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NOTE

Origine:	Secrétariat général du Conseil
Destinataire:	Comité des représentants permanents
Objet:	Proposition de Règlement du Parlement européen et du Conseil concernant les menaces transfrontières graves pour la santé et abrogeant la décision n° 1082/2013/UE

Les délégations trouveront en annexe le texte consolidé du projet de règlement suite au cinquième trilogue qui s'est tenu le 23 juin 2022.

ANNEXE

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 (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(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. Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council 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, including zoonotic-related threats, 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 between Member States and Union agencies, particularly the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and international organisations, in particular the World Health Organization (WHO) while taking into account the burden faced by national competent authorities depending on the actual public health situation. Moreover, in order to ensure Union's effective 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 as well as it should provide for the establishment of a network of EU reference laboratories and a network to support monitoring 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, while respecting the Union legislation on Data Protection such as Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR').[1]

(2a) It is important that public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures for the purpose of preparing and responding to cross-border threats to health are transparent in line with applicable legislation.

[1] 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).

(3) An important role in the coordination of prevention, 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, and support better coordination between Member States to address those threats. A representative designated by the European Parliament should be able to participate in the HSC as observer.

(3a) In order to increase the effectiveness of preparedness and response to serious cross-border threats to health, the Commission including, where relevant, the Health Emergency Preparedness and Response Authority (HERA) established as a Commission service by Commission Decision of 16 September 2021, and the Health Security Committee, the European Centre for Disease Prevention and Control, the European Medicines Agency and other relevant Union agencies and bodies should coordinate and cooperate in relation to such preparedness and response .The coordination between those bodies should build on the participation of relevant stakeholders and aim to avoid any duplication of efforts.

(4) A joint opinion issued by the European Commission's 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 recommends 'establishing a standing EU advisory body' for health threats and crises.

(4a) It is understood that all recommendations, advice, guidance and opinions mentioned in this Regulation, are inherently non-binding. A recommendation enables the Commission, ECDC and Health Security Committee to make its views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.

(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, such as the International Health Regulations (IHR) of the World Health Organization (WHO). Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health and environmental matters, covering goods such as pharmaceutical products, medical devices, in vitro diagnostic medical devices, and foodstuffs, substances of human origin (blood, plasma, tissues and cells, organs), and exposure to ionising radiation.

(5a) The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to take the 'One Health' approach to addressing current and emerging crises.

(6) In line with the ‘One Health’ and ‘Health in all policies’ approaches, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. It is crucial that the Union supports Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage and in addressing the challenges of vulnerable groups and in strengthening the resilience, responsiveness and readiness of healthcare systems to address future challenges, including pandemics. 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, and all relevant stakeholders, 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 prevention, 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 1082/2013/EU of the European Parliament and of the Council. The EWRS is to implement robust, accurate and interoperable data processes with Member States to ensure data quality and consistency. The ECDC should coordinate with Member States throughout such data exchange processes, from assessing the data requirements, transmission, and collection, to up to date actualisation and interpretation, with a view to fostering strong collaboration between the Commission, the ECDC and national and regional competent bodies.

(7) Prevention, 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' prevention, preparedness and response plans so as to ensure they are compatible within the regional level structures. It is crucial that the plans be prepared with particular attention paid to cross-border regions to enhance their health cooperation. Where appropriate, regional authorities should be able to participate in the drawing up of these plans. To support Member States in this endeavour, the Commission and the relevant Union agencies should provide targeted training and facilitate the sharing of best practices for healthcare staff and public health staff to improve their knowledge and necessary skills. Cross-border elements should also, where relevant, be included in the plan, in order to foster the sharing of best practices and a smooth exchange of information in times of crisis, such as concerning capacities for specialised treatment and intensive care across neighbouring regions. To ensure the putting into operation and the running of the Union plan, the Commission should facilitate the stress tests, exercises and in-action and after-action reviews with Member States. The Union plan should be functional and updated, and have sufficient resources for its operationalisation.

Following reviews of the plans, proposed recommendations should be addressed in an action plan and the Commission should be kept informed of any substantial revision of the national plan.

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their prevention, preparedness and response planning and implementation at national level, and regional level where applicable.

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).

Access to timely and complete data is a precondition for rapid risk assessments and crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and secured network are needed between Union agencies, the WHO and national agencies.

In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with prevention, preparedness, response planning and implementation at Union level, including on recommended actions, every three years to ensure that national prevention, preparedness and response plans are adequate. In order to support the assessment of these plans, EU assessments 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 agriculture, 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, through a One Health approach.

The obligations of Member States to provide information under this Regulation do not affect the application of point (a) of Article 346(1) TFEU pursuant to which no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security.

(8a) Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for further firmer action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions The national plans of Member States sharing a border with at least one other Member State should therefore include plans to improve the preparedness for, prevention of and response to health crises in border areas in neighbouring regions, including through cross-border training for healthcare staff and coordination exercises for the medical transfer of patients.

(8b) Health literacy plays a fundamental role in preventing and mitigating the impact of cross-border threats and contributing to a better understanding on the part of the population of the countermeasures and risk assessment of different threats. Health education campaigns based on the latest available evidence could help to improve the population's behaviour.

(8c) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration of a public health emergency at Union level would trigger increased coordination and may allow for timely development, stockpiling and joint procurement of medical countermeasures, under the *Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures [Council Regulation] or [Emergency Framework Regulation*].

(8d) This regulation should strengthen the tools to safeguard the security of supply of critical medical countermeasures within the Union, while respecting g the proper functioning of the single market in the event that serious cross-border threats to health arise.

(9) In order to prevent shortages of critical medical countermeasures and protect the security of their supply at Union and national level, as well as to support an effective and strategic stockpile location, the Commission should ensure coordination and information exchange between the entities organizing and participating in 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 framework of measures adopted under a Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures, and the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council, taking due account of the accessibility of those products for people in remote, rural and outermost regions.

(9a) A Joint Procurement Agreement for medical countermeasures was approved by the Commission on 10 April 2014. The Agreement provides for a voluntary mechanism to participating countries and the EU institutions to purchase jointly medical countermeasures for different categories of cross-border health threats including vaccines, antivirals and other treatments. It lays down common rules for practical organisation of joint procurement procedures.

This Regulation should strengthen and extend the framework for joint procurement of medical countermeasures, in accordance with measures concerning monitoring, early warning of and combating serious cross-border threats to health, laid in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council. In the event of a serious cross-border threat to health, the joint procurement of medical countermeasures laid down in this Regulation should constitute an effective operational instrument at the Union disposal, together with other procurement instruments provided for by Union legislation. In particular, contracts under the joint procurement procedure laid down in this Regulation may be concluded or activated in times of crisis, pursuant to Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. In such instances, those contracts should abide by the conditions laid down in the Joint Procurement Agreement, as provided for by this Regulation. The Commission should ensure coordination and information exchange between the entities organizing and participating in any action under different mechanisms established under this Regulation and other relevant Union acts related to procurement and stockpiling of medical countermeasures.

(9b) The Commission should support and facilitate the joint procurement of medical countermeasures by providing all relevant information for the negotiation of joint procurements, such as on envisaged prices, manufacturers, delivery timeframes and modalities of joint procurement. 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 provide for an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU, a strengthened negotiation position and a more efficient action to protect the Union's security of supply. Under the exclusivity clause, participating countries commit not to procure the medical countermeasure in question through other channels and not to run parallel negotiation processes for that countermeasure. The Commission should facilitate the decision of Member States on participation by providing an assessment, inter alia, on the application of the exclusivity clause, its necessity and the conditions thereof, to be jointly agreed with the participating countries. Member States should decide to participate in the joint procurement procedure once all the necessary information have been provided to them. In any circumstance, limitations to parallel procurement activities and negotiations should occur only when the participating countries have agreed to such restrictions. Due to the sensitive content of the assessment and its relevance for the financial interests of the Union and the participating Member States during a joint procurement procedure, the possibility to make it public should be duly weighted against the exceptions provided for by Regulation 1049/2001, and, in particular, Article 4 of that Regulation.

(9c) As serious cross-border threats to health are not limited to Union borders, the Union should adopt a coordinated approach, characterised by solidarity and responsibility, in combatting such threats. Therefore, 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, and to the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) and in accordance with Article 3(2) of Regulation (EU, Euratom) 2018/1046. Joint procurement of medical countermeasures should be expected to aim at strengthening the negotiating position of participating countries, contributing to the contracting authorities' security of supply and ensuring equitable access to medical countermeasures against serious cross-border threats to health. Joint procurement procedures should abide by high standards of transparency towards Union institutions, including the European Court of Auditors and its citizens, in line with the principle of transparency as referred to in Article 15 TFEU. While taking into account the protection of commercially sensitive information and the protection of essential national security interests, transparency should also be encouraged in relation to the disclosure of information related to the delivery schedule of the medical countermeasures, terms of liabilities and indemnifications and the number of manufacturing locations. A high degree of transparency should be applied in accordance with Regulation 1049/2001. This includes the right of citizens to request access to documents regarding jointly procured medical countermeasures in accordance with Article 2 of Regulation 1049/2001. When joint procurement is deployed, qualitative criteria should be considered in the award process, in addition to cost.

(9d) Prevention is one of the essential steps in the crisis management cycle, according to the World Health Organization. Under the four categories of prevention that have been recognised at the international level (primary, secondary, tertiary and quaternary), a number of activities constitute a cornerstone for the early warning, monitoring and combating of serious cross-border threats to health. These activities include the monitoring of vaccination coverage for communicable diseases, surveillance systems for the prevention of communicable diseases and measures to decrease the risk of communicable disease spreading at the personal and community levels, in line with the One Health approach. Investment in prevention activities against serious cross-border threats to health directly contributes to the objective of this Regulation. The term "prevention" or "disease prevention" under this Regulation should therefore be understood as covering prevention activities which aim to minimise the burden of communicable diseases and associated risk factors for the purposes of early warning, monitoring and combating serious cross-border threat to health.

(9e) The strengthened Union health framework addressing serious cross-border health threats should work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the EU4Health programme, the European Structural and Investment Funds (ESIF), Horizon Europe, the Digital Europe Programme, rescEU reserve, the European Social Fund Plus (ESF+), the Emergency Support Instrument (ESI) and the Single Market Programme (SMP).

(9f) The decision taken by the World Health Assembly during its Special Session on 1 December 2021 is set to start a global process for “a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response”. In accordance with the Council decision (EU) 2022/… of … the Union should engage with the WHO and its Member States to develop a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response.

The Union will engage with the WHO and its Member States to develop a new legally binding instrument that complements the International Health Regulations (2005), thereby strengthening multilateralism and global health architecture. The Union should also support efforts to strengthen the implementation and compliance with the International Health Regulations.

(9g) The COVID-19 pandemic has highlighted that (a) major disease(s) can put severe pressure on the capacities of healthcare systems, with negative impact, for example, on the provision of healthcare for patients with other communicable or non-communicable diseases, such as the continuity of healthcare, delay of or interruption to treatment for cancer patients and survivors and people with mental health issues. The impact of serious cross-border threat to health may thus be such as to bring further challenges in ensuring a high level of human health protection. While respecting the responsibilities of Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, it is therefore important to consider the impact of public health emergencies on the provision of healthcare services for other diseases and conditions, in order to safeguard the detection and treatment of other serious diseases and minimise their delays or interruptions.

Hence, the impact an important outbreak of a communicable disease, absorbing an important part of health system capacities, can have on the continuity of health care and on the prevention and treatment of non-communicable diseases and comorbidities needs to be considered.

(9h) In times of crisis, ensuring the security of supply within the Union of critical medical countermeasures is paramount, and the COVID-19 experience has shown that this could be prejudiced by a number of factors. Union action to safeguard commitments and protecting the supply of medical countermeasures included, among others, an export authorisation mechanism pursuant to Regulation (EU) 2015/479, enhanced cooperation agreements and procurement activities. Where relevant, actions taken under this Regulation should consider the potential activation of such mechanisms, pursuant to the applicable Union legislation.

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

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other Union Agencies or bodies, research infrastructures and the WHO to improve, through the One Health approach, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

(12) In the case of cross-border health threats pose by a communicable disease, the ECDC will cooperate with Member States to safeguard patients in need of treatment of substance of human origin, from a transmission of such communicable disease. The centre should therefore establish and operate a network of services supporting the use of substances of human origin.

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health had been put in place by Decision No 1082/2013/EU 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.

In order to foster the effectiveness of alert systems for cross-border health threats, the Commission is encouraged to integrate information in an automatic manner from different important databases, such as those comprising environmental data, climate data, water irrigation data and other data relevant to serious cross-border threats to health, that could facilitate understanding and mitigate the risk of potential health threats. 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. The EWRS should be further developed and improved, to augment the automation of information collection and analysis, reduce the administrative burden and improve the standardisation of the notifications. 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 interoperable and, subject to human oversight, automatically 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. The National authorities should notify the relevant serious cross-border threats to health events in EWRS. It allows simultaneous notification of the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6, of the IHR.

(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 and multidisciplinary 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 and bodies 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. It is important that the Commission, upon request of the HSC or on its own initiative and in close cooperation with the relevant agencies, bodies or Commission services, provides any relevant information, data and expertise at their disposal. Serious cross-border threats to health may require a multidisciplinary approach for their assessment and analysis, and coordination among agencies might therefore turn essential to ensure a swift and coordinated reaction. Where relevant, such coordination could, in particular, take the form of a multi-source risk assessment under the lead of a particular agency designated by the Commission. The Union agencies and bodies should have adequate financial and human resources to achieve a sufficient degree of expertise and effectiveness in the framework of their mandates.

(14a) Member States, the Commission and Union agencies, while applying the One Health approach, should identify recognised public health organisations and experts, and other relevant stakeholders across sectors, available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be engaged in the context of Union preparedness and response activities to contribute where relevant to the decision-making processes. National authorities should also consult and involve representatives of patient organisations and national social partners in the healthcare and social services sector in the implementation of this regulation where appropriate. It is essential that there be full compliance with transparency and conflict of interest rules for stakeholder engagement.

(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. In addition, regular dialogue between the HSC and relevant Council bodies should be reinforced in order to ensure better follow-up of HSC's work at national level.

(17) Inconsistent communication with the public and stakeholders such as healthcare and public health 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 holistic, robust and independent evaluation of public health risks, to be adapted to national and regional needs and circumstances where relevant. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. To this end, relevant public institutions contribute to sharing verified information and fighting disinformation. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the EU Civil Protection Community.

(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 and who might include representatives of healthcare and social care workers and civil society representatives, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the Member States, ECDC, of the EMA, and of other Union bodies or agencies as observers. All members of the Advisory Committee should provide declarations of interest. 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 suspected human cases of the disease or infection, between those Member States directly involved in the contact-tracing measures.

(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, such as the European Surveillance System, operated by the ECDC, 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. Those international cooperation agreements could also facilitate the donation of medical countermeasures, in particular for the benefit to low- and middle-income countries.

(22) Any processing of personal data for the purpose of implementing this Regulation should be fully compliant with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council and with Directive 2002/58/EC on privacy and electronic communications. Processing of personal data should be limited to the strictly necessary and, whenever possible, data should be anonymized. 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 where necessary to relevant authorities involved in contact tracing measures, medical evacuation or other cross-border procedures. In the case of cooperation with the health authorities of the Union, third countries, WHO or other international organizations, transfers of personal data to third countries or international organizations should always comply with the obligations laid down under Regulation (EU) No 2018/1725.

(22a) In order to avoid the administrative burden and duplication of efforts, overlap of reporting and reviewing activities with existing structures and mechanisms on prevention, preparedness and response planning and implementation at national level in relation to serious cross-border threats to health should be avoided as far as possible. To this end, Member States should not be requested to report data and information if already required by the Commission or other Union agencies and bodies, pursuant to the applicable Union legislation. In addition, the Union should further enhance its cooperation with the WHO, in particular under the International Health Regulations reporting, monitoring and evaluation frameworks.

(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 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. 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 supplement certain aspects of this Regulation and 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: covering cases and the conditions under which the third countries and international organisations might be granted partial access to the functionalities of the platform for surveillance, certain information and documents can be transmitted and conditions under which the ECDC can be granted access to the health data accessed or exchanged through the digital infrastructures, detailed requirements necessary to ensure that the operation of EWRS and processing of data complies with the data protection regulations and list of categories of personal data that might be exchanged for the purpose of contact tracing and the procedures, standards and criteria for the assessments 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. 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.

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

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

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) prevention, preparedness and response planning, including;

(i) preparedness plans at Union and national levels;

ii) reporting and assessing preparedness at national level;

(c) joint procurement of medical countermeasures;

(ca) emergency research and innovation;

(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. In keeping with the ‘One Health’ and ‘Health in all policies’ approaches, 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, including those of zoonotic origin;

(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 (including due to 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 prevention, 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 Health Security Committee 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 international level, Union level or under the Euratom Treaty whose activities are relevant for prevention, 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 to identify persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of being infected or being infectious or who have developed a communicable disease, through manual or other technological means, with the sole objective of rapidly identifying potentially newly infected persons who may have come into contact with existing cases, in order to reduce further onward transmission;

(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;

(5a) ‘One Health approach’ means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;

(5b) ‘Health in All Policies’ means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;

(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 countermeasures’ means medicinal products for human use as defined in Directive 2001/83/EC of the European Parliament and of the Council, medical devices as defined in point 8(b) and other goods or services that are necessary for the purpose of preparedness and response to serious cross-border threats to health.

(8a) 'International Health Regulations' mean the International Health Regulations adopted by the World Health Organization in 2005;

(8b) ‘medical device’ means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (2) of Article 1 and point (a) of Article 1(6) of that Regulation, and an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746.

(9) ‘health systems’ capacity’ means the degree to which a health system maximizes its performance on six health system core components or “building blocks”: (i) service delivery, (ii) health workforce, (iii) health information systems, (iv) access to medical countermeasures, (v) financing, and (vi) leadership/governance. For the purpose of this regulation, the definition shall apply only to the parts of health system components or building blocks affected by the serious cross-border threats to health outlined in Article 2(1).

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 levels:

   (a) a senior level working group for regular discussions on serious cross-border threats to health and for the adoption of opinions and guidance as referred to in point (d) of paragraph 2

   (b) technical working groups to discuss specific topics if necessary.

1a. Representatives of relevant Union agencies may participate in HSC meetings as observers.

2. The HSC shall have the following tasks in cooperation with relevant participating Union agencies and bodies;

(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 prevention, preparedness and response planning 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;

(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, based on the expert opinion of relevant technical Union bodies or agencies.

(da) adoption, on an annual basis, of a working programme setting its priorities and objectives.

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

In the event of a vote, the outcome of the vote shall be decided by two thirds 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 without the right to vote. 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.

5a. The HSC and the Commission shall ensure regular consultation with public health experts, international organisations and stakeholders, including healthcare professionals, depending on the sensitivity of the subject.

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;

(b) the participation of experts in plenary meetings, the status of possible observers, including from the European Parliament, Union agencies, third countries and WHO;

(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.

Member States shall notify the Commission and other Member States of the designations and of any change thereof. In the event of such change, the Commission shall make available to the HSC's members an updated list of such designations.

7a. The European Parliament shall designate a technical representative to participate in the HSC as an observer.

7b. The list specifying the authorities, organisations or bodies to which the HSC participants belong to should be public on the Commission's web portal.

7c. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's web portal unless such publication undermines the protection of a public or private interest, as defined in Article 4 of Regulation (EC) No. 1049/2001.

CHAPTER II

PREVENTION, PREPAREDNESS AND RESPONSE PLANNING

Article 5

Union prevention, preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies, and in accordance with the WHO emergency preparedness and response framework set out by the International Health Regulations (IHR), shall establish a Union health crisis and pandemic plan (‘the Union prevention, preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

2. The Union prevention, preparedness and response plan shall complement the national prevention, preparedness and response plans established in accordance with Article 6, and promote effective synergies between the Member States, the Commission, the ECDC and other relevant Union bodies or agencies.

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

(a) the timely cooperation between the Commission, the Council, the Member States, the HSC and the relevant Union bodies or agencies. The plan shall take into account the possible services and support provided under the EU Civil Protection Mechanism, and in particular the capacities under the RescEU stockpile as laid down in Commission implementing decision 2019/570 or other mechanisms, the capacities and resources made available for its purposes by the EU and the Member States and the cooperation with the WHO for cross-border threats to health;

(b) the secure exchange of information between the Commission, the Member States and in particular the competent authorities or designated bodies responsible at national level, the HSC and the relevant Union bodies or agencies

(c) the epidemiological surveillance and monitoring;

(d) the early warning and risk assessment, especially regarding cross-border interregional preparedness and response;

(e) the risk and crisis communication, including to health professionals and citizens;

(f) the health preparedness and response and multi-sectoral collaboration such as identifying risk factors for disease transmission and the associated disease burden, including social, economic and environmental determinants, following a one health approach for zoonotic, food and water borne diseases and relevant other diseases and special health issues;

(fa) the drawing up of an overview of the production capacities of relevant critical medical countermeasures in the Union as a whole to address serious cross border threats to health as defined in Article 2;

(fb) emergency research and innovation;

(g) the management of the plan;

(ga) supporting Member States for the monitoring of the impact of a serious cross-border threat to health on the provision and continuity of healthcare services, including for other diseases and conditions during health emergencies.

4. The Union prevention, preparedness and response plan shall include cross-border and interregional preparedness elements to support aligned multi-sectoral, cross-border public health measures, in particular considering capacities for surveillance, testing, contact tracing, laboratories, training of healthcare staff and specialised treatment or intensive care across neighbouring regions. The plan shall take into account national respective circumstances 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 prevention, preparedness and response plan, the Commission shall facilitate, in collaboration with Member States and, when applicable, with relevant Union bodies or agencies or with international organizations, stress tests, simulation exercises and in-action and after-action reviews with Member States, and update the plan as necessary.

5a. The Commission may provide technical assistance at the Member States' request, to support the development of their staffing plans in order to address specific healthcare needs and facilitate exchange of staff between Member States in the event of a cross-border threat to health.

5b. The reviews and any subsequent adjustments to the plan shall be published.

Article 6

National prevention, preparedness and response plans

1. Without prejudice to Member States competences in this area, when preparing national prevention, preparedness and response plans Member States shall liaise with each other within the HSC and coordinate with the Commission in order to seek coherence with the Union prevention, preparedness and response plan to the largest possible extent, Member States shall also inform without delay the Commission and the HSC of any substantial revision of the national plan.

1a. National prevention, preparedness and response plans may include elements for governance, capacities and resources laid down in the Union preparedness and response plan as referred to in Article 5.

2. Member States shall also inform without delay the Commission and the HSC of any substantial revision of the national plan.

3. For the purposes of paragraph 1, Member States may also consult, where relevant, patient's organisations, healthcare professional's organisations, industry and supply chain stakeholders, as well as national social partners.

Article 7

Reporting on prevention, preparedness and response planning

1. Member States shall [within 12 months of the entry into force of this regulation] and every 3 years thereafter provide the Commission and relevant Union agencies and bodies with an updated report on prevention, preparedness and response planning and implementation at national level and, where appropriate, cross-border regional levels.

That report shall be succinct, based on agreed common indicators, give an overview of the actions implemented in the Member States, and shall cover the following:

(a) identification of, and update on the status of the implementation of the capacity standards for prevention, preparedness and response planning as determined at national and, where appropriate, crossborder inter-regional level for the health sector, as provided to the WHO in accordance with the IHR, as well as, where available, the interoperability arrangements between the health sector and other critical sectors in emergency situations;

(b) an update, if needed, on the elements of emergency prevention, preparedness and response, in particular:

(i) governance: including national and, if appropriate, regional policies and legislation that integrate emergency and preparedness actions; plans for emergency prevention, preparedness, response and recovery; coordination mechanisms, including, where relevant, among administrative levels (national, regional and/or local) and in terms of multi-sectoral collaboration;

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; business continuity measures and arrangements aimed at ensuring continuous access to diagnostic services, tools and medical products during emergencies, where available; basic and safe gender-sensitive health and emergency services; an overview of the impact on the provisions and continuity of healthcare services for other diseases and conditions during public health emergencies as 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; essential supplies for health; logistics mechanisms, including for the storage of medical countermeasures dedicated, trained and equipped human resources for emergencies;

(c) implementation of national response plans, including where relevant implementation at the regional and, if appropriate, local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other serious cross-border threats to health as refer to in Article 2;

(ca) where applicable, consultation with relevant partners on risk assessment, prevention, preparedness and response plans;

(cb) actions taken to improve gaps found in the implementation of prevention, preparedness and response plans;

The report shall include, whenever relevant, cross-border interregional and intersectoral prevention, preparedness and response elements among neighbouring regions. Such elements shall include coordination mechanisms for the relevant elements of Union and national plans, including cross-border training and sharing of best practices for healthcare staff and public health staff and coordination mechanisms for the medical transfer of patients.

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 3 years.

The report shall include country profiles for monitoring progress and developing action plans, taking into account national respective circumstances, to address identified gaps at national level. For these purposes, the Commission may issue general recommendations, considering the outcomes of the assessment carried out under Article 8.

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

An overview of the recommendations of the report on preparedness and response to serious cross-border threats to health referred to in Article 2(1) shall be published on the websites of the Commission and the ECDC.

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, while avoiding any duplication of the information requested and submitted.

   The templates shall be elaborated in collaboration with HSC and shall be, as far as possible, consistent with templates used under the International Health Regulations State Parties reporting framework.

   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, the ECDC 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 and 2015/444.

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 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 and by Council Decision 2011/292/EU.

Article 8

Assessment on prevention, preparedness and response planning

1. Every 3 years, the ECDC shall assess the Member States state of implementation of the national plans and their relation with the Union plan. Such assessments shall be based on a set of agreed indicators and implemented in cooperation with the relevant Union agencies, aiming at the assessment of prevention, preparedness and response planning at national level with regard to the information referred to in Article 7(1).

1a. The ECDC shall, if applicable, present to the Member States and the Commission recommendations of the examinations referred to in paragraph 1 addressed to Member States, taking into account national respective circumstances.

2. Member States shall, if applicable, present to the Commision and the ECDC in a timely manner within nine months of receipt of its conclusions, present an action plan addressing the proposed recommendations of the asssessment with the corresponding recommended actions and milestones.

   If a Member State decides not to follow a recommendation, it shall state its reasons for doing so.

   These actions may, in particular, include:

   (a) regulatory actions, if necessary;

   (b) training initiatives;

   (c) overview of good practices.

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

Article 9

Commission report on prevention, preparedness and response planning

1. On the basis of the information provided by the Member States in accordance with Article 7, and the results of the assessment referred to in Article 8, the Commission shall one year after the entry into force and every 3 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on prevention, preparedness and response planning at Union level.

1a. The Commission report shall include, where applicable, cross-border preparedness and response elements in neighbouring regions.

2. Based on the report referred to in paragraph 1, the Commission may support the action of the Member States through the adoption of general recommendations on the prevention, preparedness and response planning.

Article 10

Coordination of prevention, preparedness and response planning in the HSC

1. The Commission, relevant Union agencies and bodies 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 prevention, preparedness and response planning;

(b) promoting the interoperability of national prevention, preparedness planning and the multi-sectoral dimension of prevention, 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) supporting the development of the prevention, preparedness and response plans referred to in Articles 5 and 6;

(e) monitoring and discussing progress for gaps identified and actions to strengthen prevention, preparedness and response planning, including in the field of research, at cross-border regional, national and at Union levels;

(f) facilitating the exchange of information on medical countermeasures, including, where appropriate, on pricing and delivery dates, outside the joint procurement procedure laid down in Article 12.

1a. The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations.

2. The HSC shall also coordinate, where relevant, response on public health emergencies with the Health Crisis Board, where it is established in accordance with Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures, and contribute accordingly to the coordination and information exchange within that body.

Article 11

Training of health care staff and public health staff

1. The Commission may organise training activities, in close cooperation with the relevant Union agencies and bodies and professional health organisations and patient organisations, for healthcare staff, social service staff and public health staff in the Member States in particular interdisciplinary One Health training, including preparedness capacities under the International Health Regulations.

   The Commission shall organise those activities in cooperation with the Member States concerned, as well as with the ECDC, in particular the EU Health Task Force, and in coordination, where possible, with the WHO. The Commission shall use the fullest potential of distance learning to broaden the number of trainees.

   In cross-border regions, joint cross-border training, sharing of best practices and familiarity with public health systems for healthcare staff and public health staff shall be promoted.

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 prevention and preparedness plans referred to in Article 6, and implement activities to strengthen crisis preparedness and surveillance capacities, especially regarding the gaps identified, including the use of digital tools, and be consistent with the One Health approach.

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 in coordination, where possible, with ECDC activities in this area.

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 and relevant Union agencies may support organising programmes, in cooperation with the Member States and Union candidate countries, for the exchange of healthcare staff and public health staff, as well as for the temporary secondment of staff between Member States, Union candidate countries to the other or Union agencies. In organising those programmes, consideration shall be taken of the contribution made by professional health organisations in each of the Member States.

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 may engage in a joint procurement procedure as contracting parties conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[2] with a view to the advance purchase of medical countermeasures for serious cross-border threats to health within a reasonable time frame.

1a. A joint procurement procedure referred to in paragraph 1 shall be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, and the decision-making process with regard to the choice of the procedure, the joint procurement assessment as referred in point c), the assessment of the tenders, and the award of the contract.

[2] 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).

2. The joint procurement procedure referred to in paragraph 1 shall comply, when it is used to procure medical countermeasures in accordance with this Regulation, including in the framework of Article 7, paragraph 1 Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures, 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, as well as Andorra, Monaco, San Marino and the State of Vatican City, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046;

b) the rights and obligations of the countries referred to in point (a) not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;

(c) before the launch of a joint procurement procedure the Commission shall prepare a joint procurement assessment. This assessment shall indicate the general envisaged conditions of the joint procurement procedure including on possible restrictions to parallel procurement and negotiations activities by the participating countries for the countermeasure in question during the specific joint procurement procedure. This assessment shall take into account the need to ensure security of supply of medical countermeasures concerned to the participating countries. Based on the joint procurement assessment and the relevant information provided therein, such as on envisaged price ranges, manufacturers, delivery timeframes, and proposed deadline for decision on participation, the parties to the Joint Procurement Agreement shall express their interest in participating at an early stage.

Those parties to the Joint Procurement Agreement having expressed their interest shall subsequently decide on their participation in the Joint Procurement Procedure under the conditions jointly agreed with the Commission, taking into account the information proposed in the joint procurement assessment.

(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 and participating in any action, including, but not limited to joint procurement procedures, development, stockpiling, distribution 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 Pharmaceutical Strategy;

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

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

(f) other programmes and instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies such as measures adopted under Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

3a. The Commission shall inform the Parliament about procedures concerning the joint procurement of medical countermeasures and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union. The Commission shall inform to the European Parliament regarding sensitive documents in accordance with Article 9(7) of Regulation 1049/2001.

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, including those of zoonotic origin, 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. The ECDC shall ensure the integrated operation of the network as set out in Article 5 of Regulation (EU) …/…[3].

   Whenever relevant, the network shall work in close cooperation with the competent bodies of the organisations operating in the field of epidemiological surveillance of the communicable diseases and of the related special health issues from the Union, third countries, the WHO, and other international organisations.

[3] [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].

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 cross-border 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 and monitor 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 with the objective to contribute to patient safety in the context of cross-border threats to health;

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

(h) contribute to the identification of research priorities and needs, and implement relevant research activities aimed at strengthening public health;

(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, based on agreed indicators and standards, 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 data required for managing cross-border health threats; and

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

3a. The information communicated by Member States referred to in point (a) of paragraph 3 may be, when available, reported at least at NUTS II level to the European Surveillance System operated by ECDC, on a timely basis.

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 strengthen the data collection and sharing capacity of Member States and 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 and evaluate epidemiological surveillance activities of the dedicated surveillance network, including adherence to these surveillance standards; support Member States with technical and scientific advice to improve the timeliness, completeness and quality of the surveillance data reported; and share regular monitoring reports with the HSC and the Commission. The ECDC shall, where applicable and in accordance with Regulation (EU) …/…[4], make available its expertise on epidemiological surveillance to third countries.

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

   The ECDC shall support the Member States to ensure the collection and sharing of data in times of health crisis for the purposes of paragraph 2.

7. The Commission may complement the action of the Member States through the adoption of recommendations on surveillance addressed to Member States. The HSC may adopt communications and recommendations on surveillance addressed to Member States, the ECDC and the Commission.

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:

[4] [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].

(a) the list of communicable diseases and related special health issues set out in the Annex and 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 set out in the Annex and 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 set out in the Annex as developed pursuant to Article 5 of Regulation (EU) …/…[5].

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.

[5] [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].

Article 14

Platform for surveillance

1. The ECDC shall ensure the continued development of the digital platform after conducting data protection impact assessment and having mitigated any risks to the rights and freedoms of the data subjects, as appropriate, 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. The Centre shall ensure that such development is subject to human oversight and shall minimise the risks that may emerge from the transfer of inaccurate, incomplete or ambiguous data from one database to another, as well as establish robust procedures for data quality review. The ECDC, in close cooperation with Member States, shall also ensure the interoperability with national systems.

2. The digital platform shall

   (a) enable the automated collection of surveillance and laboratory data, make use of relevant non-personal health data from a previously defined and authorised list from electronic health records and health databases, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting, including statistical 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, complete, accurate and information, data and documents transmitted and exchanged through the digital platform. The Member States may promote the automation of this process between the national and the Union surveillance system.

4. The ECDC shall monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission.

5. For epidemiological surveillance 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 advice 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 international and 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 including secure data backups to be applied in the event of unavailability of any of the functionalities of the platform;

   (d) arrangements for promoting standardisation of the infrastructure for storage, processing and analysis of data.

7. The Commission shall adopt delegated acts in accordance with Article 28 concerning:

   (a) 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;

   (b) 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

   (c) 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 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, including to emerging communicable diseases and pathogenic bacteria and viruses; and

   (g) training.

3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, in cooperation with the WHO Reference Laboratories. The governance structure of the network shall cover cooperation and coordination with existing national and regional reference laboratories and networks.

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

Those implementing acts shall be adopted 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.

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.

Article 16

Network for substances of human origin

1. A network of Member States' services supporting the use of substances of human origin, including transfusion, and transplantation is established to monitor, assess and help address disease outbreaks that are relevant to substances of human origin. The network shall also ensure to address any medically assisted reproduction issues in relation with disease outbreak, if relevant.

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 the use of substances of human origin, including transfusion, and transplantation 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.

1a. The European Surveillance System operated by ECDC shall be used for ad hoc monitoring of a serious cross-border threat to health referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) and (d) of Article 2(1).

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, the ECDC, 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 operational 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 when strictly necessary for the purpose for which it was transmitted, through the EWRS selective messaging functionality, in accordance with Article 26.

   Taking into account Member States' opinions, 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 or by the Union, used for the purpose of combating serious cross border health threats. The ECDC, in close cooperation with Member States, shall facilitate the interoperability with national systems for the purposes of the early warning and response system.

   The ECDC shall also provide technical assistance to the competent authorities responsible at national level, including training following updates to the EWRS platform.

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 in accordance with paragraphs 1 and 2, as well as Articles 19 and 20.

4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union and international 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 , in a coordinated One Health approach.

   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, as referred to in Article 18(2b), and in the absence of full interoperability between the WHO notification system and the EWRS, national competent authorities shall 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 including multisectoral measures;

(i) urgent need or shortage of medical countermeasures;

(j) requests and offers for cross-border emergency assistance, such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions;

(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.

4a. The Member State shall update the information referred to in paragraph 3 as new data become available.

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) …/…[6] 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 potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

   (aa) the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2021/...[7] where the threat is linked to medicinal products and medical devices;

   (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 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 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

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6 [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]]

7 insert the number of revised EMA regulation 2020/0321(COD)]

(d) the European Environment Agency (EEA) in accordance with Regulation (EC) No 401/2009 of the European Parliament and of the Council 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 Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council 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 referred to in Article 3 of Regulation (EU) 2016/794, and in cooperation 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. Processing of personal data, whenever applicable, shall be carried out in accordance with data protection requirements as laid down in Article 25a.

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 to the HSC, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it 24 hours prior to its publication, unless grounds of urgency and necessity require the immediate publication of the risk assessment.

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 consult each other and 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, to healthcare professionals and public health professionals;

(c) the adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threats to health, based on the expert opinion of relevant technical Union bodies or agencies;

(d) the support to the EU's integrated political crisis response mechanism (IPCR) in case of its activation.

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting or ceasing those measures, inform, consult and coordinate with the other Member States, in particular neighbouring Member States, 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, promptly upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures especially in cross-border regions.

3a. If necessary, in the event of a serious cross-border threat to health, Member States may request assistance from other Member States through the ERCC provided for in Decision No 1313/2013/EU of the European Parliament and of the Council[8].

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).

[8] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism.

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.

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

   (a) be based on in particular recommendations of the ECDC and the WHO, 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 necessary, suitable and 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, and promote coordination of measures between Member States;

   (d) be made available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alerts systems. Where the recommendation is to be made public, the national competent authorities shall receive it 24 hours prior to its publication, unless the need is so urgent that the immediate publication of the recommendation is necessary.

CHAPTER V

PUBLIC HEALTH EMERGENCY AT UNION LEVEL

Article 23

Recognition of public health emergency situations at Union level

1. For serious cross-border threats to health referred to in Article 2(1), the Commission may, after considering any expert opinion issued by ECDC, any other relevant agencies or bodies and 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 the applicable condition pursuant to paragraph 1 is no longer met.

3. Before recognising a situation of public health emergency at Union level, the Commission shall 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 at Union level 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. To support the decision making process on 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 or the Health Security Committee, 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) 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. The advice on response provided under point (c) of this paragraph shall build upon recommendations of the ECDC, the EMA, the WHO and other relevant agencies or bodies, as appropriate.

2. The Advisory Committee shall be composed of independent experts, who might include representatives of healthcare and social care workers and civil society representatives, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring and include representatives of the ECDC and the EMA as permanent observers. The Committee shall have multidisciplinary membership so it can advise on public health, biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the WHO may also participate as observers in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat may participate as non permanent 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, in particular from the countries within whose territory the threat arises. The Member States may propose the appointment of relevant experts to the Commission, according to the specific subject matter.

2a. The Commission shall publish the information about the Advisory Committee in accordance with the rules of the European Commission on expert groups (*Add reference*) publish the names of the experts selected to form part of the Advisory Committee and details of the professional and/or scientific backgrounds that justify their appointment. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment.

2b. Where applicable, the Advisory Committee shall act in coordination, with the Health Crisis Board, where it is established in accordance with the Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures.

3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission, the Health Security Committee or a Member State. The Commission shall share all relevant information about the Advisory Committee's meetings with the Member States through the HSC.

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 adoption of opinions and recommendations, voting and ensuring data protection and privacy. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission. The minutes of the Advisory Committee shall be public.

Article 25

Legal effects of recognition

1. The recognition of a public health emergency at Union level pursuant to Article 23 shall have the legal effect of enabling the introduction of the following non-exhaustive measures:

   (a) measures, which are applicable during the period of public health emergencies, related to medicinal products and medical devices provided for in Regulation (EU) …/… [9];

   (b) mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures, in accordance with Article 12 of this regulation and with the applicable Union legislation, in particular Regulation (EU) …/…[10], and with the Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level;

   (c) activation of support from the ECDC as referred to in Regulation (EU) …/… [11] to mobilise and deploy the EU Health Task Force;

   (d) activation of IPCR mechanism as referred to in Council Decision 2014/415/EU.

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9 [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]];

10 [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]]

11 [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]]

CHAPTER VI

GENERAL PROVISIONS

Article 25a

Transparency and conflict of interest

1. The Health security committee, referred in article 4 and the Advisory committee on public health emergencies referred in article 24 shall carry out their activities in an independent, impartial and transparent manner and shall undertake to act in the public interest.

2. Representatives appointed to Health security committee and to the Advisory Committee on public health emergencies and, where relevant, observers, shall not have any financial nor other interests which might be considered prejudicial to their independence.

3. The representatives and, where relevant, observers, shall make a declaration of their financial and other interests and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith judgment reasonably be expected to involve or give rise to a conflict of interest.

4. Representatives who participate in meetings of the Health security Committee and of the Advisory Committee on public health emergencies and, where relevant, observers, shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda.

5. Where the Commission decides that a declared interest constitutes a conflict of interest, that representative shall not take part in any discussions and decisions, nor obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.

6. Representatives to the Health security committee and to the Advisory committee on public health emergencies, and, where relevant, observers, shall be subject to requirements of professional secrecy, even after their duties have ceased.

Article 25b

Personal data protection

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC, or the obligations of the Union institutions, bodies, and agencies relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.

2. The Commission and, where applicable, other Union institutions and bodies shall not process personal data except in cases where this is necessary for the fulfilment of their mission. Where appropriate, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

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 contact tracing measures and medical evacuation procedures. 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 or medical evacuation procedures 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 or medical evacuation measures.

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

4. The selective message functionality shall be used solely for the purpose of contact tracing and medical evacuation. It shall only allow national competent authorities to receive data that were sent to them by other national competent authorities. The ECDC shall only access the data for ensuring the good functioning of the selective message functionality. Messages containing personal data shall automatically be erased from the selective message functionality 14 days after the date of their posting at the latest.

5. When necessary for the purpose of contact tracing, personal data may also be exchanged using contact tracing technologies. The national competent authorities shall not retain the contact data and health data received through the selective message functionality for longer than the retention period applicable in the context of their national contact tracing activities.

6. The Commission shall, by means of delegated 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 including the respective responsibilities of the competent authorities at national level and the ECDC;

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

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

   (a) Procedures for the interlinking of the EWRS with contact tracing systems at Union level and international levels.

   (b) the modalities for processing contract tracing technologies 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, in full compliance with the EUDPR and applicable case law of the Court of Justice;

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 27a

Cooperation with WHO

The Union shall establish a framework for enhanced cooperation with the WHO, in particular as regards reporting and reviewing activities.

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 Articles 8(3), 14(7) and 26(6) 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 Articles 8(3), 14(7) and 26(6) 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 Articles 8(3), 14(7) and 26(6) 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 28a

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 28(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 29

Evaluations concerning this Regulation

By 2024 and every 5 years at the latest, the Commission shall carry out an evaluation of this Regulation and present a report on the main findings of that review to the European Parliament and the Council. 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[in] the HSC.

The evaluation referred to in paragraph 1 shall also include an evaluation of the Commission's work in preparedness and response activities under this Regulation including, where relevant, a review of the implementation of this Regulation by HERA, as well as an assessment of the need to establish HERA as a distinct entity, considering relevant agencies or authorities active in the field of health preparedness and response. The Commission shall, if appropriate, present legislative proposals based on this evaluation in order to amend this Regulation or make further proposals.

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

The President

For the Council

The President

ANNEX

Section 1

Criteria for selection of communicable diseases and related special health issues to be covered by epidemiological surveillance within the network

EU/EEA surveillance should provide information for public health action at EU/EEA level. More specifically, one of the following criteria should be met:

1. Significant morbidity or significant mortality or emerging disease (increasing 5-year trend) in a sizeable fraction of Member States;

2. Potential to cause cross-border outbreaks;

3. High-threat pathogen (transmissibility and severity);

4. Specifically targeted national or EU public health programmes in place that require monitoring and evaluation;

5. EU/EEA surveillance adds public health value to national surveillance systems other than what is implied in criteria 1-4

Section 2

Criteria used for the definition and classification of the cases

1. Clinical criteria

2. Laboratory criteria

3. Epidemiological criteria

Classification of the cases

1. Possible case

2. Probable case

3. Confirmed case

Section 3

Procedures for the operation of the epidemiological surveillance network

The terms of procedures of the epidemiological surveillance network would cover at least the following points:

1. Membership and appointment

2. Terms of reference (detailing responsibilities of the national representatives and the ECDC secretariat of the network including roles and tasks)

3. Administrative (e.g. related to convening of meetings and decision-making) and technical work procedures (e.g. related to data reporting mechanisms, tools and platforms, data analysis and dissemination)

4. Mechanism for periodic evaluation/review of the administrative and technical work procedures