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**Report on the Results  
of the Subsidiarity Check on  
the Proposal for a Directive  
of the European Parliament and of the Council  
on Standards of Quality and Safety  
of Human Organs Intended for Transplantation**



Prepared by the COSAC Secretariat and presented to:

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# 1. Introduction

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This report, prepared by the COSAC Secretariat, presents the results of the COSAC-coordinated subsidiarity check on the **Proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation** (COM(2008) 818 final) conducted under the provisions of Protocol 2 on the Application of the Principles of Subsidiarity and Proportionality as attached to the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community<sup>1</sup> (hereinafter referred to as "the Protocol"). This is the third COSAC-coordinated subsidiarity check carried out under the provisions of the Treaty of Lisbon<sup>2</sup>. The report summarises the procedures, findings and experiences of the subsidiarity check carried out by the national parliaments or chambers of the Member States of the European Union. It aims to facilitate an exchange of views and best practices, in particular to improve understanding of the provisions of the Protocol between the parliaments within the COSAC framework.

## **1.1 Background**

Based on proposals submitted by national parliaments, the COSAC Chairpersons in their meeting on 7 July 2008 in Paris agreed to carry out a subsidiarity check on the Proposal for a Directive of the European Parliament and the Council on standards of quality and safety for the donation, procurement, testing, preservation, transport and characterisation of human organs<sup>3</sup>. This decision was confirmed by the XL COSAC Meeting on 3-4 November 2008 in Paris<sup>4</sup>.

## **1.2 Procedure for the subsidiarity check**

The subsidiarity check was carried out by national parliaments according to their own rules and procedures. However, the Protocol stipulates a set framework for the subsidiarity checks by national parliaments which has to be followed for a national parliament's reasoned opinion to qualify for the 'yellow card' and 'orange card' mechanisms outlined in the Protocol.

### **1.2.1 Timing**

Article 6 of the Protocol gives national parliaments eight weeks to examine the subsidiarity implications of a proposal and to submit reasoned opinions outlining a breach of the principle

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<sup>1</sup> Consolidated versions of the Treaty on European Union and the Treaty on the functioning of the European Union (OJ C115, 9.5.2008) <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2008:115:SOM:EN:HTML>

<sup>2</sup> The previous two subsidiarity checks under the Treaty of Lisbon were conducted on the Proposal for a Framework Decision on Combating Terrorism COM(2007) 650 final and on the Proposal for a Council Directive implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation COM(2008) 426 final. The COSAC Secretariat reports may be found at: <http://www.cosac.eu/en/info/earlywarning>.

<sup>3</sup> See Minutes of the Meeting of the Presidential Troika of COSAC of 6 July 2008, agenda point 5// <http://www.cosac.eu/en/meetings/Paris2008/chairpersons/>.

<sup>4</sup> See Minutes of the Meeting of the Presidential Troika of COSAC of 2 November 2008, agenda point 4// <http://www.cosac.eu/en/meetings/Paris2008/doc/>.

of subsidiarity "from the date of transmission of a draft legislative act, in the official languages of the Union".

**On 3 December 2008** the COSAC Secretariat informed national parliaments about the adoption by the Commission of the Proposal. At the same time the COSAC Secretariat distributed an *aide mémoire* for the subsidiarity check, which included background information and a questionnaire.

**On 10 December 2008** the COSAC Secretariat informed national parliaments that the Proposal was available in all the official languages of the European Union and that the subsidiarity checks clock was now ticking. The deadline for the completion of the check was set for **6 February 2009**.

An exchange of views and best practices on the experiences of national parliaments during this subsidiarity check will take place at the XLI COSAC Meeting on 10-12 May 2009 in Prague.

### **1.2.2 Reasoned opinions**

Under Article 6 of the Protocol any national parliament or any chamber of a national parliament may, within a period of eight weeks, send to the Presidents of the European Parliament, the Council and the Commission a reasoned opinion stating why it considers that the draft in question does NOT comply with the principle of subsidiarity. It is for each national parliament or any chamber of a national parliament to consult, where appropriate, regional parliaments with legislative powers.

National parliaments taking part in the current subsidiarity check were asked to transmit their findings to these EU Institutions and to the COSAC Secretariat.

### **1.3 Participation**

This subsidiarity check took place during the Christmas parliamentary recess - in December 2008 and January 2009, which was determined by the date of the adoption of the Proposal by the Commission. By the deadline of 6 February 2009, **27** parliaments or parliamentary chambers from **20** Member States<sup>5</sup> had concluded the check and sent their reports to the COSAC Secretariat answering the questionnaire (henceforth "the participating parliaments"). An additional **4** parliaments or parliamentary chambers from **4** Member States started the subsidiarity check, but due to the parliamentary recess had difficulties in completing it within the set deadline<sup>6</sup>. However, in the case of the German *Bundesrat*, which completed the check on 13 February 2009, the check could have been completed within the eight-week deadline, if the early warning system had already been in place. The COSAC Secretariat was informed that in such a case the *Bundesrat* "would have convened the Chamber of European Affairs".

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<sup>5</sup> The Austrian *Bundesrat*, the Belgian *Chambre des Représentants*, the Belgian *Sénat*, the Bulgarian *Narodno Sabranie*, the *Vouli Ton Antiprosopon* of Cyprus, the Czech *Poslanecká Sněmovna*, the Czech *Senát*, the Danish *Folketing*, the Finnish *Eduskunta*, the French *Assemblée nationale*, the French *Sénat*, the German *Bundestag*, the Hellenic *Vouli Ton Ellinon*, the Irish *Houses of the Oireachtas*, the Italian *Camera dei Deputati*, the Italian *Senato della Repubblica*, the Latvian *Saeima*, the Lithuanian *Seimas*, the Luxembourg *Chambre des Députés*, the Polish *Sejm*, the Polish *Senat*, the Portuguese *Assembleia da República*, the Slovenian *Državni zbor*, the Slovenian *Državni svet*, the Swedish *Riksdag*, the UK *House of Commons* and the UK *House of Lords*.

<sup>6</sup> The Dutch *States-General*, the Estonian *Riigikogu*, the German *Bundesrat*, and the Hungarian *Országgyűlés*.

In some of the parliaments the check is still on-going. Some parliaments decided not to participate. By 1 March 2009, the COSAC Secretariat received replies from the total of 31 parliaments or parliamentary chambers from 23 Member States.

**The complete replies of the parliaments and parliamentary chambers including the reasoned opinions are presented in the Annex, which is published as a separate document.**

#### **1.4 Procedures applied by national parliaments**

The Committees on European Affairs were the lead committees in the subsidiarity checks in most of the participating parliaments and chambers, i.e. in 19 out of 27. In 10 out of the 19 cases, the Committees on European Affairs received opinions of specialised (sectoral) committees.

In six cases, the lead committees were specialised committees, i.e. in the Belgian *Chambre des Représentants* the lead committee was the Committee on Public Health, Environment and Social Renewal, in the Belgian *Sénat* - the Committee on Social Affairs, in the German *Bundestag* - the Committee on Health, in the Italian *Sennato della Repubblica* - the Committee on Health, in the Luxembourg *Chambre des Députés* - the Committee on Health and Social Security, and in the Swedish *Riksdag* - the Committee on Health and Welfare.

Two participating parliamentary committees held joint meetings, i.e. in the Hellenic *Vouli Ton Ellion* a joint meeting of the Special Standing Committee on European Affairs and the Standing Committee on Social Affairs was held, while in the Slovenian *Državni svet* a joint meeting of the Commission for Social Care, Labour, Health and the Disabled and the Commission for International Relations and European Affairs was held.

In eight cases, the Committees on European Affairs carried out the subsidiarity check alone. Such checks were conducted by the Austrian *Bundesrat*, the *Vouli Ton Antiprosopon* of Cyprus, the Finnish *Eduskunta*, the French *Sénat*, the Hungarian *Országgyűlés*, the Irish *Houses of the Oireachtas*, the Polish *Sejm*, and the UK *House of Commons*.

In two cases of the participating chambers - the Czech *Senát* and the German *Bundestag* - the final decision was taken by the plenary sitting. The plenary decisions were also taken by the German *Bundesrat* and both Houses of the Dutch *States-General*. However, in the latter cases, the subsidiarity check was completed after the eight-week deadline.

In the case of bicameral parliaments, the two chambers cooperated formally only where there was a joint Committee on European Affairs. These were the Irish *Houses of the Oireachtas* and the Dutch *States-General*. In the case of the Irish Parliament, its joint Committee on European Scrutiny, including members of both the *Dáil* and the *Seanad*, involved in the subsidiarity check simultaneously both Houses. Similarly, in the Dutch Parliament, the subsidiarity checks were carried out according to a special procedure, which included involvement of the responsible committees of both Houses.

In the vast majority of the bicameral parliaments the decisions on this subsidiarity check were taken autonomously, without coordinating the procedures or decisions between the

chambers. However, in four cases the chambers did exchange information. The EU Committee of the Austrian *Bundesrat* informed the EU Committee of the *Nationalrat* about the scheduled subsidiarity check and transmitted to it its Statement addressed to the European Commission. The Belgian *Sénat* and the *Chambre des Représentants* informed each other about the results and their decisions, but the checks were performed autonomously. In the German Parliament, the offices of the respective lead committees informed each other about the progress of deliberations. In case of the Slovenian Parliament, a Member of the *Državni svet* presented a joint opinion of the responsible Commissions at the meetings of the responsible committees of the *Državni zbor*.

In the vast majority of cases governments provided the participating parliaments or chambers with written information in the form of an explanatory memorandum or a government position, as well as oral evidence during committee meetings.

Regional parliaments were consulted by the Austrian *Bundesrat* and the UK Parliament. The UK *House of Lords* received information from the National Assembly of Wales and the Scottish Parliament, while the Northern Ireland Assembly decided not to participate in the subsidiarity check.

A number of parliaments or chambers involved non-governmental organisations, interest groups, external experts and other stakeholders in the subsidiarity check. The Austrian *Bundestag* consulted the Association of Cities and Towns as well as the Association of Municipalities and received written statements from the Federal Chamber of Labour, the Federal Economic Chamber and the Federal Institute of Health. The *Vouli Ton Antiprosopon* of Cyprus consulted the National Bioethics Commission and the Paraskevaïdion Transplant Centre, representatives of which took part in the meeting of the Parliamentary Committee on European Affairs and expressed their views and opinions. The *rapporteurs* of the French *Assemblée nationale* consulted the Biomedicine Agency, the national body in charge of organ donation. The Hellenic Transplantation Organisation responded to the *Vouli Ton Ellinon*'s call for specialised advice. The *rapporteur* of the Dutch *Tweede Kamer* consulted non-governmental organisations and some stakeholders. The Polish *Senat* was provided with an external expertise prepared by an independent expert on internal medicine and clinical transplantology. In the case of the UK *House of Lords*, a range of experts and stakeholders in the field had given evidence and advised the European Union Committee during its previously undertaken inquiry into the Commission's Communication "Organ donation and transplantation: policy actions at EU level" (COM (2007) 275, 30 May 2007<sup>7</sup>). That is why no further external expertise was used in relation to the current subsidiarity check.

As to the procedural changes with regard to subsidiarity check mechanism since the latest COSAC-coordinated subsidiarity check in September 2008, several parliaments and chambers informed the COSAC Secretariat about the changes they are currently considering. The *Vouli Ton Antiprosopon* of Cyprus is considering a new procedure under which the Parliamentary Committee on European Affairs will, firstly, notify the competent specialised committees and request their views on the matter under examination; and, secondly, continue inviting interested parties, other than representatives from the competent ministries, to express their views on the matter at hand. Where deemed necessary to adopt a reasoned opinion concerning a breach of the principle of subsidiarity, the President and the plenary

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<sup>7</sup> See the UK House of Lords EU Committee Report of 2 July 2008.

could also be notified. The findings of the Committee may also be transmitted to the Government.

The Czech Parliament is also debating an introduction of procedural changes in connection with the ratification of the Treaty of Lisbon. The two Chambers have prepared changes to their respective Rules of Procedure, which are aimed at strengthening the link between parliamentary scrutiny and Government responsibility for EU affairs, especially in such sensitive issues as the transfer of competences (*passerelle*, flexibility clause). The draft law, which in a single document brings about the changes to the Rules of Procedure of the two Chambers, was approved by the *Poslanecká Sněmovna* on 19 March 2009. The *Senát* subsequently started its deliberation and is currently (as of 1 April 2009) discussing the draft law in its relevant committees.

Following the adoption of Constitutional Law 2008-724 on Modernisation of the Institutions of the 5<sup>th</sup> French Republic on 23 July 2008, which deals, *inter alia*, with parliamentary scrutiny procedures regarding European affairs, a revision of the Rules of Procedure of both Chambers of the French Parliament is under way. It is expected to be adopted in a few months.

The German *Bundesrat* is currently examining the question of whether its procedure needs to be adopted in the light of the early warning system envisaged in the Treaty of Lisbon.

In case of the Irish *Houses of the Oireachtas*, under the subsidiarity check mechanism as foreseen in the Treaty of Lisbon, each House will have an independent vote. Each House has yet to decide how, if the Treaty of Lisbon comes into force, it wishes to carry out the subsidiarity monitoring function.

The Polish *Senat* is contemplating introducing a new document selection system before the entry into force of the Treaty of Lisbon. The new system aims to identify the legislative proposals which may raise doubts as to their compliance with the principle of subsidiarity. It will therefore be necessary for an experienced team of parliamentary staff to specify precise selection criteria.

The UK *House of Lords* is also planning to adapt its procedures with regard to subsidiarity check mechanism of the Treaty of Lisbon. The current COSAC-coordinated subsidiarity check has been used as a “pilot” project.

## **2. Results of the Check**

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### **2.1 The principle of subsidiarity**

The overwhelming majority of parliaments and chambers participating in this subsidiarity check (23 out of 27) found that the Proposal was not in breach of the principle of subsidiarity. One chamber found a breach and three other chambers either requested additional information to be able to formulate their final decision or drew attention to the shortcomings in terms of determination and motivation of the principle of subsidiarity.

The Austrian *Bundesrat* was the only participating parliament that found a breach of the principle of subsidiarity. In its Statement of 3 February 2009, the EU Committee of the *Bundesrat* stated that “Article 25 authorises the Commission to determine various procedures. This is unnecessary and counter to the subsidiarity principle. These procedures can be better determined and agreed in the normal way by the collaborating national organisations themselves in accordance with the state of the art”.

The German *Bundestag* in its final plenary vote concerning the principle of subsidiarity requested clarification on certain aspects, especially regulations on national health care administration. A letter from the President of the *Bundestag* was sent to the EU Institutions informing them that the *Bundestag* had no concerns with regard to the legal basis of the Proposal, but that concerning the principle of subsidiarity clarifications on certain aspects were necessary and that there were concerns with regard to the principle of proportionality.

The UK *House of Commons* did not reach a final decision on the compliance of the Proposal with the principle of subsidiarity either. The European Scrutiny Committee of the *House of Commons* requested further information from the Government. The Committee concluded, however, that “at present there are not sufficient grounds to recommend the House of Commons to approve the sending of a written opinion to the Commission, the European parliament and the Council arguing that the draft directive does not comply with the principle of subsidiarity”. The Committee also asked the Government to comment on whether the Proposal complied with the requirement of Article 152 (5) of the EC Treaty, which provides that measures referred to in Article 152 (4) (a) should not affect national provisions on the donation or medical use of organs.

The Italian *Senato della Repubblica* in its Opinion No. 26 acknowledged that as per Article 152 of the EC Treaty, the Proposal “aims to ensure, through the adoption of binding measures, high quality and safety standards for the use of organs intended for transplantation, in line with the provisions of directives 2002/98/EC and 2004/33/EC on blood and blood products, and human tissue and cells, and through a harmonisation procedure which is necessary in order to effectively regulate cross-border exchange of organs”. However, the *Senato* was of the opinion that “the draft directive suffers from shortcomings in terms of determination and motivation of subsidiarity and therefore it should be reworded. As is the case with directives 2002/98 and 2004/33, it should include a clause enabling Member States to keep or introduce stricter health, safety and protection measures in compliance with the provisions of Article 152.4(a) of the EC Treaty, and should also take into consideration the provisions of Article 152.5, whereby “measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood”.

The Luxembourg *Chambre des Députés* raised an issue of the overlap of this initiative of the EC and the cooperation mechanisms developed by the Council of Europe. According to the Committee on Health and Social Security a process of harmonisation of the safety criteria applicable to the transplantation of organs is being developed within the Council of Europe. In this respect it is feared that the EU initiative might be an obstacle to a harmonised pan-European regulation. The Committee expressed the wish that this issue be raised during the negotiations and that, if possible, the risks of overlapping be eliminated in order to coordinate both approaches.



As a result, the opinion of the Austrian *Bundesrat* (which carries one vote) would be insufficient to trigger any of the mechanisms laid out in the Protocol. According to the Protocol the minimum votes needed to trigger the “yellow card” mechanism is 1/3 of all the votes allocated to national parliaments, i.e. 18 votes out of 54.

In addition, it is important to note the concerns of the German *Bundesrat* and the Dutch *States-General*, which submitted their replies past the deadline.

The German *Bundesrat* drew attention to the fact that it was important when scrutinising respect for the principle of subsidiarity to examine whether the European Community was actually competent to adopt the measure in question. The *Bundesrat* emphasised that with reference to human organs pursuant to Article 152 (4) of the EC Treaty, the European Community was only empowered to adopt minimum standards. Organ donation and medical utilisation of human organs is entirely outside the ambit of Community competences, as stipulated in Article 152 (5) of the EC Treaty. According to the *Bundesrat*, “on several points the draft directive steps outside this clear framework delineating competences and thus encroaches in an inadmissible manner on the intrinsic competence of the Member States”. Furthermore, the *Bundesrat* believed that it would be premature to introduce provisions governing systems for organ exchange between Member States. At present, this type of provision would lead to more bureaucracy, making procedures more costly and exacerbating shortages in organ donation, meaning this would ultimately have a negative impact on the supply of organs available to patients in need of an organ transplant.

The Dutch *States-General* was not convinced that the proposed measures fulfil the requirements of subsidiarity and proportionality either. The *States-General* therefore deferred a final assessment of this subject until it received an adequate response from the European Commission to the comments and questions set out its letter to the Vice-President of the European Commission Ms Margot Wallström of 12 February 2009 and had the opportunity to consult stakeholders about the proposed measures.

## **2.2 Reasoned opinions**

With regard to the Proposal in question, the total of 12 parliaments or chambers<sup>8</sup> adopted formal decisions, which they classified as “reasoned opinions” in their replies to the questionnaire of the COSAC Secretariat. The vast majority of them, i.e. 10, took the form of an Opinion, a Resolution, a Statement or a Report. Only one participating parliament – the Irish *Houses of the Oireachtas* – issued its final decision entitled “Reasoned Opinion”.

Among the 12 above mentioned participating parliaments or chambers, the Austrian *Bundesrat* was the only one that found a breach of the principle of subsidiarity, which was communicated by the President of the *Bundesrat* to the European Commission in the form of a Statement to the European Commission. Apart from the comments on the content of the Proposal, the Statement indicated, that “Article 25 authorises the Commission to determine

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<sup>8</sup> The Austrian *Bundesrat*, the Belgian *Chambre des Représentants*, the Czech *Poslanecká Sněmovna*, the Czech *Senát*, the Danish *Folketing*, the Hellenic *Vouli Ton Ellinon*, the Irish *Houses of the Oireachtas*, the Italian *Senato della Repubblica*, the Luxembourg *Chambre des Députés*, the Polish *Sejm*, the Portuguese *Assembleia da República* and the Slovenian *Državni zbor*.

various procedures<sup>9</sup>. This is unnecessary and counter to the subsidiarity principle. These procedures can be better determined and agreed in the normal way by the collaborating national organisations themselves in accordance with the state of the art”.

The Italian *Senato della Repubblica* did not find a formal breach, but expressed doubts about the conformity of the Proposal with the principle of subsidiarity in the form of an Opinion of its Committee on European Union Policies. In addition to commenting on the substance of the Proposal and its compliance with the principle of proportionality, the Committee on European Union Policies believed that “the draft directive suffers from shortcomings in terms of determination and motivation of subsidiarity and therefore it should be reworded. As is the case with directives 2002/98 and 2004/33 (on blood and blood products, and human tissue and cells) it should include a clause enabling Member States to keep or introduce stricter health safety and protection measures in compliance with the provisions of Article 152 (4) (a) of the EC Treaty, and should also take into consideration the provisions of Article 152 (5), whereby “measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood”.

The remaining 10 parliaments and chambers, which issued “reasoned opinions” expressed overall support to the Proposal and found no breach of the principle of subsidiarity.

One parliament and one chamber, which completed the subsidiarity check after the set deadline of 6 February 2009, also issued “reasoned opinions”. The plenary of the German *Bundesrat* issued an Opinion (“Beschluss”), in which it found that “on several points the Proposal steps outside the clear delineating competences and thus encroaches in an inadmissible manner on the intrinsic competences of the Member States”. Furthermore, the Hungarian *Országgyűlés* issued a Reasoned Opinion of its Committee on European Affairs, in which it stated that no breach was found, but “the Commission’s justifications with regard to the principles of subsidiarity and proportionality were formal and only reflected the relevant wording of the EC Treaty without any further explanation”.

### **2.3 Justification with regard to the principle of subsidiarity**

There were a number of participating parliaments and chambers that found the justification of the Commission with regard to compliance of the Proposal with the principle of subsidiarity not entirely satisfactory.

The Committee on European Affairs of the French *Sénat* considered that the intervention of the European Community in the matters of human organ donation and transplantation was generally justified. However, the Committee regretted that “the European Commission used, in order to legitimate its Proposal with regard to the principle of subsidiarity, one of its standard formulations which has no substance” and therefore found that the Commission did not make a serious analysis and did not provide a real justification with regard to the principle of subsidiarity.

In the opinion of the Joint Committee on European Scrutiny of the Irish *Houses of the Oireachtas* the Commission “did not complete all the elements of the detailed statement as required under the Protocol”. In particular information was “lacking as regards the

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<sup>9</sup> Article 25 of the Proposal deals with implementing measures.

quantitative indicators to substantiate the Proposal and a complete answer on whether the Proposal takes account of the burden falling upon national authorities, economic operators and the citizen”. “In order to be in compliance with its obligations under the Protocol, the Commission should complete a detailed comparative analysis of how the objectives of the Proposal could be effected at national level, outlining its possible advantages as well as shortcomings. There should be a comparison with other possible choices of actions other than at EU Level. The Commission should explain in greater detail why regional and national parliaments are not in the position to take similar effective action in a specific policy area”. The *Oireachtas* Joint Committee on European Affairs therefore recommended “that in the future the European Commission should improve its justification of a legislative proposal to include detailed reasoning in line with its obligations under the Protocol. It should take account of all factors and undertake a detailed comparative analysis”.

The Italian *Camera dei Deputati* and the *Senatto della Repubblica* did not find the Commission’s justification satisfactory either. In the opinion of the Committee on EU Policies of the *Camera dei Deputati*, “the motives given in the Preamble of the Proposal and in the explanatory report in respect of subsidiarity and proportionality are not clear, but simply reiterate conventional protocols”. The European Commission needs “to include in the Preamble and in the accompanying report a more specific and detailed motivation of the legislative measure proposed therein”.

Both Chambers of the UK Parliament also noted drawbacks in the Commission’s justifications of the Proposal. The *House of Commons* was not able to reach a final decision on the question of the compliance of the Proposal with the principle of subsidiarity and requested further information from the Government, in particular “whether the proposed legislation complies with the requirement of Article 152 (5) of the EC treaty, which provides that measures referred to in Article 152 (4) (a) should not affect national provisions on the donation or medical use of organs”. The *House of Lords*, for their part, noted that the Commission’s justification lacks clarity and that they “would disagree with the Commission’s assertion that the Community has an obligation to act”.

The German *Bundestag* in its final vote also requested clarifications on certain aspects of the Proposal’s compliance with the principle of subsidiarity, especially regulations on national health care administration.

The Slovenian *Državni svet* did not find the Commission’s justification satisfactory either.

In addition, although the Polish *Sejm* found the Commission’s justification satisfactory, its Bureau of Research of the Chancellery expressed concerns about the lack of the substantive justification of the conformity of the Proposal with the principle of subsidiarity.

Two parliaments, which submitted their replies after the set deadline, also had concerns with regard to Commission’s justification. The Hungarian *Országgyűlés* in the Reasoned Opinion of its Committee on European Affairs stated that the “Commission’s justifications with regard to the subsidiarity and proportionality principles are formal and only reflect the relevant wording of the EC Treaty without any further explanation”. The Committee noted that the “Explanatory Memorandum does not refer to the subsidiarity principle and the recital 23 of the Preamble does not go beyond the wording of the EC Treaty. Point 2 of the attached Impact Assessment on subsidiarity contains a brief declaration regarding the basis for

Community competence in the field covered by the Proposal, without any further detailed reasoning”. Also, the Dutch *States-General* found the Commission’s justification unsatisfactory for the time being and “were not convinced that the proposal fulfilled the requirements of subsidiarity and proportionality in the EC Treaty”. Therefore, they “deferred the final assessment of this subject until they received an adequate response from the European Commission to the comments and questions set out in the enclosure” of the letter to the European Commission “and until they had an opportunity to consult stakeholders about the proposed measures”.

Several parliaments did not express their opinion on the issue of the Commission’s justification during this subsidiarity check. These were the Austrian *Bundesrat*, the Belgian *Sénat*, the Czech *Poslanecká Sněmovna*, the French *Assemblée nationale* and the Portuguese *Assembleia de República*.

The remaining participating parliaments and chambers found the Commission’s justification satisfactory.<sup>10</sup>

## **2.4 The principle of proportionality**

Although the COSAC-coordinated subsidiarity checks conducted under the provisions of Protocol 2 of the Treaty of Lisbon concern exclusively the principle of subsidiarity<sup>11</sup>, an increasing number of participating parliaments and chambers chose to evaluate the Proposal in question from the point of view of its compliance with the principle of proportionality as well as to take a critical look at its legal basis and some substantive provisions.

In the previous COSAC-coordinated subsidiarity check three of the participating parliaments or chambers chose to indicate their views on the principle of proportionality<sup>12</sup>. This time the number rose to ten participating parliaments or chambers<sup>13</sup> and three parliaments<sup>14</sup> that completed the subsidiarity check after the deadline.

Several parliaments also looked at the legal basis<sup>15</sup> and at the substance<sup>16</sup> of the Proposal. These parliaments or chambers as well as those that did not manage to complete the check within the eight weeks will be able to make their views known to the Commission under the direct political dialogue procedure known as “the Barroso Initiative”, endorsed by the

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<sup>10</sup> The Belgian *Chambre des Représentants*, the Bulgarian *Narodno Sabranie*, *Vouli Ton Antiprosopon* of Cyprus, the Czech *Senát*, the Danish *Folketing*, the Finnish *Eduskunta*, the Hellenic *Vouli Ton Ellion*, the Latvian *Saeima*, the Lithuanian *Seimas*, the Polish *Sejm*, the Polish *Senat*, the Slovenian *Državni zbor* and the Swedish *Riksdag*.

<sup>11</sup> Please see Part 2.4 of the Report on the Results of the Subsidiarity Check on the Proposal for a Council Directive on Implementing the Principle of Equal Treatment between Persons Irrespective of Religion or Belief, Disability, Age or Sexual Orientation at: <http://www.cosac.eu/en/info/earlywarning/anti-discrimination.pdf/>

<sup>12</sup> The Hellenic *Vouli Ton Ellinon*, the Luxembourg *Chambre des Députés*, and the UK House of Commons.

<sup>13</sup> The Czech *Poslanecká Sněmovna*, the Czech *Senát*, the French *Assemblée nationale*, the German *Bundestag*, the Hellenic *Vouli Ton Ellinon*, the Italian *Camera dei Deputati*, the Italian *Senato della Repubblica*, the Latvian *Saeima*, the Luxembourg *Chambre des Députés* and the Portuguese *Assembleia da República*.

<sup>14</sup> The Dutch *States-General*, the Estonian *Riigikogu*, and the Hungarian *Országgyűlés*.

<sup>15</sup> For instance, the Czech *Poslanecká Sněmovna*, the German *Bundestag*, the Irish *Houses of the Oireachtas*, and the Italian *Camera dei Deputati*.

<sup>16</sup> For instance, the Austrian *Bundesrat*, the Belgian *Sénat*, the Italian *Senato della Repubblica*, the Portuguese *Assembleia da República*.

European Council in June 2006<sup>17</sup>. In fact, the Belgian *Sénat* stated that its Committee on Social Affairs, which carried out the subsidiarity check “prepared an opinion on the substance of the document within “the Barroso Initiative” ”.

## **2.5 Difficulties encountered during the check**

### **2.5.1 The eight-week period**

The main difficulty encountered during this subsidiarity check, which could be envisaged from the launch of the check on 10 December 2008, was the tight time frame imposed upon the parliaments and chambers by the impending Christmas recess. A number of parliaments and chambers in their replies to the COSAC Secretariat cited this reason as a substantial difficulty that they faced during this subsidiarity check<sup>18</sup>. Some parliaments failed to receive opinions from their specialised committees, to consult widely other national parliaments or regional parliaments, interested parties or altogether failed to complete the check on time.

The Joint Committee on European scrutiny of the Irish *Houses of the Oireachtas* underlined that co-operation between national parliaments with regard to subsidiarity checks is crucial in order to ensure the effective implementation of the “yellow card” and the “orange card” procedures contained in the Treaty of Lisbon. In the Committee's opinion “COSAC is the most appropriate vehicle for this important co-ordination and cooperation”. Therefore the Committee doubted whether the eight-week period provided for in the Protocol for submission of reasoned opinions by national parliaments was sufficient to allow full and effective consultation among the parliaments.

In addition, the Irish *Houses of the Oireachtas* reiterated its previous suggestion for the COSAC to look at the practical and logistical consequences for the checking procedure when a proposal is published running up to or during a period when most national parliaments are in recess.

As pointed out before, the Dutch *States-General* did not complete the scrutiny of the Proposal with regard to its compliance with the principles of subsidiarity within the eight-week period. Following the plenary decisions of both Chambers of the *States-General* a request was sent to the European Commission for additional information on the Proposal. This decision took the form of a letter signed by both Speakers of the Chambers of the *States-General* and addressed to the Vice-President of the European Commission Ms Margot Wallström. The letter contained an enclosure with a set of comments and questions of both Houses to be answered by the European Commission before the final decision of the *States-General* on the Proposal could be made.

Because of the Christmas recess, the Estonian *Riigikogu* was not able to complete the check on time either and, therefore, requested that COSAC avoid scheduling its subsidiarity checks during the period of holidays.

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<sup>17</sup> Commission Communication from 10 May 2006: “A Citizen's agenda - delivering results for Europe” ((COM(2006) 211 final)

<sup>18</sup> The Czech *Senát*, the Estonian *Riigikogu*, the French *Assemblée nationale*, the Hungarian *Országgyűlés*, the Irish *Houses of the Oireachtas*, the Dutch *States-General*, the Portuguese *Assembleia da República*, the Swedish *Riksdag*, and the UK *House of Lords*.

### **2.5.2 Problem of the interpretation of the concept of the ‘principle of subsidiarity’**

The Irish *Houses of the Oireachtas*, in its replies to the COSAC questionnaire, highlighted the need for national parliaments to develop an agreed definition and interpretation of the principle of subsidiarity. According to the Irish Parliament, “if the Lisbon Treaty is ultimately ratified, national parliaments will need to work closely together and within agreed parameters and on the same premise. Otherwise, different interpretations of the principle of subsidiarity may lead to great disparities of opinion between each of the national parliaments with the result that the threshold will never be reached for the “yellow card” or “orange card” mechanisms to be triggered. Therefore, the Joint Committee on European Scrutiny of the Irish Parliament once again pointed out the need to have a focused, result orientated discussion at COSAC on the meaning of subsidiarity so that national parliaments can come to a common understanding.

### **2.5.3 Other difficulties**

Other difficulties identified by the participating parliaments and chambers included complexity of the content of the Proposal, internal procedures and quality of the translation of the Proposal.

For instance, the German *Bundestag* pointed out that the original (English) version of the Proposal and its translation into German were not completely coherent, especially Article 19 created problems for the subsidiarity check and the final decision on the principle of subsidiarity. Also, the content of the Proposal was very complex and it was to some extent difficult to differentiate between questions of subsidiarity and content.

The Belgian *Chambre des Représentants* noted that the internal procedure of the House needed be more standardised, since every committee was still autonomous in the way they formulated their opinions.

While the Italian *Senato della Repubblica* noted that an opinion issued by the Senate committee might not always be considered a “reasoned opinion” under the Protocol, since all the opinions included compliance assessment with the principles of subsidiarity and proportionality, and also an assessment of the substance of the Proposal. Therefore, it was “very difficult to issue a neat opinion on just one of these aspects without considering the other”.

### **2.5.4 Making use of IPEX**

In order to enhance the exchange of information during the subsidiarity check, national parliaments were encouraged to share information on the IPEX website.

In their replies to the questionnaire, 12 parliaments or chambers indicated that they actively used the IPEX website to inform other parliaments about the start of the scrutiny procedure,

to publish their findings or to follow the activities of other parliaments<sup>19</sup>. By the deadline, 20 parliaments or chambers had posted information on the IPEX website: 9 indicated that they had started the scrutiny procedure and 11 indicated that they had completed it. The Austrian *Bundesrat*, German *Bundestag*, the Hellenic *Vouli Ton Ellinon*, the French *Assemblée nationale*, the Italian *Senato della Repubblica* and the Latvian *Saeima* indicated that they had important information to exchange. It is a substantial increase in the activity of parliaments and chambers compared to the previous COSAC-coordinated subsidiarity check, when only 13 parliaments or chambers posted information on the IPEX website.

### 3. Summary and Conclusions

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The third subsidiarity check within the COSAC framework conducted under the terms of Protocol No. 2 to the Treaty of Lisbon concerned the **Proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818 final)**, adopted by the European Commission on 3 December 2008.

National parliaments and chambers were called upon to scrutinise the Proposal with regard to the principle of subsidiarity from 10 December 2008 until 6 February 2009 and to send their remarks to the European Commission, the European Parliament, and the Council within the above timeframe of eight weeks.

Considering that the Proposal was published on the eve of the Christmas recess, the participation in this subsidiarity check was high. By the agreed deadline **27** parliaments or parliamentary chambers from **20** Member States had concluded the check and an additional **4** parliaments or parliamentary chambers from **4** Member States had started the check, but due to time constraints had had difficulties in completing it on time. However, in one case the subsidiarity check might have been completed on time provided the early warning system had already been in place. As a result, the COSAC Secretariat received replies from the total of **31** parliaments and parliamentary chambers from **23** Member States.

The outcome of this subsidiarity check clearly indicates that the scrutiny of proposals during a parliamentary recess poses a considerable problem to a number of parliaments and chambers, especially limiting a more in-depth debate, effective involvement of specialised committees, consultations with regional parliaments, non-governmental organisations and other stakeholders. COSAC was asked to consider how such difficulties could be overcome. Doubts were expressed on whether the eight-week period provided for in the Protocol was sufficient to allow full and effective consultation among national parliaments.

The overwhelming majority of the participating parliaments and chambers i.e. 25 out of 27, found no violation of the principle of subsidiarity. Within the eight week timeframe, the Austrian *Bundesrat* was the only Chamber to find a breach of the principle of subsidiarity. Three parliaments or chambers requested additional information from either the European

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<sup>19</sup> The Austrian *Bundesrat*, the Belgian *Sénat*, the Czech *Senát*, the French *Assemblée nationale*, the French *Sénat*, the German *Bundestag*, the German *Bundesrat*, the Hellenic *Vouli Ton Ellinon*, the Italian *Camera dei Deputati*, the Latvian *Saeima*, the Portuguese *Assembleia da República*, and the Swedish *Riksdag*.

Commission or their Government in order to have a final decision on the compliance of the Proposal with the principle of subsidiarity.

The results of the check indicate that national parliaments understand the limited scope of the Protocol which provides for the scrutiny of the proposals only in respect of their compliance with the principle of subsidiarity. Nonetheless, an increasing number of parliaments and chambers voiced their opinion on the compliance of the Proposal with the principle of proportionality, on its legal basis as well as its substantive provisions. Currently, such opinions of national parliaments are being considered by the Commission within the framework of “the Barroso Initiative”. However, this informal cooperation tool is outside the scope of the Treaty of Lisbon.

One parliament proposed to reach an agreement on a common definition and/or interpretation of the “principle of subsidiarity”. COSAC is asked to have a focused, result orientated discussion on the meaning of subsidiarity so that national parliaments can come to a common understanding.

Only 16 parliaments and chambers out of 31 were fully satisfied with the Commission's justification of the Proposal with regard to its compliance with the principle of subsidiarity. A number of parliaments or chambers, however, expressed concerns about the Commission's justification. They pointed out that the justification lacked detailed comparative analysis, that the Commission used standard formulations which have no substance and that the motives given in the Preamble of the Proposal and in the explanatory memorandum were not clear, but simply reiterated conventional protocols. In the future the European Commission was asked to improve its justification of legislative proposals by including detailed reasoning in line with its obligations under the Protocol, taking account of all factors and undertaking a detailed comparative analysis.

The results of this check show that many parliaments and chambers actively used the IPEX database and considered it a useful tool for facilitating the exchange of information on the subsidiarity check. It is of utmost importance, however, that all national parliaments fulfil their commitment to upload information on IPEX so that this database is a reliable source of information. Also, an increasing number of parliaments and chambers sought to find information on the subsidiarity check through their permanent representatives in Brussels.

Overall, the current COSAC-coordinated subsidiarity check should be considered a success as it demonstrated willingness of the vast majority of parliaments and chambers to engage in a joint exercise in their preparation for assuming the role of national parliaments foreseen in the Treaty of Lisbon.



**Table: Participation in the subsidiarity check**

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Was any breach found?	Was a reasoned opinion issued?	Was Commission's justifications satisfactory?	Other observations
<b>Austria:</b> <i>Bundesrat</i>	The check was conducted by the EU Committee. The Ministry of Health provided an explanatory memorandum. Experts of the Ministry participated in the Committee meeting. The provincial bodies, the Federal Chamber of Labour, the Federal Economic Chamber and the Federal Institute of Healthcare provided written statements.	Consultations through IPEX	A summary of the proceedings was published on the website of the Austrian Parliament.	<b>Yes. Article 25 of the Proposal was found to be counter to the principle of subsidiarity</b>	<b>Yes, in the form of a Statement of the EU Committee to the European Commission.</b>	The Statement does not relate to the issue of the Commission's justification. On the administrative level, however, the justification provided in the impact assessment was found to be comprehensive and satisfactory.	-
<b>Belgium:</b> <i>Chambre des Représentants</i>	The check was conducted by the Committee on Public Health, Environment and Social Renewal. Since the opinion of the Committee was unanimous it should be considered as the opinion of the entire <i>Chambre des Représentants</i> .	No	Yes, as a parliamentary document.	No	Yes, in the form of a Report of the Committee on Public Health, Environment and Social Renewal, stating that the Proposal complies with the principle of subsidiarity.	Yes	The internal procedure should still be more standardised. As every committee is still autonomous in the way they formulate opinions.
<b>Belgium:</b> <i>Sénat</i>	The check was conducted by the Committee on Social Affairs, which prepared an opinion on the substance of the Proposal in accordance with the Barroso initiative. The opinion will be published after confirmation by the plenary in March.	Consultations through IPEX	No	No	No	No complaints Were made on the point.	-
<b>Bulgaria:</b> <i>Narodno Sabranie</i>	The check was carried out by the Committee on European Affairs, which received an opinion of the Committee on Healthcare. The Government provided its framework position on the Proposal containing assessment of the implementation of the principle of subsidiarity.	Informal contacts with representatives of other national parliaments were made.	The report of the Committee on European Affairs was published on the website of the <i>Narodno Sabranie</i> and in its news bulletin "Evrovesti".	No	No	Yes, the Commission's justification was found satisfactory.	-

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>Cyprus:</b> <i>Vouli Ton Antiproson</i>	The check was conducted by the Committee on European Affairs, which approved the decision unanimously. The Ministry of Health, the National Bioethics Commission and the Paraskevaïdion Transplant Centre took part in the Committee meeting and expressed their views and opinions.	No	No	No	No	Yes	The time available to national parliaments would not be sufficient if the proper procedure were to be followed, to allow more interested parties and competent specialised committees be express their opinion.
<b>Czech Republic:</b> <i>Poslanecká Sněmovna</i>	The check was conducted by the Committee on European Affairs. Preliminary position of the Government was presented by the Deputy Minister of Health Care. The Proposal was also sent for deliberation to the Committee on Health Care.	Standard type of cooperation with other national parliaments through the representative s of national parliaments in Brussels.	The Resolution of the Committee on European Affairs was published on its website.	No	Yes, in the form of a Resolution of the Committee on European Affairs, concluding that the Proposal complies with the principle of subsidiarity.	The Committee did not find the justification unsatisfactory.	-
<b>Czech Republic:</b> <i>Senát</i>	The check was conducted by the Committee on EU Affairs with Members of the Committee on Health and Social Policy attending the meeting. The final decision in a form of a Resolution was adopted by the plenary after a debate. The Government submitted an explanatory memorandum without any particular reference to the compliance of the Proposal with the principle of subsidiarity.	Cooperation by means of standard procedures through the permanent representative s of national parliaments in Brussels and consultation of IPEX.	The Resolution of the <i>Senát</i> was published on the website of the <i>Senát</i> and on IPEX as well as forwarded to the Government .	No	Yes, in the form of a Resolution of the <i>Senát</i> , concluding that the Proposal is compatible with the principles of subsidiarity and proportionality.	Yes	The Proposal was adopted just before Christmas holidays, which put a strain on planning of the debates. To assure that the deadline is met, the specialised committee was not formally asked for an opinion but was invited to the meeting of the Committee on EU Affairs.

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>Denmark:</b> <i>Folketing</i>	The check was conducted by the Committee on European Affairs following a consultation with the Committee on Health. The Government provided a subsidiarity memorandum assessing the Proposal's compliance with the principle of subsidiarity.	No	The findings were published on the website of the <i>Folketing</i> .	No	Yes, in the form of an Opinion of the European Affairs Committee, which was submitted to the European Commission, stating that the Proposal complies with the principle of subsidiarity.	Yes	-
<b>Estonia:</b> <i>Riigikogu</i>	The check was conducted by the Committee on European Union Affairs, which received an opinion of the Committee on Social Affairs. The Government provided its position with an explanatory memorandum.	No	The minutes of the committee meetings are published on the website of the <i>Riigikogu</i> .	No	No	Yes	<b>The check was completed after the deadline, i.e. on 9 Feb. 2009.</b> The check coincided with the Christmas recess. COSAC is asked to avoid scheduling subsidiarity checks during recess.
<b>Finland:</b> <i>Eduskunta</i>	The check was conducted by the Grand Committee. Because of the Christmas recess, the usual subsidiarity check procedure in the sectoral committees did not take place. The Government provided a draft version of its communication of the EU legislation.	No	No	No	No	Yes	-

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>France:</b> <i>Assemblée nationale</i>	The check was conducted by the Committee in charge of the European Affairs. Two co-rapporteurs of the Committee met members of the Cabinet of the Minister for Health and representatives of the Directorate-General for Health and of the Biomedicine Agency. The Committee decision has been tacitly confirmed by the Committee on Culture, Family and Social Affairs, which decided not to scrutinise the Proposal.	Information was shared by through the permanent representative in Brussels. IPEX website was also consulted.	Minutes of the Committee meetings are public and accessible on the website of the <i>Assemblée nationale</i> .	No	No	The issue was not discussed by the Committee.	
<b>France:</b> <i>Sénat</i>	The check was conducted by the Committee on European Affairs on the basis of a report of its Chairman and a analysis document. The decision of the Committee was unanimous.	The Committee received information on the positions of some other parliaments. The findings were published on IPEX.	The findings were published on the website of the <i>Sénat</i> and in the monthly brochure "News of the European Affairs Committee".	No	No	The Commission used standard formulations, which had no substance. Thus, it did not provide a real justification with regard to the principle of subsidiarity.	-
<b>Germany:</b> <i>Bundestag</i>	The Committee on Health was the lead committee. The Proposal was also examined by the Committee on Legal Affairs and the Committee on the Affairs of the European Union, both participating in an advisory capacity. The final decision was taken by the plenary. The Federal Ministry of Health provided written reports on the Proposal and took part in the deliberation of the three Committees.	The secretariat of the Committee on the Affairs of the European Union contacted on working level the responsible administrative entities of the French <i>Assemblée nationale</i> and the UK <i>House of Commons</i> . A summary of the decision of the Committee on Health and the decision of the <i>Bundestag</i> were published on IPEX.	No	The <i>Bundestag</i> requested from the Commission further clarification on certain aspects of the Proposal regarding its compliance with the principle of subsidiarity.	No	The <i>Bundestag</i> requested further clarification	The original (English) version of the Proposal and its translation into German were not completely coherent, especially Article 19 created problems for the check. Since the content of the Proposal was very complex it was difficult to differentiate between questions of subsidiarity and content.

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>Germany:</b> <i>Bundesrat</i>	The check was carried out by the Committee on European Union (the lead committee) and three sectoral Committees: the Committee on Health, the Committee on Home Affairs and the Committee on Cultural Affairs. The final decision was adopted by the <i>Bundesrat</i> plenary. The federal Government provided a report on the Proposal and participated in the deliberations of the Committees.	Through IPEX	The <i>Bundesrat</i> resolutions are public and are freely available via the Internet.	<b>"On several points the Proposal steps outside the clear delineating competences and thus encroaches in an inadmissible manner on the intrinsic competences of the Member States".</b>	Yes, in the form of an Opinion of the <i>Bundesrat</i> (" <i>Beschluss</i> "), which was transmitted to the European Commission.	The <i>Bundesrat</i> did not object to the Commission's justification with regard to the principle of subsidiarity.	<b>The check was completed after the deadline - on 13 February 2009.</b> However, if the early warning system had already been in place, it would have been possible to comply with the 8-week deadline by convening the Chamber of European Affairs.
<b>Greece:</b> <i>Vouli Ton Ellion</i>	The check was conducted at a joint meeting of the Special Standing Committee on European Affairs and the Standing Committee on Social Affairs. The legal department of the Ministry of Health and Social Solidarity provided a memorandum. Also, the Under-Secretary of the Ministry and the Health Director of the Hellenic Transplantations Organisation participated in the Committees' meeting.	Consulted the IPEX website.	The joint Committee meeting was broadcasted on TV. The opinion of the Committees was published on IPEX and distributed to all the Members of Parliament.	No	Yes, in the form of an Opinion of the Joint Session of the Special Standing Committee on European Affairs and the Standing Committee on Social Affairs, concluding that the Proposal complies with the principle of subsidiarity.	Yes	-

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>Hungary:</b> <i>Országgyűlés</i>	<p>The check was conducted by the Committee on European Affairs.</p> <p>Since the ordinary autumn session of the Parliament usually finishes in the second half of December, the 8-week timeframe made it impossible to involve any other committee.</p>	Information was exchanged through the permanent representatives of national parliaments in Brussels.	Minutes of the meeting and a short memo on the main points of discussion were published on the website of the Committee.	No	Yes, in the form of a Reasoned Opinion of the Committee on European Affairs, finding no breach of the principle of subsidiarity, but criticising the Commission's justifications	The justifications are formal and only reflect the relevant wording of the EC Treaty without any further explanation. A more detailed justification by the Commission is expected.	<p><b>The check was completed after the set deadline – on 24 February 2009.</b></p> <p>The timing problems because the large part of 8 weeks period fell between the ordinary sessions of the Parliament</p>
<b>Ireland:</b> <i>Houses of the Oireachtas</i>	<p>The check was conducted by the Joint Committee on European Scrutiny. As this is the committee with the primary responsibility for subsidiarity checks and the scrutiny of EU legislative proposals, no other committees were involved.</p> <p>Information was provided by the Department of Health and Children.</p>	No, but the Committee is of the opinion that cooperation between national parliaments with regard to subsidiarity checks is crucial in order to ensure the effective implementation of the "yellow card" and "orange card" procedures of the Treaty of Lisbon. COSAC is the most appropriate vehicle for this very important co-ordination and cooperation.	The reasoned opinion was posted on the website of the Joint Committee.	No	Yes, in the form of a Reasoned Opinion of the Joint Committee on European Scrutiny, concluding that the Proposal appears to comply with the principle of subsidiarity.	<b>No.</b> It is incomplete. It appears that the Commission did not complete all the elements of the detailed statement as required under the Protocol on the Application of the Principles of Subsidiarity and Proportionality. Information is lacking on quantitative indicators to substantiate the Proposal and a complete answer on whether the Proposal takes into account of the burden falling upon national authorities, economic operators and citizens.	<p>The check was undertaken during the Christmas recess. The Committee suggests that COSAC once again look at the practical and logistical consequences for the checking procedure when a proposal is published running up to or during a period when most national parliaments are in recess. The Joint Committee is also of the opinion that national parliaments need to develop an agreed definition and interpretation of the principle of subsidiarity. There needs to be a focused, result-oriented discussion at COSAC on the meaning of subsidiarity.</p>

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory ?	Other observations
<b>Italy:</b> <i>Camera dei Deputati</i>	The Committee on EU Policies issued an opinion to the Committee on Social Affairs, which is entitled to adopt a final position on the Proposal. However, for the purposes of this check, the opinion of the Committee on EU Policies is to be considered.	Through IPEX	The minutes and the opinion of the Committee on EU Policies were published.	No	No	<b>No. The motives given in the Preamble of the Proposal and in the explanatory report in respect of subsidiarity and proportionality are not clear, simply reiterating conventional protocols.</b>	In the Opinion of the Committee on EU Policies states the need for the Commission to include in the Preamble and the explanatory report a more specific and detailed justification of the Proposal.
<b>Italy:</b> <i>Senato della Repubblica</i>	The check was conducted by the Committee on European Union Policies (with an advisory remit) and the Committee on Health (having jurisdiction on the subject matter).	No	A summary report of the Committee meeting was published on the Senate website the day after the meeting.	<b>No formal breach was found, but the Committee on European Union Policies was of an opinion that the Proposal "suffered from shortcomings in terms of determination and motivation of subsidiarity and should be reworded".</b>	Yes, in the form of the Opinion of the Committee on European Union Policies.	The justification was not satisfactory.	-
<b>Latvia:</b> <i>Saeima</i>	The Committee on European Affairs performed the check after receiving an opinion of the Subcommittee on Public Health Human of the Committee on Social and Employment matters. The Ministry of Health provided its opinion regarding the compliance of the Proposal with the principles of subsidiarity and proportionality.	Followed the course of the check in other national parliaments through IPEX and through the Permanent Representatives of the <i>Saeima</i> to the EU.	A press release on the meeting of the Committee on European Affairs of 30 January 2009 was sent to the Latvian news agencies.	No	No	Yes	In view of Article 152 (5) of the EC Treaty, it is necessary to evaluate the conformity of the Proposal with both the principle of subsidiarity and the principle of proportionality.

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>Lithuania:</b> <i>Seimas</i>	The Committee on European Affairs was in charge of the check. The Committee on Health Affairs submitted its expert conclusions to the Committee on European affairs. The Ministry of Health provided the Government's position on the Proposal, containing primary opinion on its compliance with the principle of subsidiarity. The National Bureau on Transplantation under the Ministry of Health and the European Law Department under the Ministry of Justice also presented their opinions.	Information on the decisions of other parliaments was exchanged through permanent representatives of national parliaments in Brussels.	No	No	No	Yes	The Committee on European Affairs will follow closely the course of consideration of the Proposal in the EU Institutions since it may undergo significant modifications.
<b>Luxemburg:</b> <i>Chambre des Députés</i>	The check was conducted by the Committee on Health and Social Security, in the presence of Government experts.	No	No	No	Yes, in the form of a letter to the Commissioner for Health Ms A. Vassiliou, stating that the Proposal complies with the principles of subsidiarity and proportionality.	-	The issue was raised of the overlap of this initiative of the EC and the cooperation mechanisms developed by the Council of Europe.
<b>The Netherlands</b> <i>The States-General</i>	The check was carried out by the Temporary Joint Committee on the Subsidiarity Check. It received opinions of the Committees on Health, Welfare and Sports/Youth and Family of the Senate and the Committee on Health, Welfare and Sports of the House of the Representatives. Both Houses in their plenary sittings adopted a joint reasoned opinion on the subsidiarity check. The Government provided the so-called fiche on the Proposal.	No	The findings were published in an official parliamentary publications No. 31 805.	<b>The States - General are not convinced that the proposed measures fulfil the requirements of subsidiarity and proportionality. The final assessment is deferred until a response from the Commission is received and stakeholders are consulted.</b>	Yes, in the form of a letter to the Vice-President of the European Commission Ms Margot Wallström with a list of questions to the European Commission from both Houses of <i>the States-General</i> .	No. <i>The States-General</i> need more information from the European Commission	<b>The check was completed after the deadline – on 12 February 2009.</b>  Due to recess of both Houses of <i>the States-General</i> the subsidiarity check could not be concluded within the time frame of 8 weeks.



Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory?	Other observations
<b>Poland:</b> <i>Sejm</i>	The check was conducted by the Committee on European Union Affairs, which is a specialised body giving opinions on the EU matters on behalf of the entire <i>Sejm</i> .		The opinion of the Committee was published on its website. The transcript of the meeting was published on the website of the <i>Sejm</i> . It was also forwarded to the Government.	No	Yes, in the form of the Opinion of the Committee on European Union Affairs acknowledging that the Proposal is in conformity with the principle of subsidiarity.	Yes, but in the opinion of the Bureau of Research of the Chancellery of the <i>Sejm</i> the Proposal does not contain a substantive justification of its compliance with the principle of subsidiarity.	-
<b>Poland:</b> <i>Senat</i>	The check was conducted by the Committee on European Union Affairs in cooperation with the Committee on Health. The Government submitted its written position on the compliance of the Proposal with the principles of subsidiarity and proportionality. A Government official provided additional information at the Committee meeting.	No	The report on the subsidiarity check was published on the website of the Committee on European Union Affairs and on IPEX.	No	No	Yes	-
<b>Portugal:</b> <i>Assembleia da República</i>	The check was conducted by the Committee on European Affairs and the Committee on Health which drew up a report to the Committee on European Affairs which took the final decision..	The work in other parliaments was followed closely through IPEX and via the network of national parliaments' representatives to the EU.	The findings were published on IPEX.	No	Yes, in the form of an Opinion of the Committee on European Affairs stating that the Proposal complies with the principles of subsidiarity and proportionality.	The issue was not discussed by the Committee on European Affairs.	The eight week period was outside the normal parliamentary term, limiting the capacity for a more in-depth debate.
<b>Slovenia:</b> <i>Državni zbor</i>	The Committee on Health heard verbal Government communication at its meeting. Taking the opinion of the Committee on Health into account, the Committee on EU Affairs took a final decision on the Proposal's compliance with the subsidiarity principle.	No	No	No	Yes, in the form of a Decision of the Committee on EU Affairs, stating that the Proposal complies with the principle of subsidiarity.	Yes	-

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory ?	Other observations
<b>Slovenia:</b> <i>Državni svet</i>	The check was conducted at the joint meeting of the Commission for Social Care, Labour, Health and the Disabled and the Commission for International Relations and European Affairs. The Ministry of Health and the Institute for Transplantation of Organs and Tissues presented their assessment of the compliance of the Proposal with the principle of subsidiarity at the joint meeting. The joint opinion was sent to the EU Affairs committee of the <i>Državni zbor</i> and the Government.	No	The joint opinion was published on the website of the <i>Državni svet</i> .	No	No	No	-
<b>Sweden:</b> <i>Riksdag</i>	The check was carried out by the Committee on Health and Welfare. A State Secretary provided oral information at a Committee meeting about the Government offices subsidiarity check.	The Committee secretariat consulted IPEX and contacted by e-mail an official in another parliament.	The findings were noted in a section in the record from the Committee meeting and published on IPEX.	No	No	Yes	The check was carried out smoothly. However, the Christmas recess caused a higher number of Committee meetings. Also, because of the recess, it would have been difficult to involve the plenary.
<b>United Kingdom:</b> <i>House of Commons</i>	The European Scrutiny Committee considered the Proposal in accordance with its usual procedure for the scrutiny of EU documents. The interim decision was taken. The Government provided an Explanatory Memorandum, but the Committee has asked for further information on the question.	No	The findings were published in the Report to the House of Commons.	<b>The final decision has not been reached until the further information provided by the Government is considered.</b>	No	The Committee has requested the Government to provide further information on the compliance of the Proposal with the principle of subsidiarity and with the requirement of Article 152(5) of the EC Treaty.	At present there are not sufficient grounds to recommend the House of Commons to approve the sending of a written opinion to the Commission, the EP and the Council arguing that the Proposal does not comply with the principle of subsidiarity.

Country, Chamber	Procedure used to conduct the check	Cooperation with other national parliaments	Publication of findings	Any breach found?	Any reasoned opinion issued?	Was Commission's justification satisfactory ?	Other observations
<b>United Kingdom:</b> <i>House of Lords</i>	The check was conducted by the Social Policy and Consumer Affairs Sub-Committee of the EU Committee. The National Assembly of Wales provided information, the Scottish Parliament provided a response. The Government provided an Explanatory Memorandum and gave evidence for the EU Committee inquiry in June 2007.	Cooperation through the permanent representatives of national parliaments in Brussels. The EU Committee report of 2 July 2008 was circulated to other national parliaments.	No	No	No	No. The justification lacks clarity. The Committee disagrees with the assertion of the Commission that the Community has an obligation to act.	The Devolved Assemblies encountered difficulties. The limited timetable of the check prevented them from considering the subsidiarity aspects of the Proposal in the detail that they would have wished.