Basic information

2020/0322(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Serious cross-border threats to health Repealing Decision 2013/1082 2011/0421(COD) **Subject** 4.20 Public health 4.20.01 Medicine, diseases **Legislative priorities** Joint Declaration 2021 Joint Declaration 2022	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Climate and Food Safety	TRILLET-LENOIR Véronique (Renew)	26/11/2020
	Shadow rapporteur DE LANGE Esther (EPP) CERDAS Sara (S&D) AUKEN Margrete (Greens /EFA) KOPCISKA Joanna (ECR) MÉLIN Joëlle (ID)	

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection		

Council of the European Union

European Commission

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
11/11/2020	Legislative proposal published	COM(2020)0727	Summary
14/12/2020	Committee referral announced in Parliament, 1st reading		
13/07/2021	Vote in committee, 1st reading		
22/07/2021	Committee report tabled for plenary, 1st reading	A9-0247/2021	
13/09/2021	Debate in Parliament	CRE link	
14/09/2021	Decision by Parliament, 1st reading	T9-0377/2021	Summary
11/11/2021	Decision by Parliament, 1st reading	T9-0449/2021	Summary
11/11/2021	Matter referred back to the committee responsible for interinstitutional negotiations		
12/07/2022	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	GEDA/A/(2022)004942	
04/10/2022	Decision by Parliament, 1st reading	T9-0333/2022	Summary
04/10/2022	Results of vote in Parliament		
24/10/2022	Act adopted by Council after Parliament's 1st reading		
23/11/2022	Final act signed		
06/12/2022	Final act published in Official Journal		

Technical information

Procedure reference	2020/0322(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Decision 2013/1082 2011/0421(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p5
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/04627

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE689.812	23/03/2021	
Amendments tabled in committee		PE691.332	21/04/2021	
Amendments tabled in committee		PE692.634	29/04/2021	
Amendments tabled in committee		PE692.635	29/04/2021	
Committee opinion	IMCO	PE689.513	31/05/2021	

Committee report tabled for plenary, 1st reading/single reading		A9-0247/2021	22/07/2021	
Text adopted by Parliament, partial vote at 1st reading /single reading		T9-0377/2021	14/09/2021	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T9-0449/2021	11/11/2021	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0333/2022	04/10/2022	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2022)004942	29/06/2022	
Draft final act	00040/2022/LEX	23/11/2022	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2020)0727	11/11/2020	Summary
Commission response to text adopted in plenary	SP(2022)623	07/12/2022	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	ES_PARLIAMENT	COM(2020)0727	22/02/2021	
Contribution	PT_PARLIAMENT	COM(2020)0727	25/02/2021	
Contribution	CZ_SENATE	COM(2020)0727	24/03/2021	
Contribution	IT_SENATE	COM(2020)0727	19/05/2021	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofR	Committee of the Regions: opinion	CDR5624/2020	07/05/2021	

Additional information

Source	Document	Date
EP Research Service	Briefing	01/10/2021

Final act

Regulation 2022/2371
OJ L 314 06.12.2022, p. 0026 Summary

Serious cross-border threats to health

2020/0322(COD) - 11/11/2021 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted **amendments** by the European Parliament to the proposal for a regulation of the European Parliament and of the Council on serious cross-border health threats and repealing Decision No 1082/2013/EU.

The matter was referred back to the committee responsible for inter-institutional negotiations. The main amendments adopted in plenary are the following:

Subject matter and scope

The proposal provides for a stronger and more comprehensive legal framework enabling the Union to react rapidly and to trigger preparedness and response measures to cross-border health threats throughout the EU.

As the health provisions of the Treaties remain largely underused, Members believe that the regulation should aim to make the best use of these provisions to demonstrate the strength of the EU's health policy.

Members proposed that the regulation should also establish rules on **emergency research and innovation plans**, including clinical trial networks and innovation platforms as well as a network of **national strategic stockpiles** and available medical countermeasures.

The Regulation should respect the **'One Health**' and 'Health in All Policies' approaches and ensure that in future health emergencies, the detection of, health interventions concerning and treatment of other serious diseases are not halted.

The strengthened EU health framework should work in synergy with other EU policies and funds. It should be implemented with full respect for the dignity and fundamental rights and freedoms of persons.

The Regulation should apply to the epidemiological surveillance of communicable diseases as well as to the surveillance of the impact of communicable diseases on **major non-communicable diseases** and on specific related health issues, such as mental health.

Members proposed that the EU call for the development of a **WHO Framework Convention on Pandemic Preparedness and Response**. This convention should facilitate the implementation of the International Health Regulations (2005) and address the shortcomings of these regulations identified during the COVID-19 crisis.

Coordination of preparedness and response planning in the Health Security Committee (HSC)

In liaison with the Commission **and the relevant EU agencies**, including the European Health Emergency Preparedness and Response Authority (HERA), the HSC should coordinate Member States' prevention, preparedness and response planning. It should adopt an annual action programme with clear priorities and objectives. Representatives of the relevant EU agencies, as well as a representative appointed by the European Parliament, should be able to participate in the HSC as observers.

Members of the Committee should have no financial or other interests that could affect their impartiality. The list of members of the HSC should be made public.

EU prevention, preparedness and response plan

This plan should be drawn up by the Commission, in cooperation with the Member States and the relevant EU agencies and taking into account the WHO framework. It should include:

- the risk and crisis communication, aimed at health professionals and at citizens;

- the mapping of the production capacities of medical products in the Union as a whole;

- the establishment of a **Union stock of critical medicinal products**, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;

- ensuring that healthcare services without disruption during health emergencies;

- the implementation of the provisions of the plan relating to emergency research and innovation aspects and ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;

- an adequate and needs-oriented staffing level;

- monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health and social care professionals.

The EU plan should also include measures to ensure that the **single market functions** normally in the event serious cross-border threats to health arise.

National prevention, preparedness and response plans

Patients' organisations, health professionals' organisations, industry and supply chain stakeholders and national social partners should be consulted when drawing up national plans.

Member States should provide the Commission with an updated report on their national and, where appropriate, regional and cross-border prevention, preparedness and response planning and implementation within 6 months of the entry into force of the Regulation and every two years thereafter. The plan should include information on the '**strategic reserve**', i.e. the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats as well as the capacity for their safekeeping and storage.

Every two years, the ECDC should conduct **audits** in Member States to verify the state of implementation of national plans and their consistency with the EU plan. These audits would be based on a set of indicators and would be carried out in cooperation with the relevant EU agencies.

Joint procurement

Members also want the EU to be **more transparent** when awarding public contracts or concluding procurement contracts. The procurement process should require all parties to deliver and respect clear commitments, including that manufacturers deliver the agreed production quantities and that authorities buy the agreed set-aside volumes.

The precise quantities ordered by and provided to each participating country and the details of their liabilities should be made public. In the case of joint procurement, the award criteria should also take into account, for example, the manufacturer's ability to ensure security of supply during a health crisis.

The **European Parliament** should be informed of the negotiations and should reserve the right, at all times, to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings.

Early warning and response system

The ECDC should broaden its communication activities to European citizens by setting up a portal for sharing verified information. In addition, Members proposed to update the Early Warning and Response System (EWRS), an instrument managed by the ECDC, with modern technology to ensure its interoperability with international, European, national and regional alert systems.

Serious cross-border threats to health

2020/0322(COD) - 14/09/2021 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 594 votes to 85, with 16 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

The matter was referred back to the committee responsible for interinstitutional negotiations.

The main amendments adopted in plenary concern the following points:

Purpose and scope

The proposal provides for a stronger and more comprehensive legal framework enabling the EU to react rapidly and to trigger preparedness and response measures to cross-border health threats throughout the EU.

According to Members, the COVID-19 crisis has shown that **more action is needed at EU level** to support cooperation between Member States, in particular between border regions. The regulation should respect the 'One Health' and 'Health in All Policies' approaches and ensure that in future health emergencies, the detection of, health interventions and treatment of other serious diseases, are not halted.

The regulation should apply to threats of biological origin including communicable diseases, including those of zoonotic origin, and to epidemiological surveillance of communicable diseases and monitoring of the impact of these diseases on **major non-communicable diseases** and health problems such as mental health.

Members proposed that the EU call for the development of a **WHO Framework Convention on Pandemic Preparedness and Response**. This convention should facilitate the implementation of the International Health Regulations (2005) and address the shortcomings of these regulations identified during the COVID-19 crisis.

Coordination of preparedness and response planning in the Health Security Committee (HSC)

Representatives of relevant EU agencies, including the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), should participate in HSC meetings as observers. The European Parliament should nominate representatives to participate in the HSC as observers. In liaison with the Commission and the relevant EU agencies, the HSC should coordinate Member States' prevention, preparedness and response planning.

EU prevention, preparedness and response plan

This plan should be drawn up by the Commission, in cooperation with the Member States and the relevant EU agencies and taking into account the WHO framework. It should include:

- the mapping of the production capacities of medical products in the Union as a whole;

- the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;

- ensuring that healthcare services, including the screening, diagnosis, monitoring, treatment and care for other diseases and conditions, are provided without disruption during health emergencies;

- ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;

- monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health and social care professionals.

The EU plan should also include measures to ensure that the EU preparedness and response plan should also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.

National prevention, preparedness and response plans

Members proposed that each Member State should consult patients' organisations, health professionals' organisations, industry and supply chain stakeholders and national social partners when drawing up national plans.

Member States should provide the Commission with an **updated report** on their national and, where appropriate, regional and cross-border prevention, preparedness and response planning and implementation within 6 months of the entry into force of the Regulation and every two years thereafter. Every two years, the ECDC should carry out **audits** in Member States to verify the state of implementation of national plans and their consistency with the EU plan. These audits would be based on a set of indicators and would be carried out in cooperation with the relevant EU agencies.

Joint procurement

Members also want the EU to be more **transparent** when awarding contracts or making purchases. The precise quantities ordered by and supplied to each participating country and the details of their commitments should be made public.

The joint procurement process should be conducted in such a way as to strengthen the purchasing power of participating countries, improve security of supply and ensure equitable access to medical countermeasures in the event of serious cross-border health threats. If joint procurement is deployed, qualitative criteria should be considered in the award process, in addition to cost. Such criteria should also take into consideration, for example, the ability of the manufacturer to ensure security of supply during a health crisis.

The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings referred to in this Regulation.

Early warning and response system

The ECDC should broaden its communication activities to European citizens by setting up a portal for sharing verified information. In addition, Members proposed to update the Early Warning and Response System (EWRS), an instrument managed by the ECDC, with modern technology to ensure its interoperability with international, European, national and regional alert systems.

Serious cross-border threats to health

2020/0322(COD) - 11/11/2020 - Legislative proposal

PURPOSE: to strengthen the EU health security framework addressing cross-border health threats.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

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

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

The revision of the health security framework proposes a stronger and more comprehensive legal basis for the EU to prepare and respond to health crises. In addition, the proposal is part of a package of closely associated measures that aim to enhance the roles of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

CONTENT: the overarching aim of the proposed regulation is to provide a strengthened framework for health crisis preparedness and response at EU level by addressing the weaknesses exposed by the COVID-19

pandemic. In particular, it would:

- set out a comprehensive legislative framework to govern action at EU level on preparedness, surveillance, risk assessment, and early warning and responses; and
- enhance the EU's guidance in the adoption of common measures at EU level to face a future cross-border health threat.

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

- national plans and transparent reporting of capacities;
- strengthened, integrated surveillance systems at EU level supported by improved data collection tools and artificial intelligence,
- environmental surveillance, to detect early signals of a possible threat;
- enhanced risk assessment for health threats;
- increased power to enforce a coordinated response at EU level through the Health Security Committee; and
- an improved mechanism for recognition of and response to public health emergencies.

Budgetary implications

The financial impact of this proposal on the EU budget should be part of the next Multiannual Financial Framework 2021-2027. The budgetary implications are related mainly to the following objectives:

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

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

Serious cross-border threats to health

2020/0322(COD) - 04/10/2022 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 544 votes to 50, with 10 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission proposal as follows:

Subject matter and scope

The proposed Regulation aims to enable the EU to **better anticipate and respond to serious cross-border health threats**. The new rules provide for improved prevention, preparedness and response planning at EU and Member State levels.

The Regulation will apply to the epidemiological surveillance of communicable diseases, **including those of zoonotic origin**. As human, animal and environmental health are inextricably linked, the Regulation will have to follow the 'One Health' approach to address current and emerging crises.

Health Security Committee (HSC)

The HSC - composed of representatives of the Member States, divided into two working levels - will be given additional responsibilities for the adoption of guidelines and opinions to better support Member States in the prevention and control of serious cross-border health threats, and to promote better coordination between Member States in dealing with such threats. Representatives of relevant EU agencies and bodies may participate in the meetings of the HSC as observers. A representative appointed by the European Parliament should also be able to participate in the HSC as an observer.

EU prevention, preparedness and response plan

This plan should be drawn up by the Commission, in cooperation with the Member States and the relevant EU agencies and taking into account the WHO framework. It will complement national prevention, preparedness and response plans and promote effective synergies between Member States, the Commission, the European Centre for Disease Prevention and Control (ECDC) and other relevant EU agencies or bodies.

It should include joint governance, capacity and resource arrangements for:

- timely cooperation between the Commission, the Council, the Member States, the HSC and relevant EU agencies or bodies;

- secure exchange of information between the Commission, the Member States, in particular the competent authorities or designated bodies at national level, the HSC and the relevant EU agencies or bodies;

- epidemiological surveillance and monitoring;

- early warning and risk assessment, in particular regarding cross-border and interregional preparedness and response;

- risk and crisis communication, including for health professionals and citizens;

- health-related preparedness and response and multi-sectoral collaboration, such as the identification of risk factors for disease transmission and the associated disease burden, including social, economic and environmental factors;

- the drawing up of an EU-wide capacity map for the production of relevant critical medical countermeasures to address serious cross-border health threats

- emergency research and innovation;

- support to Member States in monitoring the impact of a serious cross-border health threat on the provision and continuity of health care services.

National prevention, preparedness and response plans

National prevention, preparedness and response plans may include elements relating to governance, capacity and resources laid down in the EU prevention, preparedness and response plan. Member States should consult within the HSC and agree with the Commission to ensure consistency with the EU Prevention, Preparedness and Response Plan to the greatest extent possible.

No later than 12 months from the date of entry into force of the Regulation, and every three years thereafter, Member States will be required to provide the Commission and the relevant EU agencies and bodies with an updated report on the planning and implementation of prevention, preparedness and response at national level and, where appropriate, at interregional cross-border levels.

Every three years, ECDC will assess the status of implementation of national prevention, preparedness and response plans by Member States. The ECDC will make recommendations to the Member States and the Commission based on the assessments to the Member States. If a Member State decides not to follow a recommendation, it should explain the reasons for its decision.

Public health emergencies at EU level

For serious cross-border health threats, the Commission may, after considering any expert opinion issued by the ECDC, or any other relevant EU agency or body, or the Advisory Committee for Public Health Emergencies, formally **recognise a public health emergency at EU level**, including pandemic situations where the serious cross-border health threat in question endangers public health at EU level

Joint procurement

The regulation strengthens and extends the framework for **joint procurement of medical countermeasures** for different categories of cross-border health threats, including vaccines, antiviral drugs and other treatments.

The Commission should support and facilitate joint procurement of medical countermeasures by providing all relevant information for the negotiation of such joint procurement, such as information on envisaged prices, manufacturers, delivery times and joint procurement modalities.

Before launching a joint procurement procedure, the Commission will have to prepare an assessment indicating the general envisaged conditions of the procedure with regard to **possible restrictions on parallel procurement** and negotiation activities by the participating countries for the countermeasure in question during the procedure. This assessment will take into account the need to ensure the security of supply of medical countermeasures concerned to the participating countries.

Serious cross-border threats to health

2020/0322(COD) - 06/12/2022 - Final act

PURPOSE: to improve the EU's capacity to respond to future pandemics and other cross-border health crises.

LEGISLATIVE ACT: Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

CONTENT: the Regulation on **serious cross-border health threats** aims to create a stronger mandate for coordination at EU level, update reporting requirements for health system indicators and streamline cooperation between EU countries, the European Commission and EU agencies. The revised legislation on cross-border health threats is part of the broader package on a European Health Union.

Scope

This Regulation apples to public health measures in relation to the following categories of serious cross-border threats to health:

- threats of biological origin, consisting of: (i) communicable diseases, including those of zoonotic origin; (ii) antimicrobial resistance; (iii) biotoxins or other harmful biological agents not related to communicable diseases;

- threats of chemical origin;

- threats of environmental origin, including those due to the climate;

- threats of unknown origin.

Health Security Committee (HSC)

The Regulation establishes a Health Security Committee (HSC) composed of representatives of the Member States. The HSC will support **coordinated actions by the Commission and the Member States** for the implementation of the Regulation. It will coordinate, in liaison with the Commission, (i) prevention, preparedness and response planning, (ii) risk and crisis communication, and (iii) Member States' responses to serious transboundary health threats. The Committee may adopt opinions and provide guidance on response measures in relation to the prevention and control of serious cross-border health threats.

Union prevention, preparedness and response plan

The Commission, in cooperation with the Member States and the relevant EU agencies and bodies, will establish an EU health crisis and pandemic plan to support an effective and coordinated response to cross-border health threats at EU level.

The Union plan will include cross-border and inter-regional preparedness elements to support aligned multi-sectoral cross-border public health measures, in particular with regard to surveillance, screening, contact tracing, laboratory capacity, training of health personnel and specialised treatment or intensive care in neighbouring regions.

To ensure the implementation of the EU plan, the Commission will need to facilitate the organisation of **stress tests**, simulation exercises and in-action and after-action reviews with Member States.

National prevention, preparedness and response plans

When developing their national plans, Member States will consult with each other and with the Commission to ensure consistency with the EU prevention, preparedness and response plan.

By 27 December 2023, and every three years thereafter, Member States will provide the Commission and the relevant EU agencies and bodies with an **updated report** on the planning and implementation of prevention, preparedness and response at national level and, where appropriate, at interregional cross-border levels.

The report will include country profiles to monitor progress and develop action plans to address identified gaps at national level, taking into account respective national circumstances. To this end, the Commission may issue general recommendations. An overview of the recommendations contained in the reports will be made public.

Evaluation

The European Centre for Disease Prevention and Control (ECDC) will evaluate the status of implementation of the national plans. Where appropriate, it will make recommendations to the Member States and the Commission based on the evaluations.

On the basis of the information provided by the Member States and the results of the evaluation, the Commission will report to the European Parliament and the Council every three years on the **status and progress of prevention, preparedness and response planning** at EU level.

Data sharing and reporting

A strengthened and integrated monitoring system is created at EU level to improve data sharing. EU countries are invited to intensify reporting on health system indicators.

Public health emergencies at EU level

The Commission will **declare an EU public health emergency** on the basis of expert advice such as that provided by the Advisory Committee on Public Health Emergencies. The declaration of an EU emergency may lead to: (i) the joint stockpiling and procurement of medical products or devices needed in the event of a crisis; (ii) the activation of ECDC support to mobilise and deploy the EU Health Task Force.

The **Advisory Committee** on Public Health Emergencies, composed of relevant independent experts, including representatives of health professionals, social workers and representatives of civil society, will contribute to the formulation of response measures.

Procurement

The Commission and Member States will be able to initiate **joint procurement procedures** for the purchase of medical countermeasures.

Before launching a joint procurement procedure, the Commission will prepare a joint procurement assessment indicating the envisaged general conditions of the joint procurement procedure, including possible restrictions on parallel procurement and negotiation activities by participating countries for the countermeasure in question during the specific joint procurement procedure. This assessment will take into account the need to ensure the security of supply of the participating countries with the medical countermeasures concerned.

ENTRY INTO FORCE: 26.12.2022.