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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	12972/20
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 *- Preparation for the trilogue*

I. INTRODUCTION

1. On 11 November 2020, the Commission submitted the proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control to the Council and to the European Parliament[1]. The proposal is part of a set of three proposals aiming to strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies. Together they are the first building block of the European Health Union. The proposal was not accompanied by an impact assessment.

2. The proposal is based on Article 168(5) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

[1] 12972/20

3. The proposal aims to reinforce the capacities of the ECDC on the prevention and control of communicable diseases and risk assessment with a view to future cross-border health threats through: strengthening its collaboration with Member States**;** rapid digitalisation of integrated surveillance systems; strengthening the ability to anticipate and forecast; developing prevention and response plans against future epidemics and capacities for an integrated rapid response to epidemic and outbreaks; strengthening its capacity to provide non-binding recommendations for risk management; developing its capacity to implement, mobilize and deploy an EU Health Task Force for rapid intervention to support the response in Member States; enhancing monitoring and assessment of the ability of national health systems for diagnosis, prevention and treatment of specific communicable diseases as well as of patient safety; creating a new network of Union reference laboratories for public health and a new network of national services supporting transfusion, transplantation and medically assisted reproduction; strengthening its cooperation with third countries and collaboration with WHO; and ensuring complementarity with other Union and international instruments, thereby avoiding duplication of efforts.

4. The French Senate submitted a reasoned opinion, raising subsidiarity concerns. The Italian, Portuguese and Spanish Parliaments submitted positive assessments of the proposal. The Czech Senate delivered a resolution on the three proposals of the European Health Union Package whereby, while supporting certain elements of the proposals, it also raised a number of questions.

5. On 27 April the European Economic and Social Committee adopted its opinion on the proposal[2]. On 7 May, the European Committee of the Regions also adopted its opinion on the proposal[3].

6. On 23 July, the Permanent Representative Committee agreed on a mandate[4] for the Presidency to enter into negotiations with the European Parliament.

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2 8384/21
3 8965/21
4 11091/21

7. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file and MEP Joanna Kopcińska (ECR, PL) was appointed as Rapporteur. The report was voted by the ENVI Committee on 29 June 2021 and adopted by the plenary on 14 September.

II. STATE OF PLAY

8. So far, one trilogue and five technical meetings have been held with the European Parliament and the Commission. These meetings have allowed to discuss and provisionally agree on a number of provisions highlighted in green in the 4th column of the 4 column table, which was issued as doc 12910/21 ahead of the meeting of the Working Party on Pharmaceuticals and Medical Devices on 20 October.

9. The discussions during the inter-institutional negotiations allowed to provisionally identify the most important political issues as follows:

   – the expansion, by the Parliament, of ECDC's mandate to also **cover major non-communicable diseases (NCDs)**, such as cardiovascular diseases, cancer, diabetes and mental illness (EP amendments 35, 36, 42, 43, 44, 51, 53, 54, 66, 70, 74, 76, 86, 93, 112, 122 and 141);

   – the **Centre's relation to Member States**, with the Council preferring a supportive role, and the Parliament preferring a more supervisory and prescriptive role. This relates to: on-the-spot assessments and inspections (EP amendments 47 and 48); assessment of Member States' preparedness and response planning and the publication of these assessments and ensuing recommendations to Member States (EP amendment 90) and the publication of the Centre's assessments and ensuing recommendations to Member States regarding their health systems' capacities (EP amendment 94); identification of risk groups and ensuring the accessibility of applicable measures (Council mandate on Article 5, paragraph 4, point e); monitoring of preparedness gaps (Council mandate on Article 5b, paragraph 1, subparagraph 2, point d); the obligation for Member States to notify reporting delays (amendment 64) and the setting of surveillance standards and assessment indicators (EP amendment 68);

– **data reporting**, with the Parliament favouring common indicators (in amendment 47 and amendment 59) and standardized data collection (in amendment 121), and the Council favouring the reporting of available data (Council mandate on Article 4, paragraph 1, point a and Article 5a, paragraph 3)

– the addition, by the Parliament, of **tasks that would overlap with those of other EU bodies and agencies** in the Presidency's view, such as recommendations on stockpiling of medical countermeasures (amendment 52) and forecasting of demands for medical countermeasures and the identification and assessment of possible protective measures (amendment 112)

– the Council's wish that **ECDC's role on preparedness and response planning** is focused at EU, rather than national, level (Council mandate on article 5b, paragraph 1, subparagraph 2, points a and e)

III. PROPOSAL FOR A REVISED MANDATE

10. Based on the inter-institutional discussions so far, it is clear that the current mandate does not provide the Presidency with a sufficient margin to negotiate with the European Parliament. To be able to progress efficiently during the negotiations, the Presidency believes that this mandate needs to be updated.

11. The main political issues mentioned above were discussed at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 20 October. Based on the conclusions of that meeting, the Presidency considers that with a view to preparing for the forthcoming discussion, the following approach could be used:

1) on the Parliament's position to integrate **non-communicable diseases (NCDs)** in the scope of the ECDC mandate, which is not acceptable for the Council:.

   a) **adding a recital** acknowledging the impact that major outbreaks have on health systems, including on patients with NCDs, as well as on increasing mental health issues in the society;

b) **a further step**, if needed, would consist of adding a **provision in the review clause** (article 31) stating that the next review should specifically consider a possible extension of the Centre's mandate to include the impact of cross-border threats to health on NCDs.

2) on **the Centre's relation to Member States**:

a) **rejecting** the Parliament's position on references to **on-the-spot assessment** of national health systems' capacities (in amendment 47) and to **inspections at source** (amendment 48). The Council cannot accept that the Centre would regularly visit and inspect the Member States.

b) **sticking to the** Council's position **on facilitating role for the Centre for the assessment and monitoring** of Member States' preparedness and response planning (amendment 90 and Council mandate on Article 5b, paragraph 1, subparagraph 2, point d). The Council cannot accept the Parliament's positon that the Centre should assess and monitor Member States' preparedness and response planning;

c) **rejecting** the Parliament's position on **publication of the assessments and recommendations** to Member States (in amendments 90 and 94). The Council cannot accept that the Centre would make assessments with recommendations to the Member State publicly available;

d) **rejecting** the Parliament's position on obligation by Member States to **notify reporting delays** (amendment 64). The Council cannot accept that Member States would have to notify delays in reporting the data to the Centre;

e) **showing flexibility** to the Parliament's position on the ECDC's role in e**nsuring the accessibility of prevention and response** measures targeted at risk groups, while defending Member States' role in identifying those risk groups (in Article 5, paragraph 4, point e). The Council could accept that the Centre would identify population groups at risk and ensure that prevention and response measures are accessible for persons with disabilities.

f) **showing flexibility** to the Parliament's position by changing the Centre's role in epidemiological surveillance activities from prescriptive to supporting, while accepting the addition of indicators for the provision of quality assurance (amendment 68). The Council could accept the addition of the term **"indicators"** in Article 5, paragraph 2, point b, if the Parliament would agree with the Council's proposal to replace the term **"setting"** with **"developing"** .

3) on **data reporting**:

a) **rejecting** the Parliament's position on references to the **use of common indicators** (in amendment 59). The Council cannot accept that Member States would be obliged to **use the indicators** referred to in Article 3(2) to assess their **domestic health situation** ;

b) **showing flexibility** to the Parliament's position on the standardization of data collection (in amendment 121). The Council could accept the addition of **"standardized data collection procedures"** in Article 11, paragraph 1;

c) **showing flexibility** to the Parliament's position on **reporting of available data** (Council mandate on Article 4, paragraph 1, point a and Article 5a, paragraph 3) Thee Council could accept the **deletion of the term "available**" in Article 4, paragraph 1, point a and Article 5a, paragraph 3;

4) on **tasks possibly conflicting with those of other EU bodies and agencies**:

a) **rejecting** Parliament's position on references to recommendations on **stockpiling of medical countermeasures** (in amendment 52). The Council cannot accept that Centre provides recommendations on the stockpiling of medical countermeasures;

b) **rejecting the** Parliament's position on references to the Centre's role **on forecasting of demands for medical countermeasures** (in amendments 112 and 123). The Council cannot accept that Centre would forecast the demands for medical countermeasures;

c) **accepting** to consider positively the Parliament's position on the Centre's role on **forecasting of the evolution of a health crisis and the risk** of a health emergency, by **identification of vulnerable groups,** coupled with flexibility on ECDC's role in the **identification and assessment of possible non-pharmaceutical** protective measures (in amendment 112).

5) on **ECDC's role on preparedness and response planning:**

a) **defending** the Council's position that **ECDC should focus on the EU**, rather than the national level in Article 5b, paragraph 1, subparagraph 2, point a. The Council is of the opinon that Center should contribute to the development, regular review and updating of frameworks for preparedness plans **at EU level** ;

b) **accepting** to consider positively the Parliament's position not to develop exercises, as well as in-action and after-action reviews **at EU level** (in amendment 91).

An overview of Presidency's proposals in relation to European Parliament 's amendments aboveis further elaborated in Annex 1.

12. The Presidency considers that the proposal for a revised mandate is balanced and provides a sufficient margin to negotiate with the European Parliament.

IV. CONCLUSION

13. In light of the above, the Permanent Representatives Committee is invited to:

- take note of the four-column table in Annex 2 as some of the text still needs to be aligned with the issues that remain open;

- discuss the main political issues referred to in point 9 above and agree on the proposed approach as outlined in point 11 and Annex 1.

ANNEX 1

Summary of the Presidency's proposal for a revised mandate

Council **cannot accept Parliament's** amendments (entirely or partly) on:

- NCDs (in amendments: 35, 36, 42, 43, 44, 51, 53, 54, 66, 70, 74, 76, 86, 93, 112, 122, 141);
- the Centre's "regular visits to Member States to assess on the spot their health systems capacity " (in amendment 47) and its "inspections at the source in the Member States" (in amendment 48);
- the Centre's role in providing recommendations on the stockpiling of medical countermeasures (in amendment 52);
- the publication of the assessments with recommendations to Member States (in amendments 90 and 94);
- using common indicators for assessment of domestic health situation (in amendment 59);
- the obligation for Member States to notify delays in the reporting (in amendment 64);
- the Centre's forecasting of specific demand for medicines (in amendment 123);
- the Centre's tasks in amendment 112: point b (forecasting of demands of various medical products); second part of point c (identification of specific needs for medicines and hospital capacity for those vulnerable groups); and point e (assessment of the need to activate the EU Health Task Force);

Council will defend its position on:

- the Centre's **facilitating role regarding assessment and monitoring** of MSs' preparedness and response planning (Amendment 90 and Article 5b, paragraph 1, subparagraph 2, point d)
- the Centre's role of contributing to frameworks for preparedness plans **at EU level** (Article 5b, paragraph 1, subparagraph 2, point a).

With a view to providing the Presidency with a sufficient margin to negotiate with the European Parliament, the **Council could show flexibility to the Parliament's position and accept:**

- the reference to NCDs in a recital and, if needed, in the review clause;
- the inclusion of **"standardized data collection procedures"** in Article 11 – paragraph 1 (amendment 121),
- the addition of **"indicators"** in return for replacing the term **"setting"** with **"developing"** Article 5 – paragraph 2 – point b (Amendment 68);
- **"identify"** and „**support Member States in ensuring** that those measures are accessible for persons with disabilities" in Article 5, paragraph 4, point e;
- the deletion of **"available"** from Article 4, paragraph 1, point a (amendment 58) and Article 5a, paragraph 3 (refering to amendment 87); and
- the deletion of **"at EU level"** Article 5b, paragraph 1, subparagraph 2, point e (amendment 91)
- and adding the following points in Article 8a, paragraph 2 (points a, c and d of amendment 112) :

(a): **"forecast of the evolution of a health crisis and the risk of a health emergency"**;

(c): **"identification of vulnerable groups"** and

(d): **"identification of possible protective non-pharmaceutical measures and assessment of their efficacy"**.

Explanation of the table layout[1]

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. ***Text in bold italics in this column is text from the Commission proposal that the EP proposes to delete.***	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.***	Plain text in this column is text from the Commission proposal that Council wishes to maintain. **Text in bold underlined** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	This column contains comments, compromise proposals and tentatively agreed text. Text in green is tentatively agreed by the negotiators. Text in yellow is for discussion. Text in blue concerns ongoing data protection technical discussions Text in red is identified for the political trilogue. Text in ***bold italics underlined*** in this column is new text compared to Council mandate. Text in ~~double strikethrough~~ in this column is text deleted compared to Council mandate.

[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.

Articles

This section 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 above.

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	*Article 1* Regulation (EC) No 851/2004 is amended as follows:		*Article 1* Regulation (EC) No 851/2004 is amended as follows:	*Article 1* 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:	1) Article 2 is replaced by the following
46	Article 2 Article 2 – paragraph 1	*Article 2* ***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;		*'Article 2* **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;	*Article 2* **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)		**Amendment 33** ***(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;***		*[EP withdraws amendment]*
	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;		(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;	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		(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 ***that is supported and coordinated by the Centre and is intended*** to ensure collaboration between the coordinating competent bodies of the Member States;	(3) 'dedicated network' means any specific network on diseases, **related** 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]];	3) 'dedicated network' means any specific network on diseases, **related** special health issues or public health functions ***that is supported and coordinated by the Centre and is intended*** to ensure collaboration between the coordinating competent bodies of the Member States; (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]];
	Article 2 – paragraph 1 – point 4 a (new)		**Amendment 35** ***(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;***		

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) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]; (6) 'epidemiological surveillance' means epidemiological surveillance as defined in point (4) of Article 3 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]. ';		(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) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]; (6) 'epidemiological surveillance' means epidemiological surveillance as defined in point (4) of Article 3 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]. ';	(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) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]; (6) 'epidemiological surveillance' means epidemiological surveillance as defined in point (4) of Article 3 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]. ';
				(7) 'related special health issues' means related special health issues as defined in point (1) (a) ii of Article 2 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]];	**7) 'related special health issues' means related special health issues as defined in point (1) (a) ii of Article 2 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]];**
				(8) 'monitoring' means monitoring as defined in point (5) of Article 3 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]];	**8) 'monitoring' means monitoring as defined in point (5) 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
				(9) 'health system capacity' means health system capacity as defined in point (9) of Article 3 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]. ';	**9) 'health system capacity' means health system capacity as defined in point (9) of Article 3 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]. '**
47		(2) Article 3 is replaced by the following:		(2) Article 3 is replaced by the following:	2) Article 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
48	Article 3 Article 3 – paragraph 1	*'Article 3* **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,.	**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 ***relevant major non-communicable diseases and health issues, including the*** related special health issues set out in Article 2 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], the mission of the Centre shall be to identify, assess**,** report ***and, where appropriate, ensure that information is presented in an easily accessible way*** on current and emerging threats to human health from communicable diseases ***and relevant major non-communicable diseases***	*'Article 3* **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,	*Article 3* **Missions and tasks of the Centre** **Amendment 36** 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 ***relevant major non-communicable diseases and health issues, including the*** related special health issues ~~set out in Article 2 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]~~, the mission of the Centre shall be to identify, assess**,** report ***and, where appropriate, ensure that information is presented in an easily accessible way*** on current and emerging threats to human health from communicable diseases ***and relevant major non-communicable diseases***

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		and provide recommendations ***for*** response at Union and national levels, as well as at regional level, ***if necessary***.	***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.***	and provide **scientific-based** recommendations for response at Union and national levels, as well as at regional level **in coordination with Member States** if necessary.	***and health issues in collaboration with competent bodies of the Member States or on its own initiative***, ***through the dedicated network,*** and provide ~~**scientific**~~ ***science*****-based** recommendations ***and support in coordinating the*** response at Union and national levels, as well as at ***cross-border interregional and*** regional level, ***where appropriate***. ***In providing such recommendations, the Centre shall cooperate with Member States and take into account existing national crisis management plans and the respective circumstances of each 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
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 ***only*** in cooperation with the competent ***body*** upon request ***from that body***.	**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 ***bodies*** upon ***their*** request ***and provide a risk assessment***.	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 **coordinating** competent body upon request from that body.	In the case of other outbreaks of illnesses of unknown origin that may spread within or to the Union, the Centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak that clearly is not caused by a communicable disease, the Centre shall act only in cooperation with the **coordinating** competent ***bodies*** upon ***their*** request ***and provide a risk assessment.***

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 pursuing its mission, the Centre shall take full account of the responsibilities of the Member States, the Commission and other Union bodies or agencies, and of the responsibilities of international organisations active within the field of public health, in order to ensure comprehensiveness, coherence and complementarity of action	**Amendment 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.	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. **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.**	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 ***coordination,*** comprehensiveness, coherence***,*** and complementarity of action. **The Centre shall support the work of the Health Security Committee (HSC), the Council, and the Member States and *where relevant*, other Union structures to promote effective coherence between their respective activities and for coordinating responses to serious cross-border threats to health 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 Article 3 – paragraph 2 – point a	2. The Centre shall, within its ***financial capacity and*** mandate, perform the following tasks: (a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, ***considering*** the latest technologies;	**Amendment 39** 2. The Centre shall, within its mandate, perform the following tasks: **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***;	2. The Centre shall ~~, within its financial capacity and mandate,~~ perform the following tasks: (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 protecction requirements laid down in Article 20a***;***	2. The Centre shall ~~, within its financial capacity and mandate,~~ perform the following tasks: a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, **using**~~considering~~ the ~~latest~~ **most effective** technologies**,** ***including, where relevant, using artificial intelligence,*** **respecting the European standards regarding ethical aspects and, where applicable, in accordance with the data protecction requirements laid down in Article 20a** ***(aa) develop, in close collaboration and consultation with Member States, relevant common indicators for standardised data collection procedures and risk assessments;***
	Article 3 – paragraph 2 – point a a (new)		**Amendment 41** ***(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;***		

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)		**Amendemnt 42** ***(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;***		
	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***;	**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~~	b) provide analyses, scientific **and technical** advice, opinions**,** ***guidelines,*** ~~**scientific**~~ ***science-*** **based recommendations** and support for actions by the Union and Member States**, to prevent and control communicable diseases and related special health issues,** ***including possible severe impacts on patients suffering from major non-communicable diseases*** ~~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~~

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48 continued	Article 3 – paragraph 2 – point b a (new)		**Amendment 44** ***(ba) identify and monitor the impact of major non-communicable diseases on the incidence, severity and mortality rates of communicable diseases;***	~~activities within its mandate~~;	~~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~~;;
	Article 3 – paragraph 2 – point c	(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;	**Amendment 45** (c) coordinate the European networking of bodies***, organisations and experts*** operating in the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated networks***, while ensuring full compliance with the rules on transparency and conflicts of interest***;	(c) **promote and** coordinate the ~~European~~ networking of bodies operating in **Europe in** the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated **surveillance** networks;	c) **promote and** coordinate the ~~European~~ networking of bodies**, *organisations and experts*** operating in **Europe in** the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated **surveillance** networks, ***while ensuring full compliance with the rules on transparency and conflicts of interest***;

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	Article 3 – paragraph 2 – point d	(d) exchange information, expertise and best practice;	**Amendment 46** (d) exchange information, expertise and best practice***, as well as provide scientific and technical assistance, including training***;	(d) **promote and facilitate the** exchange **of technical and scientific** information **and** expertise and best practices**, including training, among Member States and other EU bodies and Agencies**;	d) **promote and facilitate the** exchange **of technical and scientific** information **and** expertise and best practices**, including training, among Member States and other EU bodies and Agencies**;
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***, 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***;	(e) **monitor the health systems' capacity in close cooperation with the Member States** ~~monitor health systems' capacity relevant~~ **and support the collection of available indicators of Member States' capacity regarding health services to the extent it is necessary for** ~~to~~ the management **and response** ~~of~~ **to** communicable disease threats and ~~other~~ **related** special health issues;	

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48 continued	Article 3 – paragraph 2 – point e a (new)		**Amendment 48** ***(ea) organise inspections at source in the Member States, on a case-by-case basis, to provide additional support and monitor progress in implementation of and compliance with the obligations set out in Article 5b of this Regulation, if necessary in light of the results of stress tests referred to in Article 5(5) of Regulation (EU) …/… [the SCBTH Regulation]; the results of the inspection in a Member State shall be submitted in a report to the Commission, the European Parliament, the Council and relevant Union agencies;***		

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	Article 3 – paragraph 2 – point e b (new)		**Amendment 49** ***(eb) support national monitoring of the response to major communicable diseases in order to measure progress in tackling them across the Union;***		
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 ***in the area of health***;	(f) **contribute to defining research priorities and to** facilitate**ing** the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions **to improve public health functions**;	(f) **contribute to defining research priorities and to** facilitate**ing** the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions ~~**to improve public health functions**~~ ***in the area of public health***;

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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**;	(g) provide, upon request of the Commission or the HSC, 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~~ **related** special health issues ~~relevant for public health~~ ***such as major non-communicable diseases***, **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** ***while avoiding any duplication of existing guidelines, except in cases where it is necessary to update such guidelines if new scientific data become available*****;**

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48 continued	Article 3 – paragraph 2 – point h	(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 ***and close coordination*** with other Union emergency response instruments, in particular the Union Civil protection mechanism***, by providing recommendations on the stockpiling of medical countermeasures in cooperation with the European Medicines Agency (EMA) and other relevant Union agencies and bodies***;	(h) support**, for example, through the EU Health Task Force referred to in Article 11a,** epidemic and outbreak response in Member States **based on profound country knowlegde**, and in third countries~~,~~ in **cooperation with WHO mechanism, and in** complementarity with other ~~Union~~ emergency response instruments, in particular the Union Civil protection mechanism;	(h) support**, for example, through the EU Health Task Force referred to in Article 11a,** epidemic and outbreak response in Member States **based on profound country knowlegde**, and in third countries~~,~~ in **cooperation with WHO mechanism, and in** complementarity ***and close coordination*** with other ~~Union~~ emergency response instruments, in particular the Union Civil protection mechanism***, by providing recommendations on the stockpiling of medical countermeasures in cooperation with the European Medicines Agency (EMA) and other relevant Union agencies and bodies***;;
	Article 3 – paragraph 2 – point h a (new)		**Amendment 53** ***(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;***		

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48 continued	Article 3 – paragraph 2 – point i	(i) contribute to strengthening preparedness capacities under the IHR in third countries, in particular EU partner countries;		(i) contribute to strengthening preparedness capacities under the IHR**, including training,** in **Member States and in** third countries, in particular EU partner countries**, while ensuring synergy with the work of WHO**;	(i) contribute to strengthening preparedness capacities under the IHR**, including training,** in **Member States and in** third countries, in particular EU partner countries**, while ensuring synergy with the work of WHO**;
	Article 3 – paragraph 2 – point j	(j) provide, upon request of the Commission ***or the Health Security Committee ('HSC')***, evidence-based communication messages to the public on communicable diseases, on the threats to health posed by them and on the relevant prevention and control measures**.**	**Amendment 54** (j) provide, upon request of the Commission***, the HSC***, ***or on its own initiative, timely, easily accessible and*** evidence-based communication messages to the public ***in all official languages of the Union*** on communicable diseases, on the threats to health posed by them**,** ***on their possible impact on patients suffering from major non-communicable diseases,*** and on the relevant prevention and control measures***;***	(j) ~~provide~~**propose**, 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 **with due respect to the competencies of the Member States;**	(j) provide, upon request of the Commission or the ~~Health Security Committee ('~~HSC'~~)~~, ***or on its own initiative, timely, easily accessible and*** evidence-based communication messages to the public ***in all official languages of the Union*** on communicable diseases, on the threats to health posed by them ***on their possible impact on patients suffering from major non-communicable diseases*** and on the relevant prevention and control measures, **with due respect to the competencies of the Member States;**

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48 continued	Article 3 – paragraph 2 – point j a (new) 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.';	**Amendment 55** ***(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.*** **Amendement 56** 3. The Centre, the Commission, the relevant Union bodies or EU agencies and the Member States shall cooperate ***in full transparency*** 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 **and synergies** between their respective activities.';	*[EP withdraws amendment]* 3. The Centre, the Commission, the relevant Union bodies or EU agencies and the Member States shall cooperate ***in a transparent manner*** to promote effective coherence **and synergies** between their respective activities.';
49		(3) Article 4 is replaced by the following:		(3) Article 4 is replaced by the following:	
50		*'Article 4* **Obligations of the Member States**		*'Article 4* **Obligations of the Member States**	

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50 continued	Article 4 – paragraph 1 – introductory part	Member States shall:	**Amendment 57** Member States shall ***ensure the coordination and collaboration with the Centre in relation to all the missions and tasks set out in Article 3, by***: **Amendment 58**	Member States shall:	Member States shall ***ensure the coordination and collaboration with the Centre in relation to all the missions and tasks set out in Article 3, by***:
	Article 4 – paragraph 1 – point a	(a) communicate to the Centre ***in a timely manner and*** according to agreed case definitions, indicators, standards, protocols and procedures data on the surveillance of communicable diseases and other special health issues undertaken in accordance with Article 13 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], and available scientific and technical data and information relevant to the Centre's mission, including on preparedness, and health systems capacities to detect, prevent, respond to and recover from outbreaks of communicable diseases;	(a) communicate ***regularly*** to the Centre according to agreed ***timelines,*** case definitions, indicators, standards, protocols and procedures data on the surveillance of communicable diseases and other special health issues undertaken in accordance with Article 13 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], and available scientific and technical data and information relevant to the Centre's mission, including on preparedness, and health systems capacities to detect, prevent, respond to and recover from outbreaks of communicable diseases;	(a) communicate to the Centre in a timely manner and according to agreed case definitions, indicators, standards, protocols and procedures**, available** data on the surveillance of communicable diseases **and serious cross-border health threats** and other **related** special health issues undertaken in accordance with Article 13 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], and available scientific and technical data and information relevant to the Centre's mission, including **relevant and available data** on **crisis** preparedness, ~~and health systems capacities~~ to detect, prevent, respond to and recover from outbreaks of communicable diseases;	(a) communicate ***regularly*** to the Centre ~~in a timely manner and~~ according to agreed ***timelines,*** case definitions, indicators, standards, protocols and procedures**, available** data on the surveillance of communicable diseases **and serious cross-border health threats** and other **related** special health issues undertaken in accordance with Article 13 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], and available scientific and technical data and information relevant to the Centre's mission, including **relevant and available data** on **crisis** preparedness, ~~and health systems capacities~~ to detect, prevent, respond to and recover from outbreaks of communicable diseases;

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	Article 4 – paragraph 1 – point a a (new)		**Amendment 59** ***(aa) use the indicators referred to in Article 3(2) to assess their domestic health situation and communicate them to the Centre to allow data to be compared;***		
50 continued	Article 4 – paragraph 1 – point b	(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***	**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]];	(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	(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]];

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	Article 4 – paragraph 1 – point c	(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 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.	(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.’;	(c) identify, within the scope of the mission of the Centre, recognised competent bodies and public health experts ***and organisations*** who could be made available to assist in Union responses to **cross-border** health threats, such as by undertaking missions to Member States**, *to cross-border regions* 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)		**Amendment 62** ***(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;***		*[EP withdraws amendment]*
	Article 4 – paragraph 1 – point c b (new)		**Amendment 63** ***(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***		***(cb) facilitate the digitalisation of data collection and the data communication process between the national and the European surveillance systems while ensuring the financial means to provide timely delivery of the necessary information; and***

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	Article 4 – paragraph 1 – point c c (new)		**Amendment 64** ***(cc) immediately notify any delay in the reporting of the data to the Centre with an explanation therefore and a planned date of submission.***		
51		(4) Article 5 is replaced by the following:		(4) Article 5 is replaced by the following:	
52	Article 5 – paragraph 1	*'Article 5* **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 ***and continuously develop*** the networking activities of the competent bodies recognised by the Member States through the provision of coordination and technical and scientific expertise to the Commission and Member States and through the operation of the dedicated networks.	*'Article 5* **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.	1. The Centre shall support ***and continuously develop*** the networking activities of the competent bodies recognised by the Member States through the provision of coordination and technical and scientific expertise to the Commission and Member States and through the operation of the dedicated networks.

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52 continued	Article 5 – paragraph 2	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]].	**Amendment 66** The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of communicable diseases and of special health issues***, such as an unpredicted rise in major non-communicable diseases or chronic conditions and in health-related environmental hazards, including those*** referred to in ***point*** (ii) of point (a) of Article 2(1) of Regulation (EU)…/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]].	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]]**, including the integrated operation of a network of EU reference laboratories**. It shall in particular:	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**, *such as an unpredicted rise in major non-communicable diseases or chronic conditions and health-related environmental hazards***, as referred to in points (i), (ii) of point (a) ***and point (c)*** of Article 2(1) of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]**, including the integrated operation of a network of EU reference laboratories, *as referred to in Article 15 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]]***. It shall in particular:

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

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52 continued			***protection by design and by default pursuant to Article 27 of Regulation (EU) 2018/1725 of the European Parliament and of the Council*, taking into account current state-of-the-art technologies;*** **** Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).***		
	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;	**Amendment 68** (b) provide quality assurance by monitoring and evaluating epidemiological surveillance activities (including setting surveillance standards and monitoring data completeness ***and assessment indicators***) of the dedicated surveillance networks to ensure optimal operation;	(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 c	(c) maintain database(s) for such epidemiological surveillance, coordinate with the hosts of other relevant databases, and work towards harmonised approaches to data collection and modelling;	**Amendment 69** (c) maintain database(s) for such epidemiological surveillance, coordinate with the hosts of other relevant databases, and work towards harmonised approaches to data collection and modelling ***in order to produce comparable Union-wide data as a basis for decision-making***; ***in carrying out that role, the Centre shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, as well as establish robust procedures for data quality review***;	(c) maintain database(s) for such epidemiological surveillance, coordinate with the hosts of other relevant databases, and work towards harmonised approaches to data collection and modelling;	(c) maintain database(s) for such epidemiological surveillance, coordinate with the hosts of other relevant databases, and work towards harmonised approaches to data collection and modelling ***in order to produce comparable Union-wide data***; ***in carrying out that role, the Centre shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, as well as establish robust procedures for data quality review***;
	Article 5 – paragraph 2 – point c a (new)		**Amendment 70** ***(ca) collect and analyse information provided by Member States on the impact of pandemics on the causes and treatment of relevant major non-communicable diseases;***		

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

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***, in compliance with points (h) and (i) of Article 9(2) of Regulation (EU) 2016/679 of the European Parliament and of the Council*, after having conducted a DPIA and having mitigated any risks to the rights and freedoms of the data subjects,*** and with a view to integrate those platforms and infrastructures in the European Health Data Space, as regulated by Union legislation, and make use of other relevant data, for example environmental factors ***or phenomena with a potential severe health impact at Union or interregional level***. _____ **** Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016***	(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**, socio-economic determinants, among others, if useful to better fulfil the Centre's mission.**	(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 ***or phenomena with a potential severe health impact at Union or cross-border interregional level*****, socio-economic determinants, among others, if useful to better fulfil the Centre's 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
52 continued			***on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).*** **Amendment 73**		
	Article 5 – paragraph 3	3. The Centre shall support the work of the HSC, the Council and other Union structures for coordinating responses to serious cross-border threats to health within its mandate.	3. The Centre shall support the work of the HSC, the Council and***, where relevant,*** other Union structures for coordinating responses to serious cross-border threats to health within its mandate.	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.~~	*[Moved up to AM 38]*
	Article 5 – paragraph 4	4. The Centre, through the operation of the network for the epidemiological surveillance, shall:		4. The Centre, through the operation of the network for the epidemiological surveillance, shall:	4. The Centre, through the operation of the network for the epidemiological surveillance, 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
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 ***and their interconnection with major non-communicable diseases and chronic conditions and implications for patients with such diseases and conditions*** over time and across Member States and in third countries, based on agreed indicators, to assess the present situation and facilitate appropriate evidence-based action, including through the identification of specifications for harmonised data collection from member states***;***	(a) monitor and report on trends in communicable diseases over time and across Member States and in third countries~~,~~ **in cooperation with the WHO,** 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 **M**~~m~~member **S**~~s~~tates**;**	(a) monitor and report on trends in communicable diseases ***and their interconnection with major non-communicable diseases and chronic conditions and implications for patients with such diseases and conditions*** over time and across Member States and in third countries~~,~~ **in cooperation with the WHO,** 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 **M**~~m~~member **S**~~s~~tates**;**

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 4 – point b Article 5 – paragraph 4 – point b a (new)	(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;		(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;**	(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 **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;**

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52 continued	Article 5 – paragraph 4 – point c	(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;		(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;	c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for ~~**scientific**~~ ***science*-based** recommendations to strengthen and
	Article 5 – paragraph 4 – point d	(d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety;	**Amendment 75** (d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety ***and the resilience of the national health systems in the event of major disease outbreaks, based on common indicators and definitions***;	(d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases**, when necessary for crisis preparedness or response** ~~as well as patients' safety~~;	(d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases**, when necessary for crisis preparedness or response** ~~as well as patients' safety~~;
	Article 5 – paragraph 4 – point e	(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;		(e) ~~identify~~ **support Member States to define** population groups at risk and in need of targeted prevention and response measures, ~~and ensure that those measures are accessible for~~ **including** persons with disabilities;	e) ~~identify~~ **support Member States to define** population groups at risk and in need of targeted prevention and response measures, ***and support Member States in ensuring*** ~~ensure~~ ***that those measures are accessible [/improving accessibility] for*** **including** persons with disabilities;

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52 continued	Article 5 – paragraph 4 – point f	(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 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***, and patients' comorbidities***;	(f) contribute to the assessment of the burden of communicable diseases ~~on the population using data~~, such as disease prevalence, **clinical** complications, hospitalisation and mortality, **among others** ~~and ensure that this data is~~ **using** ~~disaggregated~~ **stratified data** on age, gender**,** ~~and~~ disability **and other elements, if available**;	f) contribute to the assessment of the burden of communicable diseases ~~on the population using data~~, such as disease prevalence, **clinical** complications, hospitalisation and mortality, **among others** ~~and ensure that this data is~~ **using** ~~disaggregated~~ **stratified data** on age, gender**,** ~~and~~ disability **and other elements, if available**;
	Article 5 – paragraph 4 – point g	(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		(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 ensuring international cooperation**; and	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 ensuring international cooperation**; 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
	Article 5 – paragraph 4 – point h	(h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal ***and*** environmental factors, and research priorities and needs.	**Amendment 77** (h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal**,** environmental ***and climatic*** factors, and research priorities and needs.	(h) identify risk factors for disease transmission **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**~~, groups most at risk, including the correlation of disease incidence and severity with societal and environmental factors, and research priorities and needs~~.	(h) identify risk factors for disease transmission **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**~~, 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 1	5. Each Member State shall designate a coordinating competent body and nominate a national focal point and operational contact points as relevant for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases.	**Amendment 78** Each Member State shall designate a coordinating competent body and nominate a national focal point and operational contact points as relevant for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases. ***National focal points shall, to the greatest extent possible, be the same as the National IHR Focal Points, in order to minimise the duplication of resources and efforts.*** ***[Poss. to be moved to a recital]***	5. Each Member State shall designate a coordinating competent body and nominate a **national coordinator,** national focal point**s** and operational contact points as relevant for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases **as well as support to preparedness and response**.	5. Each Member State shall designate a coordinating competent body and nominate a **national coordinator,** national focal point**s** and operational contact points as relevant for public health functions, including epidemiological surveillance, and for various disease groups and individual diseases **as well as support to preparedness and response**.
	Article 5 – paragraph 5 – subparagraph 2	The national focal points shall form networks that strategically advise the Centre.		The national focal points shall form networks that ~~strategically~~ **give technical and scientific** advise **to** the Centre.	The national focal points shall form networks that ~~strategically~~ **give technical and scientific** advise **to** the Centre.

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	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.	**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 ***as well as proposals for the prevention and control of communicable diseases*** 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.	National focal points and operational contact points nominated for disease-specific interactions with the Centre shall form disease-specific or disease-group-specific networks whose tasks shall include the transmission of national surveillance data ***as well as proposals for the prevention and control of communicable diseases*** to the Centre.
	Article 5 – paragraph 5 – subparagraph 4	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.		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.	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.
	Article 5 – paragraph 5 a (new)			**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.**	**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.**

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 ***and coordinate*** the operation of the network of EU reference laboratories referred to in Article 15 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], for the diagnosis, detection, identification***, genetic sequencing*** and characterisation of infectious agents that may present a threat to public health. **Amendment 81** ***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.***	6. The Centre shall ensure the operation of the network of EU reference laboratories referred to in Article 15 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], for the diagnosis, detection, identification and characterisation of infectious agents that may present a threat to public health.	6. The Centre shall ensure ***and coordinate*** the operation of the network of EU reference laboratories referred to in Article 15 of Regulation (EU) …/… [OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]], for the diagnosis, detection, identification***, genetic sequencing*** and characterisation of infectious agents that may present a threat to public health ***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.***

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	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.		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.	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
	Article 5 – paragraph 8 – subparagraph 1	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 ***and coordination*** of the network of Member State services supporting ***the microbiological safety of substances of human origin encompassing*** transfusion, transplantation and medically assisted reproduction ***established under Article 16 of Regulation (EU) …/… [the SCBTH Regulation]*** to allow for continuous and rapid access to sero-epidemiological data via sero-epidemiological surveys within the population, including assessment of donor population exposure and immunity.	8. The Centre shall ensure the operation of the network of Member State services supporting transfusion~~,~~ **and** transplantation ~~and medically assisted reproduction~~ to **monitor , asesses and help adress dissease outbreaks that are relevant to substance of human origin and pose cross - health border threat to safeguard patients in need of such substances.**~~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	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.	**Amendment 83** The network referred to in the first subparagraph shall support the Centre by monitoring outbreaks ***of communicable diseases*** that are relevant to ***the safety and sufficiency of the supply of*** substances of human origin to patients, and with the development of guidelines for blood, tissues and cells safety and quality.	~~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.~~	
	Article 5 – paragraph 9	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.’		~~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* **Prevention of communicable diseases** 1. The Centre shall support Member States to strengthen their communicable disease prevention and control ***systems***.	**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***.	*'Article 5a* **Prevention of communicable diseases** 1. The Centre shall support Member States to strengthen their communicable disease**s** prevention and control systems.	1. The Centre shall support Member States to strengthen their communicable diseases prevention and control ~~systems~~ ***capacities, and to improve and to facilitate the data collection process with real-time and interoperable sharing of data***.
	Article 5a – paragraph 2	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 85** 2. ***In close collaboration with Member States, EMA and other relevant Union bodies and agencies, as well as with international organisations,*** the Centre shall develop a framework for the prevention of communicable diseases and special issues, including ***socio-economic risk factors,*** vaccine preventable diseases, antimicrobial resistance, health ***promotion, health*** education, health literacy and behaviour change.	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.	2. ***In close collaboration with Member States, EMA and other relevant Union bodies and agencies, as well as with international organisations,*** the Centre shall develop a framework for the prevention of communicable diseases and **related** special **health** issues, including ***socio-economic risk factors,*** vaccine preventable diseases, antimicrobial resistance, health ***promotion, 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** ***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.***		*[EP ready to withdraw amendment if issue of misinformation is integrated elsewhere, possibly in AM 88]*

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 3	3. The Centre shall evaluate and monitor communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve these programmes at the national and Union level, and where appropriate at the international levels.	**Amendment 87** 3. The Centre ***may, upon request, provide guidelines for the creation of communicable disease prevention and control programmes, and*** shall evaluate and monitor communicable disease prevention and control programmes in order to provide the evidence for recommendations to ***coordinate,*** strengthen and improve these programmes at the national***,*** ***interregional*** and Union level, and where appropriate at the international levels.	3. The Centre shall evaluate and monitor communicable disease prevention and control programmes **using available data** in order to provide the evidence for **scientific-based** recommendations to strengthen and improve th**o**~~e~~se programmes at the national and Union level, and where appropriate at the international levels.	The Centre ***may provide guidelines for the creation of communicable disease prevention and control programmes, and*** shall evaluate and monitor communicable disease prevention and control programmes **using available data** in order to provide the evidence for ~~**scientific**~~ ***science*-based** recommendations to ***coordinate*,** strengthen and improve these programmes at the national***,*** ***cross-border interregional*** and Union level, and where appropriate at the international levels
	Article 5a – paragraph 3 a (new)		**Amendment 88** ***3a. The Centre shall develop a platform to monitor the level of vaccination coverage by Member States, taking into account the specificities of the vaccination schemes at national and regional levels.***		***3a. The Centre shall develop a platform to monitor the level of vaccination coverage by Member States, taking into account the specificities of the vaccination schemes at national and regional levels.***

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 though 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.’;	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	*‘Article 5b* **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.	*‘Article 5b* **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.~~	The Centre shall provide ***science-based recommendations and*** scientific and technical expertise to the Member States and the Commission in collaboration with relevant Union bodies and agencies**,** international organisations ***and, where relevant, representatives of civil society 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	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;		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;	
	Article 5b – paragraph 1 – subparagraph 2 – point b	(b) develop preparedness monitoring and evaluation frameworks and indicators for preparedness;		(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**;	(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**;
	Article 5b – paragraph 1 – subparagraph 2 – point c	(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;***	(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	(d) ensure monitoring of preparedness gaps and provision of targeted support to EU Member States and third countries in case of needs;		(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~~;	(d) ~~ensure~~ **facilitate support for observing and overcoming** ~~monitoring of~~ preparedness gaps and provision of targeted support to EU Member States and, ***upon their request, from*** third countries, **in cooperation with the WHO** ~~upon their request~~ ~~in case of needs~~;
	Article 5b – paragraph 1 – subparagraph 2 – point e	(e) develop exercises, in-action and after-action reviews and organise capacity building actions to address identified preparedness capacity and capability gaps;	**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;	(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;	(e) develop exercises, ***stress tests,*** 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;
	Article 5b – paragraph 1 – subparagraph 2 – point f	(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;	**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;	(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~~;	f) develop **and support** specific preparedness activities addressing***, amongst other things,*** 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~~;

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

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 j Article 5b – paragraph 1 – subparagraph 2 – point k	(j) bolster modelling, anticipation and forecast capacity of the Centre; and (k) maintain a regular secondment mechanisms between the Centre, the Commission and Member States' experts.'; 		(j) bolster modelling, anticipation and forecast capacity of the Centre; and (k) maintain ~~a~~ regular secondment mechanism**s** between the Centre, the Commission**,**~~and~~ Member States' experts **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 mehanism shall contribute in strengthening the operational interface between ECDC and Member States;**	(j) bolster modelling, anticipation and forecast capacity of the Centre; and (k) maintain ~~a~~ regular secondment mechanism**s** between the Centre, the Commission**,**~~and~~ Member States' experts **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 mehanism shall contribute in strengthening the operational interface between ECDC and Member States;**
57		(7) Article 6 is amended as follows:		(7) Article 6 is amended as follows:	

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	Article 6 – paragraph 1a	(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.’;	**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 **independent technical or scientific-based** recommendations for actions to prevent and control communicable disease threats **on its own initiative or** upon request of the Commission**, Member States through HSC**.';	(a) the following paragraph 1a is inserted: **‘**1a. The Centre shall provide concrete analyses and **independent ~~technical or scientific~~ *science*-based** recommendations for actions to prevent and control communicable ***diseases and other cross-border*** threats ***to health*** **on its own initiative or** upon request of the Commission**, Member States through HSC**.';
	Article 6 – paragraph 1b	(b) paragraph 3 is replaced by the following:		(b) paragraph 3 is replaced by the following:	(b) 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
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' ***and*** Union research and health programmes, and will liaise between the public health and the research sector ***as needed***.	**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 ***and WHO*** research and health programmes, and will liaise between the public health and the research sector ***by encouraging consultation of, and cooperation with, public health experts***.	'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 **and WHO** research and health programmes, **as well as with other relevant studies** and will liaise between the public health and the research sector as needed.	'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'**,** Union **and WHO** research and health programmes, **as well as with other relevant *programmes*** ~~**studies**~~ and will liaise between the public health and the research sector.

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 – subparagraph 2 Article 6 – paragraph 3 – subparagraph 2 a (new)	To carry out the studies referred to in the first paragraph, the Centre shall have access to health data made available or exchanged through digital infrastructures and applications, in accordance with data protection rules, allowing for the health data to be used for healthcare, research, policy making and regulatory purposes. For the purposes of studies under the first paragraph, the Centre shall also make use of other relevant data, for example on environmental and socio-economic factors.’;	**Amendment 97** To carry out the studies referred to in the first paragraph, the Centre shall have access to health data made available or exchanged through digital infrastructures and applications, in accordance with data protection rules, allowing for the health data to be ***solely*** used for healthcare, ***health*** research, policy making and regulatory purposes ***in the domain of health***. For the purposes of studies under the first paragraph, the Centre shall also make use of other relevant data, for example on environmental and socio-economic factors***, after it has proven the necessity and proportionality of using those data***.	To ~~carry out~~ **promote and initiate** the studies referred to in the first paragraph, the Centre shall ~~have~~ **request** access to health data made available or exchanged through digital infrastructures and applications, ~~in accordance with data protection rules~~, allowing for the health data to be used for healthcare, research, policy making and regulatory purposes, **where applicable, in accordance with the data protection requirements laid down in Article 20a**. For the purposes of studies under the first paragraph, the Centre shall also make use of other relevant data, for example on environmental and socio-economic factors. **For consistency purposes of the scientific studies, the Centre shall seek where appropriate the expertise and guidance of the Member States to ensure correct understanding of the health data made available, their limitations, the national context and information 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
58 continued	Article 6 – paragraph 3 a (new)		**Amendment 98** ***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.***		***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.***
		(c) paragraph 4 is replaced by the following:		(c) paragraph 4 is replaced by the following	
	Article 6 – paragraph 4	'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 99** 4. The Centre shall consult with the Commission***, the HSC*** and other ***relevant*** Union bodies or agencies with regard to the planning and priority setting of research and public health studies.	'4. The Centre shall consult with the **HSC, the** Commission and other Union bodies or agencies with regard to the planning and priority setting of research and public health studies**, taking into account the opinion of the Advisory Forum**.';	. The Centre shall consult with the **HSC, the** Commission and other ***relevant*** Union bodies or agencies with regard to the planning and priority setting of research and public health studies**, taking into account the opinion of the Advisory Forum**.';
59		(8) Article 7 is replaced by the following:		(8) Article 7 is replaced by the following:	
60	Article 7 – paragraph 1	*'Article 7* **Procedure for scientific opinions** 1. The Centre shall issue a scientific opinion on matters falling within its mission:		*'Article 7* **Procedure for scientific opinions** 1. The Centre shall issue a scientific opinion on matters falling within 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
	Article 7 – paragraph 1 – point a Article 7 – paragraph 1 – point b	(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;		(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;	
60 continued	Article 7 – paragraph 1 – point c	(c) at the request of the Commission; ***and***	**Amendment 100** (c) at the request of the Commission ***or EMA***;	(c) at the request of the Commission **or the HSC**; and	(c) at the request of the Commission**, the HSC *or EMA***; and
	Article 7 – paragraph 1 – point c a (new)		**Amendment 101** ***(ca) at the request of the HSC; and***		*[EP withdraws amendment]*
	Article 7 – paragraph 1 – point d	(d) on its own initiative.		(d) on its own initiative.	(d) on its own initiative.
	Article 7 – paragraph 2	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.	**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 ***necessity to act, and shall*** be accompanied by sufficient background information regarding that issue.	2. Requests for a scientific opinion referred to in paragraph 1 shall clearly explain the scientific issue to be addressed and the Union interest and be accompanied by sufficient background information regarding that issue. **If scientific opinions are focused on a specific Member State, the Member State concerned shall be involved.**	

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
	Article 7 – paragraph 3	3. The Centre shall issue scientific opinions within a mutually agreed time frame.		3. The Centre shall **ensure that it has the ability to anticipate and react quickly to** issue scientific opinions within a mutually agreed time frame **and that these scientific opinions are accessible and operational for policy makers**.	3. The Centre shall **ensure that it has the ability to anticipate and react quickly to** issue scientific opinions within a mutually agreed time frame **and that these scientific opinions are accessible and operational for policy makers, *and shall be made publicly available as soon as possible, except those that are targeted at a particular 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 4	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.	**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.	4. Where different requests are made on the same issue or where the request does not comply with paragraph 2, the Centre may decline to issue a scientific opinion or propose amendments to that request in consultation with the institution or Member State that made the request. In case the request is declined, a justification shall be given to the institution or Member States that made the request.	4. Where different requests are made on the same issue or where the request does not comply with paragraph 2, the Centre may decline to issue a scientific opinion or propose amendments to that request in consultation with the institution***, agency*** or Member State that made the request. In case the request is declined, a justification shall be given to the institution***, agency*** or Member States that made the request.
	Article 7 – paragraph 5	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.	**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.	5. Where the Centre has already delivered a scientific opinion on the specific issue covered by a request and it concludes that no scientific elements justify the re-examination of the issue, information supporting that conclusion shall be given to the institution or Member State that made the request.	5. Where the Centre has already delivered a scientific opinion on the specific issue covered by a request and it concludes that no scientific elements justify the re-examination of the issue, information supporting that conclusion shall be given to the institution***, agency*** or Member State that made the request.

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
	Article 7 – paragraph 6	6. The Centre's internal rules shall specify requirements regarding the format, explanatory background and publication of a scientific opinion.';		6. The Centre's internal rules shall specify requirements regarding the format, explanatory background **and transparency rules for the publication** of a scientific opinion.';	6. The Centre's internal rules shall specify requirements regarding the format, explanatory background **and transparency rules for the publication** of a scientific opinion.';
61		(9) Article 8 is replaced by the following:		(9) Article 8 is replaced by the following:	
62	Article 8 – paragraph 1	*'Article 8* **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.	**Amendment 105** 1. The Centre shall support and assist the Commission by operating the EWRS ***provided for in Article 18 of Regulation (EU) .../... [the SCBTH Regulation]*** and by ensuring with the Member States the capacity to respond in a coordinated ***and timely*** manner.	*'Article 8* **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.	1. The Centre shall support and assist the Commission by operating the EWRS ***provided for in Article 18 of Regulation (EU) .../... [the SCBTH Regulation]*** and by ensuring with the Member States the capacity to respond in a coordinated ***and timely*** manner.
	Article 8 – paragraph 2	2. The Centre shall:		2. The Centre shall:	
	Article 8 – paragraph 2 – point a	(a) analyse the content of messages received by it via the EWRS;		(a) analyse the content of messages received by it via the EWRS; **the processing of personal data necessary for the purpose of contact tracing is based on Regulation (EU) ... [please insert the number of Regulation SCBTH];**	

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 2 – point b Article 8 – paragraph 2 – point c Article 8 – paragraph 2 a (new)	(b) provide information, expertise, advice and risk assessment to Member States and the Commission; and (c) ensure that the EWRS is efficiently and effectively linked with other Union alert systems.	**Amendment 106** (b) provide information, expertise, advice***, training*** and risk assessment to Member States and the Commission; and **Amendment 107** ***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.***	(b) provide information, expertise, advice and risk assessment to Member States and the Commission; and (c) ensure that the EWRS is efficiently and effectively linked with other Union alert systems.	(b) provide information, expertise, advice***, training*** and risk assessment to Member States and the Commission; and (c) ensure that the EWRS is efficiently and effectively linked with other Union alert systems. ***2a. The Centre shall work with the Commission, the HSC and Member States to improve the reporting of relevant data through the EWRS, with a view to encourage digitalization of that process and its integration into national surveillance 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 ***continuous*** updates, including for the use of modern technologies, such as digital mobile applications, artificial intelligence ***and computer modelling and simulation*** models, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States. ***Those technologies shall be used for the sole purpose of fighting pandemics, where proven to be adequate, necessary and proportionate, and in full compliance with Regulation (EU) 2016/679 and Directive 2002/58/EC of the European Parliament and of the Council*,*** and on defining the functional requirements of the EWRS. _____ **** Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002***	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.	***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).***	4. The Centre shall work with the Commission, the HSC and the eHealth Network **and relevant experts in the Member States** to further define the functional requirements for contact tracing **and warning** applications**, or where needed other digital tools,** and their interoperability, taking into account existing infrastructures and services~~, such as geolocation services provided by EU Space Programme~~ **as well as Union and national requirements regarding personal data protection**.	4. The Centre shall work with the Commission, the HSC and the eHealth Network **and relevant experts in the Member States** to further define the functional requirements for contact tracing **and warning** applications**, or where needed other digital tools,** and their interoperability, taking into account existing infrastructures and services, ***such as geolocation services provided by EU Space Programme*** **as well as Union and national requirements regarding personal data protection**.

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 ***as processor*** shall have the responsibility to ensure the security and confidentiality of the processing operations of personal data carried out within the EWRS and in the context of interoperability of contact tracing applications, in accordance with the obligations laid down in Articles 33***, 34(2)*** and 36 of Regulation (EU) 2018/1725 ***of the European Parliament and of the Council.***	**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~~.~~	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* **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**.**	*'Article 8a* **Public Health 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.	**Public Health 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.
	Article 8a – paragraph 1 a (new)		***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.***		*[To be redrafted and turned into recital]*

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64 continued	Article 8a – paragraph 2	2. The risk ***assessment*** shall include general and targeted recommendations for response as a basis for coordination in the HSC.	**Amendment 112** 2. The risk ***assessments referred to in paragraph 1*** shall include***, where possible,*** general and targeted recommendations for response as a basis for coordination in the HSC**,** ***including, but not limited to:*** ***(a) a forecast of the evolution of a health crisis and the risk of a health emergency;*** ***(b) a forecast of the demand for medicines, vaccines, medical equipment, protective equipment and hospital capacity, including within the Union Civil Protection Mechanism;*** ***(c) identification of vulnerable groups in society, such as patients suffering from chronic conditions, patients with major non-communicable diseases, the elderly, children, pregnant women and professions with a high risk of infection or transmission, including specific needs for medicines and hospital capacity for those vulnerable groups;***	2. The risk assessment shall include general and targeted **scientific-based** recommendations **and options** 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
64 continued	Article 8a – paragraph 3	3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of rapid risk assessments by involving Member States experts and relevant agencies***, if necessary***.	***(d) identification of possible protective measures and assessment of their efficacy;*** ***(e) assessment of the possible need for activation of the EU Health Task Force***. **Amendment 113** 3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of rapid risk assessments by involving Member States experts and relevant agencies ***and organisations***.	3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of **risk assessments, including** rapid risk assessments**,** by involving **national focal points or** Member States experts**,** ~~and~~ relevant agencies **or international organisations such as WHO**, if ~~necessary~~**appropriate**. **The Centre shall establish rules of procedure for risk assessments, especially regarding the involvement of experts to ensure independency and representativeness of Member States expertise.**	3. For the purposes of paragraph 1, the Centre shall coordinate the preparation of ~~**risk assessments, including**~~ rapid risk assessments**,** by involving **national focal points or** Member States experts**,** ~~and~~ relevant agencies **or international organisations such as WHO**, if ~~necessary~~**appropriate**. **The Centre shall establish rules of procedure for risk assessments, especially regarding the involvement of experts to ensure independency and representativeness of Member States expertise.**

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 4 Article 8a – paragraph 4 a (new)	4. Where the risk assessment falls outside the mandate of the Centre, at the request of the agency or body carrying out the risk assessment within its mandate, the Centre shall, without undue delay, provide it with any relevant information and data that is at its disposal.’;	**Amendment 114** ***4a. The Centre shall work together with the Member States to improve their risk assessment capacity.***	4. Where the risk assessment falls outside the mandate of the Centre, at the request of the agency or body carrying out the risk assessment within its mandate, the Centre shall, without undue delay, provide it with any relevant information and data that is at its disposal.’;	***4a. The Centre shall work together with the Member States to improve their risk assessment capacity.***
65		(11) the following Article 8b is inserted:		(11) the following Article 8b 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
66		*'Article 8b* **Response coordination**		*'Article 8b* **Response coordination**	**Response coordination**
	Article 8b – paragraph 1	1. The Centre shall support response coordination in the HSC as referred to in Article 21 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], in particular by providing recommendations for response measures for:		1. The Centre shall support response coordination in the HSC as referred to in Article 21 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], **for threats 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, potentially impacted by communicable diseases, or point (d) of Article 2(1) of that Regulation,** in particular by providing **scientific-based** recommendations **and options** for response measures for:	1. The Centre shall support response coordination in the HSC as referred to in Article 21 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], **for threats 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, potentially impacted by communicable diseases, or point (d) of Article 2(1) of that Regulation,** in particular by providing ~~**scientific**~~ ***science-based*** recommendations **and options** for response measures for:
	Article 8b – paragraph 1 – point a	(a) national responses to the serious cross-border threat to health	**Amendment 115** (a) national ***or interregional*** responses to the serious cross-border threat to health;	(a) national responses to the serious cross-border threat**s** to health;	(a) national ***or cross-border interregional*** responses to the serious cross-border threat to health;

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66 continued	Article 8b – paragraph 1 – point b	(b) adoption of ***guidance*** for the Member States for the prevention and control of a serious cross-border threat to health**.**	**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***;***	(b) adoption of guidance for the Member States for the prevention and control of a serious cross-border threat to health.	(b) adoption of ***guidelines*** ~~guidance~~ for the Member States for the prevention and control of a serious cross-border threat to health***;***
	Article 8b – paragraph 1 – point b a (new)		**Amendment 117** ***(ba) the deployment of the EU Health Task Force.***		*[EP withdraws amendment]*
	Article 8b – paragraph 2	2. The Centre shall support a Union coordinated response ***at the request of a Member State, Council, Commission, Union bodies or agencies***.	**Amendment 118** 2. The Centre shall support a Union coordinated response ***in accordance with Article 21 of Regulation (EU) …/… [the SCBTH Regulation]***.	2. The Centre shall support a Union coordinated response at the request of a Member State, Council, Commission, **HSC,** Union bodies or agencies.’;	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:	

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	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.	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 ***and assessing the efficiency of response measures***. The Centre shall provide scientific and technical expertise and assistance within its financial capacity and mandate, and in accordance with the appropriate working arrangements established with the Commission.	**'**2. The Centre may be requested by the Commission, the Member States, **the HSC or** third countries **having concluded agreements with the Union in accordance with Article 30**, 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 **evidence-based** scientific and technical expertise and assistance within its ~~financial capacity and~~ mandate, and in accordance with the **applicable agreements as well as with the** appropriate working arrangements established with the Commission **with regard to third countries and international organizations**.	2. The Centre may be requested by the Commission, the Member States, **the HSC or** third countries **having concluded agreements with the Union in accordance with Article 30**, in particular EU partner countries, and international organisations (in particular the WHO) to provide scientific or technical assistance in any field within the scope of its mission. The assistance may include aiding the Commission and Member States to develop technical guidelines on good practice and on protective measures to be taken in response to human health threats, providing expert assistance, mobilising and coordinating investigation teams ***and assessing the efficiency of response measures***. The Centre shall provide **evidence-based** scientific and technical expertise and assistance within its ~~financial capacity and~~ mandate, and in accordance with the **applicable agreements as well as with the** appropriate working arrangements established with the Commission **with regard to third countries and international organizations**.

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.’;	**‘**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.;~~ **(b) paragraph 5 is replaced by the following:**	~~(b) paragraph 5 is deleted.;~~ **(b) paragraph 5 is replaced by the following:**
71				**5. The Centre shall inform the Management Board, Member States authorities and the Commission of any such request and of its outcomes.**	**5. The Centre shall inform the Management Board, Member States authorities and the Commission of any such request and of its outcomes.**
72		(c) paragraph 6 is replaced by the following:		(c) paragraph 6 is replaced by the following:	

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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, ***and*** 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, ***response to public health emergencies,*** public health research ***and risk communication. Those programmes shall take into consideration the need for training to be kept up-to-date and shall respect the principle of proportionality and the training needs of Member States.***	**‘**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 **in order to assist the needs of the Member States**.’;	
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***,*** ***standardisation***, collection, validation, analysis and dissemination of data at Union level.	‘1. The Centre shall**:** **(a)** coordinate data collection, validation, analysis and dissemination of data at Union level **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**.’; **(b) 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.**	**(b) 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	(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]];	**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]];	(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]];	
	Article 11 – paragraph 1a – point b	(b) the progression of epidemic situations, including for modelling, anticipation and scenario development;	**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***;	(b) the progression of epidemic situations, including for modelling, anticipation and scenario development;	

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 c	(c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;		(c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries **in cooperation with the WHO**;	(c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries **in cooperation with the WHO**;
	Article 11 – paragraph 1a – point d	(d) molecular pathogen data, if required for detecting or investigating cross-border health threats; and		(d) ~~molecular~~ pathogen data, **including but not limited to molecular level,** if required **for epidemiological surveillance of communicable diseases and related special health issues and** for detecting or investigating cross-border health threats; and	(d) ~~molecular~~ pathogen data, **including but not limited to molecular level,** if required **for epidemiological surveillance of communicable diseases and related special health issues and** for detecting or investigating cross-border health threats; and
	Article 11 – paragraph 1a – point e	(e) health systems data required for managing cross-border health threats.’;		(e) health systems data required for managing **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]].’;** ~~cross-border health threats.’;~~	(e) health systems data required for managing **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]].’;** ~~cross-border health threats.’;~~
	Article 11 – paragraph 1a – point e a (new)		**Amendment 124** ***(ea) implementation of the Centre’s recommendations ~~on countermeasures~~ by Member States and the outcomes thereof.***		

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
79		(c) paragraph 2 is replaced by the following:		(c) paragraph 2 is replaced by the following:	
80 80 continued	Article 11 – paragraph 2 Article 11 – paragraph 2 – point a Article 11 – paragraph 2 – point b	‘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; (b) carry out technical and scientific evaluation of prevention and control measures at Union level;		‘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; (b) carry out technical and scientific evaluation**s** of prevention and control measures at Union level;	

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
	Article 11 – paragraph 2 – point c	(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	**Amendment 125** (c) work in close cooperation with the competent bodies of the organisations ***and relevant counterparts*** operating in the field of data collection from the Union, third countries, the WHO, other international organisations ***and the scientific community, while ensuring that robust safeguards are in place concerning transparency and accountability***; and	(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***, including anonymous data and pseudonymous data, where such data are*** made available or exchanged through digital infrastructures, in accordance with data protection rules, allowing for the health data to be ***solely*** used for healthcare, ***health*** research, policy making and regulatory purposes ***in the domain of health***; and provide and facilitate controlled access to health data to support public health research.	(d) develop solutions to access relevant health data**, publicly available or** 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 **where applicable, in accordance with the data protection requirements laid down in Article 20a**; and provide and facilitate controlled **and timely** 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:	

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
82	Article 11 – paragraph 4 Article 11 – paragraph 5	'4. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts as referred to in point (g) of Article 5(4), upon request of the ***European Medicines Agency***, in an objective, reliable and easily accessible way and on the basis of the best available information. 5. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall provide data and relevant analyses on the basis of the best available information.';	**Amendment 127** 4. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts as referred to in point (g) of Article 5(4), upon request of ***a Member State,*** the ***Commission or EMA***, in an objective, reliable and easily accessible way and on the basis of the best available information.	'4. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts as referred to in point (g) of Article 5(4**3**), **also in cooperation with other institutions and working groups established with Member State experts,** upon request of the **Commission, the HSC, the** European Medicines Agency**, the Member States or on its own initiative,** in an objective, reliable and easily accessible way and on the basis of the best available information. **'**5. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall provide data and **easily accessible** relevant analyses on the basis of the best available information**, as fast as possible and in line with Art 8(a), paragraph 1**.';	4. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall make available epidemiological forecasts as referred to in point (g) of Article 5(43), **also in cooperation with other institutions and working groups established with Member State experts,** upon request of the **Commission, the HSC, the *EMA*** ~~European Medicines Agency~~**, the Member States or on its own initiative,** in an objective, reliable and easily accessible way and on the basis of the best available information. 5. In the situations of urgency related to severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Centre shall provide data and **easily accessible** relevant analyses on the basis of the best available information**, as fast as possible and in line with Art 8(a), paragraph 1**.';

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
83		(14) the following Article 11a is inserted:		(14) the following Article 11a is inserted:	
84	Article 11a – paragraph 1	*'Article 11a* **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 ***and*** experts from Member States ***and*** 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 ***a permanent capacity, as well as an enhanced emergency*** capacity to mobilise and deploy the EU Health Task Force including the Centre's staff***,*** experts from Member States***,*** fellowship programmes ***and international and non-profit organisations***, to assist local response to outbreaks of communicable diseases in Member States and in third countries.	*'Article 11a* **Support to international and field <u>preparedness and</u> response** 1. The Centre shall establish **<u>a EU Health Task Force and ensure</u>** capacity to mobilise and deploy **<u>it</u>** ~~the EU Health Task Force~~**<u>,</u>** 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>**	
	Article 11a – paragraph 1 a (new)		Amendment 129 ***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.***		

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	2. The Centre shall develop a framework and establish procedures with the Commission to mobilise the EU Health Task Force.	**Amendment 130** 2. The Centre shall develop a framework and establish procedures with the Commission to ***deploy the permanent capacity and*** mobilise ***the emergency capacity of*** the EU Health Task Force.	2. The Centre shall develop a framework and establish procedures with the Commission to **rapidly** mobilise the EU Health Task Force. **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.** **This implementing act shall be adopted in accordance with the examination procedure referred to in Article 30a(2).**	
	Article 11a – paragraph 3	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.		3. The Centre shall ensure that the EU Health Task Force ~~are~~ **is** coordinated **with,** ~~and~~ complementary to **and integrating** the capacities ~~integrating~~ the European Medical Corps**,** ~~and~~ other relevant capacities under the Union Civil Protection Mechanism **and other mechanisms of international organisations (WHO in particular) in order to avoid overlaps and duplications**.	

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	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.	**Amendment 131** The Centre shall develop with the Commission a framework for ***the deployment of the permanent capacity and*** the mobilisation of the EU Health Task Force, in view of action under Decision No 1313/2013/EU	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~~	
	Article 11a – paragraph 4 – subparagraph 2	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.		~~The Centre~~ **Through the EU Health Task Force, 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.	

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 5	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.		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 **and in collaboration with Member States**.	
	Article 11a – paragraph 6	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.	**Amendment 132** 6. The Centre shall maintain ***a permanent*** capacity to carry out missions to Member States, upon request of the Commission and Member States, to provide recommendations on response to threats to health within its mandate.	6. **By establishing a mechanism to mobilise and deploy the EU Health Task Force,** ~~T~~**t**he Centre shall maintain capacity **and country knowledge** to carry out missions to Member States, upon **the joint** request of the Commission and Member States **concerned** ,to provide **scientific-based** recommendations on **preparedness,** response **and after action review** to threats to health 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
	Article 11a – paragraph 7	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.		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 collaboration with WHO**.	
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:	
87	Article 12 – paragraph 1 – subparagraph 1	'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.		'1. The Centre shall communicate **the activities and results of its work** on its own initiative within the scope of its mission, after having given prior information to the Member States and to the Commission.	1. The Centre shall communicate **the activities and results of its work** on its own initiative within the scope of its mission, after having given prior information to the Member States and to 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
	Article 12 – paragraph 1 – subparagraph 2	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 ***with essential information available in all official languages of the Union.*** It shall also publish its opinions produced in accordance with Article 6 ***in a timely manner***.	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 **activities and the** results of its work. The Centre shall make available **scientific** information for the general public, including through a dedicated website **as well as an active presence on social media or analogous platforms.** It shall also publish its **scientific** opinions produced in accordance with Article 6. **The information relevant for the EU citizens is made available in all languages of the European Uninon to ensure appropriate outreach to them**;	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 **activities and the** results of its work. The Centre shall make available **scientific** information for the general public, including through a dedicated website **as well as an active presence on social media or analogous platforms.** It shall also publish its **scientific** opinions produced in accordance with Article 6 ***in a timely manner***. **The information relevant for the EU citizens is made available in all languages of the European Uninon to ensure appropriate outreach to them**;
88		***(b) paragraph 2 is deleted;***	**Amendment 134** ***deleted***	(b) paragraph 2 is deleted;	***(Commission proposed deletion) deleted***
89		(c) paragraph 3 is replaced by the following:		(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***, the WHO*** 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.';	3. The Centre shall cooperate as appropriate with the competent bodies in the Member States***, the WHO*** and other interested parties with regard to public information campaigns.
91		(16) Article 14 is amended as follows:		(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:	(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***, if necessary***.	'Members' term of office shall be three years and can be extended.';	'Members' term of office shall be three years and can be extended.'; *[EP withdraws amendment]*
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:	(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;	'(d) adopt, before 31 January each year, the Centre's programme of work for the coming year;

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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) ***by 30 November of each year,*** adopt a draft single programming document in line with Article 32 of the Commission Delegated Regulation (EU) 2019/715* and the related Commission's guidelines for the Single Programming Document; ***the single programming document shall be adopted where a positive opinion has been given by the Commission and, as regards multiannual programming, after consulting the European Parliament and the Council;*** _____ * Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1).	'(e) adopt a draft single programming document in line with Article 32 of the Commission Delegated Regulation (EU) 2019/715 and the related Commission's guidelines for the Single Programming Document,	'(e) adopt a draft single programming document in line with Article 32 of the Commission Delegated Regulation (EU) 2019/715 and the related Commission's guidelines for the Single Programming Document; ; ***the single programming document shall be adopted where a positive opinion has been given by the Commission and, as regards multiannual programming, after consulting the European Parliament and the Council;*** _____ * Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1).

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95 continued	Article 14 – paragraph 5 – subparagraph 1 – point f	(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.		'(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.	
	Article 14 – paragraph 5 – subparagraph 1 – point g	(g) before 30 March each year, adopt the general report on the Centre's activities for the previous year;		(g) before 30 March each year, adopt the general report on the Centre's activities for the previous year;	(g) before 30 March each year, adopt the general report on the Centre's activities for the previous year;
	Article 14 – paragraph 5 – subparagraph 1 – point h	(h) adopt the financial rules applicable to the Centre after the Commission has been consulted;		(h) adopt the financial rules applicable to the Centre after the Commission has been consulted;	(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 ***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.	**Amendment 138** (i) determine ***by unanimity*** the rules governing the languages of the Centre, including the possibility of a distinction between the ***ordinary*** internal workings of the Centre and ***its*** external communication, taking into account the need to ensure access ***for all interested parties*** to the work of the Centre ***in as many official languages of the Union as possible, as well as expert scrutiny of scientific findings and public understanding of the Centre's work and recommendations; those rules may include the use of qualified interpreters (working with sign language, or via oral or tactile interpretation) if needed.***	(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.	
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:	(17) point (b) of Article 16(2) is replaced by the following:

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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 **according to Article 32 paragraph 7 of the Commission Delegated Regulation (EU) 2019/715. The Commision opinion will be submitted to the Management Board at the earliest possible stage**;’	‘(b) drawing up draft work programmes taking into account the recommendations adopted in the annual Commission Opinion on the single programming document **according to Article 32 paragraph 7 of the Commission Delegated Regulation (EU) 2019/715. The Commision opinion will be submitted to the Management Board at the earliest possible stage**;’
98	Article 17 – paragraph 1	***(18) Article 17 is replaced by the following:*** ***‘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.; ’***	**Amendment 139** ***deleted***	(18) Article 17 is **amended** ~~replaced by the~~ **as** follow**s**~~ing~~: **(a) paragraph 1 is replaced by the following:** ‘1. Without prejudice to Article 3(2), the director shall be appointed by the Management Board on the basis of a list of **at least three** 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, **previously validated by the Management Board,** for a period of five years, which may be extended once for a further period of up to five years.’;	(18) Article 17 is **amended** ~~replaced by the~~ **as** follow**s**~~ing~~: **(a) paragraph 1 is replaced by the following:** ‘1. Without prejudice to Article 3(2), the director shall be appointed by the Management Board on the basis of a list of **at least three** 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, **previously validated by the Management Board,** 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:	*(19) Article 18 is amended as follows:*
100		(a) paragraph 2 is replaced by the following:		(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. 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.***	'2. Members of the Advisory Forum shall not be members of the Management Board. **Advisory Forum** ~~M~~**m**embers'term of office shall be three years and can be extended.';	'2. Members of the Advisory Forum shall not be members of the Management Board. **Advisory Forum** ~~M~~**m**embers'term of office shall be three years and can be extended. ***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.***';
102		(b) in paragraph 4, point (f) is replaced by the following:		(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.';	*'(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:	(c) paragraph 8 is replaced by the following:

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

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** ***(19a) in Article 19, paragraph 2 is replaced by the following:*** ***"***2. The members of the Management Board, the director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing ***and be available to the public****."*		***(19a) in Article 19, paragraph 2 is replaced by the following:*** ***"***2. The members of the Management Board, the director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing ***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:	*(20) paragraph 3 of Article 20 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
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.’;	‘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.’;
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 (***EC***) ***No 45/2001 of the European Parliament and of the Council of18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (8)*** shall apply.	**Amendment 143** ***(20a) in Article 20, paragraph 4 is replaced by the following:*** ***"***4. Personal data shall not be processed or communicated except in cases where this is strictly necessary for the fulfilment of the mission of the Centre. In such cases, Regulation (***EU***) ***2018/1725*** shall apply.***";***		*EP AM ok in principle, but linked to data protection provisions*

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110	Article 20 – paragraph 4 a (new)		**Amendment 144** ***(20b) in Article 20, the following paragraph is added: "4a. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC, or the obligations of the Centre and the Commission relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.*** ***The Centre shall put in place procedures and data protection safeguards designed to guarantee that its processing operations fully respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity, confidentiality, and data protection by design and by default.*** ***The Centre shall only process***		

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110 continued			***personal data, in particular in the case of health data relating to identified or identifiable individuals, when it is proven to be necessary and proportionate to do so. Whenever possible, in line with the principle of data minimisation, the Centre shall make use of anonymised data, achieved through techniques used such as randomisation or generalisation. The Commission shall adopt delegated acts in accordance with Article 20a to supplement this Regulation by setting out the categories of data subjects under the scope of the processing and the categories of the personal data processed, together with a description of the specific measures to safeguard the rights and freedoms of the data subjects involved, in line with relevant data protection legislation, in particular with regard to concrete safeguards to prevent abuse or unlawful access or transfer, and the storage periods.";***		

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
111				**(20a) paragraph 4 of Article 20 is deleted and the following Article is inserted:**	
112	Article 20 a (new) – paragraph 1			***Article 20a*** **Personal data protection** **1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Commission, the Centre and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities.**	

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
112 continued	Article 20 a (new) – paragraph 2 Article 20 a (new) – paragraph 3			**2. Personal data shall not be processed or communicated except in cases where this is strictly necessary to the fulfilment of the mission of the Centre. In such cases, the conditions of Regulation (EU) No 2016/679 and Regulation (EU) No 2018/1725 shall apply as appropriate.** **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.**	

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113	Article 20 a (new)		**Amendment 145** ***(20c) the following Article is inserted:*** ***"Article 20a*** ***Exercise of the delegation*** ***1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.*** ***2. The power to adopt delegated acts referred to in Article 20(4a) shall be conferred on the Commission for a period of five years from … [date of entry into force of this amending Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***		

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
113 continued			***3. The delegation of power referred to in Article 20(4a) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.*** ***4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making*.*** ***5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council***		

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113 continued			***6. A delegated act adopted pursuant to Article 20(4a) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.*** **** OJ L 123, 12.5.2016, p. 1.";***		
114		(21) Article 21 is replaced by the following:		(21) Article 21 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
115	Article 21 – paragraph 1	*'Article 21* **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.		*'Article 21* **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.	

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 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.		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.	
	Article 21 – paragraph 3	3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential.		3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential.	
	Article 21 – paragraph 4	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.		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	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.		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 **the applicable legislation on data protection and confidentiality and** appropriate working arrangements established with the Commission.	
	Article 21 – paragraph 6	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***, in accordance with Articles 27 and 33 of Regulation (EU) 2018/1725***.	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:	(22) Article 22 is amended as follows:

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
117		(a) in paragraph 3, point (d) is replaced by the following:		(a) in paragraph 3, point (d) is replaced by the following:	(a) in paragraph 3, point (d) is replaced by the following:
118 118 continued	Article 22 – paragraph 3 – point d Article 22 – paragraph 3 – point e	‘(d) any voluntary contribution from the Member States; and (e) any revenue from contribution agreements or grant agreements exceptionally concluded between the Commission and the Centre.’;		‘(d) any voluntary contribution from the Member States; and (e) any revenue from contribution agreements or grant agreements exceptionally concluded between the Commission and the Centre.’;	‘(d) any voluntary contribution from the Member States; and (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:	(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.’;	‘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.’;

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
121		(c) paragraph 5 is replaced by the following:		(c) paragraph 5 is replaced by the following:	(c) paragraph 5 is replaced by the following:
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.';	'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:	(d) paragraph 7 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
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.	'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:	(23) Article 23 is amended as follows:
129		(a) paragraph 2 is replaced by the following:		(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.';	'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.';

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
131		(b) paragraph 4 is replaced by the following:		(b) paragraph 4 is replaced by the following:	(b) paragraph 4 is replaced by the following:
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. **Without prejudice to Article 24(1) of Council Regulation (EU) 2017/1939** ~~T~~t**h**e 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 **and in accordance with the relevant data protection regulations**.';	

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
133		(c) paragraphs 8 and 9 are replaced by the following:		(c) paragraphs 8 and 9 are replaced by the following:	
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.';	'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. '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	*Article 24* *Application of the Financial Regulation* Article ***185*** of ***the Financial*** Regulation shall apply to the discharge of the Centre's budget, its audits and accounting rules.	**Amendment 148** ***(23a) Article 24 is replaced by the following:*** *"Article 24* *Application of the Financial Regulation* Article ***70*** of Regulation ***(EU, Euratom) 2018/1046*** shall apply to the discharge of the Centre's budget, its audits and accounting rules."		*"Article 24* *Application of the Financial Regulation* Article ***70*** of Regulation ***(EU, Euratom) 2018/1046*** shall apply to the discharge of the Centre's budget, its audits and accounting rules

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
136		(24) Article 25 is amended as follows:		(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:	(a) paragraph 1 is replaced by the following:
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.';	'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:	(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**.'	'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:	(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~~ **grant the necessary rights and access required for** the Court of Auditors, OLAF and the EPPO **to comprehensively exert their respective competences** ~~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:	(25) Article 26 is amended as follows:
144		(a) paragraph 1 is replaced by the following:		(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.';	'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:	(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.';	'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.';

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
148		(c) paragraph 2 is replaced by the following:		(c) paragraph 2 is replaced by the following:	(c) paragraph 2 is replaced by the following:
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.’;	‘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:	(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.”;	‘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:	*(27) Article 28 is replaced by the following:*
153	Article 28 – paragraph 1	*‘Article 28* **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’).		*‘Article 28* **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’).	‘Article 28 **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’).

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
153 continued	Article 28 – paragraph 2 Article 28 – paragraph 3 Article 28 – paragraph 4	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. 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.';		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. 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.';	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. 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				**(27a) The following Article is inserted:**	
155	Article 30 a (new) Article 30 a (new) – paragraph 1			***Article 30a*** **Committee procedure** **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.**	

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			**2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.** **Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagrapf of Article 5(4) of Regulation (EU) No 182/2011 shall apply.**	
156		(28) Article 31 is replaced by the following:		(28) Article 31 is replaced by the following:	
157		*'Article 31* **Review clause**		*'Article 31* **Review clause**	
	Article 31 – paragraph 1 – subparagraph 1 – introductory part	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:	**Amendment 149** By **…** [please insert date three years after the date of entry into force ***of this amending Regulation***], the Commission shall submit a report to the European Parliament, the Council and the Management Board on the Centre's activities, including an assessment of:	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:	
	Article 31 – paragraph 1 – subparagraph 1 – point a	(a) how the Centre progressed with implementing the amended mandate in the light of the COVID-19 pandemic;		(a) how the Centre progressed with implementing the amended mandate in the light of the COVID-19 pandemic;	

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157 continued	Article 31 – paragraph 1 – subparagraph 1 – point a a (new)		**Amendment 150** ***(aa) how the Centre has implemented the governance structures referred to in Articles 14, 17 and 18;***		*[EP withdraws amendment]*
	Article 31 – paragraph 1 – subparagraph 1 – point b	(b) how the Centre complies with the obligations laid down in the Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]] and other relevant Union legislation;		(b) how the Centre complies with the obligations laid down in the Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]] and other relevant Union legislation;	(b) how the Centre complies with the obligations laid down in the Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]] and other relevant Union legislation;
	Article 31 – paragraph 1 – subparagraph 1 – point c	(c) how effectively the Centre's activities address international, Union or national health priorities;		(c) how effectively the Centre's activities address international, Union or national health priorities;	(c) how effectively the Centre's activities address international, Union or national health priorities;
	Article 31 – paragraph 1 – subparagraph 1 – point d	(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.		(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.	(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 ***three*** years after the date of entry into force] ***2028***, and every 5 years thereafter, the Commission shall assess the Centre's performance in relation to its objectives, mandate, tasks, procedure and location. The evaluation shall, in particular, address the possible need to modify the mandate of the Centre, and the financial implications of any such modification.	**Amendment 151** 2. By **…** [please insert date ***five*** years after the date of entry into force ***of this amending Regulation***], and every 5 years thereafter, the Commission shall assess the Centre's performance in relation to its objectives, mandate, tasks, procedure and location. The evaluation shall, in particular, address the possible need to modify the mandate of the Centre, and the financial implications of any such modification.	2. By *[please insert date three years after the date of entry into force]* ~~2028~~**2025**, and every 5 years thereafter, the Commission shall **commission an independent external evaluation on the basis of terms of reference agreed with the Management Board to** assess the Centre's performance in relation to its objectives, mandate, tasks **and** procedures~~and location~~. The **external** evaluation shall, in particular, address the possible need to modify the mandate of the Centre, and the financial implications of any such modification. **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.**	

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	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.	**Amendment 152** 3. ***Based on the assessment referred to in paragraph 2, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.*** Where the Commission considers that the continued operation of the Centre is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.	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. **The Commission shall take into account the evaluation report and the recommendations of the Management Board.**	
	Article 31 – paragraph 4	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.'		4. The Commission shall report to the European Parliament, to the Council and to the Management Board on the **recommendation of the Management Board and** findings of its reviews and evaluations carried out under paragraph 2 **and 3**. 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		*Article 2* This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,		*Article 2* This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,	