

Serious cross-border threats to health

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The Council took **stock of progress made** on a draft decision aimed at strengthening EU capacities and structures for effectively responding to serious cross-border health threats, and gave the Irish Presidency a basis on which to start negotiations.

Under the Cypriot Presidency, good progress has been achieved and the draft decision has been amended in line with Member States' comments. The changes proposed by the Cypriot Presidency:

- **ensure notably Member States' autonomy** in preparedness and response planning as well as the non mandatory character of preparedness planning at European level;
- **give the Health Security Committee a key role** in consultations among Member States and with the Commission. The Health Security Committee should be a central body for consultations among the Member States and the Commission with a view to coordinating their capacities for monitoring, early warning and response to serious cross-border health threats.

However, the Commission considers that its proposal has been weakened in several respects, which makes it difficult for the Commission to accept the direction in which the consensus among the Member States is moving.

This is in particular the case as regards preparedness planning and the possibility to provide a "safety net" via "temporary public health measures". The Commission has therefore reserved its position on related articles.

A few issues still remain open and further discussions are needed in order to reach agreement in the Council ahead of possible negotiations with the European Parliament with a view to a first reading agreement. **The main changes introduced during the Cypriot Presidency**, also focusing on the open questions, are described below:

Scope: it has been clarified that it does not include threats from ionizing radiation as these are sufficiently covered by the Treaty establishing the European Atomic Energy Community. In the event of exceptional emergencies, the structures to be established by the draft Decision should also be available to the Member States and the Commission for threats that are not covered by the scope of this draft Decision.

Preparedness and response planning: the question of empowering the Commission to adopt implementing acts to determine the procedures necessary for the exchange of information and mutual consultation among Member States in accordance with Article 4 has been extensively debated. The Presidency is now proposing to delete Article 4(5) and to instruct the HSC in Article 17(5) (e) to adopt those procedures. This is supported by a majority of the Member States, while some Member States are opposed to this proposal.

Joint procurement of medical countermeasures: the introduction of a voluntary system for joint procurement of medical countermeasures, especially pandemic vaccines, should contribute to fairer access to them for the Member States participating. Nevertheless, a few Member States cannot agree to this article and are calling for the Commission to propose a separate decision.

Epidemiological surveillance: in line with the judgment of the Court of Justice of the EU, the criteria for the selection of communicable diseases and special health issues to be covered by the Community Network as currently set out in Annex II to Commission Decision 2000/96/EC have been stipulated in the Annex to the draft decision.

***Ad hoc* monitoring:** the Commission's proposal to set up an *ad hoc* monitoring network by means of implementing acts for health threats other than communicable diseases and special health issues permanently monitored by the Union's Early Warning and Response System (e.g. threats of chemical, environmental or unknown origin), has not received support.

Public health risk assessment: according to the current version of the article, the Commission shall, upon request of the Health Security Committee, or on its own initiative, ask the Member States to propose through single contact points independent experts for an *ad hoc* nomination by the Commission to establish risk assessment where expertise beyond the mandate of the EU agencies is needed.

Coordination of response: this article, which was largely agreed on during the Danish Presidency, was subject to an addition stipulating that Member States shall not be obliged to submit information the disclosure of which they consider contrary to essential interests of their security.

Recognition of emergency situations: the text now states that a recognition of emergency, applicable only to the EU, can be made by the Commission if the WHO has not yet reacted, the cross-border health threat is rapidly spreading across the Union and can be prevented by medicinal products.

Conclusion of international agreements: a recital has been added to clarify that conclusion of international cooperation agreements may be in the interest of the Union in order to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health.

Establishment of the Health Security Committee (HSC): the composition of the HSC has been the subject of repeated discussions. It has finally been agreed that the HSC should be composed of one designated representative of each Member State and one alternate, who should meet in plenary meetings. Membership of the HSC will therefore be nominative and will not generally be ensured by authorities of Member States.