






# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Preparatory phase in Parliament
Serious cross-border threats to health Repealing Decision 2013/1082 <a href="#">2011/0421(COD)</a>	
Subject 4.20 Public health 4.20.01 Medicine, diseases	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 <a href="#">Environment, Public Health and Food Safety</a>		26/11/2020
		 <a href="#">TRILLET-LENOIR</a> <a href="#">Véronique</a>	
		Shadow rapporteur	
Council of the European Union		 <a href="#">CERDAS Sara</a>	
	Committee for opinion	Rapporteur for opinion	Appointed
	 <a href="#">Budgets</a>	The committee decided not to give an opinion.	
	 <a href="#">Internal Market and Consumer Protection</a>		
European Commission	Commission DG	Commissioner	
	<a href="#">Health and Food Safety</a>	KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events			
11/11/2020	Legislative proposal published	<a href="#">COM(2020)0727</a>	Summary

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 <a href="#">2011/0421(COD)</a>
Legal basis	Treaty on the Functioning of the EU TFEU 168-p5
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a> <a href="#">European Committee of the Regions</a>

Stage reached in procedure		Preparatory phase in Parliament			
Documentation gateway					
Legislative proposal		<a href="#">COM(2020)0727</a>	11/11/2020	EC	Summary

## 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.