

# Serious cross-border threats to health

2011/0421(COD) - 08/12/2011 - Legislative proposal

**PURPOSE:** establish a European initiative to combat serious cross-border threats to health.

**PROPOSED ACT:** Decision of the European Parliament and of the Council.

**BACKGROUND:** many activities related to preparedness and response planning and risk assessment for communicable diseases but also for chemical threats to health and events caused by climate change have been supported at European level, in particular the current Community network for the epidemiological surveillance and control of communicable diseases (see [Decision No 2119/98/EC of the European Parliament and the Council](#) establishing a network for the epidemiological surveillance and control of communicable diseases in the Community). The EU already has policies, mechanisms and instruments in place for the prevention and control of serious cross-border threats and for the development of capacities to manage crises. A non-exhaustive list includes the EU Civil Protection Mechanism, the Cohesion and Solidarity Funds, the EU action plan on chemical, biological, radiological and nuclear security, and European alert networks, such as ECURIE.

In order to avoid overlaps with these areas and duplicating existing disaster prevention and control structures, a gap analysis has been carried out to assess how far these existing systems cover the monitoring of threats to health, their notification, risk assessment and crisis management capacities and structures from the public health perspective. This gap analysis revealed that the **existing structures and mechanisms at EU level do not address these threats sufficiently as far as public health is concerned.**

The lack of public health risk assessment at EU level leads to discrepancies in evaluating the danger of a given threat, duplication of assessments between Member States and inconsistent measures at EU level. Such a situation can also lead to inefficient use of the limited resources currently available.

Although the Member States have the responsibility to manage public health crises at national level, no country can tackle a cross border public health crisis on its own. At EU level, the legal basis for addressing serious cross-border health threats has been reinforced with the Lisbon Treaty. The EU can now take action in this field that complement and support national policies and encourage cooperation between Member States.

This is the reason why it is proposed to create a new instrument to step up cooperation and strengthen coordination in the area of the notification and risk assessment.

The aim is to **streamline and strengthen European Union capacities and structures** for effectively responding to serious cross-border health threats. These threats can be events caused by communicable diseases, biological agents responsible for non-communicable diseases, and threats of chemical, environmental, or unknown origin, as well as threats deriving from the effects of climate change.

**IMPACT ASSESSMENT:**

The Commission has carried out detailed analysis of three options:

- **Option 1:** status quo: maintaining the current level of activities;
- **Option 2:** separate and different handling of serious cross-border threats to health - enhanced EU cooperation through the use of soft instruments based on a voluntary approach;

- **Option 3:** establishing a common EU legal framework covering all serious cross-border threats to health through improved cooperation and legally binding measures.

The results of the analysis led to the conclusion that **option 3 has the strongest positive health impacts** as it improves the protection of citizens against serious cross-border threats to health.

**LEGAL BASIS:** Article 168, paragraphs (4)(c) and (5) of the Treaty on the Functioning of the European Union (TFEU).

**CONTENT:** this proposal lays down the rules on monitoring, early warning of and combating serious cross-border threats to health, as well as on preparedness and response planning related to those activities. It aims to support the prevention and control of the spread of severe human diseases across the borders of the Member States, and to obviate other major sources of serious cross-border threat to health in order to contribute to a high level of public health protection in the Union.

**Scope:** the proposal applies in case of serious cross-border threats to health falling within the following categories:

- threats of biological origin, consisting of: (i) communicable diseases; (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases; (iii) biotoxins or other toxic biological agents not related to communicable diseases;
- threats of chemical origin with the exception of threats arising from ionizing radiation;
- threats of environmental origin, including threats deriving from the effects of climate change;
- threats of unknown origin;
- events which may constitute public health emergencies of international concern determined pursuant to the International Health Regulations (2005).

**General structure:** the monitoring system revolves around the following four fields:

- 1) **preparedness and response planning:** the proposal provides for the coordination of the efforts of the Member States in terms of improved preparedness and capacity building. To this end, the Commission will ensure coordination between national planning and between key sectors such as transport, energy and civil protection, and will support Member States in setting **up a joint procurement mechanism** for medical countermeasures, e.g. vaccines against influenza, which would enable the EU to be better prepared for future pandemics;
- 2) **establishment of an epidemiological monitoring network:** to provide the relevant information and data for risk assessment and monitoring of emerging threats, an ad hoc network will be set up in situations where a Member State has raised an alert on a serious threat other than a communicable disease. Communicable diseases will continue to be monitored as they are today;
- 3) **the use of the existing Early Warning and Response System** to cover all serious threats to health, and not only communicable diseases as is the case today;
- 4) **coordinated development of national or European public health risk assessments** for threats of biological, chemical, environmental or unknown origin in a crisis situation.

**EU response to a public health crisis:** the proposal sets up a coherent framework for the EU response to a **public health crisis**. In concrete terms, by formalising the existing Health Security Committee, the EU will be in a better position to coordinate national crisis responses in a public health emergency. A procedure for the mobilisation and coordination of the European response to a serious cross-border risk is proposed. Thus, if a Member State intends to adopt public health measures to combat a serious cross-border health risk, it shall, before adopting any measures consult the other Member States and the

Commission on the nature, purpose and scope of the measures. The measures taken shall be decided by means of implementing acts.

Provision is also made for the following specific measures:

- **Common temporary public health measures** to control the spread of a serious cross-border threat to health between the Member States or to the Union as a whole;
- **Emergency and pandemic influenza situations at the Union level;**
- **International agreements** with third countries or international organisations.

**BUDGETARY IMPACT:** this legal proposal does not impact on decentralised agencies. In addition, the current EU health programme already covers some activities in relation to monitoring, alerting and risk assessment of some health threats. After 2013, the Commission intends to cover these activities under the proposed Health for growth programme 2014-2020. The cost is included in the proposed envelope of the new programme.

**DELEGATED ACTS:** in accordance with Article 290 of the TFEU, the Commission should be empowered to adopt delegated acts in respect of measures needed to complement the action of the Member States, **in very specific and urgent situations**, for the transnational aspects of the control of serious cross-border threats to health. In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission to adopt implementing acts in relation to:

- the procedures for the coordination,
- the exchange of information and the mutual consultation on preparedness and response planning;
- the adoption of a list of communicable diseases subject to the network of epidemiological surveillance and the procedures for the operation of such a network;
- the setting up and termination of ad hoc monitoring networks and the procedures for the operation of such networks;
- the adoption of case definitions for serious cross-border threats to health;
- the procedures for the operation of the Early Warning and Response System;
- the procedures for the coordination of the responses of the Member States; the recognition of situations of emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level.