



EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinion on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health {COM (2011) 866 final}.

The Commission would like to confirm that the coordination of response at the Union level as provided in the legislative proposal seeks to ensure that the measures taken at national level are proportionate to and commensurate with the risks to public health arising from serious cross-border threats to health, that they are coherent and that they do not interfere with the competence of other Member States and of the Union. In addition, such Union action will respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.

Consequently, the legislative proposal establishes a set of instruments enabling the development of evaluations of risks to public health using independent, evidence-based, scientific opinions and allowing for the coordination of preparedness planning and response in the framework of the Health Security Committee. This includes communication to the public, providing this committee with a central role for risk management of serious cross-border threats to health, while ensuring adequate linkage between these instruments and the structures and mechanisms in place in other sectors, such as civil protection.

As regards the establishment of homogeneous criteria for risk assessment, the Commission would like to stress that, as a principle, the evaluation of risks to public health would be done by the EU Agencies – the European Centre for the Disease Prevention and Control and the European Food Safety Authority – in accordance with their respective mandates and based on their internal evaluation criteria.

In any other cases, and only where a given risk assessment falls outside of the mandates of these EU Agencies, such an evaluation would take place on an ad hoc basis and be performed by available resources at the Union level. In doing so, the ad hoc risk assessment structure would proceed with a scientific opinion according to specific procedures developed for this purpose by the Commission. The following aspects would in particular be addressed: reviewing key research to identify any potential health impacts that the given threat may cause; determining the amount, duration, and pattern of exposure to the threat; assessing the ability of the agent to cause illness or death and

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identifying vulnerable groups; estimating dose-related health effects that may lead to illness or death; developing models for the likely progression of spread and disease outcome; defining options for public health measures and assess the potential impacts of those options on critical sectors of society.

The Commission would like to recall that threats to health arising from ionizing radiation are excluded from the scope of the proposal. The Commission therefore may act only in relation to serious cross-border threats to health of biological, chemical, environmental and unknown origin. This exclusion is due to the fact that the establishment of uniform safety standards to protect the population against the dangers arising from ionizing radiation is foreseen by the provisions of the Treaty establishing the European Atomic Energy Community (EURATOM), namely Articles 2(b) and 30-39, which constitute a "lex specialis" and prevail in case of conflicting rules. In particular, Article 38 of the EURATOM Treaty confers on the Commission the power to issue a directive requiring Member States to take all necessary measures to prevent the infringement of the basic standards on health and safety and to ensure compliance with regulations in relation to the protection of the population against the dangers arising from ionizing radiation.

As regards the coordination of public health instruments with the Union Civil Protection Mechanism, the Commission would like to emphasise that the proposal in Articles 11(5), refers to the provisions of the Council Decision of 8 November 2007, establishing a Community Civil Protection Mechanism, in order to make the Union emergency response more consistent and efficient. Indeed, the Mechanism, in the event of a major emergency, allows the provision of support on specific request from a country in need and facilitates improved coordination of civil protection assistance intervention provided by Member States and the Union. In particular, it provides protection to people in the event of natural and made-made disasters, acts of terrorism and, technological, radiological or environmental accidents, occurring outside and inside the Union. Therefore, the Mechanism, combined with the instruments identified in the proposal, such as detection, monitoring, risk assessment and risk management of public health consequences from a serious cross-border threat to health, would certainly minimise the lead time needed to respond to disasters and alerting citizens.

The preparedness planning, information exchange channels and the mobilisation of resources available at Union level would also strengthen effective response capability. In order to ensure adequate synergies between civil protection and public health domains, administrative arrangements foreseen under Article 2(3) of the legislative proposal would be put in place during the implementation process of the proposal.

I hope that these clarifications address the considerations raised in the Opinion of the Senato della Repubblica and look forward to continuing our political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*