



# European Union Legal System for Health Emergencies

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## Abstract

**Background** - The aim is to analyze how the legal system in the European Union that deals with the public health emergencies in terms of organization and readiness to respond to public health emergencies.

**Methods** - The method used is desk research, based on the current secondary scientific literature, both from the online resources and from the variant publications.

**Results** - The primary responsibility for responding to public health emergencies falls within the domain of the EU Member States, while the EU action is intended to complement the national policies of the EU Member States and to coordinate and support their actions. The Commission plays a vital role, both in coordinating and in exchanging the information among the EU Member States. Based on the experience with the public health emergencies the Commission initiated new legislation in 2011 which resulted in a new Decision No. 1082/2013 on Serious Cross-Border Threats to Health. The national authorities are required to send to all authorities connected through the network data related to serious threats to public health.

**Conclusion** - There is still a room for collaboration improvement. Further actions should be undertaken to bring the coordination and network for the public health emergencies surveillance, preparedness and response planning to a higher level.

## Introduction:

Due to its specific nature as an area with no internal borders and the free circulation of people and goods, the European Union (EU) faces special challenges in the event of public health emergencies (threats of biological origin, threats of chemical origin, threats of environment origin and threats of unknown origin).

A public health emergency (the condition that requires the governor to declare a state of public health emergency) is defined as “an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability”.<sup>[1]</sup> In the event of any public health emergency all 28 EU Member States should coordinate the action in a fast and efficient manner.

Levels of preparedness remain uneven across and within countries, leaving the communities and the states at a risk of a significant short - and long-term health impacts. The overall responsibility for safeguarding, maintaining, and restoring the health and wellbeing of communities’ lie with national governments. Based on previous experience with the public health emergencies the European Commission initiated new legislation in 2011 which resulted in a new Decision No. 1082/2013 on Serious Cross-Border Threats to Health.<sup>[2]</sup> The Decision No 1082/2013 has designated national authorities to control serious public health emergencies and to take care of the epidemiological surveillance and the alert notification.

EU action in the field of public health is intended to complement the national policies of the EU Member States and to coordinate and support their action. The Commission plays a vital role, both in coordinating and exchanging information among the EU Member States.

**Objectives**: to describe how the system to respond to health emergencies is organised in the EU and whether the EU Member States are ready to respond to public health emergencies promptly and effectively.

## Methods:

The method used is a literary work, mostly based on the current secondary scientific literature, both from the online resources and from the variant publications. The analysis besides the examination of the role of the existing legislative system for public health emergencies, considers also the role of the Committees responsible for early warning and the prevention of the health crisis. The efficiency of the legislative instruments is considered. The example used is Croatia, being the youngest member of EU.

## Results:

Results have shown the primary responsibility for responding to public health emergencies falls within the domain of the Member States. MS are mainly individually responsible for responding to public health and other major emergencies within their borders. The EU has legal authority in the field of public health based on Article 168 of the Treaty on the Functioning of the European Union (TFEU) and consequently to public health emergencies.

In general, EU action in the field of public health is intended to complement the national policies of the EU Members and to coordinate and support their action. The Commission plays a vital role, both in coordinating and exchanging information among the EU Member States.

The past experience with the public health crises in the EU have clearly demonstrated that such crises affect numerous sectors, including health, food safety, environment, transport, and national security. Thus, Commission in 2011 initiated new legislation to address the existing deficiencies in tackling health crises. A new decision, Decision No. 1082/2013 on Serious Cross-Border Threats to Health, expands the list of sources of danger to health to include not only communicable diseases but also biological, chemical, and environmental events, or events of unknown origin that may pose a risk to the EU citizens. Decision No. 1082/2013 extended the scope of the network for the epidemiological surveillance of communicable diseases. The network is operated and coordinated through European Centre for Disease Prevention and Control (ECDC).

The Ministry of Health is the central authority in public health crises and takes appropriate emergency measures to confront such crises.

Four years have passed since the Decision is implemented in the MS. Decision 1082/2013/EU has promoted and strengthened the preparedness coordination between the EU Member States.

Member States have developed and strengthened the capacities that are needed to respond to any health event, such as coordination and command and control mechanisms, as well as communication between sectors and from national to the local level.

Even though each and every MS has a responsibility to manage a public health crises, there is a need for further actions to bring the coordination and network for the epidemiological surveillance, preparedness and response planning at the higher level in the case of public health emergencies.

There is a need for the uniform training and exercises

in each MS coordinated with the EU institutions, namely ECDC, and for sharing the experience as well as for strengthening the guidelines and procedures. Also, the technical support and expertise with preparedness and response planning is needed. For example, in 2018 the focus should be on the guidelines and procedures, in 2019 on sharing the experience and further training, and in 2020 on the cross-border exercises. The plan should be for the three-year period, since the proposal is for an yearly report for the three consecutive years.

## Discussion:

The legal base which deals with the health threats is the Article 168 of the TFEU (Treaty on the Functioning of the European Union). It defines that community activities accompanies national policies towards the improving of the public health, preventing diseases, and obviating sources of danger to human health.<sup>[3]</sup> The action of the EU is primarily concerned with complementing the national policies and with encouraging the cooperation between the Member States as well as with fostering international collaboration. The EU can adopt legislative measures in some fields and incentive measures designed to protect and improve human health.<sup>[4]</sup> The EU has developed a legal framework in some areas of public health, covering health care and people rights in cross-border emergencies and the EU preparedness capacity to coordinate the response to health threats.<sup>[5]</sup>

Article 168 of the TFEU set up actions for the EU to reduce to or prevent serious health threats which often have a possible international impact (“only the Union may legislate and adopt legally binding acts.... The EU competence shared with the MS in a specific area, the EU and the MS may legislate and adopt legally binding acts in that area” ).<sup>[6]</sup> Accordingly, actions of the EU concentrate on coordinating data and measures on communicable diseases and materials associated with Chemical, Biological and Radio-Nuclear (CBRN) agents.

Related activities that promote cooperation and coordination between the national governments on serious cross-border threats, are as follows:

- EU alert systems (The Early Warning and Response System (EWRS) and the Rapid Alert System for Food and Feed (RASFF));
- EU Health Security Committee (HSC);
- European Centre for Disease Prevention and Control (ECDC);
- EU-wide research networks linked to serious cross-border threats to health (an Alerting System for Chemical Health Threats (ASHT)).

In connection with the legislative activities, the EU stepped up the cooperation between the Commission and the Member States, mainly on health promotion and disease prevention. The EU has also developed tools to support the collaboration within MS, such as the action plan on antimicrobial resistance.<sup>[7]</sup>

Since the responsibility in public health measures on serious cross-border threats lies with the Member States, the EU Decision 1082/2013 puts the obligation on them to inform/communicate of such measures in order to enhance the coordination among themselves in collaboration with the Commission.<sup>[8]</sup> This Decision requires that the Member States and the Commission consult each other within the Health Security Committee in order to develop and strengthen their capacities for the monitoring, early warning and assessment response to serious cross-border threats to health.<sup>[9]</sup>

Additionally, the decision on serious cross-border threats to health puts some specific recommendations on the Member States. The aims in coordinating the responses to serious health threats established by this Decision are the following<sup>[10]</sup>:

- To share best practice and experience in preparedness and response planning;
- To promote the interoperability of national preparedness planning;
- To address the intersectoral dimension of preparedness and response planning at Union level;
- To support the implementation of core capacity requirements for surveillance and response to threats in accordance with the International Health Regulations (IHR) rules.

Table 1. shows comparison between TFEU (Article 168) and Decision No. 1082/2013 on health threat actions in EU Member States

Decision No 1082/2013/EU extend the Member States responsibilities for epidemiological surveillance and the responsibility for delivering data to the European Surveil-

lance System and to notify alerts to the Early Warning and Response System (EWRS) under the rules set out in the Decision.<sup>[11]</sup> There is a need however to emphasise that Decision 1083/2013 represents the soft law and each and every MS has no binding acts in public health emergencies. The MS has to work on close cooperation for the monitoring, early warning on serious cross-border threats.

This Decision aims to support cooperation and coordination between the MS in order to improve the prevention and control of the spread of severe human diseases across the borders of the MS. In order to coordinate and complement national policies the Decision lays down rules on epidemiological surveillance, monitoring, early warning and combating serious cross-border threats to health, including preparedness and response planning related to those activities. The Commission will strengthen cooperation and activities with the ECDC (European Centre for Disease Prevention and Control), the MS, the European Medicines Agency and the World Health Organisation (WHO) in order to improve the methods and processes in the event of serious cross-border threats to health.

The national authorities are required to send all EU MS authorities connected through network certain data, including comparable and compatible data related to the communicable diseases and other threats to the public health. The Ministry of Health (MoH) is the central authority in public health crises and takes appropriate emergency measures to confront such crises. The coordination between a state and other EU institutions goes through separate agencies appointed by MoH.

There is a need however to emphasise that Decision 1083/2013 represents the soft law and each and every MS has no binding acts in public health emergencies. The MS has to work on close cooperation for the monitoring, early warning on serious cross-border threats. However, there is no obligation towards MS.

The example of public health emergencies and responsibilities for early warning and prevention of the health crises was based on the youngest EU Member State – Croatia.

Table 1. Comparison between TFEU (Article 168) and Decision No. 1082/2013 on health threat actions in EU Member States

TFEU (Art. 168)	Decision No. 1082/2013
<ul style="list-style-type: none"> <li>• Improving the public health</li> <li>• Preventing diseases</li> <li>• Obviating sources of danger to human health</li> <li>• Reduce or prevent serious health threats</li> </ul>	<ul style="list-style-type: none"> <li>• Developing and strengthening capacities for monitoring, early warning and assessment response to serious cross-border threats to health</li> <li>• Share best practice and experience in preparedness and response planning</li> <li>• Promote the interoperability of national preparedness planning</li> <li>• Address the intersectoral dimension of preparedness and response planning at Union level</li> <li>• Support the implementation of core capacity requirements for surveillance and</li> <li>• response to threats in accordance with the IHR rules</li> </ul>

Besides National Healthcare Development strategy, Croatia adopted a Healthcare Plan and Programme and established Public Health Framework. Furthermore, the Croatian National Institute of Public Health (CNIPH) provides risk assessments in all areas of communicable and non-communicable infections and diseases, social and school medicine, prevention of drug addiction, environmental health, and microbiology.<sup>[12]</sup> Also, CNIPH serves as a central point for the communication, coordination and information exchange with the EU institutions.

The current Croatian systems on communicable diseases surveillance and control include the EWRS (Early Warning and Response System of the European Union) and reporting to the WHO Centralized Information System for Infectious Diseases (CISID).

The Croatian Platform for Disaster Risk Reduction was established in 2009 as a permanent forum for the exchange of the opinions and information in the area of disaster risk reduction. The National Protection and Rescue Directorate coordinates the Platform.<sup>[13]</sup>

Also, Croatia is in the process of developing a Disaster Risk Reduction Strategy that will enable more precise activities and financial planning as well as give legislative recommendations.<sup>[14]</sup> The legal framework applies to all concerned governmental bodies at the national, county and municipal levels. Response to a disaster is carried out according to the subsidiarity principle under the responsibility of those in charge at the county and lower levels. Table 2. shows Croatia preparedness plan for the prevention of the health crises; which actions are already done and action planned.

Currently, the existing legal framework does not address disaster risk reduction and disaster prevention and mitigation in Croatia. The Protection and Response Law equates activities in these areas with those aimed at eliminating the consequences of disasters. Within this framework, the national protection and rescue system and its crucial actor, the National Protection and Rescue Directorate, are oriented more towards preparedness for rescue and emergency response than disaster prevention.<sup>[15]</sup>

## Conclusion:

According to the TFEU, the role of EU in the public health is limited to compliment the federal policies of the EU Members: to coordinate their activities and exchange of the information between the European Commission and the EU Members.

Four years have passed since Decision is implemented in the MS. Decision 1082/2013/EU has promoted and strengthen the preparedness coordination among the EU Member States.

Member States have developed and strengthen the capacities that are needed to respond to any health event, such as coordination, command and control mechanisms, as well as communication between sectors from national to local level. The Commission has received the first report in 2015 on the Decision implementation. The obligation is to submit the next report to the European Parliament and the Council every three years after the first report. Recommendation would be the report from each MS has to be prepared each year in the next three consecutive years, every two years afterwards and every four years thereafter. This will give the opportunity for better evaluation and reducing any existing gaps especially when MS have to learn more from each other and have to coordinate better among themselves.

There is still room for collaboration improvement. Further actions should be undertaken to bring the coordination and network for the public health emergencies surveillance, preparedness and response planning to a higher level. One example of such actions could be the uniform training in all EU Member States, done in coordination with the EU institutions, as well as strengthening of the relevant guidelines and procedures. Also, during a three-year period, a shared IT platform, to facilitate the information flow among the stakeholders, should be done along with the joint meetings.

Neither any financial support nor conflict of interest.

Table 2. Croatia preparedness plan for the prevention of the health crises

Action done	Action planned
<ul style="list-style-type: none"> <li>HealthCare Plan and Programme adopted</li> <li>Risk assessment of infections and diseases by</li> <li>CNIPH being provided</li> </ul>	<ul style="list-style-type: none"> <li>Development of a disaster risk reduction strategy</li> <li>Activities to be planned in line with a disaster risk reduction strategy</li> <li>Legal framework to be updated to address disaster risk reduction/prevention/mitigation</li> </ul>

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