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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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

As a building block of the European Health Union, this proposal reinforces the mandate of the European Centre for Disease Prevention and Control ('the Centre') addressing surveillance, preparedness, early warning and response under a strengthened EU health security framework. The COVID-19 pandemic has revealed shortcomings in Union mechanisms for managing health threats, which call for a more structured Union-level approach, which is also built on the European value of solidarity, to future health crises. This should include a reinforced role for the Centre. It should also take a One-Health approach, together with other relevant EU Agencies, to the issue, considering the interactions between humans, animals and the environment.

The Centre's mandate, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[1], was adopted before the mechanisms and structures under the current EU health security framework under Decision 1082/2013/EU on serious cross-border threats to health[2].

Given the review of this framework, the Centre's founding regulation needs to be amended, to ensure consistency with other Union instruments and with the proposal for an amending Regulation on serious cross-border threats to health. The review will also ensure that the Centre fully complies with the 'common approach' for decentralised agencies, as laid down in the 'Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralized agencies'[3].

• Consistency with existing Union measures in this field

The proposal is part of a package of closely associated measures, and forms part of the Union's overall health response to COVID-19 as well as an improved crisis management framework.

The amendments proposed will therefore be in compliance with the 'common approach' for decentralised agencies, from 2012.

• Consistency with other Union policies

This proposal is in line with the Union's overarching objectives, including a stronger health Union, a smooth functioning of the single market, complementarity with the Union Civil Protection Mechanism, sustainable and resilient health systems, and an ambitious research and innovation agenda. In addition, it will provide useful input to and synergies with the EU Digital Single Market agenda and the future European Health Data Space, encouraging innovation and research, facilitating information sharing (including of real-time data), and supporting the development of EU-level IT infrastructure for epidemiological surveillance and monitoring.

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1 OJ L 142, 30.4.2004, p. 1

2 OJ L 293, 5.11.2013, p. 1

3 https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

  The proposed Regulation is based on Article 168(5) of the Treaty on the Functioning of the European Union (TFEU). This approach is based on the specific objectives of the proposal, namely to adopt measures to protect and improve human health and in particular combating major cross-border health threats, especially through monitoring and early warning.

- **Subsidiarity (for non-exclusive competence)**

  Although the Member States are responsible for managing public health crises at national level, no country can tackle a cross-border public health crisis alone. Under Article 2(5) TFEU, the Union has competence to carry out measures to support, coordinate or supplement actions by Member States, without thereby superseding their competence in this area.

  Serious cross-border threats to health have, by their nature, transnational implications. In a globalised society, people and goods are moving across borders in high numbers, facilitating illnesses and contaminated products to circulate rapidly across the globe. Public health measures at national level therefore need to be consistent with each other and be coordinated to contain any further spread and minimise the consequences of these threats.

  Public health emergencies of the magnitude of COVID-19 have an impact on all Member States. The proposal builds on lessons learnt during the COVID-19 crisis, and proposes to strengthen the existing Union level structures and mechanisms for improved levels of protection, prevention, preparedness and response, against all health hazards across the EU.

  Since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of the threats described and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on European Union (TEU).

- **Proportionality**

  The proposal constitutes a proportionate and necessary response to the problems described in section 1. In accordance with the principle of proportionality, as set out in Article 5(4) TEU, this Regulation does not go beyond what is necessary to achieve those objectives.

- **Choice of the instrument**

  The proposal takes the form of an amendment of the existing Regulation. This type of instrument is considered most suitable, considering that a key element of the proposal is to establish well-aligned procedures and structures for joint work at Union level, focussing on giving additional tasks to the Centre. The measures do not require the implementation of national measures and can be directly applicable.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

  As part of a package of urgent measures based on lessons learnt so far from COVID-19, the initiative is supported by the findings of the recent evaluation of the functioning of the Centre[4], by an assessment of data collected and by exchanges held with public and private stakeholders on issues encountered during the COVID-19 pandemic and possible means to address them. Due consideration is given also to the findings of the Court of Auditors' Report on the EU health security framework[5]. This information is summarised in the Commission Communication accompanying the whole package. Considering that the initiative proposes to enlarge the scope of existing legislation, it will not be based on an ex-post evaluation, as the needs identified where not addressed by the existing framework.

  It is proposed that the Commission will report, by 2023, on the Centre's activities, including an analysis of how the amended mandate has been implemented, the interaction and consistency of the Centre's activities with the proposed Regulation on serious cross-border threats to health, and, by 2028, possible amendments to the mandate of the Centre. This will also include an analysis of the Centre's relevance in relation to international, Union and national health priorities, as well as the relationship between the Centre's outputs and Member States' capacities. This report will be accompanied by a study, commissioned by the Commission. Moreover, every five years the Commission will evaluate the Centre's performance in relation to its objectives, mandate, tasks, procedure and location, in accordance with Commission Better Regulation guidelines.

- **Stakeholder consultations**

  At the informal Health Council meeting on 16 July 2020, Germany's Presidency of the Council of the EU chaired a discussion about strengthening the Centre. Member States showed support for an initiative directed at doing so as part of the overall EU health crisis preparedness and response mechanism. This implies an amendment of the Centre's founding Regulation. The informal Health Council Working Party on Public Health on 29 October 2020 further discussed draft Council conclusions on COVID-19 lessons learnt in health. Bilateral meetings at political and technical levels were further held, and a public webinar was organized on 29 October to discuss the package.

- **Impact assessment**

  Due to its urgent nature, this proposal is not accompanied by a formal impact assessment. Instead, the changes are mainly based on an assessment of the data collected during the first months of the pandemic and exchanges with public and private stakeholders on COVID-19 issues and possible means to address them and are based on the findings of a recent evaluation. This information has been summarised in a Commission Communication that accompanies the overall package of proposals providing or referring to all available evidence, given that a public consultation and an impact assessment could not be delivered in the timeframe available prior to the adoption of this proposal.

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4 https://www.ecdc.europa.eu/en/publications-data/third-external-evaluation-ecdc-2013-2017

5 https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=40126

- **Fundamental rights**

The proposal contributes to achieving a high level of human, gender-sensitive, health protection, as well as to upholding the highest standards in the protection of human rights and civil liberties, as enshrined in the Charter of Fundamental Rights and in the European Pillar of Social Rights, during health crisis. Where personal data is processed under this Regulation as proposed, it will be done in accordance with the relevant Union legislation on personal data protection, in particular Regulation (EU) 2018/1725 and Regulation (EU) 2016/679.

4. BUDGETARY IMPLICATIONS

The implementation of this proposal has no impact on the current Multiannual Financial Framework 2014-2020.

The financial impact of this proposal on the Union budget will be part of the next Multiannual Financial Framework 2021-2027.

The budgetary implications are mainly related to the following objectives:

- setting-up a new vaccine monitoring platform hosted jointly by the European Medicines Agency and the Centre;
- preparedness and response planning activities including modelling, anticipation, monitoring and assessment;
- new networks on Union reference laboratories and on transfusion, transplantation and medically assisted reproduction;
- reinforcing surveillance systems and the Early Warning and Response System;
- monitoring and assessing health systems capacity and identifying population groups at risk and in need of targeted prevention and response measures
- creating a 'EU Health Task Force' to support countries with preparedness strengthening and quickly intervene in a health crisis;
- improving international collaboration and gathering of regional/national intelligence.

5. OTHER ELEMENTS

- **Detailed explanation of the specific provisions of the proposal**

The proposal aims to provide reinforced capacities of the Centre, to support preparedness, surveillance, risk assessment, and early warning and response to face future cross-border health threats.

Key areas of the proposal:

- situational awareness: rapid digitalisation of integrated surveillance systems;
- better preparedness in Member States: develop prevention and response plans against future epidemics and stronger capacities for integrated rapid epidemic and outbreak response;
- reinforced measures to control epidemics and outbreaks: provision of non-binding recommendations for risk management;

- expanded capacity to mobilise and deploy the EU Health Task Force to assist the response in Member States;
- reinforced capacity and building key competences to monitor and assess health systems capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patient safety;
- reinforced capacity and to identify population groups at risk and in need of targeted prevention and response measures;
- linking research and preparedness and response: liaise between public health and research communities, contribute to defining research priorities related to preparedness and response, ensure integration of research findings in policy recommendations;
- building up the key competences for health protection in Member States: the Centre will be tasked with coordinating a new network of Union reference laboratories for public health and a new network of national services supporting transfusion, transplantation and medically assisted reproduction;
- expanding work on the prevention of communicable diseases and specific health issues, e.g., antimicrobial resistance, vaccination and biosecurity;
- reinforcing the contribution to the EU's international cooperation and development and EU commitment to global health security preparedness.

The proposal will also seek to ensure smooth cooperation during such emergencies between the Centre and the EU's other decentralised agencies, most notably with the European Medicines Agency.

This proposal is aligned with the Common Approach[6] regarding structure and governance, its operations, programming and accountability.

[6] Joint Statement and Common Approach (Parliament, Council & Commission), 2012; https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

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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[7],

Having regard to the opinion of the Committee of the Regions[8],

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.

(2) Regulation (EC) No 851/2004 of the European Parliament and of the Council[9] 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

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7 OJ C , , , p. .

8 OJ C , , , p. .

9 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).

serious cross-border threats to health in the Union in accordance with Regulation EU …/… of the European Parliament and of the Council[10] [ISC/2020/12524].

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

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

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

(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

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

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, monitor and assess the capacity of national health systems for diagnosis, prevention and treatment of communicable diseases, including in a gender-sensitive way, identify population groups at risk requiring specific measures, analyse the correlation of disease incidence with societal and environmental factors, and identify risk factors for transmission and disease severity of communicable diseases, and identify research needs and priorities. The Centre should work with nominated national focal points for surveillance, forming a network that strategically advises the Centre on such matters and would promote the use of enabling sectors, such as EU space data and services.

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

(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 of Union and national preparedness and response plans and preparedness monitoring and evaluation frameworks, provide recommendations on capacities to prevent, prepare and respond to disease outbreaks and on the strengthening of national

health systems. The Centre should broaden its collection and analysis of data in terms of epidemiological surveillance and related special health issues, progression of epidemic situations, unusual epidemic phenomena or new diseases of unknown origin, including in third countries, molecular pathogen data and health systems data. To this end, the Centre should ensure appropriate datasets as well as the procedures to facilitate consultation and data transmission and access, carry out scientific and technical evaluation of prevention and control measures at Union level and work with agencies, competent bodies and organisations operating in the field of data collection.

(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 recommendations on response to health threats. These teams will also be able to be deployed under the Union Civil Protection Mechanism with the support of the Emergency Response Coordination Centre. The Centre should also support the strengthening of preparedness capacities under the International Health Regulations (IHR) in third countries, in order to address serious cross border threats to health and the consequences thereof.

(17) To assist responses to outbreaks, which may spread within or to the Union, the Centre is to develop a framework for the mobilisation the EU Health Task Force in accordance with Decision No 1313/2013/EU of the European Parliament and of the Council[11] and facilitate the participation of Union field response experts in international response teams in support of the Union Civil Protection Mechanism. The Centre should enhance the capability of its staff as well as experts from Union and EEA countries, candidate countries and potential candidates, as well as European Neighbourhood Policy countries and EU partner countries as referred to in Regulation (EU) No 233/2014 of the European Parliament and of the Council[12], to effectively participate in field missions and crisis management.

(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.

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

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

(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.

(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.

(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.

(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:

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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, 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]]. ’;

(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 set out in Article 2 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], the mission of the Centre shall be to identify, assess and report on current and emerging threats to human health from communicable diseases, and provide recommendations for response at Union and national levels, as well as at regional level, if necessary.

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

   In pursuing its mission, the Centre shall take full account of the responsibilities of the Member States, the Commission and other Union bodies or agencies, and of the responsibilities of international organisations active within the field of public health, in order to ensure comprehensiveness, coherence and complementarity of action.

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

   (a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data and information, considering the latest technologies;

   (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;

   (c) coordinate the European networking of bodies operating in the fields within the Centre’s mission, including networks arising from public

health activities supported by the Commission and operating the dedicated networks;

(d) exchange information, expertise and best practice;

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

(f) facilitate the development and implementation of actions, funded by relevant Union funding programmes and instruments, including the implementation of joint actions;

(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;

(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;

(i) contribute to strengthening preparedness capacities under the IHR in third countries, in particular EU partner countries;

(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.

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.';

(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 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;

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

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

(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 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]].

It shall in particular:

(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;

(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;

(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 and Member States;

(e) harmonise and rationalise the operating methodologies;

(f) ensure the interoperability of automated applications, including for contact tracing, developed at national level;

(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.

3. The Centre shall support the work of the HSC, the Council and other Union structures for coordinating responses to serious cross-border threats to health within its mandate.

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

(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

(b) detect, monitor and report on serious cross-border threats to health in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1) of Regulation (EU) …/… [*OJ: Please insert the number of Regulation SCBTH* [ISC/2020/12524]], including a threat to substances of human origin, such as blood, organs, tissues and cells potentially impacted by communicable diseases, or in point (d) of Article 2(1) of that Regulation, with respect to source, time, population and place in order to provide a rationale for public health action;

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

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

(e) identify population groups at risk and in need of targeted prevention and response measures, and ensure that those measures are accessible for persons with disabilities;

(f) contribute to the assessment of the burden of communicable diseases on the population using data, such as disease prevalence, complications, hospitalisation and mortality, and ensure that this data is disaggregated on age, gender and disability;

(g) carry out epidemiological modelling, anticipation and scenario development for response and coordinate such efforts with a view to exchange best practices and improve modelling capacity across the Union; and

(h) identify risk factors for disease transmission, groups most at risk, including the correlation of disease incidence and severity with societal and environmental factors, and research priorities and needs.

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.

The national focal points shall form networks that strategically advise 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.

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, transplantation and medically assisted reproduction to allow for continuous and rapid access to sero-epidemiological data via sero-epidemiological surveys within the population, including assessment of donor population exposure and immunity.

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

9. The Centre shall cooperate with the competent bodies recognised by the Member States, particularly on preparatory work for scientific opinions, scientific and technical assistance, the collection of comparable data based on common formats that allows for ease of aggregation, and the identification of emerging health threats.'

(5) the following Article 5a is inserted:

'Article 5a

Prevention of communicable diseases

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

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

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.

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.';

(6) the following Article 5b is inserted:

'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, in close collaboration with the Member States and the Commission:

   (a) contribute to the development, regular review and updating of preparedness plans and blueprints of threat-specific preparedness plans for adoption by the HSC;

   (b) develop preparedness monitoring and evaluation frameworks and indicators for preparedness;

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

   (d) ensure monitoring of preparedness gaps and provision of targeted support to EU Member States and third countries in case of needs;

   (e) develop exercises, in-action and after-action reviews and organise capacity building actions to address identified preparedness capacity and capability gaps;

   (f) develop specific preparedness activities addressing vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity in accordance with Commission priorities and based upon gaps identified;

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

   (h) develop targeted activities addressing at-risk groups and community preparedness;

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

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

   (k) maintain a regular secondment mechanisms between the Centre, the Commission and Member States' experts.';

(7) Article 6 is amended as follows:

(a) the following paragraph 1a is inserted:

‘1a. The Centre shall provide concrete analyses and recommendations for actions to prevent and control communicable disease threats upon request of the Commission.’;

(b) paragraph 3 is replaced by the following:

‘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.

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.’;

(c) paragraph 4 is replaced by the following:

‘4. The Centre shall consult with the Commission and other Union bodies or agencies with regard to the planning and priority setting of research and public health studies.’;

(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; 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.

3. The Centre shall issue scientific opinions within a mutually agreed time frame.

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

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

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

(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;

   (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, 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 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.

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*

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* 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).';

(10) the following Article 8a is inserted:

'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

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

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.

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]], in particular by providing recommendations for response measures for:

   (a) national responses to the 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.

2. The Centre shall support a Union coordinated response at the request of a Member State, Council, Commission, 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 review and updating of preparedness plans, 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, 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.

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 deleted.;

(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.';

(13) Article 11 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Centre shall coordinate data collection, validation, analysis and dissemination of data at Union level.';

(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;

(d) molecular pathogen data, if required for detecting or investigating cross-border health threats; and

(e) health systems data required for managing cross-border health threats.';

(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 evaluation of prevention and control measures at Union level;

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

(d) develop solutions to access relevant health data made available or exchanged through digital infrastructures, in accordance with data protection rules, allowing for the health data to be used for healthcare, research, policy making and regulatory purposes; and provide and facilitate controlled access to health data to support public health research.';

(d) 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(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.';

(14) the following Article 11a is inserted:

'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.

2. The Centre shall develop a framework and establish procedures with the Commission to mobilise the EU Health Task Force.

3. The Centre shall ensure that the EU Health Task Force are coordinated and complementary to the capacities integrating the European Medical Corps and other relevant capacities under the Union Civil Protection Mechanism.

4. The Centre shall develop with the Commission a framework for the mobilisation of the EU Health Task Force, in view of action under Decision No 1313/2013/EU*.

The Centre shall provide contributions of Union field response experts in international response teams mobilised by the WHO Health Emergencies Programme mechanism and the Global Outbreak Alert and Response Network (GOARN) and in accordance with appropriate working arrangements established with the Commission.

5. The Centre shall facilitate the development of field response capabilities and crisis management expertise among the Centre's staff and experts from EU and EEA countries, EU candidate countries and potential candidates, as well as European Neighbourhood Policy and EU partner countries, upon request of the Commission.

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

7. Upon request of the Commission and Member States, the Centre shall engage in long term capacity building projects aiming to strengthen preparedness capacities under the IHR in non-European third countries, in particular partner countries.

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* 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).';

(15) Article 12 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Centre shall communicate on its own initiative within the scope of its mission, after having given prior information to the Member States and to the Commission.

The Centre shall ensure that the public or any interested party is rapidly given objective, reliable, evidence-based and easily accessible information with regard to the results of its work. The Centre shall make available information for the general public, including through a dedicated website It shall also publish its opinions produced in accordance with Article 6.';

(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* 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 follow the recommendations adopted in the annual Commission Opinion.

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

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

(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.

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* 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).';

(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;'

(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.';

(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. 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 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.';

(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.';

(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* and (EU, Euratom) 2015/444** 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.

5. The Centre shall take all necessary measures to facilitate the exchange of information relevant to its tasks with the Commission, the Member States and, where appropriate, other Union institutions, and the Union bodies, offices and agencies and international organisations and third countries, in accordance with appropriate working arrangements established with the Commission.

6. The Centre shall develop, deploy and operate an information system capable of exchanging classified and sensitive non-classified information as specified in this Article.

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

** 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).';

(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*, 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.';

(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**, 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.

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* 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..).

** 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.

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.';

(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* shall apply without restriction to the Centre.';

(b) paragraph 3 is replaced by the following:

'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.'

(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 contain provisions expressly empowering the Court of Auditors, OLAF and the EPPO to conduct such audits and investigations, in accordance with their respective competences.

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* 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).';

(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.';

(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]* 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.

3. Where the Commission considers that the continued operation of the Centre is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.

4. The Commission shall report to the European Parliament, to the Council and to the Management Board on the findings of its reviews and evaluations carried out under paragraph 2. Those findings shall be made public.'

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*

LEGISLATIVE FINANCIAL STATEMENT

Contents

1. CONTEXT OF THE PROPOSAL 1
- Reasons for and objectives of the proposal 1
- Consistency with existing Union measures in this field 1
- Consistency with other Union policies 1

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY 2
- Legal basis 2
- Subsidiarity (for non-exclusive competence) 2
- Proportionality 2
- Choice of the instrument 2

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS 3
- Ex-post evaluations/fitness checks of existing legislation 3
- Stakeholder consultations 3
- Impact assessment 3
- Fundamental rights 4

4. BUDGETARY IMPLICATIONS 4

5. OTHER ELEMENTS 4
- Detailed explanation of the specific provisions of the proposal 4

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE 31

1.1. Title of the proposal/initiative 31

1.2. Policy area(s) concerned 31

1.3. The proposal relates to 31

1.4. Objective(s) 31

1.4.1. General objective(s) 31

1.4.2. Specific objective(s) 31

1.4.3. Expected result(s) and impact 32

1.4.4. Indicators of performance 32

1.5. Grounds for the proposal/initiative 32

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative 32

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which

is additional to the value that would have been otherwise created by Member States alone. 33
1.5.3. Lessons learnt from similar experiences in the past 33
1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments 33
1.5.5. Assessment of the different available financing options, including scope for redeployment 33
1.6. Duration and financial impact of the proposal/initiative 34
1.7. Management mode(s) planned 34
2. MANAGEMENT MEASURES 35
2.1. Monitoring and reporting rules 35
2.2. Management and control system(s) 35
2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed 35
2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them 35
2.3. Measures to prevent fraud and irregularities 36
3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE 36
3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected 36
3.2. Estimated impact on expenditure 38
3.2.1. Summary of estimated impact on expenditure 38
3.2.2. Estimated impact on ECDC's appropriations 40
3.2.3. Estimated impact on [body]'s human resources 45
3.2.4. Compatibility with the current multiannual financial framework 49
3.2.5. Third-party contributions 49
3.3. Estimated impact on revenue 50

LEGISLATIVE FINANCIAL STATEMENT 'AGENCIES'

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Draft Regulation (EU) XXX of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control

1.2. Policy area(s) concerned

Policy area: Recovery and Resilience

Activity: Health

1.3. The proposal relates to

X **a new action**

☐ **a new action following a pilot project/preparatory action**[13]

X **the extension of an existing action**

☐ **a merger of one or more actions towards another/a new action**

1.4. Objective(s)

1.4.1. General objective(s)

The general objective of ECDC's work is to assess and communicate current and emerging threats to human health from communicable diseases and provide recommendations for response at EU and national level.

1.4.2. Specific objective(s)

Specific objectives

The ECDC will provide timely information to the Commission, the Member States, EU bodies and agencies and international organisations active within the field of public health, including risk assessments.

The ECDC will provide scientific and technical expertise to the Member States and the Commission in the field of preparedness and response planning, including training.

The ECDC will coordinate data collection, validation, analysis and dissemination of data at EU level and thus establish a robust European surveillance system for communicable diseases in the frame of the European Health Data Space.

The ECDC will operate dedicated networks in the field of communicable diseases and substances of human origin.

The ECDC will host a EU Health Task Force to constantly support countries with preparedness strengthening and quickly intervene in a health crisis.

ECDC will improve international collaboration and gather regional/national intelligence.

[13] As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

- Up-dated preparedness plans in all EU Member States, including audit and corretive action
- Regularly trained specialists in all EU Member States to manage public health crises
- Established, functioning European networks of specialists for all key communicable diseases including emerging diseases
- Timely and pro-active input and support from the ECDC to all Member States and the European Commission onresponses to health crises
- Timely and targeted support in case of a health crisis through the EU Health Task Force
- Timely and up-to-date information and fluent collaboration with other CDCs and international health organisations.

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Detailed objectives and expected results including performance indicators will be established by the annual work programme, while the multi-annual work programme will set out overall strategic objectives, expected results and performance indicators.

For the specific tasks and actions presented in the current proposal, the following indicators are put forward:

- Number of risk assessments in a pro-active manner if and when needed or upon request by the European Commission or the Health Security Committee within 1-5 days, depending on the size of the outbreak or other health security incident.

- Number of training modules for preparedness being created.

- Percentage of increase of TESSy capacity and up-scaling of EWRS while preserving its rapidity in exchange of information.

- Number of rapid, targeted interventions by the EU Health Task Force.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

One of the lessons learnt in the COVID-19 pandemic is that the health security framework of the EU needs strengthening for a better EU coordination of preparedness and responses to serious cross-border health threats. The ECDC is a key player in this framework and needs to be strengthened in a targeted manner to carry out an increased array of actions.

The mandate revision should take place in early 2021 and be implemented immediately.

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at European level (ex-ante): the ECDC is an established EU decentralised Agency and its support to Member States and scientific publications are key elements for

preparedness response for cross-border health threats. Based on lessons learnt from the COVID-19 pandemic, a mandate revision is timely to enhance the preparedness work in the European Union.

Expected generated Union added value (ex-post) – Member States will be better prepared to confront possible future pandemics and other cross-border health threats.

1.5.3. Lessons learnt from similar experiences in the past

While the Covid-19 pandemic is still ongoing, this proposal builds on the lessons learnt from the past months of this pandemic. In particular, better preparedness and monitoring is needed.

Experience with past revisions of mandates of other EU decentralised agencies was taken into account e.g. EFSA.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

The Agency should cooperate and promote synergies with other Union bodies and agencies, such as the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Environment Agency (EEA) and take full advantage and ensure consistency with the EU4Health programme and other EU programmes financing actions in the domain of public health.

1.5.5. Assessment of the different available financing options, including scope for redeployment

N/A

1.6. Duration and financial impact of the proposal/initiative

☐ **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

X **unlimited duration**

– Implementation with a start-up period from Jan 2021 to Dec 2023,

– followed by full-scale operation.

1.7. Management mode(s) planned[14]

☐ **Direct management** by the Commission through

– ☐ executive agencies

☐ **Shared management** with the Member States

X **Indirect management** by entrusting budget implementation tasks to:

☐ international organisations and their agencies (to be specified);

☐the EIB and the European Investment Fund;

X bodies referred to in Articles 70 and 71;

☐ public law bodies;

☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

Comments

[14] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

All Union agencies work under a strict monitoring system involving an internal control coordinator, the Internal Audit Service of the Commission, the Management Board, the Commission, the Court of Auditors and the Budgetary Authority. This system is reflected and laid down in the ECDC's founding regulation.

In accordance with the Joint Statement on the EU decentralised agencies (the 'common approach') and the framework financial regulation (2019/715), the annual work programme of the Agency shall comprise detailed objectives and expected results including set up performance indicators. The Agency will accompany its activities included in its working programme by key performance indicators. The activities of the Agency will then be measured against these indicators in the Consolidated Annual Activity Report. The annual work programme shall be coherent with the multi-annual work programme and both shall be included in an annual single programming document which shall be submitted to the European Parliament, the Council and the Commission.

The Management Board of the Agency is responsible for the supervision of the administrative, operational and budgetary efficient management of the Agency

Every five years (next evaluation to cover 2018-2022) the Commission shall assess the Agency's performance in relation to its objectives, mandate and tasks. The evaluation shall, in particular, address the possible need to modify the mandate of the Agency, and the financial implications of any such modification. The Commission shall report to the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public.

2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The annual EU subsidy is transferred to the Agency in accordance with its payment needs and upon its request.

The Agency will be subject to administrative controls including budgetary control, internal audit, annual reports by the European Court of Auditors, the annual discharge for the execution of the EU budget and possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to agencies are put to proper use. The activities of the Agency will also be subject to the supervision of the Ombudsman in accordance with Article 228 of the Treaty. These administrative controls provide a number of procedural safeguards to ensure that account is taken of the interests of the stakeholders.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The main risk relates to under or non implementation of the tasks foreseen. In order to mitigate this, enough resources should be made available in both financial and staffing terms.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

Anti-fraud measures are foreseen in Article 25 of the founding regulation of European Centre for Disease Prevention and Control and the Executive Director and the Management Board will take the appropriate measures in accordance with the Internal Control Principles applied across all EU institutions. In line with the Common Approach the anti-fraud strategy has been developed and is applied by the Agency.

The mandate of the ECDC clearly states that the provisions of Regulation (EU, Euratom) No 883/2013 shall apply without restriction.

The ECDC also accedes to the Inter-institutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-fraud Office (OLAF) (10) and shall issue, without delay, the appropriate provisions applicable to all of its staff.

The ECDC's decisions concerning funding and the implementing agreements and instruments resulting therefrom shall explicitly stipulate 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 Regulation (EU) 2017/1939, the European Public Prosecutor's Office (EPPO) may investigate and prosecute fraud and other illegal activities affecting the financial interests of the Union as provided for in Directive (EU) 2017/1371.

If the ECDC concludes working arrangements with third countries and with international organisations, grant agreements, grant decisions and contracts, these shall contain provisions expressly empowering the Court of Auditors, OLAF and EPPO to conduct such audits and investigations, in accordance with their respective competences.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

Given the on-going reflection on the creation of an EU BARDA, the Commission retains the right to adjust the proposed resources and staff allocation when a precise proposal for a EU BARDA is tabled.

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Non-diff.[15]	from EFTA countries [16]	from candidate countries[17]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation

15 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

16 EFTA: European Free Trade Association.

17 Candidate countries and, where applicable, potential candidates from the Western Balkans.

2	06.1001	Diff.	YES	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	[XX.YY.YY.YY]		YES/NO	YES/NO	YES/NO	YES/NO

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	Heading 2 : Cohesion, Resilience and Values

[Body]: ECDC			Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.	**TOTAL**
Title 1:	Commitments	(1)	2.965	5.475	6.680	7.165	7.165	7.165	7.165	**43.780**
	Payments	(2)	2.965	5.475	6.680	7.165	7.165	7.165	7.165	**43.780**
Title 2:	Commitments	(1a)	0.775	1.375	1.700	1.825	1.825	1.825	1.825	**11.150**
	Payments	(2a)	0.775	1.375	1.700	1.825	1.825	1.825	1.825	**11.150**
Title 3:	Commitments	(3a)	12.300	16.500	16.700	17.000	14.000	13.000	13.000	**102.500**
	Payments	(3b)	12.300	16.500	16.700	17.000	14.000	13.000	13.000	**102.500**
TOTAL appropriations for ECDC	Commitments	=1+1a +3a	**16.040**	**23.350**	**25.080**	**25.990**	**22.990**	**21.990**	**21.990**	**157.430**
	Payments	=2+2a +3b	**16.040**	**23.350**	**25.080**	**25.990**	**22.990**	**21.990**	**21.990**	**157.430**

Heading of multiannual financial framework	**7**	'Administrative expenditure'

EUR million (to three decimal places)

		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.	**TOTAL**
DG: <…….>									
• Human Resources									
• Other administrative expenditure									
TOTAL DG <…….>	Appropriations								

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)								

EUR million (to three decimal places)

		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	**16.040**	**23.350**	**25.080**	**25.990**	**22.990**	**21.990**	**21.990**	**157.430**
	Payments	**16.040**	**23.350**	**25.080**	**25.990**	**22.990**	**21.990**	**21.990**	**157.430**

3.2.2. Estimated impact on ECDC's appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ✔ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2021**		Year **2022**		Year **2023**		Year **2024**		Year **2025**		Year **2026**		Year **2027** et seqq.		**TOTAL**	
	OUTPUTS																	
	Type [18]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 provide timely information to the Commission, the Member States, EU agencies and international organisations active within the field of public health, including risk assessments																		

[18] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

- Output set-up a new platform hosted jointly by EMA and ECDC, for post-marketing surveillance studies, monitoring the safety, effectiveness and impact of vaccination, forthcoming COVID-19 vaccines should be the first vaccines to be monitored under this platform mechanism				7.000		7.000		6.800		6.800		6.800		6.800		6.800		48.000
- Output																		
- Output																		
Subtotal for specific objective No 1				7.000		7.000		6.800		6.800		6.800		6.800		6.800		48.000
SPECIFIC OBJECTIVE No 2 ECDC will provide scientific and technical expertise to the Member States and the Commission in the field of preparedness and response planning, including training																		
Output: training programmes for specialists, in particular in epidemiological surveillance and field investigations, and to have a capability to define health measures to control disease outbreaks.				0.100		0.100		0.100		0.100		0.100		0.100		0.100		0.700
Output: preparedness and response planning activities including modelling, monitoring and assessment				1.000		1.000		1.000		1.000		1.000		1.000		1.000		7.000

Subtotal for specific objective No 2		1.100		1.100		1.100		1.100		1.100		1.100		1.100		7.700
SPECIFIC OBJECTIVE No 3 operate dedicated networks in the field of communicable diseases and substances of human origin																
- Output: new network on transfusion, transplantation and medically assisted reproduction			0.300		0.300		0.300		0.300		0.300		0.300		0.300	2.100
- Output: strengthen the network of laboratories, inline with EC Communication C(2020) 2391 "Guidelines on COVID-19 in vitro diagnostic tests and			0.200		0.200		0.200		0.200		0.200		0.200		0.200	1.400
Subtotal for specific objective No 3			0.500		0.500		0.500		0.500		0.500		0.500		0.500	3.500
SPECIFIC OBJECTIVE No 4 ECDC will coordinate data collection, validation, analysis and dissemination of data at EU level and thus establish a robust European surveillance system for communicable diseases in the frame of the European Health Data Space																
Output: new node at ECDC for the transmission of information from national level to ECDC by enlarging Tessy (greater capacity).		2.000		5.000		5.000		5.000		3.000		2.000		2.000		24.000
Output: strengthened EWRS making the system more scalable, without changing purpose of the		1.000		2.000		2.000		2.000		1.000		1.000		1.000		10.000

system to support the rapid exchange of information with epidemiological institutions and public research institutions during pandemic at national and EU level.															
Subtotal for specific objective No 4		3.000		7.000		7.000		7.000		4.000		3.000		3.000		34.000
SPECIFIC OBJECTIVE No 5 ECDC will host an outbreak assitance team ("EU Health Task Force") to constantly support countries with preparedness preparation and quickly intervene in a health crisis															
Output: pro-active, demand driven, practical support to EU /EEA countries		0.500		0.500		0.500		0.500		0.500		0.500		0.500		3.500
Output: local intervention in EU crisis spots -upon request, coordination with national specialists supporting the team		0.100		0.100		0.100		0.100		0.100		0.100		0.100		0.700
Subtotal for specific objective No 5		0.600		0.600		0.600		0.600		0.600		0.600		0.600		4.200
SPECIFIC OBJECTIVE No 6 improve international collaboration and gather regional/national intelligence															
Output: on the spot coordination with with international authorities and other CDCs		0.050		0.150		0.350		0.500		0.500		0.500		0.500		2.550
Output: gathering of local intelligence and providing expert support		0.050		0.150		0.350		0.500		0.500		0.500		0.500		2.550
Subtotal for specific objective No 6		0.100		0.300		0.700		1.000		1.000		1.000		1.000		5.100

TOTAL COST		**12.300**		**16.500**		**16.700**		**17.000**		**14.000**		**13.000**		**13.000**		**102.500**

3.2.3. Estimated impact on [body]'s human resources

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ✔ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.	**TOTAL**
Temporary agents (AD Grades)	1.650	3.300	4.350	4.800	4.800	4.800	4.800	**28.500**
Temporary agents (AST grades)	1.050	1.950	1.950	1.950	1.950	1.950	1.950	**12.750**
Contract staff	1.040	1.600	2.080	2.240	2.240	2.240	2.240	**13.680**
Seconded National Experts	0	0	0	0	0	0	**0**	0
TOTAL	**3.740**	**6.850**	**8.380**	**8.990**	**8.990**	**8.990**	**8.990**	**54.930**

Staff requirements (FTE):

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.	**TOTAL**
Temporary agents (AD Grades)	11	22	29	32	32	32	32	32
Temporary agents (AST grades)	7	13	13	13	13	13	13	13
Contract staff	13	20	26	28	28	28	28	28
Seconded National Experts	0	0	0	0	0	0	**0**	0
TOTAL	**31**	**55**	**68**	**73**	**73**	**73**	**73**	**73**

Please indicate the planned recruitment date and adapt the amount accordingly (if recruitment occurs in July, only 50 % of the average cost is taken into account) and provide further explanations.

3.2.3.2. Estimated requirements of human resources for the parent DG

– X The proposal/initiative does not require the use of human resources.

– ☐ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.
• **Establishment plan posts (officials and temporary staff)**								
XX 01 01 01 (Headquarters and Commission's Representation Offices)								
XX 01 01 02 (Delegations)								
XX 01 05 01 (Indirect research)								
10 01 05 01 (Direct research)								
• **External staff (in Full Time Equivalent unit: FTE)**[19]								
XX 01 02 01 (AC, END, INT from the 'global envelope')								
XX 01 02 02 (AC, AL, END, INT and JPD in the Delegations)								
XX 01 04 ***yy***[20]	- at Headquarters[21]							
	- in Delegations							
XX 01 05 02 (AC, END, INT – Indirect research)								
10 01 05 02 (AC, END, INT – Direct research)								
Other budget lines (specify)								
TOTAL								

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary

19 AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT = agency staff; JPD = Junior Professionals in Delegations .

20 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

21 Mainly for the Structural Funds, the European Agricultural Fund for Rural Development (EAFRD) and the European Fisheries Fund (EFF).

with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	
External staff	

Description of the calculation of cost for FTE units should be included in the Annex V, section 3.

3.2.4. Compatibility with the current multiannual financial framework

– ☐ The proposal/initiative is compatible the current multiannual financial framework.

– X The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. The proposed additional budget for ECDC may be financed by a reduction of EU4Health budget in future years.

– ☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[22].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties.

– The proposal/initiative provides for the co-financing estimated below:

EUR million (to three decimal places)

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.	**TOTAL**
Specify the co-financing body	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
TOTAL appropriations co-financed	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.

[22] See Articles 11 and 17 of Council Regulation (EU, Euratom) No 1311/2013 laying down the multiannual financial framework for the years 2014-2020.

3.3. Estimated impact on revenue

– X The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[23]						
		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027** et seqq.
Article …….								

For miscellaneous 'assigned' revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

[23] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.