



2020/0320(COD)

23.3.2021

AMENDMENTS

6 - 39

Draft opinion

Niclas Herbst

(PE663.222v01-00)

Amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control

Proposal for a regulation

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

Amendment 6
Hélène Laporte, Joachim Kuhs

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) Since health continues to be a supporting competence of the EU, Member States should remain in charge of their own health policies;

Or. fr

Amendment 7
Hélène Laporte, Joachim Kuhs, Anna Bonfrisco

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) The Commission is called upon to look into the ECDC's tasks and to eliminate overlaps that could result from missions already under way in Member States' agencies;

Or. fr

Amendment 8
Johan Van Overtveldt

Proposal for a regulation
Recital 3

Text proposed by the Commission

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

(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.

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.***

Or. en

Amendment 9
Johan Van Overtveldt

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission

Amendment

(3 a) European action is targeted to delivering added value, in support and respect of the Member States' competences. Strengthening the existing Union level structures and expertise, ensuring coherence and synergies and avoiding duplication are essential.

Or. en

Amendment 10
Johan Van Overtveldt

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission

Amendment

(3 b) The relationship between the ECDC, EU4Health, the European Medicines Agency and the WHO has to be performant, coherent and seamless and needs to avoid duplication and overlap, both regarding the mandate and the budget.

Or. en

Amendment 11
Hélène Laporte, Joachim Kuhs

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) European value added should be constantly established in order to be able to use ECDC diagnoses;

Or. fr

Amendment 12
Hélène Laporte, Joachim Kuhs

Proposal for a regulation
Recital 7

Text proposed by the Commission

Amendment

(7) To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should be tasked to communicate to the Centre data on the surveillance of communicable diseases and other special health issues such as antimicrobial resistance and healthcare-associated infections related to communicable diseases, available scientific and technical data and information relevant to the Centre's mission, to notify the Centre of any serious cross-border threats to health, information on preparedness and response planning and health system capacity, and provide relevant information that may be useful for coordinating the response, as well as identify recognised competent bodies and public health experts available to assist in Union responses to health threats.

(7) To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should be tasked, ***on a voluntary basis and if they deem it necessary***, to communicate to the Centre data on the surveillance of communicable diseases and other special health issues such as antimicrobial resistance and healthcare-associated infections related to communicable diseases, available scientific and technical data and information relevant to the Centre's mission, to notify the Centre of any serious cross-border threats to health, information on preparedness and response planning and health system capacity, and provide relevant information that may be useful for coordinating the response, as well as identify recognised competent bodies and public health experts available to assist in Union responses to health threats.

Or. fr

Amendment 13

Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Vlad Gheorghe, Valérie Hayer

Proposal for a regulation

Recital 8 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 14

Victor Negrescu

Proposal for a regulation

Recital 8 a (new)

Text proposed by the Commission

Amendment

(8 a) These networks should provide the Centre with the necessary data for the swift mitigation of medical supply shortages through joint procurement procedures at Union Level.

Or. en

Amendment 15

Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Vlad Gheorghe, Valérie Hayer

Proposal for a regulation

Recital 8 b (new)

Text proposed by the Commission

Amendment

(8 b) The fulfilment of the Centre's tasks and missions depends on an adequate budget and good cooperation and compliance by the Member States. In order to keep track of Member States' progress in implementing the obligations contained in the Regulation, the Centre may carry out source inspections.

Or. en

Amendment 16
Victor Negrescu

Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

Amendment

(8 b) To retrieve medical information from data in one or more Member States with a single query a European interconnected database should be foreseen, making data more accessible.

Or. en

Amendment 17
Victor Negrescu

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

Amendment

(9 a) The Centre should analyze the efficiency of its essential systems for detection alerts (EWRS), epidemic intelligence (EPIS) and disease surveillance (TESSy) and make use of new digital technologies available to enhance their capabilities.

Or. en

Amendment 18
Victor Negrescu

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

Amendment

(9 b) The creation of a permanent common European medical emergency units, under the name of EU Blue Medical Corps should be envisaged. This new corps should be composed of medical and emergency intervention professionals from different Member States. Those medical emergency units should be in charge of providing support for cross-border and pan-European medical situations or crisis. The new permanent medical emergency units should use the positive outcomes of the successful voluntary-based medical mobilities financed by the EU Civil Protection Mechanism.

Or. en

Amendment 19
Victor Negrescu

Proposal for a regulation
Recital 10

Text proposed by the Commission

Amendment

(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,

(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.

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 **and reinforce** 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.

Or. en

Amendment 20

Hélène Laporte, Joachim Kuhs

Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) With the aim of reducing the occurrence of epidemics and strengthening capacities to prevent communicable diseases in the Union, the Centre should develop a framework for the prevention of communicable diseases, which addresses such issues as vaccine preventable diseases, antimicrobial resistance, health education, health literacy and behaviour change.

Amendment

(13) With the aim of reducing the occurrence of epidemics and strengthening capacities to prevent communicable diseases in the Union, the Centre should develop a **reasonable** framework for the prevention of communicable diseases, which addresses such issues as vaccine preventable diseases, antimicrobial resistance, health education, health literacy and behaviour change.

Or. fr

Amendment 21

Victor Negrescu

Proposal for a regulation

Recital 14

Text proposed by the Commission

(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.

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 **and broader** monitoring and evaluation frameworks **of the epidemiological situation in Europe**, 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.

Or. en

Amendment 22

Hélène Laporte, Joachim Kuhs

Proposal for a regulation

Recital 16

(16) The Centre should establish appropriate capacities to support international and field response, in accordance with Regulation .../... [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. These capacities should enable the Centre to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’, to assist local responses to outbreaks of diseases. The Centre should therefore ensure capacity to carry out missions to Member States as well as in third countries and to provide recommendations on response to health threats. These teams will also be able to be deployed under the Union Civil Protection Mechanism with the support of the Emergency Response Coordination Centre. The Centre should also support the strengthening of preparedness capacities under the International Health Regulations (IHR) in third countries, in order to address serious cross border threats to health and the consequences thereof.

(16) The Centre should establish appropriate capacities to support international and field response, in accordance with Regulation .../... [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. These capacities should enable the Centre to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’, to assist local responses to outbreaks of diseases. The Centre should therefore ensure capacity to carry out missions to Member States *that so wish* as well as in third countries and to provide recommendations on response to health threats. These teams will also be able to be deployed under the Union Civil Protection Mechanism with the support of the Emergency Response Coordination Centre. The Centre should also support the strengthening of preparedness capacities under the International Health Regulations (IHR) in third countries, in order to address serious cross border threats to health and the consequences thereof.

Or. fr

Amendment 23

Hélène Laporte, Joachim Kuhs

Proposal for a regulation

Recital 22

Text proposed by the Commission

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***

(22) 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.

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.

Or. fr

Amendment 24
Victor Negrescu

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 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.

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, ***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.

Or. en

Amendment 25
Elisabetta Gualmini

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 26
Elisabetta Gualmini

Proposal for a regulation
Recital 22 b (new)

Text proposed by the Commission

Amendment

(22 b) 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), the European Health Emergency Preparedness and Response Authority (HERA) so to ensure an effective and more coordinated Union preparedness and response in the event health crises;

Amendment 27
Johan Van Overtveldt

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

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.

Amendment

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.**

Or. en

Amendment 28
Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Nils Torvalds, Vlad Gheorghe, Valérie Hayer

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

2. The Centre shall, within its **financial capacity and** mandate, perform the following tasks:

Amendment

2. The Centre shall, within its mandate, perform the following tasks:

Or. en

Amendment 29

Nicolae Ștefănuță, Olivier Chastel, Vlad Gheorghe, Valérie Hayer

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;

Or. en

Amendment 30

Nicolae Ștefănuță, Fabienne Keller, Olivier Chastel, Nils Torvalds, Vlad Gheorghe, Valérie Hayer

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

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

Or. en

Amendment 31

Nicolae Ștefănuță, Olivier Chastel, Vlad Gheorghe, Valérie Hayer

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

(j b) The inspection at source must be

organized in each Member State, by an inspector from the body of inspectors appointed by the Centre for a period of 4 years. Each Member States should have at least one inspection within the 4-year period, but more inspection 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 must be submitted in a report to the European Commission, the European Parliament, the European Council and relevant EU agencies. The report shall assess Member State's compliance with the obligations imposed by the Regulation and recommendations from the inspectors in order to improve the situation.

Or. en

Amendment 32

Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Vlad Gheorghe, Valérie Hayer

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 3 – paragraph 3

Text proposed by the Commission

3. The Centre, the Commission, the relevant Union bodies or EU agencies **and the Member States** shall cooperate to promote effective coherence between their respective activities.;

Amendment

3. The Centre, the Commission **and** the relevant Union bodies or EU agencies shall cooperate to promote effective coherence between their respective activities;

Or. en

Amendment 33

Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Vlad Gheorghe, Valérie Hayer

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

3 a. The Member States shall ensure without delay the coordination and collaboration with the Centre in all the missions and tasks mentioned in article 3.

Or. en

Amendment 34

Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Nils Torvalds, Vlad Gheorghe, Valérie Hayer

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) ensure the financial means and digital infrastructure for the coordinating competent body and facilitate the mission of the Centre by providing timely the information requested

Or. en

Amendment 35

Johan Van Overtveldt

Proposal for a regulation

Article 1 – paragraph 1 – point 4

Regulation (EC) No 851/2004

Article 5 – paragraph 4 – point d

Text proposed by the Commission

Amendment

(d) monitor and **assess** health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety;

(d) monitor and **support the competent authorities in the Member States in their assessment of their** health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety;

Or. en

Amendment 36

Nicolae Ștefănuță, Olivier Chastel, Fabienne Keller, Vlad Gheorghe, Valérie Hayer

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

6 a. The Centre shall provide technical assistance to European laboratories to develop their detection and sequencing capacities especially in Member States that do not have the necessary capacity.

Or. en

Amendment 37

Johan Van Overtveldt

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.

Or. en

Amendment 38

Johan Van Overtveldt

Proposal for a regulation

Article 1 – paragraph 1 – point 6

Regulation (EC) No 851/2004

Article 5b – paragraph 1 – subparagraph 2 – point i

Text proposed by the Commission

(i) assess health systems' capacity to detect, prevent, respond to and recover from outbreaks of communicable diseases, identify gaps and provide recommendations for the strengthening of health systems, to be implemented with Union support as appropriate;

Amendment

(i) ***support the competent authorities in the Member States to*** assess health systems' capacity to detect, prevent, respond to and recover from outbreaks of communicable diseases, identify gaps and provide recommendations for the strengthening of health systems, to be implemented with Union support as appropriate;

Or. en

Amendment 39

Henrike Hahn

on behalf of the Verts/ALE Group

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

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.;

Amendment

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, ***in particular*** through a dedicated website ***available in all EU official languages.*** It shall also publish its opinions produced in accordance with Article 6.;

Or. en