved, and avoiding duplication are essential.

Amendment 3

Proposal for a regulation

Recital 3 b (new)

Text proposed by the Commission

Amendment

(3b) It is essential that the relationship between the ECDC, EU4Health, the European Medicines Agency and the WHO be effective, coherent and seamless and that duplication and overlaps, both as regards mandates and budgets, are avoided.

Amendment 4

Proposal for a regulation

Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) One of the lessons of the COVID-19 pandemic was that the Centre needs to be strengthened and that there is a need for more coordination at Union level of disease prevention and control mechanisms. Good coordination at Union level of the prevention and control of diseases that are cross-border health threats is essential. To this end, the Centre should have the ability to evaluate on the ground how national coordinating bodies apply this Regulation.

Amendment 5

Proposal for a regulation

Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) The fulfilment of the Centre's tasks and missions depends on it having an adequate budget and the existence of good cooperation and compliance on the part of the Member States. In order to keep track of Member States' progress in implementing the obligations contained in the Regulation, the Centre should be allowed to carry out inspections on the ground.

Amendment 6

Proposal for a regulation Recital 10

Text proposed by the Commission

(10) To strengthen the capacity of the Union and Member States to assess the epidemiological situation and perform accurate risk assessment and response, the Centre should in particular monitor and report on trends in communicable diseases, support and facilitate evidence-based response action, provide recommendations for improvement of communicable disease prevention and control programmes established at the national and Union level, monitor and assess the capacity of national health systems for diagnosis, prevention and treatment of communicable diseases, including in a gender-sensitive way, identify population groups at risk requiring specific measures, analyse the correlation of disease incidence with societal and environmental factors, and identify risk factors for transmission and disease severity of communicable diseases, and identify research needs and priorities. The Centre should work with nominated national focal points for surveillance, forming a network that strategically advises the Centre on such matters and would promote the use of enabling sectors, such as EU space data and services.

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Amendment 7

Proposal for a regulation Recital 14

Text proposed by the Commission

(14) The Centre should enhance preparedness and response capabilities at

Amendment

(14) The Centre should enhance preparedness and response capabilities at

national and Union level by providing scientific and technical expertise to the Member States and the Commission. In this context the Centre, in close collaboration with the Member States and the Commission, should carry out various actions, including the development of Union and national preparedness and response plans and preparedness monitoring and evaluation frameworks, provide recommendations on capacities to prevent, prepare and respond to disease outbreaks and on the strengthening of national health systems. The Centre should broaden its collection and analysis of data in terms of epidemiological surveillance and related special health issues, progression of epidemic situations, unusual epidemic phenomena or new diseases of unknown origin, including in third countries, molecular pathogen data and health systems data. To this end, the Centre should ensure appropriate datasets as well as the procedures to facilitate consultation and data transmission and access, carry out scientific and technical evaluation of prevention and control measures at Union level and work with agencies, competent bodies and organisations operating in the field of data collection.

national and Union level by providing scientific and technical expertise to the Member States and the Commission. In this context the Centre, in close collaboration with the Member States and the Commission, should carry out various actions, including the development of Union and national preparedness and response plans and preparedness **and broader** monitoring and evaluation frameworks **of the epidemiological situation in the Union**, provide recommendations on capacities to prevent, prepare and respond to disease outbreaks and on the strengthening of national health systems. The Centre should broaden its collection and analysis of data in terms of epidemiological surveillance and related special health issues, progression of epidemic situations, unusual epidemic phenomena or new diseases of unknown origin, including in third countries, molecular pathogen data and health systems data. To this end, the Centre should ensure appropriate datasets as well as the procedures to facilitate consultation and data transmission and access, carry out scientific and technical evaluation of prevention and control measures at Union level and work with agencies, competent bodies and organisations operating in the field of data collection.

Amendment 8

Proposal for a regulation

Recital 22

Text proposed by the Commission

(22) Since the objectives of this Regulation to expand the mission and tasks of the Centre in order 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 cannot be sufficiently achieved by the Member States

Amendment

(22) Since the objectives of this Regulation to expand the mission and tasks of the Centre in order 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 cannot be sufficiently achieved by the Member States

but can rather, by reason of the cross-border nature of the health threats and the need for rapid, coordinated and coherent response, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

but can rather, by reason of the cross-border nature of the health threats and the need for rapid, **better** coordinated and coherent response **to new emerging health threats**, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Amendment 9

Proposal for a regulation Recital 22 a (new)

Text proposed by the Commission

Amendment

(22a) By giving new objectives and responsibilities to the Centre, it will reinforce the Union's capacities to support preparedness, surveillance, risk assessment, early warning and rapid response to face future cross-border health threats. Such new objectives and responsibilities will have a financial impact on the multiannual financial framework 2021-27 and therefore should be accompanied by additional resources to be available under the different flexibility instruments of the annual budgetary procedures. Such additional resources would ensure that the financial resources of activities or programmes already foreseen in the domain of public health, such as EU4Health, will not be adversely impacted;

Amendment 10

Proposal for a regulation Recital 22 b (new)

(22b) *The Centre should promote synergies with other Union bodies and agencies, such as the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Environment Agency (EEA), and the European Health Emergency Preparedness and Response Authority (HERA), so to ensure that there is effective and more coordinated Union preparedness and response in the event of health crises;*

Amendment 11

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 1 – subparagraph 3

Text proposed by the Commission

Amendment

In pursuing its mission, the Centre shall take full account of the responsibilities 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 order to ensure comprehensiveness, coherence and complementarity of action.

In pursuing its mission, the Centre shall 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 order to ensure comprehensiveness, coherence and complementarity of action, ***to avoid duplication and to ensure that the principle of subsidiarity is respected.***

Amendment 12

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. The Centre shall, within its

2. The Centre shall, within its

financial capacity and mandate, perform the following tasks:

mandate, perform the following tasks:

Amendment 13

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 2 – point e

Text proposed by the Commission

(e) monitor health systems' capacity relevant to the management of communicable disease threats and other special health issues;

Amendment

(e) monitor ***and inspect*** health systems' capacity relevant to the management of communicable disease threats and other special health issues;

Amendment 14

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 2 – point j a (new)

Text proposed by the Commission

Amendment

(ja) provide timely information to the Commission, the Member States, Union agencies and international organisations active within the field of public health;

Amendment 15

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 2 – point j b (new)

Text proposed by the Commission

Amendment

(jb) organise inspections on the ground in each Member State, to be carried out by an inspector from the body of inspectors appointed by the Centre for a period of 4 years. Each Member State shall carry out at least one inspection

within the 4-year period, but more inspections can be mandated on a case-to-case basis to offer additional support and monitor progress. The results of the inspection in a Member State shall be submitted in a report to the European Commission, the European Parliament, the European Council and relevant EU agencies. The report shall assess the Member State's compliance with the obligations imposed by the Regulation and recommendations from the inspectors concerning how to improve the situation.

Amendment 16

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. *The Member States shall, without delay, coordinate and collaborate with the Centre in all the missions and tasks mentioned in Article 3.*

Amendment 17

Proposal for a regulation

Article 1 – paragraph 1 – point 3

Regulation (EC) No 851/2004

Article 4 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) *provide the financial means and digital infrastructure necessary for the coordinating competent body and facilitate the mission of the Centre by providing the information requested in a timely manner;*

Amendment 18

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. *The Centre shall provide technical assistance to Union laboratories so as to enable them to develop their detection and sequencing capacities, especially in Member States that do not have the necessary capacity.*

Amendment 19

Proposal for a regulation
Article 1 – paragraph 1 – point 5
Regulation (EC) No 851/2004
Article 5a – paragraph 2

Text proposed by the Commission

Amendment

2. The Centre shall develop a framework for the prevention of communicable diseases and special issues, including vaccine preventable diseases, antimicrobial resistance, health education, health literacy and behaviour change.

2. *In close cooperation with the competent authorities in the Member States, the European Medicines Agency and other relevant Union bodies and agencies, as well as with international organisations,* the Centre shall develop a framework for the prevention of communicable diseases and special issues, including vaccine preventable diseases, antimicrobial resistance, health education, health literacy and behaviour change.

Amendment 20

Proposal for a regulation
Article 1 – paragraph 1 – point 15 – point a
Regulation (EC) No 851/2004
Article 12 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

The Centre shall ensure that the public or any interested party is rapidly given objective, reliable, evidence-based and

The Centre shall ensure that the public or any interested party is rapidly given objective, reliable, evidence-based and

easily accessible information with regard to the results of its work. The Centre shall make available information for the general public, *including* through a dedicated website. It shall also publish its opinions produced in accordance with Article 6.;

easily accessible information with regard to the results of its work. The Centre shall make available information for the general public, *in particular* through a dedicated website *available in all official languages of the Union*. It shall also publish its opinions produced in accordance with Article 6.;

Amendment 21

Proposal for a regulation

Article 1 – paragraph 1 – point 16 – point b

Regulation (EC) No 851/2004

Article 14 – paragraph 5 – point e

Text proposed by the Commission

(e) adopt a draft single programming document in line with Article 32 of the Commission Delegated Regulation (EU) 2019/715* and the related Commission's guidelines for the Single Programming Document**;

Amendment

(e) ***by 30 November of each year,*** adopt a draft single programming document in line with Article 32 of the Commission Delegated Regulation (EU) 2019/715* and the related Commission's guidelines for the Single Programming Document**. ***The single programming document shall be adopted where a positive opinion has been given by the Commission and, as regards multiannual programming, after consulting the European Parliament and the Council.***

Justification

Addition in line with wording in other basic acts of agencies.

Amendment 22

Proposal for a regulation

Article 1 – paragraph 1 – point 18

Regulation (EC) No 851/2004

Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. Before appointment, the candidate nominated by the Management Board

shall be invited without delay to make a statement before the European Parliament and to answer questions put by members of that institution.

Justification

This paragraph exist in Regulation (EC) No 851/2004 and should be maintained here.

Amendment 23

Proposal for a regulation

Article 1 – paragraph 1 – point 23 – point c

Regulation (EC) No 851/2004

Article 23 – paragraph 8

Text proposed by the Commission

8. The director shall send the Court of Auditors a reply to its observations by 30 September at the latest. The director shall also send this reply to the Management Board and to the Commission.

Amendment

8. The director shall send the Court of Auditors a reply to its observations by 30 September at the latest. The director shall also send this reply to the Management Board, *the European Parliament, the Council* and to the Commission.

Amendment 24

Proposal for a regulation

Article 1 – paragraph 1 – point 23a (new)

Regulation (EC) No 851/2004

Article 24

Present text

Article 24

Application of the Financial Regulation
Article **185** of the Financial Regulation shall apply to the discharge of the Centre's budget, its audits and accounting rules.

Amendment

(23a) Article 24 is replaced by the following:

Article 24

Application of the Financial Regulation
Article **70** of the Financial Regulation shall apply to the discharge of the Centre's budget, its audits and accounting rules.

Justification

Article 24 of the old Regulation has not been amended but the relating reference to the

Financial Regulation is outdated. The Article 70 of Regulation (EU, Euratom) 2018/1046 (the presently applicable FR) is proposed.

Amendment 25

Proposal for a regulation

Article 1 – paragraph 1 – point 28

Regulation (EC) No 851/2004

Article 31 – paragraph 1 – point aa (new)

Text proposed by the Commission

Amendment

(aa) how the Centre has implemented the governance structures referred to in Articles 14, 17 and 18;

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control
References	COM(2020)0726 – C9-0366/2020 – 2020/0320(COD)
Committee responsible Date announced in plenary	ENVI 14.12.2020
Opinion by Date announced in plenary	BUDG 14.12.2020
Rapporteur Date appointed	Niclas Herbst 2.12.2020
Discussed in committee	4.3.2021
Date adopted	12.4.2021
Result of final vote	+: 31 –: 1 0: 5
Members present for the final vote	Rasmus Andresen, Robert Biedroń, Anna Bonfrisco, Olivier Chastel, Lefteris Christoforou, David Cormand, Paolo De Castro, José Manuel Fernandes, Eider Gardiazabal Rubial, Geese Alexandra, Vlad Gheorghe, Valentino Grant, Elisabetta Gualmini, Francisco Guerreiro, Valérie Hayer, Eero Heinäluoma, Niclas Herbst, Monika Hohlmeier, Moritz Körner, Joachim Kuhs, Zbigniew Kuźmiuk, Hélène Laporte, Janusz Lewandowski, Margarida Marques, Silvia Modig, Siegfried Mureşan, Victor Negrescu, Andrey Novakov, Jan Olbrycht, Dimitrios Papadimoulis, Karlo Ressler, Bogdan Rzońca, Nils Torvalds, Nils Ušakovs, Johan Van Overtveldt, Rainer Wieland, Angelika Winzig

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

31	+
ID	Hélène Laporte
PPE	Lefteris Christoforou, José Manuel Fernandes, Niclas Herbst, Monika Hohlmeier, Janusz Lewandowski, Siegfried Mureşan, Andrey Novakov, Jan Olbrycht, Karlo Ressler, Rainer Wieland, Angelika Winzig
Renew	Olivier Chastel, Vlad Gheorghe, Valérie Hayer, Moritz Körner, Nils Torvalds
S&D	Robert Biedroń, Paolo De Castro, Eider Gardiazabal Rubial, Elisabetta Gualmini, Eero Heinäluoma, Margarida Marques, Victor Negrescu, Nils Ušakovs
The Left	Silvia Modig, Dimitrios Papadimoulis
Verts/ALE	Rasmus Andresen, David Cormand, Alexandra Geese, Francisco Guerreiro

1	-
ID	Joachim Kuhs

5	0
ECR	Zbigniew Kuźmiuk, Bogdan Rzońca, Johan Van Overtveldt
ID	Anna Bonfrisco, Grant Valentino

Key To Symbols:

+ : in favour

- : against

0 : abstention