



**FVE feedback on the European Commission's
Proposal for a Regulation on serious cross-border threats to
health and repealing Decision No 1-82/2013/EU**

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The Federation of Veterinarians of Europe (FVE) welcomes the proposal of the European Commission for a Regulation on serious cross-border threats to health. The veterinary profession is one of the important health professions contributing to public health. Veterinarians have profound knowledge and expertise in prevention, preparedness and management of both cross-border and cross-species (zoonotic) threats to human and animal health. FVE highlights the importance of embanking the One Health approach within such an EU regulation.

FVE welcomes that One Health and the need for interdisciplinary collaboration are recognised in few parts, but misses in the proposal a true endorsement of the need for **implementation of a truly integrated One-Health approach that promotes interdisciplinary collaboration for a coordinated response at EU level.**

Whereas:

- EU^{i,ii} and international organizations, such as the World Health Organization (WHO), the World Organization for Animal Health (OIE), the Food and Agriculture Organization of the United Nations,^{iii,iv} the World Bank,^{v,vi} and the United Nations Biodiversity Convention,^{vii} call for more interdisciplinary collaboration to tackle emerging and zoonotic diseases as well as antimicrobial resistance, it is important that this is clearly recognised and endorsed by the EU legislation.
- Human emerging diseases often start in animals, **it is important to consider also (cross-species) zoonotic threats as cross-border threats.**

President

Rens van Dobbenburgh

Vice-Presidents

Thierry Chambon

Siegfried Moder

Torill Moseng

Stanislaw Winiarczyk

Undoubtedly the Covid-19 pandemic, likewise SARS and MERS have demonstrated to us that the health of humans, animals and the environment are inextricably linked. Our planet becomes more populated, more interconnected with increasing global trade and is challenged by climate change. This leads to increasing contacts between wildlife and intermediate hosts, animals and humans, which enhances the possibility for outbreaks of zoonotic diseases. The majority (72%) of emerging diseases of humans are caused by zoonotic pathogens, with most originating in wildlife. This crisis revealed the need for a paradigm shift, including holistic consideration of our environment and the intersectoral collaboration between doctors, veterinarians and environmental experts using the One-Health approach.

Control of zoonotic diseases in animals, so that they do not move to humans and potentially initiate a pandemic (e.g., some of the influenza viruses) is fundamental and **highlights the need for One-Health interdisciplinary collaboration in practice**. Veterinarians are often the first to notice outbreaks of zoonotic disease. **We particularly welcome that this is recognised already in the Commission's proposal.**

- A true implementation of the One Health approach encompasses:
 - The inclusive use of all available knowledge and expertise of experts in the human, veterinary and environmental field, e.g., veterinarians can make an essential contribution to the management of the current and future pandemics (i.e., viral surveillance in animal reservoirs, epidemiological models, testing strategies and in research).
 - Setting up proper surveillance systems and sharing of information, data and laboratory genomic analysis between veterinarians, researchers and healthcare professionals via integrated informative systems.
 - A communication plan that includes a direct exchange between public health colleagues, governments, stakeholder organisations and the general public.
 - R&D requirements for funding to promote and integrate veterinary and medical professional studies. While prevention of human

health relies to a large extent upon the prevention and control of zoonotic diseases in animals, so far all-important grants are available for research only in human healthcare (e.g., epidemiology, diagnostics, vaccines). It is imperative to ensure equal and adequate allocation of EU funds for veterinary research (e.g., epidemiology, vaccines or treatment for animals) to prevent disease in humans.

- Intersectoral collaboration between healthcare, veterinary and environmental field integrated in daily practice, education and research starting in peace times.

FVE would like to propose a better acknowledgement of One Health in the core of this legislative act and urge you to consider the adoption of the following amendments in the final legal text.

COMMISSION PROPOSAL	Suggested Amendment
<p>1. CONTEXT OF THE PROPOSAL</p> <ul style="list-style-type: none"> Reasons for and objectives of the proposal <p><i>1st paragraph</i> ...and response measures to cross-border threats to health across the EU...</p> <p><i>2nd paragraph</i> ... Decision No 1082/2013/EU on serious cross-border to health...</p>	<p><i>1st paragraph</i> ...and response measures through a One-Health approach to cross-border threats to health across the EU...</p> <p><i>2nd paragraph</i> ... Decision No 1082/2013/EU on serious cross-border and/or zoonotic threats to health...</p>
<p>2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY</p> <ul style="list-style-type: none"> Subsidiarity (for non-exclusive competence) <p><i>6th paragraph</i> ... complemented by:</p> <ul style="list-style-type: none"> – national plans and transparent reporting of capacities; – strengthened, integrated surveillance systems; – enhanced risk assessment for health threats; – increased power to enforce a coordinated response at EU level through the Health Security Committee; and – an improved mechanism for recognition of and response to public health emergencies. 	<p>... complemented by:</p> <ul style="list-style-type: none"> – One Health national plans and transparent reporting of capacities; – strengthened, integrated surveillance systems; – enhanced risk assessment for health threats; – increased power to enforce a coordinated response at EU level through the Health Security Committee; and – an improved mechanism for recognition of and response to public health emergencies, including zoonotic outbreaks.

<p>3. RESULTS OF <i>EX POST</i> EVALUATIONS, TAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS</p> <ul style="list-style-type: none"> • Stakeholder consultations ... cross-border threats... • Impact assessment Due to the urgency of the matter, this proposal is not accompanied by a formal impact assessment 	<ul style="list-style-type: none"> • Stakeholder consultations ... cross-border and/or zoonotic threats... • Impact assessment Due to the urgency of the matter, this proposal is not accompanied by a formal impact assessment, which however should be performed as soon as possible.
<p>4. BUDGETARY IMPLICATIONS <i>2nd bullet point</i></p> <ul style="list-style-type: none"> • training programmes for specialists; 	<ul style="list-style-type: none"> • training programmes for specialists and other public health professionals;

<p>5. OTHER ELEMENTS</p> <ul style="list-style-type: none"> • Detailed explanation of the specific provisions of the proposal <p>The proposal puts forward the following key amendments:</p> <ul style="list-style-type: none"> • preparedness capacities: ...for the plans at national level, and coupled with a comprehensive and transparent framework for reporting and auditing; • rules on the provision of training for healthcare and public health workforce; • rules for a ...; • provision for ..; • rules for the surveillance of novel pathogens ... for the management of cross-border threats; • increased EU and Member States capacity ...; <p>...</p>	<ul style="list-style-type: none"> • preparedness capacities: ...for the plans at national level, anchored to One-Health approach and coupled with a comprehensive and transparent framework for reporting and auditing; • rules on the provision of training for healthcare and public health workforce, in particular promoting interdisciplinary training; • rules for a ...; • provision for ..; • rules for the surveillance of novel pathogens ... for the management of cross-border and/or zoonotic threats; • increased EU and Member States capacity ...;
<p>(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate</p>	<p>(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate</p>

<p>adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance... Moreover, in order to ensure effective Union response to novel cross-border threats to health... 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</p>	<p>adequate Union-wide preparedness and response to all cross-border and/or zoonotic threats to health, the legal framework for epidemiological surveillance... Moreover, in order to ensure effective Union response to novel cross-border threats to health... the establishment of a network of EU reference laboratories and a One-Health network to support monitoring of disease outbreaks that are relevant to substances of human or animal origin. The capacity ...</p>
<p>(5) ... 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.</p>	<p>(5) ... 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 or animal origin (blood, tissues and cells, organs), and exposure to ionising radiation.</p>
<p>(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member</p>	<p>(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border and/or zoonotic threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission based on One Health principles and approved by the HSC. This should</p>

<p>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</p>	<p>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 interdisciplinary training and knowledge exchange activities for healthcare staff and public health staff should be provided. A framework regarding knowledge</p>
<p>(8) To this end... 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.</p>	<p>(8) To this end... Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, agriculture, food-chain, natural resources, 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.</p> <p>(NEW) As the health of humans, animals and the environment are inextricably linked, it is crucial to ensure the implementation of a One Health approach, which encompass the use of multidisciplinary knowledge and</p>

	<p>the integration of interdisciplinary collaboration. Whereas the majority (72%) of emerging diseases of humans are caused by zoonotic pathogens, with origin in animals, mostly wildlife, it is paramount to ensure the implementation of One Health approach in preparedness and crisis management. In the event of a serious cross-border threat to health originating from a zoonotic or food-borne infection, it is particularly important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.</p>
<p>(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 antimicrobial resistance.</p>	<p>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 Tripartite (WHO, OIE and FAO) to improve the prevention of communicable diseases through a One Health approach, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.</p>
<p>(13) A system... To avoid duplication and ensure coordination across Union</p>	<p>(13) A system... To avoid duplication and ensure coordination across Union</p>

<p>alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked ...</p>	<p>alert systems, the Commission and ECDC should ensure that alert notifications of all serious cross-border and/or zoonotic threats under the EWRS and other rapid alert systems at Union level are linked ...</p>
<p>(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...</p>	<p>(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border and/or zoonotic 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 interdisciplinary 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 science, excellence, independence...</p>
<p>(15) The Member States ... The aim to coordinate the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty on the Functioning of the European Union such as those related to free</p>	<p>(15) The Member States ... 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 and/or zoonotic threats to health, and do not conflict with obligations and rights laid down in the Treaty on the Functioning of the European Union</p>

<p>movement of persons, goods and services.</p>	<p>such as those related to free movement of persons, animals, goods and services.</p>
<p>(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...</p>	<p>(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 and/or zoonotic threats to health...</p>
<p>(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 ... with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, ... Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as Veterinary services and the Union Civil Protection Mechanism established by Decision (EU) 2019/420...</p>	<p>(17) Inconsistent communication with the public and stakeholders such as healthcare, public health professionals, e.g., veterinarians, 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 ... with a view to coordinating risk and crisis communication, based on holistic, robust and independent evaluation of public health risks, ... Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as Veterinary services and the Union Civil Protection Mechanism established by Decision (EU) 2019/420...</p>

<p>(18) The recognition of public health emergency ... In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.</p>	<p>(18) The recognition of public health emergency ... In order to recognise such an emergency situation, the Commission should establish an independent advisory inter-disciplinary committee (One Health 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 One Health 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 based on scientific evidence as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.</p>
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<p>(25) In order to ensure uniform conditions for the implementation of this Regulation, ...; 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...</p>	<p>(25) In order to ensure uniform conditions for the implementation of this Regulation, ...; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases, including those of zoonotic origin, 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...</p>
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<p style="text-align: center;"><i>Article 1</i></p> <p style="text-align: center;">Subject matter</p>	<p style="text-align: center;"><i>Article 1</i></p> <p style="text-align: center;">Subject matter</p>
<p>1. In order ...</p> <p>...</p> <p>(b) preparedness and response planning, including:</p> <p style="padding-left: 20px;">(i) preparedness plans at Union and national levels;</p> <p style="padding-left: 20px;">(ii) reporting ...</p> <p>2. This Regulation establishes:</p> <p>...</p> <p>(c) an advisory committee for the occurrence and recognition of emergency situation at Union level</p>	<p>1. In order ...</p> <p>...</p> <p>(b) preparedness and response planning, including:</p> <p style="padding-left: 20px;">(i) One Health preparedness plans at Union and national levels;</p> <p style="padding-left: 20px;">(ii) reporting ...</p> <p>2. This Regulation establishes:</p> <p>...</p> <p>(c) an interdisciplinary advisory committee for the occurrence and recognition of emergency situation at Union level</p>

<p style="text-align: center;"><i>Article 2</i></p> <p style="text-align: center;">Scope</p>	<p style="text-align: center;"><i>Article 2</i></p> <p style="text-align: center;">Scope</p>
<p>1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:</p> <p>(a) threats of biological origin, consisting of:</p> <p>(i) communicable diseases;</p> <p>(ii) antimicrobial resistance...</p> <p>...</p> <p>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.</p> <p>...</p> <p>5. The Commission shall... and combating serious cross-border threats to health.</p> <p>...</p>	<p>1. This Regulation shall apply to public health measures in relation to the following categories of serious cross-border threats to health:</p> <p>(a) threats of biological origin, consisting of:</p> <p>(i) communicable diseases;</p> <p>(NEW) communicable diseases of zoonotic origin;</p> <p>(ii) antimicrobial resistance...</p> <p>...</p> <p>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 and/or zoonotic threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.</p> <p>...</p> <p>5. The Commission shall... and combating serious cross-border and/or zoonotic threats to health.</p> <p>...</p>

<i>Article 3</i> Definitions			<i>Article 3</i> Definitions		
(2)	'communicable means ...	disease'	(2)	'communicable means ...	disease'
				(NEW) 'communicable disease of zoonotic origin' means	
	
(5)	'monitoring' means ...		(5)	'monitoring' means ...	
				(NEW) 'One Health' means...	
(6)	...		(6)	...	

<p style="text-align: center;"><i>Article 4</i></p> <p style="text-align: center;">Health Security Committee</p>	<p style="text-align: center;"><i>Article 4</i></p> <p style="text-align: center;">Health Security Committee</p>
<p>1. The Health Security Committee ('HSC') is ...</p> <p>(b) technical working groups to discuss specific topics of technical nature.</p> <p>...</p> <p>7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1.</p> <p>...</p>	<p>1. The Health Security Committee ('HSC') is ...</p> <p>(b) technical working groups, as far as possible interdisciplinary in order to ensure a One health holistic approach, to discuss specific topics of technical nature.</p> <p>...</p> <p>7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1 trying to ensure as far as possible an interdisciplinary national representation in order to ensure a One health holistic approach.</p> <p>...</p>

<i>Article 5</i>	<i>Article 5</i>
<p>Union preparedness and response plan</p> <p>1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.</p> <p>2. The Union ...</p> <p>3. The Union</p> <p>(d) the early warning and risk assessment;</p> <p>(e) the risk and crisis communication;</p> <p>(f) the health preparedness and response and intersectoral collaboration;</p> <p>(g) the management of the plan.</p> <p>4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, ...</p> <p>5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews</p>	<p>Union preparedness and response plan</p> <p>1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union One Health crisis and pandemic plan ('the Union One Health preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.</p> <p>2. The Union ...</p> <p>3. The Union</p> <p>(d) the intersectoral early warning and risk assessment;</p> <p>(e) the One Health risk and crisis communication;</p> <p>(f) the One Health preparedness and response and intersectoral collaboration;</p> <p>(g) the One Health management of the plan.</p> <p>4. The Union One Health preparedness and response plan shall include interregional and intersectoral preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, ...</p> <p>5. In order to ensure the operation of the Union One Health preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-</p>

with Member States, and update the plan as necessary.	action reviews with Member States, and update the plan as necessary.
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<p style="text-align: center;"><i>Article 6</i></p> <p style="text-align: center;">National preparedness and response plans</p> <p>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.</p>	<p style="text-align: center;"><i>Article 6</i></p> <p style="text-align: center;">National One Health preparedness and response plans</p> <p>1. When preparing One Health national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union One Health preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.</p>
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<p><i>Article 7</i></p> <p>Reporting on One Health preparedness and response planning</p> <p>1. Member States shall ...</p> <p>(b) elements of emergency preparedness, in particular:</p> <p>(i) governance: including national policies and legislation that integrate and recovery; coordination mechanisms;</p> <p>(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; ...;</p> <p>(iii) resources: including financial resources for emergency preparedness and contingency funding for response; ...; and</p> <p>(c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues.</p> <p>The report shall include, whenever relevant, interregional preparedness and response elements in line with the</p>	<p><i>Article 7</i></p> <p>Reporting on One Health preparedness and response planning</p> <p>1. Member States shall ...</p> <p>(b) elements of emergency preparedness, in particular:</p> <p>(i) governance: including national policies and legislation that integrate One Health emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms;</p> <p>(ii) capacities: including assessments of risks and capacities to determine priorities for One Health emergency preparedness; ...;</p> <p>(iii) resources: including financial resources for One Health emergency preparedness and contingency funding for response; ...; and</p> <p>(c) implementation of national One Health response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues.</p> <p>The report shall include, whenever relevant, interregional and intersectoral preparedness and</p>
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Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions.	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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<p style="text-align: center;"><i>Article 8</i></p> <p style="text-align: center;">Auditing on One Health preparedness and response planning</p> <p>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 ...</p>	<p style="text-align: center;"><i>Article 8</i></p> <p style="text-align: center;">Auditing on One Health preparedness and response planning</p> <p>1. Every 3 years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national One Health plans and their coherence with the Union One Health plan. Such audits ...</p>
<p style="text-align: center;"><i>Article 9</i></p> <p style="text-align: center;">Commission report on preparedness planning</p> <p>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.</p> <p>2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.</p>	<p style="text-align: center;"><i>Article 9</i></p> <p style="text-align: center;">Commission report on One Health preparedness planning</p> <p>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 One Health preparedness and response planning at Union level.</p> <p>2. The Commission may adopt One Health recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.</p>

<p style="text-align: center;"><i>Article 10</i></p> <p style="text-align: center;">Coordination of preparedness and response planning in the HSC</p> <p>1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health.</p> <p>...</p>	<p style="text-align: center;"><i>Article 10</i></p> <p style="text-align: center;">Coordination of One Health preparedness and response planning in the HSC</p> <p>1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border and/or zoonotic threats to health.</p> <p>...</p>
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<i>Article 11</i>	<i>Article 11</i>
One Health training of health care staff and public health staff	One Health training of health care staff and public health staff
<p>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.</p> <p>The Commission shall organise those activities in cooperation with the Member States concerned.</p> <p>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.</p> <p>....</p>	<p>1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, in particular interdisciplinary One Health training, including preparedness capacities under the International Health Regulations.</p> <p>The Commission shall organise those activities in cooperation with the Member States concerned.</p> <p>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 One Health preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.</p> <p>....</p>

<p style="text-align: center;"><i>Article 13</i></p> <p style="text-align: center;">Epidemiological surveillance</p>	<p style="text-align: center;"><i>Article 13</i></p> <p style="text-align: center;">Epidemiological surveillance</p>
<p>1. The network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to ...</p> <p>2. The epidemiological surveillance network shall aim to:</p> <p style="padding-left: 20px;">(a) monitor trends in communicable diseases over time and across Member States and in third countries to ...;</p> <p style="padding-left: 20px;">(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;</p> <p style="padding-left: 20px;">(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;</p> <p>...</p>	<p>1. The network for the epidemiological surveillance of the communicable diseases, including communicable diseases of zoonotic origin, and of the related special health issues referred to ...</p> <p>2. The epidemiological surveillance network shall aim to:</p> <p style="padding-left: 20px;">(a) monitor trends in communicable diseases, including communicable diseases of zoonotic origin, over time and across Member States and in third countries to ...;</p> <p style="padding-left: 20px;">(b) detect and monitor any multinational communicable disease outbreaks, including communicable diseases outbreaks of zoonotic origin, with respect to source, time, population and place in order to provide a rationale for public health action;</p> <p style="padding-left: 20px;">(c) contribute to the evaluation and monitoring of communicable and zoonotic 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;</p> <p>...</p>

<p>(g) contribute to modelling and scenario development for response;</p> <p>(h) identify research priorities and needs, and implement relevant research activities;</p> <p>...</p> <p>...</p> <p>9. The Commission shall, by means of implementing acts, establish and update:</p> <p>(a) the list of communicable diseases and related special health issues referred to ...;</p> <p>(b) case definitions concerning each communicable disease and related special health issue subject to epidemiological surveillance, in order to ...</p> <p>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...</p>	<p>(g) contribute to One health modelling and scenario development for response;</p> <p>(h) identify research priorities and needs, and implement relevant research activities, making use of potentials provided via One Health approach;</p> <p>...</p> <p>...</p> <p>9. The Commission shall, by means of implementing acts, establish and update:</p> <p>(a) the list of communicable diseases, including communicable diseases of zoonotic origin, and related special health issues referred to ...;</p> <p>(b) case definitions concerning each communicable disease, including communicable diseases of zoonotic origin, and related special health issue subject to epidemiological surveillance, in order to ...</p> <p>10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border and/or zoonotic threat to health or to the rapidity of its spread among the Member States...</p>
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<i>Article 19</i>	<i>Article 19</i>
Alert notification	Alert notification
...	...
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, including those of zoonotic origin , and public health measures related to serious cross-border and zoonotic threats to health already transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty.

<p style="text-align: center;"><i>Article 21</i></p> <p style="text-align: center;">Coordination of response within the HSC</p> <p>1. Following an alert notification ... the Commission:</p> <p>(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;</p> <p>(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;</p> <p>(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.</p> <p>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</p>	<p style="text-align: center;"><i>Article 21</i></p> <p style="text-align: center;">Coordination of response within the HSC</p> <p>1. Following an alert notification ... the Commission:</p> <p>(a) national responses, including research needs, to the serious cross-border or zoonotic 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;</p> <p>(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 and when appropriate to other public health professionals, e.g., veterinarians;</p> <p>(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 or zoonotic threat to health.</p> <p>2. Where a Member State intends to adopt public health measures to combat a serious cross-border or zoonotic threat to health, it shall, before adopting those measures, inform and consult the other Member</p>
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<p>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.</p> <p>3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption</p> <p>...</p>	<p>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.</p> <p>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 or zoonotic threat to health, it shall, immediately upon adoption</p> <p>...</p>
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<p style="text-align: center;"><i>Article 22</i></p> <p style="text-align: center;">Recommendations on common temporary public health measures</p> <p>2. The recommendation for measures adopted under paragraph 1 shall:</p> <p>(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;</p> <p>(b) respect ...</p>	<p style="text-align: center;"><i>Article 22</i></p> <p style="text-align: center;">Recommendations on common temporary public health measures</p> <p>2. The recommendation for measures adopted under paragraph 1 shall:</p> <p>(a) be based on in particular recommendations of the ECDC in particular, other relevant agencies or bodies, or the One Health Advisory Committee referred to in Article 24;</p> <p>(b) respect ...</p>
<p style="text-align: center;"><i>Article 23</i></p> <p style="text-align: center;">Recognition of emergency situations</p> <p>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.</p> <p>...</p>	<p style="text-align: center;"><i>Article 23</i></p> <p style="text-align: center;">Recognition of emergency situations</p> <p>1. The Commission may, based on the expert opinion of the One Health Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level; including pandemic situations where the serious cross-border or zoonotic threat to health in question endangers public health at the Union level.</p> <p>...</p>

<i>Article 24</i>	<i>Article 24</i>
<p>One Health Advisory Committee on public health emergencies</p>	<p>One Health Advisory Committee on public health emergencies</p>
<p>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:</p>	<p>1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an interdisciplinary Advisory Committee on public health emergencies ('One Health Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:</p>
<p>(a) ...;</p>	<p>(a) ...;</p>
<p>(b) ...; and</p>	<p>(b) ...; and</p>
<p>(c) advice on response including:</p>	<p>(c) advice on response including:</p>
<p>(i) formulation of response measures, including risk and crisis communication, to be addressed to all Member States ...</p>	<p>(i) formulation of response measures, including cross-sectoral actions as well as risk and crisis communication, to be addressed to all Member States ...</p>
<p>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.</p> <p>...</p>	<p>2. The One Health 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.</p> <p>...</p>
<p>The representatives of the ECDC and of the EMA participate as observers in the Advisory Committee.</p> <p>...</p>	<p>The representatives of the ECDC and of the EMA participate as observers in the One Health Advisory Committee.</p> <p>...</p>

<p>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.</p> <p>3. The Advisory Committee shall meet ...</p> <p>4. The Advisory Committee shall be chaired by a representative of the Commission.</p> <p>5. The Secretariat of the Advisory Committee shall be provided by the Commission.</p> <p>6. The Advisory Committee shall establish its rules of procedure ...</p>	<p>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 One Health Advisory Committee on an ad-hoc basis.</p> <p>3. The One Health Advisory Committee shall meet ...</p> <p>4. The One Health Advisory Committee shall be chaired by a representative of the Commission.</p> <p>5. The Secretariat of the One Health Advisory Committee shall be provided by the Commission.</p> <p>6. The One Health Advisory Committee shall establish its rules of procedure ...</p>
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Further to the above and while it is acknowledged that "*The measures put forward in this proposal go hand in hand with those put forward in the other parts of the package, to revise the mandates of the European Medicines Agency (EMA) and that of the European Centre for Disease Prevention and Control (ECDC)*", we note that **similar amendments foreseen the implementation of a true One health approach must be integrated to all linked proposals.**

ⁱ A European One Health Action Plan against Antimicrobial Resistance (AMR) https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

ⁱⁱ Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance <https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-antimicrobial-resistance/>

ⁱⁱⁱ World Health Organization (WHO); Food and Agriculture Organization of the United Nations (FAO); World Organisation for Animal Health (OIE). Taking a multisectoral, One Health approach: a tripartite guide to addressing zoonotic diseases in countries. Geneva: WHO; 2019: https://www.oie.int/fileadmin/Home/eng/Media_Center/docs/EN_TripartiteZoonosesGuide_web_version.pdf.

^{iv} World Health Organization (WHO); Food and Agriculture Organization of the United Nations (FAO); World Organisation for Animal Health (OIE). Taking a multisectoral, One Health approach: a tripartite guide to addressing zoonotic diseases in countries. Geneva: WHO; 2019: https://www.oie.int/fileadmin/Home/eng/Media_Center/docs/EN_TripartiteZoonosesGuide_web_version.pdf.

^v The World Bank: People, pathogens, and our planet. Volume 1: towards a One Health approach for controlling zoonotic diseases. Report no. 50833-GLB [Internet]. Washington, DC: World Bank;2010:

<http://documents.worldbank.org/curated/en/214701468338937565/pdf/508330ESW0whit1410B01PUBLIC1PPP1Web.pdf> .

^{vi} Berthe FCJ, Bouley T, Karesh WB, et al. One Health: operational framework for strengthening human, animal, and environmental public health systems at their interface (English). Report no. 122980. Washington, DC: World Bank; 2018 Jan 1:

<http://documents.worldbank.org/curated/en/961101524657708673/One-health-operational-framework-forstrengthening-human-animal-and-environmental-public-healthsystems-at-their-interface>

^{vii} The Berlin principles on one health – Bridging global health and conservation
<https://www.sciencedirect.com/science/article/pii/S0048969720364494?via%3Dihub>