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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	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

Delegations will find enclosed the four-column table on the above-mentioned proposal.

This document contains in Annex A the explanations on the layout of the table used in this document and, in Annexes B and C, the changes to the draft Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU

ANNEX A

Explanation of the table layout[1]

Item	Article/ Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
1 item is unchanged compared to the previous document		Plain text in this column is text from the Commission proposal. ***Text in bold italics in this column is text from the Commission proposal that the EP proposes to delete.***	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.*** When an empty cell in this column is on the same row as a Commission proposal, it means that that text was not changed by the EP.	Plain text in this column is text from the Commission proposal that Council wishes to maintain. **Text in bold underlined** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	*This column contains comments, compromise proposals and tentatively agreed text.*

[1] For the sake of readability this document does not contain footnotes. The footnotes will be reintroduced in the consolidated compromise text at the end of the negotiation process.

ANNEX B

Citations and Recitals

This Annex contains the Citations and Recitals in the 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. For explanations of layout and fonts see Annex A.

Item	Citation / Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
1	Citations	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
2		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,	
3		Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	
4		After transmission of the draft legislative act to the national parliaments,		After transmission of the draft legislative act to the national parliaments,	
5		Having regard to the opinion of the European Economic and Social Committee,		Having regard to the opinion of the European Economic and Social Committee,	
6		Having regard to the opinion of the Committee of the Regions,		Having regard to the opinion of the Committee of the Regions,	

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7 8		Acting in accordance with the ordinary legislative procedure, Whereas:		Acting in accordance with the ordinary legislative procedure, Whereas:	
9	Recital 1	(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.		(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.	
10	Recital 1 a (new)		**Amendment 1** ***(1a) The health provisions of the Treaties are still largely under-used in terms of the purposes they were designed to achieve. This Regulation should therefore be aimed at making the best possible use of such health provisions, in order to demonstrate the strength of the Union's health policy, while***		

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			preserving the normal functioning of the single market in the event serious cross-border threats to health arise		
11	Recital 2	(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation ***by*** Member States ***with*** the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross- border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of	**Amendments 2 and 244** (2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide ***prevention of***, preparedness and response to all cross-border threats to health***, including zoonotic-related threats***, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation ***between*** Member States ***and Union agencies, particularly*** the European Centre for Disease Prevention and Control (ECDC***), the Health Emergency Preparedness and Response Authority (HERA), the European Medicines Agency (EMA), and international organisations, in particular the World Health Organization (WHO***). Moreover, in order to ensure effective Union response to novel cross- border threats to health, the legal framework to	(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision ~~No~~ 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the ~~European Centre for Disease Prevention and Control~~ **(**ECDC**)**. Moreover, in order to ensure ~~effective~~ Union**'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 ~~and~~ **as well as it** should provide for the establishment of a network of EU reference laboratories and a network to support monitoring	

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		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.	combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies***, while respecting Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR')***. _____ ***[1a] 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).***	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.	
12	Recital 2 a (new)		**Amendment 245** (***2 a) The HERA was set up to strengthen the Union's ability to prevent, detect and rapidly respond to cross-border health threats, by ensuring the supply of crisis-***		

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			relevant medical countermeasures, including through their monitoring, procurement and purchase, by activating emergency research and innovation plans, providing emergency funding and financing, and by taking measures concerning the production, availability and supply of such key medical countermeasures.		
13	Recital 2 b (new)		**Amendment 246** ***(2 b) All such public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures should be transparent.***		
14	Recital 3	(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border	**Amendment 3** (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	(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border	

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		threats to health.	health, ***and support better coordination between Member States to address those threats***. ***Representatives designated by the European Parliament should be able to participate in the HSC as observers.***	threats to health.	
15	Recital 3 a (new)		**Amendment 247** ***(3 a) In order to avoid duplication of efforts and to have coherence in decisionmaking at Union level, the HSC should closely cooperate with the HERA Board, established under the Commission Decision of 16 September 2021, the Health Crisis Board, established under a 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, and other relevant Union agencies and bodies, to ensure that effective preparedness and response mechanisms are in place for health emergencies.***		
16	Recital 4	(4) A joint opinion issued by the European Commission's Group of Chief Scientific Advisors, the European Group on Ethics in Science and New Technologies , and the Special Advisor to the President of the		(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	

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		European Commission on the response to COVID-19 recommends 'establishing a standing EU advisory body' for health threats and crises.		President of the European Commission on the response to COVID-19 recommends 'establishing a standing EU advisory body' for health threats and crises.	
17	Recital 4 a (new)		**Amendment 4** ***(4a) Prevention and promotion strategies concern all sectoral policies including fiscal, commercial, economic, agro-environmental, educational, housing, cultural and relating to social assistance. 'Health in all Policies' should be a principle of all public policies. An instrument already used at the national level to assess the health impact of the different sectoral policies is the so-called Health Test. A Health impact assessment should be undertaken for all programmes managed by the Union.***		
18				***(4a)*** **It is understood that all recommendations, advices, guidance and opinions mentioned in this Regulation, are inherently non-binding. A recommendation allows 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**	

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				whom it is addressed.	
19	Recital 5	(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.	**Amendment 5** (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.	(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.	
20	Recital 5 a (new)		**Amendment 242** ***(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***		

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			linked, it is crucial to respect the principles of the 'One Health' approach to address current and emerging crises.		
21	Recital 6	(6) ***The*** protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered	**Amendment 6** (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***. The Union should support Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage and in addressing the challenges of vulnerable groups. The Union should also urge Member States to implement the health-specific country-specific recommendations and support Member States 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, such as health professionals, patient associations, industry and supply chain actors***,	(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered	

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		and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.	should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. ***Those mechanisms should look for synergies between Union and national measures, while seeking to avoid duplicating measures undertaken in the context of the WHO framework.*** In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.	and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC **of the European Parliament and of the Council.**	
22	Recital 7	(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to	**Amendment 7** (7) ***Prevention,*** preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to	(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to	

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		health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and ***knowledge exchange activities*** for healthcare staff and public health staff ***should be provided*** knowledge and necessary skills ***should be provided by the Commission and Union Agencies***. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.	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. ***The plans should be implemented through interregional crisis anticipation planning with particular attention paid to cross-border regions to enhance their health cooperation. Where appropriate, regional authorities should participate in the drawing up of these plans.*** To support Member States in this endeavour, ***the Commission and 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 ***ensure*** necessary skills. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should ***include recommendations for policy interventions related to mitigating the impact of communicable diseases on health services and care, including on major non-***	health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and **the relevant** Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. ~~Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission must be kept informed of all updates.~~	

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			communicable diseases (NCDs). The plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation***. Specific considerations should be given to border regions, where joint cross-border exercises should be promoted and health practitioners encouraged to gain familiarity with the public health systems in neighbouring countries***. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.		
23	Recital 8	(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)[15]. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness,	**Amendment 8** (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)[15]***. Access to timely and complete data is a precondition for rapid risk assessments and***	(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness,	

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		response planning and implementation at Union level, including on corrective actions, every ***2 years*** to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.	***crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and fluid information exchanges should take place 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 corrective actions, every ***year*** to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical ***long-term healthcare and 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	response planning and implementation at Union level, ~~including on corrective actions,~~ every two years to ensure that national preparedness and response plans are adequate. ~~In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies.~~ Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning**, through a One Health approach**.	

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			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.		
24	Recital 8 a (new)		**Amendment 9** ***(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 mandatory cross-border training for healthcare staff and coordination exercises for the medical transfer of patients. The Commission should regularly report on the state of play of cross-border crisis preparation in neighbouring regions.***		
25	Recital 8 b (new)		**Amendment 10** ***(8b) The role of frontline***		

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			health professionals has also become apparent during the pandemic as they have been key to ensuring access to medicine and continuity of care, providing moral support and being a source of trusted information against false information. For future emergencies, it is necessary to strengthen the knowledge of health professionals by laying down rules to provide training for workers in the fields of health care and public health. It is also necessary to integrate them through their professional organisations in the definition of public health policies as well as in the digital transformation in order to improve the quality and efficiency of health systems and ensure their sustainability for the health, social and territorial cohesion work they carry out.		
26	Recital 8 c (new)		**Amendment 11** ***(8c) 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. Respiratory etiquette, correct hand washing, avoiding unnecessary close contact with anyone with flu-***		

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			like symptoms, and avoiding unprotected contact with wild animals should be part of health education campaigns to improve the population's behaviour, based on the latest available evidence.		
27	Recital 8 d (new)		**Amendments 12 and 248** ***(8d) 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 Union emergency situation would trigger increased coordination and allow for timely development, stockpiling and joint procurement of medical countermeasures, under the umbrella of the HERA.***		
28	Recital 8 e (new)		**Amendment 13** ***(8e) This Regulation also ensures coordinated action at Union level, in order to ensure that the internal market functions properly, and to ensure that basic supplies, including medicines, medical products and personal protective equipment (PPE) circulate freely.***		
29	Recital 8 f (new)		**Amendment 14** ***(8f) Health logistics mechanisms should meet the***		

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			specific legal requirements of Directive 2001/83/EC of the European Parliament and of the Council[1a] and Regulation (EU) 2017/745 of the European Parliament and of the Council[1b]. _____ ***[1a] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. (OJ L 311, 28.11.2001, p. 67).*** ***[1b] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. (OJ L 117, 5.5.2017, p. 1).***		
30	Recital 9	(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement,	**Amendments 15 and 249** (9) 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. The*** joint procurement of medical countermeasures should***, therefore,*** be extended to include European Free Trade Association	(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. ~~The Joint Procurement Agreement,~~	

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		determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council[16]. _____ [16] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).	States and Union candidate countries, ***the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State,*** in accordance with the applicable Union legislation***. Joint procurement of medical countermeasures would strengthen the negotiating position of participating countries, improve the security of supply and ensure equitable access to medical countermeasures. Joint procurement procedures, including purchases coordinated by the HERA and related emergency funding programmes, such as rescEU, should abide by high standards of transparency, including in relation to the disclosure of the amounts ordered by and delivered to each participating country and details of their liabilities***. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow	~~determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU.~~ The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council **on a Union Civil Protection Mechanism**.	

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			for better coordination within the EU. The ***exclusivity clause should entail that countries participating in the joint procurement procedure do not negotiate and sign parallel contracts with producers, and define clear consequences for those that do. 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 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, and the*** strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council***. The Member States should ensure a sufficient reserve of critical medical products to counter the risk of shortages of critical products***.		
31	Recital 9a (new)		**Amendment 16** ***(9a) Joint procurement should***		

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			be based on shared responsibilities and a fair approach with rights and obligations for all parties involved. Clear commitments should be provided and respected, with manufacturers delivering the agreed production levels and the authorities purchasing their agreed reserved volumes.		
32				**9a) It is understood that joint procurement of medical countermeasures can be exclusive or a non-exclusive depending on the agreement of theMember State,praticipating in the specific procurement. In addition, small countries like Andorra, Monaco, San Marino and the Vatican State City, highly rely on the EU to access medical countermeasures in a health emergency context. 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 therefore also be extended to Andorra, Monaco, the Vatican State and San Marino.**	
33	Recital 9 b (new)		**Amendment 17** ***(9b) In times of crisis, temporary measures should be introduced by the Commission to***		

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			mitigate shortages and facilitate the circulation of medicines between Member States, including the acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, extending the validity of good manufacturing practices certificates, longer expiry periods, and the use of veterinary medicinal products. The Commission should strictly monitor the use of such measures, to ensure that patient safety is not compromised and to keep medicines available in the event of difficulties or shortages.		
34	Recital 9 c (new)		**Amendment 18** ***(9c) Joint procurement should be carried out in a transparent, timely and effective way. In this respect, clear and transparent stages for the process, scope, tender, specifications, timelines and formalities should be defined. A preliminary consultation phase, subject to adequate safeguards against conflict of interest and asymmetry of information, involving relevant actors should be guaranteed, as well as two-way communication throughout the procedure.***		

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35	Recital 9 d (new)		**Amendment 19** ***(9d) The Commission should pay special attention to ensuring that joint procurement of medical countermeasures within the meaning of Article 12 also includes procurement of orphan drugs.***		
36	Recital 9 e (new)		**Amendment 20** ***(9e) If joint procurement is deployed, the awarding process should take into account qualitative criteria, such as the ability of the manufacturer to ensure security of supply during a health crisis, as well as price.***		
37	Recital 9 f (new)		**Amendment 21** ***(9f) In order to achieve transparency, the European Parliament should scrutinise contracts concluded under the Joint Procurement Procedure. The Commission should provide to the Parliament complete, timely and accurate information on the ongoing negotiations and give access to the tender documents as well as to the contracts concluded.***		
38	Recital 9 g (new)		**Amendment 22** ***(9g) Where a joint procurement procedure has not***		

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			been used to purchase medical countermeasures, the Commission should encourage Member States to exchange information on pricing and delivery dates of medical countermeasures, to provide an increased level of transparency and thus allow Member States to access and negotiate medical countermeasures in more equitable conditions.		
39	Recital 9 h (new)		**Amendment 23** ***(9h) In times of crisis, other mechanisms should be used to enable global response and crises mitigation. Such mechanisms could, for example, include a Union export control mechanism, enhanced cooperation agreements on the production of medical countermeasures, pre-allocating part of the Union joint procurement, and both voluntary and compulsory technology know-how pools and licensing agreements between companies, which should facilitate access to counter-measures for people, including those in Eastern Partnership and low- and middle-income countries.***		
40	Recital 10	(10) Unlike for communicable	**Amendment 24** (10) Unlike for communicable	(10) Unlike for communicable	

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		diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats.	diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats. ***Nevertheless, the ECDC should have the ability to monitor the impact of communicable diseases on major non-communicable diseases, including mental diseases, assessing the continuity of screening, diagnosis, monitoring, treatment and care in the healthcare system, in coordination with existing data sets, tools and registers.***	diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other ~~potentially~~ serious cross-border threats to health do not currently necessitate **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.	
41	Recital 11	(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as	**Amendments 25 and 250** (11) The Commission***, in particular the HERA,*** 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	(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other EU Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as	

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		antimicrobial resistance.	preventable diseases, as well as other health issues, such as antimicrobial resistance***, and other major non-communicable diseases. During health crises, particular attention should be paid to the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions, and to the mental health implications of the crisis and psychosocial needs of the population.***	antimicrobial resistance.	
42	Recital 12	(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The	**Amendment 26** (12) In case of cross-border health threats due to a communicable disease, the blood and transplant services***, pharmacies and other licensed health care establishments*** in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin or ***undergoing a process of medically assisted reproduction*** from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting	(12) In case of cross-border health threats due to a communicable disease, ~~the blood and transplant services in the Member~~ States ~~can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the~~ ECDC **shall cooperate with Member States** to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. ~~Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such~~	

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		ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.	standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities***, as well as pharmacy services and other licensed health services and establishments,*** to serve this dual purpose.	~~substances of human origin.~~ The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this ~~dual~~ purpose.	
43	Recital 12 a (new)		**Amendments 27 and 251** ***(12 a) In order to improve early preparedness for, and response to, the emergence of cross-border health threats, it is crucial to enable continuous and rapid access to data on the availability of the necessary medical counter measures. Therefore, a network of Member States' services providing up-to-date information on national strategic stockpiles and the availability of medical countermeasures, stockpiles of medical products, essential health products and diagnostic tests should be established, operated and coordinated at Union level by the HERA. Strengthening coordination and exchange of information with Member States on strategic stockpiles and medical countermeasures available is necessary to enhance the collection, modelling and use of prospective data that allow***		

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			early alert notifications in the Union.		
44	Recital 13	(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the	**Amendment 28** (13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are ***fully interoperable and, subject to human oversight, automatically*** linked to each ***other to*** the extent possible so that the competent authorities of the	(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the	

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		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.	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.	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.	
45	Recital 14	(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.	**Amendment 29** (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. ***In order to achieve a sufficient degree of expertise and effectiveness, the financial and***	(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.	

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			human resources of Union agencies and bodies should be increased.		
46	Recital 14 a (new)		**Amendments 30 and 252** ***(14 a) Member States, the Commission, in particular the HERA, and Union agencies, while applying the One Health approach, should identify recognised public health organisations and experts, both in the area of communicable and major non-communicable diseases, 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 structurally engaged throughout all crisis response activities and contribute 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***		

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47	Recital 14 b (new)		**Amendment 31** ***(14b) Green lanes should only be considered as an appropriate tool for pandemic situations of a declared public health emergency where they are aimed at ensuring that essential goods, medical countermeasures and cross border workers circulate freely and safely within the internal market. The creation of green lanes in such situations should not affect the relevant treaty provisions or legislation regulating border controls.***		
48	Recital 15	(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		(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	

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		European Union such as those related to free movement of persons, goods and services.		European Union such as those related to free movement of persons, goods and services.	
49	Recital 15 a (new)		**Amendment 32** ***(15a) The Commission should ensure that, at the time of the declaration of a state of emergency, the number of accommodation facilities in hospitals in the Member States, as well as the number of available accommodation units in intensive care units in the Member States, are known, for the purpose of cross-border movement of patients.***		
50	Recital 16	(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.		~~(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**	

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				reinforced in order to ensure better follow-up of HSC's work at national level.	
51	Recital 16 a (new)		**Amendment 33** ***(16a) Regular dialogue and exchange of information between authorities, industry, relevant entities of the pharmaceutical supply chain, healthcare professionals' and patients' organisations should also be ensured, in order to start early discussions about expected potential serious cross-border threats to health in the market, by way of sharing information about expected supply constraints or raising specific clinical needs, thereby allowing better coordination, synergies and appropriate reaction when needed.***		
52	Recital 17	(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid	**Amendment 34** (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	(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid	

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		information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council.	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***. In those Member States with regions having health competences, those regions should provide this information***. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals***. Following its recommendations to Member States and healthcare professionals, the ECDC should broaden its communication activity to include the general public by establishing and managing an online portal to share verified information and fight against disinformation***. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council.	information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the **EU** ~~Union~~ Civil Protection **Community** ~~Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council~~.	
53	Recital 18	(18) The recognition of public	**Amendments 35 and 253** (18) The recognition of public	(18) The recognition of public	

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		health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from	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, ***representatives of health and care workers, including nurses and medical doctors, and representatives of civil society,*** selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, ***of the HERA*** and of other Union bodies or agencies as observers***. All members of the Advisory Committee should provide declarations of interest. The advisory committee should work in close cooperation with***	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 advice on public health response measures and views on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the **Member States,** ECDC, of EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support	

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		the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.	***national advisory bodies***. 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, ***Union export control mechanisms,*** flexible mechanisms to develop, procure, manage and deploy medical countermeasures ***through the HERA*** as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'. ***The recognition of a public health emergency may trigger the activation of the framework set out in a 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. That framework should remain operational for an initial period of 6 months, renewable as long as the public health emergency exists.***	from the ECDC to mobilise and deploy outbreak assistance teams, known as 'Health Task Force'.	
54	Recital 19	(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		(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	

Item	Citation / Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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.		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.	
55	Recital 20	(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, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.	**Amendment 36** (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 or potentially*** 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. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.	(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, between those Member States directly involved in the contact-tracing measures. ~~The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.~~	
56	Recital 21		**Amendment 37**		

Item	Citation / Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the	(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 (TESSy),*** and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and	(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the	

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		research response.	collaboration on response coordination, including the research response. ***The Commission and the Member States should actively work towards the establishment of a WHO framework convention on pandemic preparedness and response, which should lay down principles and priorities for pandemic preparedness and response. Such a framework convention should facilitate the implementation of the International Health Regulations (2005)[1a] and should support the strengthening of the international health framework and the improvement of cooperation with regard to early detection, prevention, response and resilience in respect of future pandemics.*** _____ ***[1a] World Health Organisation International Health Regulations (2005) Third Edition available at https://www.who.int/publications/i/item/9789241580496***	research response.	
57	Recital 22	(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European	**Amendment 38** (22) ***Due to the sensitive nature of health data, Member States, the Commission and Union agencies should safeguard and guarantee that their processing operations respect the***	(22) ~~The~~ **Any** processing of personal data for the purpose of implementing this Regulation should ~~comply~~ **be fully compliant** with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of	

Item	Citation / Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		Parliament and of the Council[19]. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.	***data protection principles in accordance with Article 5 of the GDPR.*** The processing of personal data for the purpose of implementing this Regulation should comply with the GDPR and Regulation (EU) 2018/1725 of the European Parliament and of the Council. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing***. Regulation (EU) 2018/1725 of the European Parliament and of the Council should be strictly respected and appropriate technical and organisational security*** measures***, in accordance with that Regulation, should be put in place***.	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 to relevant authorities involved in contact tracing measures. **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.**	
58	Recital 22a (new)			**(22a) Overlap of reporting and reviewing activities with existing structures and mechanisms on preparedness**	

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				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, the Union should further enhance its cooperation with the WHO, in particular under the International Health Regulations' reporting, monitoring and evaluation frameworks.	
59	Recital 23	(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.		(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.	
60	Recital 24	(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		(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	

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		the relevant competent authorities in the implementation of this Regulation.		the relevant competent authorities in the implementation of this Regulation.	
61	Recital 25	(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** ***establishment and update of a list of relevant health data to be automatically collected by digital platform; the functioning of the***	**Amendment 39** (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 ***procedures for the operation of the*** network of epidemiological surveillance; the designation of EU reference laboratories to provide support to national ***and regional*** 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	(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	

Item	Citation / Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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.	accordance with the data protection legislation.	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. **Furthermore, implementing powers should be conferred on the Commission in order to ensure compliance with the obligations stemming from the EU data protection legal framework, in particular insofar as the roles and responsibilities of the parties involved in the different bodies set up by this Regulation are clearly defined. The European Data Protection Supervisor should be consulted during the preparation of the implementing act, pursuant to Regulation 2018/1725.**	
62	Recital 26	(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		(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	

Item	Citation / Recital Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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.		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.	
63	Recital 27	(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.		(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.	
64	Recital 28	(28) In order to ascertain the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission ***in respect of*** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during	**Amendment 40** (28) ***In order to supplement certain aspects of this Regulation and*** to ascertain the state of implementation of the national ***and regional*** 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: the establishment and updating of a list of communicable diseases and related special health issues subject to the network of***	~~(28) In order to ascertain the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during~~	

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		its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[21]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	***epidemiological surveillance; 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 that are the subject of ad hoc monitoring; the requirements necessary to ensure the compliance of the operation of the EWRS and the processing of data with the relevant Regulations; the establishment and updating of a list of relevant health data to be automatically collected by a digital platform, subject to human oversight; the functioning of the surveillance platform; and the*** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national ***and regional*** level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[21]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the	~~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.~~	

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			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.		
65	Recital 28 a (new)		**Amendment 41** ***(28a) In respect of the establishment and updating 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 the case definitions to be used for ad hoc monitoring, the Commission should adopt delegated acts under the urgency procedure where 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 between the Member States so require.***		
66	Recital 29	(29) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU)		(29) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU)	

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		No 2018/1725 and has adopted an opinion.		No 2018/1725 and has adopted an opinion.	
67	Recital 30	(30) This Regulation fully respects the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union.		(30) This Regulation fully respects the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union.	
68	Recital 31	(31) Decision No 1082/2013/EU should therefore be repealed and replaced by this Regulation,		(31) Accordingly, Decision No 1082/2013/EU should therefore be repealed and replaced by this Regulation,	
69		HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	

ANNEX C

Articles

This Annex contains the Articles in the 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. For explanations of layout and fonts see Annex A.

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
70	CHAPTER I	**CHAPTER I**		**CHAPTER I**	
71		**GENERAL PROVISIONS**		**GENERAL PROVISIONS**	
72 73	Article 1	*Article 1* **Subject matter**		*Article 1* **Subject matter**	
74	Article 1 – paragraph 1	1. In order to address serious cross border threats to health and the consequences thereof, this Regulation lays down rules on:		1. In order to address serious cross border threats to health and the consequences thereof, this Regulation lays down rules on:	
75	Article 1 – paragraph 1- point a	(a) the health security committee		(a) the **H**~~h~~ealth **S**~~s~~ecurity **C**~~c~~ommittee	
76	Article 1 – paragraph 1 - point b	(b) preparedness and response planning, including:		(b) preparedness and response planning, including:	
77	Article 1 –	(i) preparedness plans at		(i) preparedness plan~~s~~ at	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	paragraph 1 - point b- point i	Union and national levels;		Union ~~and national~~ levels;	
78	Article 1 – paragraph 1 - point b - point ii	(ii) reporting and auditing on preparedness;		(ii) reporting and **examining** ~~auditing~~ on preparedness **at national level**;	
79	Article 1 – paragraph 1 - point c	(c) joint procurement of medical countermeasures;	**Amendment 42** (c) joint procurement***, management and deployment*** of medical countermeasures;	(c) joint procurement of medical countermeasures;	
80	Article 1 – paragraph 1 – point c a (new)		**Amendment 254** ***(c a) emergency research and innovation plans, including clinical trial networks and innovation platforms;***		
81	Article 1 – paragraph 1 – point d	(d) epidemiological surveillance and monitoring;		(d) epidemiological surveillance and monitoring;	
82	Article 1 – paragraph 1 – point e	(e) the network for epidemiological surveillance		(e) the network for epidemiological surveillance;	
83	Article 1 – paragraph 1 – point f	(f) the early warning and response system;		(f) the early warning and response system;	
84	Article 1 – paragraph 1 – point g	(g) risk assessment;		(g) risk assessment;	
85	Article 1 – paragraph 1 –	(h) coordination of response;		(h) coordination of response;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point h				
86	Article 1 – paragraph 1 – point i	(i) recognition of a public health emergency situation at Union level.		(i) recognition of a public health emergency situation at Union level.	
87	Article 1 – paragraph 2	2. This Regulation establishes:		2. This Regulation establishes:	
88	Article 1 – paragraph 2 – point a	(a) a network of EU reference laboratories for public health;		(a) a network of EU reference laboratories for public health;	
89	Article 1 – paragraph 2 – point b	(b) a network for substances of human origin;		(b) a network for substances of human origin;	
90	Article 1 – paragraph 2 – point b a (new)		**Amendment 43** ***(ba) a network of national strategic stockpiles and available medical countermeasures;***		
91	Article 1 – paragraph 2 – point c	(c) an advisory committee for the occurrence and recognition of emergency situation at Union level.		(c) an advisory committee for the occurrence and recognition of emergency situation at Union level.	
92	Article 1 – paragraph 3	3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.	**Amendment 44** 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. ***The strengthened Union health***	3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			framework addressing serious cross-border health threats shall 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).		
93	Article 1 – paragraph 3 a (new)		**Amendment 45** ***3a. This Regulation shall ensure that in future health emergencies, the detection of, health interventions concerning and treatment of other serious diseases are not halted.***		
94	Article 1 – paragraph 3 b (new)		**Amendment 46** ***3b. This Regulation shall be implemented with full respect for the dignity and fundamental rights and freedoms of persons.***		
95 96	Article 2	*Article 2* **Scope**		*Article 2* **Scope**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
97	Article 2 – paragraph 1	1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:		1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:	
98	Article 2 – paragraph 1 – point a	(a) threats of biological origin, consisting of:		(a) threats of biological origin, consisting of:	
99	Article 2 – paragraph 1 – point a –point i	(i) communicable diseases;	**Amendment 243** (i) communicable diseases***, including those of zoonotic origin***;	(i) communicable diseases;	
100	Article 2 – paragraph 1 – point a –point ii	(ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter 'related special health issues');		(ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter 'related special health issues');	
101	Article 2 – paragraph 1 – point a –point iii	(iii) biotoxins or other harmful biological agents not related to communicable diseases;		(iii) biotoxins or other harmful biological agents not related to communicable diseases;	
102	Article 2 – paragraph 1 – point b	(b) threats of chemical origin;		(b) threats of chemical origin;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
103	Article 2 – paragraph 1 – point c	(c) threats of environmental or climate origin;		(c) threats of environmental **(including due to** ~~or~~ climate**)** origin;	
104	Article 2 – paragraph 1 – point d	(d) threats of unknown origin;		(d) threats of unknown origin;	
105	Article 2 – paragraph 1 – point e	(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).		(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).	
106	Article 2 – paragraph 2	2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases ***and of*** related special health issues.	**Amendment 47** 2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases***, the monitoring of the impact of such diseases on major non-communicable diseases and on*** related special health issues***, such as mental health, and the impact on deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions***.	2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
107	Article 2 – paragraph 3	3. The provisions of this Regulation are without prejudice to provisions of other Union acts governing specific aspects of monitoring, early warning of, the coordination of preparedness and response planning for, and the coordination of, combatting serious cross-border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.		3. The provisions of this Regulation are without prejudice to provisions of other Union acts governing specific aspects of monitoring, early warning of, the coordination of preparedness and response planning for, and the coordination of, combatting serious cross-border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.	
108	Article 2 – paragraph 3 a (new)		**Amendment 48** ***3a. This Regulation shall promote the implementation of the International Health Regulations, reduce administrative burden and duplication of resources, and strengthen the gaps exposed during the COVID-19 pandemic in the prevention of, preparedness for and response to public health threats.***		
109	Article 2 – paragraph 4	4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred	**Amendment 49** 4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred	4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the **Health Security Committee** ~~HSC~~ as referred to in Article 21, for serious cross-border threats to	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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.	to in Article 2(1), ***especially in relation to major non-communicable diseases,*** if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.	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.	
110	Article 2 – paragraph 5	5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.	**Amendment 50** 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 preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.	5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.	
111	Article 2 – paragraph 6	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	**Amendment 51** 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	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	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.	conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation. ***The Union shall call for the establishment of a WHO framework convention on pandemic preparedness and response. That convention shall be such as to facilitate the implementation of the International Health Regulation (2005)[1a] and resolve the weaknesses of that Regulation, identified during the COVID-19 crisis.*** _____ ***[1a] World Health Organisation International Health Regulations (2005) Third Edition available at https://www.who.int/publications/i/item/9789241596664/en/***	conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.	
112	Article 2 – paragraph 6 a (new)		**Amendment 52** ***6a. This Regulation shall also apply, where appropriate, to regional competent authorities, systems and programmes in the fields covered by this Regulation.***		
113	Article 3	*Article 3*		*Article 3*	
114		**Definitions**		**Definitions**	
115		For the purposes of this Regulation, the following		For the purposes of this Regulation, the following	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		definitions shall apply:		definitions shall apply:	
116	Article 3 – paragraph 1 - point -1 (new)		**Amendment 255** ***(-1) 'public health emergency' means a public health emergency at Union level recognised by the Commission based on an opinion of the Advisory Committee in accordance with Article 23 of this Regulation;***		
117	Article 3 – paragraph 1 - point -1	(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;		(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;	
118	Article 3 – paragraph 1 - point -2	(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;		(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;	
119	Article 3 – paragraph 1 - point -3	(3) 'contact tracing' means measures ***implemented in order to trace*** persons who have been	**Amendment 53** (3) 'contact tracing' means measures ***to identify, assess and manage*** persons who have been	(3) 'contact tracing' means measures implemented in order to trace persons who have been	

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		exposed to a source of a serious cross-border threat to health, and who are in danger of ***developing*** or have developed a disease, through manual or other technological means;	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***;	exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease, through manual or other technological means;	
120	Article 3 – paragraph 1 - point 4	(4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;	**Amendment 54** (4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases***, the monitoring of the impact of such diseases on major non-communicable diseases, such as those relating to mental health,*** and ***on*** related special health issues;	(4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;	
121	Article 3 – paragraph 1 - point 5	(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		(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	

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		health;		health;	
122	Article 3 – paragraph 1 – point 5 a (new)		**Amendment 55** ***(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;***		
123	Article 3 – paragraph 1 – point 5 b (new)		**Amendment 56** ***(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;***		
124	Article 3 – paragraph 1 - point 6	(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;		(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;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
125	Article 3 – paragraph 1 - point 7	(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;		(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;	
126	Article 3 – paragraph 1 – point 7 a (new)		**Amendment 57** ***(7a) 'major non-communicable disease' means a disease as defined in point (4a) of Article 2 of Regulation (EU) [ECDC regulation, correct reference to be inserted];***		
127	Article 3 – paragraph 1 – point 8	(8) 'medical countermeasure' means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council and in Regulation (EU) 2017/745 of the European Parliament and of the Council or other goods or services ***for the*** for the purpose of preparedness and response to a serious cross-border	**Amendment 58** (8) 'medical countermeasure' means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council[23] and in Regulation (EU) 2017/745 of the European Parliament and of the Council[24] or other goods or services for the purpose ***of facilitating diagnosis and treatment in the framework*** of preparedness and response to a	(8) 'medical countermeasure' means ~~medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council and in Regulation (EU) 2017/745 of the European Parliament and of the Council or other goods or services for the purpose of preparedness and response to a serious cross-border threat to health.~~ **any medicines,**	

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		threat to health.	serious cross-border threat to health.	**medical devices, other goods or services that are aimed at combating serious cross-border threats to health, as referred to in this Regulation;**	
128	Article 3 – paragraph 1 – point 8 a (new)		**Amendment 59** ***(8a) 'International Health Regulations' mean the International Health Regulations adopted by the World Health Organization in 2005;***		
129	Article 3 – paragraph 1 – point 8 b (new)		**Amendment 60** ***(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;***		
130	Article 3 – paragraph 1 – point 8 c (new)		**Amendment 61** ***(8c) ‘green lanes’ means passable and safe transit corridors that preserve supply chains in the event of a declared public health emergency at Union level in a pandemic situation by ensuring that essential goods, medical countermeasures and cross border workers can circulate***		

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			freely and safely within the internal market, while fully respecting Article 77 (2)(e) TFEU.		
131	Article 3 – paragraph 1 – point 9 (new)			**(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).**	
132	Article 3 – paragraph 1 – point 10 (new)			**(10) 'One Health concept' means a multi-dimensional approach to health, which recognises that human, animal and environmental health are interconnected.**	
133	Article 4	*Article 4*		*Article 4*	
134		**Health Security Committee**		**Health Security Committee**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
135	Article 4 – paragraph 1	1. The Health Security Committee ('HSC') is hereby established. It shall be composed of representatives of the Member States, in two working formations:		1. The Health Security Committee ('HSC') is hereby established. It shall be composed of representatives of the Member States,in two working **levels**~~formations~~:	
136	Article 4 – paragraph 1- point a	(a) a high-level working group to discuss topics of political importance and decisions referred to in point (d) of paragraph 3 and paragraph 7;		(a) a ~~high-level~~ **steering panel** ~~working group to discuss topics of political importance and decisions referred to in point (d) of paragraph 3 and paragraph 7~~;	
137	Article 4 – paragraph 1- point b	(b) technical working groups to discuss specific topics of technical nature.		(b) technical working groups to discuss specific topics ~~of technical nature~~**if necessary**.	
138	Article 4 – paragraph 1 a (new)		**Amendment 62** ***1a. Representatives of relevant Union agencies shall participate in HSC meetings as observers.***		
139	Article 4 – paragraph 2	2. The HSC shall have the following tasks:		2. The HSC shall have the following tasks:	
140	Article 4 – paragraph 2- point a	(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;		(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation**, in cooperation with, where applicable, other structures**;	
141	Article 4 – paragraph 2-	(b) coordination in liaison	**Amendment 63** (b) coordination in liaison	(b) coordination in liaison	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point b	with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;	with the Commission ***and relevant Union agencies*** of the ***prevention,*** preparedness and response planning of the Member States in accordance with Article 10;	with the Commission of the preparedness and response planning **in accordance with Article 10 and without prejudice to the competences of** Member States; ~~in accordance with Article 10;~~	
142	Article 4 – paragraph 2- point c	(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;	**Amendment 64** (c) coordination in liaison with the Commission ***and relevant Union agencies*** of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;	(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;	
143	Article 4 – paragraph 2- point d	(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.		(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**.	
144	Article 4 – paragraph 2 – point d a (new)		**Amendment 65** ***(da) adoption, on an annual basis, of an action programme to clearly set its priorities and objectives at the high level working group and the technical working group levels.***		

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145	Article 4 – paragraph 3 - subparagraph 1	3. As far as possible, the group shall adopt its guidance or opinions by consensus.		3. As far as possible, the group shall adopt its guidance or opinions by consensus.	
146	Article 4 – paragraph 3 - subparagraph 2	In the event of a vote, the outcome of the vote shall be decided by simple majority of the members.		In the event of a vote, the outcome of the vote shall be decided by **two thirds** ~~simple~~ majority of the members.	
147	Article 4 – paragraph 3 - subparagraph 3	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.		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.	
148	Article 4 – paragraph 4	4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.	**Amendment 66** 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.	4. The HSC shall be **co-** chaired by a representative of the Commission **and a representative of the Member States**. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.	
149	Article 4 – paragraph 5	5. The secretariat shall be provided by the Commission.		5. The secretariat shall be provided by the Commission.	
150	Article 4 – paragraph 5 a (new)		**Amendment 67** ***5a. Members of the HSC and the Commission shall ensure thorough consultation with relevant Union agencies, public***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			health experts, international organisations and stakeholders, including healthcare professionals.		
151	Article 4 – paragraph 6	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:		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:	
152	Article 4 – paragraph 6 – point a	(a) the procedures for plenary meetings at high level and technical working groups;		(a) the procedures for plenary meetings ~~at high level and technical working groups~~;	
153	Article 4 – paragraph 6 – point b	(b) the participation of experts in plenary meetings at high level, the status of possible observers, including from third countries;		(b) the participation of experts in plenary meetings ~~at high level~~, the status of possible observers, including from third countries **and WHO**;	
154	Article 4 – paragraph 6 – point c	(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.		(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.	
155	Article 4 – paragraph 7 -	7. Member States shall designate one representative and		7. Member States shall designate one representative and	

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	subparagraph 1	not more than two alternate members of the HSC in each working formation referred to in paragraph 1.		not more than two alternate members of the HSC ~~in each working formation referred to in paragraph 1~~.	
156	Article 4 – paragraph 7 - subparagraph 2	Member States shall notify the Commission and other Member States of the designations and of any change thereof.		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 distribute immediately to the HSC's members an updated list of such designations.**	
157	Article 4 – paragraph 7 a (new)		**Amendment 68** ***7a. The European Parliament shall designate representatives to participate in the Health Security Committee ('HSC') as observers.***		
158	Article 4 – paragraph 7 b (new)		**Amendment 69** ***7b. The list of members of the HSC at both the political and technical levels shall be made public on the Commission and Council websites. Members of the Committee shall have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All direct interests which could relate to the medical***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			or another relevant sector shall be entered in a register held by the Commission and be accessible to the public, upon request.		
159	Article 4 – paragraph 7 c (new)		**Amendment 70** ***7c. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's web-portal.***		
160	Article 4 – paragraph 7d (new)		**Amendment 256** ***7d. The HSC shall act in cooperation with the board of HERA established under the Commission decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, and the Health Crisis Board (HCB) to be established under a 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. The coordination between those bodies shall ensure the participation of all relevant stakeholders, including healthcare professionals' organisations, patients' associations, and industry and supply chain actors with***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			recognised experience in disciplines related to the HSC, HCB and to the work of the HERA. The provisions related to conflict of interests and transparency, as provided for in paragraphs 7b and 7c, shall apply in relation to this paragraph also. The Commission shall invite a representative of the European Parliament to serve as an active member of the HCB.		
161	***CHAPTER II***	**CHAPTER II**		**CHAPTER II**	
162		**PREPAREDNESS AND RESPONSE PLANNING**	**Amendment 71** ***PREVENTION,*** PREPAREDNESS AND RESPONSE PLANNING	**PREPAREDNESS AND RESPONSE PLANNING**	
163	Article 5	*Article 5*		*Article 5*	
164		**Union preparedness and response plan**	**Amendment 72** Union ***prevention,*** preparedness and response plan	**Union preparedness and response plan**	
165	Article 5 – paragraph 1	1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-	**Amendment 73** 1. The Commission, in cooperation with Member States and the relevant Union agencies ***and taking into account the WHO framework***, shall establish a Union health crisis and pandemic plan ('the Union ***prevention***, preparedness and	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	

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		border health threats at Union level.	response plan') to promote effective and coordinated response to cross-border health threats at Union level.	establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.	
166	Article 5 – paragraph 2	2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.	**Amendment 74** 2. The Union ***prevention,*** preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.	2. The Union preparedness and response plan shall complement the national 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**.	
167	Article 5 – paragraph 3	3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:	**Amendment 75** 3. The Union ***prevention,*** preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:	3. The Union preparedness and response plan shall, in particular, include **provisions of joint** arrangements for governance, capacities and resources for:	
168	Article 5 – paragraph 3 - point a	(a) the timely cooperation between the Commission, the Member States and the Union agencies;	**Amendment 257** (a) the timely cooperation between the Commission, the Member States and the Union agencies ***and bodies***;	(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**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
				provided under the EU Civil Protection Mechanism, 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;	
169	Article 5 – paragraph 3 - point b	(b) the secure exchange of information between the Commission, Union agencies and the Member States;	**Amendment 258** (b) the secure exchange of information between the Commission, Union agencies and ***bodies and*** the Member States;	(b) the secure exchange of information between the Commission**, the competent authorities or designated bodies responsible at national level, the HSC and the relevant** Union **bodies or** agencies ~~and the Member States~~;	
170	Article 5 – paragraph 3 - point c	(c) the epidemiological surveillance and monitoring;	**Amendment 76** (c) the epidemiological surveillance and monitoring***, as well as the impact of communicable diseases on major non-communicable diseases***;	(c) the epidemiological surveillance and monitoring;	
171	Article 5 – paragraph 3 - point d	(d) the early warning and risk assessment;		(d) the early warning and risk assessment**, especially regarding cross-border interregional preparedness and response**;	
172	Article 5 – paragraph 3 - point e	(e) the risk and crisis communication;	**Amendment 77** (e) the risk and crisis communication***, aimed at health***	(e) the risk and crisis communication;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			professionals and at citizens;		
173	Article 5 – paragraph 3 - point f	(f) the health preparedness and response and intersectoral collaboration;		(f) the health preparedness and response and **multi-sectoral** ~~intersectoral~~ 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.**	
174	Article 5 – paragraph 3 – point f a (new)		**Amendment 78** ***(fa) the mapping of the production capacities of medical products in the Union as a whole;***		
175	Article 5 – paragraph 3 – point f b (new)		**Amendment 79** ***(fb) the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;***		
176	Article 5 – paragraph 3 – point f c (new)		**Amendment 259** ***(fc) the implementation of the provisions of the plan relating to emergency research and innovation aspects;***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
177	Article 5 – paragraph 3 - point g	(g) the management of the plan.		~~(g) the management of the plan.~~	
178	Article 5 – paragraph 3 – point g a (new)		**Amendment 80** ***(ga) the criteria for activating and deactivating the actions;***		
179	Article 5 – paragraph 3 – point g b (new)		**Amendment 81** ***(gb) ensuring that healthcare services, including the screening, diagnosis, monitoring, treatment and care for other diseases and conditions, are provided without disruption during health emergencies;***		
180	Article 5 – paragraph 3 – point g c (new)		**Amendment 82** ***(gc) ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;***		
181	Article 5 – paragraph 3 – point g d (new)		**Amendment 83** ***(gd) an adequate and needs-oriented staffing level;***		
182	Article 5 – paragraph 3 – point g e (new)		**Amendment 84** ***(ge) monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			and social care professionals.		
183	Article 5 – paragraph 4	4. The Union preparedness and response plan shall include interregional preparedness ***elements*** to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.	**Amendment 85** 4. The Union ***prevention,*** preparedness and response plan shall include ***cross-border and*** interregional preparedness ***plans*** to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, ***training of healthcare staff*** and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.	4. The Union preparedness and response plan shall include **cross-border** interregional preparedness elements to **support** ~~establish~~ **aligned** ~~coherent~~, multi-sectoral, cross-border public health measures, in particular considering capacities for **surveillance,** testing, **capacities and structures for** contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plan~~s~~ shall **take into account national circumstances and preconditions and** include preparedness and response means to address the situation of those citizens with higher risks.	
184	Article 5 – paragraph 4 a (new)		**Amendment 86** ***4a. The Union preparedness and response plan shall also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.***		
185	Article 5 – paragraph 5	5. In order to ensure the operation of the Union preparedness and response plan,	**Amendment 87** 5. In order to ensure the operation of the Union ***prevention,*** preparedness and	5. In order to ensure the operation of the Union preparedness and response plan,	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.	response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary. ***The prevention, preparedness and response plan shall take into account health systems data and relevant data to be collected at national or regional level.***	the Commission ~~shall~~ **may, in collaboration with Member States and, when applicable, with relevant Union bodies or agencies or with international organizations,** conduct stress tests, **simulation** exercises and in-action and after-action reviews ~~with Member States~~, and update the plan as necessary.	
186	Article 5 – paragraph 5 a (new)		**Amendment 88** ***5a. In order to respond to public health emergencies, the European Commission may issue recommendations, based on Union health systems data, on the minimum resources needed, in relation, among other things, to each Member State's population, for the provision of baseline universal health coverage of adequate quality, including on the option of pooling resources at Union level.***		
187	Article 5 – paragraph 5 b (new)		**Amendment 89** ***5b. The reviews and any subsequent adjustments to the plan shall be published to increase the transparency of the process of prevention, preparedness and response planning.***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
188	Article 6	*Article 6*		*Article 6*	
189		**National preparedness and response plans**	**Amendment 90** National ***prevention,*** preparedness and response plans	**National preparedness and response plans**	
190	Article 6 – paragraph 1	1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, ***also*** inform without delay the Commission and the HSC of any substantial revision of the national plan.	**Amendments 91 and 260** 1. When preparing national ***prevention,*** preparedness and response plans each Member State shall ***consult patients' organisations, healthcare professionals' organisations, industry and supply chain stakeholders, and national social partners,*** coordinate with the Commission***, in particular with the HERA,*** in order to reach consistency with the Union ***prevention,*** preparedness and response plan, ***which shall be in accordance with arrangements for governance, capacities and resources referred to in Article 5(3), including with regard to national stockpiling requirements and the management of Union strategic reserves, and*** inform without delay the Commission***, the HCB*** and the HSC of any substantial revision of the national plan.	1. **Without prejudice to Member States competences in this area, w**~~W~~hen preparing national preparedness and response plans ~~each~~ Member State**s** shall **liaise with each other within the HSC and** coordinate with the Commission in order to ~~reach~~ **seek** ~~consistency~~ **coherence** with the Union 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.	
191	Article 6 – paragraph 1 a		**Amendment 92** ***1a. National prevention,***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	(new)		***preparedness and response plans shall include arrangements for governance and information on capacities and resources referred to in Article 5(3).***		
192	Article 7	*Article 7*		*Article 7*	
193		**Reporting on preparedness and response planning**	**Amendment 93** Reporting on ***prevention,*** preparedness and response planning	**Reporting on preparedness and response planning**	
194	Article 7 – paragraph 1- subparagraph 1	1. Member States shall ***by the end of November 2021*** and every 2 years thereafter provide the Commission with ***a*** report on their preparedness and response planning and implementation at national level.	**Amendments 94 and 261** 1. Member States shall ***within 6 months of the entry into force of this regulation*** and every 2 years thereafter provide the Commission ***and relevant Union agencies and bodies*** with ***an updated*** report on their ***prevention,*** preparedness and response planning and implementation at national level ***and, where appropriate, regional and cross-border levels***.	1. Member States shall by the end of November **2022** ~~2021~~ and every **3** ~~2~~ years thereafter provide the Commission **and the ECDC** with a report on their preparedness and response planning and implementation at national level **in relation to the serious cross-border threats to health referred to in Article 2(1).**	
195	Article 7 – paragraph 1- subparagraph 2	That report shall cover the following:	**Amendment 95** That report ***shall be succinct, based on common indicators, give an overview of the actions implemented in the Member States, and*** shall cover the following:	That report shall cover the following:	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
196	Article 7 – paragraph 1- subparagraph 2- point a	(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;	**Amendment 96** (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, regional*** level for the health sector, as provided to the WHO in accordance with the IHR;	(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;	
197	Article 7 – paragraph 1 – subparagraph 2 – point a a (new)		**Amendment 97** ***(aa) a description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors that are critical in the case of an emergency;***		
198	Article 7 – paragraph 1 – subparagraph 2 – point a b (new)		**Amendment 98** ***(ab) a description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products;***		
199	Article 7 – paragraph 1- subparagraph 2- point b	(b) elements of emergency preparedness, in particular:	**Amendment 99** (b) ***an update, if needed, on the*** elements of emergency ***prevention,*** preparedness ***and response***, in particular:	(b) elements of emergency preparedness, in particular:	

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200	Article 7 – paragraph 1- subparagraph 2- point b- point i	(i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms;	**Amendment 100** (i) governance: including national ***and, if appropriate, regional*** policies and legislation that integrate emergency ***prevention and*** preparedness; plans for emergency ***prevention,*** preparedness, response and recovery coordination mechanisms ***at national and, where relevant, regional and cross-border levels***; ***continuity of critical long-term healthcare;***	(i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms, **including, where relevant, among administrative levels (national, regional and/or local) and in terms of multi-sectoral collaboration**;	
201	Article 7 – paragraph 1- subparagraph 2- point b- point ii	(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;	**Amendment 101** (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; ***the capacities to produce medicinal products; stocks of medical countermeasures, including personal protective equipment of the highest quality; equitable*** access to diagnostic services ***and tools, and medical products*** during emergencies; ***information relevant for the internal market and Union strategic reserves of medical products; equitable, high-quality,*** basic and safe gender-sensitive health and emergency services ***that take account of the needs of***	(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			populations at higher risk; continuity of screening, diagnosis, monitoring and treatment for care in relation to other diseases and conditions, in particular critical long-term healthcare; risk communications; research development and evaluations to inform and accelerate emergency preparedness;		
202	Article 7 – paragraph 1- subparagraph 2- point b- point iii	(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and	**Amendment 102** (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; ***measures to ensure continuity of critical long-term healthcare; and health and social services with an adequate number of*** dedicated, trained and equipped human resources for emergencies;	(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and	
203	Article 7 – paragraph 1 – subparagraph 2 – point b – point iii a (new)		**Amendment 103** ***(iiia) strategic stockpile: each Member State shall provide information on the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats set out in Article 2(1), as well as the***		

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			capacity for their safekeeping and storage. In order to have a greater response capacity, storage shall be carried out in the premises closest to and most accessible for the population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, which meet the necessary requirements to provide the service in accordance with the regulations applicable to medicinal products, medical devices[1b] and other medical countermeasures; and _____ ***[1b] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. (OJ L 117, 5.5.2017, p. 1).***		
204	Article 7 – paragraph 1 – subparagraph 2 – point c	(c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and		(c) implementation of national response plans, including where relevant implementation at the regional ~~and local~~ levels~~,~~ covering epidemic response~~;~~ ~~antimicrobial resistance~~, **related special health issues**, ~~health care~~	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		other specific issues.		~~associated infection,~~ and other **serious cross-border threats to health** ~~specific issues~~.	
205	Article 7 – paragraph 1 – subparagraph 2 – point c a (new)		**Amendment 104** ***(ca) the consultation with relevant partners that has taken place to ensure risk assessments, prevention, preparedness and response plans and implementation are broadly shared and supported and in line with applicable labour legislation and collective agreements;***		
206	Article 7 – paragraph 1 – subparagraph 2 – point c b (new)		**Amendment 105** ***(cb) gaps found in the implementation and any necessary actions that will be taken by the Member States to improve their preparedness and response capacity.***		
207	Article 7 – paragraph 1 – subparagraph 3	The report shall include**,** ***whenever relevant*****,** interregional preparedness and response elements ***in line with the Union and national plans, covering in particular the existing capacities, resources*** and coordination mechanisms ***across neighbouring regions***.	**Amendment 106** ***For Member States sharing a land border with at least one other Member State,*** the report shall include ***cross-border***, interregional ***and intersectoral prevention,*** preparedness and response ***plans with neighbouring regions including coordination mechanisms for all*** elements ***listed in points (a), (b) and (c), cross-border training and***	The report shall include, whenever relevant, **cross-border** interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions.	

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			sharing of best practices for healthcare staff and public health staff and coordination mechanisms ***for the medical transfer of patients***. ***Union or national entities that are engaged in stockpiling of medical products shall engage with the Commission and Member States in reporting of stocks that are available and taken into account in both Union and national preparedness and response planning.***		
208	Article 7 – paragraph 1 – subparagraph 3 a (new)		**Amendment 107** ***The report shall also include, as far as feasible, information on the impact of communicable diseases on major non-communicable diseases.***		
209	Article 7 – paragraph 1 – subparagraph 3 b (new)		**Amendment 108** ***The latest available version of the prevention, preparedness and response plans shall be attached to the report.***		
210	Article 7 – paragraph 2 - subparagraph 1	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	**Amendment 262** 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	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	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		agencies and bodies every 2 years.	agencies and bodies every 2 years. ***For the purpose of drawing up the report, the HERA shall assess the availability of crisis-relevant medical countermeasures, the production capacity for and the existing stockpiles of such countermeasures and the risk of disruption in supply chains in the framework of the national preparedness and response planning, taking into account information obtained pursuant to Regulation (EU) …/… [OJ: Please insert the number of the Regulation on EMA [ISC/2020/12532]] and in particular Articles XX [Article numbers to be confirmed after adoption] thereof, concerning the monitoring and mitigation of shortages of critical medicinal products, medical devices and in vitro diagnostic medical devices.***	agencies and bodies every ***3*** ~~2~~ years.	
211	Article 7 – paragraph 2 - subparagraph 2	The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national level.		The report shall include country profiles for monitoring progress and developing action plans**, taking into account national circumstances and preconditions,** to address identified gaps at national level.	
212	Article 7 – paragraph 2 - subparagraph 3	Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC to discuss progress and gaps		Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC to discuss progress and gaps	

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		in preparedness.		in preparedness**, allowing continuous improvement**.	
213	Article 7 – paragraph 2 - subparagraph 4	The recommendations of the report shall be published on ***at the website*** of the Commission.	**Amendment 109** The recommendations of the report shall be published on ***the websites*** of the Commission ***and the ECDC***.	**An overview of** ~~The~~ **general** 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 at the website of the Commission.	
214	Article 7 – paragraph 3 - subparagraph 1	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.		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.	
215	Article 7 – paragraph 3 - subparagraph 1a (new)			**The templates shall be based on the opinion of the HSC and shall be, as far as possible, based on/consistent with templates used under the International Health Regulations State Parties reporting framework in order to avoid double reporting activities for Member States.**	
216	Article 7 – paragraph 3 - subparagraph 2	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
217	Article 7 – paragraph 4	4. When receiving classified information transmitted pursuant to paragraph 1, the Commission and the HSC shall apply the rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 and 2015/444.		4. **In the performance of their obligations pursuant to this Article, Member States shall not be required to disclose information in the report that would harm their essential national security interests.** 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.	
218	Article 7 – paragraph 5	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.		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.	

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219	Article 8	*Article 8*		*Article 8*	
220		**Auditing on preparedness and response planning**	**Amendment 110** Auditing on ***prevention,*** preparedness and response planning	**<u>Examining</u>~~Auditing~~ on preparedness and response planning**	
221	Article 8 – paragraph 1	1. Every ***3*** years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).	**Amendment 111** 1. Every ***2*** years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be ***based on a set of 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)**..**	1. Every **<u>4</u>** ~~3~~ years, the ECDC shall ~~conduct~~ **<u>examine</u>** ~~audits~~ the Member States ~~aimed at ascertaining~~ state of implementation of the national plans and their **<u>relation</u>** ~~coherence~~ with the Union plan. Such **<u>examinations</u>** ~~audits~~ shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).	
222	Article 8 – paragraph 1a (new)			**<u>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 circumstances and preconditions.</u>**	
223	Article 8 –		**Amendment 112**		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	paragraph 2-subparagraph 1	2. Member ***States*** shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones.	2. ***In the event the audit identifies deficiencies, the*** Member ***State*** shall***, within six months of receipt of its conclusions,*** present an action plan addressing the proposed recommendations of the audit and ***setting out*** the corresponding corrective actions and milestones.	2. Member States shall, **if applicable,** present **to the Commission and the ECDC** an action plan addressing the proposed recommendations of the **examination** ~~audit~~**, with** ~~and~~ the corresponding **improvement** ~~corrective~~ actions and milestones**, or reasoning if the proposed recommendations of the examination are not considered**.	
224	Article 8 – paragraph 2 – subparagraph 1 a (new)		**Amendment 113** ***If a Member State decides not to follow a recommendation, it shall state its reasons for doing so***		
225	Article 8 – paragraph 2-subparagraph 2	These actions may, in particular, include:		~~These actions may, in particular, include:~~	
226	Article 8 – paragraph 2 subparagraph 2 point a	(a) review/adjustment of the legislation, if necessary;		~~(a) review/adjustment of the legislation, if necessary;~~	
227	Article 8 – paragraph 2-subparagraph 2 point b	(b) training initiatives;		~~(b) training initiatives;~~	
228	Article 8 – paragraph 2 - subparagraph 2 point c	(c) overview reports of audits series, which present cases of good practice.		~~(c) overview reports of audits series, which present cases of good practice.~~	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
229	Article 8 – paragraph 3	3. The Commission shall adopt delegated acts in accordance with Article 28 concerning procedures, standards and criteria for the audits referred to in paragraph 1.		3. The Commission shall**,** **by means of implementing acts, establish** ~~adopt delegated acts in accordance with Article 28 concerning~~ procedures, standards and criteria for the **examinations** ~~audits~~ referred to in paragraph 1.	
230	Article 8 – paragraph 3 - subparagraph 1a (new)			**Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).**	
231	Article 9	*Article 9*		*Article 9*	
232		***Commission report on preparedness planning***	**Amendment 114** Commission report on ***prevention,*** preparedness planning	**Commission report on preparedness and response planning**	
233	Article 9 – paragraph 1	1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.	**Amendment 115** 1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on ***prevention,*** preparedness and	1. On the basis of the information provided by the Member States in accordance with Article 7, and ~~of~~ the results of the **examine** ~~audits~~ referred to in Article 8, the Commission shall by July **2023** ~~2022~~ and every **3** ~~2~~ years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union	

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			response planning at Union level.	level.	
234	Article 9 – paragraph 1 a (new)		**Amendment 116** ***1a. The Commission report shall include the state of cross-border preparedness and response planning in neighbouring regions.***		
235	Article 9 – paragraph 2	2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.	**Amendment 117** 2. The Commission may adopt recommendations on ***prevention,*** preparedness and response planning addressed to Member States based on the report referred to in paragraph 1. ***Those recommendations may cover, inter alia, the minimum resources needed to respond to public health emergencies in relation to, among other things, population size, and they shall be developed on the basis of good practice and policy assessments.***	2. **Based on the report referred to in paragraph 1, t**~~T~~he Commission may **complement the action of the Member States through the adoption of** ~~adopt~~ **general** recommendations on **the** preparedness and response planning ~~addressed to Member States based on the report referred to in paragraph 1~~.	
236	Article 10	*Article 10*		*Article 10*	
237		**Coordination of preparedness and response planning in the HSC**	**Amendment 118** Coordination of ***prevention,*** preparedness and response planning in the HSC	**Coordination of preparedness and response planning in the HSC**	
238	Article 10 – paragraph 1	1. The Commission and the Member States shall work	**Amendments 119 and 263** 1. The Commission***,*** ***relevant Union agencies*** and the	1. The Commission and the Member States shall work	

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		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.	Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, ***prevention,*** early warning and assessment of, and response to serious cross-border threats to health.	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.	
239		The coordination shall, in particular, be aimed at:		The coordination shall, in particular, be aimed at:	
240	Article 10 – paragraph 1 – point a	(a) sharing best practice and experience in preparedness and response planning;	**Amendment 120** (a) sharing best practice and experience in ***prevention,*** preparedness and response planning;	(a) sharing best practice and experience in preparedness and response planning;	
241	Article 10 – paragraph 1b	(b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;	**Amendment 121** (b) promoting the interoperability of national ***prevention,*** preparedness planning and the intersectoral dimension of ***prevention,*** preparedness and response planning at Union level;	(b) promoting the interoperability of national preparedness planning and the **multi-sectoral** ~~intersectoral~~ dimension of preparedness and response planning at Union level;	
242	Article 10 – paragraph 1- point c	(c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;		(c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;	
243	Article 10 – paragraph 1- point d	(d) developing the preparedness plans referred to in Articles 5 and 6;		(d) **supporting the** develop**ment**~~ing~~ **of** the preparedness **and response** plans	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
				referred to in Articles 5 and 6;	
244	Article 10 – paragraph 1- point e	(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.	**Amendment 122** (e) monitoring progress, identifying gaps and actions to strengthen ***prevention,*** preparedness and response planning, including in the field of research, at ***regional,*** national and at Union levels;	e) **monitoring and discussing** ~~monitoring~~ progress, ~~identifying~~ gaps **identified** and actions to strengthen preparedness and response planning~~, including in the field of research,~~ at national and ~~at~~ Union levels.	
245	Article 10 – paragraph 1 a (new)		**Amendment 123** ***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. That dialogue shall include regular exchanges of information between authorities, industry and relevant actors in the pharmaceutical supply chain to identify expected supply constraints so as to allow better coordination, development of synergies and appropriate responses.***		
246	Article 11	*Article 11*		*Article 11*	
247		**Training of health care staff and public health staff**		**Training of health care staff and public health staff**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
248	Article 11 – paragraph 1 - subparagraph 1	1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.	**Amendment 124** 1. The Commission may organise training activities***, supported by the relevant Union agencies, in close cooperation with medical associations 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.	1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.	
249	Article 11 – paragraph 1 - subparagraph 2	The Commission shall organise those activities in cooperation with the Member States concerned.	**Amendment 125** The Commission shall organise those activities in cooperation with the Member States concerned ***or potentially concerned, and in coordination, where possible, with the WHO to avoid duplication of activities, 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 the WHO**.	
250	Article 11 – paragraph 1 – subparagraph 2 a (new)		**Amendment 126** ***In cross-border regions, joint cross-border training and sharing of best practices for healthcare staff and public health staff shall be promoted and familiarity with public health systems shall be mandatory.***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
251	Article 11 – paragraph 1 – subparagraph 2 b (new)		**Amendment 127** ***The Commission shall use the fullest potential of distance learning to broaden the number of trainees.***		
252	Article 11 – paragraph 2	2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.	**Amendment 128** 2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools***, ensure the continuity of critical long-term healthcare services and be consistent with the One Health approach***.	2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, **and** implement activities to strengthen crisis preparedness and surveillance capacities**, especially regarding the gaps identified,** including the use of digital tools.	
253	Article 11 – paragraph 3	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.	**Amendment 129** 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***.	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.	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
254	Article 11 – paragraph 4	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.		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.	
255	Article 11 – paragraph 5	5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other.	**Amendment 130** 5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. ***In organising those programmes, account shall be taken of the contribution made by professional health organisations in each of the Member States.***	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** ~~and~~ for the temporary secondment of staff **between** ~~from one~~ Member State**s, Union candidate countries** ~~to the other~~ **or Union agencies**.	
256	Article 11 – paragraph 6 - subparagraph 1	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.		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.	
257	Article 11 – paragraph 6 -	Those implementing acts shall be adopted in accordance with the		Those implementing acts shall be adopted in accordance with the	

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	subparagraph 2	examination procedure referred to in Article 27(2).		examination procedure referred to in Article 27(2).	
258	Article 12	*Article 12*		*Article 12*	
259		**Joint procurement of medical countermeasures**		**Joint procurement of medical countermeasures**	
260	Article 12 – paragraph 1	1. The Commission and any Member States ***which so desire*** may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[29] with a view to the advance purchase of medical countermeasures for serious cross-border threats to health. _____ [29] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p.	**Amendments 131 and 264** 1. The Commission***, in particular with the HERA,*** 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[29] with a view to the advance purchase of medical countermeasures for serious cross-border threats to health ***within a reasonable time frame***. _____ [29] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No	1. The Commission and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.	

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		1).	541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).		
261	Article 12 – paragraph 1a (new)			**1a. The 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 assessment of the tenders and the award of the contract.**	
262	Article 12 – paragraph 2	2. The joint procurement procedure referred to in paragraph 1, shall comply with the following conditions:		2. The joint procurement procedure referred to in paragraph 1, shall comply with the following conditions:	
263	Article 12 – paragraph 2 – point a	(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States ***and*** Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046;	**Amendment 132** (a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States**,** Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046***, and to the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State***;	(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,** ~~in accordance with~~ **by way of derogation from** Article 165(2) of Regulation (EU, Euratom) 2018/1046;	

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264	Article 12 – paragraph 2 – point b	(b) the rights and obligations of Members States, EFTA States and Union candidate countries not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;		(b) the rights and obligations of **the countries referred to in point (a)** ~~Members States, EFTA States and Union candidate countries~~ not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;	
265	Article 12 – paragraph 2 - point c	(c) ***Member States, EFTA States and Union candidate*** countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;	**Amendment 133** c) countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product ***from that moment onwards. Countries that engage in parallel negotiation processes from that moment onwards shall be excluded from the group of participating countries, irrespective of whether those processes have reached the signature stage***;	(c) ~~Member States, EFTA States and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;~~	
266	Article 12 – paragraph 2 – point c a (new)		**Amendment 134** ***(ca) the joint procurement shall define clear procedural steps for the process, scope, tender specifications and timelines, and it shall require all parties to deliver and respect clear commitments, including***		

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			manufacturers delivering agreed production quantities and authorities purchasing agreed reserved volumes. The precise amounts ordered by and provided to each participating country and details of their liabilities shall be disclosed;		
267	Article 12 – paragraph 2 – point c b (new)		**Amendment 135** ***(cb) A high degree of transparency shall be applied to all joint procurement activities and related purchase agreements. The European Court of Auditors shall have full access to all relevant documents to provide accurate annual scrutiny of signed contracts and the public investment involved;***		
268	Article 12 – paragraph 2 – point c c (new)		**Amendment 136** ***(cc) if joint procurement is deployed, qualitative criteria shall be considered in the award process, in addition to cost. Such criteria shall also take into consideration, for example, the ability of the manufacturer to ensure security of supply during a health crisis;***		
269	Article 12 – paragraph 2 – point c d (new)		**Amendment 137** ***(cd) the joint procurement shall be conducted in such a way***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			so as to strengthen the purchasing power of participating countries, improve the security of supply and ensure equitable access to medical countermeasures against serious cross-border threats to health;		
270	Article 12 – paragraph 2 – point d	(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;		(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;	
271	Article 12 – paragraph 2 – point e	(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.		(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.	
272	Article 12 – paragraph 2 – point e a (new)		**Amendment 265** ***(ea) when joint procurement is performed under Article 7 of a 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 (ISC/2020/12524), the Commission shall have the right to require the licensing, under fair and reasonable conditions, of intellectual***		

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			property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure the sufficient and timely delivery of such countermeasures under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of that right may be set out in the specific agreements with economic operators;		
273	Article 12 – paragraph 2 – point e b (new)		**Amendment 266** ***(eb) to ensure transparency as regards the expenditure of public funds, when joint procurement is performed under Article 7 of a 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 [ISC/2020/12524], the Commission shall in a timely manner make publicly available the contracts and agreements established with economic operators at least stipulating the following:***		
274	Article 12 – paragraph 2 – point e b point i		***(i) the delivery schedule of the good or service;***		

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	(new)				
275	Article 12 – paragraph 2 – point e b point ii (new)		***(ii) terms of liabilities and indemnifications;***		
276	Article 12 – paragraph 2 – point e b point iii (new)		***(iii) where relevant, the quantity and number of manufacturing locations.***		
277	Article 12 – paragraph 3	3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:	**Amendment 138** 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 ***in facilities that meet the specific legal requirements for the storage of medical countermeasures and having the greatest proximity to and accessibility for the greatest number of population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, distribution*** and donation of medical countermeasures***, which shall be of benefit to low- and middle-income countries,*** under different mechanisms established at Union	3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:	

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			level, in particular under:		
278	Article 12 – paragraph 3 – point a	(a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;	**Amendment 139** (a) stockpiling under the rescEU referred to in Article ***23*** of Decision No 1313/2013/EU;	(a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;	
279	Article 12 – paragraph 3 – point b	(b) Regulation (EU) 2016/369;		(b) Regulation (EU) 2016/369;	
280	Article 12 – paragraph 3– point c	(c) the upcoming Pharmaceutical Strategy ;		(c) the ~~upcoming~~ Pharmaceutical Strategy ;	
281	Article 12 – paragraph 3– point d	(d) the EU4Health Programme established by Regulation (EU) …/… of the European Parliament and of the Council;		(d) the EU4Health Programme established by Regulation (EU) …/… of the European Parliament and of the Council;	
282	Article 12 – paragraph 3– point e	(e) Regulation (EU) No…/… of the European Parliament and of the Council; and		(e) Regulation (EU) No…/… of the European Parliament and of the Council; and	
283	Article 12 – paragraph 3– point f	(f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.	**Amendments 140 and 267** (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 a Council Regulation on a framework of measures for ensuring the supply of crisis-***	(f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.	

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			relevant medical countermeasures in the event of a public health emergency at Union level [ISC/2020/12524].		
284	Article 12 – paragraph 3 a (new)		**Amendment 141** ***3a. Participating countries shall ensure that there is adequate stockpiling and distribution of procured medical countermeasures. The main details and characteristics of that stockpiling and distribution shall be set out in national plans.***		
285	Article 12 – paragraph 3 b (new)		**Amendment 142** ***3b. In accordance with the principle of transparency, the Commission shall regularly inform the European Parliament about negotiations concerning the joint procurement of medical countermeasures.***		
286	Article 12 – paragraph 3 c (new)		**Amendment 143** ***3c. The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings under this Article.***		
287	Article 12 – paragraph 3 d		**Amendment 144** ***3d. The Commission and***		

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	(new)		***Member States shall provide up-to-date, accessible and clear information to consumers on their rights and duties regarding jointly procured medical countermeasures, including details on liability for damages, and access to legal protection and to consumer representation.***		
288	Article 12 – paragraph 3 e (new)		**Amendment 145** ***3e. Where the joint procurement procedure for medical countermeasures to cross-border threats to health is not applied, the Commission shall encourage Member States to exchange information on pricing and delivery dates for medical countermeasures.***		
289	CHAPTER III	**CHAPTER III**		**CHAPTER III**	
290		**EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC MONITORING**		**EPIDEMIOLOGICAL SURVEILLANCE, EU REFERENCE LABORATORIES AND AD HOC MONITORING**	
291	Article 13	*Article 13*		*Article 13*	
292		**Epidemiological surveillance**		**Epidemiological surveillance**	
293	Article 13 – paragraph 1	1. The network for the	**Amendments 146 and 268** 1. The network for the	1. The network for the	

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		epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.	epidemiological surveillance of the communicable diseases***, including communicable diseases 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, ***in particular the HERA,*** the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.	epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance. **The ECDC shall ensure the integrated operation of the network as set out in Article 5 of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].**	
294	Article 13 – paragraph 1 - subparagraph 1a (new)			**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.**	
295	Article 13 – paragraph 2	2. The epidemiological surveillance network shall aim to:		2. The epidemiological surveillance network shall aim to:	
296	Article 13 – paragraph 2- point a	(a) monitor trends in communicable diseases over time and across Member States and in		(a) monitor trends in communicable diseases over time and across Member States and in	

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		third countries to assess the situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;		third countries to assess the situation, respond to rises above warning thresholds and facilitate appropriate evidence-based action;	
297	Article 13 – paragraph 2- point b	(b) detect and monitor any multinational communicable disease outbreaks with respect to source, time, population and place in order to provide a rationale for public health action;		(b) detect and monitor any ~~multinational~~ **cross-border** communicable disease outbreaks with respect to source, time, population and place in order to provide a rationale for public health action;	
298	Article 13 – paragraph 2 – point b a (new)		**Amendment 147** ***(ba) monitor the impact of communicable diseases on the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions;***		
299	Article 13 – paragraph 2 – point b b (new)		**Amendment 148** ***(bb) monitor the impact of communicable diseases on mental health;***		
300	Article 13 – paragraph 2- point c	(c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve those programmes at the national and Union level;		(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;	

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301	Article 13 – paragraph 2- point d	(d) identify risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;	**Amendment 149** (d) identify ***and monitor*** risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;	(d) identify risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;	
302	Article 13 – paragraph 2- point e	(e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation ***and*** mortality;	**Amendment 150** (e) contribute to the assessment of the burden of communicable diseases ***on health systems and care delivery and*** on the population using such data as disease prevalence, complications, hospitalisation**,** mortality**, *the mental health impact, deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions and their social and economic impact***;	(e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation and mortality;	
303	Article 13 – paragraph 2- point f	(f) contribute to the assessment of health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases as well as patients' safety;		(f) contribute to the assessment of health systems' capacity for diagnosis, prevention and treatment of specific communicable diseases ~~as well as patients' safety~~;	
304	Article 13 – paragraph 2- point g	(g) contribute to modelling and scenario development for response;		(g) contribute to modelling and scenario development for response;	
305	Article 13 – paragraph 2- point h	(h) identify research priorities and needs, and implement relevant research		(h) **contribute to the identification** ~~identify~~ **of** research priorities and needs, and	

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		activities;		implement relevant research activities **aimed at strenghtening public health** ;	
306	Article 13 – paragraph 2 – point h a (new)		**Amendment 151** ***(ha) identify any weaknesses in the global supply chain involved in the production and manufacturing of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of communicable diseases, and make plans to mitigate such weaknesses. Other mechanisms, such as a Union export control mechanism, regulatory flexibility, cooperation agreements, compulsory or voluntary licensing agreements between companies, may enable the Union to facilitate access to counter-measures for its citizens and residents as well as for people from the Eastern Partnership countries and low and middle-income countries;***		
307	Article 13 – paragraph 2- point i	(i) support the contract tracing measures of competent health authorities.		(i) support the contract tracing measures of competent health authorities.	
308	Article 13 – paragraph 3	3. The national competent authorities referred to in paragraph 1 shall communicate the following information to the participating authorities of the epidemiological		3. The national competent authorities referred to in paragraph 1 shall communicate the following information**, based on agreed indicators and standards, taking into account the actual public**	

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		surveillance network:		**health situation,** to the participating authorities of the epidemiological surveillance network:	
309	Article 13 – paragraph 3 – point a	(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);		(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)	
310	Article 13 – paragraph 3– point b	(b) relevant information concerning the progression of epidemic situations, including for modelling and scenario development;		(b) relevant information concerning the progression of epidemic situations, including for modelling and scenario development;	
311	Article 13 – paragraph 3– point c	(c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;		(c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries;	
312	Article 13 – paragraph 3 – point d	(d) molecular pathogen data, if required for detecting or investigating cross-border health threats;		(d) molecular pathogen data, if required for detecting or investigating cross-border health threats;	
313	Article 13 – paragraph 3 – point e	(e) health systems system data required for managing cross-border health threats; and		(e) health systems ~~system~~ data required for managing cross-border health threats; and	
314	Article 13 – paragraph 3–	(f) information about contract tracing monitoring systems developed at national		(f) information about contract tracing monitoring systems developed at national	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point f	level.		level.	
315	Article 13 – paragraph 3 – point f a (new)		**Amendment 152** ***(fa) information on the availability of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of the disease.***		
316	Article 13 – paragraph 3 a (new)		**Amendment 153** ***3a. The information communicated by Member States referred to in point (a) of paragraph 3 shall be reported at least at NUTS II level to the European Surveillance System (TESSy) or another platform, on a timely basis determined in accordance with Article 7.***		
317	Article 13 – paragraph 4	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.		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.	
318	Article 13 – paragraph 5	5. The Commission and the Member States shall work together to define disease-specific European surveillance standards based on the proposal of the		5. The Commission and the Member States shall work together **to strenghten the data collection capacity of Member States and** to define disease-	

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		ECDC, in consultation with the relevant surveillance networks.		specific European surveillance standards based on the proposal of the ECDC, in consultation with the relevant surveillance networks.	
319	Article 13 – paragraph 6 - subparagraph 1	6. The ECDC shall monitor Member States' adherence to these surveillance standards and share regular monitoring reports with the HSC and the Commission.		6. The ECDC shall **liaise with** ~~monitor~~ Member States[2] **to examine the** adherence to these surveillance standards, **supporting 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.~~	
320	Article 13 – paragraph 6 - subparagraph 2	The ECDC shall regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC.		~~The ECDC shall regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC.~~	
321	Article 13 – paragraph 6 – subparagraph 2 a (new)		**Amendment 154** ***The ECDC shall support the Member States to ensure the collection and sharing of data in times of health crisis and the integrated operation of the network for the epidemiological surveillance of communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1). The ECDC shall, where appropriate, also make available***		

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			its expertise in that domain to third countries.		
322	Article 13 – paragraph 7	7. The Commission may complement the action of the Member States through the adoption of recommendations on surveillance addressed to Member States.		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.**	
323	Article 13 – paragraph 8	8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.		8. Each Member State shall designate the competent authorities responsible within the Member State for epidemiological surveillance as referred to in paragraph 1.	
324	Article 13 – paragraph 9	9. The Commission shall***, by means of implementing acts,*** establish and update:	**Amendment 155** 9. The Commission shall ***adopt delegated*** acts ***in accordance with Article 28 concerning the establishment and*** update ***of***:	9. The Commission shall, by means of implementing acts, establish and update:	
325	Article 13 – paragraph 9 – subparagraph 1- point a	(a) the list of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1), in order to ensure coverage of communicable diseases and related special health issues by the		(a) the list of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1), in order to ensure coverage of communicable diseases and related special health issues by the	

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		epidemiological surveillance network;		epidemiological surveillance network;	
326	Article 13 – paragraph 9– subparagraph 1- point b	(b) case definitions concerning each communicable disease and related special health issue subject to epidemiological surveillance, in order to ensure the comparability and compatibility at Union level of the collected data;		(b) case definitions concerning each communicable disease and related special health issue subject to epidemiological surveillance, in order to ensure the comparability and compatibility at Union level of the collected data;	
327	Article 13 – paragraph 9– subparagraph 1- point c	***(c) procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].***	**Amendment 156** ***deleted***	(c) procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of Regulation (EU) …/… [*OJ: Please insert the number of Regulation ECDC* [ISC/2020/ 12527]].	
328	Article 13 – paragraph 9 – subparagraph 2	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	
329	Article 13 – paragraph 9 a (new)		**Amendment 157** ***9a. Where 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 between Member States so require, the procedure provided for in Article 28a shall apply to delegated acts adopted pursuant***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			to this Article.		
330	Article 13 – paragraph 9 b (new)		**Amendment 158** ***9b. The Commission shall, by means of implementing acts, establish and update procedures for the operation of the epidemiological surveillance network developed pursuant to Article 5 of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].***		
331	Article 13 – paragraph 10	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.***	**Amendment 159** 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 procedures 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).	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.	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
332	Article 14	*Article 14*		*Article 14*	
333		**Platform for surveillance**		**Platform for surveillance**	
334	Article 14 – paragraph 1	1. The ECDC shall ensure the ***further*** development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.	**Amendment 160** 1. The ECDC shall ensure the ***continued*** development of the digital platform ***after having conducted a data protection impact assessment and having mitigated any risks to the rights and freedoms of the data subjects,*** 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. ***It shall ensure there is human oversight of the digital platform and include specific measures for minimising risks that may emerge from the transfer of biases or incomplete data from multiple sources, as well as establish procedures for data quality review. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Article 27(1)***	1. The ECDC shall ensure the further development of the digital platform through which data are managed and automatically exchanged, **in order** to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control**, in particular in the frame of the European Health Data Space, pursuant to point (g) of Article 5(2) of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]]**. **The ECDC, in close cooperation with Member States, shall also ensure the interoperability with national systems.**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			of Regulation (EU) 2018/1725.		
335	Article 14 – paragraph 2	2. The digital platform shall		2. The digital platform shall	
336	Article 14 – paragraph 2 – point a	(a) enable the automated collection of surveillance and laboratory data, make use of ***information from*** electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;	**Amendment 161** (a) enable the automated collection of surveillance and laboratory data, make use of ***relevant 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 ***statistical*** reporting ***in accordance with Article 22 GDPR***;	(a) enable the automated collection of surveillance and laboratory data, ~~make use of information from electronic health records,~~ media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;	
337	Article 14 – paragraph 2 - point b	(b) allow for the computerised handling and exchange of information, data and documents.	**Amendment 162** (b) allow for the computerised processing and exchange of information, data and documents, ***taking into account Union law concerning the protection of personal data;***	(b) allow for the computerised handling and exchange of information, data and documents.	
338	Article 14 – paragraph 2 – point b a (new)		**Amendment 163** ***(ba) allow for automated notification on EWRS when communicable diseases rise above warning thresholds, as referred to in point (a) of Article 13(2). The notification shall be validated by the competent health***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			authority.		
339	Article 14 – paragraph 3	3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely ***and*** complete information, data and documents transmitted and exchanged through the digital platform.	**Amendment 164** 3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely**,** complete ***and accurate*** information, data and documents transmitted and exchanged through the digital platform. ***The Member States shall promote the automation of this process between the national and the Union surveillance system.***	3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information**, that is available in the Member States**, data and documents transmitted and exchanged through the digital platform.	
340	Article 14 – paragraph 4	4. The ECDC shall		4. **For the purposes of this Article, t**~~T~~he ECDC shall	
341	Article 14 – paragraph 4-point a	(a) monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission;		(a) monitor the functioning of the integrated surveillance system and share regular monitoring reports with the Member States and the Commission;	
342	Article 14 – paragraph 4-point b	(b) regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC and transmitted and exchanged through the digital platform.		(b) regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC and transmitted and exchanged through the digital platform.	
343	Article 14 – paragraph 5	5. For epidemiological purposes, ECDC shall also have	**Amendment 165** 5. For epidemiological ***surveillance*** purposes, ECDC	5. For epidemiological purposes, ECDC shall also have	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.	shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes. ***The access to the health data shall be proportionate to specific and concrete purposes that shall have been defined previously by ECDC.***	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.	
344	Article 14 – paragraph 5a (new)			**5a. Any processing of personal data for the purposes of this Article shall be carried out, whenever applicable, in accordance with the data protection requirements as laid down in Article 25a.**	
345	Article 14 – paragraph 6	6. The Commission shall adopt ***implementing*** acts ***for*** the functioning of the surveillance platform ***which lay*** down:	**Amendment 166** 6. ***The Commission, following the carrying out of a consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725,*** shall adopt ***delegated*** acts ***in accordance with Article 28 concerning*** the functioning of the surveillance platform ***laying*** down:	6. The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:	
346	Article 14 – paragraph 6-point a	(a) the technical specifications of the platform, including the electronic data exchange mechanism for	**Amendment 167** (a) the technical specifications of the platform, including the electronic data exchange mechanism for	(a) the technical specifications of the platform, including the electronic data exchange mechanism for	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;	exchanges with existing ***international and*** national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;	exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;	
347	Article 14 – paragraph 6-point b	(b) the specific rules for the functioning of the platform, including to ensure protection of personal data and security of exchange of information;		(b) the specific rules for the functioning of the platform, including to ensure protection of personal data and security of exchange of information;	
348	Article 14 – paragraph 6-point c	(c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;	**Amendment 168** (c) contingency arrangements ***and secure data backups*** to be applied in the event of unavailability of any of the functionalities of the platform;	(c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;	
349	Article 14 – paragraph 6-point d	(d) the cases where, and the conditions under which the ***third countries and*** international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;	**Amendment 169** (d) the cases where, and the conditions under which the international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access, ***in full compliance with Regulations (EU) 2018/1725 and (EU) 2016/679 and Directive (EU) 2016/680;***	(d) the cases where, and the conditions under which the third countries and international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;	
350	Article 14 – paragraph 6-	(e) the cases where, and the conditions under which the data,		(e) the cases where, and the conditions under which the data,	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point e	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		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	
351	Article 14 – paragraph 6- point f	(f) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures referred to in paragraph 5.		(f) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures referred to in paragraph 5.	
352	Article 14 – paragraph 6 – point f a (new)		**Amendment 170** ***(fa) ensure standardisation of the infrastructure for storage, processing and analysis of data.***		
353	Article 14 – paragraph 6a (new)		**Amendment 171** ***6a. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Article 27(1) of Regulation (EU) 2018/1725.***		
354	Article 15	*Article 15*		*Article 15*	
355		**EU reference laboratories**		**EU reference laboratories**	
356	Article 15 – paragraph 1	1. In the area of public	**Amendment 172** 1. In the area of public	1. In the area of public	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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.	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 diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.	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, **define specific selection criteria and** 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 **specific** ~~certain~~ tests for the uniform surveillance, notification and reporting of diseases by Member States.	
357	Article 15 – paragraph 2	2. The EU reference laboratories shall be responsible in particular for the following tasks to coordinate the network of national reference laboratories, in particular, in the following areas:		2. The EU reference laboratories shall be responsible ~~in particular~~ for the following tasks to coordinate the network of national reference laboratories, in particular, in the following areas:	
358	Article 15 – paragraph 2-point a	(a) reference diagnostics, including test protocols;		(a) reference diagnostics, including test protocols;	
359	Article 15 – paragraph 2-point b	(b) reference material resources;		(b) reference material resources;	
360	Article 15 – paragraph 2-	(c) external quality assessments;		(c) external quality assessments;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point c				
361	Article 15 – paragraph 2- point d	(d) scientific advice and technical assistance;		(d) scientific advice and technical assistance;	
362	Article 15 – paragraph 2- point e	(e) collaboration and research;		(e) collaboration and research;	
363	Article 15 – paragraph 2- point f	(f) monitoring, alert and support in outbreak response; and	**Amendment 173** (f) monitoring, alert and support in outbreak response***, in particular for emerging pathogens;*** and	(f) monitoring, alert and support in outbreak response**, including to emerging communicable diseases and pathogenic bacteria and viruses**; and	
364	Article 15 – paragraph 2- point g	(g) training.		(g) training.	
365	Article 15 – paragraph 3	3. The network of EU reference laboratories shall be operated and coordinated by the ECDC.	**Amendment 174** 3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, ***in cooperation with WHO network laboratories to avoid duplication of activities. The governance structure of the network shall cover cooperation and coordination with existing national and regional reference laboratories and networks***.	3. The network of EU reference laboratories shall be operated and coordinated by the ECDC**, in cooperation with the WHO Reference Laboratories**.	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
366	Article 15 – paragraph 3 a (new)		**Amendment 175** ***3a. The laboratories referred to in paragraph 1 shall contribute to sharing good practices and to improving the epidemiological surveillance referred to in Article 13.***		
367	Article 15 – paragraph 4 - subparagraph 1	4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. Designations shall establish the responsibilities and tasks of the designated laboratories.	**Amendment 176** 4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. ***The Commission shall consult the Member States and the ECDC to elaborate the terms of reference and the criteria of the designation process.*** Designations shall establish the responsibilities and tasks of the designated laboratories. ***Laboratory consortia shall be eligible for designation.***	4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of ***3*** ~~5~~ years, and be reviewed regularly.Designations shall establish the responsibilities and tasks of the designated laboratories.	
368	Article 15 – paragraph 4 - subparagraph 2	Those implementing acts shall be adopted with the in accordance with the examination procedure referred to in Article 27(2).		Those implementing acts shall be adopted ~~with the~~ in accordance with the examination procedure referred to in Article 27(2).	
369	Article 15 – paragraph 5 - subparagraph 1	5. The laboratories referred to in paragraph 1 shall		5. The laboratories referred to in paragraph 1 shall	
370	Article 15 –		**Amendment 177**		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	paragraph 5 - subparagraph 1- point a	(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;	(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. ***Particular attention shall be paid to proprietary tests and methods that may be the property of laboratories***;	(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;	
371	Article 15 – paragraph 5- subparagraph 1- point b	(b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;		(b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;	
372	Article 15 – paragraph 5- subparagraph 1- point c	(c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;		(c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;	
373	Article 15 – paragraph 5- subparagraph 1- point d	(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;		(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;	
374	Article 15 – paragraph 5- subparagraph 1-	(e) be equipped, or have access to, the necessary equipment to perform their tasks in		(e) be equipped, or have access to, the necessary equipment to perform their tasks in	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point e	emergency situations; and		emergency situations; and	
375	Article 15 – paragraph 5- subparagraph 1- point f	(f) where relevant, be equipped to comply with relevant biosecurity standards.		(f) where relevant, be equipped to comply with relevant biosecurity standards.	
376	Article 15 – paragraph 5 - subparagraph 2	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.		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.	
377	Article 15 – paragraph 6	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.		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.	
378	Article 16	*Article 16*		*Article* 16	
379		**Network for substances of human origin**		**Network for substances of human origin**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
380	Article 16 – paragraph 1	1. A network of Member States' services supporting transfusion, transplantation and medically assisted reproduction is established to allow for the continuous and rapid access to sero-epidemiological data, including assessment of donor population exposure and immunity, and to monitor, assess and help address disease outbreaks that are relevant to substances of human origin.		1. A network of Member States' services supporting transfusion~~,~~ and **transplantation** ~~medically assisted reproduction is established to allow for the continuous and rapid access to sero-epidemiological data, including assessment of donor population exposure and immunity, and~~ to monitor, assess and help address disease outbreaks that are relevant to substances of human origin. **The network shall ensure to address any medically assisted reproduction issues in relation with disease outbreak, if relevant.**	
381	Article 16 – paragraph 2	2. The network shall be operated and coordinated by the ECDC.		2. The network shall be operated and coordinated by the ECDC.	
382	Article 16 – paragraph 3	3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting transfusion, transplantation and medically assisted reproduction as referred to in paragraph 1.		3. Each Member State shall designate the competent authorities responsible within their territory for the services supporting transfusion~~,~~ ~~transplantation~~ and **transplantation** ~~medically assisted reproduction~~ as referred to in paragraph 1.	
383	Article 17	*Article 17*		*Article 17*	
384		**Ad hoc monitoring**		**Ad hoc monitoring**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
385	Article 17 – paragraph 1	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.		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.	
386	Article 17 – paragraph 1 a (new)		**Amendment 178** ***1a. The European Surveillance System (TESSy) 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).***		
387	Article 17 – paragraph 2	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.		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.	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
388	Article 17 – paragraph 3 - subparagraph 1	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.	**Amendment 179** 3. The Commission shall adopt, where necessary, ***delegated acts in accordance with Article 28*** concerning 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.	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.	
389	Article 17 – paragraph 3 - subparagraph 2	***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).***	**Amendment 180** ***deleted***	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	
390	Article 17 – paragraph 3 - subparagraph 3	***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).***	**Amendment 181** ***Where*** 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 between the Member States ***so require,*** the ***procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.***	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).	
391	CHAPTER IV	**CHAPTER IV**		**CHAPTER IV**	
392		**EARLY WARNING AND**		**EARLY WARNING AND**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		RESPONSE		**RESPONSE**	
393	Article 18	*Article 18*		*Article 18*	
394		**Early warning and response system**		**Early warning and response system**	
395	Article 18 – paragraph 1	1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.	**Amendment 182** 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.	1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.	
396	Article 18 – paragraph 2 - subparagraph 1	2. The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:	**Amendment 183** 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:	2. The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:	
397	Article 18 – paragraph 2 – subparagraph 1- point a	(a) the processing of personal data of authorised users of the system;		(a) the processing of personal data of authorised users of the system;	
398	Article 18 – paragraph 2 – subparagraph 1-	(b) the processing of health data and other personal data, in particular, the contact tracing data		(b) the processing of health data and other personal data **when strictly necessary for the**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point b	through the EWRS selective messaging functionality.		**purpose of contact tracing**, ~~in particular, the contact tracing data~~ through the EWRS selective messaging functionality**, in accordance with Article 26**.	
399	Article 18 – paragraph 2 - subparagraph 2	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.	**Amendment 184** 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 sole purpose of fighting the pandemic and proven to be adequate, necessary and proportionate, and in full compliance with Regulation (EU) 2016/679 and Directive 2002/58/EC.***	**Taking into account Member States' opinions, the** ~~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**, provided that these technologies ensure an equivalent protection of personal data**. **The ECDC, in close cooperation with Member States, shall ensure the interoperability with national systems for the purposes of the early warning and response system.**	
400	Article 18 – paragraph 2 - subparagraph 2a (new)			**The ECDC shall also provide technical assistance to the competent authorities responsible at national level, including training following updates to the EWRS platform.**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
401	Article 18 – paragraph 2 – subparagraph 2 a (new)		**Amendment 185** ***To ensure data quality and consistency, the EWRS shall implement robust, accurate and interoperable data processes with Member States. The ECDC shall coordinate with Member States throughout such data exchange processes, from assessing the data requirements, transmission and collection, to up to date actualisation and interpretation, ensuring strong collaboration between the Commission, the ECDC and national and regional competent bodies.***		
402	Article 18 – paragraph 2 a (new)		**Amendment 186** ***2a. The ECDC shall develop and improve the EWRS, to augment the automation of information collection and analysis, upgrade the categorisation of notifications, reduce open text communication, reduce the administrative burden and improve the standardisation of the notifications.***		
403	Article 18 – paragraph 2 b (new)		**Amendment 187** ***2b. The EWRS shall be improved to reduce the burden of bureaucracy and duplications of notification. The EWRS shall allow the national competent***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			authorities to notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, and shall integrate this information in the EWRS system, in order to automatically notify an alert in the EWRS.		
404	Article 18 – paragraph 3	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.		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**.	
405	Article 18 – paragraph 4 - subparagraph 1	4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.	**Amendment 188** 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	4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health**, in a coordinated One Health**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			cross-border threats to health.	**approach**.	
406	Article 18 – paragraph 4 - subparagraph 2	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	
407	Article 18 – paragraph 4 - subparagraph 2 a (new)			**For the purposes of this Article, any processing of personal data shall be carried out in accordance with data protection requirements, pursuant to Article 25a.**	
408	Article 18 – paragraph 4 a (new)		**Amendment 189** ***4a. The EWRS shall be able to automatically collect information from other 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.***		
409	Article 19	*Article 19*		*Article 19*	
410		**Alert notification**		**Alert notification**	
411	Article 19 – paragraph 1	1. National competent authorities or the Commission shall notify an alert in the EWRS where the emergence or development of a serious cross-		1. National competent authorities or the Commission shall notify an alert in the EWRS where the emergence or development of a serious cross-	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		border threat to health fulfils the following criteria:		border threat to health fulfils the following criteria:	
412	Article 19 – paragraph 1- point a	(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		(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	
413	Article 19 – paragraph 1- point b	(b) it affects or may affect more than one Member State; and		(b) it affects or may affect more than one Member State; and	
414	Article 19 – paragraph 1- point c	(c) it requires or may require a coordinated response at Union level.		(c) it requires or may require a coordinated response at Union level.	
415	Article 19 – paragraph 2	2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, ***they*** shall ***at the latest*** simultaneously ***notify an alert*** in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.	**Amendment 190** 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),*** shall ***be*** simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.	2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, they shall at the latest simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.	
416	Article 19 –	3. When notifying an alert,		3. When notifying an alert,	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	paragraph 3	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:		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:	
417	Article 19 – paragraph 3- point a	(a) the type and origin of the agent;		(a) the type and origin of the agent;	
418	Article 19 – paragraph 3- point b	(b) the date and place of the incident or outbreak;		(b) the date and place of the incident or outbreak;	
419	Article 19 – paragraph 3- point c	(c) means of transmission or dissemination;		(c) means of transmission or dissemination;	
420	Article 19 – paragraph 3- point d	(d) toxicological data;		(d) toxicological data;	
421	Article 19 – paragraph 3- point e	(e) detection and confirmation methods;		(e) detection and confirmation methods;	
422	Article 19 – paragraph 3- point f	(f) public health risks;	**Amendment 191** (f) public health risks***, especially for vulnerable groups, including, as far as possible, their impact on major non-communicable diseases***;	(f) public health risks;	
423	Article 19 –	(g) public health measures		(g) public health measures	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	paragraph 3- point g	implemented or intended to be taken at national level;		implemented or intended to be taken at national level;	
424	Article 19 – paragraph 3- point h	(h) measures other than public health measures;	**Amendment 192** (h) ***multisectoral*** measures other than public health measures;	(h) measures other than public health measures;	
425	Article 19 – paragraph 3- point i	(i) urgent need or shortage of medical countermeasures;		(i) urgent need or shortage of medical countermeasures;	
426	Article 19 – paragraph 3 – point i a (new)		**Amendment 193** ***(ia) the existing and potential production sites, with the sole aim of allowing the Union to map the strategic production capacities for the Union as a whole;***		
427	Article 19 – paragraph 3- point j	(j) requests and offers for cross-border emergency assistance;	**Amendment 194** (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***;	(j) requests and offers for cross-border emergency assistance**, including requests for medical evacuation**;	
428	Article 19 – paragraph 3- point k	(k) personal data necessary for the purpose of contact tracing in accordance with Article 26;		(k) personal data necessary for the purpose of contact tracing in accordance with Article 26;	
429	Article 19 – paragraph 3-	(l) any other information relevant to the serious cross-		(l) any other information relevant to the serious cross-	

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	point l	border threat to health in question.		border threat to health in question.	
430	Article 19 – paragraph 4	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.		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.	
431	Article 19 – paragraph 4 a (new)		**Amendment 195** ***4a. The Member State shall update the information referred to in paragraph 3 as new data become available.***		
432	Article 20	*Article 20*		*Article 20*	
433		**Public health risk assessment**		**Public health risk assessment**	
434	Article 20 – paragraph 1	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	**Amendment 196** 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	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	

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		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:	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***, including a risk assessment of the mental health of the affected population***. That risk assessment shall be carried out by:	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:	
435	Article 20 – paragraph 1 – point -a (new)		**Amendment 269** ***(-a) the HERA in accordance with Article 2(2) (a) of the Commission Decision of 16 September 2021. The assessment by the HERA shall be carried out in such a way as to allow a decision to be taken on the activation of the emergency framework as set out in Article 3 of a Council Regulation on a framework for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and on which measures as set out in Articles 5 to 11 and Article 13 of that Regulation it is appropriate to activate;***		
436	Article 20 – paragraph 1 –	(a) the ECDC in accordance	**Amendment 197** (a) the ECDC in accordance	(a) the ECDC in accordance	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point a	with Article 8a of Regulation (EU) .../... *[OJ: Please insert the number of Regulation ECDC* [ISC/2020/ 12527]] in the case of a threat referred to in ***points (i) and (ii) of*** point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or	with Article 8a of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]] in the case of a threat referred to in point (a) of Article 2(1) including substances of human origin: ***such as*** blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or	with Article 8a of Regulation (EU) …/… *[OJ: Please insert the number of Regulation ECDC* [ISC/2020/ 12527]] in the case of a threat referred to in ~~points (i) and (ii) of~~ point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or	
437	Article 20 – paragraph 1 – point a a (new)		**Amendment 198** ***(aa) the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2021/... [insert the number of revised EMA regulation 2020/0321(COD)], in the case of a threat linked to a defective medical product or in the event a threat is becoming more severe as a result of a shortage of medical products for human use or medical devices; and/or***		
438	Article 20 – paragraph 1 – point b	(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		(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	

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439	Article 20 – paragraph 1 – point c	(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		(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	
440	Article 20 – paragraph 1 – point d	(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;		(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;	
441	Article 20 – paragraph 1 – point e	(e) the European Centre for Monitoring Centre for Drugs and Drug Addictions (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council 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.		(e) the European Centre for Monitoring ~~Centre~~ for Drugs and Drug Addictions (EMCDDA) in accordance with Regulation (EC) No 1920/2006 of the European Parliament and of the Council 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.	
442	Article 20 – paragraph 1 – point f	(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		(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	

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		or criminal activity, and in cooperation with the European Medicines Agency ('EMA)', where the threat is linked to medicinal products.		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.	
443	Article 20 – paragraph 1 – point f a (new)		**Amendment 199** ***(fa) Union or national entities engaged in stockpiling of medical products.***		
444	Article 20 – paragraph 2	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.	**Amendment 200** 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 data ***and expertise*** at their disposal. ***When delivering its risk assessment, the agency or body shall be designated as the 'lead' agency in accordance with paragraph 3 . The agency or body shall ensure that it takes note of any information or expertise obtained from other agencies or bodies referred to in paragraph 1.***	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.**	
445	Article 20 – paragraph 3 - subparagraph 1	3. Where the risk assessment needed is totally or partially outside the mandates of	**Amendment 201** 3. Where the risk assessment needed is totally or partially outside the mandates of	3. Where the risk assessment needed is totally or partially outside the mandates of	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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 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. ***Where the risk assessment needed falls under the mandate of several of the agencies referred to in paragraph 1, the Commission shall designate a lead agency to be in charge of carrying out the risk assessment, in collaboration with the other agencies concerned, and set a deadline for the submission of the assessment by that agency.***	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.	
446	Article 20 – paragraph 3 - subparagraph 2	The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication.	**Amendment 202** The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication ***through the EWRS and the HSC***.	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 need is so urgent that the immediate publication of the risk assessment is necessary**.	

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447	Article 20 – paragraph 3 - subparagraph 3	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.	**Amendment 203** The risk assessment shall take into account, if available, relevant information provided by ***public health experts and*** other entities, in particular by the WHO in the case of a public health emergency of international concern.	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.	
448	Article 20 – paragraph 4	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.		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.	
449	Article 21	*Article 21*		*Article 21*	
450		**Coordination of response within the HSC**		**Coordination of response within the HSC**	
451	Article 21 – paragraph 1	1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission:	**Amendment 270** 1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission ***in particular with the HERA***:	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:	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
452	Article 21 – paragraph 1- point a	(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;		(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;	
453	Article 21 – paragraph 1- point b	(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public ***and*** to healthcare professionals;	**Amendment 204** (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***;	(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare professionals;	
454	Article 21 – paragraph 1- point c	(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health.	**Amendment 205** (c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health***, including coordination of response measures***.	(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 threat**s** to health**, based on the expert opinion of relevant technical Union bodies or agencies;**	
455	Article 21 – paragraph 1 – point c a (new)		**Amendment 206** ***(ca) national travel restrictions and other cross-border restrictions on movement***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			and the gathering of people, as well as quarantine requirements and supervision of quarantines following cross-border travel.		
456	Article 21 – paragraph 1- point d (new)			**(d) the support to the EU's integrated political crisis response mechanism (IPCR) in case of its activation.**	
457	Article 21 – paragraph 2	2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform ***and*** consult the other Member States ***and*** the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.	**Amendments 207 and 271** 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***, in particular the HERA, the HCB and the Health Security Committee*** 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.	2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform and consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.	
458	Article 21 – paragraph 3	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,	**Amendments 208 and 272** 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,	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,	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		immediately upon adoption, inform the other Member States ***and*** the Commission on the nature, purpose and scope of those measures.	immediately upon adoption, inform the other Member States***, relevant regional authorities,*** the Commission***, in particular the HERA, the HCB and the Health Security Committee*** on the nature, purpose and scope of those measures ***especially in cross-border regions***.	**promptly** ~~immediately~~ upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.	
459	Article 21 – paragraph 3 a (new)		**Amendment 209** ***3a. In the event of a serious cross-border threat to health overwhelming national response capacities in a Member State, that Member State may also 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[1a].*** _____ ***[1a] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism.***		
460	Article 21 – paragraph 4	4. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination		4. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		provided for in paragraphs 1, 2 and 3.		provided for in paragraphs 1, 2 and 3.	
461		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	
462	Article 22	*Article 22*		*Article 22*	
463		**Recommendations on common temporary public health measures**		**Recommendations on common temporary public health measures**	
464	Article 22 – paragraph 1	1. The Commission may complement the action of the Member States through the adoption of recommendations on common temporary public health measures for Member States.		1. The Commission may complement the action of the Member States through the adoption of recommendations on common temporary public health measures **at Union level** ~~for Member States~~.	
465	Article 22 – paragraph 2	2. The recommendation for measures adopted under paragraph 1 shall:		2. The recommendation for measures adopted under paragraph 1 shall:	
466	Article 22 – paragraph 2-point a	(a) be based on in particular recommendations of the ECDC in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;	**Amendment 273** (a) be based on in particular recommendations of the ECDC ***and the HERA*** in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;	(a) be based on ~~in particular~~ recommendations of the ECDC **and the WHO** in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;	
467	Article 22 – paragraph 2-	(b) respect the responsibilities of the Member		(b) respect the responsibilities of the Member	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	point b	States for the definition of their health policy and for the organisation and delivery of health services and medical care;		States for the definition of their health policy and for the organisation and delivery of health services and medical care;	
468	Article 22 – paragraph 2- point c	(c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services.	**Amendment 210** (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 to the rights, freedoms and principles enshrined in the Charter of Fundamental Rights of the European Union, and promote coordination of measures between Member States;***	(c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services**;** -	
469	Article 22 – paragraph 2 – point c a (new)		**Amendment 211** ***(ca) be time limited, and cease as soon as one of the applicable conditions set out in points (a), (b) and (c) is no longer met;***		
470	Article 22 – paragraph 2 – point c b (new)		**Amendment 212** ***(cb) take into account the need for an internal market that functions normally, in particular the existence of green lanes for free circulation of food and medical countermeasures.***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
471	Article 22 – paragraph 2 – point d (new)			**(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.**	
472	CHAPTER V	**CHAPTER V**		**CHAPTER V**	
473		**PUBLIC HEALTH EMERGENCY AT UNION LEVEL**		**PUBLIC HEALTH EMERGENCY AT UNION LEVEL**	
474	Article 23	*Article 23*		*Article 23*	
475		**Recognition of emergency situations**		**Recognition of public health emergency situations at Union level**	
476	Article 23 – paragraph 1	1. The Commission may, based on the expert opinion of the Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level; including pandemic situations where the serious cross-border threat to health in question endangers public health at the Union level.		1. **For serious cross-border threats to health referred to in Article 2(1), t**~~T~~he Commission may, based on the expert opinion of the **ECDC, any other relevant Union agencies or bodies and the** Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level;	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
				including pandemic situations where the serious cross-border threat to health in question endangers public health at the Union level.	
477	Article 23 – paragraph 2	2. The Commission shall terminate the recognition referred to in paragraph 1 as soon as one of the applicable conditions laid down therein is no longer met.		2. The Commission shall terminate the recognition referred to in paragraph 1 as soon as one of the applicable conditions **pursuant to paragraphs 1 and 4** ~~laid down therein is~~ **are** no longer met.	
478	Article 23 – paragraph 3	3. Before recognising a situation of public health emergency at Union level, the Commission ***should*** liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.	**Amendment 213** 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.	3. Before recognising a situation of public health emergency at Union level, the Commission **shall** ~~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.	
479	Article 23 – paragraph 4 subparagraph 1	4. The Commission shall adopt the measure referred to in paragraphs 1 and 2 by means of implementing acts.		4. The Commission shall **define specific criteria for a public health emergency at Union level** ~~adopt the measure referred to in paragraphs 1 and 2~~ by means of implementing acts.	
480	Article 23 – paragraph 4 – subparagraph 2	Those implementing acts shall be adopted in accordance with the examination procedure referred to	**Amendment 214** Those implementing acts shall be adopted in accordance with the examination procedure referred to	Those implementing acts shall be adopted in accordance with the examination procedure referred to	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		in Article 27(2).	in Article ***27(3)***.	in Article 27(2).	
481	Article 23 – paragraph 4 – subparagraph 3	On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise situations of public health emergency pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).		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).	
482	Article 23 – paragraph 4 a (new)		**Amendment 274** ***4a. Following the recognition of public health emergency, the Council, upon the proposal of the Commission, may adopt a regulation activating the emergency framework where that is appropriate to the economic situation, pursuant to Article 3 of a 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. Where the emergency framework is activated, the HCB shall be set up to coordinate action by the Council, the Commission, the relevant Union agencies and***		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
			bodies, and Member States to ensure the supply and access of medical countermeasures. In such situations, pursuant to the Joint Declaration on budgetary scrutiny of new proposals based on Article 122 TFEU, a Joint Committee consisting of representatives of the European Parliament and of the Council shall be established.		
483	Article 23 – paragraph 5 (new)			**5. The Commission shall adopt the decisions referred to in paragraphs 1 and 2 by means of implementing acts.**	
484	Article 24	*Article 24*		*Article 24*	
485		**Advisory Committee on public health emergencies**		**Advisory Committee on public health emergencies**	
486	Article 24 – paragraph 1 - subparagraph 1	1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:	**Amendment 215** 1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission***, with the consultation of the Health Security Committee*** 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 ***and the Health Security Committee*** by	1. **To support** ~~For the purpose of~~ the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:	

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			providing its views on:		
487	Article 24 – paragraph 1- subparagraph 1- point a	(a) whether a threat constitutes a public health emergency at Union level;		(a) whether a threat constitutes a public health emergency at Union level;	
488	Article 24 – paragraph 1- subparagraph 1- point b	(b) the termination of a public health emergency at Union level; and		(b) the termination of a public health emergency at Union level; and	
489	Article 24 – paragraph 1- subparagraph 1- point c	(c) advice on response including:		(c) advice on response **at Union level,** including:	
490	Article 24 – paragraph 1- subparagraph 1- point c-point i	(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;		(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;	
491	Article 24 – paragraph 1- subparagraph 1- point c – point ii	(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;	**Amendment 216** (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, and public health research needs;	(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;	

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492	Article 24 – paragraph 1 – subparagraph 1- point c – point ii a (new)		**Amendment 217** ***(iia) in consultation with EMA pursuant to Regulation (EU) …/… [OJ: Please insert the number of EMA Regulation], the stability of supply chains and production capacity of medical supply chains involved in the production and manufacturing of medical countermeasures needed for the diagnosis, treatment and follow-up of the disease concerned;***		
493	Article 24 – paragraph 1- subparagraph 1 - point c – point iii	(iii) prioritisation of health care, civil protection and other resources as well as support measures to be organised or coordinated at Union level;		(iii) prioritisation of health care, civil protection and other resources as well as support measures to be organised or coordinated at Union level;	
494	Article 24 – paragraph 1- subparagraph 1 - point c – point iv	(iv) subsequently, recommendation of policy measures for addressing and mitigating long-term consequences of the specific threat.		(iv) subsequently, recommendation of policy measures for addressing and mitigating long-term consequences of the specific threat.	
495	Article 24 – paragraph 1 – subparagraph 1a			**The advice on response provided under point (c) of this paragraph shall build upon recommendations of the ECDC, the WHO and other relevant agencies or bodies, accordingly**.	
496	Article 24 –		**Amendment 218**		

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
	paragraph 2	2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ECDC and of the EMA ***participate as observers*** in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis.	2. The Advisory Committee shall be composed of independent experts***, representatives of health and 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. The Committee should have multidisciplinary membership so it can advise on ***sanitary,*** biomedical, behavioural, social, economic, ***research, development, manufacturing,*** cultural***, transport*** and international aspects. The representatives of the ECDC and of the EMA ***shall take an active part*** in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission ***or the Health Security Committee*** may invite experts ***and stakeholders*** 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. ***The Commission shall 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***	2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring**, and include representatives of the ECDC and the EMA, as well as at least one expert nominated by each of the Member States within whose territory the threat arises, if applicable**. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representative~~s~~ of the **WHO** ~~ECDC and of the EMA~~ **may** participate as observer~~s~~ in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat ~~shall~~ **may** participate as **non-permanent members** ~~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. **The Member States may propose the appointment of relevant experts to the Commission, according to the**	

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			appointment.	**<u>specific subject matter.</u>**	
497	Article 24 – paragraph 2 a (new)		**Amendment 219** ***2a. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment. A geographical balance of the membership shall be ensured whenever possible. The members shall act in the public interest and in an independent manner. They shall make declarations of interest and of commitments. Such declarations shall include any activity, position, circumstances or other facts potentially involving a direct or indirect interest, in order to make it possible to identify interests which might be considered prejudicial to those experts' independence.***		
498	Article 24 – paragraph 2 b (new)		**Amendment 275** ***2b. The Advisory Committee shall act in cooperation with the HCB and the HERA Advisory Forum established under the Commission Decision of 16 September 2021. Representatives of the HERA Advisory Forum shall participate as observers on the Advisory Committee. The coordination between those***		

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			bodies shall ensure that there is participation by all relevant stakeholders, including healthcare professionals' organisations, patients' associations, and industry and supply chain actors with recognised experience in disciplines related to providing advice on response to health emergencies and to the work of the HERA.		
499	Article 24 – paragraph 3	3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State.	**Amendment 220** 3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission***, the Health Security Committee*** or a Member State.	3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State. **The Commission shall share all relevant information on Advisory Committee's meetings with the Member States through the HSC.**	
500	Article 24 – paragraph 4	4. The Advisory Committee shall be chaired by a representative of the Commission.		4. The Advisory Committee shall be chaired by a representative of the Commission.	
501	Article 24 – paragraph 5	5. The Secretariat of the Advisory Committee shall be provided by the Commission.		5. The Secretariat of the Advisory Committee shall be provided by the Commission.	
502	Article 24 – paragraph 6	6. The Advisory Committee shall establish its rules of procedure including on the rules	**Amendment 221** 6. The Advisory Committee shall establish its rules of procedure including on the rules	6. The Advisory Committee shall establish its rules of procedure including on the rules	

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		for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.	for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission ***and the Health Security Committee***.	for the declaration and termination of **a public health emergency at Union level** ~~an emergency situation~~, ~~and~~ adoption of recommendations**,** ~~and~~ voting **and ensuring data protection and privacy**. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.	
503	Article 24 – paragraph 6 a (new)		**Amendment 222** ***6a. The minutes of the Advisory Committee shall be public.***		
504	Article 24 – paragraph 6 b (new)		**Amendment 223** ***6b. The advisory committee shall work in close cooperation with national advisory bodies.***		
505	Article 25	*Article 25*		*Article 25*	
506		**Legal effects of recognition**		**Legal effects of recognition**	
507	Article 25 – paragraph 1	1. The recognition of an emergency situation pursuant to Article 23 shall have the legal effect of enabling the introduction of:		1. The recognition of **a public health emergency at Union level** ~~an emergency situation~~ pursuant to Article 23 shall have the legal effect of enabling the introduction of **the following non-exhaustive measures**:	
508	Article 25 – paragraph 1 -	(a) measures, which are applicable during the period of		(a) measures, which are applicable during the period of	

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	point a	public health emergencies, related to medicinal products and medical devices provided for in Regulation (EU) …/… [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]];		public health emergencies, related to medicinal products and medical devices provided for in Regulation (EU) …/… [*OJ: Please insert the number of Regulation EMA* [ISC/2020/12532]];	
509	Article 25 – paragraph 1 - point b	(b) ***mechanisms*** to monitor shortages of, ***develop, procure, manage and deploy*** medical countermeasures;	**Amendments 224 and 276** (b) ***measures, pursuant to a 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,*** to monitor shortages of, ***the development, the manufacture, the procurement, actions taken to ensure security of supply, the management, the storage, the distribution and the deployment of*** medical countermeasures;	(b) mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures**, in accordance with the applicable Union legislation, in particular Regulation (EU) …/… [OJ: Please insert the number of Regulation EMA [ISC/2020/12532]], and Article 12**;	
510	Article 25 – paragraph 1- point c	(c) activation of support from the ECDC as referred to in Regulation (EU) .../... *[OJ: Please insert the number of Regulation ECDC* [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force.	**Amendment 225** (c) activation of support from the ECDC as referred to in Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force ***and in particular the establishment of a list of accommodation facilities in intensive care units in the Member States for the purpose of***	(c) activation of support from the ECDC as referred to in Regulation (EU) …/… [*OJ: Please insert the number of Regulation ECDC* [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force**;**	

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			potential cross-border relocation of patients;		
511	Article 25 – paragraph 1 point d (new)			**(d) activation of IPCR mechanism as referred to in Council Decision 2014/415/EU.**	
512	Article 25 – paragraph 1 – point c a (new)		**Amendment 226** ***(ca) a Union export control mechanism with the aim of enabling the Union to guarantee timely and effective access to counter-measures;***		
513	Article 25 – paragraph 1 – point c b (new)		**Amendment 227** ***(cb) green lanes referred to in Article 25a of this Regulation, in exceptional cases.***		
514	Article 25 a (new)		**Amendment 228** ***Green lanes*** ***1. After recognising a public health emergency for a pandemic situation under Article 23(1), the Commission shall, in the case of border restrictions, establish green lanes to ensure that essential goods, medical countermeasures and cross border workers can move freely within the internal market.*** ***2. The Commission is empowered to adopt delegated acts to supplement this Regulation with provisions on the***		

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			establishment of the green lanes referred to in paragraph 1. ***3. A Member State may only prohibit or restrict exports of medical countermeasures in cases defined in Article 36 TFEU during a public health emergency at Union level, on condition that it obtains prior authorisation from the Commission.*** ***4. The Commission shall decide on the request for prior authorisation within five days of the request. If the Commission takes no decision within this period, the authorisation shall be deemed granted.***		
515	CHAPTER VI	**CHAPTER VI**		**CHAPTER VI**	
516		**PROCEDURAL PROVISIONS**		**~~PROCEDURAL~~ GENERAL PROVISIONS**	
517	Article 25a (new)			**Article 25a**	
518				**Personal data protection**	
519	Article 25a paragraph 1 (new)			**1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
				the obligations of the Commission, the ECDC and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities.	
520	Article 25a paragraph 2 (new)			**2. Personal data shall not be processed or communicated except in cases where this is strictly necessary to the purposes of this Regulation. In such cases, the conditions of Regulation (EU) No 2016/679 and Regulation (EU) No 2018/1725 shall apply as appropriate.**	
521	Article 25a paragraph 3 (new)			**3. Where processing of personal data is not strictly necessary to the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.**	
522	Article 25a paragraph 4 - subparagraph 1 (new)			**4. The Commission, by means of an implementing act, shall adopt detailed rules to ensure that the requirements provided for by Union legislation concerning the roles of the actors involved in the collection and processing of**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
				personal data are fully complied with.	
523	Article 25a paragraph 4 - subparagraph 2 (new)			**These implementing acts shall be adopted in accordance with the examination procedure referred to Article 27(2).**	
524	Article 26	*Article 26*		*Article 26*	
525		**Protection of personal data concerning the EWRS selective messaging functionality**		**Protection of personal data concerning the EWRS selective messaging functionality**	
526	Article 26 – paragraph 1	1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed ***and*** operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.	**Amendment 229** 1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed ***with respect for the principle of data minimisation and data protection by design and by default, and shall be*** operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.	1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed and operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.	
527	Article 26 – paragraph 2	2. Where competent authorities implementing contact		2. Where competent authorities implementing contact	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		tracing measures communicate through the EWRS personal data necessary for contact tracing purposes pursuant to Article 19(3), they shall use the selective messaging functionality referred to in paragraph 1 of this Article and communicate the data only to the other Member States involved in the contact tracing measures.		tracing measures communicate through the EWRS personal data necessary for contact tracing purposes pursuant to Article 19(3), they shall use the selective messaging functionality referred to in paragraph 1 of this Article and communicate the data only to the other Member States involved in the contact tracing measures. **Where the national competent authority notifying the alert can identify all the Member States concerned, based on the data at its disposal, it shall transmit data only to the national competent authorities of those Member States.**	
528	Article 26 – paragraph 3	3. When circulating the information referred to in paragraph 2, the competent authorities shall refer to the alert communicated previously through the EWRS.		3. When circulating the information referred to in paragraph 2, the competent authorities shall refer to the alert communicated previously through the EWRS.	
529	Article 26 – paragraph 4	4. Messages containing personal data shall automatically be erased from the selective message functionality 14 days after the date of their posting.		4. **The selective message functionality shall not store the contact data or health data. It shall only allow national competent authorities to receive data that were sent to them by other national competent authorities for the sole purpose of contact tracing. The ECDC shall only access the data for ensuring the good functioning of**	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
				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.~~	
530	Article 26 – paragraph 5	5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.	**Amendment 230** 5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications***, in full compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR')[1a]*** _____ ***[1a] 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).***	5. **The national competent authorities shall not retain the conatact 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.**~~Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.~~	
531	Article 26 – paragraph 6	6. The Commission shall, by means of implementing acts, adopt:	**Amendment 231** 6. ***Following a prior consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725, the*** Commission shall adopt ***delegated acts in accordance with Article 28***	6. The Commission shall, by means of implementing acts, adopt:	

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			concerning:		
532	Article 26 – paragraph 6- point a	(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;		(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**;	
533	Article 26 – paragraph 6- point b	(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;	**Amendment 232** (b) procedures for the interlinking of the EWRS with contact tracing systems at Union level ***and international level;***	(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;	
534	Article 26 – paragraph 6- point c	(c) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact tracing measures;		(c) a list of the categories of personal data that may be exchanged for the purpose of the coordination of contact tracing measures;	
535	Article 26 – paragraph 6- point d	(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical	**Amendment 233** (d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access, ***in***	(~~d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical~~	

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		arrangements for such access.	***full compliance with the EUDPR and applicable case law of the Court of Justice;***	~~arrangements for such access.~~	
536	Article 26 – paragraph 6 – subparagraph 1 – point d a (new)		**Amendment 234** ***(da) a detailed description of the roles of the actors involved in the processing of personal data through the proposed IT tools and systems.***		
537		***These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).***	**Amendment 235** ***deleted***	These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	
538	Article 27	*Article 27*		*Article 27*	
539		**Committee procedure**		**Committee procedure**	
540	Article 27 – paragraph 1	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.		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.	
541	Article 27 – paragraph 2	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	
542		Where the Committee delivers no		Where the Committee delivers no	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		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.		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.	
543	Article 27 – paragraph 3	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, 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.	
544	**Article 27a (new)**			**Article 27a**	
545				**Cooperation with WHO**	
546				**The Union shall establish a framework for enhanced cooperation with the WHO, in particular as regards reporting and reviewing activities.**	
547	Article 28	*Article 28*		~~*Article 28*~~	
548		**Exercise of the delegation**		~~**Exercise of the delegation**~~	
549	Article 28 – paragraph 1	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		~~1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.~~	
550	Article 28 – paragraph 2	2. The power to adopt delegated acts referred to in	**Amendment 236** 2. The power to adopt delegated acts referred to in	~~2. The power to adopt delegated acts referred to in~~	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		Article 8(3) shall be conferred on the Commission for an indeterminate period of time from ... [date of entry into force of the basic legislative act or any other date set by the co-legislators].	***Articles*** 8(3), ***13(9), 14(6), 17(3), 25a(2), and 26(6)*** shall be conferred on the Commission for a ***for a period of five years from … [date of entry into force of the basic legislative act or any other date set by the co-legislators]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period***.	~~Article 8(3) shall be conferred on the Commission for an indeterminate period of time from ... [date of entry into force of the basic legislative act or any other date set by the co-legislators].~~	
551	Article 28 – paragraph 3	3. The delegation of power referred to in ***Article*** 8(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	**Amendment 237** 3. The delegation of power referred to in ***Articles*** 8(3), ***13(9), 14(6), 17(3), 25a(2) 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.	~~3. The delegation of power referred to in Article 8(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.~~	

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552	Article 28 – paragraph 4	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.		~~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.~~	
553	Article 28 – paragraph 5	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		~~5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.~~	
554	Article 28 – paragraph 6	6. A delegated act adopted pursuant to ***Article*** 8(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	**Amendment 238** 6. A delegated act adopted pursuant to ***Articles*** 8(3), ***13(9), 14(6), 17(3), 25a(2) 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.	~~6. A delegated act adopted pursuant to Article 8(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.~~	

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555	Article 28 a (new)		**Amendment 239** ***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.***		
556	Article 29	*Article 29*		*Article 29*	
557		**Evaluations concerning this Regulation**		**Evaluations concerning this Regulation**	
558		By 2025 and every ***5*** years thereafter the Commission shall carry out an evaluation of this	**Amendments 240 and 277** By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this	By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this	

Item	Article Number	Commission text (2020/0322 (COD))	EP amendments voted on 11 November 2021	Text agreed by COREPER on 23 July 2021	Tentatively agreed text, compromise proposals and comments
		Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.	Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC***, the HERA and the impact of the Regulation on the proper functioning of the single market when serious cross-border threats to health arise***. ***By 2023 and every 2 years thereafter, the Commission shall carry out an in-depth review of the implementation of the operations of HERA, including its structure, governance, funding and human resources. Those reviews shall address, in particular, any need to modify HERA's structure, including but not limited to the possibility of upgrading HERA to a standalone agency, the mandate of HERA and the financial implications of any such modification. The Commission shall report to the European Parliament and to the Council on the findings of the reviews. Those findings shall be made public. The reviews shall be***	Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.	

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			accompanied, where appropriate, by a legislative proposal to address the issues referred to in this paragraph, in full respect of the role of the European Parliament as co-legislator.		
559	Article 29 – paragraph 1 a (new)		**Amendment 241** ***Based on the evaluation referred to in the previous paragraph, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.***		
560	CHAPTER VII	**CHAPTER VII**		**CHAPTER VII**	
561		**FINAL PROVISIONS**		**FINAL PROVISIONS**	
562	Article 30	*Article 30*		*Article 30*	
563		**Repeal**		**Repeal**	
564	Article 30 – paragraph 1	1. Decision No 1082/2013/EU is repealed.		1. Decision No 1082/2013/EU is repealed.	
565	Article 30 – paragraph 2	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.		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.	
566	Article 31	*Article 31*		*Article 31*	

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567		**Entry into force**		**Entry into force**	
568		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 enter into force on the day following that of its publication in the *Official Journal of the European Union*.	
569		This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	
570		Done at Brussels,		Done at Brussels,	
		For the European Parliament		*For the European Parliament*	
		The President		*The President*	
		For the Council		*For the Council*	
		The President		*The President*	