

Serious cross-border threats to health

2011/0421(COD) - 22/10/2013 - Final act

PURPOSE: to strengthen the capacities and structures of the EU to respond effectively to serious cross-border threats to health.

LEGISLATIVE ACT: Decision No 1082/2013/EU of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 2119/98/EC

CONTENT: the decision lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning related to those activities, in order to coordinate and complement national policies.

The decision applies to **serious cross-border threats to health** such as threats of biological origin (for example, communicable diseases such as the pandemic flu H1N1 in 2009), antimicrobial resistance, biotoxins (for example, the outbreaks of E Coli infection in 2011) or threats of chemical origin, or unknown or environmental (for example, the volcanic ash cloud in 2010).

Preparedness and response planning: the decision confers a legal base on the **Health Security Committee (HSC)** which currently exists informally and whose role is strengthened.

The decision stipulates that the **Member States and the Commission should consult each other within the HSC** with a view to coordinating their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health.

That consultation should be aimed at in particular **sharing best practice** and experience in preparedness and response planning and promoting the **interoperability of national systems** of preparedness planning.

Member States should, **by 7 November 2014, and every three years thereafter**, provide the Commission with an update on the latest situation with regard to their preparedness and response planning at national level.

Joint procurement of medical countermeasures: the decision allows the institutions of the Union and any Member States which so desire to engage in a joint procurement procedure with a view to the **advance purchase of medical countermeasures (in particular, vaccines)** for serious cross-border threats to health.

Epidemiological surveillance and ad hoc monitoring: the decision institutes a **network for the epidemiological surveillance** of the communicable diseases and of the related special health issues.

The epidemiological surveillance network shall bring into permanent communication the Commission, the European Centre for Disease Prevention and Control (ECDC), and the competent authorities responsible at national level for epidemiological surveillance. The network shall be operated and coordinated by the ECDC.

A **list of diseases** to be monitored is set out in the Annex to the decision.

Following an alert concerning a threat to health, the Member States should inform each other through the Early Warning Response System (EWRS) and, if the urgency of the situation so requires, through the HSC, about developments with regard to the threat concerned at national level.

Establishment of an early warning and response system: the EWRS, created on an informal basis in 1998, is strengthened and its scope extended to all cross-border threats to health to enable coordination and response at the EU level.

The EWRS should enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

National competent authorities or the Commission should **notify an alert in the EWRS** where the emergence or development of a serious cross-border threat to health fulfils the following criteria:

- the threat is unusual or unexpected for the given place and time, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and
- the threat affects or may affect more than one Member State; and
- the threat requires or may require a coordinated response at Union level.

Recognition of emergency situations: the decision introduces the possibility for the Commission to recognise a situation of public health emergency to accelerate the availability of medicines to combat the health crisis.

Before recognising a situation of public health emergency at Union level, **the Commission should liaise with the World Health Organisation (WHO)** in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to issue such a decision. Where such a decision is adopted, the Commission should also inform the WHO thereof.

The occurrence of an event that is linked to serious cross-border threats to health and is likely to have Europe-wide consequences could **require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner** to identify those persons already contaminated and those persons exposed to risk.

Independent experts: the new decision introduces a clause on independence and transparency which applies to experts involved in the system. The EWRS experts must also declare the presence or absence of any interests, direct or indirect, which could be considered prejudicial to their independence.

ENTRY INTO FORCE: 06/11/2013.