

Serious cross-border threats to health

2011/0421(COD) - 03/07/2013 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 678 votes to 21, with 4 abstentions, a legislative resolution on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health.

Parliament adopted its position at first reading, under the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between the European Parliament and the Council. They amend the Commission proposal as follows:

Subject matter: the decision should **define the roles, duties and responsibilities of the key actors and structures** at Union level, as well as the methods of cooperation and coordination envisaged between the various institutions. It shall apply to **public health measures** in case of serious cross-border threats to health falling within the categories outlined in the decision. It lays down rules on monitoring, **epidemiological surveillance**, early warning of and combating serious cross-border threats to health. It aims to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union.

In **exceptional emergency situations** a Member State or the Commission may refer cross-border health threats other than those covered in the Directive for coordination of response to the Health Security Committee in accordance with Article 11, if it is considered that public health measures taken prove insufficient to ensure a high level of protection of the human health.

Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Decision.

Preparedness and response planning: Member States shall, in liaison with the Commission and on the basis of its recommendations, within the Health Security Committee, address the following issues: (i) **sharing best practice and experience** in preparedness and response planning; (ii) promoting the interoperability of national preparedness planning; (iii) addressing the **intersectoral dimension** of preparedness and response planning at Union level.

Exchange of information: Member States should regularly provide the Commission with information on the state of play of their preparedness and response planning at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the WHO in the context of the International Health Regulations (2005). The information should particularly address the cross-border dimension of preparedness and response planning. The Commission should compile the information received and should ensure its exchange among Member States through the Health Security Committee.

The obligation to provide the information only applies if such measures or arrangements are in place or are foreseen as part of the national preparedness and response planning.

Risk assessment and common public health measures: public health risk assessment should also be **based on the opinion of the WHO** in the case of an international public health emergency. The common temporary measures adopted should be consistent with the recommendations established by the World Health Organisation in the case of an international public health emergency. When adopting common temporary public health measures, the Commission must specify the reasons for adopting these measures.

Epidemiological surveillance: there are provisions to strengthen cross-border epidemiological surveillance through a mutual information system on epidemics and the development of epidemic phenomena. A list of diseases to be monitored is provided in the annex to the decision.

A procedure is also provided in case of specific disease outbreaks (early warning and ad hoc epidemiological surveillance system). To this end, a specific rapid alert could be triggered in the event of serious cross-border threats to health originating from a **zoonotic infection**.

Situation of public health emergency: in advance of recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share its analysis of the situation of the outbreak and to inform of its intention to issue such a Decision. Where such a Decision is adopted, the Commission should inform the WHO thereof. The occurrence of an event that is linked with serious cross-border threats to health and is likely to have Europe-wide consequences may 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. Such cooperation may require the exchange of personal data through the system, including sensitive information related to health, confirmed or suspected human cases, amongst those Member States directly affected by the contact tracing measures.

Common procedure for purchasing vaccinations: the resolution stresses the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases, e.g. by obtaining **advantageous prices and order flexibility** with regard to a given product.

Authorities and national representatives: as there are some Member States where responsibility for public health is not an exclusively national matter, but is substantially decentralised, **national authorities should, where appropriate, involve the relevant competent authorities** in the implementation of this Decision.

Provisions are regards confidentiality and data protection have been enhanced.

Independence of experts: scientific experts should make declarations of interest and declarations of commitments. Such declarations should include any activity, situation, circumstances or other facts potentially involving direct or indirect interest in order to allow identifying those interests which could be considered prejudicial to their independence.

Reports: the Commission shall submit to the European Parliament and the Council within two years of the entry into force of this Decision, and subsequently every three years a report on the implementation of this Decision. The report shall include, in particular, an assessment of the operation of the Early Warning and Response System and of the epidemiological surveillance network, as well as information on how the mechanisms and structures established under this Decision complement other alert systems at Union level and efficiently protect public health while **avoiding structural duplications**. The Commission may accompany this report with proposals to modify the relevant Union provisions.

Annex: a new Annex has been introduced laying down the criteria for selection of communicable diseases and special health issues to be covered by epidemiological surveillance within the network.