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from : Presidency
to : Permanent Representatives Committee (Part 1)/Council
No. Cion prop.: 18509/11 SAN 273 PHARM 8 PROCIV 169 CODEC 2404
Subject : **Employment, Social Policy, Health and Consumers** Council meeting on
6 and 7 December 2012

Proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health (**First reading**) (*Legislative deliberation*)
- *Progress report*

I. INTRODUCTION

1. On 8 December 2011, the Commission submitted to the Council the above-mentioned proposal based on Article 168, paragraphs (4)(c) and (5) of the Treaty.
2. The Economic and Social Committee gave its opinion on the proposal on 28 March 2012¹ (the rapporteur was Ms Béatrice Ouin, FR).

¹ SOC/443.

3. The European Data Protection Supervisor gave his opinion on the proposal on 30 March 2012².
4. The proposal was examined at eight meetings of the Working Party on Public Health during the Danish Presidency, and the Council (EPSCO) held a policy debate on 22 June 2012. During that debate, the Council:
- agreed to give a **legal basis to the Health Security Committee** (HSC) established in 2001, which is now an informal cooperation and coordination body;
 - supported the **deletion of Article 12** of the proposal, thus removing the possibility for the Commission to adopt common temporary health measures by delegated acts, and expressed the view that such measures should instead be agreed by the HSC; the Commission does not agree with the deletion of this provision as in its view the common temporary public health measures would provide a safety net in case the coordination of national responses proves insufficient to cope with an extreme emergency situation and the protection of the population of the Union as a whole is thereby jeopardised.
 - did not support the provision enabling the Commission to adopt **implementing acts (Article 4(5))** in order to determine the procedures necessary for coordination among Member States with regard to their capacities for the monitoring, early warning and assessment of and response to cross-border health threats (Article 4(1)). In fact, the Member States have been divided in their opinions concerning this point (see also below).

² 8381/12.

5. The European Parliament ENVI Committee adopted its report³ on the above proposal on 10 October 2012 containing 48 draft amendments. The rapporteur is Mr Gilles Pargneaux (S&D - FR).
6. The Working Party on Public Health continued the discussions on the proposal at seven meetings during the Cyprus Presidency, namely on 3 July, 3, 19 and 24 September, 8 and 25 October and 30 November 2012. The last meeting on this file under Cyprus Presidency is planned for 19 December 2012. The most recent text that reflects the current state of discussion in the Working Party on Public Health is in document 17214/12.

II. STATE OF PLAY

Good progress has been achieved during the Cyprus Presidency with respect to the text of the draft Decision. The text as discussed at the Working Party on Public Health now reflects what the Member States have repeatedly stressed throughout the discussions, namely, that they should keep their autonomy with regard to preparedness and response planning, that preparedness planning should not be mandatory at European level and that the Commission's main role should be to support the actions by Member States. 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.

³ Not yet publicly available.

Positions of delegations have been clarified to a large extent and many articles have the support of the Member States. The recitals have been reviewed as well and, with a few exceptions, can be considered to have been provisionally agreed on.

However, few issues still remain open and further discussion 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 Cyprus Presidency, also focusing on the open questions, are described below.

1) Scope (Article 2)

The scope consists of a list of categories of serious cross-border threats to health, which – combined with a specific definition of such threats described in Article 3(g) – provides for more legal certainty and clarity. 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.

2) *Preparedness and response planning (Article 4)*

Progress has been made on this article, which may be considered one of the central articles of the proposal. In a follow-up to the Council's discussions on 22 June 2012, 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. The Commission is also not in favour of this development and reserves its position on this article. The Presidency is of the view that the regular provision of information by the Member States to the Commission in accordance with paragraph 2, as well as the requirement to report any review of preparedness planning as stated in paragraph 4, provides sufficient information flow for the purposes of Member States' consultations on preparedness and response planning. Details, including format and possibly templates, for the provision of such information by Member States may further be discussed and agreed in the HSC in accordance with Article 17(5) (e).

3) *Joint procurement of medical countermeasures (Article 5)*

This article is acceptable to a large majority of Member States as it responds to the invitation made by the Council in its conclusions of 13 September 2010⁴. 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. The Commission disagrees and points out that voluntary system for joint procurement of medical countermeasures is an element of preparedness planning and therefore integral part of this proposal. The Commission also underlines that a legal basis is required to establish a joint procurement mechanism at European level and a separate legal proposal would unnecessarily delay the introduction of joint procurement. The Commission also underlines the voluntary character of the joint procurement and the fact that the current proposal does not create any obligations upon Member States.

4) *Epidemiological surveillance (Article 6)*

In line with the judgment of the European Court of Justice⁵, 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.

⁴ Council conclusions on lessons learned from A/H1N1 pandemic - Health security in the EU (doc. 12665/10).

⁵ See in particular the recent ruling in case C-355/10, European Parliament v. Council of 5 September 2012."

5) *Ad hoc monitoring (Article 7)*

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), it is up to Member States in liaison with the Commission to ensure exchange of information about developments at national level. The Commission's proposal to set up an ad hoc monitoring network by means of implementing acts has not received support. The Commission expressed its reservation on this position by Member States as it considers that setting up, termination and adoption of procedures for the operation of ad hoc monitoring networks by implementing acts would provide for consistency at EU level. Not having these measures in place entails the risk of contradictory messages being circulated during emergency situations.

6) *Public health risk assessment (Article 10)*

According to the present 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. Furthermore, the Commission shall always make the risk assessment promptly available to the national competent authorities through the Early Warning and Response System, and certainly before making it public. The Commission shall also make available to national authorities through the Early Warning and Response System curricula vitae and declarations of nominated experts. The assessments shall take into account, if available, relevant information provided by the scientific committees of the Commission.

The Commission has entered a reservation based on the rationale that the way public health risk assessment is proposed interferes with the Commission's institutional autonomy to appoint experts for risk assessment. The Commission has offered to provide a declaration annexed to the legal text explaining how the Commission intends to set up risk assessment where expertise beyond the mandate of the EU agencies is needed.

6) *Coordination of response (Article 11)*

This article was largely agreed on during the Danish Presidency. An addition was made in paragraph 1 stipulating that Member States shall not be obliged to submit information the disclosure of which they consider contrary to essential interests of their security. This right of the Member States is already enshrined in Article 346(1)(a) of the TFEU. Nevertheless, the Commission maintains its reservation on this addition.

7) *Recognition of emergency situations (Articles 12,13 and 14 under the new numbering following the deletion of original Article 12)*

Recognition of emergency situations by the Commission, applicable within the EU for the purposes of applying conditional marketing authorisations of medicinal products for human use and variations to the terms of marketing authorisations for human influenza vaccines, has been extensively discussed, in particular its relationship to the recognition of emergency situations by the World Health Organisation (WHO). A solution was finally found and the modified wording of Article 12 now makes it clearer that such 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. The Commission reserves its position to the fact that the World Health Organisation has to be consulted, as in its view this is in contradiction with comitology procedures;

8) *Conclusion of international agreements (original Article 16)*

Article 16 of the proposal was deleted during the Danish Presidency as it was considered unnecessary. Title V of Part V of the TFEU provides the legal basis and the procedure for the 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.

9) *Establishment of the Health Security Committee (Article 17, new numbering)*

Article 17(5) stipulates that the HSC shall adopt its rules of procedure by two thirds of its members and outlines what those rules shall cover. The list is not exhaustive and focuses on issues that have been subject to discussion in the Working Party on Public Health. It was generally felt that the HSC, as the main body for consultation between the Member States and the Commission, is best placed to agree on these matters.

The composition of the HSC has been the subject of repeated discussions. Finally it has been agreed that the HSC should be composed of one designated representative of each Member State and one alternate (see Article 15(1)(c)), 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. In addition to that, the HSC shall provide for participation of experts at its plenary meetings and procedures for working groups established for specific issues.

The level of the HSC representatives is an issue that has often been raised in the discussions. Although it is expected that the officials of Member States who are responsible for preparedness planning and response will take part, it is not necessary for the text of the Decision to stipulate a 'high level' of HSC representatives. There is no standard definition and administrative practices as well as levels of responsibilities of national officials differ among the Member States. The Commission nevertheless maintains its reservation on this point.

The Commission keeps its reservation on this point as it takes the view that the representatives of the Health authorities of the Member States in the HSC should be decision makers in their ministries and insists therefore on 'high level' representation. The Commission has also a reserve on the fact that the Health Security Committee should define the procedures for preparedness planning. The Commission points at article 291 of the Treaty on the Functioning of the EU which confers the power of adopting implementing acts on the Commission where uniform conditions for implementing legally binding Union acts are needed.
