



EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Bundesrat 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}.

In the annex of this letter you will find a detailed reply to the issues raised in your Opinion.

I hope that these clarifications address your different comments and concerns. The Commission looks forward to continuing its political dialogue with the Bundesrat in the future.

Yours faithfully,

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ANNEX

The Commission shares the view that systems operating in different sectors concerned by preparedness planning and response to serious cross-border threats to health need to be interconnected. The Commission would, in accordance with Article 2(3) of the proposal, ensure coordination and mutual information between mechanisms and structures established at Union level whose activities are relevant for monitoring, early warning and combating serious cross-border threats to health. In particular, the Commission would, according to Article 9(4) of the proposal, make available through the Early Warning and Response System (EWRS) any information that might be useful for coordinating the response at Union level to national authorities responsible for determining public health measures, including information on hazards and measures relating to threats transmitted through other alert systems.

These technical arrangements and operating protocols are intended to guarantee interconnectivity and interoperability between the various systems in place at Union level and ensure prompt exchange of information with public health authorities at national level in normal operating conditions (e.g. monitoring of events) as well as in crisis situations (exchange of information on public health measures). This course of action would not entail disproportionate intervention in Member States' health systems, as it focuses essentially on strengthening cooperation between existing EU systems and its commitment is solely to the EU Institutions, Agencies and bodies.

As regards the issue of double reporting to rapid alert systems (food safety, animal health, civil protection, etc.), Article 2(2) of the proposal ensures that the special provisions of the proposal will not prevail over general provisions established in other binding Union acts related to measures on monitoring, early warning and combating of serious cross-border threats to health. This rule also applies to legal instruments providing for mechanisms such as surveillance, risk assessment and risk management of risks to public health set up in other sectors.

Moreover, the proposal – which is based on the current systems in place for communicable diseases – does not establish new permanent structures. Instead, it extends the existing structures (EWRS rapid alert system and EWRS network for coordination of measures) in order to cover gaps, from a public health perspective, in the monitoring and assessing risks to public health would complement the health security framework and would be put in place only in cases where similar activities are not undertaken by existing structures in other sectors – the latter would be linked via technical arrangements with health security structures thereby avoiding unnecessary duplication.

A solution of this kind, which reflects the comments expressed on this subject in the Bundesrat's Opinion, would ensure that the systems provided for under the proposal would apply only in cases where no other Union instruments are available to cover the monitoring, early warning and combating of serious cross-border threats to health.

This practice would also ensure that the financial impact on the Union budget would be modest – no new bodies would be created and the current mandates of the Agencies would remain unchanged. The ad hoc monitoring and risk assessment networks would be covered by the Health Programme 2014 - 2020 and the technical arrangements designed to interconnect the various systems in place would be financed by the Commission, assisted where appropriate by the European Centre for Disease Prevention and Control

in accordance with Article 8(2) of Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control.

As regards the application of the International Health Regulations (IHR), these provide for bilateral collaboration between the World Health Organisation and a particular Member State, whereas the European Union encourages cooperation among all Member States on public health issues which necessitate a coordinated action. The Bundesrat opinion favours omitting this area from the scope of the proposal. In practice, leaving this area unregulated at Union level would mean that individual Member States would be implementing the requirements of the IHR at the entry points separately from each other, without coordinating measures for the whole Union in a coherent manner. This might lead to some discrepancies among Member States' responses, which may impact on fundamental principles and goals of the EU, such as free movement of persons or the functioning of the internal market. Moreover, such an approach would be a step backwards as far as current practice is concerned, and against the acquis of the communicable diseases framework which has covered such activities since 1998.

The Bundesrat also raised a number of points regarding the autonomy of Member States with regard to protecting and improving public health. The Commission would like to stress that, based on its supporting, coordinating or complementary competencies in this area, the Union action covers monitoring, early warning of and combating serious cross-border threats to health, including the adoption of measures in those fields. Such action does not supersede Member States' competence in this area and it respects the responsibilities of the Member States in defining their health policy and in the organisation and delivery of health services and medical care. If the objectives cannot be sufficiently achieved by the Member States alone, due to the cross-border character of the threats, and can be better achieved at EU level, the Union may adopt measures concerning monitoring, early warning and combating of serious cross-border threats to health, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union.

As regards the eventual transfer of decision-making, implementing or financial powers to the Commission in respect of joint action, the Commission would like to refer to the provisions of Decision No 2119/98/EC of the European Parliament and of the Council setting up a network for the epidemiological surveillance and control of communicable diseases in the Community. The Commission provides for the coordination of this network in collaboration with the Member States and is empowered to adopt legal measures in this field. These measures concern, inter alia, the list of diseases to be covered by epidemiological surveillance, the epidemiological data to be collected and transmitted by national authorities at Union level, the case definitions (a set of standard diagnostic criteria to identify a human case of a particular disease), guidelines on the protective measures to be taken (in particular at the external borders of the Member States) particularly in emergency situations, guidelines on information and guides to good practice for the public, as well as procedures on information exchange, consultation and coordination of measures. In addition, with regard to the coordination of measures, Article 6 of that Decision states that Member States shall, on the basis of their consultations and the information provided, coordinate among themselves in liaison with the Commission with regard to the measures which they have adopted, or intend to adopt at national level.

A similar approach has been set out in the proposal, whereby the competences of the Commission in the field of communicable diseases would be extended to cover other

types of serious cross-border threats to health in relation to monitoring, early warning and combating such threats. Provision has also been made for a new coordination role with respect to preparedness planning, the latter being an integral part of combating serious cross-border threats to health, whereas new implementing powers would be conferred on the Commission in connection with the recognition of emergency situations in order to trigger the fast track procedure for marketing authorisation of medicinal products and variations thereof, as laid down in Article 2(2) of Commission Regulation No 507/2006 and Article 21 of Commission Regulation No 1234/2008 respectively.

As far as the role of the Health Security Committee (HSC) is concerned, the Committee would focus, as stated in Article 19 of the proposal, on the coordination aspects of preparedness planning and national responses, as well as on matters related to the implementation of the legislative act. The role of the HSC would be limited to advisory functions, whereas the regulatory functions would be carried out by the Committee on serious cross-border threats to health (Examination Committee) as set out in Article 20 of the proposal. This distinction is due to the fact that it is necessary to establish a separate committee to comply with rules on mechanisms for control by the Member States of the Commission's exercise of implementing powers, which are embodied in Regulation (EC) No 182/2011 of the European Parliament and of the Council. In addition, this distinction between HSC and the Examination Committee reflects the current legal framework, where the entity responsible for coordination of measures ('EWRS network') is also separate from the comitology-type committee ("Network Committee"). This clear separation of tasks is also reflected in Decision 2119/98/EC, in the second subparagraph of Article 1 and Article 7 of that Decision respectively.

The Commission takes the view that the HSC, as established under Article 19 of the proposal, will be the appropriate forum for the future coordination of preparedness planning and national responses in relation to the serious cross-border threats to health.

As regards the need for preparedness planning, it should be noted that while in IHR core capacity requirements for surveillance of and response to public health emergencies of international concern form an integral part of the comprehensive agreement, the Union does not have the relevant binding provisions at its disposal to set up coordination based on such standards. Currently, the activity of sharing information and experience on preparedness and response plans, and advising Health Ministers and the European Commission on coordination of emergency planning at EU level, takes place within the informal setting of the Health Security Committee according to its terms of reference adopted in the Council conclusions of 5 February 2007. This activity is complemented by scientific and technical assistance from the ECDC in the development, regular review and updating of preparedness plans pursuant to Article 9(1) of Regulation 851/2004. To this end, the Commission adopted two Communications in 2005 – the first on Pandemic Influenza Preparedness and Response Planning in the European Community and the second on strengthening the coordination of generic preparedness planning for public health emergencies at EU level – in addition to developing a Strategy for Generic Preparedness Planning - Technical guidance in 2009 on generic preparedness planning for public health emergencies, which has been kept regularly updated.

The European Parliament and the Council have stressed the need to strengthen such preparedness co-operation mechanisms. For example, in its Conclusions of 13 September 2010 on Lessons learned from the A/H1N1 pandemic, the Council acknowledges that, while pandemic preparedness and response planning as well as implementation remain primarily a matter of national competence, there is a need to enhance the coordination

of these national measures at EU level. Similarly, in its Resolution of 8 March 2011, the European Parliament calls for a revision of the prevention plans established in the Union and its Member States for future influenza pandemics in order to increase effectiveness and coherence.

The Commission believes that the provisions of Article 4 of the proposal, which strengthen the coordination of preparedness and response planning by providing for a comprehensive legal framework, independently of the type of serious cross-border threats, fully take account of the considerations expressed. A mechanism for the coordination of preparedness planning at Union level would ensure an adequate level of preparedness to respond efficiently and effectively in the event of a future health-related crisis and consistent implementation of the core capacity requirements of IHR (2005) among the Member States.

As regards the potential financial implications of the joint procurement of medical countermeasures by Member States not participating in this mechanism, the Commission would like to draw attention to the condition laid down in Article 5(2)(b) of the proposal stating that the rights and obligations of the Member States not participating in the joint procurement are respected, in particular those relating to the protection and improvement of human health. Moreover, this provision should be read in the context of Article 168(7) of the Treaty on the Functioning of the European Union, which states that the Union action respects the responsibilities of the Member States for the definition of their health policy and delivery of health services and medical care, including the allocation of the resources assigned to health services and medical care. The respect for the competence of the Member States in the area of public health covers, in particular, aspects related to any adverse financial impacts on Member States which do not participate in the joint procurement.

As regards any potential interference between the EU and the competence of the Member States, as a result of adopting common temporary public health measures by means of 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 the competence of the Member States in this field.

The Commission would also like to emphasise that the possibility of common temporary public health measures based on Article 12 of the proposed decision 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 only be undertaken when the coordination of national responses provided for in Article 11 of the proposal proves insufficient to control the spread of the serious cross-border threat to health. Moreover, under the terms of Article 12(2), such delegated acts would only be used in the context of the most severe threats, which is reflected in the notion of "deaths or hospitalisations on a large scale across the Member States". In addition, it is specifically stated that such measures must respect the individual responsibility 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 laid down in Article 168(7) TEFU), as well as the fact that they must be proportionate to the public health risks and compatible with the international obligations of the EU or of the Member States.

Hence, Article 12(1) would 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.

The Bundesrat also raises a number of issues regarding the application of Articles 290 and 291 TFEU. The Commission takes note in particular of the comments concerning the choice between delegated and implementing acts.

When 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 as an implementing act must be based on a careful analysis of the nature of the power to be conferred on the Commission. The Commission considers that the legal criteria established by the Treaty itself must be the starting point. Those criteria are also referred to in Communication COM(2009)673.

In other words, if in a given case the Commission is required to take action to supplement the actions of Member States which is of general application and 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 proposed. In such a case, it is not legally possible to use implementing powers. As explained in Communication COM(2009)673, Articles 290 and 291 TFEU are mutually exclusive and, if an act falls within the scope of Article 290, it is by definition excluded from the scope of Article 291 TFEU. With reference more specifically to Article 12, the Commission believes that, given the way in which this Article is currently structured, the adoption of common temporary public health measures can be done only by means of delegated powers.

As regards the possibility for Member States to take a position on the content of a delegated act, the Commission would like to recall the Common understanding with the European Parliament and the Council concluded in 2011 which lays down the conditions for consultations in the preparation and drawing-up of delegated acts. 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 stipulates the conditions that govern the delegation of power conferred on the Commission. Thus, the European Parliament and the Council may express their opinion by objecting to a delegated act before its entry into force. In such a case, the act cannot be published and thus cannot enter into force. The Commission can 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 which provides for it.