












Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2020/0322(COD) Awaiting Parliament's position in 1st reading
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	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Environment, Public Health and Food Safety	 TRILLET-LENOIR Véronique	26/11/2020
	Committee for opinion	Shadow rapporteur	
	 Budgets	 DE LANGE Esther  CERDAS Sara  AUKEN Margrete  MÉLIN Joëlle  KOPCIŃSKA Joanna  KONEČNÁ Kateřina	Appointed
	 Internal Market and Consumer Protection	The committee decided not to give an opinion.	26/01/2021
Council of the European Union European Commission	Commission DG Health and Food Safety	Commissioner KYRIAKIDES Stella	
European Economic and Social Committee European Committee of the Regions			

Key events

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		
14/09/2021	Decision by Parliament, 1st reading	T9-0377/2021	Summary
14/09/2021	Matter referred back to the committee responsible		

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	Awaiting Parliament's position in 1st reading
Committee dossier	ENVI/9/04627

Documentation gateway

Legislative proposal		COM(2020)0727	11/11/2020	EC	Summary
Committee draft report		PE689.812	23/03/2021	EP	
Amendments tabled in committee		PE692.634	29/04/2021	EP	
Amendments tabled in committee		PE692.635	29/04/2021	EP	
Committee of the Regions: opinion		CDR5624/2020	07/05/2021	CofR	
Committee opinion	IMCO	PE689.513	31/05/2021	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0247/2021	22/07/2021	EP	
Text adopted by Parliament, partial vote at 1st reading/single reading		T9-0377/2021	14/09/2021	EP	Summary

Additional information

Serious cross-border threats to health

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

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.