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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 *- Mandate for negotiation with the European Parliament*

Delegations will find enclosed the mandate for the negotiations with the European Parliament on the above-mentioned subject as agreed by the Committee of Permanent Representatives at its meeting on 23 July 2021.

ANNEX

2020/0320 (COD)

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The Union is committed to protect and improve human health, in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health.

[1] OJ C , , , p. .
[2] OJ C , , , p. .

(2) Regulation (EC) No 851/2004 of the European Parliament and of the Council[3] established an independent European agency – the European Centre for Disease Prevention and Control (the 'Centre') with the mission to identify, assess and communicate current and emerging threats to human health from communicable diseases.

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

(4) A joint opinion issued by The European Commission's Group of Chief Scientific Advisors, the European Group on Ethics in Science and New Technologies, and the Special Advisor to the President of the European Commission on the response to COVID-19 recommends 'establishing a standing EU advisory body for health threats and crises'.

(5) This Regulation accordingly expands the mission and tasks of the Centre to enhance the Centre's capacity to provide the required scientific expertise and to support actions which are relevant to the prevention, preparedness, response planning and combating serious cross-border threats to health in the Union in accordance with Regulation EU …/… of the European Parliament and of the Council[4] [ISC/2020/12524].

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[3] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

[4] Regulation (EU) XXXX/XXXX of the European Parliament and of the Council of DATE on serious cross-border threats to health and repealing Decision No 1082/2013/EU [OJ: please, insert full title and publication reference to Regulation on serious cross-border threats to health (SCBTH).]

(6) In this respect, the Centre should be tasked with providing epidemiological information and its analysis, epidemiological modelling, anticipation and forecasting, relevant risk assessments and scientific-based recommendations which set out options for prevention and control of communicable diseases. Its actions should be consistent with a One-Health approach, recognising the interconnections between human and animal health and the environment. It should monitor the capacity of their national health systems to respond to communicable disease threats, in particular given the importance of this information in the preparation of the Union and national preparedness and response plans. The Centre should support the implementation of actions funded by the relevant Union funding programmes and instruments and related to communicable diseases, provide guidelines for case management and support for professional networks to improve guidelines for treatment based on a thorough assessment of the latest evidence, support epidemic and outbreak responses in Member States and third countries, including field response, and provide timely objective, reliable and easily accessible information on communicable diseases to the public. The Centre should also establish clear procedures for cooperation with the public health actors in third countries, as well as international organisations competent in the field of public health, such as WHO, hence contributing to EU's commitment to reinforcing partners' preparedness and response capacity.

(6a) It is understood that all recommendations, advices, guidance or opinions made by the Centre under this Regulation, are inherently non-binding on their addressees. A recommendation allows the Centre to make its views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

(7) To effectively support the work of the Centre and ensure the fulfilment of its mission, Member States should be tasked to communicate to the Centre data on the surveillance of communicable diseases and other related special health issues such as antimicrobial resistance and healthcare-associated infections related to communicable diseases, available scientific and technical data and information relevant to the Centre's mission, to notify the Centre of any serious cross-border threats to health, information on preparedness and response planning and health system capacity, and provide relevant information that may be useful for coordinating the response, as well as identify recognised competent bodies and public health experts available to assist in Union responses to health threats. In any event, Member States should provide the data required by this Regulation, in so far as it does not conflict with the safeguard of national security.

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

(9) With a view to enhance the effectiveness of epidemiological surveillance of communicable diseases and of the related special health issues in the Union, the Centre should be tasked with the further development of digital platforms and applications, supporting epidemiological surveillance at Union level, enabling the use of digital technologies, such as artificial intelligence, in the compilation and analysis of data, and providing Member States with technical and scientific advice to establish integrated epidemiological surveillance systems. Such digital platforms and applications should be developed with integrated EU space generated data with the intention to be integrate them in the future European Health Data Space as governed by the Union legislation.

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

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

(12) In case of cross-border health threats posed by communicable diseases, the Centre should cooperate with Member States to safeguard patients in need of a therapy from a substance of human origin from the transmission of such a communicable disease. The Centre should therefore establish and operate a network of national blood and transplant services and their authorities to serve this purpose.

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

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

(14a) Within its mandate, ECDC should respond to the requests of Member States or the Commission in a timely manner.

(15) Regulation …/… [*OJ: please, insert reference to Regulation SCBTH* [ISC/2020/12524]] provides for the early warning and response system enabling the notification at Union level of alerts related to serious cross-border threats to health which continues to be operated by the ECDC. Given that modern technologies can be of substantial support to combat health threats and to contain and reverse epidemics, the ECDC should work on updating this system to enable the use of artificial intelligence technologies and interoperable and privacy-preserving digital tools, such as mobile applications, with tracing functionalities identifying at-risk individuals.

(16) The Centre should establish appropriate capacities to support international and field response, in accordance with Regulation …/… [*OJ: please, insert reference to Regulation SCBTH [ISC/2020/12524]*]. These capacities should enable the Centre to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force', to assist local responses to outbreaks of diseases. The Centre should therefore ensure capacity to carry out missions to Member States as well as in third countries and to provide scientific-based recommendations on response to health threats. These teams will also be able to be deployed under the Union Civil Protection Mechanism with the support of the Emergency Response Coordination Centre. The effective operation of the 'EU Health Task Force' should be based on profound country knowledge which can be achieved through input from national experts. The Centre should also support the strengthening of preparedness capacities under the International Health Regulations (IHR) in third countries, in order to address serious cross-border threats to health and the consequences thereof. The Centre should also maintain regular secondment mechanisms between the Centre, the Commission, Member States' experts and international organisations to strengthen the operational interface between ECDC and Member States as well as ensure systematic and permanent working arrngements introduced within the ECDC (for example through the desk officers).

(17) To assist responses to outbreaks, which may spread within or to the Union, the Centre is to develop a framework for the mobilisation the EU Health Task Force in accordance with Decision No 1313/2013/EU of the European Parliament and of the Council[5] and facilitate the participation of Union field response experts in international response teams in support of the Union Civil Protection Mechanism. The Centre should enhance the capability of its staff as well as experts from Union and EEA countries, candidate countries and potential candidates, as well as European Neighbourhood Policy countries and EU partner countries as referred to in Regulation (EU) No 233/2014 of the European Parliament and of the Council[6], to effectively participate in field missions and crisis management.

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

(19) This Regulation should not confer any regulatory powers on the Centre.

(20) The Centre should implement an information system capable of exchanging classified and sensitive non-classified information to ensure that such information is managed with the utmost discretion.

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

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

(20a) Any processing of personal data based on this Regulation should be fully compliant with Regulations (EU) No 2016/679[7] and (EU) No 2018/1725[8] and with Directive 2002/58/EC on privacy and electronic communications[9]. Processing of personal data should be limited to the strictly necessary and, whenever possible, data should be anonymized. For these purposes, rights of data subjects should be fully respected notably in terms of licit, loyal and transparent collection and information in case of change of purpose of the data collected. In the case of cooperation with the health authorities of the Union, third countries, WHO or other international organizations, transfers of personal data to third countries or international organizations should always comply with the obligations laid down under Regulation (EU) No 2018/1725.

(21) In view of the urgency entailed by the exceptional circumstances caused by the COVID-19 pandemic, it is considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

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7 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

8 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).

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

(22) Since the objectives of this Regulation to expand the mission and tasks of the Centre in order to enhance the Centre's capacity to provide the required scientific expertise and to support actions which combat serious cross-border threats to health in the Union cannot be sufficiently achieved by the Member States but can rather, by reason of the cross-border nature of the health threats and the need for rapid, coordinated and coherent response, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(22a) In order to ensure uniform conditions for the implementation of this Regulation, notably on the rapid mobilisation and responseness of the EU Health Task Force under Article 11a, implementing powers should be conferred on the Commission. These powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.[10]

(23) Regulation (EC) No 851/2004 should therefore be amended.

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 851/2004 is amended as follows:

(1) Article 2 is replaced by the following:

[10] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13)

‘*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;

(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;

(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]];

(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]];

(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]];

(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]]. ’;

(2) Article 3 is replaced by the following:

‘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, the mission of the Centre shall be to identify, assess and report on current and emerging threats to human health from communicable diseases, and provide scientific-based recommendations for response at Union and national levels, as well as at regional level in coordination with Member States if necessary.

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 pursuing its mission, the Centre shall respect the responsibilities of the Member States, the Commission and other Union bodies or agencies, and 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.

2. The Centre shall perform the following tasks:

(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, using the 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*;*

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, including risk assessments, analysis of epidemiological information, epidemiological modelling, preparedness and response planning anticipation and forecast;

(c) promote and coordinate the 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;

(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;

(e) monitor the health systems' capacity in close cooperation with the Member States and support the collection of available indicators of Member States' capacity regarding health services to the extent it is necessary for the management and response to communicable disease threats and related special health issues;

(f) contribute to defining research priorities and to facilitating 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;

(g) provide, upon request of the Commission or the HSC, or its own initiative, guidelines for case management of communicable diseases and related special health issues and support for professional networks to improve treatment guidelines in cooperation with relevant organizations and associations, national competent bodies and international organizations such as WHO;

(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 emergency response instruments, in particular the Union Civil protection mechanism;

(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;

(j) propose, upon request of the Commission or the 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;

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.';

(3) Article 4 is replaced by the following:

'Article 4

Obligations of the Member States

Member States shall:

(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, to detect, prevent, respond to and recover from outbreaks of communicable diseases;

(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 is useful for coordinating the response as referred to in Article 21 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]]; and

(c) identify, within the scope of the mission of the Centre, recognised competent bodies and public health experts who could be made available to assist in Union responses to cross-border health threats, such as by undertaking missions to Member States, and third countries in cooperation with the WHO, to provide expert advice and field investigations in the event of disease clusters or outbreaks.';

(4) Article 5 is replaced by the following:

'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.

2. The Centre shall ensure the integrated operation of the network for the epidemiological surveillance of communicable diseases and of 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:

   (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;

   (b) provide quality assurance by monitoring and evaluating epidemiological surveillance activities (including proposing surveillance standards and monitoring data completeness) of the dedicated surveillance networks to ensure optimal operation;

(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;

(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;

(e) promote and support harmonised and rationalised operating methodologies for epidemiological surveillance in collaboration with the competent bodies;

(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;

(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.

4. The Centre, through the operation of the network for the epidemiological surveillance, shall:

(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 Member States;

(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, or in point (d) of Article 2(1) of that Regulation, with respect to source, time, population and place in order to provide a rationale for public health action;

(ba) support the national reference laboratories referred to Article 15 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH [ISC/2020/12524]*] in the implementation of the external quality control schemes, including professional testing scheme;

(c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for scientific-based recommendations to strengthen and improve these programmes at the national and Union levels;

(d) monitor and assess health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases, when necessary for crisis preparedness or response;

(e) support Member States to define population groups at risk and in need of targeted prevention and response measures, including persons with disabilities;

(f) contribute to the assessment of the burden of communicable diseases, such as disease prevalence, clinical complications, hospitalisation and mortality, among others using stratified data on age, gender, disability and other elements, if available;

(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

(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.

5. Each Member State shall designate a coordinating competent body and nominate a national coordinator, national focal points 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.

The national focal points shall form networks that give technical and scientific advise to the Centre.

National focal points and operational contact points nominated for disease-specific interactions with the Centre shall form disease-specific or disease-group-specific networks whose tasks shall include the transmission of national surveillance data to the Centre.

Member States shall notify the Centre and other Member States of the designations and nominations provided for in this paragraph and of any change thereof.

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.

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.

7. By encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Union for the diagnosis, detection, identification and characterisation of infectious agents, which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes.

8. The Centre shall ensure the operation of the network of Member State services supporting transfusion and transplantation 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.

(5) the following Article 5a is inserted:

'Article 5a

Prevention of communicable diseases

1. The Centre shall support Member States to strengthen their communicable diseases prevention and control systems.

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

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 those programmes at the national and Union level, and where appropriate at the international levels.

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.';

(6) the following Article 5b is inserted:

'Article 5b

Preparedness and response planning

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.

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 for adoption by the HSC;

(b) develop preparedness, monitoring and evaluation frameworks, and indicators for preparedness based on the IHR, in cooperation with WHO, to be discussed at the HSC;

(c) facilitate self-assessments of Member States' preparedness and response planning, in complement of the IHR, and contribute to reporting and examining preparedness and response planning under Articles 7 and 8 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]];

(d) facilitate support for observing and overcoming preparedness gaps and provision of targeted support to EU Member States and third countries in cooperation with the WHO upon their request;

(e) develop exercises, in-action and after-action reviews at EU level, support and complement Member States on those activities and organise additional actions to address identified preparedness capacity and capability gaps;

(f) develop and support specific preparedness activities addressing vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity, among others, based on identified gaps or upon request from Member States or the Commission;

(g) support the integration of research preparedness in the preparedness and response plans;

(h) support and complement additional targeted activities addressing at-risk groups and community preparedness;

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

(j) bolster modelling, anticipation and forecast capacity of the Centre; and

(k) maintain regular secondment mechanisms between the Centre, the Commission, 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;

(7) Article 6 is amended as follows:

(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.';

(b) paragraph 3 is replaced by the following:

'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 studies and will liaise between the public health and the research sector as needed.

To promote and initiate the studies referred to in the first paragraph, the Centre shall request access to health data made available or exchanged through digital infrastructures and applications, 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;

(c) paragraph 4 is replaced by the following:

‘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.’;

(8) Article 7 is replaced by the following:

'Article 7

Procedure for scientific opinions

1. The Centre shall issue a scientific opinion on matters falling within its mission:

   (a) in all cases where Union legislation provides that the Centre is to be consulted;

   (b) at the request of the European Parliament or a Member State;

   (c) at the request of the Commission or the HSC; and

   (d) on its own initiative.

2. Requests for a scientific opinion referred to in paragraph 1 shall clearly explain the scientific issue to be addressed and the Union interest and be accompanied by sufficient background information regarding that issue. If scientific opinions are focused on a specific Member State, the Member State concerned shall be involved.

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.

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

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

6. The Centre's internal rules shall specify requirements regarding the format, explanatory background and transparency rules for the publication of a scientific opinion.';

(9) Article 8 is replaced by the following:

'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.

2. The Centre shall:

(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];

(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.

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.

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 as well as Union and national requirements regarding personal data protection.

5. The Centre 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.

(10) the following Article 8a is inserted:

'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 potentially impacted by communicable diseases, or point (d) of Article 2(1) of that Regulation.

2. The risk assessment shall include general and targeted scientific-based recommendations and options for response as a basis for coordination in the HSC.

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, relevant agencies or international organisations such as WHO, if 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.

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.';

(11) the following Article 8b is inserted:

'Article 8b

Response coordination

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:

   (a) national responses to the serious cross-border threats to health;

   (b) adoption of guidance for the Member States for the prevention and control of a serious cross-border threat to health.

2. The Centre shall support a Union coordinated response at the request of a Member State, Council, Commission, HSC, Union bodies or agencies.';

(12) Article 9 is amended as follows:

   (a) paragraphs 1, 2 and 3 are replaced by the following:

      '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 examination and updating of preparedness plans, training activities and in the development of intervention strategies within the scope of its mission.

‘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 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.

‘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.’;

(b) paragraph 5 is replaced by the following:

5. The Centre shall inform the Management Board, Member States authorities and the Commission of any such request and of its outcomes.

(c) paragraph 6 is replaced by the following:

‘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.’;

(13) Article 11 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘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) the following paragraph 1a is inserted:

‘1a. The Centre shall collect data and information, and will ensure links to relevant research data and outputs on:

(a) epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]];

(b) the progression of epidemic situations, including for modelling, anticipation and scenario development;

(c) unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries in cooperation with the WHO;

(d) 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

(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]].';

(c) paragraph 2 is replaced by the following:

'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 evaluations of prevention and control measures at Union level;

(c) work in close cooperation with the competent bodies of the organisations operating in the field of data collection from the Union, third countries, the WHO, and other international organisations; and

(d) develop solutions to access relevant health data, publicly available or made available or exchanged through digital infrastructures, 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.'.

(d) the following paragraphs 4 and 5 are added:

'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(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.';

(14) the following Article 11a is inserted:

'Article 11a

Support to international and field preparedness and response

1. The Centre shall establish a EU Health Task Force and ensure capacity to mobilise and deploy it, including the Centre's staff and experts from Member States and fellowship programmes, to assist on requests for preparedness and response planning, local response to outbreaks of communicable diseases and after action reviews in Member States and in third countries, in cooperation with the WHO.

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[11].

   This implementing act shall be adopted in accordance with the examination procedure referred to in Article 30a(2).

3. The Centre shall ensure that the EU Health Task Force is coordinated with, complementary to and integrating the capacities the European Medical Corps, 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.

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

4. 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.

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.

6. By establishing a mechanism to mobilise and deploy the EU Health Task Force, the 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.

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, in collaboration with WHO.

(15) Article 12 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘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.

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;

(b) paragraph 2 is deleted;

(c) paragraph 3 is replaced by the following:

‘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.’;

(16) Article 14 is amended as follows:

(a) the third subparagraph of paragraph 2 is replaced by the following:

‘Members’ term of office shall be three years and can be extended.’;

(b) in paragraph 5, points (d), (e) and (f) are replaced by the following:

‘(d) adopt, before 31 January each year, the Centre’s programme of work for the coming year;

‘(e) adopt a draft single programming document in line with Article 32 of the Commission Delegated Regulation (EU) 2019/715[12] and the related Commission’s guidelines for the Single Programming Document**,

‘(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 the recommendations adopted in the annual Commission Opinion.

(g) before 30 March each year, adopt the general report on the Centre’s activities for the previous year;

(h) adopt the financial rules applicable to the Centre after the Commission has been consulted;

(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.

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[12] 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).’;

** (missing)

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.

(17) point (b) of Article 16(2) is replaced by the following:

'(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;'

(18) Article 17 is amended as follows:

(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.';

(19) Article 18 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. Members of the Advisory Forum shall not be members of the Management Board. Advisory Forum members'term of office shall be three years and can be extended.';

(b) in paragraph 4, point (f) is replaced by the following:

‘(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.’;

(c) paragraph 8 is replaced by the following:

‘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.’;

(20) paragraph 3 of Article 20 is replaced by the following:

‘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.’;

(20a) paragraph 4 of Article 20 is deleted and the following Article is inserted:

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.

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.

(21) Article 21 is replaced by the following:

'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[13] and (EU, Euratom) 2015/444[14] shall apply to the work of the Centre and its staff.

2. Members of the Management Board, the director, members of the Advisory Forum, as well as external experts participating in the scientific panels, and members of the staff of the Centre, even after their duties have ceased, shall be subject to the obligation of professional secrecy pursuant to Article 339 TFEU.

3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential.

4. The Centre shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

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[13] Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

[14] Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).';

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.

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.

(22) Article 22 is amended as follows:

(a) in paragraph 3, point (d) is replaced by the following:

'(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.';

(b) the following paragraph 3a is inserted:

'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[15], 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.';

[15] Regulation (EU) …/… of the European Parliament and of the Council of … on the establishment of a Programme for the Union's action in the field of health for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ('EU4Health Programme') (OJ..).

(c) paragraph 5 is replaced by the following:

‘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[16], 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.’;

(d) paragraph 7 is replaced by the following:

‘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.

[16] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).’;

(23) Article 23 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘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.’;

(b) paragraph 4 is replaced by the following:

‘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 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 and in accordance with the relevant data protection regulations.’;

(c) paragraphs 8 and 9 are replaced by the following:

‘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.’;

(24) Article 25 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[17] shall apply without restriction to the Centre.’;

(c) paragraph 3 is replaced by the following:

‘3. The decisions concerning funding and the implementing agreements and instruments resulting therefrom shall explicitly indicate that the EPPO may investigate and that the Court of Auditors 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.’

[17] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).’;

(c) the following paragraph 4 is added:

‘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 grant the necessary rights and access required for the Court of Auditors, OLAF and the EPPO to comprehensively exert their respective competences.

(25) Article 26 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Centre shall be a body of the Union. It shall have legal personality.’;

(b) the following paragraph 1a is inserted:

‘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.’;

(c) paragraph 2 is replaced by the following:

‘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.’;

(26) paragraph 1 of Article 27 is amended as follows:

‘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.”;

(27) Article 28 is replaced by the following:

'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').

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.';

(27a) The following Article is inserted:

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.

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.

(28) Article 31 is replaced by the following:

'Article 31

Review clause

1. By *[please insert date three years after the date of entry into force]* 2023, the Commission shall submit a report to the European Parliament, the Council and the Management Board on the Centre's activities, including an assessment of:

   (a) how the Centre progressed with implementing the amended mandate in the light of the COVID-19 pandemic;

   (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;

(c) how effectively the Centre's activities address international, Union or national health priorities;

(d) how the work of the Centre is targeted to and affect Member States' capacities.

The report shall reflect the views of the stakeholders, at both Union and national level.

The report shall be accompanied by an independent study commissioned by the Commission.

2. By *[please insert date three years after the date of entry into force]* 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.

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.

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.

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.'

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,

For the European Parliament	*For the Council*
The President	*The President*