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28.7.2021

***I
REPORT

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Joanna Kopcińska

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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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))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2020)0726),

– having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0366/2020),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 27 April 2021[1],

– having regard to the opinion of the Committee of the Regions of 7 May 2021[2],

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the opinion of the Committee on Budgets,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0253/2021),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

[1] OJ C 286, 16.7.2021, p. 109.
[2] Not yet published in the Official Journal.

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) The Union 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.	(1) The Union is committed ***as a priority*** to protect and improve human health ***through the prevention of disease and by tackling*** major health scourges ***by means of*** monitoring, ***assessing, communicating on, improving preparedness for, providing*** early warning of***,*** and combating serious cross-border threats to health.

Amendment 2

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) In order to have high-performing health systems accessible for all, there is a need for a holistic approach to public health. The Centre should be tasked with the identification and monitoring of the relationship between major non-communicable diseases, with a view to assessing the impact that infectious diseases have on health systems at large and the effect of comorbidities on health outcomes as observed during the COVID-19 pandemic. Based on the Centre's vast experience with Union-level surveillance and monitoring of communicable diseases, its existing tool for data collection (TESSy) and its links to national public health bodies responsible for both communicable and non-communicable diseases, the Centre is in a unique position to deliver comprehensive information on public health that can be used for policy decision-making.

Amendment 3

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 preparedness and response should be strengthened.	(3) On 11 March 2020, the World Health Organization (WHO) declared the novel coronavirus COVID-19 outbreak a global pandemic. ***Given*** the challenges experienced in responding to the pandemic***, in particular for people suffering from non-communicable diseases, and in view of the effectiveness gaps which have been identified in the Union's reaction in that regard,*** it became clear that the Union's framework for health crisis preparedness and response should be strengthened ***and extended to better use the potential of the Union's and Member States' capacities to respond to future pandemics***.

Amendment 4

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) The European Ombudsman's decision of 5 February 2021 in strategic inquiry OI/3/2020/TE identified some important effectiveness gaps in the Centre's response to the COVID-19 pandemic. The Centre's information gathering system is such that it results in a lack of timely, complete and comparable data and thus affects the modelling and forecasting potential of the Centre, the level of transparency of that information and how it is communicated to the public. Those shortcomings should be addressed in this Regulation to ensure that, inter alia, there is improved coordination and epidemiological surveillance, and timely communication of the Centre's actions and that those actions are more

transparent.

Amendment 5

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) 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. Such new resources cannot come to the Centre only from ad hoc project-oriented funds, such as those allocated in accordance with Regulation (EU) 2021/522 of the European Parliament and of the Council[1a] (the 'EU4Health Programme'), and the resources already allocated to the Centre in the 2021-2027 multiannual financial framework period are not sufficient. It is therefore important that the Centre's funding and staffing be increased at the earliest opportunity.
	[1a] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

Amendment 6

Proposal for a regulation
Recital 3 c (new)

Text proposed by the Commission	*Amendment*
	(3c) Improving overall population health through disease prevention will help to reduce susceptibility to future infectious outbreaks. Synergies should be fostered with other Union health initiatives, for instance Europe's Beating Cancer Plan, or Union instruments, such as the EU4Health Programme.

Amendment 7

Proposal for a regulation
Recital 3 d (new)

Text proposed by the Commission	*Amendment*
	(3d) The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to take the 'One Health' approach to addressing current and emerging crises.

Amendment 8

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) This Regulation accordingly expands the mission and tasks of the Centre to enhance the Centre's capacity to provide the required scientific expertise and to support actions which are relevant to the prevention, preparedness, response planning and combating serious cross-border threats to health in the Union in accordance with Regulation EU …/… of the European Parliament and of the Council[10] [ISC/2020/12524].	(5) This Regulation accordingly expands the mission and tasks of the Centre to enhance the Centre's capacity to provide the required ***robust and independent*** scientific expertise and to support actions which are relevant to the prevention, preparedness, response planning and combating serious cross-border threats to health in the Union***, including in relation to the impact of communicable diseases on major non-***

	communicable diseases and especially the interconnections between them, in accordance with Regulation EU …/… of the European Parliament and of the Council[10] [ISC/2020/12524].
[10] Regulation (EU) XXXX/XXXX of the European Parliament and of the Council of DATE on serious cross-border threats to health and repealing Decision No 1082/2013/EU [OJ: please, insert full title and publication reference to Regulation on serious cross border threats to health (SCBTH).]	[10] Regulation (EU) XXXX/XXXX of the European Parliament and of the Council of DATE on serious cross-border threats to health and repealing Decision No 1082/2013/EU [OJ: please, insert full title and publication reference to Regulation on serious cross border threats to health (SCBTH).]

Amendment 9

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) In this respect, the Centre should be tasked with providing epidemiological information and its analysis, epidemiological modelling, anticipation and forecasting, relevant risk assessments and recommendations, which set out options for prevention and control of communicable diseases. Its actions should be consistent with a One-Health approach, recognising the interconnections between human and animal health and the environment. It should monitor the capacity of the national health systems to respond to communicable disease threats, in particular given the importance of this information in the preparation of the national preparedness and response plans. The Centre should support the implementation of actions funded by the relevant Union funding programmes and instruments and related to communicable diseases, provide guidelines for treatment and case management based on a thorough assessment of the latest evidence, support epidemic and outbreak responses in	(6) In this respect, the Centre should be tasked with providing ***timely*** epidemiological information and its analysis, epidemiological modelling, anticipation and forecasting, relevant risk assessments and recommendations, which set out options for prevention and control of communicable diseases. Its actions should be consistent with a One-Health approach, recognising the interconnections between human and animal health and the environment***, as many outbreaks are of zoonotic origin***. It should monitor***, assess and support*** the capacity of the national health systems to respond to communicable disease threats, in particular given the importance of this information in the preparation of the national preparedness and response plans***, with a view to enabling Member States to improve their health systems' capacities. Such plans should include recommendations for policy interventions related to mitigation of the impact of communicable diseases on health services and care, in particular***

Member States and third countries, including field response, and provide timely objective, reliable and easily accessible information on communicable diseases to the public. The Centre should also establish clear procedures for cooperation with the public health actors in third countries, as well as international organisations competent in the field of public health hence contributing to EU's commitment to reinforcing partners' preparedness and response capacity.

with regard to the situation of patients suffering from major non-communicable diseases. The monitoring of Member State health systems' capacity should be based on common indicators and definitions in order to ensure comparability. The Centre should have a right to 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. The Centre should support the implementation of actions funded by the relevant Union funding programmes and instruments and related to communicable diseases, provide guidelines for treatment and case management based on a thorough assessment of the latest evidence, support epidemic and outbreak responses in Member States and third countries, including field response ***and personnel training***, and provide timely objective, reliable and easily accessible information on communicable diseases to the public. The Centre should also establish clear procedures for cooperation with the public health actors in third countries, as well as international organisations competent in the field of public health hence contributing to EU's commitment to reinforcing partners' preparedness and response capacity.

Amendment 10

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***	(7) ***Having access to timely and complete data is a precondition for the Centre to be able to conduct rapid risk assessments, including epidemiological modelling and forecasting.*** To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should communicate***, in a timely***

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***.

manner, to the Centre ***comparable and high quality*** data on the surveillance of communicable diseases***, such as HIV, viral hepatitis B and C and Tuberculosis,*** and other special health issues such as antimicrobial resistance and healthcare-associated infections ***and their impact on major non-communicable*** diseases***, including those relating to mental health. Member States should provide*** available scientific and technical data and information relevant to the Centre's mission, notify the Centre of any serious cross-border threats to health ***and provide*** information on preparedness and response planning and health system capacity***. To avoid duplication of efforts and diverging recommendations, timelines, case definitions, indicators, standards, protocols and procedures for communications should be agreed between the Centre and the Member States and a fluid*** information ***exchange should take place between the Centre, the WHO and national agencies***.

Amendment 11

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) Systematic integration of the analysis and assessment of risks associated with environmental, climate and food factors with epidemiological surveillance, the weaknesses of national health systems and the concentration of vulnerable groups in the population should be fostered by the Commission in collaboration with the Centre, the European Environment Agency, the European Chemicals Agency and the European Food Safety Authority, to work towards a holistic approach to the prevention and early detection of communicable diseases. Existing

	instruments, such as the European Climate and Health Observatory, and instruments under development, such as the European Health Emergency Preparedness and Response Authority (HERA), should be used for this purpose.

Amendment 12

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) To enhance preparedness and response planning activities in the Union, the Centre's operation of dedicated networks and networking activities should be broadened to reflect the scope of Regulation (EU) …/…. [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. To this end, the Centre should coordinate and provide technical and scientific expertise to the Commission ***and*** Member States through dedicated networks with competent coordinating bodies, including newly established networks for laboratories and for supporting transfusion, transplantation and medically assisted reproduction**,**	(8) To enhance preparedness and response planning activities in the Union, the Centre's operation of dedicated networks and networking activities should be broadened to reflect the scope of Regulation (EU) …/…. [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. To this end, the Centre should coordinate and provide technical and scientific expertise to the Commission**,** Member States ***and the Health Security Committee ('HSC')*** through dedicated networks with competent coordinating bodies, including ***by encouraging cooperation within the Union's*** newly established networks for laboratories and for supporting transfusion, transplantation and medically assisted reproduction**.**

Amendment 13

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) With a view to enhance the effectiveness of epidemiological surveillance of communicable diseases and of the related special health issues in the Union, the Centre should be tasked with the further development of digital	(9) With a view to enhance the effectiveness of epidemiological surveillance ***and monitoring of testing for and treatment*** of communicable ***diseases, their interconnection with major non-communicable*** diseases and of the related

platforms and applications, supporting epidemiological surveillance at Union level, enabling the use of digital technologies, such as artificial intelligence, in the compilation and analysis of data, and providing Member States with technical and scientific advice to establish integrated epidemiological surveillance systems. Such digital platforms and applications should be developed with integrated EU space generated data with the intention to be integrate them in the future European Health Data Space as governed by the Union legislation.

special health issues in the Union, the Centre should be tasked with the further development of ***secure and interoperable*** digital platforms and applications, supporting epidemiological surveillance at Union level, enabling the use of digital technologies, such as artificial intelligence ***and computer modelling and simulation***, in the compilation and analysis of data, and providing Member States with technical and scientific advice to establish integrated epidemiological surveillance systems. Such digital platforms and applications should be developed with integrated EU space generated data with the intention to be integrate them in the future European Health Data Space as governed by the Union legislation.

Amendment 14

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, 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	(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***, based on a set of common indicators proposed by the Centre and developed in close collaboration and consultation with Member States, identify emerging health threats,*** monitor and report on trends in communicable diseases, support***, coordinate*** 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***,*** assess ***and support Member States with the aim of achieving upward convergence of*** the capacity of national health systems for diagnosis, prevention***,*** treatment ***and containment of the spread*** of communicable diseases, including in a

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.	gender-sensitive way, identify population groups at risk requiring specific measures, analyse the correlation of disease incidence with societal**,** environmental ***and climate*** factors, ***consider the impact of comorbidities on patients with communicable diseases and on their treatment*** 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.

Amendment 15

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) The Centre should help strengthen the capacity within the Union to diagnose, detect, identify and characterise infectious agents which may threaten public health by ensuring the operation ***of the*** network of Union reference laboratories in accordance with Regulation (EU) …/… [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. This network is responsible for the promotion of good practice and alignment on diagnostics, testing methods, and use of tests, in order to ensure uniform surveillance, notification and reporting of diseases, as well as strengthened quality of testing and surveillance.	(11) The Centre should help strengthen the capacity within the Union to diagnose, detect, identify and characterise infectious agents which may threaten public health by ensuring the operation ***in an integrated manner of a dedicated*** network of Union reference laboratories in accordance with Regulation (EU) …/… [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. This network is responsible for the promotion of good practice and alignment on diagnostics, testing methods, ***training in current and innovative procedures*** and use of tests, in order to ensure uniform surveillance, notification and ***standardised*** reporting of diseases, as well as strengthened quality of testing and surveillance.

Amendment 16

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Where in case of cross-border health threats posed by communicable diseases, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services are dependent on rapid risk ***assessments*** by the Centre to safeguard patients in need of a therapy from a substance of human origin from the transmission of such a communicable disease. Such risk assessments serve as the basis for appropriate adaptation of measures setting standards for quality and safety of the substances of human origin. The Centre should therefore establish and operate a network of national ***blood and transplant*** services and their authorities ***to serve this purpose***.	(12) Where in case of cross-border health threats posed by communicable diseases, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services are dependent on rapid***, comprehensive and accurate*** risk ***assessment*** by the Centre to safeguard patients in need of a therapy from a substance of human origin from the transmission of such a communicable disease. Such risk assessments serve as the basis for appropriate adaptation of measures setting standards for quality and safety of the substances of human origin. The Centre should therefore establish and operate a network of national services and their authorities ***for the microbiological safety of substances of human origin (SoHO) encompassing transfusion, transplantation and assisted reproduction***.

Amendment 17

Proposal for a regulation
Recital 13

Text proposed by the Commission	*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 framework for the prevention of communicable diseases, which addresses such issues as vaccine preventable diseases, antimicrobial resistance, health education, health literacy ***and*** behaviour change.	(13) With the aim of reducing the occurrence of epidemics and strengthening capacities to prevent communicable diseases in the Union, the Centre should***, working in conjunction with Member States so as to take account of their experiences and respective situations,*** develop a framework for the prevention of communicable diseases, which addresses such issues as vaccine preventable diseases, ***vaccine hesitancy, awareness of***

transmission routes, antimicrobial resistance, health education, health literacy***, health inequalities and disease prevention,*** behaviour change ***and links with major non-communicable diseases***. ***The Centre should provide guidelines for Member States and monitor the implementation of that framework by Member States.***

Amendment 18

Proposal for a regulation
Recital 14

Text proposed by the Commission	*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	(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 ***preparedness and response plans and contributing to the development of the*** 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***, including by providing training and by sharing best practices***. 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***,*** health systems data***, and data on interconnections between communicable diseases and major non-communicable diseases***. To this end, the Centre should ensure appropriate datasets as well as the

field of data collection.	procedures to facilitate consultation and ***secure*** data transmission and access, carry out scientific and technical evaluation of prevention and control measures at Union level and work with ***the WHO, relevant Union*** agencies, competent bodies and organisations operating in the field of data collection.

Amendment 19

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) Regulation **…/…** [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]] provides for the early warning and response system enabling the notification at Union level of alerts related to serious cross-border threats to health which continues to be operated by the ECDC. Given that modern technologies can be of substantial support to combat health threats and to contain and reverse epidemics, the ECDC should work on updating this system to enable the use of artificial intelligence technologies and interoperable and privacy-preserving digital tools, such as mobile applications, with tracing functionalities identifying at-risk individuals.	(15) Regulation **.../...** [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]] provides for the early warning and response system enabling the notification at Union level of alerts related to serious cross-border threats to health which continues to be operated by the ECDC. Given that modern technologies can be of substantial support to combat health threats and to contain and reverse epidemics, the ECDC should work on updating this system to enable the use of artificial intelligence***, high performance computing, in silico clinical trials and digital twin*** technologies and interoperable and privacy-preserving digital tools, such as mobile applications, with tracing functionalities identifying at-risk individuals***, while mitigating the risks, such as those related to biased datasets, flawed system design, lack of quality data, and overdependence on automated decision-making, and taking into account the importance of establishing safeguards to mitigate those risks during the design and implementation phases of artificial intelligence technologies.***

Amendment 20

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(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***, interregional*** 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 ***and collect field data***. The Centre should therefore ensure ***permanent*** 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.

Amendment 21

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) To assist responses to outbreaks, which may spread within or to the Union, the Centre is to develop a ***framework for the mobilisation the*** EU Health Task Force in accordance with Decision No 1313/2013/EU of the European Parliament and of the Council[11] and facilitate the participation of Union field response experts in international response teams in support of the Union Civil Protection	(17) To assist responses to outbreaks, which may spread within or to the Union, the Centre is to develop a ***permanent*** EU Health Task Force ***and a framework for its mobilisation*** in accordance with Decision No 1313/2013/EU of the European Parliament and of the Council[11] and facilitate the participation of Union field response experts in international response teams in support of ***and in close***

Mechanism. The Centre should enhance the capability of its staff as well as experts from Union and EEA countries, candidate countries and potential candidates, as well as European Neighbourhood Policy countries and EU partner countries as referred to in Regulation (EU) No 233/2014 of the European Parliament and of the Council[12] , to effectively participate in field missions and crisis management.

coordination with the Union Civil Protection Mechanism. The Centre should enhance the capability of its staff as well as experts from Union and EEA countries, candidate countries and potential candidates, as well as European Neighbourhood Policy countries and EU partner countries as referred to in Regulation (EU) No 233/2014 of the European Parliament and of the Council [12] ,to effectively participate in field missions and crisis management. ***Therefore, the Centre should develop a framework of recognisable expertise levels.***

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[11] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

[12] Regulation (EU) No 233/2014 of the European Parliament and of the Council of 11 March 2014 establishing a financing instrument for development cooperation for the period 2014-2020 (OJ L 77, 15.3.2014, p. 44).

[11] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

[12] Regulation (EU) No 233/2014 of the European Parliament and of the Council of 11 March 2014 establishing a financing instrument for development cooperation for the period 2014-2020 (OJ L 77, 15.3.2014, p. 44).

Amendment 22

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) Member States, the Commission and the Centre should identify recognised competent bodies and public health experts, both in the areas of communicable and non-communicable diseases, available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be structurally engaged throughout all activities of the Centre and contribute to its advisory and decision-making processes. Full

compliance with transparency and conflict of interest rules for stakeholder engagement should be ensured.

Amendment 23

Proposal for a regulation
Recital 17 b (new)

Text proposed by the Commission	*Amendment*
	(17b) In order to build a strong European Health Union, the Centre should facilitate the increased cooperation and the exchange of best practices with other Union institutions and agencies, including the future HERA, and ensure coordination of approaches as well as minimise duplication of efforts.

Amendment 24

Proposal for a regulation
Recital 17 c (new)

Text proposed by the Commission	*Amendment*
	(17c) The Centre should work in close cooperation with the competent bodies and the international organisations in the field of public health in particular the WHO.

Amendment 25

Proposal for a regulation
Recital 17 d (new)

Text proposed by the Commission	*Amendment*
	(17d) The Centre should communicate in an effective and transparent manner about current and emerging health risks to the general public. The Centre should publish in a timely manner the scientific studies, overviews, surveys, reports, rapid

risk assessments and the assessments of the health systems' capacities in order to increase transparency. The Centre should in this regard address issues regarding transparency as stated in the European Ombudsman's decision of 5 February 2021 in strategic inquiry OI/3/2020/TE.

Amendment 26

Proposal for a regulation
Recital 17 e (new)

Text proposed by the Commission	*Amendment*
	(17e) The Centre should ensure gender and geographical balance at staff and management levels as well as ensure a gender sensitive approach in all its operations.

Amendment 27

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) In order to assess the effectiveness and efficiency of the legal provisions applicable to the Centre, it is appropriate to provide for ***a regular*** Commission evaluation of the performance of the Centre.	(18) In order to assess the effectiveness and efficiency of the legal provisions applicable to the Centre, it is appropriate to provide for ***an annual*** Commission evaluation of the performance of the Centre.

Amendment 28

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) This Regulation should not confer any regulatory powers on the Centre.	(19) This Regulation should not confer any regulatory powers on the Centre. ***However, the Centre should exercise broad coordination competences and the***

power to provide recommendations at Union, national and interregional level in the form of clear and uniform science-based proposals.

Amendment 29

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) Due to the sensitive nature of health data, the Centre should safeguard and guarantee that its processing operations respect the data protection principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. With respect to the new tasks conferred on the Centre by this Regulation, the Centre should adopt specific measures for minimising risks that can emerge from the transfer of bias or incomplete data from multiple sources, as well as establish procedures for data quality review. The Centre should strictly respect the principles of data protection as set out in Article 27 of Regulation (EU) 2018/1725 of the European Parliament and of the Council[1a], while also determining appropriate technical and organisational security measures in accordance with Article 33 of that Regulation.

[1a] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Amendment 30

Proposal for a regulation
Recital 20 b (new)

Text proposed by the Commission	*Amendment*
	(20b) The European Data Protection Supervisor should be responsible for monitoring and ensuring the application of the provisions of this Regulation relating to the protection of fundamental rights and freedoms of natural persons with regard to the processing of personal data by the Centre, and for advising the Centre and data subjects on all matters concerning the processing of personal data. Where processing of personal data is not necessary to perform the activities of the Centre, measures should be put in place to ensure use of anonymous data in line with the principle of data minimisation. Where anonymisation would not allow the specific purpose of the processing to be achieved, the data should be pseudonymised. Where it is necessary for the purposes of this Regulation to process personal data, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation should take place in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council[1a], Regulation (EU) 2018/1725 and Directive 2002/58/EC of the European Parliament and of the Council[1b]. This Regulation should be without prejudice to the obligations of Member States under Regulation (EU) 2016/679 and Directive 2002/58/EC.
	[1a] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the

processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

[1b] Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

Amendment 31

Proposal for a regulation
Recital 20 c (new)

Text proposed by the Commission	*Amendment*
	(20c) In order to comply with relevant data protection legislation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of setting out the categories of data subjects within the scope of the processing and the categories of the personal data processed, together with a description of the specific measures to safeguard the rights and freedoms of the data subjects involved. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[1a] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts

systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[1a] OJ L 123, 12.5.2016, p. 1.

Amendment 32

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 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.	(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.

Amendment 33

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

Text proposed by the Commission	*Amendment*
	(1a) 'prevention and control of human disease' means the range of

recommendations issued by and measures taken by the competent public health authorities in the Member States and the Union, such as the Centre, to prevent and stop the spread of disease;

Amendment 34

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 851/2004
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'dedicated network' means any specific network on diseases, special health issues or public health functions to ensure collaboration between the coordinating competent bodies of the Member States;	(3) 'dedicated network' means any specific network on diseases, special health issues or public health functions ***that is supported and coordinated by the Centre and is intended*** to ensure collaboration between the coordinating competent bodies of the Member States;

Amendment 35

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 851/2004
Article 2 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) 'major non-communicable disease' means a life-threatening or chronic disease which tends to be of long duration and is the result of a combination of genetic, physiological, environmental and behavioural factors, such as a cardiovascular disease, cancer, respiratory disease, diabetes or mental illness, and which affects a significant number of people in the Union;

Amendment 36

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
In order to enhance the capacity of the Union and the Member States to protect human health through the prevention and control of communicable diseases in humans and ***those*** related special health issues set out in Article 2 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], the mission of the Centre shall be to identify, assess ***and*** report on current and emerging threats to human health from communicable diseases, and provide recommendations ***for*** response at Union and national levels, as well as at regional level, ***if necessary***.	In order to enhance the capacity of the Union and the Member States to protect human health through the prevention and control of communicable diseases in humans and ***relevant major non-communicable diseases and health issues, including the*** related special health issues set out in Article 2 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], the mission of the Centre shall 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,*** and 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.***

Amendment 37

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
In the case of other outbreaks of illnesses of unknown origin that may spread within or to the Union, the Centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak that clearly is not caused by a communicable disease, the Centre shall act ***only*** in cooperation with the competent ***body*** upon request ***from that body***.	In the case of other outbreaks of illnesses of unknown origin that may spread within or to the Union, the Centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak that clearly is not caused by a communicable disease, the Centre shall act in cooperation with the competent ***bodies*** upon ***their*** request ***and provide a risk assessment***.

Amendment 38

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 ***coordination,*** comprehensiveness, coherence***, consistency*** and complementarity of action.

Amendment 39

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

Amendment 40

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, ***considering*** the latest technologies;	(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, ***taking into account*** the latest ***available*** technologies***, including artificial intelligence***;

Amendment 41

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) develop in close collaboration and consultation with Member States relevant common indicators for standardised data collection procedures, risk assessments and supporting upwards convergence of the management of communicable diseases by Member States;

Amendment 42

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point a b (new)

Text proposed by the Commission	*Amendment*
	(ab) in close collaboration and consultation with Member States, establish timelines and procedures for exchange of the information on major

	non-communicable diseases referred to in point (ha) and necessary indicators to assess the impacts referred to in that point;

Amendment 43

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide analyses, scientific advice, opinions and support for actions by the Union and Member States on cross-border health threats, including risk assessments, analysis of epidemiological information, epidemiological modelling, anticipation and forecast, recommendations for actions to prevent and control communicable disease threats and other special health issues, ***contribution*** to defining research priorities***, and scientific and technical assistance including training and other activities within its mandate***;	(b) provide analyses, scientific advice, opinions***, guidelines*** and support for actions by the Union and Member States on cross-border health threats, including risk assessments, analysis of epidemiological information, epidemiological modelling, anticipation and forecast, recommendations for actions to prevent and control communicable disease threats and other special health issues, ***including possible severe impacts on patients suffering from major non-communicable diseases, and contributions with regard*** to defining research priorities;

Amendment 44

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) identify and monitor the impact of major non-communicable diseases on the incidence, severity and mortality rates of communicable diseases;

Amendment 45

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) coordinate the European networking of bodies operating in the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated networks;	(c) coordinate the European networking of bodies***, organisations and experts*** operating in the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated networks***, while ensuring full compliance with the rules on transparency and conflicts of interest***;

Amendment 46

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) exchange information, expertise and best practice;	(d) exchange information, expertise and best practice***, as well as provide scientific and technical assistance, including training***;

Amendment 47

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

common indicators referred to in point (aa) of this paragraph and the elements set out in Article 7(1) of Regulation (EU) …/… [the SCBTH Regulation]; the Centre shall organise regular visits to Member States to assess on the spot their health systems' capacity referred to in the first part of this point and exchange information with the competent authorities to manage health crises;

Amendment 48

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) organise inspections at source in the Member States, on a case-by-case basis, to provide additional support and monitor progress in implementation of and compliance with the obligations set out in Article 5b of this Regulation, if necessary in light of the results of stress tests referred to in Article 5(5) of Regulation (EU) …/… [the SCBTH Regulation]; the results of the inspection in a Member State shall be submitted in a report to the Commission, the European Parliament, the Council and relevant Union agencies;

Amendment 49

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) support national monitoring of the response to major communicable diseases

	in order to measure progress in tackling them across the Union;

Amendment 50

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) facilitate the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions;	(f) facilitate the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions ***in the area of health***;

Amendment 51

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point g

Text proposed by the Commission	*Amendment*
(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***;	(g) provide, upon request of the Commission or the ***Health Security Committee ('HSC') established under Article 4 of Regulation (EU) …/… [the SCBTH Regulation],*** or ***on*** its own initiative, guidelines***, recommendations and proposals for coordinated action for surveillance, monitoring, diagnosis,*** treatment and case management of communicable diseases and other special health issues relevant for public health, ***such as major non-communicable diseases, including*** in cooperation with relevant ***organisations with experience and expertise in treatment and case management of those diseases and health issues, while avoiding any duplication of existing guidelines, except in cases where it is necessary to update such guidelines if***

	new scientific data become available;

Amendment 52

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point h

Text proposed by the Commission	*Amendment*
(h) support epidemic and outbreak response in Member States, and in third countries, in complementarity with other Union emergency response instruments, in particular the Union Civil protection mechanism;	(h) support epidemic and outbreak response in Member States, and in third countries, in complementarity ***and close coordination*** with other Union emergency response instruments, in particular the Union Civil protection mechanism***, by providing recommendations on the stockpiling of medical countermeasures in cooperation with the European Mecicines Agency (EMA) and other relevant Union agencies and bodies***;

Amendment 53

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) collect information, within its existing infrastructure, on major non-communicable diseases, in particular those whose development and treatment are impacted significantly by pandemics, such as cancer, diabetes or mental illness;

Amendment 54

Proposal for a regulation
Article 1 – paragraph 1 – point 2

Regulation (EC) No 851/2004
Article 3 – paragraph 2 – point j

Text proposed by the Commission	*Amendment*
(j) provide, upon request of the Commission ***or the Health Security Committee ('HSC')***, evidence-based communication messages to the public on communicable diseases, on the threats to health posed by them and on the relevant prevention and control measures***.***	(j) provide, upon request of the Commission***, the HSC***, ***or on its own initiative, timely, easily accessible and*** evidence-based communication messages to the public ***in all official languages of the Union*** on communicable diseases, on the threats to health posed by them***, on their possible impact on patients suffering from major non-communicable diseases,*** and on the relevant prevention and control measures***;***

Amendment 55

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) establish and continually update a publicly available database with recognised national competent bodies and their public health experts that act within the scope of the mission of the Centre, with relevant data provided by Member States.

Amendment 56

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 851/2004
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Centre, the Commission, the relevant Union bodies or EU agencies and	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.	the Member States shall cooperate ***in full transparency*** to promote effective coherence between their respective activities.

Amendment 57

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Member States shall:	Member States shall ***ensure the coordination and collaboration with the Centre in relation to all the missions and tasks set out in Article 3, by***:

Amendment 58

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) communicate to the Centre ***in a timely manner and*** according to agreed case definitions, indicators, standards, protocols and procedures data on the surveillance of communicable diseases and other special health issues undertaken in accordance with Article 13 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], and available scientific and technical data and information relevant to the Centre's mission, including on preparedness, and health systems capacities to detect, prevent, respond to and recover from outbreaks of communicable diseases;	(a) communicate ***regularly*** to the Centre according to agreed ***timelines,*** case definitions, indicators, standards, protocols and procedures data on the surveillance of communicable diseases and other special health issues undertaken in accordance with Article 13 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], and available scientific and technical data and information relevant to the Centre's mission, including on preparedness, and health systems capacities to detect, prevent, respond to and recover from outbreaks of communicable diseases;

Amendment 59

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) use the indicators referred to in Article 3(2) to assess their domestic health situation and communicate them to the Centre to allow data to be compared;

Amendment 60

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) notify the Centre of any serious cross-border threats to health, as soon as detected, through the Early Warning and Response System (EWRS), and promptly communicate response measures taken, as well as any relevant information that may be useful for coordinating the response as referred to in Article 21 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]; ***and***	(b) notify the Centre of any serious cross-border threats to health, as soon as detected, through the Early Warning and Response System (EWRS), and promptly communicate response measures taken, as well as any relevant information that may be useful for coordinating the response as referred to in Article 21 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];

Amendment 61

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) identify, within the scope of the mission of the Centre, recognised	(c) identify, within the scope of the mission of the Centre, recognised

competent bodies ***and*** public health experts who could be made available to assist in Union responses to health threats, such as by undertaking missions to Member States to provide expert advice and field investigations in the event of disease clusters or outbreaks.	competent bodies**,** public health experts ***and organisations*** who could be made available to assist in Union responses to health threats, such as by undertaking missions to Member States***, to cross-border regions or to third countries*** to provide expert advice and field investigations in the event of disease clusters or outbreaks.

Amendment 62

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) develop national preparedness and response plans in accordance with Article 6 of Regulation (EU) .../... [the SCBTH Regulation], update them in a timely manner taking into account the Centre's recommendations, and report on their preparedness and response planning and implementation at national level in accordance with Article 7 of that Regulation;

Amendment 63

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) facilitate the digitalisation of data collection and the data communication process between the national and the Union surveillance systems while ensuring the financial means to provide timely delivery of the necessary information; and

Amendment 64

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 851/2004
Article 4 – paragraph 1 – point c c (new)

Text proposed by the Commission	*Amendment*
	(cc) immediately notify any delay in the reporting of the data to the Centre with an explanation therefore and a planned date of submission.

Amendment 65

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

Text proposed by the Commission	*Amendment*
1. The Centre shall support the networking activities of the competent bodies recognised by the Member States through the provision of coordination and technical and scientific expertise to the Commission and Member States and through the operation of the dedicated networks.	1. The Centre shall support ***and continuously develop*** the networking activities of the competent bodies recognised by the Member States through the provision of coordination and technical and scientific expertise to the Commission and Member States and through the operation of the dedicated networks.

Amendment 66

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of ***the*** communicable diseases and of ***the related***	The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of communicable diseases and of special

special health issues referred to in ***points (i) and*** (ii) of point (a) of Article 2(1) of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]].	health issues***, such as an unpredicted rise in major non-communicable diseases or chronic conditions and in health-related environmental hazards, including those*** referred to in ***point*** (ii) of point (a) of Article 2(1) of Regulation (EU)…/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]].

Amendment 67

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ensure the ***further*** development of the digital platforms and applications supporting epidemiological surveillance at Union level, supporting Member States with technical and scientific advice to establish integrated surveillance systems enabling real-time surveillance where appropriate, benefiting from existing EU space infrastructures and services;	(a) ensure the ***continuous*** development of the digital platforms and applications***, including the platform for surveillance established under Article 14 of Regulation (EU) .../... [the SCBTH Regulation],*** supporting epidemiological surveillance at Union level, supporting Member States with technical and scientific advice to establish integrated surveillance systems enabling real-time surveillance where appropriate, ***and proving the necessity and proportionality of data collection and use following a data protection impact assessment ('DPIA'),*** benefiting from existing EU ***digital*** space infrastructures and services***, with the aim of simplifying the data exchange process and reducing the administrative burden at Union and Member State levels***; ***those digital platforms and applications shall be implemented with data protection by design and by default pursuant to Article 27 of Regulation (EU) 2018/1725 of the European Parliament and of the Council*, taking into account current state-of-the-art technologies;***
	**** Regulation (EU) 2018/1725 of the European Parliament and of the Council***

	of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Amendment 68

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide quality assurance by monitoring and evaluating epidemiological surveillance activities (including setting surveillance standards and monitoring data completeness) of the dedicated surveillance networks to ensure optimal operation;	(b) provide quality assurance by monitoring and evaluating epidemiological surveillance activities (including setting surveillance standards and monitoring data completeness ***and assessment indicators***) of the dedicated surveillance networks to ensure optimal operation;

Amendment 69

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) maintain database(s) for such epidemiological surveillance, coordinate with the hosts of other relevant databases, and work towards harmonised approaches to data collection and modelling;	(c) maintain database(s) for such epidemiological surveillance, coordinate with the hosts of other relevant databases, and work towards harmonised approaches to data collection and modelling ***in order to produce comparable Union-wide data as a basis for decision-making***; ***in carrying out that role, the Centre shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, as well as***

	establish robust procedures for data quality review;

Amendment 70

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) collect and analyse information provided by Member States on the impact of pandemics on the causes and treatment of relevant major non-communicable diseases;

Amendment 71

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) communicate the results of the analysis of data to the Commission and Member States;	(d) communicate the results of the analysis of data to the Commission and Member States ***and propose communications to inform the public***;

Amendment 72

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 2 – subparagraph 2 – point g

Text proposed by the Commission	*Amendment*
(g) ensure the interoperability of the digital platforms for surveillance with digital infrastructures allowing for the health data to be used for healthcare,	(g) ensure the interoperability of the digital platforms for surveillance with digital infrastructures allowing for the health data to be used for healthcare,

research, policy making and regulatory purposes and with a view to integrate those platforms and infrastructures in the European Health Data Space, as regulated by Union legislation, and make use of other relevant data, for example environmental factors.	research, policy making and regulatory purposes***, in compliance with points (h) and (i) of Article 9(2) of Regulation (EU) 2016/679 of the European Parliament and of the Council*, after having conducted a DPIA and having mitigated any risks to the rights and freedoms of the data subjects,*** and with a view to integrate those platforms and infrastructures in the European Health Data Space, as regulated by Union legislation, and make use of other relevant data, for example environmental factors ***or phenomena with a potential severe health impact at Union or interregional level***.
	**** Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).***

Amendment 73

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Centre shall support the work of the HSC, the Council and other Union structures for coordinating responses to serious cross-border threats to health within its mandate.	3. The Centre shall support the work of the HSC, the Council and***, where relevant,*** other Union structures for coordinating responses to serious cross-border threats to health within its mandate.

Amendment 74

Proposal for a regulation
Article 1 – paragraph 1 – point 4

Regulation (EC) No 851/2004
Article 5 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) monitor and report on trends in communicable diseases over time and across Member States and in third countries, based on agreed indicators, to assess the present situation and facilitate appropriate evidence-based action, including through the identification of specifications for harmonised data collection from member states	(a) monitor and report on trends in communicable diseases ***and their interconnection with major non-communicable diseases and chronic conditions and implications for patients with such diseases and conditions*** over time and across Member States and in third countries, based on agreed indicators, to assess the present situation and facilitate appropriate evidence-based action, including through the identification of specifications for harmonised data collection from member states***;***

Amendment 75

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 assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety ***and the resilience of the national health systems in the event of major disease outbreaks, based on common indicators and definitions***;

Amendment 76

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

Text proposed by the Commission	*Amendment*
(f) contribute to the assessment of the burden of communicable diseases on the population using data, such as disease prevalence, complications, hospitalisation and mortality, and ensure that this data is disaggregated on age, gender and disability;	(f) contribute to the assessment of the burden of communicable diseases on the population using data, such as disease prevalence, complications, hospitalisation and mortality, and ensure that this data is disaggregated on age, gender and disability***, and patients' comorbidities***;

Amendment 77

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

Text proposed by the Commission	*Amendment*
(h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal ***and*** environmental factors, and research priorities and needs.	(h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal***,*** environmental ***and climatic*** factors, and research priorities and needs.

Amendment 78

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

Text proposed by the Commission	*Amendment*
Each Member State shall designate a coordinating competent body and nominate a national focal point and operational contact points as relevant for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases.	Each Member State shall designate a coordinating competent body and nominate a national focal point and operational contact points as relevant for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases. ***National focal points shall, to the greatest extent possible, be the same as the National IHR Focal Points, in order to minimise the***

duplication of resources and efforts.

Amendment 79

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 5 – subparagraph 3

Text proposed by the Commission	*Amendment*
National focal points and operational contact points nominated for disease-specific interactions with the Centre shall form disease-specific or disease-group-specific networks whose tasks shall include the transmission of national surveillance data to the Centre.	National focal points and operational contact points nominated for disease-specific interactions with the Centre shall form disease-specific or disease-group-specific networks whose tasks shall include the transmission of national surveillance data ***as well as proposals for the prevention and control of communicable diseases*** to the Centre.

Amendment 80

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

Text proposed by the Commission	*Amendment*
6. The Centre shall ensure the operation of the network of EU reference laboratories referred to in Article 15 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], for the diagnosis, detection, identification and characterisation of infectious agents that may present a threat to public health.	6. The Centre shall ensure ***and coordinate*** the operation of the network of EU reference laboratories referred to in Article 15 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], for the diagnosis, detection, identification***, genetic sequencing*** and characterisation of infectious agents that may present a threat to public health.

Amendment 81

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 and scientific assistance to Member States to develop their detection and sequencing capacities, especially assisting those Member States that do not have sufficient capacities.

Amendment 82

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 8 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Centre shall ensure the operation of the network of Member State services supporting transfusion, transplantation and medically assisted reproduction to allow for continuous and rapid access to sero-epidemiological data via sero-epidemiological surveys within the population, including assessment of donor population exposure and immunity.	The Centre shall ensure the operation ***and coordination*** of the network of Member State services supporting ***the microbiological safety of substances of human origin encompassing*** transfusion, transplantation and medically assisted reproduction ***established under Article 16 of Regulation (EU) …/… [the SCBTH Regulation]*** to allow for continuous and rapid access to sero-epidemiological data via sero-epidemiological surveys within the population, including assessment of donor population exposure and immunity.

Amendment 83

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 851/2004
Article 5 – paragraph 8 – subparagraph 2

Text proposed by the Commission	*Amendment*
The network referred to in the first subparagraph shall support the Centre by monitoring ***disease*** outbreaks that are relevant to substances of human origin ***and their supply*** to patients, and with the development of guidelines for blood, tissues and cells safety and quality.	The network referred to in the first subparagraph shall support the Centre by monitoring outbreaks ***of communicable diseases*** that are relevant to ***the safety and sufficiency of the supply of*** substances of human origin to patients, and with the development of guidelines for blood, tissues and cells safety and quality.

Amendment 84

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

Text proposed by the Commission	*Amendment*
1. The Centre shall support Member States to strengthen their communicable disease prevention and control ***systems***.	1. The Centre shall support Member States to strengthen their communicable disease prevention and control ***capacities, and to improve and facilitate the data collection process with real-time and interoperable sharing of data***.

Amendment 85

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 collaboration with Member States, the European Medicines Agency (EMA) 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 ***socio-economic***

risk factors, vaccine preventable diseases, antimicrobial resistance, health ***promotion, health*** education, health literacy and behaviour change.

Amendment 86

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

Text proposed by the Commission	*Amendment*
	That framework shall facilitate permanent consultation of representatives of civil society and industry, in particular scientific bodies, in relation to the activities of the Centre aimed at the prevention of communicable diseases, fighting against misinformation regarding vaccination and which causes vaccine hesitancy, preventive measures and medical treatment, as well as information campaigns regarding the links between disease areas and regarding the risks for patients with major non-communicable diseases.

Amendment 87

Proposal for a regulation
Article 1 – paragraph 1 – point 5
Regulation (EC) No 851/2004
Article 5a – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Centre shall evaluate and monitor communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve these programmes at the national and Union level, and where appropriate at the international levels.	3. The Centre ***may, upon request, provide guidelines for the creation of communicable disease prevention and control programmes, and*** shall evaluate and monitor communicable disease prevention and control programmes in order to provide the evidence for recommendations to ***coordinate,*** strengthen

and improve these programmes at the national***, interregional*** and Union level, and where appropriate at the international levels.

Amendment 88

Proposal for a regulation
Article 1 – paragraph 1 – point 5
Regulation (EC) No 851/2004
Article 5a – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Centre shall develop a platform to monitor the level of vaccination coverage by Member States, taking into account the specificities of the vaccination schemes at national and regional levels.

Amendment 89

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

Text proposed by the Commission	*Amendment*
The Centre shall provide scientific and technical expertise to the Member States and the Commission in collaboration with relevant Union bodies and agencies ***and*** international organisations in accordance with appropriate working arrangements established with the Commission in the field of preparedness and response planning.	The Centre shall provide ***recommendations and*** scientific and technical expertise to the Member States and the Commission in collaboration with relevant Union bodies and agencies***,*** international organisations ***and representatives of civil society*** in accordance with appropriate working arrangements established with the Commission in the field of preparedness and response planning.

Amendment 90

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 851/2004
Article 5b – paragraph 1 – subparagraph 2 – point c

Text proposed by the Commission	*Amendment*
(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]];	(c) ***assess*** 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]]; ***the Centre shall send its assessment with recommendations to the Member State and shall make it public;***

Amendment 91

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 851/2004
Article 5b – paragraph 1 – subparagraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) develop exercises, in-action and after-action reviews and organise capacity building actions to address identified preparedness capacity and capability gaps;	(e) develop exercises***, stress tests***, in-action and after-action reviews and organise capacity building actions to address identified preparedness capacity and capability gaps;

Amendment 92

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 851/2004
Article 5b – paragraph 1 – subparagraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) develop specific preparedness activities addressing vaccine preventable	(f) develop specific preparedness activities addressing***, amongst other***

diseases, antimicrobial resistance, laboratory capacity and biosecurity in accordance with Commission priorities and based upon gaps identified;	***things,*** vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity in accordance with Commission priorities and based upon gaps identified;

Amendment 93

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 851/2004
Article 5b – paragraph 1 – subparagraph 2 – point h

Text proposed by the Commission	*Amendment*
(h) develop targeted activities addressing at-risk groups and community preparedness;	(h) develop targeted activities addressing at-risk groups and community preparedness***, in particular taking into account the risks associated with the causes and treatment of major non-communicable diseases***;

Amendment 94

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	*Amendment*
(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;	(i) assess health systems' capacity ***based on common indicators*** to detect, prevent, respond to and recover from outbreaks of communicable diseases ***and related health risks***, identify gaps and provide recommendations for the strengthening of health systems, ***in particular as regards minimum testing capacities,*** to be implemented with Union support as appropriate; ***the Centre shall send its assessment with recommendations to the Member State and shall make it public;***

Amendment 95

Proposal for a regulation
Article 1 – paragraph 1 – point 7 – point a
Regulation (EC) No 851/2004
Article 6 – paragraph 1a

Text proposed by the Commission	*Amendment*
1a. The Centre shall provide concrete analyses and recommendations for actions to prevent and control communicable ***disease*** threats upon request of the Commission.	1a. The Centre shall provide concrete analyses and recommendations for actions to prevent and control communicable ***diseases and other cross-border*** threats ***to health*** upon request of the Commission.

Amendment 96

Proposal for a regulation
Article 1 – paragraph 1 – point 7 – point b
Regulation (EC) No 851/2004
Article 6 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Centre may promote and initiate scientific studies necessary for the performance of its mission and applied scientific studies and projects on the feasibility, development and preparation of its activities. The Centre shall avoid duplication with Commission's, Member States' ***and*** Union research and health programmes, and will liaise between the public health and the research sector ***as needed***.	The Centre may promote and initiate scientific studies necessary for the performance of its mission and applied scientific studies and projects on the feasibility, development and preparation of its activities. The Centre shall avoid duplication with Commission's, Member States'***,*** Union ***and WHO*** research and health programmes, and will liaise between the public health and the research sector ***by encouraging consultation of, and cooperation with, public health experts***.

Amendment 97

Proposal for a regulation
Article 1 – paragraph 1 – point 7 – point b
Regulation (EC) No 851/2004
Article 6 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
To carry out the studies referred to in the first paragraph, the Centre shall have access to health data made available or exchanged through digital infrastructures and applications, in accordance with data protection rules, allowing for the health data to be used for healthcare, research, policy making and regulatory purposes. For the purposes of studies under the first paragraph, the Centre shall also make use of other relevant data, for example on environmental and socio-economic factors.	To carry out the studies referred to in the first paragraph, the Centre shall have access to health data made available or exchanged through digital infrastructures and applications, in accordance with data protection rules, allowing for the health data to be ***solely*** used for healthcare, ***health*** research, policy making and regulatory purposes ***in the domain of health***. For the purposes of studies under the first paragraph, the Centre shall also make use of other relevant data, for example on environmental and socio-economic factors***, after it has proven the necessity and proportionality of using those data***.

Amendment 98

Proposal for a regulation
Article 1 – paragraph 1 – point 7 – point b
Regulation (EC) No 851/2004
Article 6 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Centre may use its resources and make use of reference laboratories, in order to perform field research, data gathering and data analysis, to help relevant national bodies gather reliable data.

Amendment 99

Proposal for a regulation
Article 1 – paragraph 1 – point 7 – point c
Regulation (EC) No 851/2004
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Centre shall consult with the Commission and other Union bodies or	4. The Centre shall consult with the Commission***, the HSC*** and other ***relevant***

agencies with regard to the planning and priority setting of research and public health studies.	Union bodies or agencies with regard to the planning and priority setting of research and public health studies.

Amendment 100

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 851/2004
Article 7 – paragraph 1– point c

Text proposed by the Commission	*Amendment*
(c) at the request of the Commission; ***and***	(c) at the request of the Commission ***or EMA***;

Amendment 101

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 851/2004
Article 7 – paragraph 1– point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) at the request of the HSC; and

Amendment 102

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 851/2004
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Requests for a scientific opinion referred to in paragraph 1 shall clearly explain the scientific issue to be addressed and the Union interest and be accompanied by sufficient background information regarding that issue.	2. Requests for a scientific opinion referred to in paragraph 1 shall clearly explain the scientific issue to be addressed and the Union interest and ***necessity to act, and shall*** be accompanied by sufficient background information regarding that issue.

Amendment 103

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 851/2004
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where different requests are made on the same issue or where the request does not comply with paragraph 2, the Centre may decline to issue a scientific opinion or propose amendments to that request in consultation with the institution or Member State that made the request. In case the request is declined, a justification shall be given to the institution or Member States that made the request.	4. Where different requests are made on the same issue or where the request does not comply with paragraph 2, the Centre may decline to issue a scientific opinion or propose amendments to that request in consultation with the institution***, agency*** or Member State that made the request. In case the request is declined, a justification shall be given to the institution***, agency*** or Member States that made the request.

Amendment 104

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 851/2004
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where the Centre has already delivered a scientific opinion on the specific issue covered by a request and it concludes that no scientific elements justify the re-examination of the issue, information supporting that conclusion shall be given to the institution or Member State that made the request.	5. Where the Centre has already delivered a scientific opinion on the specific issue covered by a request and it concludes that no scientific elements justify the re-examination of the issue, information supporting that conclusion shall be given to the institution***, agency*** or Member State that made the request.

Amendment 105

Proposal for a regulation
Article 1 – paragraph 1 – point 9

Regulation (EC) No 851/2004
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Centre shall support and assist the Commission by operating the EWRS and by ensuring with the Member States the capacity to respond in a coordinated manner.	1. The Centre shall support and assist the Commission by operating the EWRS ***provided for in Article 18 of Regulation (EU) .../... [the SCBTH Regulation]*** and by ensuring with the Member States the capacity to respond in a coordinated ***and timely*** manner.

Amendment 106

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EC) No 851/2004
Article 8 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide information, expertise, advice and risk assessment to Member States and the Commission; and	(b) provide information, expertise, advice***, training*** and risk assessment to Member States and the Commission; and

Amendment 107

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EC) No 851/2004
Article 8 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Centre shall work with the Commission, the HSC and Member States to improve the reporting of relevant data through the EWRS, aiming to digitalise that process and integrate it into national surveillance systems.

Amendment 108

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EC) No 851/2004
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Centre shall work with the Commission and the HSC on the EWRS updates, including for the use of modern technologies, such as digital mobile applications, artificial intelligence models, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States and on defining the functional requirements of the EWRS.	3. The Centre shall work with the Commission and the HSC on the EWRS ***continuous*** updates, including for the use of modern technologies, such as digital mobile applications, artificial intelligence ***and computer modelling and simulation*** models, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States. ***Those technologies shall be used for the sole purpose of fighting pandemics, where proven to be adequate, necessary and proportionate, and in full compliance with Regulation (EU) 2016/679 and Directive 2002/58/EC of the European Parliament and of the Council*,*** and on defining the functional requirements of the EWRS. _____ **** Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).***

Amendment 109

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EC) No 851/2004
Article 8 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Centre ***as processor*** shall have the responsibility to ensure the security and confidentiality of the processing operations	5. The Centre shall have the responsibility to ensure the security and confidentiality of the processing operations

of personal data carried out within the EWRS and in the context of interoperability of contact tracing applications, in accordance with the obligations laid down in Articles 33***, 34(2)*** and 36 of Regulation (EU) 2018/1725 ***of the European Parliament and of the Council****	of personal data carried out within the EWRS and in the context of interoperability of contact tracing applications, in accordance with the obligations laid down in Articles 33 and 36 of Regulation (EU) 2018/1725**.**
**** Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).***	

Amendment 110

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 851/2004
Article 8a – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Centre shall provide timely ***rapid*** risk assessments, in accordance with Article 20 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], in the case of a threat referred to in ***points (i) and (ii) of*** point (a) of Article 2(1) of that Regulation including a threat to substances of human origin, such as blood, organs, tissues and cells potentially impacted by communicable diseases, or point (d) of Article 2(1) of that Regulation	1. The Centre shall provide timely risk assessments, in accordance with Article 20 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], in the case of a threat referred to in point (a) of Article 2(1) of that Regulation including a threat to substances of human origin, such as blood, organs, tissues and cells potentially impacted by communicable diseases, or point (d) of Article 2(1) of that Regulation**.**

Amendment 111

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 851/2004
Article 8a – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The risk assessments referred to in paragraph 1 shall be carried out in a timely manner and in as short a period of time as possible in order to gather the necessary information.

Amendment 112

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 851/2004
Article 8a – paragraph 2

Text proposed by the Commission	*Amendment*
2. The risk ***assessment*** shall include general and targeted recommendations for response as a basis for coordination in the HSC.	2. The risk ***assessments referred to in paragraph 1*** shall include***, where possible,*** general and targeted recommendations for response as a basis for coordination in the HSC***, including, but not limited to:***
	(a) a forecast of the evolution of a health crisis and the risk of a health emergency;
	(b) a forecast of the demand for medicines, vaccines, medical equipment, protective equipment and hospital capacity, including within the Union Civil Protection Mechanism;
	(c) identification of vulnerable groups in society, such as patients suffering from chronic conditions, patients with major non-communicable diseases, the elderly, children, pregnant women and professions with a high risk of infection or transmission, including specific needs for medicines and hospital capacity for those vulnerable groups;
	(d) identification of possible protective measures and assessment of their

	efficacy;
	(e) assessment of the possible need for activation of the EU Health Task Force.

Amendment 113

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 851/2004
Article 8a – paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of rapid risk assessments by involving Member States experts and relevant agencies***, if necessary***.	3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of rapid risk assessments by involving Member States experts and relevant agencies ***and organisations***.

Amendment 114

Proposal for a regulation
Article 1 – paragraph 1 – point 10
Regulation (EC) No 851/2004
Article 8a – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Centre shall work together with the Member States to improve their risk assessment capacity.

Amendment 115

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 851/2004
Article 8b – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) national responses to the serious cross-border threat to health;	(a) national ***or interregional*** responses to the serious cross-border threat to health;

Amendment 116

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 851/2004
Article 8b – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) adoption of ***guidance*** for the Member States for the prevention and control of a serious cross-border threat to health***.***	(b) adoption of ***common guidelines*** for the Member States for the prevention***,*** ***treatment*** and control of a serious cross-border threat to health***;***

Amendment 117

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 851/2004
Article 8b – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the deployment of the EU Health Task Force.

Amendment 118

Proposal for a regulation
Article 1 – paragraph 1 – point 11
Regulation (EC) No 851/2004
Article 8b – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Centre shall support a Union coordinated response ***at the request of a Member State, Council, Commission, Union bodies or agencies***.	2. The Centre shall support a Union coordinated response ***in accordance with Article 21 of Regulation (EU) …/… [the SCBTH Regulation]***.

Amendment 119

Proposal for a regulation
Article 1 – paragraph 1 – point 12 – point a

Regulation (EC) No 851/2004
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Centre may be requested by the Commission, the Member States, third countries, in particular EU partner countries, and international organisations (in particular the WHO) to provide scientific or technical assistance in any field within the scope of its mission. The assistance may include aiding the Commission and Member States to develop technical guidelines on good practice and on protective measures to be taken in response to human health threats, providing expert assistance, mobilising and coordinating investigation teams. The Centre shall provide scientific and technical expertise and assistance within its financial capacity and mandate, and in accordance with the appropriate working arrangements established with the Commission.	2. The Centre may be requested by the Commission, the Member States, third countries, in particular EU partner countries, and international organisations (in particular the WHO) to provide scientific or technical assistance in any field within the scope of its mission. The assistance may include aiding the Commission and Member States to develop technical guidelines on good practice and on protective measures to be taken in response to human health threats, providing expert assistance, mobilising and coordinating investigation teams ***and assessing the efficiency of response measures***. The Centre shall provide scientific and technical expertise and assistance within its financial capacity and mandate, and in accordance with the appropriate working arrangements established with the Commission.

Amendment 120

Proposal for a regulation
Article 1 – paragraph 1 – point 12 – point c
Regulation (EC) No 851/2004
Article 9 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Centre shall, as appropriate, support and coordinate training programmes, in particular in epidemiological surveillance, field investigations, preparedness and prevention, ***and*** public health research.	6. The Centre shall, as appropriate, support and coordinate training programmes, in particular in epidemiological surveillance, field investigations, preparedness and prevention, ***response to public health emergencies,*** public health research ***and risk communication***. ***Those programmes shall take into consideration the need for training to be kept up-to-date and shall respect the principle of proportionality***

and the training needs of Member States.

Amendment 121

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point a
Regulation (EC) No 851/2004
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Centre shall coordinate data collection, validation, analysis and dissemination of data at Union level.	1. The Centre shall coordinate data***, standardisation,*** collection, validation, analysis and dissemination of data at Union level.

Amendment 122

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point b
Regulation (EC) No 851/2004
Article 11 – paragraph 1a – point a

Text proposed by the Commission	*Amendment*
(a) epidemiological surveillance of communicable diseases and related special health issues referred to in ***points (i) and*** (ii) of point (a) of Article 2(1) of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];	(a) epidemiological surveillance of communicable diseases***, other health threats, such as major non-communicable diseases,*** and related special health issues referred to in ***point*** (ii) of point (a) of Article 2(1) of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];

Amendment 123

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point b
Regulation (EC) No 851/2004
Article 11 – paragraph 1a – point b

Text proposed by the Commission	*Amendment*
(b) the progression of epidemic situations, including for modelling,	(b) the progression of epidemic situations, including for modelling,

anticipation and scenario development;	anticipation and scenario development***, the assessment of vulnerable groups and the forecast of specific demand for medicines, equipment and hospital capacity***;

Amendment 124

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point b
Regulation (EC) No 851/2004
Article 11 – paragraph 1a – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) implementation of the Centre's recommendations on countermeasures by Member States and the outcomes thereof.

Amendment 125

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point c
Regulation (EC) No 851/2004
Article 11 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) work in close cooperation with the competent bodies of the organisations operating in the field of data collection from the Union, third countries, the WHO, ***and*** other international organisations; and	(c) work in close cooperation with the competent bodies of the organisations ***and relevant counterparts*** operating in the field of data collection from the Union, third countries, the WHO, other international organisations ***and the scientific community, while ensuring that robust safeguards are in place concerning transparency and accountability***; and

Amendment 126

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point c
Regulation (EC) No 851/2004
Article 11 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) develop solutions to access relevant health data made available or exchanged through digital infrastructures, in accordance with data protection rules, allowing for the health data to be used for healthcare, research, policy making and regulatory purposes; and provide and facilitate controlled access to health data to support public health research.	(d) develop solutions to access relevant health data***, including anonymous data and pseudonymous data, where such data are*** made available or exchanged through digital infrastructures, in accordance with data protection rules, allowing for the health data to be ***solely*** used for healthcare, ***health*** research, policy making and regulatory purposes ***in the domain of health***; and provide and facilitate controlled access to health data to support public health research.

Amendment 127

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – point d
Regulation (EC) No 851/2004
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts as referred to in point (g) of Article 5(4), upon request of the ***European Medicines Agency***, in an objective, reliable and easily accessible way and on the basis of the best available information.	4. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts as referred to in point (g) of Article 5(4), upon request of ***a Member State,*** the ***Commission or EMA***, in an objective, reliable and easily accessible way and on the basis of the best available information.

Amendment 128

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EC) No 851/2004
Article 11a – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Centre shall establish capacity to mobilise and deploy the EU Health Task Force including the Centre's staff ***and*** experts from Member States ***and*** fellowship programmes, to assist local response to outbreaks of communicable diseases in Member States and in third countries.	1. The Centre shall establish ***a permanent capacity, as well as an enhanced emergency*** capacity to mobilise and deploy the EU Health Task Force including the Centre's staff***,*** experts from Member States***,*** fellowship programmes ***and international and non-profit organisations***, to assist local response to outbreaks of communicable diseases in Member States and in third countries.

Amendment 129

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EC) No 851/2004
Article 11a – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Centre shall develop capacities to conduct field research and gather relevant data, such as on the genetic variation of communicable diseases, using the dedicated reference laboratory network or its own resources.

Amendment 130

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EC) No 851/2004
Article 11a – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Centre shall develop a framework and establish procedures with the Commission to mobilise the EU Health Task Force.	2. The Centre shall develop a framework and establish procedures with the Commission to ***deploy the permanent capacity and*** mobilise ***the emergency capacity of*** the EU Health Task Force.

Amendment 131

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EC) No 851/2004
Article 11a – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Centre shall develop with the Commission a framework for the mobilisation of the EU Health Task Force, in view of action under Decision No 1313/2013/EU*.	The Centre shall develop with the Commission a framework for ***the deployment of the permanent capacity and*** the mobilisation of the EU Health Task Force, in view of action under Decision No 1313/2013/EU*.
_____	_____
* Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).	* Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

Amendment 132

Proposal for a regulation
Article 1 – paragraph 1 – point 14
Regulation (EC) No 851/2004
Article 11a – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Centre shall maintain capacity to carry out missions to Member States, upon request of the Commission and Member States, to provide recommendations on response to threats to health within its mandate.	6. The Centre shall maintain ***a permanent*** capacity to carry out missions to Member States, upon request of the Commission and Member States, to provide recommendations on response to threats to health within its mandate.

Amendment 133

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 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.	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 ***with essential information available in all official languages of the Union.*** It shall also publish its opinions produced in accordance with Article 6 ***in a timely manner***.

Amendment 134

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

Text proposed by the Commission	*Amendment*
(b) paragraph 2 is deleted;	***deleted***

Amendment 135

Proposal for a regulation
Article 1 – paragraph 1 – point 15 – point c
Regulation (EC) No 851/2004
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Centre shall cooperate as appropriate with the competent bodies in the Member States and other interested parties with regard to public information campaigns.	3. The Centre shall cooperate as appropriate with the competent bodies in the Member States***, the WHO*** and other interested parties with regard to public information campaigns.

Amendment 136

Proposal for a regulation
Article 1 – paragraph 1 – point 16 – point a
Regulation (EC) No 851/2004
Article 14 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
Members' term of office shall be three years and can be extended.	Members' term of office shall be three years and can be extended***, if necessary***.

Amendment 137

Proposal for a regulation
Article 1 – paragraph 1 – point 16 – point b
Regulation (EC) No 851/2004
Article 14 – paragraph 5 – subparagraph 1 – point e

Text proposed by the Commission	*Amendment*
(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**;	(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;***
* 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 Council (OJ L 122, 10.5.2019, p. 1).	* 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 Council (OJ L 122, 10.5.2019, p. 1).

Justification

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

Amendment 138

Proposal for a regulation
Article 1 – paragraph 1 – point 16 – point b
Regulation (EC) No 851/2004
Article 14 – paragraph 5 – subparagraph 1 – point i

Text proposed by the Commission	*Amendment*
(i) determine the rules governing the languages of the Centre, including the possibility of a distinction between the internal workings of the Centre and ***the*** external communication, taking into account the need to ensure access to***, and participation in,*** the work of the Centre ***by all interested parties in both cases***.	(i) determine ***by unanimity*** the rules governing the languages of the Centre, including the possibility of a distinction between the ***ordinary*** internal workings of the Centre and ***its***external communication, taking into account the need to ensure access ***for all interested parties*** to the work of the Centre ***in as many official languages of the Union as possible, as well as expert scrutiny of scientific findings and public understanding of the Centre's work and recommendations; those rules may include the use of qualified interpreters (working with sign language, or via oral or tactile interpretation) if needed.***

Amendment 139

Proposal for a regulation
Article 1 – paragraph 1 – point 18
Regulation (EC) No 851/2004
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
(18) Article 17 is replaced by the following:	***deleted***
'1. Without prejudice to Article 3(2), the director shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission after an open competition,	

following publication in the Official Journal of the European Union and elsewhere of a call for expressions of interest, for a period of five years, which may be extended once for a further period of up to five years.; '

Justification

The addition of the words 'Without prejudice to Article 3(2)' makes no sense in this context. Hence, the original wording of Regulation (EC) No 851/2004 should be restored.

Amendment 140

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 141

Proposal for a regulation
Article 1 – paragraph 1 – point 19 – point c
Regulation (EC) No 851/2004
Article 18 – paragraph 8

Text proposed by the Commission	*Amendment*
8. The ***director may invite*** experts ***or*** representatives of professional ***or*** scientific bodies***, or*** non-governmental organisations with recognised experience in disciplines	8. The ***Centre shall structurally engage with public health*** experts***,*** representatives of professional ***and*** scientific bodies ***and*** non-governmental

related to the work of the Centre ***to cooperate in specific tasks and*** to take part in ***the relevant*** activities of the Advisory Forum. In addition, the Commission may suggest to the ***director*** experts or representatives of professional or scientific bodies, or non-governmental ***organizations*** to be ***invited*** on an ad-hoc basis.	organisations***, in particular those*** with recognised experience in disciplines related to the work of the Centre***, as well as in other areas, including non-communicable diseases and environmental protection,*** to take part in ***all key*** activities of the ***Centre, dedicated networks and the*** Advisory Forum ***and to cooperate on specific tasks***. In addition, the Commission ***and Member States*** may suggest to the ***Centre*** experts or representatives of professional or scientific bodies, or non-governmental ***organisations*** to be ***consulted*** on an ad-hoc basis.

Amendment 142

Proposal for a regulation
Article 1 – paragraph 1 – point 19 a (new)
Regulation (EC) No 851/2004
Article 19 – paragraph 2

Present text	*Amendment*
	(19a) in Article 19, paragraph 2 is replaced by the following:
2. The members of the Management Board, the director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.	"2. The members of the Management Board, the director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing ***and be available to the public***."

(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R0851&qid=1613474789335)

Amendment 143

Proposal for a regulation
Article 1 – paragraph 1 – point 20 a (new)
Regulation (EC) No 851/2004
Article 20 – paragraph 4

Present text	*Amendment*
	(20a) in Article 20, paragraph 4 is replaced by the following:
4. Personal data shall not be processed or communicated except in cases where this is strictly necessary for the fulfilment of the mission of the Centre. In such cases, Regulation (***EC***) ***No 45/2001 of the European Parliament and of the Council of18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (8)*** shall apply.	***"***4. Personal data shall not be processed or communicated except in cases where this is strictly necessary for the fulfilment of the mission of the Centre. In such cases, Regulation (***EU***) ***2018/1725*** shall apply.***";***

(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R0851&qid=1626616104898)

Amendment 144

Proposal for a regulation
Article 1 – paragraph 1 – point 20 b (new)
Regulation (EC) No 851/2004
Article 20 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	(20b) in Article 20, the following paragraph is added:
	"4a. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC, or the obligations of the Centre and the Commission relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.

The Centre shall put in place procedures and data protection safeguards designed to guarantee that its processing operations fully respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity, confidentiality, and data protection by design and by default.

The Centre shall only process personal data, in particular in the case of health data relating to identified or identifiable individuals, when it is proven to be necessary and proportionate to do so. Whenever possible, in line with the principle of data minimisation, the Centre shall make use of anonymised data, achieved through techniques used such as randomisation or generalisation.

The Commission shall adopt delegated acts in accordance with Article 20a to supplement this Regulation by setting out the categories of data subjects under the scope of the processing and the categories of the personal data processed, together with a description of the specific measures to safeguard the rights and freedoms of the data subjects involved, in line with relevant data protection legislation, in particular with regard to concrete safeguards to prevent abuse or unlawful access or transfer, and the storage periods.";

Amendment 145

Proposal for a regulation
Article 1 – paragraph 1 – point 20 c (new)
Regulation (EC) No 851/2004
Article 20 a (new)

Text proposed by the Commission	*Amendment*
	(20c) the following Article is inserted:
	"Article 20a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 20(4a) shall be conferred on the Commission for a period of five years from … [date of entry into force of this amending Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 20(4a) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making*.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 20(4a) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months

	of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
	**** OJ L 123, 12.5.2016, p. 1.";***

Amendment 146

Proposal for a regulation
Article 1 – paragraph 1 – point 21
Regulation (EC) No 851/2004
Article 21 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Centre shall develop, deploy and operate an information system capable of exchanging classified and sensitive non-classified information as specified in this Article.	6. The Centre shall develop, deploy and operate an information system capable of exchanging classified and sensitive non-classified information as specified in this Article***, in accordance with Articles 27 and 33 of Regulation (EU) 2018/1725***.

Amendment 147

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	*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 and to 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***, the European Parliament, the Council*** and to the Commission.

Amendment 148

Proposal for a regulation
Article 1 – paragraph 1 – point 23 a (new)
Regulation (EC) No 851/2004
Article 24

Present text	*Amendment*
	(23a) Article 24 is replaced by the following:
Article 24	"Article 24
Application of the Financial Regulation	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.	Article ***70*** of Regulation ***(EU, Euratom) 2018/1046*** shall apply to the discharge of the Centre's budget, its audits and accounting rules."

Justification

The Financial Regulation (Council Regulation (EC, Euratom) No 1606/2002, described in Recital 12 of Regulation (EC) No 851/2004, was repealed by Regulation (EU, Euratom) No 966/2012, which in turn has since been repealed by Regulation (EU, Euratom) 2018/1046.

Amendment 149

Proposal for a regulation
Article 1 – paragraph 1 – point 28
Regulation (EC) No 851/2004
Article 31 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
By [please insert date three years after the date of entry into force] ***2023***, the Commission shall submit a report to the European Parliament, the Council and the Management Board on the Centre's activities, including an assessment of:	By **…** [please insert date three years after the date of entry into force ***of this amending Regulation***], the Commission shall submit a report to the European Parliament, the Council and the Management Board on the Centre's activities, including an assessment of:

Justification

The reference to 2023 appears to be a drafting error given that the report is to be published three years after the entry into force of this amending Regulation.

Amendment 150

Proposal for a regulation
Article 1 – paragraph 1 – point 28
Regulation (EC) No 851/2004
Article 31 – paragraph 1 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) how the Centre has implemented the governance structures referred to in Articles 14, 17 and 18;

Amendment 151

Proposal for a regulation
Article 1 – paragraph 1 – point 28
Regulation (EC) No 851/2004
Article 31 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By [please insert date ***three*** years after the date of entry into force] ***2028***, and every 5 years thereafter, the Commission shall assess the Centre's performance in relation to its objectives, mandate, tasks, procedure and location. The evaluation shall, in particular, address the possible need to modify the mandate of the Centre, and the financial implications of any such modification.	2. By **…** [please insert date ***five*** years after the date of entry into force ***of this amending Regulation***], and every 5 years thereafter, the Commission shall assess the Centre's performance in relation to its objectives, mandate, tasks, procedure and location. The evaluation shall, in particular, address the possible need to modify the mandate of the Centre, and the financial implications of any such modification.

Justification

The reference to 2028 appears to be a drafting error as the review of the Centre's performance in relation to its objectives, mandate, tasks, procedure and location will in all likelihood be later than three years after the entry into force of the amending Regulation. Moreover, given the essence of the review process, which may result in legislative changes, additional time should be given to the Commission.

Amendment 152

Proposal for a regulation
Article 1 – paragraph 1 – point 28

Regulation (EC) No 851/2004
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Commission considers that the continued operation of the Centre is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.	3. ***Based on the assessment referred to in paragraph 2, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.*** Where the Commission considers that the continued operation of the Centre is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.

Justification

The Commission proposal does not clearly articulate the right of the Commission to propose changes to the Centre's mandate.

EXPLANATORY STATEMENT

As part of the Union's efforts to improve its health crisis preparedness and response mechanisms, the founding Regulation of the European Centre for Disease Prevention and Control (ECDC), adopted in 2004, is due to undergo its first revision. The COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has revealed significant gaps in the Union's preparedness and response. The Union has never faced a more serious public health threat; the current pandemic remains far from over and future outbreaks are expected to emerge more often.

The Union must be able to better anticipate, prepare for, and manage future epidemics. Three important elements need to be accounted for in the amendment of the ECDC's founding Regulation (the 'ECDC amending regulation').

First, the Commission proposal is part of a consolidated and interlinked package of legislative and non-legislative measures aimed at building a European Health Union that will also reinforce the European Medicines Agency's mandate, and set out the central elements of a future Health Emergency Response Authority (HERA) in order to tackle cross-border health threats more effectively. However, given that the legislative proposal for HERA is foreseen for the fourth quarter of 2021, its implications for the ECDC will not be determined for some time. Therefore, although this report should be understood in the context of the European Health Union package, it must, in particular, be read in conjunction with the proposal for a regulation on serious cross-border health threats and repealing Decision No 1082/2013/EU, which sets out a number of methods and criteria that are applicable to the ECDC amending Regulation.

Second, the ECDC is limited by its financial resources. The ECDC has an approximate annual budget of EUR 60 million with around 300 posts foreseen under the 2021-2027 Multiannual Financial Framework. This is substantially lower than what is required if the Union is to be better prepared and more resilient in the area of public health. It is important to recognise that at present, almost the entire staff of the ECDC works on the SARS-CoV-2 pandemic while other critical areas of work on infectious diseases are being neglected. These resource limitations have led to contrasting comparisons with the United States' Centers for Disease Control and Prevention (US CDC), which has grown and developed over seven decades and is currently equipped with a yearly budget in excess of USD 10 billion and the availability of more than 10,000 posts.

Third, the Treaty on the Functioning of the European Union (TFEU) clearly states that 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care' (Article 168(7)). The legal basis for the Commission proposal is Article 168(5) TFEU, which provides for Union measures 'to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health (...)

excluding any harmonisation of the laws and regulations of the Member States'.

Consequently, I believe that the ECDC amending regulation should prioritise workable and pragmatic solutions aimed at improving cooperation, the exchange of information, expertise, and best practices between Member State authorities and the Commission, the Health Security Committee and the ECDC itself, as well as other organisations where relevant (for example, the European Medicines Agency). This improved cooperation should enable better preparedness and response coordination.

To be effective, such augmented collaboration requires mutual transparency and accountability between the Member States and the Union's institutions and bodies – only together can they achieve comparable results to that of the US CDC. Nevertheless, any provision in the ECDC amending regulation should not give rise to concerns that the Union is encroaching into the exclusive competences of the Member States. Therefore, I have softened the language around the assessment and auditing of the capacity of Member States' health systems in order to allay any potential criticism from national capitals.

The Commission proposal also foresees some new tasks for the ECDC, such as detecting, monitoring, and reporting on threats to substances of human origin, such as blood, organs, tissues, and cells. While I understand the importance of this new role, I believe the participation by Member States in this network in the first phase should be voluntary. If this new element of the ECDC's epidemiological surveillance proves to be successful, it could then be made mandatory following a review. For the time being however, the ECDC should primarily focus on its core tasks, namely, to identify, assess, and communicate current and emerging threats posed by communicable diseases.

This report also includes a number of technical adaptations, as there have been many changes both to the Treaties and other Union legislation, such as, for example, financial regulations, which must also be reflected in the ECDC amending regulation to ensure clarity and consistency.

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

SHORT JUSTIFICATION

The proposed changes to Regulation (EC) No 851/2004 of the European Parliament and of the Council[1], 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:

[1] OJ L 142, 30.4.2004, p. 1
[2] COM(2020) 727 final
[3]https://europa.eu/europeanunion/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

- 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 Council[4]
- 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 agencies[6]
- Policy department C study - EU agencies and conflict of interest[7]
- 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;

[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

- 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	*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.	(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	*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, 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.	(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 ***and address*** 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.

Amendment 7

Proposal for a regulation
Recital 14

Text proposed by the Commission	*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.	(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 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	*Amendment*
(22) Since the objectives of this Regulation to expand the mission and tasks of the Centre in order to enhance the	(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.	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.

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)

Text proposed by the Commission	*Amendment*
	(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 ***financial capacity and*** mandate, perform the following tasks:	2. The Centre shall, within its 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	*Amendment*
(e) monitor health systems' capacity relevant to the management of communicable disease threats and other special health issues;	(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 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.;	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 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	*Amendment*
(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**;	(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	*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 and to 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***, 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	*Amendment*
	(23a) Article 24 is replaced by the following:
Article 24	Article 24
Application of the Financial Regulation	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.	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

PROCEDURE – COMMITTEE RESPONSIBLE

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)
Date submitted to Parliament	12.11.2020
Committee responsible Date announced in plenary	ENVI 14.12.2020
Committees asked for opinions Date announced in plenary	BUDG 14.12.2020
Rapporteurs Date appointed	Joanna Kopcińska 14.12.2020
Discussed in committee	25.2.2021 23.3.2021 28.6.2021
Date adopted	29.6.2021
Result of final vote	+: 67 –: 8 0: 1
Members present for the final vote	Bartosz Arłukowicz, Margrete Auken, Simona Baldassarre, Marek Paweł Balt, Traian Băsescu, Aurélia Beigneux, Monika Beňová, Sergio Berlato, Alexander Bernhuber, Simona Bonafè, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Nathalie Colin-Oesterlé, Esther de Lange, Christian Doleschal, Marco Dreosto, Cyrus Engerer, Eleonora Evi, Agnès Evren, Pietro Fiocchi, Andreas Glück, Catherine Griset, Jytte Guteland, Teuvo Hakkarainen, Martin Hojsík, Pär Holmgren, Jan Huitema, Yannick Jadot, Adam Jarubas, Petros Kokkalis, Ewa Kopacz, Joanna Kopcińska, Ryszard Antoni Legutko, Peter Liese, Javi López, César Luena, Fulvio Martusciello, Liudas Mažylis, Tilly Metz, Silvia Modig, Dolors Montserrat, Alessandra Moretti, Dan-Ştefan Motreanu, Ville Niinistö, Ljudmila Novak, Jutta Paulus, Stanislav Polčák, Jessica Polfjärd, Frédérique Ries, María Soraya Rodríguez Ramos, Sándor Rónai, Rob Rooken, Silvia Sardone, Christine Schneider, Günther Sidl, Ivan Vilibor Sinčić, Linea Søgaard-Lidell, Maria Spyraki, Nicolae Ştefănuță, Nils Torvalds, Véronique Trillet-Lenoir, Petar Vitanov, Alexandr Vondra, Mick Wallace, Pernille Weiss, Emma Wiesner, Michal Wiezik, Tiemo Wölken, Anna Zalewska
Substitutes present for the final vote	Manuel Bompard, Annika Bruna, Kateřina Konečná, Sara Matthieu
Date tabled	28.7.2021

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

67	+
ECR	Sergio Berlato, Pietro Fiocchi, Joanna Kopcińska, Ryszard Antoni Legutko, Alexandr Vondra, Anna Zalewska
PPE	Bartosz Arłukowicz, Traian Băsescu, Alexander Bernhuber, Nathalie Colin-Oesterlé, Christian Doleschal, Agnès Evren, Adam Jarubas, Ewa Kopacz, Esther de Lange, Peter Liese, Fulvio Martusciello, Liudas Mažylis, Dolors Montserrat, Dan-Ştefan Motreanu, Ljudmila Novak, Stanislav Polčák, Jessica Polfjärd, Christine Schneider, Maria Spyraki, Pernille Weiss, Michal Wiezik
RENEW	Pascal Canfin, Andreas Glück, Martin Hojsík, Jan Huitema, Frédérique Ries, María Soraya Rodríguez Ramos, Nicolae Ştefănuţă, Linea Søgaard-Lidell, Nils Torvalds, Véronique Trillet-Lenoir, Emma Wiesner
S&D	Marek Paweł Balt, Monika Beňová, Simona Bonafè, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Cyrus Engerer, Jytte Guteland, Javi López, César Luena, Alessandra Moretti, Sándor Rónai, Günther Sidl, Petar Vitanov, Tiemo Wölken
The Left	Manuel Bompard, Petros Kokkalis, Kateřina Konečná, Silvia Modig, Mick Wallace
Verts/ALE	Margrete Auken, Eleonora Evi, Pär Holmgren, Yannick Jadot, Sara Matthieu, Tilly Metz, Ville Niinistö, Jutta Paulus

8	-
ECR	Rob Rooken
ID	Simona Baldassarre, Aurélia Beigneux, Annika Bruna, Marco Dreosto, Catherine Griset, Teuvo Hakkarainen, Silvia Sardone

1	0
NI	Ivan Vilibor Sinčić

Key to symbols:
+ : in favour
- : against
0 : abstention