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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on serious cross-border threats to health and repealing Decision No 1082/2013/EU

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 provides for a stronger and more comprehensive legal framework within which the Union can react rapidly and trigger the implementation of preparedness and response measures to cross-border threats to health across the EU in the form of a Regulation. The COVID-19 pandemic has shown that the EU's mechanisms for managing health threats suffer from general shortcomings that require a more structured Union-level approach if we are to deal better with future health crises. Since the start of the outbreak, multiple discussions have taken place with Member States including at health ministers' level, have seen calls for a more consistent and coordinated approach to preparing for and managing health crises in the EU.

The current health security arrangements, as established by Decision No 1082/2013/EU on serious cross-border threats to health[1], provide a limited legal framework for EU level coordination, based essentially on the Early Warning and Response System (EWRS) and the exchange of information and cooperation within the Health Security Committee. Early lessons learnt with COVID-19 have shown that the current system has not ensured an optimal response at EU level to the COVID-19 pandemic.

Structures and mechanisms under the Decision, while essential in facilitating the exchange of information on the evolution of the pandemic and supporting the adoption of national measures, could do little to trigger a timely common EU level response, co-ordinate the crucial aspects of risk communication, or ensure solidarity among Member States.

The revision of the health security framework proposes a stronger and more comprehensive legal framework within which the Union can prepare for and respond to health crises.

The proposal provides a strengthened framework for health crisis preparedness and response at EU level by addressing the weaknesses exposed by the COVID-19 pandemic. In particular, it will:

– set out a comprehensive legislative framework to govern action at Union level on preparedness, surveillance, risk assessment, and early warning and responses; and

– enhance the Union's guidance in the adoption of common measures at EU level to face a future cross-border health threat.

• Consistency with existing policy provisions in the policy area

As part of a package of closely associated measures, this proposal forms the backbone of the Union's overall health response to the COVID-19 pandemic and provides for an enhanced crisis management framework. The measures put forward in this proposal go hand in hand with those put forward in the other parts of the

[1] OJ L 293, 5.11.2013, p. 1.

package, to revise the mandates of the European Medicines Agency (EMA) and that of the European Centre for Disease Prevention and Control (ECDC).

The proposed measures would complement the following current Union provisions in the fields of crisis response and health:

– strategic stockpiling under the rescEU scheme (Article 12 of Decision No 1313/2013/EU on a Union Civil Protection Mechanism[2]);

– the EU emergency support instrument (Council Regulation (EU) 2016/369 on the provision of emergency support within the Union[3]);

– the upcoming pharmaceutical strategy;

– the Commission's proposal for a Regulation of the European Parliament and the Council 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')[4]; and

– other structures supporting biomedical research and development at EU level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

The proposed measures also complement other policies and actions under the European Green Deal in the field of climate and environment that will support enhanced environmental health, disease prevention and increased resilience.

The EU's international cooperation priorities, while not a central part of this revised legal framework, are important as the EU will not only support Member States but also EEA countries, candidate countries and potential candidates, as well as European Neighbourhood Policy countries and EU partner countries, not only to access vaccines early on, but also to authorise and deploy them effectively, supporting health systems strengthening including global health security, as well as providing for international and field emergency responses. The Commission, the European Parliament and the Council have recently strongly affirmed the EU's commitment to scaling up global health emergency preparedness. In October the European Council committed to strengthening EU support to health systems and the reinforcement of partners' preparedness and response capacity in Africa.

- **Consistency with other Union policies**

This proposal is in line with the EU's overarching objectives, including a stronger health union, the smooth functioning of the internal market, sustainable health systems including the cohesion policy supporting regional authorities for investments in public health and supporting cross-border cooperation notably in neighbouring regions and global healthy security preparedness, 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, by encouraging innovation and research, facilitating the sharing of information (including of real world evidence), and supporting the development of a Union-level IT infrastructure for epidemiological surveillance.

2 OJ L 347, 20.12.2013, p. 924.
3 OJ L 70, 16.3.2016, p. 1.
4 COM (2020) 405 of 28. 5.2020.

The proposal also strengthens the framework of preparedness and response to threats of biological, chemical, environmental(including due to climate), or unknown origin threats at Union level in a coordinated One Health approach.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

Given that the proposal aims to address serious cross-border threats to health and the consequences thereof thereby ensuring the protection of human health, it is based on Article 168(5) of the Treaty on the Functioning of the European Union (TFEU).

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

Public health emergencies of the magnitude of the COVID-19 pandemic have an impact on all Member States, which are unable to provide a sufficient response on their own.

Although the Member States are responsible for managing public health crises at national level, no country can tackle a cross-border public health crisis on its own.

Under Article 2(5) TFEU, the Union is to take action to support, coordinate or supplement that of the Member States, without thereby superseding their competence in these areas.

By their nature, serious cross-border threats to health have transnational implications. In a globalised society- people and goods move across borders and illnesses and contaminated products can circulate rapidly across the globe. Public health measures at national level therefore need to be consistent with each other and coordinated, in order to contain further spread and minimise the consequences of such threats.

The proposal builds on lessons learnt from the COVID-19 crisis, and proposes that existing structures and mechanisms be strengthened for better protection, prevention, preparedness and response against all health hazards.

In particular, it aims to provide EU added value through the development of an EU health crisis and pandemic preparedness plan, complemented by:

– national plans and transparent reporting of capacities;

– strengthened, integrated surveillance systems;

– enhanced risk assessment for health threats;

– increased power to enforce a coordinated response at EU level through the Health Security Committee; and

– an improved mechanism for recognition of and response to public health emergencies.

Special attention should be paid to maintaining the free movement of people and goods, in order to ensure the smooth functioning of the internal market, while safeguarding the health of citizens. In particular, this concerns a coordinated approach for the adoption of measures directed at avoiding or limiting disruptions of the movement of health care personnel and medical countermeasures, as well as measures including screening, quarantine and contact tracing.

- **Proportionality**

The proposal constitutes a proportionate response to addressing the problems described in point 1, in particular, by requiring a more structured and more robust EU-level health security framework and strengthening of the EU's key public health EU agencies (the European Centre for Disease Prevention and Control, 'ECDC', and the European Medicines Agency, 'EMA').

Since the objectives of this Regulation cannot be achieved sufficiently by the Member States alone due to the cross-border dimension of those threats but can be better 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 also set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

- **Choice of the instrument**

The proposal takes the form of a new Regulation. This is considered to be the most suitable instrument as a key element of the proposal is to establish procedures and structures for cooperation on joint, EU-level work focussing on preparedness for and response to serious cross-border threats to health. 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 pandemic, the initiative will be supported by an assessment of data collected and exchanges held with public and private stakeholders during the COVID-19 pandemic on issues encountered and possible means to address them. The initiative will broaden the scope of existing legislation and will not be based on an *ex-post* evaluation, as the needs identified were not addressed by the existing framework. However, Article 29 of the proposal includes provisions for future evaluations, assessing the performance of this Regulation. The main findings of the evaluation will be presented in a report to the European Parliament and the Council.

- **Stakeholder consultations**

The need to strengthen the EU's health security response has been raised in a variety of fora, such as the Council[5], Member States, non-governmental organisations and EU citizens.[6] This has been largely in response to the COVID-19 pandemic, which has exposed the limitations of the existing framework on serious cross-border threats to health to correctly respond to the disease and that the EU agencies (ECDC and the EMA) need to be bolstered.

5 https://www.consilium.europa.eu/de/meetings/epsco/2020/02/13/

6 https://europarl.europa.eu/at-your-service/en/be-heard/eurobarometer/public-opinion-in-the-eu-in-time-of-coronavirus-crisis-2

- **Impact assessment**

  Due to the urgency of the matter, this proposal is not accompanied by a formal impact assessment. The initiative will broaden the scope of the existing legislation, mainly on the basis of an assessment of data collected in the first months of the COVID-19 pandemic and exchanges held with public and private stakeholders in the framework of the COVID-19 pandemic on issues encountered and possible ways of addressing them. The findings have been summarised in a Commission Communication that accompanies the overall package to provide all available supporting evidence, as neither the public consultation nor an impact assessment could be delivered in the timeframe available prior to the adoption of this proposal. As regards medical devices, the proposal however takes into account the impact assessment carried out in preparation for the adoption of Regulations (EU) 2017/745 on medical devices[7] and 2017/746 on in vitro diagnostic medical devices[8].

  The proposal also draws on the recommendations contained in the forthcoming joint opinion 'Improving pandemics preparedness and management' by the Group of Chief Scientific Advisors (GCSA), the European Group on Ethics in Science and New Technologies (EGE), and the Special Advisor to the President of the European Commission on the response to COVID-19.

- **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 of the European Union and in the European Pillar of Social Rights, during health crisis. Where personal data are 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[9] and Regulation (EU) 2016/679[10].

4. BUDGETARY IMPLICATIONS

The implementation of this proposal has no impact on the current (2014-2020) multiannual financial framework.

The financial impact on the EU budget after 2020 will be covered in the next multiannual financial framework.

The budgetary implications are related mainly to the following objectives:

- preparedness plans established at EU and national level accompanied by reporting and auditing;
- training programmes for specialists;
- digitalized, integrated surveillance system at EU level, better detection of early signals for accurate risk assessment and response;
- establishment of new EU networks of laboratories;

[7] OJ L 117, 5.5.2017, p. 1.
[8] OJ L 117, 5.5.2017, p. 176.
[9] OJ L 295, 21.11.2018, p. 39.
[10] OJ L 119, 4.5.2016, p. 1.

- reinforcement of risk assessments for chemical, environmental and climate threats; and
- established structure and processes for the recognition of emergency at EU level

5. OTHER ELEMENTS

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

The proposal puts forward the following key amendments:

- preparedness capacities: the development of an EU health crisis and pandemic preparedness plan and requirements for the plans at national level, coupled with a comprehensive and transparent framework for reporting and auditing;
- rules on the provision of training for healthcare and public health workforce;
- rules for a strengthened, integrated epidemiological surveillance system at EU level, supported by improved data collection tools and artificial intelligence, environmental surveillance, to detect early signals of a possible threat;
- provision for designating and funding EU reference laboratories for public health;
- rules for the surveillance of novel pathogens based on common EU case definitions, and for the reporting of health systems data and other relevant data for the management of cross-border threats;
- increased EU and Member States capacity for accurate risk assessment and response;
- enhanced capacities for risk assessment by the relevant agencies and risk assessment coordination where more agencies are concerned in an all-hazards approach; and
- rules on the recognition of emergency situations, and for the activation of Union emergency mechanisms for the management of health crises (e.g. measures for medicinal products and medical devices).

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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[11],

Having regard to the opinion of the Committee of the Regions[12],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) A network for the epidemiological surveillance and control of communicable diseases was set up by Decision No 2119/98/EC of the European Parliament and of the Council.[13] Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council[14] to strengthen and provide for a further coordinated and wider approach to health security at Union level. The implementation of that legislation confirmed that coordinated Union action on monitoring, early warning of and combating those threats adds value to the protection and improvement of human health.

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross- border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and

11 OJ C , , p. .

12 OJ C , , p. .

13 Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p.1).

14 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.

(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 should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their

operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)[15]. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council[16] .

(10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats.

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases,

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15 World Health Organization. International Health Regulation (IHR, 2005) https://www.who.int/ihr/publications/9789241596664/en/

16 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).

such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

(12) In case of cross-border health threats due to a communicable disease, 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 in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.

(15) The Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. The aim to coordinate the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty on the Functioning of the European Union such as those related to free movement of persons, goods and services.

(16) To this effect, the HSC responsible for the coordination of response at Union level, should assume additional responsibility for the adoption of opinions and guidance for

Member States related to the prevention and control of a serious cross border threats to health. Furthermore, should the coordination of national public health measures prove insufficient to ensure an adequate Union response, the Commission should further support Member States via the adoption of recommendations on temporary public health measures.

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council[17].

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.

(19) Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision. Where such a recognition is adopted, the Commission should also inform the WHO thereof.

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or

[17] Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I , 20.3.2019, p. 1).

suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council[18].

(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response.

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council[19]. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

(23) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States due to the cross-border dimension of serious threats to health but can be better 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.

(24) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation.

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health

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

[19] 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).

care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

(26) Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[20]. As the implementing acts provided for by this Regulation concern the protection of human health, the Commission may not adopt a draft implementing act where the Committee on serious cross-border threats to health delivers no opinion, in accordance with point (a) of the second subparagraph of Article 5(4) of Regulation (EU) No 182/2011.

(27) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States imperative grounds of urgency so require.

(28) In order to ascertain the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[21]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(29) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725 and has adopted an opinion[22].

(30) This Regulation fully respects the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union.

(31) Decision No 1082/2013/EU should therefore be repealed and replaced by this Regulation,

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

21 OJ L 123, 12.5.2016, p. 1.

22 Reference to add once available

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. In order to address serious cross border threats to health and the consequences thereof, this Regulation lays down rules on:
   (a) the health security committee
   (b) preparedness and response planning, including:
      (i) preparedness plans at Union and national levels;
      (ii) reporting and auditing on preparedness;
   (c) joint procurement of medical countermeasures;
   (d) epidemiological surveillance and monitoring;
   (e) the network for epidemiological surveillance
   (f) the early warning and response system;
   (g) risk assessment;
   (h) coordination of response;
   (i) recognition of a public health emergency situation at Union level.
2. This Regulation establishes:
   (a) a network of EU reference laboratories for public health;
   (b) a network for substances of human origin;
   (c) an advisory committee for the occurrence and recognition of emergency situation at Union level.
3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

Article 2

Scope

1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:
   (a) threats of biological origin, consisting of:
      (i) communicable diseases;
      (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter ‘related special health issues’);
      (iii) biotoxins or other harmful biological agents not related to communicable diseases;

(b) threats of chemical origin;

(c) threats of environmental or climate origin;

(d) threats of unknown origin;

(e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR), provided that they fall under one of the categories of threats set out in points (a) to (d).

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.

3. The provisions of this Regulation are without prejudice to provisions of other Union acts governing specific aspects of monitoring, early warning of, the coordination of preparedness and response planning for, and the coordination of, combatting serious cross-border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.

4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.

5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘case definition’ means a set of commonly agreed diagnostic criteria that have to be fulfilled in order to accurately identify cases of a targeted serious cross-border threat to health in a given population, while excluding the detection of unrelated threats;

(2) ‘communicable disease’ means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent;

(3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in

danger of developing or have developed a disease, through manual or other technological means;

(4) ‘epidemiological surveillance’ means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;

(5) ‘monitoring’ means the continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection of data and analysis on specified indicators relating to serious cross-border threats to health;

(6) ‘public health measure’ means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combating severe risks to public health or mitigating their impact on public health;

(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

(8) ‘medical countermeasure’ means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council[23] and in Regulation (EU) 2017/745 of the European Parliament and of the Council[24] or other goods or services for the for the purpose of preparedness and response to a serious cross-border threat to health.

Article 4

Health Security Committee

1. The Health Security Committee (’HSC’) is hereby established. It shall be composed of representatives of the Member States, in two working formations:

   (a) a high-level working group to discuss topics of political importance and decisions referred to in point (d) of paragraph 3 and paragraph 7;

   (b) technical working groups to discuss specific topics of technical nature.

2. The HSC shall have the following tasks:

   (a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;

   (b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;

   (c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

[23] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[24] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

(d) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health.

3. As far as possible, the group shall adopt its guidance or opinions by consensus.

In the event of a vote, the outcome of the vote shall be decided by simple majority of the members.

The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the guidance or opinions.

4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

5. The secretariat shall be provided by the Commission.

6. The HSC shall adopt, by a majority of two thirds of its members, its rules of procedure. Those rules of procedure shall establish working arrangements, in particular with regard to:

(a) the procedures for plenary meetings at high level and technical working groups;

(b) the participation of experts in plenary meetings at high level, the status of possible observers, including from third countries;

(c) the arrangements for the HSC to examine the relevance to its mandate of a matter submitted to it and the possibility of recommending referral of that matter to a body competent under a provision of another act of the Union or under the Euratom Treaty; those arrangements shall not affect the obligations of the Member States under Articles 10 and 21 of this Regulation.

7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1.

Member States shall notify the Commission and other Member States of the designations and of any change thereof.

CHAPTER II

PREPAREDNESS AND RESPONSE PLANNING

Article 5

Union preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

(a) the timely cooperation between the Commission, the Member States and the Union agencies;

(b) the secure exchange of information between the Commission, Union agencies and the Member States;

(c) the epidemiological surveillance and monitoring;

(d) the early warning and risk assessment;

(e) the risk and crisis communication;

(f) the health preparedness and response and intersectoral collaboration;

(g) the management of the plan.

4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.

Article 6

National preparedness and response plans

1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.

Article 7

Reporting on preparedness and response planning

1. Member States shall by the end of November 2021 and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level.

That report shall cover the following:

(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;

(b) elements of emergency preparedness, in particular:

(i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms;

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;

(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and

(c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues.

The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions.

2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years.

The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national level.

Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC to discuss progress and gaps in preparedness.

The recommendations of the report shall be published on at the website of the Commission.

3. The Commission shall, by means of implementing acts, adopt templates to be used by the Member States when providing the information referred to in paragraph 1, in order to ensure its relevance to the objectives identified in that paragraph, and its comparability.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

4. When receiving classified information transmitted pursuant to paragraph 1, the Commission and the HSC shall apply the rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443[25] and 2015/444[26].

5. Each Member State shall ensure that its national security regulations apply to all natural persons resident on its territory and all legal persons established on its territory that handle the information referred to in paragraphs 1 and 2, where it is classified as EU classified information. Those national security regulations shall

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

[26] 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).

offer a degree of protection of classified information at least equivalent to that provided by the rules on security as set out in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom[27] and by Council Decision 2011/292/EU[28].

Article 8

Auditing on preparedness and response planning

1. Every 3 years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).

2. Member States shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones.

   These actions may, in particular, include:

   (a) review/adjustment of the legislation, if necessary;

   (b) training initiatives;

   (c) overview reports of audits series, which present cases of good practice.

3. The Commission shall adopt delegated acts in accordance with Article 28 concerning procedures, standards and criteria for the audits referred to in paragraph 1.

Article 9

Commission report on preparedness planning

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.

2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.

Article 10

Coordination of preparedness and response planning in the HSC

1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health.

   The coordination shall, in particular, be aimed at:

   (a) sharing best practice and experience in preparedness and response planning;

[27] OJ L 317, 3.12.2001, p. 1.
[28] OJ L 141, 27.5.2011, p. 17.

(b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;

(c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;

(d) developing the preparedness plans referred to in Articles 5 and 6;

(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.

Article 11

Training of health care staff and public health staff

1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.

   The Commission shall organise those activities in cooperation with the Member States concerned.

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.

4. The bodies whose staff participates in the training activities organised in accordance with paragraph 1 shall ensure that the knowledge acquired through those activities is disseminated as necessary and is appropriately used in the staff training activities they organised.

5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other.

6. The Commission may, by means of implementing acts, lay down rules on the organisation of the training activities referred to in paragraph 1, and of the programmes referred to in paragraph 5.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Article 12

Joint procurement of medical countermeasures

1. The Commission and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU,

Euratom) 2018/1046 of the European Parliament and of the Council[29] with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

2. The joint procurement procedure referred to in paragraph 1, shall comply with the following conditions:

(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States and Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046;

(b) the rights and obligations of Members States, EFTA States and Union candidate countries not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;

(c) Member States, EFTA States and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;

(d) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortion of competition;

(e) the joint procurement shall not have any direct financial impact on the budget of Member States, EFTA States and Union candidate countries not participating in the joint procurement.

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:

(a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;

(b) Regulation (EU) 2016/369;

(c) the upcoming Pharmaceutical Strategy ;

(d) the EU4Health Programme established by Regulation (EU) …/… of the European Parliament and of the Council[30];

(e) Regulation (EU) No…/… of the European Parliament and of the Council[31]; and

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29 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).

30 [*Please insert title and OJ reference of the regulation.*]

31 Regulation (EU)…/… of the European Parliament and of the Council of … establishing the European Defence Fund (OJ ….).

(f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

CHAPTER III

EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC MONITORING

Article 13

Epidemiological surveillance

1. 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) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

2. The epidemiological surveillance network shall aim to:

   (a) monitor trends in communicable diseases over time and across Member States and in third countries to assess the situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;

   (b) detect and monitor any multinational communicable disease outbreaks 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 those programmes at the national and Union level;

   (d) identify risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;

   (e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation and mortality;

   (f) contribute to the assessment of health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety;

   (g) contribute to modelling and scenario development for response;

   (h) identify research priorities and needs, and implement relevant research activities;

   (i) support the contract tracing measures of competent health authorities.

3. The national competent authorities referred to in paragraph 1 shall communicate the following information to the participating authorities of the epidemiological surveillance network:

(a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1);

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

(c) relevant information concerning 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;

(e) health systems system data required for managing cross-border health threats; and

(f) information about contract tracing monitoring systems developed at national level.

4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 9 for each communicable disease and related special health issue referred to in paragraph 1.

5. The Commission and the Member States shall work together to define disease-specific European surveillance standards based on the proposal of the ECDC, in consultation with the relevant surveillance networks.

6. The ECDC shall monitor Member States' adherence to these surveillance standards and share regular monitoring reports with the HSC and the Commission.

The ECDC shall regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC.

7. The Commission may complement the action of the Member States through the adoption of recommendations on surveillance addressed to Member States.

8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.

9. The Commission shall, by means of implementing acts, establish and update:

(a) the list of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1), in order to ensure coverage of communicable diseases and related special health issues by the epidemiological surveillance network;

(b) case definitions concerning each communicable disease and related special health issue subject to epidemiological surveillance, in order to ensure the comparability and compatibility at Union level of the collected data;

(c) procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation ECDC* [ISC/2020/ 12527]].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the

Member States, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption of case definitions, procedures and indicators for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1). The indicators mentioned above shall also support the assessment of capacity for diagnosis, prevention and treatment.

Article 14

Platform for surveillance

1. The ECDC shall ensure the further development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.

2. The digital platform shall

   (a) enable the automated collection of surveillance and laboratory data, make use of information from electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;

   (b) allow for the computerised handling and exchange of information, data and documents.

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information, data and documents transmitted and exchanged through the digital platform.

4. The ECDC shall

   (a) monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission;

   (b) regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC and transmitted and exchanged through the digital platform.

5. For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.

6. The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:

   (a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;

   (b) the specific rules for the functioning of the platform, including to ensure protection of personal data and security of exchange of information;

   (c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;

   (d) the cases where, and the conditions under which the third countries and international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;

(e) the cases where, and the conditions under which the data, information and documents referred to in Article 13 are to be transmitted using the platform and the list of such data, information and documents; and

(f) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures referred to in paragraph 5.

Article 15

EU reference laboratories

1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

2. The EU reference laboratories shall be responsible in particular for the following tasks to coordinate the network of national reference laboratories, in particular, in the following areas:

   (a) reference diagnostics, including test protocols;

   (b) reference material resources;

   (c) external quality assessments;

   (d) scientific advice and technical assistance;

   (e) collaboration and research;

   (f) monitoring, alert and support in outbreak response; and

   (g) training.

3. The network of EU reference laboratories shall be operated and coordinated by the ECDC.

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. Designations shall establish the responsibilities and tasks of the designated laboratories.

   Those implementing acts shall be adopted with the in accordance with the examination procedure referred to in Article 27(2).

5. The laboratories referred to in paragraph 1 shall

   (a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;

   (b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;

(c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;

(d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;

(e) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and

(f) where relevant, be equipped to comply with relevant biosecurity standards.

In addition to the requirements laid down in the first subparagraph, the EU reference laboratories shall also be accredited in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council[32].

6. Grants may be awarded to the laboratories referred to in paragraph 1 for the costs that they incur in implementing annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the work programmes adopted by the Commission in accordance with the EU4Health Programme established by Regulation (EU) …/… of the European Parliament and of the Council[33].

Article 16

Network for substances of human origin

1. A network of Member States' services supporting transfusion, transplantation and medically assisted reproduction is established to allow for the continuous and rapid access to sero-epidemiological data, including assessment of donor population exposure and immunity, and to monitor, assess and help address disease outbreaks that are relevant to substances of human origin.

2. The network shall be operated and coordinated by the ECDC.

3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting transfusion, transplantation and medically assisted reproduction as referred to in paragraph 1.

Article 17

Ad hoc monitoring

1. Following an alert notified pursuant to Article 19 concerning a serious cross-border threat to health referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) or (d) of Article 2(1), Member States shall, in liaison with the Commission and on the basis of the available information from their monitoring systems, inform each other through the 'Early Warning and Response System' ('EWRS') and, if the urgency of the situation so requires, through the HSC about developments with regard to the threat concerned at national level.

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32 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

33 [*Please insert title and OJ reference of the regulation.*]

2. The information transmitted pursuant to paragraph 1 shall include in particular any change in geographical distribution, spread and severity of the threat concerned and of the means of detection, if available.

3. The Commission shall, by means of implementing acts, adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt or update the case definitions referred to in the first subparagraph through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).

CHAPTER IV

EARLY WARNING AND RESPONSE

Article 18

Early warning and response system

1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

2. The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:

(a) the processing of personal data of authorised users of the system;

(b) the processing of health data and other personal data, in particular, the contact tracing data through the EWRS selective messaging functionality.

The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States.

3. Each Member State shall designate the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of early warning and response.

4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Article 19

Alert notification

1. National competent authorities or the Commission shall notify an alert in the EWRS where the emergence or development of a serious cross-border threat to health fulfils the following criteria:

   (a) it is unusual or unexpected for the given place and time, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and

   (b) it affects or may affect more than one Member State; and

   (c) it requires or may require a coordinated response at Union level.

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, they shall at the latest simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as:

   (a) the type and origin of the agent;

   (b) the date and place of the incident or outbreak;

   (c) means of transmission or dissemination;

   (d) toxicological data;

   (e) detection and confirmation methods;

   (f) public health risks;

   (g) public health measures implemented or intended to be taken at national level;

   (h) measures other than public health measures;

   (i) urgent need or shortage of medical countermeasures;

   (j) requests and offers for cross-border emergency assistance;

   (k) personal data necessary for the purpose of contact tracing in accordance with Article 26;

   (l) any other information relevant to the serious cross-border threat to health in question.

4. The Commission shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response referred to in Article 21, including information related to serious cross-border threats to health and public health measures related to serious cross-border threats to health already transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty.

Article 20

Public health risk assessment

1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures. That risk assessment shall be carried out by:

   (a) the ECDC in accordance with Article 8a of Regulation (EU) …/… *[OJ: Please insert the number of Regulation ECDC* [ISC/2020/ 12527]] in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

   (b) the European Food Safety Authority (EFSA) in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[34] in the case of a threat referred to in Article 2 of this Regulation where the threat falls under the mandate of the EFSA; and/or

   (c) the European Chemicals Agency (ECHA) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[35] in the case of a threat referred to in points (b) and (c) of Article 2(1) where the threat falls under the mandate of the ECHA; and/or

   (d) the European Environment Agency (EEA) in accordance with Regulation (EC) No 401/2009 of the European Parliament and of the Council[36] in the case of a threat referred to in point (c) of Article 2(1) where the threat falls under the mandate of the EEA; and/or;

   (e) the European Centre for Monitoring Centre for Drugs and Drug Addictions (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council[37] in the case of a threat referred to in point (b) of Article 2(1) where the threat falls under the mandate of the EMCDDA.

   (f) The risk assessment shall be carried out in the case of a threat referred to in Article 2(1) in cooperation with the European Police Office (Europol) where the threat is emanating from terrorist or criminal activity, and in cooperation

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34 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

35 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

36 Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13).

37 Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).

with the European Medicines Agency ('EMA)', where the threat is linked to medicinal products.

2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information and data at their disposal.

3. Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication.

The risk assessment shall take into account, if available, relevant information provided by other entities, in particular by the WHO in the case of a public health emergency of international concern.

4. The Commission shall ensure that information that may be relevant for the risk assessment is made available to the national competent authorities through the EWRS and to the HSC.

Article 21

Coordination of response within the HSC

1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission:

(a) national responses, including research needs, to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the IHR and falls within Article 2 of this Regulation;

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare professionals;

(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health.

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform and consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health,

it shall, immediately upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.

4. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination provided for in paragraphs 1, 2 and 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Article 22

Recommendations on common temporary public health measures

1. The Commission may complement the action of the Member States through the adoption of recommendations on common temporary public health measures for Member States.

2. The recommendation for measures adopted under paragraph 1 shall:

(a) be based on in particular recommendations of the ECDC in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;

(b) respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care;

(c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services.

CHAPTER V

PUBLIC HEALTH EMERGENCY AT UNION LEVEL

Article 23

Recognition of emergency situations

1. The Commission may, based on the expert opinion of the Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level; including pandemic situations where the serious cross-border threat to health in question endangers public health at the Union level.

2. The Commission shall terminate the recognition referred to in paragraph 1 as soon as one of the applicable conditions laid down therein is no longer met.

3. Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.

4. The Commission shall adopt the measure referred to in paragraphs 1 and 2 by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise situations of public health emergency pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).

Article 24

Advisory Committee on public health emergencies

1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:

   (a) whether a threat constitutes a public health emergency at Union level;

   (b) the termination of a public health emergency at Union level; and

   (c) advice on response including:

      (i) formulation of response measures, including risk and crisis communication, to be addressed to all Member States in line with the different stages of the threat in the Union;

      (ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, non-pharmaceutical countermeasures and public health research needs;

      (iii) prioritisation of health care, civil protection and other resources as well as support measures to be organised or coordinated at Union level;

      (iv) subsequently, recommendation of policy measures for addressing and mitigating long-term consequences of the specific threat.

2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ECDC and of the EMA participate as observers in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis.

3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State.

4. The Advisory Committee shall be chaired by a representative of the Commission.

5. The Secretariat of the Advisory Committee shall be provided by the Commission.

6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.

Article 25

Legal effects of recognition

1. The recognition of an emergency situation pursuant to Article 23 shall have the legal effect of enabling the introduction of:

   (a) measures, which are applicable during the period of public health emergencies, related to medicinal products and medical devices provided for in Regulation (EU) …/… [*OJ: Please insert the number of Regulation EMA* [ISC/2020/12532]];

   (b) mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures;

   (c) activation of support from the ECDC as referred to in Regulation (EU) …/… [*OJ: Please insert the number of Regulation ECDC* [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force.

CHAPTER VI

PROCEDURAL PROVISIONS

Article 26

Protection of personal data concerning the EWRS selective messaging functionality

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed and operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.

2. Where competent authorities implementing contact tracing measures communicate through the EWRS personal data necessary for contact tracing purposes pursuant to Article 19(3), they shall use the selective messaging functionality referred to in paragraph 1 of this Article and communicate the data only to the other Member States involved in the contact tracing measures.

3. When circulating the information referred to in paragraph 2, the competent authorities shall refer to the alert communicated previously through the EWRS.

4. Messages containing personal data shall automatically be erased from the selective message functionality 14 days after the date of their posting.

5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.

6. The Commission shall, by means of implementing acts, adopt:

(a) detailed requirements necessary to ensure that the operation of the EWRS and the processing of data complies with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725;

(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;

(c) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact tracing measures;

(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access.

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Article 27

Committee procedure

1. The Commission shall be assisted by a committee on serious cross-border threats to health. That Committee shall be a committee within the meaning of Article 3(2) of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

   Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 28

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Article 8(3) shall be conferred on the Commission for an indeterminate period of time from ... [date of entry into force of the basic legislative act or any other date set by the co-legislators].

3. The delegation of power referred to in Article 8(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

6. A delegated act adopted pursuant to Article 8(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 29

Evaluations concerning this Regulation

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.

CHAPTER VII

FINAL PROVISIONS

Article 30

Repeal

1. Decision No 1082/2013/EU is repealed.

2. References to the repealed Decision shall be construed as references to this Regulation and read in accordance with the correlation table in the Annex.

Article 31

Entry into force

This Regulation shall enter into force on the 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

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on a strengthened Union health security framework addressing cross-border health threats

1.2. Policy area(s) concerned

Heading 2: Cohesion, Resilience and Values

1.3. The proposal/initiative relates to:

☐ **a new action**

☐ **a new action following a pilot project/preparatory action**[38]

X **the extension of an existing action**

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

1.4. Objective(s)

1.4.1. General objective(s)

The general objective of the proposal is to provide a strengthened framework for health crisis preparedness and response at EU level by addressing the weaknesses evidenced by the COVID-19 pandemic.

The framework includes a comprehensive legislative basis to govern actions at Union level on preparedness, surveillance, risk assessment, and early warning and responses enhancing the Union's role in the adoption of common measures at EU level to face a future cross-border health threat.

1.4.2. Specific objective(s)

Specific objectives

1. Strengthen preparedness capacities through the development of an EU health crisis and pandemic preparedness plan and requirements for the plans at regional and national level, coupled with comprehensive and transparent framework for reporting and auditing;

2. Strengthen health workforce by providing rules to allow the provision of training to healthcare and public health workforce;

3. Strengthen surveillance by establishing an integrated surveillance system at EU level, supported by improved data collection tools and artificial intelligence, to detect early signals of a possible threat; the possibility to designate and fund EU reference laboratories for public health;

4. Enhance surveillance, monitoring and accuracy of risk assessments at EU level by establishing rules for the surveillance of novel pathogens based on common EU case definitions in case of emergencies, and for the reporting of health systems and other relevant data for the management of cross-border threats;

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

5. Enhance cooperation of Member States in specific areas: establishment of new EU networks operated by the European Centre for Disease Prevention and Control (ECDC), including on EU reference laboratories that would allow alignment on diagnostics, serological testing, testing methods, use of certain tests, etc., as well as networks including Member State services supporting transfusion, transplantation and medically assisted reproduction;

6. Enhance capacities for all-hazard risk assessment by the relevant agencies (ECDC, the European Medicines Agency (EMA), and others) and risk assessment coordination where more agencies are concerned;

7. Strengthen EU level response coordination in the HSC by recommendations from the Commission to ensure coordinated response following ECDC's risk assessment;

8. Strengthen EU response to health emergencies by establishing rules on the recognition of emergency situations, and for the activation of new Union emergency mechanisms for the management of health crisis (e.g., measures for medicinal products and medical devices).

1.4.3. Expected result(s) and impact

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

Specific objective 1.

Preparedness plans established at EU, inter-regional and national level

Framework and platform for reporting on preparedness capacities, followed by stress tests, audits and corrective actions.

Continuous development of the Early Warning and Response System, new functionalities for preparedness and linking with EU alert systems (ECDC fiche)

Specific objective 2.

Continuously trained health specialists to manage public health crises

Specific objective 3.

Digitalized, integrated surveillance system at EU level, better detection of early signals for accurate risk assessment and response

Specific objective 4.

Establishment of new networks of reference laboratories and in the field of substances of human origin

Specific objective 5.

Responsibility of risk assessments for chemical, environmental, climate threats established within agencies

Specific objective 6.

Established structure and processes for the recognition of emergency at EU level (advisory panel, emergency activation of processes)

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 of the EU4Health, 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, following indicators are put forward:

- Number of new/updated preparedness plans

- Number of stress tests and audits carried out in Member States

- Number of training events and modules for health care workforce

- Number of nominated competent authorities (at least 1 competent authority / MS) in the new networks established

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

The current health security framework, established by Decision 1082/2013/EU on serious cross-border threats to health, provides a limited legal framework for EU level coordination, based essentially on a) an early warning system (EWRS) and the exchange of information and cooperation within the HSC. Early lessons learnt have shown that the current system has not allowed an optimal response at EU level to the COVID-19 pandemic.

Structures and mechanisms under the Decision, while key in facilitating the exchange of information on the evolution of the pandemic and in supporting the adoption of national measures, could do little to trigger a timely common EU level response, co-ordinate the crucial aspects of risk communication, or ensure solidarity among Member States.

The revision of the health security framework proposes a stronger and more comprehensive legal basis for the Union to prepare and respond to health crises, complemented by the revised mandate of ECDC and EMA.

The adoption of the Regulation should take place in early 2021 and be implemented immediately (tbc).

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)

Although the Member States have the responsibility to manage public health crises at national level, no country can tackle a cross border public health crisis on its own.

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

Public health emergencies of the magnitude of COVID-19 have an impact on all Member States, which, on their own are unable to provide a sufficient response. The proposal builds on lessons learnt with the COVID-19 crises, and proposes strengthening the existing structures and mechanisms for better EU level protection, prevention, preparedness and response against all health hazards.

Expected generated Union added value (ex-post)

In particular, the proposal aims to provide EU added value through the development of an EU health crisis and pandemic preparedness plan, complemented by national plans and transparent reporting of capacities; strengthened, integrated surveillance systems; enhanced risk assessment for health threats; power to enforce coordinated response at EU level in the HSC; and improved mechanism for EU level recognition and response to public health emergencies.

The Regulation will support the implementation of Article 168 of the Treaty on the Functioning of the European Union (TFEU), to set measures to support, coordinate or supplement the actions of EU Member States for the protection and improvement of human health.

1.5.3. Lessons learnt from similar experiences in the past

The COVID-19 pandemic taking place all over the world and in the EU since beginning of 2020 has highlighted important gaps

While the outbreak is still ongoing and most EU countries are facing a resurgence of cases with the return of travellers and de-escalation of measures at national level, early lessons learnt can be identified with regards to public health response.

The outbreak of COVID-19 has highlighted that more needs to be done at an EU and national level with regards to health security and preparedness and response planning for epidemics and other health threats. Structures and mechanisms under the Decision on serious cross-border health threats facilitated the exchange of information on the evolution of the pandemic and supported specific national measures taken, but could do little to trigger a timely common EU level response, co-ordinate the crucial aspects of risk communication, or ensure solidarity among Member States, due to the lack of powers and coordination at EU level.

Partial lessons learn have also been considered in the Commission Communication on Short-term EU health preparedness for COVID-19 outbreaks (15/07/2020) and are being addressed through short-term action undertaken by Member States and the Commission.

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

The strengthened Union health security framework addressing cross-border health threats will amongst other be funded through the EU4Health programme and will work in synergy and complementarity with other EU policies and funds such as actions implemented under the ESIF, Horizon Europe, Digital Europe Programme, rescEU, ESI, ESF+, SMP.

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**

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

– ☐ Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

✔ **unlimited duration**

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

– followed by full-scale operation.

1.7. Management mode(s) planned[39]

✔ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

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

– ☐ third countries or the bodies they have designated;

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

– ☐ the EIB and the European Investment Fund;

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation;

– ☐ 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.

– *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

[…]

[39] 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.

Performance frameworks will be developed building on the relevant practices of the previous Health programme 2014-2020 to ensure that data is collected efficiently, effectively and timely.

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 actions addressing cross-border health threats will be implemented through direct management, using the implementation modes offered by the Financial Regulation, mainly being grants and procurement. Direct management allows to establish grant agreements/contracts with beneficiaries/contractors directly engaged in activities that serve Union policies. The Commission ensures direct monitoring over the outcome of the actions financed. The payment modalities of the actions funded will be adapted to the risks pertaining to the financial transactions.

In order to ensure the effectiveness, efficiency and economy of the Commission controls, the control strategy will be oriented towards a balance of ex-ante and ex-post checks and focus on three key stages of grant/contract implementation, in accordance with the Financial Regulation:

– Selection of proposals/tenders that fit the policy objectives of the Regulation;

– Operational, monitoring and ex-ante controls that cover project implementation, public procurement, pre-financing, interim and final payments, management of guarantees;

Ex-post controls at the beneficiaries/contractors' sites will also be carried out on a sample of transactions. The selection of these transactions will combine a risk assessment and a random selection.

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

The implementation of the strengthened Union health security framework addressing cross-border health threats focuses on the attribution of public procurement contracts as well as a number of grants for specific activities and organisations.

The public procurement contracts will mainly be concluded in areas such as surveys, studies, collection of data, benchmark exercises, monitoring and assessment activities, trainings, IT and communication services, etc.

Grants will mainly be awarded for support activities to non-governmental organisations, respective competent authorities of the Member States, health organisations, national agencies, etc. The period of execution of the subsidised projects and activities varies from one to three years mostly.

The main risks are the following:

• Risk of not fully achievening the objectives of the Regulation due to insufficient uptake or quality/delays in the implementation of the selected projects or contracts;

• Risk of inefficient or non-economic use of funds awarded, both for grants (complexity of funding rules) and for procurement (limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers in some sectors);

• Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system.

The Commission put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. Within this framework, the Commission continues to explore possibilities to enhance the management and to realise efficiency gains. Main features of the control framework are the following:

Controls before and during the implementation of the projects:

• An appropriate project management system will be put in place focussing on the contributions of projects and contracts to the policy objectives, ensuring a systematic involvement of all actors, establishing a regular project management reporting complemented by on-site-visits on a case by case basis, including risk reports to senior management, as well as maintaining appropriate budgetary flexibility.

• Model grant agreements and service contracts used are developed within the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF. The rules governing the eligibility of costs are being simplified, for example, by using unit costs, lump sums, contributions not linked to costs and other possibilities offered by the Financial Regulation. This will reduce the cost of controls and put the focus on checks and controls in high risk areas.

• All staff sign up to the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the grant agreements/contracts (also) sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.

• Technical implementation of a project is checked at regular intervals at the desk on the basis of technical progress reports of the contractors and beneficiaries; in addition contractors'/beneficiaries' meetings and on-site-visits are foreseen on a case by case basis.

Controls at the end of the project: Ex-post audits are performed on a sample of transactions to verify on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control impact, the selection of beneficiaries to be audited foresees to combine a risk based selection with a random sampling, and to pay attention to operational aspects whenever possible during the on-site audit.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

The yearly costs of the suggested level of controls under the third Health programme 2014-2020 represented approximately 4 to 7% of the yearly budget of the operational expenditure. This is justified by the diversity of transactions to be controlled. Indeed, in the area of health, direct management involves the attribution of numerous contracts and grants for actions of very small to very large sizes, and the payment of numerous operating grants to non-governmental organisations. The risk related to these activities concerns the capacity of (especially) smaller organisations to effectively control expenditure.

The Commission considers that the average costs of controls is likely to be the same for the actions proposed under this Regulation.

Under the third Health Programme 2014-2020, on a 5 years basis, the error rate for the on-the-spot audits of grants under direct management was 1.8% while for procurement contracts it was below 1%. This level of error is considered acceptable, as it is under the materiality level of 2%.

The proposed actions will not affect the way the appropriations are currently managed. The existing control system proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them. It will be adapted to include the new actions and to ensure that residual error rates (after correction) remain below the threshold of 2%.

2.3. Measures to prevent fraud and irregularities

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

As for its activities in direct management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019) 196), covering notably the following preventive, detective and corrective measures:

The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding.

The Commission also implements a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the Regulation will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections and to recover amounts unduly paid and, where appropriate, impose administrative sanctions;

- during the evaluation phase of a call for proposals/tender, the applicants and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

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	Diff./Non-diff.[40]	from EFTA countries [41]	from candidate countries[42]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
2	06 06 01 - EU4Health Programme	Diff.	YES	YES	YES	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

[40] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

[41] EFTA: European Free Trade Association.

[42] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

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

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

EUR million (to three decimal places)

Heading of multiannual financial framework	2	Cohesion, resilience and values

DG: SANTE			Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027 et seqq.**		**TOTAL**
• Operational appropriations											
06 06 01 - EU4Health Programme	Commitments	(1a)	51.500	51.500	51.500	51.500	51.500	51.500	51.500		**360.500**
	Payments	(2a)	25.750	51.500	51.500	51.500	51.500	51.500	51.500	25.750	**360.500**
Budget line	Commitments	(1b)									
	Payments	(2b)									
Appropriations of an administrative nature financed from the envelope of specific programmes[43]											
Budget line		(3)									
TOTAL appropriations for DG SANTE	Commitments	=1a+1b +3	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**		**360.500**
	Payments	=2a+2b +3	**25.750**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**25.750**	**360.500**

[43] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)									
	Payments	(5)									
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)									
TOTAL appropriations under HEADING 2 of the multiannual financial framework	Commitments	=4+ 6	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**		**360.500**
	Payments	=5+ 6	**25.750**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**25.750**	**360.500**

If more than one operational heading is affected by the proposal / initiative, repeat the section above:

• TOTAL operational appropriations (all operational headings)	Commitments	(4)									
	Payments	(5)									
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)									
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**		**360.500**
	Payments	=5+ 6	**25.750**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**51.500**	**25.750**	**360.500**

Heading of multiannual financial framework	7	'Administrative expenditure'

This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the Annex to the Legislative Financial Statement (Annex V to the internal rules), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	Year **2027 et seqq.**		**TOTAL**
DG: SANTE										
• Human resources		2.870	2.870	2.870	2.870	2.870	2.870	2.870		**20.090**
• Other administrative expenditure		0.120	0.120	0.120	0.120	0.120	0.120	0.120		**0.840**
TOTAL DG SANTE	Appropriations	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**		**20.930**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**		**20.930**

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	**54.490**	**54.490**	**54.490**	**54.490**	**54.490**	**54.490**	**54.490**		**381.430**
	Payments	**28.740**	**54.490**	**54.490**	**54.490**	**54.490**	**54.490**	**54.490**	**25.750**	**381.430**

3.2.2. Estimated output funded with operational appropriations

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[44]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 Strengthen preparedness capacities																		
EU preparedness plan,interregional preparedness elements				1.000		1.000		1.000		1.000		1.000		1.000		1.000		7.000
Preparedness platform for reporting and country profiles in EWRS + audits				6.000		6.000		6.000		6.000		6.000		6.000		6.000		42.000
- Output																		
Subtotal for specific objective No 1				7.000		7.000		7.000		7.000		7.000		7.000		7.000		49.000
SPECIFIC OBJECTIVE No 2 Continuously trained health specialists to manage public health																		

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

crises																
training programmes				6.000		6.000		6.000		6.000		6.000		6.000		42.000
Subtotal for specific objective No 2				6.000		6.000		6.000		6.000		6.000		6.000		42.000
SPECIFIC OBJECTIVE No 3 Digitalized, integrated surveillance system at EU level, better detection of early signals for accurate risk assessment and response																
Digitalized surveillance platform and national systems				36.000		36.000		36.000		36.000		36.000		36.000		252.000
Subtotal for specific objective No 3				36.000		36.000		36.000		36.000		36.000		36.000		252.000
SPECIFIC OBJECTIVE No 4 Establishment of new networks of laboratories and in the field of substances of human origin																
EU reference laboratories				1.200		1.200		1.200		1.200		1.200		1.200		8.400
Subtotal for specific objective No 4				1.200		1.200		1.200		1.200		1.200		1.200		8.400
SPECIFIC OBJECTIVE No 5 Responsibility of risk assessments for chemical, environmental and climate established threats within agencies																
Risk assessments				0.600		0.600		0.600		0.600		0.600		0.600		4.200
Subtotal for specific objective No 5				0.600		0.600		0.600		0.600		0.600		0.600		4.200
SPECIFIC OBJECTIVE No 6. Established structure and processes for the recognition of emergency at EU level (advisory committee,																

emergency activation of processes).															
advisory committee established (operating ad-hoc, in case of emergency)		0.700		0.700		0.700		0.700		0.700		0.700		0.700		4.900
Subtotal for specific objective No 6		0.700		0.700		0.700		0.700		0.700		0.700		0.700		4.900
TOTALS		**51.500**		**51.500**		**51.500**		**51.500**		**51.500**		**51.500**		**51.500**		**360.500**

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ 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**
HEADING 7 of the multiannual financial framework								
Human resources	2.870	2.870	2.870	2.870	2.870	2.870	2.870	**20.090**
Other administrative expenditure	0.120	0.120	0.120	0.120	0.120	0.120	0.120	**0.840**
Subtotal HEADING 7 of the multiannual financial framework	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**20.930**

Outside HEADING 7[45] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 7 of the multiannual financial framework								

TOTAL	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**2.990**	**20.930**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

45 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.2.3.1. Estimated requirements of human resources

– ☐ 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 time equivalent units

		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)		17	17	17	17	17	17	17
XX 01 01 02 (Delegations)								
XX 01 05 01/11/21 (Indirect research)								
10 01 05 01/11 (Direct research)								
• External staff (in Full Time Equivalent unit: FTE)[46]								
XX 01 02 01 (AC, END, INT from the 'global envelope')		4	4	4	4	4	4	4
XX 01 02 02 (AC, AL, END, INT and JPD in the delegations)								
XX 01 04 **yy** [47]	- at Headquarters							
	- in Delegations							
XX 01 05 02/12/22 (AC, END, INT - Indirect research)								
10 01 05 02/12 (AC, END, INT - Direct research)								
Other budget lines (specify)								
TOTAL		**21**	**21**	**21**	**21**	**21**	**21**	**21**

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 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	Staff to perform supervision of actions under CBHT delegated to ECDC, organize meetings with Member states, scientific overview of the studies, integration of study results, coordination of expert groups, contract management, administration and IT support
External staff	Administrative support tasks

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

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

3.2.4. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ✔ can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

The actions under the current proposal will be financed through the EU4Health programme (directly or by redeployment from the same programme).

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used.

– ☐ requires a revision of the MFF.

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

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **N**[48]	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

[48] Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

3.3. Estimated impact on revenue

– ✔ 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[49]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article …….								

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

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[49] 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.