



EUROPEAN COMMISSION

Brussels, 17.7.2012  
C(2012) 4802 final

Dear President,

*The Commission would like to thank the Senat 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}.*

*As regards the the potential interference of the EU with the competence of the Member States, through the adoption of common temporary public health measures by delegated acts, the Commission would like to clarify that the purpose of Article 12 of the proposed Decision, in line with Article 6a TFEU, is to supplement the actions of the Member States where necessary in specific exceptional circumstances. Furthermore, in line with Article 2(5) TFEU, measures adopted on the basis of Article 12 of the proposed Decision would not entail any harmonisation of national laws or regulations and would not supersede Member States competence in this field.*

*The Commission would also like to emphasise that the possibility of common temporary public health measures on the basis of Article 12 is subject to very strict conditions and that such measures would be exceptional in nature. Article 12(1) states in particular that such measures may not concern the control of a given threat within each Member State and may be undertaken only when the coordination of national responses provided for in Article 11 of the legislative proposal proves insufficient to control the spread of the serious cross-border threat to health. Moreover, in accordance with Article 12(2), the possibility to adopt such delegated acts would not be granted in the context of any serious cross-border threat to health, but in the context of the most severe ones only, which is reflected in the notion of "deaths or hospitalisations on a large scale across the Member States". In addition, it is specified that such measures must respect the responsibilities of the Member States for the definition of their policies and the organisation and delivery of health services and medical care (which reflects the specific limitations of Union action in the field of public health laid down in Article 168(7) TEFU), as well as that they must be proportionate to the public health risks and compatible with international obligations of the EU or of the Member States.*

*Article 12(1) would thus apply in exceptional circumstances where, in accordance with the principle of subsidiarity (Article 5(3) TFEU), the objectives of the proposed action could not be sufficiently achieved by the Member States, but could rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.*

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*The Senat also raises a number of points on the application of Articles 290 and 291 TFEU. The Commission takes note in particular of the comments related to the choice between delegated and implementing acts.*

*In drafting legislative proposals, the Commission is guided by the principle that the choice as to whether an act is to be classified as a delegated act or an implementing act must be based on a careful analysis of the nature of the power conferred on the Commission, having regard to the provisions of Articles 290 and 291 TFEU. The Commission considers that the starting point must be the legal criteria established by the Treaty itself. Those criteria are also referred to in the Communication COM(2009) 673.*

*In other words, if in a given case the Commission is required to carry out action to supplement the actions of Member States (1) which is of general application and (2) which would serve to supplement or amend certain non-essential elements of a legislative act, then the two conditions of Article 290(1) TFEU are fulfilled and a delegated act is necessary. In such a case, it is not legally possible to use implementing acts. As explained in the Communication COM(2009) 673, Articles 290 and 291 TFEU are mutually exclusive and if an act falls into the scope of Article 290, it is by definition excluded from the scope of Article 291 TFEU. More concretely on Article 12, the Commission believes that under the current structure of this Article, the adoption of common temporary public health measures can be classified only as delegated acts.*

*As far as the possibility for Member States to take position on the content of a delegated act is concerned, the Commission would like to recall the Common understanding with the European Parliament and the Council concluded in 2011 where conditions for consultations in the preparation and drawing-up of delegated acts are laid down. Such conditions include simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council and appropriate consultations during the preparatory work, including at expert level. This is reflected in recital 20 of the legislative proposal.*

*The legislative proposal explicitly lays down the conditions to which the delegation of power conferred to the Commission is subject. Thus, the European Parliament and the Council may express their opinion by objecting to a delegated act before its entry into force. In such case the act cannot be published and thus cannot enter into force. The Commission may either prepare a new delegated act or decide to discontinue the process. The European Parliament and the Council may also decide to revoke such delegation at any time after the entry into force of the basic legislative act providing for it.*

*I hope that these clarifications address the comments and concerns raised in the Opinion submitted by the Senat.*

*I look forward to continuing our political dialogue in the future.*

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*