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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	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

Delegations will find enclosed the four-column table on the above-mentioned proposal.

This document contains in Annex A the explanations on the layout of the tables used in this document and in Annexes B (Recitals) and C (Articles) the text of the Commission proposal, the amendments voted by the European Parliament on 14 September 2021 and the text approved by Coreper on 23 July 2021.

Explanation of the table layout¹

Item	Article/ Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
1 item is unchanged compared to the previous document		Plain text in this column is text from the Commission proposal. <i>Text in bold italics in this column is text from the Commission proposal that the EP proposes to delete.</i>	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. <i>Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.</i>	Plain text in this column is text from the Commission proposal that Council wishes to maintain. <u>Text in bold underlined</u> in this column is text that Council has agreed to add. Text in ~~strike through~~ in this column is text that Council has agreed to delete.	<i>This column contains comments, compromise proposals and tentatively agreed text.</i>

¹ For the sake of readability this document does not contain footnotes. The footnotes will be reintroduced in the consolidated compromise text at the end of the negotiation process.

Citations and Recitals

This Annex contains the Citations and Recitals in the Proposal for a Regulation Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control. For explanations of layout and fonts see Annex A.

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
1	Citations	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
2	Recital 1	(1) The Union is committed to protect and improve human health, <i>in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health.</i>	Amendment 1 (1) The Union is committed <i>as a priority</i> to protect and improve human health <i>through the prevention of disease and by tackling</i> major health scourges <i>by means of</i> monitoring, <i>assessing, communicating on, improving preparedness for, providing</i> early warning of, and combating serious cross-border threats to health.	(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.	
3	Recital 2	(2) Regulation (EC) No 851/2004 of the European Parliament and of the Council established an independent European agency – the European Centre for Disease Prevention and Control (the ‘Centre’) with the mission to identify, assess and communicate current and emerging threats to human health from communicable diseases.		(2) Regulation (EC) No 851/2004 of the European Parliament and of the Council established an independent European agency – the European Centre for Disease Prevention and Control (the ‘Centre’) with the mission to identify, assess and communicate current and emerging threats to human health from communicable diseases.	

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4	Recital 2 a (new)		Amendment 2 <i>(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.</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
5	Recital 3	(3) On 11 March 2020, the World Health Organization (WHO) declared the novel coronavirus COVID-19 outbreak a global pandemic. From the challenges experienced in responding to the pandemic it became clear that the Centre's role in the Union's framework for health crisis preparedness and response should be strengthened.	Amendment 3 (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	(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.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
6	Recital 3 a (new)		Amendment 4 <i>(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.</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
7	Recital 3 b (new)		Amendment 5 <i>(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.</i>		

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7 continued			<i>^{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).</i>		
8	Recital 3 c (new)		Amendment 6 <i>(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.</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
9	Recital 3 d (new)		Amendment 7 <i>(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.</i>		
10	Recital 4	(4) A joint opinion issued by The European Commission’s Group of Chief Scientific Advisors, the European Group on Ethics in Science and New Technologies , and the Special Advisor to the President of the European Commission on the response to COVID-19 recommends ‘establishing a standing EU advisory body for health threats and crises’.		(4) A joint opinion issued by The European Commission’s Group of Chief Scientific Advisors, the European Group on Ethics in Science and New Technologies, and the Special Advisor to the President of the European Commission on the response to COVID-19 recommends ‘establishing a standing EU advisory body for health threats and crises’.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
11	Recital 5	(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 [ISC/2020/12524].	Amendment 8 (5) This Regulation accordingly expands the mission and tasks of the Centre to enhance the Centre's capacity to provide the required <i>robust and independent</i> 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, <i>including in relation to the impact of communicable diseases on major non-communicable diseases and especially the interconnections between them</i> , in accordance with Regulation EU .../... of the European Parliament and of the Council [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 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 [ISC/2020/12524].	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
12	Recital 6	(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.	Amendment 9 (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	(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 scientific-based 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 their national health systems to respond to communicable disease threats, in particular given the importance of this information in the preparation of the Union and national preparedness and response plans.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
12 continued		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 provide timely objective,	<i>mitigation of the impact of communicable diseases on health services and care, in particular 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.</i> 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 <i>and personnel training</i>, and provide timely objective,	The Centre should support the implementation of actions funded by the relevant Union funding programmes and instruments and related to communicable diseases, <u>provide guidelines for case management and support for professional networks to improve</u> ~~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 provide timely objective,	

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12 continued		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.	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.	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, <u>such as WHO,</u> hence contributing to EU's commitment to reinforcing partners' preparedness and response capacity.	
13	Recital 6 a (new)			<u>(6a) It is understood that all recommendations, advices, guidance or opinions made by the Centre under this Regulation, are inherently non-binding on their addressees. A recommendation allows the Centre to make its views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.</u>	

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14	Recital 7	(7) To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should <i>be tasked to</i> communicate to the Centre data on the surveillance of communicable diseases and other special health issues such as antimicrobial resistance and healthcare-associated infections <i>related to communicable</i> diseases, available scientific and technical data and information relevant to the Centre's mission, <i>to</i> notify the Centre of any serious cross-border threats to health, information on preparedness and response planning and health system capacity, <i>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.</i>	Amendment 10 (7) <i>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.</i> To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should communicate, <i>in a timely manner,</i> to the Centre <i>comparable and high quality</i> data on the surveillance of communicable diseases, <i>such as HIV, viral hepatitis B and C and Tuberculosis,</i> and other special health issues such as antimicrobial resistance and healthcare-associated infections <i>and their impact on major non-communicable diseases, including those relating to mental health. Member States should provide</i> available scientific and technical data and information relevant to the Centre's mission, notify the Centre of any serious cross-border threats to health <i>and provide</i> information on preparedness and response planning and health system capacity. <i>To</i>	(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 <u>related</u> special health issues such as antimicrobial resistance and healthcare-associated infections related to communicable diseases, available scientific and technical data and information relevant to the Centre's mission, to notify the Centre of any serious cross-border threats to health, information on preparedness and response planning and health system capacity, and provide relevant information that may be useful for coordinating the response, as well as identify recognised competent bodies and public health experts available to assist in Union responses to health threats. <u>In any event, Member States should provide the data required by this Regulation, in so far as it does not conflict with the safeguard of national security.</u>	

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14 continued			<i>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.</i>		

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15	Recital 7 a (new)		Amendment 11 <i>(7a) Systematic integration of the analysis and assessment of risks associated with environmental, climate and food factors with epidemiological surveillance, taking into consideration 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.</i>		

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16	Recital 8	(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 <i>and</i> Member States through dedicated networks with competent coordinating bodies, including newly established networks for laboratories and for supporting transfusion, transplantation and medically assisted reproduction,	Amendment 12 (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 <i>and the Health Security Committee ('HSC')</i> through dedicated networks with competent coordinating bodies, including <i>by encouraging cooperation within the Union's</i> 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 and Member States through dedicated networks with competent coordinating bodies, including newly established networks for laboratories and for supporting transfusion and transplantation services and medically assisted reproduction.	

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17	Recital 9	(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 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.	Amendment 13 (9) With a view to enhance the effectiveness of epidemiological surveillance <i>and monitoring of testing for and treatment of</i> communicable <i>diseases, their interconnection with major non-communicable</i> diseases and of the related special health issues in the Union, the Centre should be tasked with the further development of <i>secure and interoperable</i> digital platforms and applications, supporting epidemiological surveillance at Union level, enabling the use of digital technologies, such as artificial intelligence <i>and computer modelling and simulation</i> , 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.	(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 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.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
18	Recital 10	(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	Amendment 14 (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, <i>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</i> , monitor and report on trends in communicable diseases, support, <i>coordinate</i> 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 <i>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</i> communicable diseases, including in a gender-sensitive way, identify population groups at risk requiring	(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, <u>support the collection of available indicators</u> ~~monitor and assess the capacity of~~ national health systems <u>capacity</u> for diagnosis, prevention and treatment of communicable diseases, including in a gender-sensitive way, ~~identify~~ <u>support Member States to define</u> population groups at risk requiring	

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18 continued		specific measures, analyse the correlation of disease incidence with societal <i>and</i> 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.	specific measures, analyse the correlation of disease incidence with societal, environmental <i>and climate</i> factors, <i>consider the impact of comorbidities on patients with communicable diseases and on their treatment</i> 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.	specific measures, analyse the correlation of disease incidence with societal and environmental factors, and identify risk factors for transmission and disease severity of communicable diseases, and identify research needs and priorities. The Centre should work with nominated national focal points for surveillance, forming a network that strategically advises the Centre on such matters and would promote the use of enabling sectors, such as EU space data and services.	

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19	Recital 11	(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 <i>of the</i> 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.	Amendment 15 (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 <i>in an integrated manner of a dedicated</i> 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, <i>training in current and innovative procedures</i> and use of tests, in order to ensure uniform surveillance, notification and <i>standardised</i> 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 of the network of Union reference laboratories in accordance with <i>Regulation (EU) .../... [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]].</i> 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.	

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20	Recital 12	(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.	Amendment 16 (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.	(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~~ should cooperate with Member States 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.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
21	Recital 13	(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 <i>and</i> behaviour change.	Amendment 17 (13) With the aim of reducing the occurrence of epidemics and strengthening capacities to prevent communicable diseases in the Union, the Centre should, <i>working in conjunction with Member States so as to take account of their experiences and respective situations</i> , develop a framework for the prevention of communicable diseases, which addresses such issues as vaccine preventable diseases, <i>vaccine hesitancy, awareness of transmission routes</i> , antimicrobial resistance, health education, health literacy, <i>health inequalities and disease prevention</i> , behaviour change <i>and links with major non-communicable diseases</i> . <i>The Centre should provide guidelines for Member States and monitor the implementation of that framework by Member States.</i>	(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.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
22	Recital 14	(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	Amendment 18 (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 <i>preparedness and response plans</i> and <i>contributing to the development of the</i> 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, <i>including by providing training and by sharing best practices</i> . 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	(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, <u>regular review and updating of frameworks for</u> ~~Union and national~~ preparedness and response plans <u>at EU level</u> , and ~~preparedness~~ monitoring and evaluation <u>of those</u> frameworks, provide <u>scientific-based</u> 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	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
22 continued		epidemic phenomena or new diseases of unknown origin, including in third countries, molecular pathogen data <i>and</i> 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.	epidemic phenomena or new diseases of unknown origin, including in third countries, molecular pathogen data, health systems data, <i>and data on interconnections between communicable diseases and major non-communicable diseases</i> . To this end, the Centre should ensure appropriate datasets as well as the procedures to facilitate consultation and <i>secure</i> data transmission and access, carry out scientific and technical evaluation of prevention and control measures at Union level and work with <i>the WHO, relevant Union</i> agencies, competent bodies and organisations operating in the field of data collection.	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.	
23	Recital 14 a (new)			<u>(14a) Within its mandate, ECDC should respond to the requests of Member States or the Commission in a timely manner.</u>	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
24	Recital 15	(15) Regulation .../... [OJ: <i>please, insert reference to Regulation SCBTH</i> [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.	Amendment 19 (15) Regulation .../... [OJ: <i>please, insert reference to Regulation SCBTH</i> [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, <i>high performance computing, in silico clinical trials and digital twin</i> technologies and interoperable and privacy-preserving digital tools, such as mobile applications, with tracing functionalities identifying at-risk individuals, <i>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.</i>	(15) <i>Regulation .../... [OJ: please, insert reference to Regulation SCBTH</i> [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.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
25	Recital 16	(16) The Centre should establish appropriate capacities to support international and field response, in accordance with Regulation .../... [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]. These capacities should enable the Centre to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’, to assist local responses to outbreaks of diseases. The Centre should therefore ensure capacity to carry out missions to Member States as well as in third countries and to provide recommendations on response to health threats. These teams will also be able to be deployed under the Union Civil Protection Mechanism with the support of the Emergency Response Coordination Centre.	Amendment 20 (16) The Centre should establish appropriate capacities to support international, <i>interregional</i> 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 <i>and collect field data</i>. The Centre should therefore ensure <i>permanent</i> 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.	(16) The Centre should establish appropriate capacities to support international and field response, in accordance with <i>Regulation .../... [OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]]</i>. 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 <u>scientific-based</u> 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. <u>The effective operation of the ‘EU Health Task Force’ should be based on profound country knowledge which can be achieved through input from</u>	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
25 continued		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.	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.	<u>national experts.</u> 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. <u>The Centre should also maintain regular secondment mechanisms between the Centre, the Commission, Member States' experts and international organisations to strengthen the operational interface between ECDC and Member States as well as ensure systematic and permanent working arrangements introduced within the ECDC (for example through the desk officers).</u>	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
26	Recital 17	(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 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.	Amendment 21 (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 and facilitate the participation of Union field response experts in international response teams in support of and in close 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, to effectively participate in field missions and crisis management. Therefore, the Centre should develop a framework of recognisable expertise levels.	(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 and facilitate the participation of Union field response experts in international response teams in support of 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, to effectively participate in field missions and crisis management.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
27	Recital 17 a (new)		Amendment 22 <i>(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.</i>		
28	Recital 17 b (new)		Amendment 23 <i>(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.</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
29	Recital 17 c (new)		Amendment 24 <i>(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.</i>		
30	Recital 17 d (new)		Amendment 25 <i>(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.</i>		
31	Recital 17 e (new)		Amendment 26 <i>(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.</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
32	Recital 18	(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.	Amendment 27 (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.	(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.	
33	Recital 19	(19) This Regulation should not confer any regulatory powers on the Centre.	Amendment 28 (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.	(19) This Regulation should not confer any regulatory powers on the Centre.	
34	Recital 20	(20) The Centre should implement an information system capable of exchanging classified and sensitive non-classified information to ensure that such information is managed with the utmost discretion.		(20) The Centre should implement an information system capable of exchanging classified and sensitive non-classified information to ensure that such information is managed with the utmost discretion.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
35	Recital 20 a (new)			<u>(20a) Any processing of personal data based on this Regulation should be fully compliant with Regulations (EU) No 2016/679 and (EU) No 2018/1725 and with Directive 2002/58/EC on privacy and electronic communications. Processing of personal data should be limited to the strictly necessary and, whenever possible, data should be anonymized. For these purposes, rights of data subjects should be fully respected notably in terms of licit, loyal and transparent collection and information in case of change of purpose of the data collected. In the case of cooperation with the health authorities of the Union, third countries, WHO or other international organizations, transfers of personal data to third countries or international organizations should always comply with the obligations laid down under Regulation (EU) No 2018/1725.</u>	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
36	Recital 20 a (new)		Amendment 29 <i>(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.</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
36 continued			<i>^{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).</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
37	Recital 20 b (new)		Amendment 30 <i>(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</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
37 continued			<i>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.</i> ^{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).		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
38	Recital 20 c (new)		Amendment 31 <i>(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</i>		

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
38 continued			<i>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.</i> <i>^{1a} OJ L 123, 12.5.2016, p. 1.</i>		
39	Recital 21	(21) In view of the urgency entailed by the exceptional circumstances caused by the COVID-19 pandemic, it is considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.		(21) In view of the urgency entailed by the exceptional circumstances caused by the COVID-19 pandemic, it is considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
40	Recital 22	(22) Since the objectives of this Regulation to expand the mission and tasks of the Centre in order to enhance the Centre's capacity to provide the required scientific expertise and to support actions which combat serious cross-border threats to health in the Union cannot be sufficiently achieved by the Member States but can rather, by reason of the cross-border nature of the health threats and the need for rapid, coordinated and coherent response, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	Amendment 32 (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.	(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.	

Item	Citation / Recital Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
41	Recital 22 a (new)			<u>(22a) In order to ensure uniform conditions for the implementation of this Regulation, notably on the rapid mobilisation and responsiveness of the EU Health Task Force under Article 11a, implementing powers should be conferred on the Commission. These powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.</u>	
42	Recital 23	(23) Regulation (EC) No 851/2004 should therefore be amended,		(23) Regulation (EC) No 851/2004 should therefore be amended,	
43		HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	

Articles

This Annex contains the Articles in the Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control. For explanations of layout and fonts see Annex A.

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
44	Article 1	<i>Article 1</i> Regulation (EC) No 851/2004 is amended as follows:		<i>Article 1</i> Regulation (EC) No 851/2004 is amended as follows:	
45		(1) Article 2 is replaced by the following:		(1) Article 2 is replaced by the following:	
46	Article 2 Article 2 – paragraph 1	<i>Article 2</i> Definitions For the purposes of this Regulation, the following definitions apply: (1) ‘competent body’ means any structure, institute, agent or other scientific body recognised by Member States authorities as providing independent scientific and technical advice or capacity for action in the field of the prevention and control of human disease;		~~<i>Article 2</i>~~ Definitions For the purposes of this Regulation, the following definitions apply: (1) ‘competent body’ means any structure, institute, agent or other scientific body recognised by Member States authorities as providing independent scientific and technical advice or capacity for action in the field of the prevention and control of human disease;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
46 continued	Article 2 – paragraph 1 – point 1 a (new) Article 2 – paragraph 2	(2) ‘coordinating competent body’ means a body in each Member State with a designated national coordinator responsible for institutional contacts with the Centre, as well as national focal points and operational contact points responsible for strategic and operational collaboration on technical and scientific issues for specific diseases areas and public health functions;	Amendment 33 <i>(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;</i>	(2) ‘coordinating competent body’ means a body in each Member State with a designated national coordinator responsible for institutional contacts with the Centre, as well as national focal points and operational contact points responsible for strategic and operational collaboration on technical and scientific issues for specific diseases areas and public health functions;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
46 continued	Article 2 – paragraph 1 – point 4 a (new)	(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; (4) ‘communicable disease’ means communicable disease as defined in point (2) of Article 3 of Regulation (EU) .../... [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];	Amendment 34 (3) ‘dedicated network’ means any specific network on diseases, special health issues or public health functions <i>that is supported and coordinated by the Centre and is intended</i> to ensure collaboration between the coordinating competent bodies of the Member States; Amendment 35 <i>(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;</i>	(3) ‘dedicated network’ means any specific network on diseases, <u>related</u> special health issues or public health functions to ensure collaboration between the coordinating competent bodies of the Member States; (4) ‘communicable disease’ means communicable disease as defined in point (2) of Article 3 of Regulation (EU) .../... [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
46 continued		(5) ‘serious cross-border threat to health’ means serious cross-border threat to health as defined in point (7) of Article 3 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> ; (6) ‘epidemiological surveillance’ means epidemiological surveillance as defined in point (4) of Article 3 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> . ’;		(5) ‘serious cross-border threat to health’ means serious cross-border threat to health as defined in point (7) of Article 3 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> ; (6) ‘epidemiological surveillance’ means epidemiological surveillance as defined in point (4) of Article 3 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> . ’;	
				(7) ‘related special health issues’ means related special health issues as defined in point (1) (a) ii of Article 2 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> ;	
				(8) ‘monitoring’ means monitoring as defined in point (5) of Article 3 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> ;	
				(9) ‘health system capacity’ means health system capacity as defined in point (9) of Article 3 of Regulation (EU) .../... <i>[OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]</i> . ’;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
47		(2) Article 3 is replaced by the following:		(2) Article 3 is replaced by the following:	
48	Article 3 Article 3 – paragraph 1	<i>‘Article 3</i> Missions and tasks of the Centre 1. 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 <i>those</i> 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 <i>and</i> report on current and emerging threats to human health from communicable diseases,.	Amendment 36 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 <i>relevant major non-communicable diseases and health issues, including the</i> 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 <i>and, where appropriate, ensure that information is presented in an easily accessible way</i> on current and emerging threats to human health from communicable diseases <i>and relevant major non-communicable diseases</i>	<i>‘Article 3</i> Missions and tasks of the Centre 1. 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,	

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48 continued		and provide recommendations <i>for</i> response at Union and national levels, as well as at regional level, <i>if necessary</i> .	<i>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.</i>	and provide <u>scientific-based</u> recommendations for response at Union and national levels, as well as at regional level <u>in coordination with Member States</u> if necessary.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued		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 <i>only</i> in cooperation with the competent <i>body</i> upon request <i>from that body</i> .	Amendment 37 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 <i>bodies</i> upon <i>their</i> request <i>and provide a risk assessment</i> .	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 <u>coordinating</u> competent body upon request from that body.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2	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 2. The Centre shall, within its financial capacity and mandate, perform the following tasks:	Amendment 38 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 2. The Centre shall, within its mandate, perform the following tasks:	In pursuing its mission, the Centre shall ~~take full account~~ respect of the responsibilities of the Member States, the Commission and other Union bodies or agencies, and of the responsibilities of third countries and international organisations active within the field of public health, particularly the WHO, in order to ensure comprehensiveness, coherence and complementarity of action. <u>The Centre shall support the work of the Health Security Committee (HSC), the Council, other Union structures and the Member States to promote effective coherence between their respective activities and for coordinating responses to serious cross-border threats to health within its mandate.</u> 2. The Centre shall ~~within its financial capacity and mandate~~, perform the following tasks:	

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48 continued	Article 3 – paragraph 2 – point a Article 3 – paragraph 2 – point a a (new)	(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, considering the latest technologies;	Amendment 40 (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 <i>(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;</i>	(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, ~~using~~ considering the latest ~~most effective~~ technologies, respecting the European standards regarding ethical aspects and, where applicable, in accordance with the data protection requirements laid down in Article 20a ;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2 – point a b (new) Article 3 – paragraph 2 – point b	(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 ;	Amendement 42 <i>(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;</i> Amendment 43 (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;	b) provide analyses, scientific and technical advice, opinions, scientific-based recommendations and support for actions by the Union and Member States, to prevent and control communicable diseases and related special health issues , ~~on cross border health threats,~~ including risk assessments, analysis of epidemiological information, epidemiological modelling, preparedness and response planning 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;~~	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2 – point b a (new) Article 3 – paragraph 2 – point c Article 3 – paragraph 2 – point d	(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; (d) exchange information, expertise and best practice;	Amendment 44 <i>(ba) identify and monitor the impact of major non-communicable diseases on the incidence, severity and mortality rates of communicable diseases;</i> Amendment 45 (c) coordinate the European networking of bodies, <i>organisations and experts</i> 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, <i>while ensuring full compliance with the rules on transparency and conflicts of interest;</i> Amendment 46 (d) exchange information, expertise and best practice, <i>as well as provide scientific and technical assistance, including training;</i>	(c) <u>promote and</u> coordinate the ~~European~~ networking of bodies operating in <u>Europe in</u> the fields within the Centre’s mission, including networks arising from public health activities supported by the Commission and operating the dedicated <u>surveillance</u> networks; (d) <u>promote and facilitate the exchange of technical and scientific information and</u> expertise and best practices, <u>including training, among Member States and other EU bodies and Agencies;</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2 – point e	(e) monitor health systems' capacity relevant to the management of communicable disease threats and other special health issues;	Amendment 47 (e) monitor health systems' capacity relevant to the management of communicable disease threats and other special health issues, <i>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;</i>	(e) <u>monitor the health systems' capacity in close cooperation with the Member States</u> ~~monitor health systems' capacity relevant~~ <u>and support the collection of available indicators of Member States' capacity regarding health services to the extent it is necessary for</u> ~~to~~ the management <u>and response</u> ~~of~~ <u>to</u> communicable disease threats and ~~other~~ <u>related</u> special health issues;	

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48 continued	Article 3 – paragraph 2 – point f	(f) facilitate the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions;	Amendment 50 (f) facilitate the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions <i>in the area of health</i> ;	(f) <u>contribute to defining research priorities and to facilitate</u> ing the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions <u>to improve public health functions</u> ;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2 – point g	(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 ;	Amendment 51 (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 ;	(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~~ related special health issues ~~relevant for public health, and~~ support for professional networks to improve treatment guidelines in cooperation with ~~relevant societies~~ relevant organizations and associations, national competent bodies and international organizations such as WHO ;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2 – point h Article 3 – paragraph 2 – point h a (new)	(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;	Amendment 52 (h) support epidemic and outbreak response in Member States, and in third countries, in complementarity <i>and close coordination</i> with other Union emergency response instruments, in particular the Union Civil protection mechanism, <i>by providing recommendations on the stockpiling of medical countermeasures in cooperation with the European Medicines Agency (EMA) and other relevant Union agencies and bodies</i> ; Amendment 53 <i>(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;</i>	(h) support, <u>for example, through the EU Health Task Force referred to in Article 11a,</u> epidemic and outbreak response in Member States <u>based on profound country knowlegde,</u> and in third countries; in <u>cooperation with WHO mechanism, and in</u> complementarity with other ~~Union~~ emergency response instruments, in particular the Union Civil protection mechanism;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 2 – point i Article 3 – paragraph 2 – point j Article 3 – paragraph 2 – point j a (new)	(i) contribute to strengthening preparedness capacities under the IHR in third countries, in particular EU partner countries; (j) provide, upon request of the Commission <i>or the Health Security Committee ('HSC')</i>, 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.	Amendment 54 (j) provide, upon request of the Commission, <i>the HSC, or on its own initiative, timely, easily accessible and</i> evidence-based communication messages to the public <i>in all official languages of the Union</i> on communicable diseases, on the threats to health posed by them, <i>on their possible impact on patients suffering from major non-communicable diseases,</i> and on the relevant prevention and control measures; Amendment 55 <i>(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.</i>	(i) contribute to strengthening preparedness capacities under the IHR, <u>including training, in Member States and in</u> third countries, in particular EU partner countries, <u>while ensuring synergy with the work of WHO;</u> (j) ~~provide~~<u>propose</u>, 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 <u>with due respect to the competencies of the Member States;</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
48 continued	Article 3 – paragraph 3	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.’;	Amendement 56 3. The Centre, the Commission, the relevant Union bodies or EU agencies and the Member States shall cooperate <i>in full transparency</i> to promote effective coherence between their respective activities.	3. The Centre, the Commission, the relevant Union bodies or EU agencies and the Member States shall cooperate to promote effective coherence <u>and synergies</u> between their respective activities.’;	
49		(3) Article 4 is replaced by the following:		(3) Article 4 is replaced by the following:	
50	Article 4 – paragraph 1 – introductory part	<i>‘Article 4</i> Obligations of the Member States Member States shall:	Amendment 57 Member States shall <i>ensure the coordination and collaboration with the Centre in relation to all the missions and tasks set out in Article 3, by:</i>	<i>‘Article 4</i> Obligations of the Member States Member States shall:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
50 continued	Article 4 – paragraph 1 – point b Article 4 – paragraph 1 – point c	(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 (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.	Amendment 60 (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 (c) identify, within the scope of the mission of the Centre, recognised 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.	(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~~ is 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 (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 cross-border health threats, such as by undertaking missions to Member States, and third countries in cooperation with the WHO , to provide expert advice and field investigations in the event of disease clusters or outbreaks.’;	

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50 continued	Article 4 – paragraph 1 – point c a (new) Article 4 – paragraph 1 – point c b (new) Article 4 – paragraph 1 – point c c (new)		Amendment 62 <i>(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;</i> Amendment 63 <i>(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</i> Amendment 64 <i>(cc) immediately notify any delay in the reporting of the data to the Centre with an explanation therefore and a planned date of submission.</i>		

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
51		(4) Article 5 is replaced by the following:		(4) Article 5 is replaced by the following:	
52	Article 5 – paragraph 1	<i>‘Article 5</i> Operation of dedicated networks and networking activities 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.	Amendment 65 1. The Centre shall support <i>and continuously develop</i> 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.	<i>‘Article 5</i> Operation of dedicated networks and networking activities 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.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 2	2. The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of <i>the</i> communicable diseases and of <i>the related</i> special health issues referred to in <i>points (i) and</i> (ii) of point (a) of Article 2(1) of Regulation (EU) .../... [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]].	Amendment 66 The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of communicable diseases and of special health issues, <i>such as an unpredicted rise in major non-communicable diseases or chronic conditions and in health-related environmental hazards, including those</i> referred to in <i>point</i> (ii) of point (a) of Article 2(1) of Regulation (EU).../... [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]].	2. The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of ~~the~~ communicable diseases and of ~~the~~ 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]]. <u>including the integrated operation of a network of EU reference laboratories.</u> It shall in particular:	

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52 continued	Article 5 – paragraph 2 – point a	(a) ensure the <i>further</i> 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;	Amendment 67 (a) ensure the <i>continuous</i> development of the digital platforms and applications, <i>including the platform for surveillance established under Article 14 of Regulation (EU) .../... [the SCBTH Regulation],</i> 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, <i>and proving the necessity and proportionality of data collection and use following a data protection impact assessment ('DPIA'),</i> benefiting from existing EU <i>digital</i> space infrastructures and services, <i>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</i>	(a) ensure the further development of the <u>automated</u> digital platforms and applications supporting epidemiological surveillance at Union level, supporting Member States with technical and scientific <u>data and</u> advice to establish integrated surveillance systems enabling real-time surveillance where appropriate <u>and feasible for preparedness,</u> benefiting from existing EU space infrastructures and services; <u>The digital platforms and applications shall be implemented with privacy-enhancing technologies taking into account the state of the art;</u>	

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52 continued	Article 5 – paragraph 2 – point b	(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;	<i>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;</i> <i>* 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</i> (b) provide quality assurance by monitoring and evaluating epidemiological surveillance activities (including setting surveillance standards and monitoring data completeness <i>and assessment indicators</i>) of the dedicated surveillance networks to ensure optimal operation;	(b) provide quality assurance by monitoring and evaluating epidemiological surveillance activities (including ~~setting~~ proposing surveillance standards and monitoring data completeness) of the dedicated surveillance networks to ensure optimal operation;	

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52 continued	Article 5 – paragraph 2 – point d Article 5 – paragraph 2 – point e Article 5 – paragraph 2 – point f	(d) communicate the results of the analysis of data to the Commission and Member States; (e) harmonise and rationalise the operating methodologies; (f) ensure the interoperability of automated applications, including for contact tracing, developed at national level;	Amendment 71 (d) communicate the results of the analysis of data to the Commission and Member States <i>and propose communications to inform the public;</i>	(d) communicate the results of the analysis of data to the Commission, <u>the HSC</u> and Member States, <u>and make databases accessible and usable by Member States to support national policy making and their bilateral and multilateral collaboration;</u> (e) <u>promote and support</u> harmonised and rationalised operating methodologies <u>for epidemiological surveillance in collaboration with the competent bodies;</u> (f) ensure the interoperability of automated applications <u>and other digital tools that support cross-border public health activities,</u> including for contact tracing <u>and warning applications,</u> developed at <u>EU level or national level in close collaboration with Member States;</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 2 – point g	(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.	Amendment 72 (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, <i>in compliance with points (h) and (i) of Article 9(2) of Regulation (EU) 2016/679 of the European Parliament and of the Council*</i>, 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 <i>or phenomena with a potential severe health impact at Union or interregional level.</i> <i>* Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016</i>	(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, <u>socio-economic determinants, among others, if useful to better fulfil the Centre's mission.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 3 Article 5 – paragraph 4	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. 4. The Centre, through the operation of the network for the epidemiological surveillance, shall:	<i>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).</i> Amendment 73 3. The Centre shall support the work of the HSC, the Council and, <i>where relevant</i> , 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 other Union structures for coordinating responses to serious cross border threats to health within its mandate.~~ 4. The Centre, through the operation of the network for the epidemiological surveillance, shall:	

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52 continued	Article 5 – paragraph 4 – point a	(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	Amendment 74 (a) monitor and report on trends in communicable diseases <i>and their interconnection with major non-communicable diseases and chronic conditions and implications for patients with such diseases and conditions</i> 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 over time and across Member States and in third countries; <u>in cooperation with the WHO,</u> 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 <u>M</u> member <u>S</u> tates;	

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52 continued	Article 5 – paragraph 4 – point b Article 5 – paragraph 4 – point b a (new) Article 5 – paragraph 4 – point c	(b) detect, monitor and report on serious cross-border threats to health in the case of a threat 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]], including a threat to substances of human origin, such as blood, organs, tissues and cells potentially impacted by communicable diseases, or in point (d) of Article 2(1) of that Regulation, with respect to source, time, population and place in order to provide a rationale for public health action; (c) contribute to the evaluation and monitoring of 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 levels;		(b) detect, monitor and report on serious cross-border threats to health in the case of a threat 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]], including a threat to substances of human origin, ~~such as blood, organs, tissues and cells potentially impacted by communicable diseases~~, or in point (d) of Article 2(1) of that Regulation, with respect to source, time, population and place in order to provide a rationale for public health action; (ba) support the national reference laboratories referred to Article 15 of Regulation (EU) .../... [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]] in the implementation of the external quality control schemes, including professional testing scheme; (c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for scientific-based recommendations to strengthen and improve these programmes at the national and Union levels;	

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52 continued	Article 5 – paragraph 4 – point d Article 5 – paragraph 4 – point e Article 5 – paragraph 4 – point f	(d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety; (e) identify population groups at risk and in need of targeted prevention and response measures, and ensure that those measures are accessible for persons with disabilities; (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;	Amendment 75 (d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety <i>and the resilience of the national health systems in the event of major disease outbreaks, based on common indicators and definitions;</i> Amendment 76 (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, <i>and patients' comorbidities;</i>	(d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases, <u>when necessary for crisis preparedness or response</u> as well as patients' safety; (e) ~~identify~~ <u>support Member States to define</u> population groups at risk and in need of targeted prevention and response measures, ~~and ensure that those measures are accessible for~~ <u>including</u> persons with disabilities; (f) contribute to the assessment of the burden of communicable diseases ~~on the population using data,~~ such as disease prevalence, <u>clinical</u> complications, hospitalisation and mortality, <u>among others and ensure that this data is using disaggregated stratified data</u> on age, gender, and disability <u>and other elements, if available;</u>	

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52 continued	Article 5 – paragraph 4 – point g Article 5 – paragraph 4 – point h	(g) carry out epidemiological modelling, anticipation and scenario development for response and coordinate such efforts with a view to exchange best practices and improve modelling capacity across the Union; and (h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal <i>and</i> environmental factors, and research priorities and needs.	Amendment 77 (h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal, environmental <i>and climatic</i> factors, and research priorities and needs.	(g) carry out epidemiological modelling, anticipation and scenario development for response and coordinate such efforts with a view to exchange best practices and improve modelling capacity across the Union <u>and ensuring international cooperation</u> ; and (h) identify risk factors for disease transmission <u>and the associated disease burden, including social, economic and environmental determinants, following a one health approach for zoonotic, food and water borne diseases and relevant other diseases and special health issues</u> ; ~~groups most at risk, including the correlation of disease incidence and severity with societal and environmental factors, and research priorities and needs.~~	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 5 – subparagraph 3 Article 5 – paragraph 5 – subparagraph 4 Article 5 – paragraph 5 a (new)	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. Member States shall notify the Centre and other Member States of the designations and nominations provided for in this paragraph and of any change thereof.	Amendment 79 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 <i>as well as proposals for the prevention and control of communicable diseases</i> 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 to the Centre. Member States shall notify the Centre and other Member States of the designations and nominations provided for in this paragraph and of any change thereof. <u>5a. The Centre shall cooperate with the competent bodies recognised by the Member States, particularly on preparatory work for scientific opinions, scientific and technical assistance, the collection of comparable data based on common formats that allows for ease of aggregation, and the identification of emerging health threats.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 6 Article 5 – paragraph 6 a (new)	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.	Amendment 80 6. The Centre shall ensure <i>and coordinate</i> 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, <i>genetic sequencing</i> and characterisation of infectious agents that may present a threat to public health. Amendment 81 <i>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.</i>	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.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 7 Article 5 – paragraph 8 – subparagraph 1	7. By encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Union for the diagnosis, detection, identification and characterisation of infectious agents, which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes. 8. 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.	Amendment 82 The Centre shall ensure the operation <i>and coordination</i> of the network of Member State services supporting <i>the microbiological safety of substances of human origin encompassing</i> transfusion, transplantation and medically assisted reproduction <i>established under Article 16 of Regulation (EU) .../... [the SCBTH Regulation]</i> 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.	7. By encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Union for the diagnosis, detection, identification and characterisation of infectious agents, which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes. 8. The Centre shall ensure the operation of the network of Member State services supporting transfusion, ~~and~~ transplantation ~~and medically assisted reproduction to~~ <u>monitor , asesess and help adress disease outbreaks that are relevant to substance of human origin and pose cross - health border threat to safeguard patients in need of such substances.</u> ~~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.~~	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
52 continued	Article 5 – paragraph 8 – subparagraph 2 Article 5 – paragraph 9	The network referred to in the first subparagraph shall support the Centre by monitoring <i>disease</i> outbreaks that are relevant to substances of human origin <i>and their supply</i> to patients, and with the development of guidelines for blood, tissues and cells safety and quality. 9. The Centre shall cooperate with the competent bodies recognised by the Member States, particularly on preparatory work for scientific opinions, scientific and technical assistance, the collection of comparable data based on common formats that allows for ease of aggregation, and the identification of emerging health threats.’	Amendment 83 The network referred to in the first subparagraph shall support the Centre by monitoring outbreaks <i>of communicable diseases</i> that are relevant to <i>the safety and sufficiency of the supply of</i> substances of human origin 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 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.~~ ~~9. The Centre shall cooperate with the competent bodies recognised by the Member States, particularly on preparatory work for scientific opinions, scientific and technical assistance, the collection of comparable data based on common formats that allows for ease of aggregation, and the identification of emerging health threats.’~~	
53		(5) the following Article 5a is inserted:		(5) the following Article 5a is inserted:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
54	Article 5a – paragraph 1 Article 5a – paragraph 2	<i>'Article 5a</i> Prevention of communicable diseases 1. The Centre shall support Member States to strengthen their communicable disease prevention and control systems. 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.	Amendment 84 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 2. <i>In close collaboration with Member States, EMA and other relevant Union bodies and agencies, as well as with international organisations,</i> the Centre shall develop a framework for the prevention of communicable diseases and special issues, including <i>socio-economic risk factors,</i> vaccine preventable diseases, antimicrobial resistance, health <i>promotion, health</i> education, health literacy and behaviour change.	<i>'Article 5a</i> Prevention of communicable diseases 1. The Centre shall support Member States to strengthen their communicable diseases <u>prevention</u> and control systems. 2. The Centre shall develop a framework for the prevention of communicable diseases and related special health issues, including vaccine preventable diseases, antimicrobial resistance, health education, health literacy and behaviour change.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
54 continued	Article 5a – paragraph 2 – subparagraph 1 a (new)		Amendment 86 <i>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.</i>		

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
54 continued	Article 5a – paragraph 4	4. The Centre shall coordinate independent post-marketing vaccines effectiveness and safety monitoring studies collecting new information and/or using the relevant data collected by competent bodies. That work shall be conducted jointly with the European Medicines Agency and notably through a new vaccine monitoring platform.’;		4. The Centre shall coordinate independent post-marketing vaccines effectiveness and safety monitoring studies collecting new information and/or using the relevant data collected by competent bodies. That work shall be conducted jointly with the European Medicines Agency and notably through a new vaccine monitoring platform.’;	
55		(6) the following Article 5b is inserted:		(6) the following Article 5b is inserted:	
56	Article 5b – paragraph 1 – subparagraph 1	<i>‘Article 5b</i> Preparedness and response planning 1. 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.	Amendment 89 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.	<i>‘Article 5b</i> Preparedness and response planning 4. 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.~~	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
56 continued	Article 5b – paragraph 1 – subparagraph 2 Article 5b – paragraph 1 – subparagraph 2 – point a Article 5b – paragraph 1 – subparagraph 2 – point b Article 5b – paragraph 1 – subparagraph 2 – point c	The Centre shall, in close collaboration with the Member States and the Commission: (a) contribute to the development, regular review and updating of preparedness plans and blueprints of threat-specific preparedness plans for adoption by the HSC; (b) develop preparedness monitoring and evaluation frameworks and indicators for preparedness; (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]];	Amendment 90 (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;	The Centre shall, in close collaboration with the Member States and the Commission: (a) contribute to the development, regular review and updating of frameworks for preparedness plans at EU level and blueprints of threat-specific preparedness plans for adoption by the HSC; (b) develop preparedness, monitoring and evaluation frameworks, and indicators for preparedness based on the IHR, in cooperation with WHO, to be discussed at the HSC; (c) facilitate self-assessments ~~and external evaluation of~~ Member States' preparedness and response planning, in complement of the IHR, and contribute to reporting and ~~auditing-examining on~~ preparedness and response planning under Articles 7 and 8 of Regulation (EU) .../... [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]];	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
56 continued	Article 5b – paragraph 1 – subparagraph 2 – point d Article 5b – paragraph 1 – subparagraph 2 – point e Article 5b – paragraph 1 – subparagraph 2 – point f Article 5b – paragraph 1 – subparagraph 2 – point g	(d) ensure monitoring of preparedness gaps and provision of targeted support to EU Member States and third countries in case of needs; (e) develop exercises, in-action and after-action reviews and organise capacity building actions to address identified preparedness capacity and capability gaps; (f) develop specific preparedness activities addressing vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity in accordance with Commission priorities and based upon gaps identified; (g) support the integration of research preparedness in the preparedness and response plans;	Amendment 91 (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 (f) develop specific preparedness activities addressing, amongst other things, vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity in accordance with Commission priorities and based upon gaps identified;	(d) ~~ensure~~ facilitate support for observing and overcoming ~~monitoring of~~ preparedness gaps and provision of targeted support to EU Member States and third countries in cooperation with the WHO upon their request ~~in case of~~ needs; (e) develop exercises, in-action and after-action reviews at EU level, support and complement Member States on those activities and organise ~~capacity building~~ additional actions to address identified preparedness capacity and capability gaps; (f) develop and support specific preparedness activities addressing vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity, among others, in accordance with Commission priorities and based upon identified gaps or upon request from Member States or the Commission ~~identified~~; (g) support the integration of research preparedness in the preparedness and response plans;	

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56 continued	Article 5b – paragraph 1 – subparagraph 2 – point h Article 5b – paragraph 1 – subparagraph 2 – point i Article 5b – paragraph 1 – subparagraph 2 – point j	(h) develop targeted activities addressing at-risk groups and community preparedness; (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; (j) bolster modelling, anticipation and forecast capacity of the Centre; and	Amendment 93 (h) develop targeted activities addressing at-risk groups and community preparedness, <i>in particular taking into account the risks associated with the causes and treatment of major non-communicable diseases;</i> Amendment 94 (i) assess health systems' capacity <i>based on common indicators</i> to detect, prevent, respond to and recover from outbreaks of communicable diseases <i>and related health risks</i>, identify gaps and provide recommendations for the strengthening of health systems, <i>in particular as regards minimum testing capacities</i>, to be implemented with Union support as appropriate; <i>the Centre shall send its assessment with recommendations to the Member State and shall make it public;</i>	(h) ~~develop~~ support and complement additional targeted activities addressing at-risk groups and community preparedness; (i) support Member States to assess health systems' capacity to detect, prevent, respond to and recover from outbreaks of communicable diseases, ~~identify gaps~~ and provide scientific-based recommendations for the strengthening of health systems, to be implemented with Union support as appropriate; (j) bolster modelling, anticipation and forecast capacity of the Centre; and	

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56 continued	Article 5b – paragraph 1 – subparagraph 2 – point k	(k) maintain a regular secondment mechanisms between the Centre, the Commission and Member States’ experts.’;		(k) maintain a regular secondment mechanisms between the Centre, the Commission, and Member States’ experts <u>and international organisations including a EU Health Task Force that support activities under points (d), (f), (h) and (i) and Art. 5a paragraph 1. The secondment mechanism shall contribute in strengthening the operational interface between ECDC and Member States;</u>	
57		(7) Article 6 is amended as follows:		(7) Article 6 is amended as follows:	
58	Article 6 – paragraph 1a Article 6 – paragraph 1b	(a) the following paragraph 1a is inserted: ‘1a. The Centre shall provide concrete analyses and recommendations for actions to prevent and control communicable disease threats upon request of the Commission.’; (b) paragraph 3 is replaced by the following:	Amendment 95 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.	(a) the following paragraph 1a is inserted: ‘1a. The Centre shall provide concrete analyses and <u>independent technical or scientific-based</u> recommendations for actions to prevent and control communicable disease threats <u>on its own initiative or</u> upon request of the Commission, <u>Member States through HSC</u> .’; (b) paragraph 3 is replaced by the following:	

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58 continued	Article 6 – paragraph 3 – subparagraph 1	‘3. 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’ <i>and</i> Union research and health programmes, and will liaise between the public health and the research sector <i>as needed</i> .	Amendment 96 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 <i>and WHO</i> research and health programmes, and will liaise between the public health and the research sector <i>by encouraging consultation of, and cooperation with, public health experts</i> .	‘3. 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 <u>and WHO</u> research and health programmes, <u>as well as with other relevant studies</u> and will liaise between the public health and the research sector as needed.	

[illegible]

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
58 continued	Article 6 – paragraph 3 a (new) Article 6 – paragraph 4	(c) paragraph 4 is replaced by the following: ‘4. The Centre shall consult with the Commission and other Union bodies or agencies with regard to the planning and priority setting of research and public health studies.’;	Amendment 98 <i>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.</i> Amendment 99 4. The Centre shall consult with the Commission, <i>the HSC</i> and other <i>relevant</i> Union bodies or agencies with regard to the planning and priority setting of research and public health studies.	(c) paragraph 4 is replaced by the following ‘4. The Centre shall consult with the <u>HSC, the</u> Commission and other Union bodies or agencies with regard to the planning and priority setting of research and public health studies, <u>taking into account the opinion of the Advisory Forum.</u> ’;	
59		(8) Article 7 is replaced by the following: ‘Article 7		(8) Article 7 is replaced by the following: ‘Article 7	
60	Article 7 – paragraph 1 Article 7 – paragraph 1 – point a Article 7 – paragraph 1 – point b	Procedure for scientific opinions 1. The Centre shall issue a scientific opinion on matters falling within its mission: (a) in all cases where Union legislation provides that the Centre is to be consulted; (b) at the request of the European Parliament or a Member State;		Procedure for scientific opinions 1. The Centre shall issue a scientific opinion on matters falling within its mission: (a) in all cases where Union legislation provides that the Centre is to be consulted; (b) at the request of the European Parliament or a Member State;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
60 continued	Article 7 – paragraph 1 – point c Article 7 – paragraph 1 – point c a (new) Article 7 – paragraph 1 – point d Article 7 – paragraph 2 Article 7 – paragraph 3	(c) at the request of the Commission; <i>and</i> (d) on its own initiative. 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. 3. The Centre shall issue scientific opinions within a mutually agreed time frame.	Amendment 100 (c) at the request of the Commission <i>or EMA</i>; Amendment 101 <i>(ca) at the request of the HSC; and</i> Amendment 102 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 <i>necessity to act, and shall</i> be accompanied by sufficient background information regarding that issue.	(c) at the request of the Commission <u>or the HSC</u>; and (d) on its own initiative. 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. <u>If scientific opinions are focused on a specific Member State, the Member State concerned shall be involved.</u> 3. The Centre shall <u>ensure that it has the ability to anticipate and react quickly to</u> issue scientific opinions within a mutually agreed time frame <u>and that these scientific opinions are accessible and operational for policy makers.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
60 continued	Article 7 – paragraph 4 Article 7 – paragraph 5 Article 7 – paragraph 6	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. 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. 6. The Centre’s internal rules shall specify requirements regarding the format, explanatory background and publication of a scientific opinion.’;	Amendment 103 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 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.	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. 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. 6. The Centre’s internal rules shall specify requirements regarding the format, explanatory background and transparency rules for the publication of a scientific opinion.’;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
61		(9) Article 8 is replaced by the following:		(9) Article 8 is replaced by the following:	
62	Article 8 – paragraph 1 Article 8 – paragraph 2 Article 8 – paragraph 2 – point a Article 8 – paragraph 2 – point b	<i>‘Article 8</i> Operation of the Early Warning and Response System 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. 2. The Centre shall: (a) analyse the content of messages received by it via the EWRS; (b) provide information, expertise, advice and risk assessment to Member States and the Commission; and	Amendment 105 1. The Centre shall support and assist the Commission by operating the EWRS <i>provided for in Article 18 of Regulation (EU) .../... [the SCBTH Regulation]</i> and by ensuring with the Member States the capacity to respond in a coordinated <i>and timely</i> manner. Amendment 106 (b) provide information, expertise, advice, <i>training</i> and risk assessment to Member States and the Commission; and	<i>‘Article 8</i> Operation of the Early Warning and Response System 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. 2. The Centre shall: (a) analyse the content of messages received by it via the EWRS; <u>the processing of personal data necessary for the purpose of contact tracing is based on Regulation (EU) ... [please insert the number of Regulation SCBTH];</u> (b) provide information, expertise, advice and risk assessment to Member States and the Commission; and	

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62 continued	Article 8 – paragraph 2 – point c Article 8 – paragraph 2 a (new)	(c) ensure that the EWRS is efficiently and effectively linked with other Union alert systems.	Amendment 107 <i>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.</i>	(c) ensure that the EWRS is efficiently and effectively linked with other Union alert systems.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
62 continued	Article 8 – paragraph 3	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.	Amendment 108 3. The Centre shall work with the Commission and the HSC on the EWRS <i>continuous</i> updates, including for the use of modern technologies, such as digital mobile applications, artificial intelligence <i>and computer modelling and simulation</i> models, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States. <i>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*</i>, and on defining the functional requirements of the EWRS. <i>* Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002</i>	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 and warning applications , building upon the contact tracing technologies developed by the Member States and on defining the functional requirements of the EWRS.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
62 continued	Article 8 – paragraph 4	4. The Centre shall work with the Commission, the HSC and the eHealth Network to further define the functional requirements for contact tracing applications and their interoperability, taking into account existing infrastructures and services, such as geolocation services provided by EU Space Programme.	<i>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).</i>	4. The Centre shall work with the Commission, the HSC and the eHealth Network <u>and relevant experts in the Member States</u> to further define the functional requirements for contact tracing <u>and warning</u> applications, <u>or where needed other digital tools</u> , and their interoperability, taking into account existing infrastructures and services, ~~such as geolocation services provided by EU Space Programme~~ <u>as well as Union and national requirements regarding personal data protection</u> .	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
62 continued	Article 8 – paragraph 5	5. The Centre <i>as processor</i> 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, <i>34(2)</i> and 36 of Regulation (EU) 2018/1725 <i>of the European Parliament and of the Council</i> .	Amendment 109 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 and 36 of Regulation (EU) 2018/1725.	5. The Centre ~~as processor~~ shall have the responsibility to ensure the legality , security and confidentiality of the processing operations of personal data carried out within the EWRS and in the context of interoperability of contact tracing and warning applications or where needed other digital tools , 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.	
63		(10) the following Article 8a is inserted:		(10) the following Article 8a is inserted:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
64	Article 8a – paragraph 1 Article 8a – paragraph 1 a (new)	<i>'Article 8a</i> Risk assessment 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	Amendment 110 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 <i>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.</i>	<i>'Article 8a</i> <u>Public Health</u> Risk assessment 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.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
64 continued	Article 8a – paragraph 2	2. The risk <i>assessment</i> shall include general and targeted recommendations for response as a basis for coordination in the HSC.	Amendment 112 2. The risk <i>assessments referred to in paragraph 1</i> shall include, <i>where possible</i> , general and targeted recommendations for response as a basis for coordination in the HSC, <i>including, but not limited to:</i> <i>(a) a forecast of the evolution of a health crisis and the risk of a health emergency;</i> <i>(b) a forecast of the demand for medicines, vaccines, medical equipment, protective equipment and hospital capacity, including within the Union Civil Protection Mechanism;</i> <i>(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;</i>	2. The risk assessment shall include general and targeted <u>scientific-based</u> recommendations <u>and options</u> for response as a basis for coordination in the HSC.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
66 continued	Article 8b – paragraph 1 – point b Article 8b – paragraph 1 – point b a (new) Article 8b – paragraph 2	(b) adoption of guidance for the Member States for the prevention and control of a serious cross-border threat to health. 2. The Centre shall support a Union coordinated response at the request of a Member State, Council, Commission, Union bodies or agencies.	Amendment 116 (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 (ba) the deployment of the EU Health Task Force. Amendment 118 2. The Centre shall support a Union coordinated response in accordance with Article 21 of Regulation (EU) .../... [the SCBTH Regulation].	(b) adoption of guidance for the Member States for the prevention and control of a serious cross-border threat to health. 2. The Centre shall support a Union coordinated response at the request of a Member State, Council, Commission, HSC , Union bodies or agencies.’;	
67		(12) Article 9 is amended as follows:		(12) Article 9 is amended as follows:	
68		(a) paragraphs 1, 2 and 3 are replaced by the following:		(a) paragraphs 1, 2 and 3 are replaced by the following:	
69	Article 9 – paragraph 1	‘1. The Centre shall provide scientific and technical expertise to the Member States, the Commission and other Union bodies or agencies in the development, regular review and updating of preparedness plans, and in the development of intervention strategies within the scope of its mission.		‘1. The Centre shall provide scientific and technical expertise to the Member States, the Commission and other Union bodies or agencies in the development, regular ~~review~~ examination and updating of preparedness plans, training activities and in the development of intervention strategies within the scope of its mission.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 9 – paragraph 2	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.	Amendment 119 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 <i>and assessing the efficiency of response measures</i>. 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, <u>the HSC or</u> third countries <u>having concluded agreements with the Union in accordance with Article 30,</u> 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 <u>evidence-based</u> scientific and technical expertise and assistance within its ~~financial capacity and~~ mandate, and in accordance with the <u>applicable agreements as well as with the appropriate working arrangements established with the Commission with regard to third countries and international organizations.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 9 – paragraph 3	3. Requests for scientific or technical assistance to the Centre shall be accompanied by a set deadline, which must be mutually agreed with the Centre.’;		‘3. Requests for scientific or technical assistance to the Centre shall be accompanied by a set deadline, which must be mutually agreed with the Centre.’;	
70		(b) paragraph 5 is deleted.;		(b) ~~paragraph 5 is deleted.;~~ <u>(b) paragraph 5 is replaced by the following:</u>	
71				<u>5. The Centre shall inform the Management Board, Member States authorities and the Commission of any such request and of its outcomes.</u>	
72		(c) paragraph 6 is replaced by the following:		(c) paragraph 6 is replaced by the following:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
73	Article 9 – paragraph 6	6. The Centre shall, as appropriate, support and coordinate training programmes, in particular in epidemiological surveillance, field investigations, preparedness and prevention, <i>and</i> public health research.	Amendment 120 6. The Centre shall, as appropriate, support and coordinate training programmes, in particular in epidemiological surveillance, field investigations, preparedness and prevention, <i>response to public health emergencies</i> , public health research <i>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.</i>	‘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 <u>in order to assist the needs of the Member States.</u> ’;	
74		(13) Article 11 is amended as follows:		(13) Article 11 is amended as follows:	
75		(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
76	Article 11 – paragraph 1	‘1. The Centre shall coordinate data collection, validation, analysis and dissemination of data at Union level.’;	Amendment 121 1. The Centre shall coordinate data, <i>standardisation</i> , collection, validation, analysis and dissemination of data at Union level.	‘1. The Centre shall; <u>(a)</u> coordinate data collection, validation, analysis and dissemination of data at Union level <u>necessary for pursuing the mandate of the Centre, where applicable in accordance with the data protection requirements laid down in Article 20a, and avoiding duplication of efforts for the Member States.</u> ’; <u>(b)</u> seek, where appropriate, the expertise and guidance of the Member States to ensure correct understanding of the health data made available, its limitations, the national context and information systems.	
77		(b) the following paragraph 1a is inserted:		(b) the following paragraph 1a is inserted:	
78	Article 11 – paragraph 1a	‘1a. The Centre shall collect data and information, and will ensure links to relevant research data and outputs on:		‘1a. The Centre shall collect data and information, and will ensure links to relevant research data and outputs on:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
78 continued	Article 11 – paragraph 1a – point a Article 11 – paragraph 1a – point b Article 11 – paragraph 1a – point c	(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]]; (b) the progression of epidemic situations, including for modelling, anticipation and scenario development; (c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;	Amendment 122 (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 (b) the progression of epidemic situations, including for modelling, anticipation and scenario development, the assessment of vulnerable groups and the forecast of specific demand for medicines, equipment and hospital capacity ; (c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries	(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]]; (b) the progression of epidemic situations, including for modelling, anticipation and scenario development; (c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries in cooperation with the WHO ;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
78 continued	Article 11 – paragraph 1a – point d Article 11 – paragraph 1a – point e Article 11 – paragraph 1a – point e a (new)	(d) molecular pathogen data, if required for detecting or investigating cross-border health threats; and (e) health systems data required for managing cross-border health threats.’;	Amendment 124 <i>(ea) implementation of the Centre’s recommendations on countermeasures by Member States and the outcomes thereof.</i>	(d) ~~molecular~~-pathogen data, <u>including but not limited to molecular level</u>, if required <u>for epidemiological surveillance of communicable diseases and related special health issues and</u> for detecting or investigating cross-border health threats; and (e) health systems data required for managing <u>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]].</u>’; ~~cross-border health threats.’;~~	
79		(c) paragraph 2 is replaced by the following:		(c) paragraph 2 is replaced by the following:	
80	Article 11 – paragraph 2 Article 11 – paragraph 2 – point a	‘2. For the purposes of paragraph 1, the Centre shall: (a) develop, together with the competent bodies of the Member States and the Commission, appropriate procedures to facilitate consultation and data transmission and access;		‘2. For the purposes of paragraph 1, the Centre shall: (a) develop, together with the competent bodies of the Member States and the Commission, appropriate procedures to facilitate consultation and data transmission and access;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
80 continued	Article 11 – paragraph 2 – point b Article 11 – paragraph 2 – point c	(b) carry out technical and scientific evaluation of prevention and control measures at Union level; (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, <i>and</i> other international organisations; and	Amendment 125 (c) work in close cooperation with the competent bodies of the organisations <i>and relevant counterparts</i> operating in the field of data collection from the Union, third countries, the WHO, other international organisations <i>and the scientific community, while ensuring that robust safeguards are in place concerning transparency and accountability</i> ; and	(b) carry out technical and scientific evaluations of prevention and control measures at Union level; (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	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
80 continued	Article 11 – paragraph 2 – point d	(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.’;	Amendment 126 (d) develop solutions to access relevant health data, <i>including anonymous data and pseudonymous data, where such data are</i> made available or exchanged through digital infrastructures, in accordance with data protection rules, allowing for the health data to be <i>solely</i> used for healthcare, <i>health</i> research, policy making and regulatory purposes <i>in the domain of health</i> ; and provide and facilitate controlled access to health data to support public health research.	(d) develop solutions to access relevant health data, <u>publicly available or</u> 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 <u>where applicable, in accordance with the data protection requirements laid down in Article 20a</u> ; and provide and facilitate controlled <u>and timely</u> access to health data to support public health research.’;	
81		(d) the following paragraphs 4 and 5 are added:		(d) the following paragraphs 4 and 5 are added:	

[illegible]

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
84	Article 11a – paragraph 1 Article 11a – paragraph 1 a (new)	<i>‘Article 11a</i> Support to international and field response 1. The Centre shall establish capacity to mobilise and deploy the EU Health Task Force including the Centre’s staff <i>and</i> experts from Member States <i>and</i> fellowship programmes, to assist local response to outbreaks of communicable diseases in Member States and in third countries.	Amendment 128 1. The Centre shall establish <i>a permanent capacity, as well as an enhanced emergency</i> capacity to mobilise and deploy the EU Health Task Force including the Centre's staff, experts from Member States, fellowship programmes <i>and international and non-profit organisations</i>, to assist local response to outbreaks of communicable diseases in Member States and in third countries. Amendment 129 <i>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.</i>	<i>‘Article 11a</i> Support to international and field <u>preparedness and</u> response 1. The Centre shall establish a EU Health Task Force and ensure capacity to mobilise and deploy it ~~the EU Health Task Force~~, including the Centre’s staff and experts from Member States and fellowship programmes, to assist <u>on requests for preparedness and response planning</u>, local response to outbreaks of communicable diseases <u>and after action reviews</u> in Member States and in third countries, <u>in cooperation with the WHO</u>.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
84 continued	Article 11a – paragraph 2 Article 11a – paragraph 3	2. The Centre shall develop a framework and establish procedures with the Commission to mobilise the EU Health Task Force. 3. The Centre shall ensure that the EU Health Task Force are coordinated and complementary to the capacities integrating the European Medical Corps and other relevant capacities under the Union Civil Protection Mechanism.	Amendment 130 2. The Centre shall develop a framework and establish procedures with the Commission to <i>deploy the permanent capacity and mobilise the emergency capacity of</i> the EU Health Task Force.	2. The Centre shall develop a framework and establish procedures with the Commission to rapidly mobilise the EU Health Task Force. <u>The Commission shall, by means of an implementing act, adopt the organizational structure and rules concerning the mobilisation of the EU Health Task Force, notably in view of action under Decision No 1313/2013/EU.</u> <u>This implementing act shall be adopted in accordance with the examination procedure referred to in Article 30a(2).</u> 3. The Centre shall ensure that the EU Health Task Force ~~are~~ is coordinated ~~with, and~~ complementary to <u>and integrating</u> the capacities ~~integrating~~ the European Medical Corps, ~~and~~ other relevant capacities under the Union Civil Protection Mechanism <u>and other mechanisms of international organisations (WHO in particular) in order to avoid overlaps and duplications.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
84 continued	Article 11a – paragraph 4 – subparagraph 1 Article 11a – paragraph 4 – subparagraph 2 Article 11a – paragraph 5	4. 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 provide contributions of Union field response experts in international response teams mobilised by the WHO Health Emergencies Programme mechanism and the Global Outbreak Alert and Response Network (GOARN) and in accordance with appropriate working arrangements established with the Commission. 5. The Centre shall facilitate the development of field response capabilities and crisis management expertise among the Centre's staff and experts from EU and EEA countries, EU candidate countries and potential candidates, as well as European Neighbourhood Policy and EU partner countries, upon request of the Commission.	Amendment 131 The Centre shall develop with the Commission a framework for <i>the deployment of the permanent capacity and</i> the mobilisation of the EU Health Task Force, in view of action under Decision No 1313/2013/EU	~~4. 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~~ <u>The Centre Through the EU Health Task Force, the Centre</u> shall provide contributions of Union field response experts in international response teams mobilised by the WHO Health Emergencies Programme mechanism and the Global Outbreak Alert and Response Network (GOARN) and in accordance with appropriate working arrangements established with the Commission. 5. The Centre shall facilitate the development of field response capabilities and crisis management expertise among the Centre's staff and experts from EU and EEA countries, EU candidate countries and potential candidates, as well as European Neighbourhood Policy and EU partner countries, upon request of the Commission <u>and in collaboration with Member States.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
84 continued	Article 11a – paragraph 6 Article 11a – paragraph 7	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. 7. Upon request of the Commission and Member States, the Centre shall engage in long term capacity building projects aiming to strengthen preparedness capacities under the IHR in non-European third countries, in particular partner countries.	Amendment 132 6. The Centre shall maintain <i>a permanent</i> 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. <u>By establishing a mechanism to mobilise and deploy the EU Health Task Force, the</u> Centre shall maintain capacity <u>and country knowledge</u> to carry out missions to Member States, upon <u>the joint</u> request of the Commission and Member States <u>concerned</u> , to provide <u>scientific-based</u> recommendations on <u>preparedness, response and after action review</u> to threats to health within its mandate. 7. Upon request of the Commission and Member States, the Centre shall engage in long term capacity building projects aiming to strengthen preparedness capacities under the IHR in non-European third countries, in particular partner countries, <u>in collaboration with WHO.</u>	
85		(15) Article 12 is amended as follows:		(15) Article 12 is amended as follows:	
86		(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
87	Article 12 – paragraph 1 – subparagraph 1 Article 12 – paragraph 1 – subparagraph 2	‘1. The Centre shall communicate on its own initiative within the scope of its mission, after having given prior information to the Member States and to the Commission. The Centre shall ensure that the public or any interested party is rapidly given objective, reliable, evidence-based and easily accessible information with regard to the results of its work. The Centre shall make available information for the general public, including through a dedicated website It shall also publish its opinions produced in accordance with Article 6.’;	Amendment 133 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 <i>with essential information available in all official languages of the Union</i> . It shall also publish its opinions produced in accordance with Article 6 <i>in a timely manner</i> .	‘1. The Centre shall communicate <u>the activities and results of its work</u> on its own initiative within the scope of its mission, after having given prior information to the Member States and to the Commission. The Centre shall ensure that the public or any interested party is rapidly given objective, reliable, evidence-based and easily accessible information with regard to the <u>activities and the</u> results of its work. The Centre shall make available <u>scientific</u> information for the general public, including through a dedicated website <u>as well as an active presence on social media or analogous platforms</u> . It shall also publish its <u>scientific</u> opinions produced in accordance with Article 6. <u>The information relevant for the EU citizens is made available in all languages of the European Union to ensure appropriate outreach to them;</u>	
88		<i>(b) paragraph 2 is deleted;</i>	Amendment 134 <i>deleted</i>	(b) paragraph 2 is deleted;	
89		(c) paragraph 3 is replaced by the following:		(c) paragraph 3 is replaced by the following:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
90	Article 12 – paragraph 3	‘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.’;	Amendment 135 3. The Centre shall cooperate as appropriate with the competent bodies in the Member States, <i>the WHO</i> 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 and other interested parties with regard to public information campaigns.’;	
91		(16) Article 14 is amended as follows:		(16) Article 14 is amended as follows:	
92		(a) the third subparagraph of paragraph 2 is replaced by the following:		(a) the third subparagraph of paragraph 2 is replaced by the following:	
93	Article 14 – paragraph 2 – subparagraph 3	‘Members’ term of office shall be three years and can be extended.’;	Amendment 136 Members’ term of office shall be three years and can be extended, <i>if necessary</i> .	‘Members’ term of office shall be three years and can be extended.’;	
94		(b) in paragraph 5, points (d), (e) and (f) are replaced by the following:		(b) in paragraph 5, points (d), (e) and (f) are replaced by the following:	
95	Article 14 – paragraph 5 – subparagraph 1 – point d	‘(d) adopt, before 31 January each year, the Centre’s programme of work for the coming year;		‘(d) adopt, before 31 January each year, the Centre’s programme of work for the coming year;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
95 continued	Article 14 – paragraph 5 – subparagraph 1 – point e	(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**; * 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).	Amendment 137 (e) <i>by 30 November of each year</i>, 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; <i>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;</i> * 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).	‘(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,	

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95 continued	Article 14 – paragraph 5 – subparagraph 1 – point f Article 14 – paragraph 5 – subparagraph 1 – point g Article 14 – paragraph 5 – subparagraph 1 – point h	(f) ensure that the programme of work of the coming year and multiannual programmes are consistent with the Union’s legislative and policy priorities in the area of its mission and tasks, and follow the recommendations adopted in the annual Commission Opinion. (g) before 30 March each year, adopt the general report on the Centre’s activities for the previous year; (h) adopt the financial rules applicable to the Centre after the Commission has been consulted;		‘(f) ensure that the programme of work of the coming year and multiannual programmes are consistent with the Union’s legislative and policy priorities in the area of its mission and tasks, and take into account follow the recommendations adopted in the annual Commission Opinion. (g) before 30 March each year, adopt the general report on the Centre’s activities for the previous year; (h) adopt the financial rules applicable to the Centre after the Commission has been consulted;	

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95 continued	Article 14 – paragraph 5 – subparagraph 1 – point i	(i) determine the rules governing the languages of the Centre, including the possibility of a distinction between the internal workings of the Centre and <i>the</i> external communication, taking into account the need to ensure access to, <i>and participation in</i> , the work of the Centre <i>by all interested parties in both cases</i> . The financial rules applicable to the Centre as referred to in point (h) of the first subparagraph may not depart from Commission Delegated Regulation (EU) 2019/715, unless specifically required for the Centre's operation and with the Commission's prior consent.	Amendment 138 (i) determine <i>by unanimity</i> the rules governing the languages of the Centre, including the possibility of a distinction between the <i>ordinary</i> internal workings of the Centre and <i>its</i> external communication, taking into account the need to ensure access <i>for all interested parties</i> to the work of the Centre <i>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.</i>	(i) determine by unanimity of its members 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. The financial rules applicable to the Centre as referred to in point (h) of the first subparagraph may not depart from Commission Delegated Regulation (EU) 2019/715, unless specifically required for the Centre's operation and with the Commission's prior consent.	

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96		(17) point (b) of Article 16(2) is replaced by the following:		(17) point (b) of Article 16(2) is replaced by the following:	
97	Article 16 – paragraph 2 – point b	‘(b) drawing up draft work programmes taking into account the recommendations adopted in the annual Commission Opinion on the single programming document;’		‘(b) drawing up draft work programmes taking into account the recommendations adopted in the annual Commission Opinion on the single programming document <u>according to Article 32 paragraph 7 of the Commission Delegated Regulation (EU) 2019/715. The Commission opinion will be submitted to the Management Board at the earliest possible stage;</u> ’	
98	Article 17 – paragraph 1	<i>(18) Article 17 is replaced by the following:</i> <i>‘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.;’</i>	Amendment 139 <i>deleted</i>	(18) Article 17 is <u>amended</u> ~~replaced by the as follows~~ ing: <u>(a) paragraph 1 is replaced by the following:</u> ‘1. Without prejudice to Article 3(2), the director shall be appointed by the Management Board on the basis of a list of <u>at least three</u> candidates proposed by the Commission after an open competition, following publication in the <i>Official Journal of the European Union</i> and elsewhere of a call for expressions of interest, <u>previously validated by the Management Board,</u> for a period of five years, which may be extended once for a further period of up to five years.’;	

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99		(19) Article 18 is amended as follows:		(19) Article 18 is amended as follows:	
100		(a) paragraph 2 is replaced by the following:		(a) paragraph 2 is replaced by the following:	
101	Article 17 – paragraph 2	‘2. Members of the Advisory Forum shall not be members of the Management Board. Members’ term of office shall be three years and can be extended.’;	Amendment 140 2. <i>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.</i>	‘2. Members of the Advisory Forum shall not be members of the Management Board. <u>Advisory Forum</u> ~~Members~~ ’ term of office shall be three years and can be extended.’;	
102		(b) in paragraph 4, point (f) is replaced by the following:		(b) in paragraph 4, point (f) is replaced by the following:	
103		‘(f) scientific and public health priorities to be addressed in the work programme; and (g) key publications under preparation by the Centre such as forecasting studies.’;		‘(f) scientific and public health priorities to be addressed in the work programme; and (g) key publications under preparation by the Centre such as forecasting studies.’;	
104		(c) paragraph 8 is replaced by the following		(c) paragraph 8 is replaced by the following:	

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105	Article 18 – paragraph 8	8. The <i>director may invite</i> experts <i>or</i> representatives of professional <i>or</i> scientific bodies, <i>or</i> non-governmental organisations with recognised experience in disciplines related to the work of the Centre <i>to cooperate in specific tasks and</i> to take part in <i>the relevant</i> activities of the Advisory Forum. In addition, the Commission may suggest to the <i>director</i> experts or representatives of professional or scientific bodies, or non-governmental <i>organizations</i> to be <i>invited</i> on an ad-hoc basis.	Amendement 141 8. The <i>Centre shall structurally engage with public health</i> experts, representatives of professional <i>and</i> scientific bodies <i>and</i> non-governmental organisations, <i>in particular those</i> with recognised experience in disciplines related to the work of the Centre, <i>as well as in other areas, including non-communicable diseases and environmental protection</i> , to take part in <i>all key</i> activities of the <i>Centre, dedicated networks and the</i> Advisory Forum <i>and to cooperate on specific tasks</i> . In addition, the Commission <i>and Member States</i> may suggest to the <i>Centre</i> experts or representatives of professional or scientific bodies, or non-governmental <i>organisations</i> to be <i>consulted</i> on an ad-hoc basis.	‘8. The director may invite experts or representatives of professional or scientific bodies, or non-governmental organisations with recognised experience in disciplines 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, <u>the Member States or the Advisory Forum Members</u> , 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, <u>including experts from third countries</u> .’;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
106	Article 19 – paragraph 2	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.	Amendment 142 <i>(19a) in Article 19, paragraph 2 is replaced by the following:</i> "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. "		
107		(20) paragraph 3 of Article 20 is replaced by the following:		(20) paragraph 3 of Article 20 is replaced by the following:	
108	Article 20 – paragraph 3	‘3. Decisions taken by the Centre pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint to the Ombudsman or form the subject of an action before the Court of Justice of the European Union (‘the Court of Justice’), under the conditions laid down in Articles 228 and 230 TFEU respectively.’;		‘3. Decisions taken by the Centre pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint to the Ombudsman or form the subject of an action before the Court of Justice of the European Union (‘the Court of Justice’), under the conditions laid down in Articles 228 and 230 TFEU respectively.’;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
109	Article 20 – paragraph 4	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 <i>(EC) No 45/2001 of the European Parliament and of the Council of 18 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)</i> shall apply.	Amendment 143 <i>(20a) in Article 20, paragraph 4 is replaced by the following:</i> "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 <i>(EU) 2018/1725</i> shall apply.";		

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110	Article 20 – paragraph 4 a (new)		Amendment 144 <i>(20b) in Article 20, the following paragraph is added:</i> <i>“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.</i> <i>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.</i> <i>The Centre shall only process</i>		

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110 continued			<i>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.</i> <i>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.”;</i>		

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112 continued	Article 20 a (new) – paragraph 3			<u>3. Where processing of personal data is not strictly necessary to the fulfilment of the mission of the Centre, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.</u>	

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113	Article 20 a (new)		Amendment 145 <i>(20c) the following Article is inserted:</i> <i>“Article 20a</i> <i>Exercise of the delegation</i> <i>1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.</i> <i>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.</i>		

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113 continued			3. <i>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.</i> 4. <i>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*.</i> 5. <i>As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council</i>		

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113 continued			<i>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.</i> <i>* OJ L 123, 12.5.2016, p. 1."</i>		
114		(21) Article 21 is replaced by the following:		(21) Article 21 is replaced by the following:	

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115	Article 21 – paragraph 1	<i>'Article 21</i> Professional secrecy and confidentiality 1. Without prejudice to Article 20, the Centre shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public, if circumstances so require, in order to protect public health. If the confidential information has been submitted by a Member State, that information cannot be disclosed without the prior consent of that Member State. The Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 and (EU, Euratom) 2015/444 shall apply to the work of the Centre and its staff.		<i>'Article 21</i> Professional secrecy and confidentiality 1. Without prejudice to Article 20, the Centre shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public, if circumstances so require, in order to protect public health. If the confidential information has been submitted by a Member State, that information cannot be disclosed without the prior consent of that Member State. The Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 and (EU, Euratom) 2015/444 shall apply to the work of the Centre and its staff.	

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115 continued	Article 21 – paragraph 2 Article 21 – paragraph 3 Article 21 – paragraph 4	2. Members of the Management Board, the director, members of the Advisory Forum, as well as external experts participating in the scientific panels, and members of the staff of the Centre, even after their duties have ceased, shall be subject to the obligation of professional secrecy pursuant to Article 339 TFEU. 3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential. 4. The Centre shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.		2. Members of the Management Board, the director, members of the Advisory Forum, as well as external experts participating in the scientific panels, and members of the staff of the Centre, even after their duties have ceased, shall be subject to the obligation of professional secrecy pursuant to Article 339 TFEU. 3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential. 4. The Centre shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
115 continued	Article 21 – paragraph 5 Article 21 – paragraph 6	5. The Centre shall take all necessary measures to facilitate the exchange of information relevant to its tasks with the Commission, the Member States and, where appropriate, other Union institutions, and the Union bodies, offices and agencies and international organisations and third countries, in accordance with appropriate working arrangements established with the Commission. 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.	Amendment 146 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, <i>in accordance with Articles 27 and 33 of Regulation (EU) 2018/1725</i> .	5. The Centre shall take all necessary measures to facilitate the exchange of information relevant to its tasks with the Commission, the Member States and, where appropriate, other Union institutions, and the Union bodies, offices and agencies and international organisations and third countries, in accordance with <u>the applicable legislation on data protection and confidentiality and</u> appropriate working arrangements established with the Commission. 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.	
116		(22) Article 22 is amended as follows:		(22) Article 22 is amended as follows:	
117		(a) in paragraph 3, point (d) is replaced by the following:		(a) in paragraph 3, point (d) is replaced by the following:	
118	Article 22 – paragraph 3 – point d	‘(d) any voluntary contribution from the Member States; and		‘(d) any voluntary contribution from the Member States; and	

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118 continued	Article 22 – paragraph 3 – point e	(e) any revenue from contribution agreements or grant agreements exceptionally concluded between the Commission and the Centre.’;		(e) any revenue from contribution agreements or grant agreements exceptionally concluded between the Commission and the Centre.’;	
119		(b) the following paragraph 3a is inserted:		(b) the following paragraph 3a is inserted:	
120	Article 22 – paragraph 3 a	‘3a Financing from the Union budget may be awarded to the Centre for the costs that it incurs in implementing its work programme that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with Regulation (EU) .../.... of the European Parliament and the Council, and the EU Research and Innovation programmes. This financing shall not cover expenditure already covered by the general budget of the European Union or any other resource of the Centre defined in paragraph 3 of this Article.’;		‘3a Financing from the Union budget may be awarded to the Centre for the costs that it incurs in implementing its work programme that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with Regulation (EU) .../.... of the European Parliament and the Council, and the EU Research and Innovation programmes. This financing shall not cover expenditure already covered by the general budget of the European Union or any other resource of the Centre defined in paragraph 3 of this Article.’;	
121		(c) paragraph 5 is replaced by the following:		(c) paragraph 5 is replaced by the following:	

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122	Article 22 – paragraph 5	‘5. Each year, on the basis of a draft drawn up by the director, the Management Board shall produce an estimate of revenue and expenditure for the Centre for the following financial year. This estimate, including a draft establishment plan, shall be included in the draft single programming document. In accordance with Article 40 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, by 31 January each year the Centre shall send to the European Parliament, the Council and the Commission its draft single programming document, as endorsed by its Management Board.’;		‘5. Each year, on the basis of a draft drawn up by the director, the Management Board shall produce an estimate of revenue and expenditure for the Centre for the following financial year. This estimate, including a draft establishment plan, shall be included in the draft single programming document. In accordance with Article 40 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, by 31 January each year the Centre shall send to the European Parliament, the Council and the Commission its draft single programming document, as endorsed by its Management Board.’;	
123		(d) paragraph 7 is replaced by the following:		(d) paragraph 7 is replaced by the following:	
124	Article 22 – paragraph 7	‘7. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 314 TFEU.		‘7. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 314 TFEU.	
128		(23) Article 23 is amended as follows:		(23) Article 23 is amended as follows:	

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129		(a) paragraph 2 is replaced by the following:		(a) paragraph 2 is replaced by the following:	
130	Article 23 – paragraph 2	‘2. By 1 March at the latest following each financial year, the Centre’s accounting officer shall communicate the provisional accounts to the Commission’s accounting officer together with a report on the budgetary and financial management for that financial year. The Commission’s accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 245 of Regulation (EU, Euratom) 2018/1046.’;		‘2. By 1 March at the latest following each financial year, the Centre’s accounting officer shall communicate the provisional accounts to the Commission’s accounting officer together with a report on the budgetary and financial management for that financial year. The Commission’s accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 245 of Regulation (EU, Euratom) 2018/1046.’;	
131		(b) paragraph 4 is replaced by the following:		(b) paragraph 4 is replaced by the following:	

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132	Article 23 – paragraph 4	‘4. On receipt of the Court of Auditors’ observations on the Centre’s provisional accounts, pursuant to Article 246 of Regulation (EU, Euratom) 2018/1046, the director shall draw up the Centre’s final accounts under the director’s own responsibility and forward them to the Management Board for an opinion. The Centre shall inform the Commission without delay on cases of presumed fraud and other financial irregularities, of any completed or ongoing investigations by the European Public Prosecutor's Office (the EPPO) or the European anti-Fraud Office (OLAF), and of any audits or controls by the Court of Auditors or the Internal Audit Service (IAS), without endangering the confidentiality of the investigations.’;		‘4. On receipt of the Court of Auditors’ observations on the Centre’s provisional accounts, pursuant to Article 246 of Regulation (EU, Euratom) 2018/1046, the director shall draw up the Centre’s final accounts under the director’s own responsibility and forward them to the Management Board for an opinion. <u>Without prejudice to Article 24(1) of Council Regulation (EU) 2017/1939</u> the Centre shall inform the Commission without delay on cases of presumed fraud and other financial irregularities, of any completed or ongoing investigations by the European Public Prosecutor's Office (the EPPO) or the European anti-Fraud Office (OLAF), and of any audits or controls by the Court of Auditors or the Internal Audit Service (IAS), without endangering the confidentiality of the investigations <u>and in accordance with the relevant data protection regulations</u> .’;	
133		(c) paragraphs 8 and 9 are replaced by the following:		(c) paragraphs 8 and 9 are replaced by the following:	

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134	Article 23 – paragraph 8 Article 23 – paragraph 9	‘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. 9. The director shall submit to the European Parliament, at the latter’s request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 261(3) of Regulation (EU, Euratom) 2018/1046.’;	Amendment 147 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.	‘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. ‘9. The director shall submit to the European Parliament, at the latter’s request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 261(3) of Regulation (EU, Euratom) 2018/1046.’;	
135	Article 24	<i>Article 24</i> <i>Application of the Financial Regulation</i> Article 185 of the Financial Regulation shall apply to the discharge of the Centre’s budget, its audits and accounting rules.	Amendment 148 (23a) Article 24 is replaced by the following: "Article 24 <i>Application of the Financial Regulation</i> Article 70 of Regulation (EU, Euratom) 2018/1046 shall apply to the discharge of the Centre’s budget, its audits and accounting rules."		
136		(24) Article 25 is amended as follows:		(24) Article 25 is amended as follows:	
137		(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
138	Article 25 – paragraph 1	‘1. Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council shall apply without restriction to the Centre.’;		‘1. Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council shall apply without restriction to the Centre.’;	
139		(b) paragraph 3 is replaced by the following:		(b) paragraph 3 is replaced by the following:	
140	Article 25 – paragraph 3	‘3. The decisions concerning funding and the implementing agreements and instruments resulting therefrom shall explicitly stipulate that the Court of Auditors, the EPPO and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Centre’s funding and the agents responsible for allocating it.’		‘3. The decisions concerning funding and the implementing agreements and instruments resulting therefrom shall explicitly ~~stipulate~~ indicate that the EPPO may investigate and that the Court of Auditors, ~~the EPPO~~ and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Centre’s funding and the agents responsible for allocating it, in accordance with their respective competences. ’	
141		(c) the following paragraph 4 is added:		(c) the following paragraph 4 is added:	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
142	Article 25 – paragraph 4	‘4. Without prejudice to paragraphs 1 to 3, working arrangements with third countries and with international organisations, grant agreements, grant decisions and contracts of the Centre shall contain provisions expressly empowering the Court of Auditors, OLAF and the EPPO to conduct such audits and investigations, in accordance with their respective competences.		‘4. Without prejudice to paragraphs 1 to 3, working arrangements with third countries and with international organisations, grant agreements, grant decisions and contracts of the Centre shall ~~contain provisions expressly empowering~~ <u>grant the necessary rights and access required for</u> the Court of Auditors, OLAF and the EPPO <u>to comprehensively exert their respective competences</u> ~~to conduct such audits and investigations, in accordance with their respective competences.~~	
143		(25) Article 26 is amended as follows:		(25) Article 26 is amended as follows:	
144		(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	
145	Article 26 – paragraph 1	‘1. The Centre shall be a body of the Union. It shall have legal personality.’;		‘1. The Centre shall be a body of the Union. It shall have legal personality.’;	
146		(b) the following paragraph 1a is inserted:		(b) the following paragraph 1a is inserted:	
147	Article 26 – paragraph 1 a	‘1a. In each of the Member States, the Centre shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property and may be party to legal proceedings.’;		‘1a. In each of the Member States, the Centre shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property and may be party to legal proceedings.’;	
148		(c) paragraph 2 is replaced by the following:		(c) paragraph 2 is replaced by the following:	

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149	Article 26 – paragraph 2	‘2. Protocol No 7 on the Privileges and Immunities of the European Union annexed to the Treaties shall apply to the Centre and its statutory staff.’;		‘2. Protocol No 7 on the Privileges and Immunities of the European Union annexed to the Treaties shall apply to the Centre and its statutory staff.’;	
150		(26) paragraph 1 of Article 27 is amended as follows:		(26) paragraph 1 of Article 27 is amended as follows:	
151	Article 27 – paragraph 1	‘1. The contractual liability of the Centre shall be governed by the law applicable to the contract in question. The Court of Justice shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Centre.’;		‘1. The contractual liability of the Centre shall be governed by the law applicable to the contract in question. The Court of Justice shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Centre.’;	
152		(27) Article 28 is replaced by the following:		(27) Article 28 is replaced by the following:	
153	Article 28 – paragraph 1 Article 28 – paragraph 2	<i>‘Article 28</i> Examination of legality 1. Member States, members of the Management Board and third parties directly and individually concerned may refer to the Commission any act of the Centre, whether express or implied, for the Commission to examine the legality of that act (‘administrative appeal’). 2. Administrative appeal shall be made to the Commission within 15 days of the day on which the party concerned first became aware of the act in question.		<i>‘Article 28</i> Examination of legality 1. Member States, members of the Management Board and third parties directly and individually concerned may refer to the Commission any act of the Centre, whether express or implied, for the Commission to examine the legality of that act (‘administrative appeal’). 2. Administrative appeal shall be made to the Commission within 15 days of the day on which the party concerned first became aware of the act in question.	

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153 continued	Article 28 – paragraph 3 Article 28 – paragraph 4	3. The Commission shall take a decision within one month. If no decision has been taken within this period, the administrative appeal shall be deemed to have been dismissed. 4. An action for annulment of the Commission’s explicit or implicit decision referred to in paragraph 3 to dismiss the administrative appeal may be brought before the Court of Justice in accordance with Article 263 TFEU.’;		3. The Commission shall take a decision within one month. If no decision has been taken within this period, the administrative appeal shall be deemed to have been dismissed. 4. An action for annulment of the Commission’s explicit or implicit decision referred to in paragraph 3 to dismiss the administrative appeal may be brought before the Court of Justice in accordance with Article 263 TFEU.’;	
154				<u>(27a) The following Article is inserted:</u>	
155	Article 30 a (new) Article 30 a (new) – paragraph 1			<u>Article 30a</u> <u>Committee procedure</u> <u>1. The Commission shall be assisted by a committee on serious cross-border threats to health. That Committee shall be a committee within the meaning of Article 3(2) of Regulation (EU) No 182/2011.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
155 continued	Article 30 a (new) – paragraph 2			<u>2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.</u> <u>Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.</u>	
156		(28) Article 31 is replaced by the following:		(28) Article 31 is replaced by the following:	
157	Article 31 – paragraph 1 – subparagraph 1 – introductory part Article 31 – paragraph 1 – subparagraph 1 – point a	<i>'Article 31</i> Review clause 1. 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: (a) how the Centre progressed with implementing the amended mandate in the light of the COVID-19 pandemic;	Amendment 149 By ... [please insert date three years after the date of entry into force <i>of this amending Regulation</i>], 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:	<i>'Article 31</i> Review clause 1. By <i>[please insert date three years after the date of entry into force]</i> 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: (a) how the Centre progressed with implementing the amended mandate in the light of the COVID-19 pandemic;	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
157 continued	Article 31 – paragraph 1 – subparagraph 1 – point a a (new) Article 31 – paragraph 1 – subparagraph 1 – point b Article 31 – paragraph 1 – subparagraph 1 – point c Article 31 – paragraph 1 – subparagraph 1 – point d	(b) how the Centre complies with the obligations laid down in the Regulation (EU) .../... [OJ: <i>Please insert the number of Regulation SCBTH [ISC/2020/12524]</i>] and other relevant Union legislation; (c) how effectively the Centre’s activities address international, Union or national health priorities; (d) how the work of the Centre is targeted to and affect Member States’ capacities. The report shall reflect the views of the stakeholders, at both Union and national level. The report shall be accompanied by an independent study commissioned by the Commission.	Amendment 150 <i>(aa) how the Centre has implemented the governance structures referred to in Articles 14, 17 and 18;</i>	(b) how the Centre complies with the obligations laid down in the Regulation (EU) .../... [OJ: <i>Please insert the number of Regulation SCBTH [ISC/2020/12524]</i>] and other relevant Union legislation; (c) how effectively the Centre’s activities address international, Union or national health priorities; (d) how the work of the Centre is targeted to and affect Member States’ capacities. The report shall reflect the views of the stakeholders, at both Union and national level. The report shall be accompanied by an independent study commissioned by the Commission.	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
157 continued	Article 31 – paragraph 2	2. By [please insert date <i>three</i> 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.	Amendment 151 2. By ... [please insert date <i>five</i> years after the date of entry into force <i>of this amending Regulation</i>], 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 <i>three years after the date of entry into force</i>] ~~2028~~ 2025 , and every 5 years thereafter, the Commission shall <u>commission an independent external evaluation on the basis of terms of reference agreed with the Management Board to</u> assess the Centre’s performance in relation to its objectives, mandate, tasks <u>and</u> procedures ~~and location~~ . The <u>external</u> evaluation shall, in particular, address the possible need to modify the mandate of the Centre, and the financial implications of any such modification. <u>The Management Board shall examine the conclusions of the external evaluation and may issue recommendations, if necessary, to the Commission regarding changes in the Centre, its working practices and the scope of its mission. The Commission shall forward the evaluation report and the recommendations to the European Parliament and the Council.</u>	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
157 continued	Article 31 – paragraph 3 Article 31 – paragraph 4	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. 4. The Commission shall report to the European Parliament, to the Council and to the Management Board on the findings of its reviews and evaluations carried out under paragraph 2. Those findings shall be made public.’	Amendment 152 3. <i>Based on the assessment referred to in paragraph 2, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.</i> 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. 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. <u>The Commission shall take into account the evaluation report and the recommendations of the Management Board.</u> 4. The Commission shall report to the European Parliament, to the Council and to the Management Board on the <u>recommendation of the Management Board</u> and findings of its reviews and evaluations carried out under paragraph 2 <u>and 3</u>. Those findings shall be made public.’	

Item	Article Number	Commission text (2020/0320 (COD))	EP amendments voted on 14 September 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
158		<i>Article 2</i> This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i>. This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,		<i>Article 2</i> This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i>. This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,	