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Committee on the Environment, Public Health and Food Safety

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COMPROMISE AMENDMENTS 1 - 52

Draft report
Véronique Trillet-Lenoir
(PE692 .634v01-00, PE692.635v01-00)

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

Proposal for a regulation
(COM(2020)0727 – C9-0367/2020 – 2020/0322(COD))

Amendment 1
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 20 (Trillet-Lenoir), 224 (Comín i Oliveres), 225 (de Lange & others) + 116 (Comín i Oliveres)

Proposal for a regulation
Article 1 – paragraph 3 + Recital 4 b (new)

Text proposed by the Commission	*Amendment*
3. ***The*** implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.	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 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).***
	(4b) 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 in all programmes managed by the Union.

Or. en

Amendment 2
Véronique Trillet-Lenoir

Compromise amendment replacing Amendments 226 (Cerdas & others), 228 (Konečná)

Proposal for a regulation
Article 1 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. This Regulation shall be implemented with full respect for the dignity and fundamental rights and freedoms of persons.

Or. en

Amendment 3
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 21 (Trillet-Lenoir), 121 (Comin i Oliveres), 229 (Cerdas & others), 230 (Auken), 231 (Comin i Oliveres) + 103 (Auken)

Proposal for a regulation
Article 2 – paragraph 1 – point a – point i + recital N

Text proposed by the Commission	*Amendment*
(i) communicable diseases;	(i) communicable diseases***, including those of zoonotic origin***;
	(N) The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to respect the principles of the 'One Health' approach to address current and emerging crises.

Or. en

Amendment 4
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 22 (Trillet-Lenoir), 235 (de Lange & others), 236 (Comin i Oliveres)

Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases, and of related special health issues.	2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases, ***the monitoring of the impact of such diseases on 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***.

Or. en

Amendment 5
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 24 (Trillet-Lenoir), 243 (Comin i Oliveres) 244 (Cerdas & others)

Comment: aligned with https://apps.who.int/iris/bitstream/handle/10665/332049/WHO-2019-nCoV-Contact_Tracing-2020.1-eng.pdf

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'contact tracing' means measures ***implemented in order to trace*** persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of ***developing*** or have developed a disease, through manual or other technological means;	(3) 'contact tracing' means measures ***to identify, assess and manage*** persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of ***being infected, being infectious*** or 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;***

Or. en

Amendment 6
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 25 (Trillet-Lenoir), 245 (Comín i Oliveres)

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;	(4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases***, the monitoringof the impact of such diseases on non-communicable diseases such as mental health*** and related special health issues;

Or. en

Amendment 7
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 246 (Auken), 252 (Comín i Oliveres), 253 (Comín i Oliveres)

Comment: Definitions taken from Article 2 point 5 and point 10 of Regulation 522/2021

Proposal for a regulation
Article 3 – paragraph 1 – point 5 a (new) and point 5 b (new)

Text proposed by the Commission	*Amendment*
	(5a) 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;
	(5b) 'Health in All Policies' means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of

the population and health equity;

Or. en

Amendment 8
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 28 (Trillet-Lenoir), 29 (Trillet-Lenoir), 254 (Auken), 255 (de la Pisa Carrión), 256 (Auken), 257 (de la Pisa Carrión), 258 (Cerdas & others), 259 (Auken), 260 (de la Pisa Carrión), 261 (Polčák), 262 (Lancini), 263 (Comín i Oliveres), 264 (Kopcińska), 265 (Comín i Oliveres), 266 (Comín i Oliveres), 267 (Polčák), 268 (Kopcińska), 269 (Comín i Oliveres), 270 (Auken), 271 (de la Pisa Carrión), 272 (Polčák), 273 (Comín i Oliveres), 274 (Comín i Oliveres), 275 (Konečná) 276 (Comín i Oliveres), 277 (Auken), 278 (Cerdas & others), 279 (Auken), IMCO 29, IMCO 30, IMCO 31, IMCO 32

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Article 4	
Health Security Committee	
1. The Health Security Committee ('HSC') is hereby established. It shall be composed of representatives of the Member States, in two working formations:	1. The Health Security Committee ('HSC') is hereby established. It shall be composed of representatives of the Member States, in two working formations:
(a) a high-level working group to discuss topics of political importance and decisions referred to in point (d) of paragraph 3 and paragraph 7;	(a) a high-level working group to discuss topics of political importance and decisions referred to in point (d) of paragraph 3 and paragraph 7;
(b) technical working groups to discuss specific topics of technical nature.	(b) technical working groups to discuss specific topics of technical nature.
	1a. Representatives of relevant Union agencies shall participate in HSC meetings as observers.
2. The HSC shall have the following tasks:	2. The HSC shall have the following tasks:
(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;	(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;
(b) coordination in liaison with the	(b) coordination in liaison with the

Commission of the preparedness and response planning of the Member States in accordance with Article 10;	Commission ***and relevant Union agencies*** of the ***prevention,*** preparedness and response planning of the Member States in accordance with Article 10;
(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;	(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;
(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.
	(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 groups levels
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.
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 simple majority of the members.
The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the guidance or opinions.	The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the guidance or opinions.
4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.	4. The HSC shall be chaired by a representative of the Commission ***without the right to vote***. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.
5. The secretariat shall be provided by the Commission.	5. The secretariat shall be provided by the Commission.
	5 a. Members of the HSC and the Commission shall ensure thorough consultation with relevant Union agencies, public health experts, international organisations and stakeholders, including healthcare

	professionals.
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:
(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;
(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;
(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.
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.	7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1.
Member States shall notify the Commission and other Member States of the designations and of any change thereof.	Member States shall notify the Commission and other Member States of the designations and of any change thereof.
	7a. The European Parliament shall designate representatives to participate in the Health Security Committee (HSC) as observers.
	7b. The list of members of the Health Security Committee at both the political and technical levels shall be made public on the Commission and Council websites. Members of the Committee must 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 or other relevant sector shall be entered in

a register held by the Commission and be accessible to the public, upon request.

7c. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's web-portal.

Or. en

Amendment 9
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 30 (Trillet-Lenoir), 31 (Trillet-Lenoir), 290 (Konečná), 291 (Comín i Oliveres), 292 (Comín i Oliveres), 293 (de Lange & others), 294 (Comín i Oliveres), 295 (de Lange & others), 296 (Cerdas & others), 297 (Polčák), 298 (Colin-Oesterlé), 299 (Cerdas & others), 300 (Konečná), 301 (Konečná), 302 (Cerdas & others), 303 (Konečná), 304 (Konečná), IMCO 33

Proposal for a regulation
Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:	3. The Union ***prevention,*** preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:
(a) the timely cooperation between the Commission, the Member States and the Union agencies;	(a) the timely cooperation between the Commission, the Member States and the Union agencies;
(b) the secure exchange of information between the Commission, Union agencies and the Member States;	(b) the secure exchange of information between the Commission, Union agencies and the Member States;
(c) the epidemiological surveillance and monitoring;	(c) the epidemiological surveillance and monitoring***, as well as the impact of communicable diseases on non-communicable diseases***;
(d) the early warning and risk assessment;	(d) the early warning and risk assessment;
(e) the risk and crisis communication;	(e) the risk and crisis communication***, aimed at health professionals and at citizens***;
(f) the health preparedness and response and intersectoral collaboration;	(f) the health preparedness and response and intersectoral collaboration;
	(fa) the mapping of the production capacities of medical products in the Union as a whole;

	(fb) the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;
(g) the management of the plan**.**	(g) the management of the plan***;***
	(ga) the criteria for activating and deactivating the actions;
	(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;
	(gc) ensuring that national health systems are inclusive and provide equal access to health and related services and that quality treatments are available without a delay.
	(ge) an adequate and needs-oriented staffing level;
	(gf) monitoring whether adequate risk assessments, preparedness plans and trainings are foreseen for health and social care professionals;

Or. en

Amendment 10
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 305 (Lancini), 306 (Auken), 307 (Weiss), 308 (de Lange & others), 309 (Konečná), 310 (Cerdas & others), 311 (Polčák)

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission	*Amendment*
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	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

include preparedness and response means to address the situation of those citizens with higher risks.	across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

Or. en

Amendment 11
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 312 1st part (Konečná), 313 (Cerdas & others), 315 (Cerdas & others) + 184 (Rodríguez Ramos & others), IMCO 8

Proposal for a regulation
Article 5 – paragraphs 5 and 5 b (new) + recital 12a

Text proposed by the Commission	*Amendment*
5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.	5. In order to ensure the operation of the Union ***prevention,*** preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary. ***The prevention, preparedness and response plan shall take into account health systems data and relevant data to be collected at national or regional level.***
	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 plans.
	(12a) In order to improve early preparedness 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 countermeasures 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 will be established, operated and coordinated at Union level. Strengthening coordination and 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 early alert notifications in the Union.

Or. en

Amendment 12
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 312 2nd part (Konečná), 314 (Cerdas & others)

Proposal for a regulation
Article 5 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. 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.

Or. en

Amendment 13
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 319 (Patriciello), 320 (Lancini), 321 (Konečná), 322 (Vitanov), 323 (Polčák), 324 (Comín i Oliveres), 325 (Kopcińska), 326 (Cerdas & others), 327 (Cerdas & others)

Proposal for a regulation
Article 6 – paragraph 1 and paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
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	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

substantial revision of the national plan.	Commission 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 and the HSC of any substantial revision of the national plan.
	1a. National prevention, preparedness and response plans shall include arrangements for governance, capacities and resources referred to in Article 5(3).

Or. en

Amendment 14
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 32 (Trillet-Lenoir), 33 (Trillet-Lenoir), 34 (Trillet-Lenoir), 35 (Trillet-Lenoir), 36 (Trillet-Lenoir), 37, (Trillet-Lenoir), 38 (Trillet-Lenoir), 39 (Trillet-Lenoir), 330 (de Lange & others), 331 (Polčák), 332 (Cerdas & others), 333 (Comín i Oliveres), 334 (Konečná), 335 (Cerdas & others), 336 (Auken), 337 (Cerdas & others), 338 (Comín i Oliveres), 339 (Polčák), 340 (Cerdas & others), 341 (de Lange & others), 342 (Weiss), 343 (Lancini), 344 (Kopcińska), 345 (Cerdas & others), 346 (Polčák), 347 (Rodríguez Ramos & others), 348 (de Lange & others), 349 (Lancini), 350 (Fiocchi), 351 (Konečná), 352 (Vitanov), 353 (Polčák), 354 (Weiss), 355 (Cerdas & others), 356 (Kopcińska), 357 (Montserrat), 358 (Konečná), 359 (de Lange & others), 360 (Weiss), 361 (Lancini), 362 (Polčák), 363 (de Lange & others), 364 (de Lange & others), 365 (Comín i Oliveres), 366 (Konečná), 367 (Cerdas & others), 368 (Auken), 369 (de Lange & others), 370 (Cerdas & others), 371 (Comín i Oliveres), 372 (Konečná), 373 (Kopcińska), 374 (Cerdas & others), IMCO 35

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
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***.	1. Member States shall ***[within 6 months of the entry into force of this regulation]*** and every 2 years thereafter provide the Commission with ***an updated*** report on their ***prevention,*** preparedness and response planning and implementation at national ***and, where appropriate, regional and cross-border levels***.

That report shall cover the following:

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

(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national 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 ***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;

(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.

(ab) a description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products;

(b) elements of emergency preparedness, in particular:

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

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

(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;***

(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;

(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 populations at higher risk***; ***continuity of screening, diagnosis, monitoring, 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;
(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	(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; and
	(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 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 these 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.
(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.	(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.

(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;

(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.

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***.

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 paragraphs 1 (a), (b) and (c), cross-border training and 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 available stocks and taken into account in both Union and national preparedness and response planning.***

The report shall also include, as far as feasible, information on the impact of communicable diseases on non-communicable diseases as referred to in Article 2 - paragraph 1 - point 4a (new) [ECDC regulation, correct reference to be inserted].

The latest available version of the prevention, preparedness and response plans shall be attached to the report.

Recital

N Health logistics mechanisms should meet the 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].

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*[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.)***

Or. en

Amendment 15
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 41 (Trillet-Lenoir), 381 (Auken), 382 (Kopcińska), 383 (Polčák), 384 (Comín i Oliveres), 385 (Konečná)

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
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).	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).

Or. en

Amendment 16
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 396 (de Lange & others), 397 (Cerdas &

others), 398 (Konečná), 399 (Konečná)

Proposal for a regulation
Article 9 – paragraphs 1 a (new) and 2

Text proposed by the Commission	*Amendment*
	1a. The Commission report shall include the state of cross-border preparedness and response planning in neighbouring regions.
2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.	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. ***These recommendations may cover, inter alia, the minimum resources needed to respond to public health emergencies in relation to, among other things, population size, developed on the basis of good practice and policy assessments.***

Or. en

Amendment 17
Véronique Trillet-Lenoir

Compromise amendment replacing Amendments 400 (Konečná), 401 (Cerdas & others), 402 (Auken), 403 (Cerdas & others), 404 (Kopcińska), 405 (Cerdas & others), 406 (Cerdas & others), 407 (Comín i Oliveres), 408 (Polčák), 409 (Polčák), 410 (Cerdas & others), 411 (Konečná), 412 (Comín i Oliveres), 413 (Patriciello), 414 (de Lange & others) + 137 (Comín i Oliveres), 138 (Comín i Oliveres), 188 (de Lange & others), 189 (Patriciello), 192 (Auken), 217 (Konečná)

Proposal for a regulation
Article 10 + recitals 14 a, 14 b

Text proposed by the Commission	*Amendment*
Coordination of preparedness and response planning in the HSC	Coordination of ***prevention,*** preparedness and response planning in the HSC
1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health.	1. The Commission***, relevant Union agencies*** and the 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.
The coordination shall, in particular, be aimed at:	The coordination shall, in particular, be aimed at:
(a) sharing best practice and experience in preparedness and response planning;	(a) sharing best practice and experience in ***prevention,*** preparedness and response planning;
(b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;	(b) promoting the interoperability of national ***prevention,*** preparedness planning and the intersectoral dimension of ***prevention,*** preparedness and response planning at Union level;
(c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;	(c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;
(d) developing the preparedness plans referred to in Articles 5 and 6;	(d) developing the preparedness plans referred to in Articles 5 and 6;
(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.	(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.
	1 a. The Commission and the Member States shall, when appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations. This 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;
	Recitals
	(14a) Member States, the Commission and Union agencies, while applying the One Health approach, should identify recognised public health organisations and experts, both in the area of communicable and 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.

(14b) Regular dialogue and exchange of information between authorities, industry, relevant entities of the pharmaceutical supply chain, healthcare professionals' and patients' organizations should also be ensured to start early discussions about expected potential serious cross-border threats to health in the market by way of sharing expected supply constraints or raising of specific clinical needs, allowing better coordination, synergies and appropriate reaction when needed.

Or. en

Amendment 18
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 415 (Cerdas & others), 416 (Auken), 417 (Konečná), 418 (Polčák),

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
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.	1. The Commission may organise training activities***, supported by the relevant Union agencies, in close cooperation with medical societies 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.

Or. en

Amendment 19
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 43 (Trillet-Lenoir), 419 (Cerdas & others), 420 (de Lange & others), 421 (Konečná), 428 (Konečná) + 135 (de Lange & others), 429 (Polčák)

Proposal for a regulation
Article 11 – paragraph 1 – subparagraph 1 and paragraph 3 + recital 7a

Text proposed by the Commission	*Amendment*
The Commission shall organise those activities in cooperation with the Member States concerned.	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.***
	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.
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.	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***.
	Recital
	(7a) Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a 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, prevention 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.

Or. en

Amendment 20
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 44 (Trillet-Lenoir), 431 (Lancini), 432 (Weiss), 433 (de Lange & others), 434 (Auken), 435 (Polčák), IMCO 36

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. The Commission and any Member States may engage in a joint procurement procedure ***as contracting parties*** conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[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 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).	[29] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

Or. en

Amendment 21
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 7 (Trillet-Lenoir), 149 (Patriciello), 150 (Fiocchi), 151 (Vitanov), 152 (de Lange & others), 153 (Auken), 154 (Montserrat), 155

(Comín i Oliveres), 156 (Kopcińska), 157 (Fiocchi), 158 (Moretti), 159 (Lancini), 160 (Colin-Oesterlé), 161 (Kopcinska), 162 (Auken), 163 de Lange & others), 164 (Fiocchi), 165 (Montserrat), 166 (Fiocchi), 167 de Lange & others), 168 (Montserrat), 170 (Fiocchi), 171 (Fiocchi), 172 (Fiocchi), 220 (Konečná), 436 (Colin-Oesterlé), 437 (Moretti), 438 (Fiocchi), 439 (Lancini), 440 (Fiocchi), 441 (Comín i Oliveres), 442, (Fiocchi) 443 (Lancini), 444 (Colin-Oesterlé), 445 (Moretti), 446 (Auken), 447 (Fiocchi), 448 (Auken), 449 (Fiocchi), 450 (Lancini), 451 (Fiocchi), 452 (de Lange & others), 453 (Montserrat), 454 (Auken), 455 (Fiocchi), 456 (de Lange & others), 457 (Montserrat), 458 (Montserrat), 459 (Colin-Oesterlé), 460 (Lancini), 462 (Weiss), 469 (Patriciello), 470 (Auken), IMCO 5, IMCO 7, IMCO 9, IMCO 10, IMCO 13, IMCO 15, IMCO 16, IMCO 17, IMCO 20, IMCO 21, IMCO 24, IMCO 37, IMCO 38, IMCO 39, IMCO 40, IMCO 41, IMCO 42, IMCO 43, IMCO 44

Proposal for a regulation
Article 12 – paragraph 2 and recitals 9, 9 a (new) , 9 b (new) , 9 c (new) , 9 d (new)

Text proposed by the Commission	*Amendment*
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:
(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;	(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***;
(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 Members States, EFTA States and Union candidate countries not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;
(c) ***Member States, EFTA States and Union candidate countries*** participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;	(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;
	(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 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.
	(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;
	(cc) if joint procurement is deployed, qualitative criteria shall also be considered in the awarding 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;
	(cd) the joint procurement shall be conducted in such a way 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;
(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;
(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.
Recitals	
(9) As serious cross-border threats to	(9) As serious cross-border threats to

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

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 States, 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.

The functioning of the Joint Procurement Agreement and 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 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 strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council[16]. ***The Member States should ensure a sufficient reserve of critical medical products to counter the risk of shortages of critical products.***

[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).

[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).

(9a) Joint procurement should 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 and the authorities purchasing their agreed reserved volumes;

(9b) Joint procurement should be carried 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;

(9c) 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;

(9d) 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 to people including those in Eastern Partnership and low- and middle-income countries.

Or. en

Amendment 22
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 45 (Trillet-Lenoir), 463 (Montserrat), 464 (Lancini), 465 (Fiocchi), 466 (Weiss), 467 (Vitanov), IMCO 45

Proposal for a regulation
Article 12 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
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:	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 with the greatest proximity to and accessibility for the greatest number of population centres, without compromising the accessibility of these 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 level, in particular under:

Or. en

Amendment 24
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 50 (Trillet-Lenoir), 482 (de Lange & others), 483 (Auken), 484 (Polčák)

Proposal for a regulation
Article 13 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation ***and*** mortality;	(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, the deferred screening, diagnosis, monitoring, treatment for and care in relation to other diseases and conditions and their social and economic impact***;

Or. en

Amendment 25
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 47 (Trillet-Lenoir), 51 (Trillet-Lenoir), 472 (de Lange & others), 473 (Auken), 486 (de Lange & others), 487 (Comín i Oliveres)

Proposal for a regulation
Article 13 – paragraph 2 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) identify any weakness 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 ~~shall~~ 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.

Or. en

Amendment 26
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 53 (Trillet-Lenoir), 500 (Cerdas & others)

Proposal for a regulation
Article 13 – paragraph 6 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	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 the 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 its expertise in that domain to third countries.

Or. en

Amendment 27
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 59 (Trillet-Lenoir), 502 (Rodríguez Ramos & others), 503 (Kopcińska), 504 (de Lange & others), 505 (Cerdas & others), 506 (Konečná), 507 (Polčák)

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 bias 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 with in compliance with the principle of data protection by design pursuant to Art. 27(1) of Regulation (EU) 2018/1725.

Or. en

Amendment 28
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 74 (Trillet-Lenoir), 563 (Kopcińska)

Proposal for a regulation
Article 19 – paragraph 3 – point f

Text proposed by the Commission	*Amendment*
(f) public health risks;	(f) public health risks***, especially for vulnerable groups, including, as far as possible, their impact on major non-communicable diseases***;

Or. en

Amendment 29
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 84 (Trillet-Lenoir), 591 (Cerdas & others), 592 (Comín i Oliveres), 593 (de Lange & others), 594 (Polčák)

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States ***and*** the Commission on the nature, purpose and scope of those measures.	3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States***, relevant regional authorities,*** the Commission ***and the Health Security Committee*** on the nature, purpose and

	scope of those measures ***especially in cross-border regions***.

Or. en

Amendment 30
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 86 (Trillet-Lenoir), 613 (de Lange & others), 614 (Auken)

Proposal for a regulation
Article 24 – paragraph 1 – point c – points ii and ii a (new)

Text proposed by the Commission	*Amendment*
(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;	(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;
	(***iia) in consultation with EMA pursuant to (EU) …/… [OJ: Please insert the number of EMA Regulation] on 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;***

Or. en

Amendment 31
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 14 (Trillet Lenoir), 87 (Trillet-Lenoir), 198 (Comín i Oliveres), 199 (de Lange), 200 (Polčák), 201 (Patriciello), 202 (Lancini), 203 (Cerdas & others), 204 (Auken) 616 (Comín i Oliveres), 617 (Kopcińska), 618 (Cerdas & others), 619 (de Lange & others), 620 (Weiss), 621 (Lancini), 622 (Polčák), 623 (Auken), 624 (de la Pisa Carrión), IMCO 24

Proposal for a regulation
Article 24 – paragraph 2 & recital 18

Text proposed by the Commission	*Amendment*
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 their professional and/or scientific backgrounds that justify their appointment.***
Recital	
(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at	(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at

Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.	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, 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 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 as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.

Or. en

Amendment 32
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 88 (Trillet-Lenoir), 625 (de Lange & others), 630 (Auken) and including part of 616 (Comín i Oliveres)

Proposal for a regulation
Article 24 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	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 should 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 could be considered prejudicial to those experts' independence.

Or. en

Amendment 33
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 90 (Trillet-Lenoir), 632 (Comín i Oliveres), 633 (de Lange & others)

Proposal for a regulation
Article 25 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) mechanisms to monitor shortages of, ***develop, procure, manage and deploy*** medical countermeasures;	(b) mechanisms 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;

Or. en

Amendment 34
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 92 (Trillet-Lenoir), 636 (Comín i Oliveres), 637 (de Lange & others)

Proposal for a regulation
Article 26 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.	5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications***, in full compliance with the 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).***

Or. en

Amendment 34A
Véronique Trillet-Lenoir
Compromise amendment replacing 102 (Trillet-Lenoir), 642 (Kopcińska), IMCO 58

Proposal for a regulation
Article 29 - paragraph 1

Text proposed by the Commission	*Amendment*
By 2025 and every ***5*** years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.	By 2025 and every ***3*** years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC ***and the impact of the Regulation on the proper functioning of the single market when serious cross-border threats to health arise***.

Or. en

Amendment 35
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 107 (Auken), 108 (Kopcińska), 109 (Cerdas & others), IMCO 2

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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 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.	(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide ***prevention,*** 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***) and the European Medicines Agency (EMA), and international organisations, namely the World Health Organization (WHO***). 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 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]***.
	[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).

Or. en

Amendment 36
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 1 (Trillet-Lenoir), 113 (Cerdas & others), 114 (Comín i Oliveres)

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.	(3) An important role in the coordination of ***prevention,*** preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health ***and support better coordination between Member States to address these threats***. ***Representatives designated by the European Parliament should be able to participate in the Health Security Committee (HSC) as observers.***

Or. en

Amendment 37
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 2 (Trillet-Lenoir), 117 (Cerdas & others), 118 (Auken), 119 (Comín i Oliveres), IMCO 3

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) This Regulation should apply without prejudice to other binding	(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.	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.

Or. en

Amendment 38
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 3 (Trillet-Lenoir), 120 (de Lange & others), 121 (Comín i Oliveres), 122 (Kopcińska), 123 (Colin-Oesterlé), 124 (Cerdas & others), 125 (Patriciello), 126 (Lancini), 127 (Auken), IMCO 4

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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	(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

combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.

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,*** 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. ***These mechanisms should look for synergies between EU 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.

Or. en

Amendment 39
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 4 (Trillet-Lenoir), 129 (Konečná), 130 (Cerdas & others), 131 (Auken), 132 (Comín i Oliveres), 133 (de Lange & others), 134 (Polčák)

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) ***Preparedness*** and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to	(7) ***Prevention, preparedness*** and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats

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.	to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' ***prevention,*** preparedness and response plans so as to ensure they are compatible within the regional level structures. ***The plan 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 non-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 systemsin 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.

Or. en

Amendment 40
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 5 (Trillet-Lenoir), 139 (Auken), 140

(Rodríguez Ramos, Cañas), 141 (Comín i Oliveres), 142 (Lancini), 143 (Cerdas & others), 144 (Polčák), 145 (Kopcińska)

Proposal for a regulation
Recital 8

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

Or. en

Amendment 41
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 9 (Trillet-Lenoir), 173 (de Lange & others), 174 (Comín i Oliveres)

Proposal for a regulation
Recital 10

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

Or. en

Amendment 42
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 10 (Trillet-Lenoir), 176 (de Lange & others), 177 (Kopcińska), 178 (Auken), 179 (Comín i Oliveres)

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(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.	(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***, through the One Health approach,*** the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance***, 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.***

Or. en

Amendment 44
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 11 (Trillet-Lenoir), 185 (Comín i Oliveres), 186 (Cerdas & others)

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(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	(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or

could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.	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 otherto the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

Or. en

Amendment 45
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 12 (Trillet-Lenoir), 190 (Comín i Oliveres), 191 (Auken)

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(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	(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

agencies and relevant Commission services to support the preparation of risk assessments.	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 human resources of Union agencies and bodies should be increased.***

Or. en

Amendment 46
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 13 (Trillet-Lenoir), 196 (Comín i Oliveres), 197 (Auken), IMCO 23

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council[17].	(17) Inconsistent communication with the public and stakeholders such as healthcare ***and public health*** professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on ***holistic,*** robust and independent evaluation of public health risks, to be adapted to national ***and regional*** needs and circumstances***. In those Member States with regions having health competences, these 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[17].
[17] Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I, 20.3.2019, p. 1).	[17] Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I, 20.3.2019, p. 1).

Or. en

Amendment 47
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 15 (Trillet-Lenoir), 206 (Cerdas & others), IMCO 25

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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[18].	(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[18].

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

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

Or. en

Amendment 48
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 16 (Trillet-Lenoir), 207 (Cerdas & others), 208 (Polčák), 209 (de Lange & others)

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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	(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

health risk-assessment and collaboration on response coordination, including the research response.	areas of preparedness and response capacity and planning, public health risk-assessment and 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 the international health framework and improving cooperation with regard to early detection, prevention, response and resilience to future pandemics.***
_____	_____
	[1a] World Health Organisation International Health Regulations (2005) Third Edition available at https://www.who.int/publications/i/item/9789241580496

Or. en

Amendment 49
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 210 (Auken), 211 (Comín i Oliveres), 212 (Cerdas & others)

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council[19]. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this	(22) ***Due to the sensitive nature of the health data, Member States, the Commission and Union agencies should safeguard and guarantee that their processing operations respect the 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 Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the

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***.

European Parliament and of the Council[19]. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing. ***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.***

[19] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

[19] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Amendment 50
Véronique Trillet-Lenoir
Compromise amendment replacing 17 (Trillet-Lenoir), 216 (Comín i Oliveres)

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(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***	(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 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.

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 accordance with the data protection legislation.

Or. en

Amendment 51
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 18 (Trillet-Lenoir), 214 (Konečná), 215 (Cerdas & others), 219 (Comín i Oliveres)

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(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	(28) In order to ***supplement certain aspects of this Regulation in order 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

Commission ***in respect of*** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[21]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	Functioning of the European Union should be delegated to the Commission ***the establishment and update of a list of communicable diseases and related special health issues subject to the network of 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 update 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 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.
[21] OJ L 123, 12.5.2016, p. 1.	[21] OJ L 123, 12.5.2016, p. 1.

Or. en

Amendment 52
Véronique Trillet-Lenoir
Compromise amendment replacing Amendments 240 (Comín i Oliveres), 480 (Comín i

Oliveres), 490 (Comín i Oliveres), 493 (Comín i Oliveres), 496 (Comín i Oliveres), 521 (Comín i Oliveres), 540 (Comín i Oliveres), 543 (Comín i Oliveres), 554(Comín i Oliveres), 556 (Comín i Oliveres), 559 (Comín i Oliveres), 562 (Comín i Oliveres), 564 (Comín i Oliveres), 567 (Comín i Oliveres), 579 (Comín i Oliveres), 635 (Comín i Oliveres), 193 (Comín i Oliveres), 213 (Comín i Oliveres)

Proposal for a regulation
Article 2 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. This Regulation shall also apply, where appropriate, to regional competent authorities, systems and programmes in the fields covered by this Regulation.

Or. en