

COUNCIL OF THE EUROPEAN UNION



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Cross-border health threats: Council confirms agreement with EP

The Permanent Representatives Committee¹ today approved a compromise agreed with the European Parliament on a draft decision aimed at strengthening EU capacities and structures for effectively responding to serious cross-border health threats.

The draft decision covers serious cross-border threats to health, such as those of biological origin (e.g. communicable diseases, for instance the H1N1 pandemic in 2009, or biotoxins, for example the outbreak of E. coli 2011), chemical, unknown and environmental origin (such as the volcanic ash cloud in 2010).

The compromise, agreed between the Irish presidency, representatives of the European Parliament and the Commission on 6 May 2013, seeks to strengthen the cooperation and coordination between member states on preventing the spread of severe human diseases across the borders of member states and to combat other serious cross-border health threats.

More concretely, the draft decision includes the following key elements:

 The existing coordination mechanism for communicable diseases is extended to all health threats of biological, chemical, environmental and unknown origin. This means that information also on other serious cross-border health threats than communicable diseases will be exchanged through the early warning and response system operated by the European Centre for Disease Prevention and Control (ECDC). This allows for a coordinated wider approach to health security at EU level.

¹ The Permanent Representatives Committee is composed of the ambassadors of the 27 EU member states. Its role is to prepare decisions of the Council.



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- The existing Health Security Committee, composed of representatives of the member states and of the Commission, is given a legal base and its role is strengthened. Member states and the Commission will in future have to consult each other in order to coordinate their efforts to address serious cross-border health threats. These consultations apply notably to the member states' preparedness and response planning and the coordination of national responses, including risk and crisis communication, in cases of an immediate threat notified by any competent national authority or the Commission. Member states will also have to inform and consult each other and the Commission before they adopt public health measures to combat a serious cross-border health threat unless urgency imposes immediate action. The Health Security Committee is currently an informal body which was set up by EU health ministers in 2001 after the terrorist attack in the United States and the deliberate release of anthrax toxins.
- The draft decision sets up a legal basis for the joint procurement procedure of medical countermeasures, in particular pandemic vaccines, on a voluntary basis. It is expected that the joint procurement will allow member states to obtain better prices and order flexibility. It should also help them to get a more equitable access to vaccines and to meet the vaccination needs of their citizens in view of limited production capacities of vaccines at the global level.
- The draft decision also provides for the possibility that the Commission recognises a situation of public health emergency for the purposes of conditional marketing authorisations for medicinal products and for derogations of the terms of a marketing authorisation for a human influenza vaccine. This would allow **accelerated marketing of medicinal products** or vaccines **in an emergency situation**.

In order to enter into force the draft decision still needs to be formally approved by the European Parliament (probably before the summer break) and the Council (probably after the summer break).