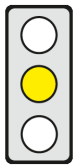


## KEY ISSUES

**Background:** The Commission believes that the existing legal framework was inadequate for a timely and common EU-level response to the COVID-19 pandemic.

**Objective of the Regulation:** The Regulation will strengthen the EU's ability to respond more effectively to cross-border health threats.

**Affected parties:** All citizens, stakeholders involved in preparedness and response to health threats.



**Pro:** (1) A formalised plan and review cycle of national preparedness and response plans may achieve more consistency and cooperation across the EU. This could limit the impact which cross-border health threats have on national health systems and economies.

(2) The ability of the Commission to organise training for healthcare staff, and to support the exchange and temporary secondment of such staff, will increase expertise and staff capacity, benefiting all Member States.

**Contra:** (1) The proposal lacks a clear definition of a public health emergency at Union level. A definition in the regulation is needed to increase predictability and accountability to both Member States and EU citizens.

(2) The recognition and termination of a public health emergency at Union level entails a wide range of legal effects. Member States are not currently involved in these decisions at a political level.

**Proposal:** Adequate political involvement of Member States in the recognition and termination of a public health emergency at Union level could be secured through the "high-level working group" of the Health Security Committee (HSC) that will be made up of national Deputy Health Ministers.

The most important passages in the text are indicated by a line in the margin.

## CONTENT

### Title

**Proposal COM(2020) 727** of 11 November 2020 for a **Regulation** of the European Parliament and of the Council on **serious cross-border threats to health**

### Brief Summary

#### ► Background and Context of the Proposal

- According to the Commission, the current legal basis was inadequate for a timely and common EU-level response to the COVID-19 pandemic [p. 1].
- The Commission wants to strengthen the EU's ability to respond more effectively to cross-border health threats [p. 3].
- In order to tackle the shortcomings, the Commission's vision of a European Health Union encompasses three regulation proposals concerning
  - the European Medicines Agency (EMA) [COM(2020) 725; see [cepPolicyBrief 12/2021](#)],
  - the European Centre for Disease Prevention and Control (ECDC) [COM(2020) 726; see [cepPolicyBrief 17/2021](#)],
  - serious cross-border threats to health [this [cepPolicyBrief](#)].

#### ► Aim of the Proposal

- The current legal basis, namely the Decision on serious cross-border threats to health [(EU) 1082/2013], is to be replaced by this regulation proposal [Art. 30].
- The proposal aims to [p. 3]:
  - develop an EU health crisis and pandemic plan to complement national plans;
  - enhance risk assessments for health threats;
  - increase power to enforce a coordinated response at EU level;
  - improve the mechanism for the recognition of and response to public health emergencies.
- Another aim is to strengthen integrated surveillance systems [p. 3]. This will be achieved, in particular, by expanding the tasks of the European Centre for Disease Prevention and Control; for this see [cepPolicyBrief 17/2021](#).

► **Preparedness and Response Plans**

- The Commission will establish a “preparedness and response plan” to promote an effective and coordinated response to cross-border health threats, such as health crises and pandemics, at EU level [Art. 5 (1)].
- This plan will
  - complement national preparedness and response plans [Art. 5 (2)];
  - include interregional preparedness elements [Art. 5 (4)].
- Regarding national preparedness and response plans [Art. 6]:
  - Member States will provide the Commission with a report on their planning and implementation [Art. 7 (1)].
  - The European Centre for Disease Prevention and Control (ECDC) will conduct audits and propose recommendations to Member States [Art. 8 (1), (2)].
  - Member States will have to follow up on the audit of the ECDC by drafting an action plan with corresponding corrective measures and milestones [Art. 8 (2)].
- The Commission can organise training for national healthcare staff to provide knowledge and skills to develop and implement national preparedness plans. It can also support the exchange and temporary secondment of staff between Member States [Recital 7 and Art. 11 (1), (2) and (5)].

► **The Health Security Committee**

- The existing Health Security Committee (HSC) is to be strengthened to “enforce” a coordinated response and will be equipped with [p. 3 and Art. 4 (1)]
  - a “high-level working group”, to discuss topics of political importance, and
  - “technical working groups”, to discuss topics of a technical nature.
- The Health Security Committee – consisting of one representative from each Member State and chaired by the Commission – is the forum in which exchange of information and coordination takes place, especially with regard to risk and crisis communication [Art. 4 (1), (2), (4) and (7)].
- The HSC’s responsibilities will be extended to include the adoption of guidance and opinions to support Member States in the prevention and control of serious cross-border threats to health [Recital 3; Art. 4 (2) (d); Art. 21 (1) (c)].

► **Early Warning and Response**

- The existing Early Warning and Response System (EWRS) ensures that national authorities and the Commission are informed about a serious cross-border threat to health in a timely manner and that permanent communication is secured [Recital 13 and Art. 18 (1)].
- Following an alert of a serious cross-border threat to health, a risk assessment on the severity of the threat and on possible public health measures will be made available by the Commission [Art. 20 (1)].
- In order to make comprehensive use of the available scientific expertise, other EU agencies – such as the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) – will broaden their involvement in and responsibility for the risk assessments. All the agencies concerned have to submit any relevant information, without undue delay, to the leading agency carrying out the risk assessment. [Recital 14 and Art. 20 (1), (2)]
- Following an alert about a serious cross-border threat to health, the coordination of responses, risk and crisis communication and the adoption of opinions and guidance takes place within the Health Security Committee [Art. 21].
- The Commission may adopt recommendations on common temporary public health measures to complement the actions of Member States [Art. 22 (1)]. These must respect the responsibility of the Member States for the definition of their health policy [Art. 22 (2) (b)].

► **“Public Health Emergencies at Union Level”**

- Currently, the Commission can officially recognize a “public health emergency” in relation to
  - epidemics of human influenza considered to have pandemic potential and
  - certain other cases, which involve decisions of the World Health Organisation (WHO) [Art. 12 (1) of Decision [(EU) 1082/2013]].
- The current term “public health emergency” is replaced by “public health emergency at Union level”. At the same time, the legal effects of the recognition of such an emergency situation are expanded [Recital 18, Art. 23 and Art. 25].
- The recognition of a public health emergency at Union level by the Commission
  - will be “based on” advice from the Advisory Committee on public health emergencies consisting of independent experts selected by the Commission (“Advisory Committee”) [Art. 23 (1); Art. 24 (1) and (2)];
  - is technically realised by way of an implementing act of the Commission [Art. 23 (1), (4)];
  - technically involves the Member States in the decision via the law on the exercise of implementing powers [Art. 23 (4); Art. 27 (2) and (3); Regulation [(EU) 182/2011].

- On duly justified grounds of urgency, the Commission may recognise a public health emergency at Union level through immediately applicable implementing acts [Art. 23 (4); Art. 27 (3) and the law on the exercise of implementing powers [Regulation [(EU) 182/2011]].
- The recognition of a public health emergency at Union level legally allows for:
  - measures by the European Medicines Agency regarding medicinal products and medical devices [Art. 25 (1) (a) and [COM\(2020\) 725](#); see [cepPolicyBrief 12/2021](#)];
  - mechanisms to monitor shortages of, develop, procure, and deploy medical countermeasures [Art. 25 (1) (b)];
  - mobilisation and deployment of outbreak assistance teams called the EU Health Task Force [Art. 25 (1) (c) and [COM\(2020\) 726](#); see [cepPolicyBrief 17/2021](#)].
- The Commission shall terminate the recognition of a public health emergency at Union level if “one of the applicable conditions” laid down in the legal basis is no longer met. The Advisory Committee provides advice. [Art.23 (1) and (2) and Art. 24 (1)]

### Statement on Subsidiarity by the Commission

Public health emergencies of the magnitude of the COVID-19 pandemic have an impact on all Member States that are unable to provide a sufficient response on their own. Although the Member States are responsible for managing public health crises at national level, no country can tackle a cross-border public health crisis on its own. [p. 3]

### Legislative Procedure

11 November 2020	Adoption by the Commission
14 December 2020	Committee referral announced in Parliament
23 July 2021	Agreement in the Council on mandate for negotiations
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

### Options for Influencing the Political Process

Directorates General:	DG SANTE (Health and Food Safety)
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading), Rapporteur: Véronique Trillet-Lenoir (Renew Europe Group, France)
Federal Germany Ministries:	Federal Ministry of Health
Committees of the German Bundestag:	Committee on Health
Decision-making Mode in the Council:	Qualified majority (55% of Member States & 65% of the EU population)

### Formalities

Competence:	Art. 168 (5) TFEU (protection and improvement of human health)
Type of Legislative Competence:	Support, Coordinate, Supplement (Art. 6 (a) TFEU)
Procedure:	Art. 294 TFEU (ordinary legislative procedure)

## ASSESSMENT

### Economic Impact Assessment

National measures in response to a cross-border health threat may have negative consequences in other Member States. Generally, increased coordination at EU level with respect to crisis preparedness and response planning may reduce differences and at least limit the negative consequences of national measures regarding a cross-border health threat.

**The newly introduced EU preparedness and response plan allows for a faster and more coherent response at EU level.** It has the potential for better allocation of scarce resources and the efficient use of capacities across Member States in emergency situations, especially in border regions.

For example: The COVID-19 pandemic revealed differences in national capacities as regards healthcare staff and healthcare facilities. Some Member States, such as Germany, France, Italy and The Netherlands, cooperated and supported each other by transferring patients to Member States in which intensive care units in hospitals were still available. By having an EU preparedness plan to complement national plans, such cooperation can be formalised and applied more widely across all Member States, rather than on an ad-hoc basis in certain Member States only.

**A formalised plan and review cycle of national preparedness and response plans,** covering planning, reporting, auditing and adjusting, **may achieve more consistency and cooperation across the EU. This could limit the impact which cross-border health threats initially have on national health systems,** in particular, **and subsequently on economies**

in general. Recommendations from the ECDC, as well as the requirement to address these and report on milestones and corrective actions, will encourage Member States to find the most effective measures and implement them in a timely manner.

**The ability of the Commission to organise training for healthcare staff, and to support the exchange and temporary secondment of such staff** – in cooperation with the Member States concerned –, **will increase expertise generally, and staff capacity temporarily, thereby benefiting all Member States** irrespective of the organisational and financial capacities of the national health systems. Better trained staff will support the implementation of national preparedness and response plans. In addition, and at the same time, temporarily increasing staff capacity in case of emergency may help to reduce the spread of a public health threat across the EU.

Scientific expertise at EU level will be utilised more effectively by broadening the involvement and cooperation of different EU agencies on risk assessments. The duty for EU agencies to provide information, without undue delay, to the leading agency carrying out the risk assessment, will improve and increase information exchange and enhance the risk assessment. It will improve the quality of the risk assessments and ensure the availability of specialised knowledge and information about specific threats to health, both at EU and national level. This in turn may help Member States to obtain the most accurate information on the severity of a health threat and on the possible design of public health measures, irrespective of the organisational and financial capacities of their national health systems.

## Legal Assessment

### Legislative Competence of the EU

Unproblematic. Article 168 (5) TFEU allows the EU to adopt incentive measures to protect and improve human health and in particular to combat the major cross-border health scourges and measures concerning monitoring, early warning of and combating serious cross-border threats to health.

### Subsidiarity

Unproblematic. Serious cross-border health threats can be better dealt with at EU level.

### Proportionality with Respect to Member States

The new “high-level working group” of the Health Security Committee (HSC), which is to address topics of political importance, will give the HSC more political weight when it comes to “enforcing” a coordinated EU-wide response to serious cross-border threats to health. Combined with the technical expertise within the HSC, this could have a positive impact on the outcome of public health measures in Member States. However, irrespective of the Commission’s wording (“enforce”), any opinion or guidance given by the HSC to Member States will be legally non-binding, so that Member States retain their discretion regarding the implementation. Thus, Member States will still have sufficient leeway to decide on national response measures and so define their national health policy in that regard [Art. 168 (7) TFEU].

**The proposal lacks a clear definition of a public health emergency at Union level.** This must be remedied. Otherwise, it will be unclear what circumstances and conditions are needed to trigger a public health emergency at Union level, and when the law requires such an emergency situation to end. **A definition in the regulation itself is necessary to increase predictability and accountability to both Member States and EU citizens.** Even the Commission's right to set the criteria, as provided for in the Council's mandate for negotiations, is not sufficient, as the definition, as an essential element, must be established by the legislator.

**The recognition and termination of a public health emergency at Union level** does not involve the Member States except through the “Committee on serious cross border threats to health” which is composed of technical experts from the Member States, e.g. representatives from scientific institutes like the German Robert Koch Institute. Recognition nevertheless **entails a wide range of legal effects**, which can impact both Member States and EU citizens. **Member States therefore need to be involved at a political level.** This could be secured **through** the formal involvement of the “high-level working group” of the HSC that will be composed of the national Deputy Health Ministers.

## Summary of the Assessment

The EU preparedness and response plan allows for a faster and more coherent response at EU level. A formalised plan and review cycle of national preparedness and response plans may achieve more consistency and cooperation across the EU. This could limit the impact which cross-border health threats have on national health systems and economies. The ability of the Commission to organise training for healthcare staff, and to support the exchange and temporary secondment of such staff, will increase expertise and staff capacity, benefiting all Member States. The proposal lacks a clear definition of a public health emergency at Union level. A definition in the regulation itself is necessary to increase predictability and accountability to both Member States and EU citizens. The recognition and termination of a public health emergency at Union level entails a wide range of legal effects. The Member States therefore need to be involved at a political level through the “high-level working group” of the HSC.