May 2009

Annex to the 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:

National Parliaments' replies to the questionnaire

Prepared by the COSAC Secretariat and presented to:

XLI Conference of Community and European Affairs Committees of Parliaments of the European Union

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Findings:

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14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?
16. Did you encounter any specific difficulties during this subsidiarity check?
17. Any other comments?

Procédure :

1. Quelles commissions parlementaires ont été impliquées dans le test de subsidiarité et de quelle manière ?
2. La séance plénière a-t-elle été impliquée ?
3. A quel niveau la décision finale a-t-elle été prise et qui l'a paraphée ?
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7. Avez-vous consulté les parlements régionaux de votre pays qui disposeraient de pouvoirs législatifs ?

8. Avez-vous consulté des organisations non gouvernementales, des groupes d'intérêt, des experts extérieurs ou d'autres parties prenantes ?
9. Selon quelle chronologie le test a-t-il été conduit au sein de votre Parlement ?
10. Avez-vous coopéré avec d'autres parlements nationaux ? Si oui, par quels moyens ?
11. Avez-vous publié vos conclusions ? Si oui, par quels moyens ?
12. Votre parlement a-t-il adopté de nouvelles procédures de contrôle du principe de subsidiarité depuis septembre 2008 ? Si oui, merci de préciser comment ces nouvelles mesures ont été introduites.

Conclusions :

13. Avez-vous découvert un quelconque manquement au principe de subsidiarité ?
14. Avez-vous adopté un avis motivé sur la proposition de directive (Si oui, veuillez en joindre une copie) ?
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16. Avez-vous rencontré des difficultés spécifiques pendant l'examen ?
17. Avez-vous d'autres observations ?

Austria: *Bundesrat*

Commission proposal:
Directive
on standards of quality and safety
of human organs
intended for transplantation

EU Committee of the Federal Council, Austria

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The check was conducted by the EU Committee of the Federal Council.

2. Was the plenary involved?

No.

3. At which level the final decision was taken and who signed it?

The statement was issued by the EU Committee of the Federal Council. The President of the Federal Council transmitted the statement to its recipients.

4. Which administrative services of your parliament were involved and how (please specify)?

The EU- and International Service performed a subsidiarity pre-check of the proposal, coordinated information exchange with government and external experts, and was in charge of all organisational issues before, during and after the committee session.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

The Ministry of Health provided an explanatory memorandum. Ministry experts also participated in the meeting.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

Before the committee session, the EU Committees of the Austrian Nationalrat were informed about the subsidiarity check scheduled by the EU Committee of the Bundesrat. After the session, the statement was transmitted to the other chamber.

7. Did you consult your regional parliaments with legislative powers?

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

Before the session took place, the Austrian Länder (as well as the Association of Cities and Towns and the Association of Municipalities) were invited to provide written statements and to send experts to attend the meeting.
In addition, requests for written statements were addressed to the Federal Economic Chamber, the Chamber of Labour, the Chamber of Agriculture, the Federation of Trade Unions, the Federal Institute for Healthcare and the Supreme Council of Health.

9. What was the chronology of events?

As soon as the proposal became available, experts from Parliament's EU- and International Service performed a subsidiarity pre-check and gathered information from different stakeholders (including other parliaments via IPEX). When the committee session was scheduled and the agenda formally set, requests for written statements as well as invitations to attend the meeting (see questions 7 and 8) were sent out. After the committee meeting on February 3 the statement was transferred to the different recipients.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

Yes, through IPEX.

11. Did you publicise your findings? If so, by what means?

A summary of the proceedings was published on the internet website of the Parliament.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No formal changes have taken place in this period.

Findings:
13. Did you find any breach of the principle of subsidiarity?
See enclosed copy of the statement.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
Yes.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

The committee statement does not relate to this specific question. On the administrative level, however, we found the Commission's justification provided in the impact assessment comprehensive and satisfactory.

16. Did you encounter any specific difficulties during this subsidiarity check?
-
17. Any other comments?
-

EU Committee of the Federal Council 3 February 2009

Motion

regarding COM (08) 818 final
Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety for human organs intended for transplantation (2829/EU XXIV.GP)

The EU Committee has adopted the following:

I. Determination by the Committee

"**Statement to the European Commission**

The EU Committee of the Federal Council discussed the proposal of the Commission COM (08) 818 final, Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety for human organs intended for transplantation, in a public session on 3 February 2009 and on the basis of information from the competent Federal Ministries and statements from the provincial bodies, the Federal Chamber of Labour, Austrian Federal Economic Chamber and Österreichisches Bundesinstitut für Gesundheitswesen [Austrian Federal Institute of Health] arrived at the following conclusion:

1. Account will have to be taken in all transborder organ exchange/transplantation projects of the different systems in the Member States with regard to consent by the deceased or their relatives ('opt-out' vs. 'opt-in' solutions) and of the appreciable differences in the availability of donor organs that result. In view of the substantial ethical issues in this connection, the European Union should be extremely cautious with regard to uniform regulations in this area.

2. The proposed regulations are reconcilable with Article 152 paragraphs 1 and 5 of the EC Treaty only if a high level of human health protection can be ensured in the implementation of all Community policies and if the responsibility of the Member States for the organisation of the health service and medical care is fully respected.

3. The proposed regulations must not therefore compromise the functioning provision of donor organs within the individual Member States in any way. This threshold would certainly be exceeded if Member States with effective systems and legal frameworks were forced in any way to export organs to other Member States with ineffective systems or inadequate legal frameworks. This could lead to a collapse of the entire system, since the willingness of many people to donate their organs could rapidly decline if there were even concerns that the local supply of donor organs could be jeopardised by Community regulations.

4. Furthermore, the planned regulation should not provide incentives for 'organ transplant tourism' typically to the detriment of the host country but should, on the contrary, prevent such a phenomenon. This could be supported, for example by a specific provision or recital explicitly stating that the demand for donor organs within the individual Member

States must be covered. In this regard, short distances in any case contribute significantly from a technical point of view to improving transplantation outcomes.

5. Finally, the planned regulation should not result in an additional administrative burden but should be seamlessly integrated in the existing pan-European structures for cooperation, the exchange of information and quality assurance. This means that the various provisions of Chapters IV and V (for example the 'equivalence requirement') should be reviewed again in close collaboration with experts and practitioners.

6. The definition of a reportable serious adverse event in Articles 3 and 11 is inadequate and should be reviewed again with medical experts.

7. From a technical point of view, the donor characterisation in Article 7 is too detailed. Apart from anything else, the level of regulation needs to be questioned given the likely changes as a result of medical progress. This could be determined in the framework, for example, of Eurotransplant and the national institutions collaborating in it.

8. 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."

II.

The EU Committee submits this statement to the President of the Federal Council in accordance with section 34 paragraph 6 of the Rules of Procedure of the Federal Council (GO-BR) for publication as a communiqué and requests the President of the Federal Council to transmit this communiqué to the European Commission, the Austrian Federal Government, the Committee of the Regions, the Conference of Community and European Affairs (COSAC) and Interparliamentary EU Information Exchange (IPEX), and to the European Parliament.

Belgium: *Chambre des Représentants*

House of Representatives of Belgium

ADVISORY COMMITTEE ON EUROPEAN AFFAIRS

Brussels, 16 March 2009

Subsidiarity check under the provisions of Protocol 2 on the Application of the Principles of Subsidiarity and Proportionality as attached to the Treaty of Lisbon on the Proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The Standing Committee on Public Health was responsible for the Subsidiarity test.

2. Was the plenary involved?

No. Following the Regulations of the Belgian House of Representatives (Article 37bis) with regard to the subsidiarity test, the subsidiarity opinion is only sent to the plenary if 1/3 of the members of the competent Committee is asking that.

In this case, the opinion has been adopted by unanimity at the level of the Committee. In such a case, the opinion of the Committee is considered as being the opinion of the House as such.

3. At which level the final decision was taken and who signed it?

See 2

4. Which administrative services of your parliament were involved and how (please specify)?

Secretariat of the Advisory Committee on European Affairs and Secretariat of the Committee on Public Health.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

No. The Committee disposed already over the necessary knowledge acquired in the context of former parliamentary scrutinies at the occasion of the national bill to improve organ donation.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

No. Every Chamber may express its own opinion.

7. Did you consult your regional parliaments with legislative powers?

Regional parliaments are not competent in this matter.

8. Did you consult any non-governmental organizations, interest groups, external experts or other stakeholders?

No. See 5

9. What was the chronology of events?

a) Start procedure:

   Communication of the launch of a subsidiarity test to the Conference of Présidents (=instance organizing the parliamentary work).

b) The Conference of Presidents designates the competent Committee.

c) The competent Committee receives the necessary documents and information from the Secretariat of the Advisory Committee on European Affairs.

d) The competent Committee formulates an opinion.

e) The Secretariat of the Advisory Committee on European Affairs is responsible for the dispatching (forwarding to the European institutions) of the formulated opinion.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

No. However, we were informed about the opinions brought out by other parliaments.

11. Did you publicise your findings? If so, by what means?

Yes. As a parliamentary document (see annex) and on IPEX.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No. Regulation with regard to subsidiarity was already adopted in 2007.

Findings:

13. Did you find any breach of the principle of subsidiarity?

No breach on the subsidiarity principle was observed.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Yes. See annex.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

Yes.

16. Did you encounter any specific difficulties during this subsidiarity check?

No.

17. Any other comments?

The internal procedure should still be more standardized. Every committee is still autonomous in the way they will formulate an opinion.

CHAMBRE DES REPRÉSENTANTS DE BELGIQUE

29 janvier 2009-04-21

PROPOSITION

de Directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation (Document COM(2008) - 818)

AVIS DE SUBSIDIARITÉ

RAPPORT

Fait au nom de la Commission de la santé publique, de l'environnement
et du renouveau de la societé
PAR
Mme Thérèse SNOY et D'OPPUERS

Mesdames, Messieurs,

Conformément à l'article 37bis du Règlement de la Chambre, votre commission a consacré ses réunions des 13 et 27 janvier 2009 à la discussion de la Proposition de Directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation (Document COM(2008) – 818)

1. — Procédure

Sur la base des propositions des Parlements nationaux, les présidents de la COSAC (Conférence des Organes spécialisés en Affaires communautaires) ont décidé, au cours de leur réunion du 7 juillet 2008 à Paris, d'effectuer un contrôle de subsidiarité au sujet de la proposition de directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation.

L'objectif est de permettre aux parlements nationaux de tester l'application concrète des dispositions du Traité de Lisbonne qui concernent le principe de subsidiarité. Cette décision relève de l'application de l'article 37bis du Règlement de la Chambre.

Conformément à ces dispositions, la COSAC a demandé aux parlements nationaux de remettre leurs conclusions dans un délai de huit semaines à compter du jour où la proposition de résolution est devenue disponible dans toutes les langues de l'Union européenne. Ce délai expire dès lors le 6 février 2009.

Le cas échéant, les parlements nationaux sont invités à donner aux présidents de la Commission européenne, du Parlement européen et du Conseil un avis motivé dans lequel il est indiqué pourquoi la proposition de directive respecte, selon eux, le principe de subsidiarité ou y porte préjudice.

2. — Discussion

La présidente, Mme Muriel Gerkens, explique que la commission doit vérifier si la proposition de directive à l'examen est conforme aux principes de subsidiarité.

Mme Gerkens rappelle que la COSAC décide d'effectuer un contrôle de subsidiarité au sujet de certaines propositions de directive émanant de la Commission. Les parlements nationaux doivent alors émettre un avis indiquant si, selon eux, la Commission européenne respecte le principe de subsidiarité.

En vertu de ce principe, l'action politique doit être décidée au plus près du citoyen et les institutions européennes ne peuvent prendre que des meures complémentaires ou de soutien de la politique nationale, lorsque celles-ci permettent de mieux réaliser les objectifs du traité de l'Union européenne.

Il convient par ailleurs de déterminer si cette proposition de directive respecte la répartition des compétences entre les États membres et les institutions européennes et si elle présente une valeur ajoutée pour la réalisation des objectifs de l'Union européenne.

La proposition de directive règle l'organisation et le fonctionnement des banques d'organes, l'information et le soutien relatifs au don d'organes, l'amélioration de la qualité et de la sécurité de l'organe destiné à la transplantation.

M. Luc Goutry (CD&V) fait observer que son groupe soutient au niveau communautaire le principe de la directive-cadre, qui laisse aux États membres la possibilité de compléter le contenu de la réglementation.

La procédure et les aspects éthiques du don d'organes demeurent ainsi réglés au niveau des États membres, lesquels peuvent dès lors tenir compte au mieux de leurs spécificités. Il est en revanche préférable de régler la libre circulation, la distribution, la mise à disposition et l'échange d'organes par le biais d'une directive au niveau européen.

Cette directive doit alors avoir surtout pour objet d'augmenter l'accessibilité du prix et la disponibilité d'organes, en fait de réduire les délais d'attente, et la fiabilité, c'est-à-dire la qualité des organes mis à disposition. Ce dernier point est un des principaux objectifs de la proposition de directive, qui règle également la traçabilité des organes et la protection des données des donneurs et des receveurs d'organes.

M. Goutry estime que l'Europe doit prendre ses responsabilités en instituant un cadre général auquel le législateur national pourra ensuite donner un contenu.

M. Jacques Otlet (MR) souligne que, selon son groupe, la proposition de directive prend en compte le principe de subsidiarité.

M. Georges Dallemagne (cdH) est, lui aussi, d'avis que la proposition de directive prend en compte le principe de subsidiarité. Son groupe estime que la proposition passe avec succès le contrôle de subsidiarité.

Répondant à M. Dallemagne, la présidente précise que ce contrôle de subsidiarité est réalisé par les parlements nationaux. Ceux-ci peuvent, s'ils le jugent nécessaires, demander l'avis du ministre compétent à ce sujet, bien que cela ne soit pas obligatoire.

Mme Rita De Bont (VB) demande si la proposition de résolution sera aussi soumise aux parlements des entités fédérées. En vertu du principe de subsidiarité, les décisions doivent en

effet être prises au niveau le plus proche possible de la population. Des accords ont-ils été conclus avec les entités fédérées?

La présidente, Mme Gerkens, précise que la proposition de directive règle une matière qui relève de la compétence exclusive de l'autorité fédérale. Ce sont donc uniquement les chambres législatives fédérales qui doivent émettre un avis sur la subsidiarité.

Mme Marie-Claire Lambert (PS) indique que selon son groupe, l'objectif de la proposition de directive justifie une initiative au niveau de l'Union européenne. La proposition de directive vise à soutenir et à améliorer la qualité des organes et la sécurité des patients au niveau de l'Union européenne. Par ailleurs, elle protège aussi le donneur et facilite la coopération entre États membres pour les échanges d'organes.

Pour lutter contre la pénurie d'organes, une collaboration entre États membres est indispensable. Le PS considère que la proposition de directive respecte le principe de subsidiarité.

Mme Katia della Faille de Leverghem (Open Vld) souligne que la proposition de directive vise à imposer des normes de qualité élevées pour des organes destinés à la transplantation. La Belgique est membre d'Eurotransplant, un organisme qui assure l'échange d'organes entre les États membres. Dans ce cadre, une réglementation qui fixe des normes de qualité élevées, harmonise et uniformise les mesures se justifie certainement. Le groupe Vld considère, lui aussi, que la proposition respecte le principe de subsidiarité.

L'intervenante souligne, en outre, que la Belgique a imaginé un intéressant système à points destiné à remédier au problème des délais d'attente pour les patients rénaux. L'Europe pourrait s'en inspirer.

Mme Muriel Gerkens, présidente, résume le débat en précisant que la commission ne note aucun problème concernant le principe de subsidiarité. La proposition de directive contient des mesures en matière de coordination, de coopération et d'harmonisation des prescriptions relatives à la qualité et à la sécurité. Les compétences des États membres et de l'Union européenne sont respectées à cet égard. La réglementation européenne apporte une plus-value.

On peut ajouter un commentaire à l'avis en soulignant l'importance de créer un cadre communautaire pour que le don d'organe se déroule de la manière la plus sûre et efficace possible tout en permettant aux États membres de poursuivre leur politique nationale.

La proposition de directive contient des mesures qui ont pour but de raccourcir les délais d'attente pour l'obtention d'organes. À cet effet, des mesures sont notamment élaborées en vue d'améliorer l'échange d'informations et d'accroître le nombre de donneurs, tout en respectant l'autonomie de chaque État membre pour définir qui est donneur.

Mme Thérèse Snoy et d'Oppuers (Ecolo-Groen!) estime que le principe de subsidiarité est respecté. L'intervenante attire l'attention sur la plus-value de la proposition de directive. Il est important qu'il soit prévu à l'échelle de l'Union européenne que le don rémunéré et le commerce d'organes sont strictement interdits et que l'anonymat du donneur et du receveur sont garantis.

Par ailleurs, il s'impose que les exigences de qualité et de sécurité soient définies au niveau communautaire et que la création d'une plateforme destinée à soutenir la recherche dans ce domaine soit prévue.

3. — avis

La commission a émis, à l'unanimité, l'avis suivant:

La commission de la Santé publique, de l'Environnement et du Renouveau de la société considère que la proposition de directive n'appelle pas d'observation au regard du principe de subsidiarité, dans la mesure où la proposition vise à créer un cadre légal communautaire en vue de promouvoir la qualité et la sécurité des dons d'organes, chaque pays conservant la faculté d'élaborer sa propre réglementation.

La rapporteuse,	La présidente,
Thérèse	Muriel Gerkens
Snoy et d'Oppuers	

Belgium: *Sénat*

09/12/2008

La procédure de contrôle de subsidiarité au Sénat de Belgique

COM (2008) 818 – procédure 8 semaines

Nouveaux delais	événement	action à entreprendre
8/12	Réception d'un document européen (législatif ou consultatif)	Communication au service juridique pour un avis sur la compétence du Sénat
Avant le 18/12	Rédaction d'un avis sur la compétence du Sénat Communication de l'avis sur la compétence du Sénat	Rédaction et envoi de l'avis sur la compétence du Sénat au secrétariat du Comité d'avis Si l'avis sur la compétence du Sénat constate que le Sénat n'est pas compétent, le secrétariat du Comité d'avis le transmet au Président du Comité d'avis qui consulte, le cas échéant, le Bureau du Sénat. Si l'avis sur la compétence du Sénat constate que le Sénat est compétent, le secrétariat du Comité d'avis transmet l'avis sur la compétence du Sénat et le document européen concerné au(x) Président(s) de la (des) commission(s) compétente(s) et au Président du Comité d'avis.
Avant le 22/12	Communication de l'avis sur la compétence du Sénat	Si le Sénat s'estime compétent, notification via le site IPEX par le correspondant IPEX aux parlements belges
Avant le 19/01	Examen du document européen par la (les) commission(s) compétente(s) et le Comité d'avis Adoption d'un avis sur la subsidiarité par la (les) commission(s) compétente(s) et/ou le Comité d'avis	Si les membres de la (des) Commission(s) compétente(s) et du Comité d'avis n'ont pas de remarques concernant le document européen concerné ou si le point n'est pas traité, le Sénat est censé ne pas avoir d'objections concernant la subsidiarité. Dans ce cas, la procédure se termine. Si une objection est formulée, la (les) Commission(s) compétente(s) et/ou le Comité d'avis se prononcent et font rapport de leurs travaux conformément à l'article 27 du Règlement du Sénat.
Avant le 26/01	Examen de l'avis sur la subsidiarité par la séance plénière du Sénat	Le Sénat se prononce en séance plénière sur les conclusions du rapport de la (des) Commission(s) compétente(s) et/ou le Comité d'avis.
26/01	Communication de l'avis sur la subsidiarité	Le cas échéant, l'avis du Sénat est communiqué aux autres assemblées parlementaires belges et au secrétariat de la Conférence des Présidents des 7 assemblées parlementaires.
02/02	Communication de l'avis sur la subsidiarité	Les avis des parlements sont communiqués aux institutions européennes, aux gouvernements fédéral, régionaux et communautaires belges concernés et aux parlements belges. Le correspondant IPEX met l'avis sur la subsidiarité sur le site web IPEX.

Réponses du Sénat belge au questionnaire

Procédure:

1. La Commission impliquée était la Commission des Affaires sociales.
2. La séance plénière n'a pas été impliquée puisque la commission des Affaires sociales n'a pas formulé de commentaires par rapport à la subsidiarité ou la proportionnalité. La séance plénière sera impliqué pour l'avis sous la procédure de l'initiative Barroso.
3. La décision finale est prise par la Commission des Affaires sociales. Pas d'avis rendu, donc pas de paraphe.
4. Le service des Affaires européennes – réception du document, préparation du dossier, suivi de la procédure. Le service juridique – préparation d'un avis sur la compétence du Sénat en la matière. Le service des commissions – procédure dans la commission parlementaire.
5. Non
6. Les deux chambres se tiennent au courant des résultats et décisions, mais fonctionnent de manière complètement autonome en cette matière.
7. Un avis sur la compétence du Sénat a été préparé par le service juridique. Une consultation des régions n'était pas nécessaire.
8. La Commission des Affaires sociales a préparé un avis sur le contenu du document par rapport à l'initiative Barroso. Pour cela elle a consulté des experts. Pour la subsidiarité elle ne l'a pas fait.
9. Voir procédure en annexe
10. Non, seulement consultation d'IPEX.
11. La procédure s'arrête quand il n'y a pas de commentaires sur la subsidiarité ou la proportionnalité. Il n'y a donc pas de document publié. Un avis sur le contenu sera publié après confirmation de la séance plénière au mois de mars.
12. Non

Conclusions :

13. Non
14. Pas d'avis dans la procédure du contrôle de subsidiarité. Un avis sur le contenu (initiative Barroso) sera publié prochainement.
15. Nous n'avons pas eu de plaintes à ce sujet.
16. Non
17. Non

Sénat de Belgique

SESSION DE 2008-2009

11 FÉVRIER 2009

Proposition d'une Directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation

AVIS À LA COMMISSION EUROPÉENNE

AVIS DE LA COMMISSION DES AFFAIRES SOCIALES

À la suite de l'audition organisée en commission des Affaires sociales du Sénat, le 28 janvier 2009, et conformément aux règles et pratiques déjà en vigueur en Belgique, le Sénat belge formule les remarques et recommandations qui suivent.

a) Le problème du nombre de donneurs

Le problème majeur, qui se pose pour tous les organes, réside dans le fait que les listes d'attente se sont considérablement allongées et que le nombre d'organes disponibles ne suffit plus. Plusieurs pistes peuvent être explorées pour tenter de résoudre ce problème de pénurie. On peut rechercher des sources supplémentaires d'organes, travailler plus efficacement, réduire le nombre d'indications en améliorant la prévention, en recourant aux thérapies alternatives et en prévenant les retransplantations. Plusieurs initiatives ont été prises et des modifications ont été apportées afin de veiller au maximum à ce que tout organe mis à disposition puisse être utilisé. Un changement est ainsi intervenu ces dernières années dans le profil des donneurs retenus pour le prélèvement d'organes en vue d'une transplantation (« *expanded donorpool* »). Par ailleurs, les donneurs sont de plus en plus âgés: 25 % des donneurs ont plus de 65 ans.

On utilise aujourd'hui des organes que l'on n'aurait pas retenus il y a vingt ans. Il y a donc eu beaucoup de changements au cours des vingt dernières années. Tout d'abord, il faut citer les progrès de la thérapie immunosuppressive, qui permet d'utiliser désormais un plus grand nombre d'organes en toute sécurité. Ensuite, il y a suffisamment d'études scientifiques montrant que des organes en provenance d'un donneur âgé peuvent être transplantés sans problèmes chez un receveur âgé. Il faut donc certainement envisager la « moindre » qualité d'un organe en fonction du rapport risque/bénéfice qu'il présente pour le receveur.

Le Sénat demande dès lors à la Commission européenne de veiller à ne pas imposer des critères trop stricts en la matière. La notion de « *expanded donorpool* » est une donnée dynamique qu'il faut rattacher aux progrès de la science.

b) Exécutants aux différents stades

La proposition de directive fait une distinction entre les organismes d'obtention et les centres de transplantation. En Belgique, les centres de prélèvement et les centres de transplantation sont actuellement regroupés en un seul et même organisme. La Belgique obtient d'excellents résultats en termes de qualité, en raison précisément du lien contrôlé qui existe entre le prélèvement et la transplantation. Le Sénat voudrait donc demander à la Commission européenne d'indiquer qu'il ne doit pas obligatoirement s'agir d'organismes distincts.

c) Enregistrement

L'enregistrement est un point faible du système d'enregistrement européen. Le Sénat demande à la Commission européenne d'envisager la possibilité de rattacher d'une manière ou d'une autre l'enregistrement à l'agrément en tant que centre de transplantation ou de prévoir une forme de subventionnement de ces registres, en faisant par exemple affecter par la loi une partie du remboursement des frais d'une transplantation à l'enregistrement des données.

Le Sénat pense que le texte pourrait être plus strict à cet égard. En effet, ce n'est qu'en recensant les donneurs décédés et les donneurs vivants et par l'analyse des données que l'on pourra évaluer dans quelques années la pertinence des décisions prises aujourd'hui.

d) Attribution des organes

En Belgique, un patient ne peut se faire inscrire que sur une seule liste d'attente. Il serait souhaitable qu'il en aille de même dans le contexte européen et que l'on ne puisse pas figurer simultanément sur plusieurs listes d'attente dans différents États membres. Le système d'attribution diffère en fonction de l'organe dont il s'agit et implique toujours un compromis. Il n'existe pas de régime d'attribution européen et la question de l'attribution est totalement absente du champ d'application de la directive examinée. Il est pourtant essentiel pour les citoyens de tous les États membres de savoir selon quels critères un organe est attribué. Il est capital que l'attribution s'effectue en toute transparence, car c'est à ce stade que se situe particulièrement le risque de fraude.

Eurotransplant est parvenue à concevoir un système d'attribution qui tient compte des législations des différents États membres concernés. Mais, ici aussi, il y a lieu de prévoir un système de contrôle strict, car la solidarité peut également être mise en péril à ce niveau, notamment lorsque la priorité est demandée trop rapidement pour des patients.

Le Sénat demande à la Commission européenne de définir plus clairement sa position concernant la création d'un système d'attribution au niveau européen.

e) Principe de solidarité

La proposition de directive vise en premier lieu à garantir la qualité et la sécurité des transplantations d'organes. En revanche, ce que la Commission européenne a omis de régler dans sa proposition de directive, ce sont les modalités du consentement en vue de l'obtention des organes. Bien entendu, les divers États membres appliquent des systèmes fort différents, qui peuvent aller du consentement présumé du donneur jusqu'au consentement donné par la famille du donneur. La solidarité risque par conséquent d'être mise en péril.

En son temps, la législation belge a, par exemple, opté pour un système « *opting out* » et donc, pour un maximum de solidarité. Si l'on constate que cette solidarité bénéficie en fait à

un pays qui a choisi un système réputé moins efficace pour obtenir des organes, la solidarité risque d'être mise à mal.

C'est précisément ce qui se passe actuellement au sein d'Eurotransplant. Le problème posé par l'offre inégale de donneurs dans les différents pays membres d'Eurotransplant a déjà fait l'objet de nombreuses discussions au sein d'Eurotransplant. L'inégalité est évidente, certains pays ayant deux fois plus de donneurs que d'autres. La Belgique et l'Autriche ont en moyenne entre 22 et 25 donneurs par million d'habitants, les Pays-Bas et l'Allemagne, seulement 12. Cela signifie que les Néerlandais ont beaucoup moins de chances de pouvoir bénéficier d'une transplantation d'organe que les Belges, par exemple. Lors de l'instauration du nouveau système, l'on a aussi introduit le principe de la « balance nationale », du moins pour les reins. Cela signifie que lorsque 400 reins sont prélevés sur des donneurs décédés, le système informatique qui les répartit veille à ce qu'il y ait environ 400 reins transplantés en Belgique. Actuellement, nous sommes confrontés au problème que de nombreux étrangers, notamment des Néerlandais, s'inscrivent sur nos listes d'attente pour tenter de tirer profit de notre système.

On pourrait y remédier en faisant en sorte que le système informatique de la « balance nationale » tienne compte non plus du lieu de la transplantation mais du domicile du receveur. Cela permettrait de garantir le respect du principe de solidarité. Toutefois, pour un organisme comme Eurotransplant, il n'est peut-être pas facile de contrôler le domicile. Une autre solution serait d'utiliser le numéro de la carte d'identité, qui est immédiatement contrôlable.

Le Sénat demande à la Commission européenne d'élaborer un tel système afin de garantir la solidarité entre les différents États membres dont les législations divergent.

f) Coopération transfrontalière

La proposition de directive concerne les 27 États membres de l'Union européenne. Eurotransplant couvre un nombre plus limité de pays. Il existe en outre de nombreux autres organismes de transplantation, tels que *Scandiatransplant, UK Transplant, Iberiatransplant*, et d'autres, qui ne collaborent pas toujours bien entre eux.

Dans le cadre de la proposition de directive examinée, le Sénat demande dès lors à la Commission européenne de mettre sur pied une organisation paneuropéenne, qui respecte en même temps les situations locales, etc.

g) Sensibilisation du corps médical

Les médecins actifs dans le secteur de la transplantation voient régulièrement des patients mourir faute d'avoir pu bénéficier d'une transplantation. Chaque médecin a pour mission première de sauver la vie des patients et, lorsqu'il n'y parvient pas, il le ressent toujours comme un échec dans une plus ou moins grande mesure. Il existe pourtant une étape suivante, où le patient décédé peut faire office de donneur.

Le Sénat demande s'il est possible d'insérer dans la directive une disposition portant explicitement sur la sensibilisation des médecins.

h) Protection des donneurs vivants

Il est essentiel de protéger les donneurs vivants. L'article de la directive y relatif est composé de trois volets: le consentement éclairé, les critères de sélection et le registre.

Le Sénat demande que l'on évite une hyper-régulation trop stricte. L'évaluation d'un donneur vivant peut se révéler très complexe et doit dès lors être adaptée à la situation concrète. Des normes trop strictes risquent donc d'avoir un effet néfaste.

Sénat de Belgique

SESSION DE 2008-2009

11 FÉVRIER 2009

Proposition d'une Directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation

AVIS À LA COMMISSION EUROPÉENNE

RAPPORT

FAIT AU NOM DE LA COMMISSION DES AFFAIRES SOCIALES PAR

MM. CLAES ET BROTCHI

I. INTRODUCTION

Le 29 octobre 2007, le président de la délégation du Sénat du Comité d'avis fédéral chargé des questions européennes a transmis à la commission des Affaires sociales une « Proposition de Directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation » (voir annexe au présent rapport).

Il s'agit en l'espèce d'un document réglementaire qui s'inscrit dans le cadre des dispositions prévues dans le projet de « Traité de Lisbonne » concernant le contrôle de la subsidiarité, et qui relève des documents pour lesquels la Commission européenne a formulé la demande formelle, confirmée par le Conseil européen des 15 et 16 juin 2006, que lui soient communiquées, dans un délai raisonnable, les observations éventuelles à propos de la teneur du document.

La commission des Affaires sociales a mis ce point à l'ordre du jour de sa réunion du 14 janvier 2009 en vue de contrôler la procédure de subsidiarité et de proportionnalité. La commission est arrivée à la conclusion, à l'unanimité des 12 voix exprimées, que la proposition de directive respectait les principes de subsidiarité et de proportionnalité.

La commission a également décidé, à nouveau à l'unanimité des 12 voix exprimées, d'émettre un avis sur le fond à propos de ladite proposition de directive à l'attention de la Commission européenne. À cet effet, la commission a organisé, le 28 janvier 2009, l'audition des personnes suivantes:

— le professeur Xavier Rogiers, Chef de service du Centre de Transplantation, unité de Chirurgie, *Universiteit Gent*;

— la professeur Kristel Vandenbosch, service de Pédiatrie du Centre hospitalier universitaire de Liège;

— le professeur Yves Vanrenterghem, département Pathophysiologie, service Néphrologie, *UZ Leuven*;

— la professeur Martine Antoine, service de Chirurgie cardiaque, Hôpital Erasme.

Le compte rendu de ces auditions figure au chapitre III du présent rapport.

Les deux rapporteurs, les sénateurs Claes et Brotchi, ont ensuite élaboré, sur la base des renseignements et points de vue ainsi récoltés, une proposition d'avis — voyez le chapitre IV — que la commission des Affaires sociales a examinée lors de sa réunion du 11 février 2009. Plusieurs membres de la commission ont alors émis des observations et suggestions en vue d'améliorer le texte de cette proposition d'avis. Après discussion, la commission des Affaires sociales a finalement approuvé, le 11 février 2009, son avis adressé à la Commission européenne. Le texte de l'avis, tel qu'il a été approuvé par la commission, est reproduit dans le document nº 4-1148/2.

II. PORTÉE DE LA PROPOSITION DE DIRECTIVE

La proposition de directive établit des règles visant à assurer des normes élevées de qualité et de sécurité des organes d'origine humaine destinés à être transplantés dans le corps humain, afin de garantir un niveau élevé de protection de la santé humaine.

La proposition de directive s'applique au don, à l'obtention, au contrôle, à la caractérisation, à la conservation, au transport et à la transplantation d'organes d'origine humaine destinés à la transplantation.

Les États membres veillent à l'établissement d'un programme national de qualité couvrant toutes les étapes de la chaîne qui va du don à la transplantation ou à l'élimination et destiné à garantir le respect des règles définies dans la directive.

Les États membres doivent veiller à ce que l'obtention ait lieu dans des organismes d'obtention respectant les règles établies dans la directive. L'on entend par organismes d'obtention: un établissement de soins de santé, une équipe ou un service hospitalier ou un autre organisme autorisé par l'autorité compétente à procéder à l'obtention d'organes humains.

Les activités médicales, comme la sélection des donneurs, doivent être réalisées conformément aux recommandations et sous la supervision d'un médecin au sens de la directive européenne 2005/36/CE.

Le transport d'organes est également soumis à des règles strictes afin de garantir l'intégrité de l'organe au cours du transport et de réduire au maximum la durée du transport.

Les transplantations ont lieu dans des centres de transplantation qui doivent respecter les règles établies dans la directive européenne.

La proposition de directive donne également des précisions quant à la traçabilité, qui est très importante dans le cadre du don d'organes. Les États membres veillent à ce que tous les

organes obtenus et attribués sur leur territoire fassent l'objet d'une traçabilité du donneur au receveur et inversement, de manière à protéger la santé des donneurs et des receveurs. À cet égard, il convient de mettre en œuvre un système d'identification permettant d'identifier chaque don et chacun des organes qui lui sont associés.

Les États membres veillent à l'existence d'un système de notification permettant de signaler, d'examiner, d'enregistrer et de transmettre les informations pertinentes nécessaires concernant les incidents et les réactions indésirables graves susceptibles d'influer sur la qualité et la sécurité des organes humains qui pourraient être imputés à l'obtention, au contrôle ou au transport des organes, ainsi que toute réaction indésirable grave observée pendant ou après la transplantation qui pourrait être reliée à ces activités

Les principes fondamentaux régissant le don d'organes sont aussi expressément avancés. Les dons d'organes humains sont volontaires et non rémunérés; l'obtention des organes s'effectue sur une base non lucrative.

L'obtention ne peut avoir lieu que si toutes les exigences en vigueur en matière de consentement ou d'autorisation ont été remplies.

La proposition de directive préconise des mesures destinées à protéger les donneurs vivants, les données à caractère personnel, la confidentialité, la sécurité de traitement ainsi que l'anonymat des donneurs et des receveurs.

III. AUDITION

A. Exposés

a) Exposé du professeur Xavier Rogiers, Chef de service du Centre de Transplantation, unité de Chirurgie, Universiteit Gent

Pour son exposé, le professeur Rogiers s'est appuyé essentiellement sur des exemples relatifs aux transplantations hépatiques, étant donné qu'il s'agit de sa spécialité.

Globalement, les choses ont évolué de manière très positive dans le domaine des transplantations. Le registre européen de transplantation hépatique contient les données relatives à plus de 50 000 transplantations hépatiques, provenant de l'ensemble des centres européens, lesquels sont soumis à des audits. Le registre européen est l'un des meilleurs registres au monde en matière de transplantations.

Mais, pour tous les organes, un même problème se pose: le nombre de patients inscrits sur la liste d'attente a fait un tel bond en avant que les organes disponibles ne suffisent plus, ce qui entraîne une certaine mortalité et morbidité parmi ces patients. À l'heure actuelle, nous nous rapprochons progressivement du point où le risque de décès d'un patient malade est plus élevé avant qu'après la transplantation. Le professeur Rogiers souligne qu'il ne faut pas se focaliser uniquement sur la mortalité des patients inscrits sur la liste d'attente, mais qu'il faut être tout aussi attentif à la maladie et aux coûts qu'elle entraîne en raison du long délai d'attente, ce qui a des conséquences avant et après la transplantation. En outre, les médecins procèdent déjà à une certaine sélection des patients pour le simple motif que tous ne peuvent pas subir une transplantation. Pour les transplantations hépatiques, le critère qui prévaut est que le patient doit avoir un taux de survie de 50 % à 5 ans.

Plusieurs pistes peuvent être explorées pour solutionner le problème de la pénurie d'organes. Ainsi, on peut rechercher des sources supplémentaires d'organes, travailler plus efficacement, réduire le nombre d'indications en améliorant la prévention, en recourant aux thérapies alternatives et en prévenant les retransplantations.

En ce qui concerne les sources d'organes, le professeur Rogiers s'attarde quelque peu sur la question des donneurs marginaux. Il s'agit en l'espèce de donneurs dont les organes sont de qualité moindre et qui sont donc moins demandés par les centres de transplantation. Certes, aucun organe n'est parfait. Toutefois, la situation devient particulièrement délicate lorsqu'il y a un risque de transmission de pathologies du donneur au receveur, lorsque l'organe est affecté par des maladies et que celles-ci sont donc également transmises au receveur ou lorsque l'organe risque de fonctionner moins bien ou de ne pas fonctionner du tout. En outre, lorsqu'un organe devient disponible, on n'a que quelques heures pour le transplanter, si bien que l'on n'a pas le temps d'examiner s'il est exempt de toutes les maladies susceptibles de mettre la santé du receveur en danger ni d'évaluer sa qualité. C'est ainsi qu'en Allemagne, on s'est rendu compte après coup que l'on avait transplanté des organes d'un donneur contaminé par la rage. Le point positif est que grâce à Eurotransplant, on a pu déterminer dans les 24 heures quels patients avaient reçu un organe de ce donneur.

Les donneurs sont de plus en plus âgés: 25 % d'entre eux ont plus de 60 ans, ce qui provoque aussi une baisse de la qualité des organes. On constate également une diminution du nombre de donneurs à la suite d'un accident de la circulation et une augmentation du nombre de donneurs à la suite d'une anoxie, même si les risques sont plus élevés lorsqu'il s'agit de ce type de donneurs. Le fait qu'un organe est marginal ou non dépend donc du rapport risque/bénéfice pour le receveur. Il faut être conscient que le donneur parfait n'existe pas.

En ce qui concerne la directive européenne, le professeur Rogiers précise qu'il y a une certaine séquence à respecter dans la description de la transplantation d'organes. Il y a le don d'organes ou le prélèvement d'organes, l'attribution de l'organe, la transplantation et, enfin, le suivi thérapeutique. En Allemagne, chacune de ces étapes est placée sous la responsabilité d'une instance distincte alors qu'en Belgique, les centres de transplantation sont chargés à la fois du don et de la transplantation. L'attribution est effectuée par Eurotransplant. La directive emploie d'autres termes. En ce qui concerne le don, elle renvoie à l'organisme d'obtention et, pour ce qui est de l'attribution, elle fait référence à l'organisation d'échange. S'agissant de la transplantation et du suivi thérapeutique, elle renvoie aux centres de transplantation.

Selon le professeur, Eurotransplant est l'organisation idéale pour l'attribution en Europe. Tout en respectant la législation nationale de chaque pays en matière d'attribution, elle est néanmoins parvenue à développer un système de solidarité entre les différents pays au profit des patients nécessitant une transplantation en urgence. Eurotransplant joue également un rôle important dans le cadre de la normalisation, par l'intermédiaire de comités qui discutent, entre autres, du prélèvement d'organes et définissent les critères de qualité à respecter pour les différents organes. Enfin, Eurotransplant fournit un travail précieux en matière de traçabilité et de contrôle de la qualité, éléments qui figurent également parmi les priorités de la directive européenne.

À la lecture du texte de la directive, on constate avec étonnement que celle-ci vise le don, l'obtention, le contrôle, la caractérisation, la conservation, le transport et la transplantation d'organes. Un point important a manifestement été oublié: l'attribution des organes. Comment

les organes sont-ils attribués à tel ou tel patient ? Il est essentiel pour l'ensemble des citoyens de tous les pays de savoir selon quels critères objectifs un organe est attribué.

L'article 4 de la directive concerne les programmes nationaux de qualité, qui sont responsables des modes opératoires, de la traçabilité et de la notification des réactions indésirables. Le professeur Rogiers pense qu'Eurotransplant est, sans le moindre doute, l'organisation idéale pour assurer cette fonction dans notre pays.

Le texte de la directive fait ensuite une distinction entre les organismes d'obtention et les centres de transplantation. En Belgique, les centres de prélèvement et les centres de transplantation sont actuellement regroupés dans un seul et même organisme. On peut également observer une différence de qualité entre, d'une part, les pays où ces centres sont regroupés et, d'autre part, les pays où ils sont séparés. La Belgique et l'Autriche sont les pays qui obtiennent les meilleurs résultats, en raison du lien contrôlé qui unit le prélèvement et la transplantation. Il serait dommage d'envisager la création d'un centre de prélèvement national en réponse à la directive en question. Selon le professeur Rogiers, ce serait une mauvaise décision.

L'article 15 porte sur la protection du donneur vivant. Cet article particulièrement important est composé de trois volets: le consentement éclairé, les critères de sélection et le registre. La notion de consentement éclairé est définie dans la littérature spécialisée. Il est généralement admis que ce consentement doit comprendre trois parties: l'information, la compréhension de l'opération et la détermination. L'intervenant estime que ce serait effectivement un progrès de parvenir pour cette opération à une sorte de consensus sur le consentement éclairé. Un tel consensus est d'ailleurs en voie d'élaboration en ce moment en France. Cet aspect est assurément important, car la pression sur le donneur ne dépend pas seulement des facteurs classiques, mais aussi tout simplement de l'état dans lequel se trouve le receveur.

L'évaluation d'un donneur vivant peut être soit très complexe, soit très simple. Elle doit toujours être adaptée à la situation. Le professeur Rogiers doute dès lors qu'il soit possible de définir des normes en la matière. Il préférerait que ces normes ne soient pas trop détaillées, de sorte qu'il soit toujours possible, dans une situation nécessitant qu'un don soit fait de toute urgence par un donneur vivant pour sauver la vie d'un patient, d'obtenir un maximum d'informations et de tests dans un laps de temps très court en vue de pratiquer la transplantation avec le maximum de garanties.

Il existe également des registres de donneurs vivants. La question est toutefois de savoir comment organiser ces registres en y associant le pays lui-même. Il serait préférable de laisser à Eurotransplant le soin d'organiser ces registres.

En résumé, le professeur Rogiers met en garde contre une régulation trop stricte. Il est également essentiel de considérer que chaque donneur est précieux, même s'il est marginal. Il est nécessaire d'abaisser au maximum les barrières pour que les hôpitaux puissent détecter tout donneur éventuel. L'intervenant plaide pour que les centres de transplantation belges continuent à effectuer les prélèvements. Eurotransplant permet de s'appuyer sur des structures existantes et, en ce qui concerne les registres, il est possible de se baser en partie sur les registres existants et de les développer pour les mettre en conformité avec les dispositions de la directive.

b) Exposé de la professeur Kristel Vandenbosch, service de Pédiatrie du Centre hospitalier universitaire de Liège

La professeur Vandenbosch est pédiatre et clinicienne chargée de la transplantation de moelle osseuse, de cellules souches et de sang de cordon. Elle souhaite formuler quelques remarques sur le texte de la proposition de directive.

Premièrement, on remarque en lisant le texte qu'il est question d'organes que tout le monde connaît, tels que le foie, les reins, le cœur et les poumons. Mais il ne faut pas perdre de vue que d'autres organes peuvent aussi s'avérer très utiles. Par exemple, les très jeunes enfants nés avec le syndrome de l'intestin court — qui les empêche d'absorber les nutriments nécessaires à leur survie et à leur croissance — ont tout intérêt à subir une transplantation intestinale. Dans le domaine de la pédiatrie, il ne faut pas non plus oublier les enfants souffrant de problèmes oculaires, pour lesquels une transplantation de cornée est capitale. Par conséquent, lors du décès d'un donneur, il faut penser non seulement aux organes communs, tels que le foie, les reins et le cœur, mais aussi aux autres organes utiles.

En deuxième lieu, elle confirme que les donneurs sont de plus en plus âgés. Cette constatation témoigne évidemment d'une évolution positive, à savoir la diminution du nombre d'accidents de la route et l'augmentation de la qualité de vie. Or, on trouve déjà beaucoup moins de donneurs pour les enfants que pour les adultes. Il est donc aussi dans l'intérêt des enfants que la réglementation autorise une certaine souplesse, de manière à accroître leurs chances de trouver un organe à transplanter, même si cela implique, par exemple, de devoir procéder à une seconde transplantation quelques années plus tard parce que l'organe n'était pas parfait.

Enfin, elle se réfère au film « Sept vies », qui traite des transplantations d'organes.

c) Exposé du professeur Yves Vanrenterghem, département Pathophysiologie, service Néphrologie, UZ Leuven

Le professeur Vanrenterghem examine, en guise d'introduction, l'évolution qui s'est produite ces dernières années. Lorsqu'il assumait encore la présidence d'Eurotransplant, il a été informé des initiatives prises par la Commission européenne en vue de légiférer dans le domaine de la qualité des organes. À l'époque, il a eu l'opportunité de procéder à d'intenses échanges de vues à ce sujet avec la Commission européenne. Il a la conviction d'être parvenu à expliquer clairement aux membres du groupe de travail que le problème de la qualité des organes n'est pas la préoccupation première et ne pourrait en tout cas pas entraîner une diminution du nombre d'organes disponibles. Le problème majeur en effet est le manque d'organes. Dans l'intervalle, plusieurs initiatives ont été prises et des modifications ont été apportées afin de veiller au maximum à ce que tout organe mis à disposition puisse être utilisé.

Le professeur Rogiers a déjà précisé qu'un changement était intervenu ces dernières années dans le profil des donneurs retenus pour le prélèvement d'organes en vue d'une transplantation. Il a employé aussi l'expression « donneurs marginaux ». Toutefois, le professeur Vanrenterghem souhaiterait que, dans le futur, on abandonne le mot « marginal » en raison de sa connotation négative auprès du grand public. Aux États-Unis, on utilise désormais l'expression « *expanded donorpool* ». Cela peut paraître un détail, mais un mot peut avoir un impact considérable dans les médias et peut créer l'impression qu'il s'agit en l'espèce d'organes « marginaux » au sens péjoratif du terme.

On peut se demander pourquoi on utilise aujourd'hui des organes dont on ne tenait pas compte il y a vingt ans. Est-ce bien justifié ? Le professeur Vanrenterghem met l'accent sur plusieurs changements importants intervenus au cours des vingt dernières années. Tout d'abord, il faut citer les progrès de la thérapie immunosuppressive, ce qui permet d'utiliser désormais un plus grand nombre d'organes en toute sécurité. Le profil des patients inscrits sur la liste d'attente a, lui aussi, sensiblement évolué. Actuellement, plus de 25 % d'entre eux ont plus de 65 ans. Aujourd'hui, il y a suffisamment d'études scientifiques qui montrent qu'un rein provenant d'un donneur âgé de plus de 65 ans peut être transplanté sans problèmes chez un patient de plus de 65 ans. Eurotransplant a d'ailleurs développé à cet effet un système d'enregistrement spécifique qui prévoit que les organes de donneurs âgés de plus de 65 ans sont transplantés de préférence chez des receveurs de plus de 65 ans.

Le professeur Vanrenterghem signale un écueil à éviter: inscrire dans la loi des critères pour définir un « *expanded donor* ». Le débat sur l'adoption de la loi relative au don d'organes a eu lieu en 1986. À l'époque, le législateur belge a opté pour une définition de « la mort » susceptible d'évoluer en même temps que la science, en faisant référence à l'état de celle-ci au moment du constat de décès. L'intervenant estime que nous nous trouvons à présent dans une situation comparable. Il est fort possible qu'une personne non éligible aujourd'hui en qualité de donneur parce que ses organes ne peuvent entrer en ligne de compte, puisse quand même être retenue, d'ici quelque temps, comme donneur potentiel, grâce aux progrès de la science. Une législation trop stricte pourrait représenter un frein à l'application des progrès scientifiques, dans la mesure où il faudrait plusieurs années pour pouvoir l'adapter.

Au cours des deux dernières années, l'intervenant a pu suivre d'assez près les propositions émises au sein de la Commission européenne. Durant cette période, l'accent mis au départ sur la qualité des organes a été déplacé sur la pénurie d'organes. Il convient également de laisser une certaine liberté aux équipes de prélèvement et de transplantation. Ainsi, il y a cinq ans, personne n'aurait envisagé d'utiliser les organes d'un donneur séropositif. Depuis, plusieurs transplantations d'organes ont été rapportées entre un donneur séropositif et un receveur également séropositif, subordonnées à la condition que ce dernier poursuive son traitement antisida. La notion de « *expanded donorpool* » est une donnée dynamique qu'il faut associer aux progrès de la science. Bien entendu, les organes transplantés doivent être sûrs, mais il est impossible de tout prévoir. En Europe, on effectue plus de 10 000 transplantations par an. Il a été fait état d'un cas unique de transmission de la rage, dont le professeur Rogiers a déjà parlé, et d'un cas de transmission de tumeur très maligne. Il importe de souligner qu'Eurotransplant est un système transparent qui fonctionne parfaitement et qui est capable de réagir promptement, comme ce fut le cas dans l'affaire de la rage.

Le professeur Vanrenterghem estime que le texte de la directive a évolué dans le bon sens et s'efforce de protéger les receveurs sans provoquer aucunement une baisse du nombre de donneurs. Il s'est réjoui de constater qu'un certain nombre de mesures sont prises en vue de continuer à élargir l'éventail des donneurs.

Enfin, il aimerait faire une observation à propos de l'enregistrement. Pour lui, ce point demeure une des grandes faiblesses d'Eurotransplant, alors qu'aux États-Unis, par exemple, tout centre de transplantation qui, à la fin de l'année, n'a pas transmis ses résultats à l'organisme national perd son agrément. Malheureusement, le bât blesse au niveau de l'enregistrement des opérations au sein d'Eurotransplant. Pour améliorer les choses, on pourrait rattacher de l'une ou l'autre manière l'agrément en tant que centre de transplantation à

l'enregistrement des opérations, ou prévoir un subventionnement de ces registres, par exemple en réservant légalement une partie du remboursement des frais d'une transplantation à l'enregistrement des données. En effet, ce n'est que par l'enregistrement des donneurs décédés et des donneurs vivants et par l'analyse des données que l'on pourra évaluer dans quelques années la pertinence des décisions prises aujourd'hui. La nécessité d'un registre se fait surtout sentir pour les donneurs vivants. L'on recourt de plus en plus souvent à des donneurs vivants et le suivi de ceux-ci est trop peu contraignant. Par conséquent, il n'est toujours pas possible de déterminer scientifiquement si, à long terme, le don d'un rein n'est pas préjudiciable pour la santé du donneur.

d) Exposé de la professeur Martine Antoine, service de Chirurgie cardiaque, Hôpital Erasme

Mme Antoine est spécialisée en chirurgie cardiaque et pulmonaire. Elle réalise des transplantations et est également présidente du Conseil belge de transplantations.

Elle souscrit pleinement aux exposés de ses collègues et estime qu'il est normal que l'on travaille à une norme européenne permettant de contrôler la qualité et la sécurité des organes. La Belgique a la chance de pouvoir faire appel aux services d'Eurotransplant. Elle espère pouvoir encore approfondir cette coopération par le biais du Conseil belge de manière à élaborer de meilleurs registres, domaine dans lequel une amélioration est effectivement possible. Elle espère, à cet égard, une meilleure collaboration avec le ministère de sorte que les propositions des spécialistes dans ce domaine puissent être suivies d'effets sur le terrain. Le professeur Vanrenterghem a proposé par exemple de lier l'enregistrement de données à l'agrément des centres de transplantation. C'est effectivement une piste de réflexion possible. Les médecins ont envers leurs patients le devoir scientifique de disposer de données correctes.

Il ne faut surtout pas négliger l'aspect de l'attribution des organes, qui doit avoir lieu de façon aussi transparente que possible. C'est, en effet, le stade par excellence du processus où il existe un risque de fraude. Eurotransplant règle cela très bien. Il faut toutefois tenir compte de ce risque pour d'autres pays européens.

Bien que, dans sa spécialisation, elle n'ait pas affaire à des donneurs vivants, elle considère que de meilleurs registres sont effectivement nécessaires dans ce domaine. Tous les documents indiquent qu'il y a lieu de garantir l'anonymat du donneur. Il est cependant difficile à maintenir dans certains cas. Il faut parfois être certain du lien de parenté ou de l'absence de lien de parenté. Le Conseil belge vérifie également comment les donneurs vivants peuvent être assistés. En effet, il faut également penser aux conséquences physiques ou professionnelles pour le donneur. Un donneur de rein est en incapacité de travail durant un mois ou plus. Qui paiera son salaire ? Pourra-t-il encore prétendre à un emprunt hypothécaire ? Il reste encore beaucoup de choses à préciser dans ce domaine et elle peut assurer aux membres de la commission que les membres du Conseil belge de transplantations sont déterminés à contribuer à trouver des solutions aux questions qui se posent en la matière.

B. Discussion

Mme Van Ermen souligne qu'un citoyen belge peut refuser d'être donneur pour des raisons religieuses ou éthiques tout en ayant la possibilité d'être lui-même receveur. Que pensent les experts de cette situation ?

Le professeur Vanrenterghem confirme que toute personne a le droit de se faire enregistrer comme « non-donneur » et que l'on peut effectivement se demander si elle a le droit, dans ce cas, de bénéficier d'une transplantation d'organe. Il s'agit là d'une question très délicate qui fait d'ailleurs l'objet de discussions depuis déjà de longues années, plus précisément depuis l'entrée en vigueur de la loi du 13 juin 1986. C'est une situation qui s'est déjà présentée par le passé et qui a été résolue, en pratique, par l'inscription de l'intéressé en dernière position sur la liste prioritaire.

Le professeur Van Renterghem est d'avis qu'il faut en tout état de cause respecter la liberté du citoyen individuel mais qu'il faut démontrer par tous les moyens possibles qu'il n'est pas rationnel de refuser d'être donneur. À titre personnel, il estime toutefois que l'on irait trop loin si l'on pénalisait les personnes qui persistent malgré tout dans leur refus d'être donneur.

Le professeur Rogiers souligne qu'il est important que les communes fournissent des informations exactes. Une analyse des sites Internet des communes de Flandre occidentale révèle que seules 25 % d'entre elles fournissent des informations correctes sur les différentes possibilités offertes par la législation.

Mme Van Ermen demande si des étrangers viennent en Belgique afin d'y bénéficier d'une transplantation d'organe.

Le professeur Vanrenterghem admet qu'il s'agit là d'un problème délicat. Lorsqu'il assumait la présidence d'Eurotransplant, il y eut plusieurs tentatives pour le résoudre mais aucune n'a jamais abouti. La loi de 1986 dispose que les organes doivent être attribués en fonction de cinq critères, dont celui de la « balance nationale », lequel prévoit que, si la Belgique exporte cinq cents reins, par exemple, à des fins de transplantation, elle doit en recevoir un nombre équivalent en retour. Ce principe a été instauré en raison de l'existence d'écarts énormes, en termes proportionnels, au niveau du nombre de donneurs entre les différents pays membres d'Eurotransplant. Même le législateur a estimé que le principe de solidarité, qui fonde la réglementation, pourrait être mis à mal si une population déterminée venait à constater que tous les organes qu'elle met à disposition sont exportés à l'étranger à des fins de transplantation. C'est pour cette raison que le principe de la « balance nationale » a été instauré.

Le fait qu'il y ait de plus en plus de Néerlandais qui se fassent inscrire sur une liste d'attente en Belgique en vue d'une transplantation est contraire à ce principe. On pourrait facilement remédier au problème en faisant en sorte que le système informatique de la « balance nationale » tienne compte non plus du lieu de la transplantation mais du domicile du receveur. Cela permettrait de garantir le respect du principe de solidarité. L'intervenant souligne qu'il exprime là un point de vue personnel.

M. Claes approuve cette proposition et suggère qu'on la fasse figurer dans l'avis à fournir à la Commission européenne. Le critère du domicile semble être un bon critère étant donné qu'il est facile à vérifier.

Il constate que la proposition de directive vise en premier lieu à garantir la qualité et la sécurité des transplantations d'organes, ce qui devrait permettre en tout cas de mieux lutter contre le trafic d'organes. Ce que la Commission européenne a omis, en revanche, de régler dans sa proposition de directive, ce sont les modalités d'attribution et d'obtention des organes. Les États membres appliquent des systèmes différents, qui peuvent aller, par exemple, du

consentement présumé du donneur jusqu'au consentement donné par la famille du donneur. Toutefois, étant donné qu'il s'agit en l'espèce d'un problème à caractère éthique, on préfère laisser aux États membres le soin de le régler eux-mêmes. L'intervenant estime que cela risque de mettre en péril le principe de solidarité. La Commission européenne ne devrait-elle pas réglementer davantage dans ce domaine ?

Le professeur Rogiers juge l'idée intéressante mais sait, par expérience, qu'elle est totalement irréaliste. Le principe du consentement présumé, tel qu'il prévaut dans notre pays, n'est, selon lui, pas compatible avec la mentalité protestante qui règne en Allemagne ou aux Pays-Bas, par exemple.

La professeur Antoine souligne que le critère du domicile peut lui aussi entraîner souvent des abus, en raison du fait qu'il est difficile à contrôler par une organisation telle qu'Eurotransplant. Elle suggère d'utiliser éventuellement le numéro de la carte d'identité, que l'on peut contrôler immédiatement.

Le professeur Vanrenterghem rappelle qu'en vertu de la législation belge, tout centre de transplantation peut placer sur sa liste d'attente des patients domiciliés en Belgique ou dans l'un des pays faisant partie de l'organisme d'échange. Il est dès lors parfaitement autorisé de placer un Néerlandais sur la liste d'attente, bien que la législation belge n'oblige pas les centres à le faire.

L'intervenant cite l'exemple d'un patient qui a obtenu gain de cause auprès du tribunal en invoquant la libre circulation des biens et des services au sein de l'Union européenne. Il s'agit donc d'un problème plutôt complexe au niveau juridique, dont la solution se trouve peut-être dans le concept de « balance nationale ».

Ensuite, le professeur Vanrenterghem insiste pour que les législations des différents États membres soient le plus possible harmonisées. Pour ce faire, il demande aux responsables politiques de prendre contact avec leurs homologues des autres États membres. Par exemple, il existe une « *task force* » aux Pays-Bas qui a conseillé de copier le système belge d'« *opting out* » ou de « consentement présumé », mais le ministre compétent n'a malheureusement pas suivi ce conseil. Quoi qu'il en soit, une plus grande uniformité est absolument nécessaire.

Mme Vanlerberghe plaide pour que l'on maintienne, dans un premier temps, un nombre de donneurs aussi élevé que possible en vue de continuer à assurer l'offre. Il a été souligné à juste titre que la plupart des communes restent en défaut d'expliquer la législation belge à la population. La majorité de la population pense qu'une personne qui ne fait aucune démarche devient automatiquement, conformément à la législation, un donneur à sa mort. Il est pourtant possible également de faire la démarche de s'inscrire soit comme donneur, soit comme « non-donneur ». Cela peut prêter à confusion. Peut-être est-il possible de résoudre ce problème dans la législation belge.

Le professeur Rogiers reconnaît qu'il y a matière à confusion. C'est la raison pour laquelle les communes de Flandre occidentale ont reçu un texte type dont elles pouvaient se servir. Il souligne toutefois que la population belge a une attitude positive vis-à-vis du don, ce qui fait une grande différence par rapport aux pays comme les Pays-Bas ou l'Allemagne.

Le professeur Vanrenterghem rappelle que lors de l'élaboration de la loi du 13 juin 1986, l'on est parti du principe que les gens se souciaient peu de ce qu'il adviendrait de leur corps après

leur mort. C'est pourquoi il a été décidé que tout le monde serait automatiquement donneur, mais aurait malgré tout le droit de refuser de l'être. Au fil des ans, des initiatives ont été prises en vue d'inciter les gens à s'inscrire explicitement comme donneurs. Cette démarche est pourtant quelque peu contradictoire, étant donné le fondement sur lequel repose la loi en question. Il y a très peu de cas de refus parmi la population belge et ceux-ci sont généralement dus à des raisons d'ordre religieux.

La sensibilisation du corps médical est un problème quelque peu différent. Les médecins actifs dans le secteur de la transplantation voient régulièrement des patients mourir à cause de l'impossibilité de pratiquer une transplantation. Chaque médecin a comme première mission de sauver la vie des patients et, lorsqu'il n'y parvient pas, il le ressent toujours comme un échec dans une plus ou moins grande mesure. Il existe pourtant une étape suivante, où le patient décédé peut faire office de donneur. Le corps médical travaillant dans les hôpitaux (non seulement les hôpitaux universitaires mais aussi les cliniques périphériques) est confronté chaque année au manque d'organes. En effet, les médecins oublient souvent que leur patient décédé peut encore faire office de donneur. Dans ce cadre, il convient de saluer l'initiative du projet GIFT destiné au personnel médical des services de soins intensifs des hôpitaux aigus, qui a été lancé en 2006 et dont le but est d'optimiser la détection des donneurs et la gestion des organes.

Le professeur Antoine souligne que les petits hôpitaux ont besoin de moyens financiers pour pouvoir faire en sorte qu'un patient décédé puisse devenir un donneur. En effet, ce genre d'hôpital dispose rarement du personnel nécessaire pour s'occuper d'un donneur.

Mme Vanlerberghe demande si les deux types de donneurs — les personnes qui ne font rien et qui sont dès lors automatiquement considérées comme donneurs et les personnes qui se font expressément enregistrer comme donneurs — sont traités différemment par les centres de transplantation.

Le professeur Rogiers répond que le coordonnateur en matière de transplantation adoptera probablement une attitude légèrement différente selon le cas pour parler à la famille. La famille des personnes qui n'ont rien entrepris sera informée de la transplantation prévue et l'on se renseignera pour savoir s'il est certain que le défunt ne s'est jamais opposé au principe du don d'organes. La famille de l'autre catégorie de personnes est tout simplement informée qu'une transplantation aura lieu.

M. Brotchi fait remarquer que la proposition de directive concerne l'ensemble de l'Union européenne qui est composée de 27 États membres. Par contre, l'organisation Eurotransplant couvre un nombre plus limité de pays. Existe-t-il d'autres organisations actives en matière de transplantation qu'Eurotransplant ? Dans l'affirmative, y a-t-il une coopération transfrontalière avec ces organisations ? Que peut-on faire pour promouvoir la coopération transfrontalière ? En effet, à l'heure actuelle, les centres de transplantation dans notre pays reçoivent parfois une demande d'un patient qui n'est pas un ressortissant d'un des pays ayant adhéré à Eurotransplant.

Le professeur Vanrenterghem répond qu'Eurotransplant est la seule organisation internationale qui existe aujourd'hui dans ce secteur à l'échelle européenne, à l'exception de Scandiatransplant probablement. Par ailleurs, il y a UK Transplant, l'Agence de biomédecine en France, Iberiatransplant et North-Italian Transplant, mais il y a peu de coopération, voire aucune coopération, avec ces organisations. Il y a certes eu des contacts à la suite de la

proposition de directive européenne, mais un patient de Lille, par exemple, ne peut toujours pas faire appel à un donneur en Belgique parce que la France ne fait pas partie d'Eurotransplant, situation que l'intervenant déplore.

Il plaide dès lors pour une organisation paneuropéenne. Cela ne signifie évidemment pas que l'on puisse tout simplement expédier un organe par avion de Malaga à Copenhague, étant donné qu'il faut, même dans un tel cadre, tenir compte de la situation locale. Dans des cas très aigus, cela doit toutefois être possible et, pour ce faire, une organisation paneuropéenne est nécessaire. Malheureusement, on n'a toujours pas réussi jusqu'à présent à en instituer une. Le professeur Vanrenterghem espère que la Commission européenne prendra également une initiative à cet égard.

Mme Lanjri renvoie à l'exposé du professeur Rogiers qui plaide pour que la Commission européenne règle également le problème de l'attribution. Comment procède-t-on actuellement à celle-ci au niveau belge ? Existe-t-il une législation qui prévoit quels patients sont prioritaires ? Suit-on simplement un ordre chronologique ou tient-on compte d'éléments tels que l'âge, le syndrome, etc. ? Les choses se décident-elles dans chaque centre de transplantation séparément ? Un patient peut-il se faire inscrire sur différentes listes d'attente ?

Le professeur Rogiers répond qu'un patient peut se faire inscrire sur une seule liste d'attente. Il serait également souhaitable qu'il en aille de même dans un contexte européen et que l'on ne figure pas sur différentes listes d'attente dans différents États membres simultanément. Le système d'attribution diffère en fonction de l'organe dont il s'agit. Les facteurs qui jouent un rôle dans le cas de la transplantation de reins sont différents des facteurs qui jouent un rôle dans le cas d'autres organes parce qu'il est important que les reins du donneur soient compatibles avec ceux du receveur. Dans le cas du foie, l'on tient compte du « *miltscore* » qui indique le risque de mortalité dans les 3 prochains mois: plus ce score est élevé, plus la probabilité de transplantation est grande.

Les critères utilisés font l'objet d'un débat permanent entre experts dans toutes sortes de commissions et au sein même d'Eurotransplant. Il importe dès lors que ces experts disposent de registres permettant d'évaluer immédiatement quel serait l'effet si l'on touchait à ces critères. De toute façon, un système d'attribution est toujours un compromis.

Le professeur Vanrenterghem confirme l'absence d'un régime d'attribution européen. Le système actuel utilisé par Eurotransplant a pratiquement été repris tel quel par UK Transplant, en ce qui concerne les reins. Les systèmes français et espagnol sont eux totalement différents. Il n'y a donc aucune uniformité entre les États membres de l'Union européenne.

Le professeur Rogiers ajoute qu'Eurotransplant est parvenue à concevoir un système d'attribution qui tient compte des législations des différents États membres concernés. Par exemple, Eurotransplant est en mesure d'adapter immédiatement son système à une modification de la législation allemande, sans que les autres pays concernés ne s'en ressentent. Malgré le fait que la Belgique et l'Autriche aient des législations complètement différentes en matière de transplantation de foie, la collaboration entre les deux pays est parfaite dans le cadre d'une approche solidaire. C'est assurément l'un des mérites d'Eurotransplant.

Le professeur Antoine attire l'attention sur le fait que certains pays affiliés à Eurotransplant ne jouent pas toujours le jeu correctement, en particulier en ce qui concerne les transplantations de coeurs et de poumons. Si le système fonctionne selon le principe de la solidarité, chaque

médecin considère néanmoins que son patient est le plus important. Pour les transplantations de coeurs et de poumons, les délais d'attente sont très courts, de 24 à 48 heures. Eurotransplant rédige des documents décrivant l'état de santé du patient qui sont contrôlés par trois experts externes. Cependant, au sein du système Eurotransplant, il y a un pays en particulier qui demande la priorité pour 70 % de ses patients. On peut difficilement accepter une telle attitude. En Belgique, seuls 10 à 15 % des cas sont considérés comme prioritaires. Il importe dès lors d'introduire un système de contrôle au niveau européen.

Mme Van Ermen évoque les découvertes médicales récentes, présentées dans le *New England Journal of Medecine*, qui permettent de garder des reins « frais » pendant une plus longue période. Ces techniques ne peuvent-elles être utilisées que pour les reins ou peuvent-elles l'être également pour d'autres organes ? Sont-elles prometteuses d'après les experts ? Quelles sont les attentes ?

Le professeur Vanrenterghem répond que cela concerne principalement la conservation des reins sur machine. Auparavant, tous les reins étaient conservés sur machine. Il s'agissait de grands appareils qui ne permettaient pas de s'échanger des reins entre différents pays. D'autres techniques de conservation ont été utilisées depuis lors, mais on a récemment redécouvert la machine en raison des possibilités qu'elle offre en matière de contrôle de la qualité des reins transplantés. Cette technique permet en effet de mieux vérifier certaines caractéristiques et de décider, le cas échéant, de ne pas utiliser un rein en particulier pour une transplantation. On s'est aperçu également que la conservation sur machine réduisait considérablement le nombre de reins qui mettaient plus de temps à commencer à fonctionner. Un rein qui fonctionne directement offre de meilleures perspectives en matière de transplantation. Selon l'intervenant, cela ne signifie pas pour autant que tous les reins devront désormais être conservés sur machine, même lorsqu'ils ont été prélevés sur un donneur parfaitement sain. Il n'en reste pas moins que la conservation sur machine peut s'avérer utile pour une grande partie des donneurs.

Le professeur Vanrenterghem indique que cela ne concerne que les reins. Par ailleurs, des études ont été réalisées en vue de déterminer si la conservation sur machine présentait un intérêt pour la qualité des poumons et des foies, mais on ne dispose jusqu'à présent d'aucun exemple en provenance de la pratique clinique.

IV. PROPOSITION D'AVIS À LA COMMISSION EUROPÉENNE

A. Proposition d'avis des rapporteurs

À la suite de l'audition organisée en commission des Affaires sociales du Sénat, le 28 janvier 2009, au sujet des transplantations d'organes et conformément aux règles et pratiques déjà en vigueur en Belgique, le Sénat belge formule les remarques et recommandations qui suivent.

a) Le problème du nombre de donneurs

Le problème majeur, qui se pose pour tous les organes, réside dans le fait que les listes d'attente se sont considérablement allongées et que le nombre d'organes disponibles ne suffit plus. Plusieurs pistes peuvent être explorées pour tenter de résoudre ce problème de pénurie. On peut rechercher des sources supplémentaires d'organes, travailler plus efficacement, réduire le nombre d'indications en améliorant la prévention, en recourant aux thérapies

alternatives et en prévenant les retransplantations. Plusieurs initiatives ont été prises et des modifications ont été apportées afin de veiller au maximum à ce que tout organe mis à disposition puisse être utilisé. Un changement est ainsi intervenu ces dernières années dans le profil des donneurs retenus pour le prélèvement d'organes en vue d'une transplantation (« *expanded donorpool* »).

On utilise aujourd'hui des organes que l'on n'aurait pas retenus il y a vingt ans. Il y a donc eu beaucoup de changements au cours des vingt dernières années. Tout d'abord, il faut citer les progrès de la thérapie immunosuppressive, qui permet d'utiliser désormais un plus grand nombre d'organes en toute sécurité. Ensuite, il y a suffisamment d'études scientifiques montrant que des organes en provenance d'un donneur âgé peuvent être transplantés sans problèmes chez un receveur âgé. Il faut donc certainement envisager la « moindre » qualité d'un organe en fonction du rapport risque/bénéfice qu'il présente pour le receveur.

Le Sénat demande dès lors à la Commission européenne de veiller à ne pas imposer des critères trop stricts en la matière. La notion de « *expanded donorpool* » est une donnée dynamique qu'il faut rattacher aux progrès de la science.

b) Exécutants aux différents stades

Le texte de la directive fait une distinction entre les organismes d'obtention et les centres de transplantation. En Belgique, les centres de prélèvement et les centres de transplantation sont actuellement regroupés en un seul et même organisme. La Belgique obtient d'excellents résultats en termes de qualité, en raison précisément du lien contrôlé qui existe entre le prélèvement et la transplantation. Le Sénat voudrait donc demander à la Commission européenne d'indiquer qu'il ne doit pas obligatoirement s'agir d'organismes distincts.

c) Enregistrement

L'enregistrement est un point faible du système d'enregistrement européen. Le Sénat demande à la Commission européenne d'envisager la possibilité de rattacher d'une manière ou d'une autre l'enregistrement à l'agrément en tant que centre de transplantation ou de prévoir une forme de subventionnement de ces registres, en faisant par exemple affecter par la loi une partie du remboursement des frais d'une transplantation à l'enregistrement des données.

Le Sénat pense que le texte pourrait être plus strict à cet égard. En effet, ce n'est qu'en recensant les donneurs décédés et les donneurs vivants et par l'analyse des données que l'on pourra évaluer dans quelques années la pertinence des décisions prises aujourd'hui.

d) Attribution des organes

En Belgique, un patient ne peut se faire inscrire que sur une seule liste d'attente. Il serait souhaitable qu'il en aille de même dans le contexte européen et que l'on ne puisse pas figurer sur plusieurs listes d'attente dans différents États membres simultanément. Le système d'attribution diffère en fonction de l'organe dont il s'agit et implique toujours un compromis. Il n'existe pas de régime d'attribution européen et la question de l'attribution est totalement absente du champ d'application de la directive examinée. Il est pourtant essentiel pour les citoyens de tous les États membres de savoir selon quels critères un organe est attribué. Il est capital que l'attribution s'effectue en toute transparence, car c'est à ce stade que se situe particulièrement le risque de fraude.

Eurotransplant est parvenue à concevoir un système d'attribution qui tient compte des législations des différents États membres concernés. Mais ici aussi il y a lieu de prévoir un système de contrôle strict, car la solidarité peut également être mise en péril à ce niveau, notamment en demandant prématurément la priorité pour des patients.

Le Sénat demande à la Commission européenne de définir plus clairement sa position concernant la création d'un système d'attribution au niveau européen.

e) Principe de solidarité

La proposition de directive vise en premier lieu à garantir la qualité et la sécurité des transplantations d'organes. En revanche, ce que la Commission européenne a omis de régler dans sa proposition de directive, ce sont les modalités du consentement en vue de l'obtention des organes. Bien entendu, les divers États membres appliquent des systèmes fort différents, qui peuvent aller du consentement présumé du donneur jusqu'au consentement donné par la famille du donneur. La solidarité risque par conséquent d'être mise en péril.

En son temps, la législation belge a par exemple opté pour un système « *opting out* » et donc, pour un maximum de solidarité. Si l'on constate que cette solidarité bénéficie en fait à un pays qui a choisi un système réputé moins efficace pour obtenir des organes, la solidarité risque d'être mise à mal.

C'est précisément ce qui se passe actuellement au sein d'Eurotransplant. Le problème posé par l'offre inégale de donneurs dans les différents pays membres d'Eurotransplant a déjà fait l'objet de nombreuses discussions au sein d'Eurotransplant. L'inégalité est évidente, certains pays ayant deux fois plus de donneurs que d'autres. La Belgique et l'Autriche ont en moyenne entre 22 et 25 donneurs par million d'habitants, les Pays-Bas et l'Allemagne, seulement 12. Cela signifie que les Néerlandais ont beaucoup moins de chances de pouvoir bénéficier d'une transplantation d'organe que les Belges, par exemple. Lors de l'instauration du nouveau système, l'on a aussi introduit le principe de la « balance nationale », du moins pour les reins. Cela signifie que lorsque 400 reins sont prélevés sur des donneurs décédés, le système informatique qui les répartit veille à ce qu'il y ait environ 400 reins transplantés en Belgique. Actuellement, nous sommes confrontés au problème que de nombreux étrangers, notamment des Néerlandais, s'inscrivent sur nos listes d'attente pour tenter de tirer profit de notre système.

On pourrait y remédier en faisant en sorte que le système informatique de la « balance nationale » tienne compte non plus du lieu de la transplantation mais du domicile du receveur. Cela permettrait de garantir le respect du principe de solidarité. Toutefois, pour un organisme comme Eurotransplant, il n'est peut-être pas facile de contrôler le domicile. Une autre solution serait d'utiliser le numéro de la carte d'identité, qui est immédiatement contrôlable.

Le Sénat demande à la Commission européenne d'élaborer un tel système afin de garantir la solidarité entre les différents États membres, dont les législations divergent.

f) Coopération transfrontalière

La proposition de directive concerne les 27 États membres de l'Union européenne. Eurotransplant couvre un nombre plus limité de pays. Il existe en outre de nombreux autres

organismes de transplantation, tels que Scandiatransplant, UK Transplant, Iberiatransplant, et d'autres, qui ne collaborent pas toujours bien entre eux.

Dans le cadre de la proposition de directive examinée, le Sénat demande dès lors à la Commission européenne de mettre sur pied une organisation paneuropéenne, qui respecte en même temps les situations locales, etc.

B. Discussion

M. Brotchi souhaite attirer l'attention sur certains éléments spécifiques qui lui sont chers dans la proposition d'avis élaborée par les deux rapporteurs. Il s'agit tout d'abord du principe de solidarité qui fait l'objet du point *e)* de la proposition d'avis. Le problème réside dans le fait que dans l'Union européenne, les organes s'obtiennent selon divers systèmes très différents les uns des autres. En Belgique, par exemple, contrairement à d'autres pays, on part du principe que le consentement du donneur ou de sa famille est implicite. Ce système d'« *opting out* » offre une solidarité maximale.

Le fait que tous les États membres de l'Union européenne ne participent pas au système Eurotransplant — ce qui n'est pas le cas de la Belgique — pose aussi un problème de taille. Notre pays pâtit quelque peu de cette situation, notamment parce que des patients néerlandais s'inscrivent en Belgique en vue de subir une transplantation d'organe. C'est la raison pour laquelle le point *e)* de la proposition d'avis suggère d'utiliser dorénavant le critère du domicile de l'intéressé au lieu de l'endroit où est pratiquée la transplantation, dans le but de protéger nos concitoyens. En effet, des pays comme la Belgique et l'Autriche comptent environ 22 à 25 donneurs par million d'habitants, alors que l'Allemagne et les Pays-Bas n'atteignent que la moitié de cette proportion. Tout le monde ne joue donc pas le jeu de manière équitable.

L'on plaide dès lors pour l'établissement de règles plus transparentes dans le contexte d'une organisation paneuropéenne qui respecte les situations locales et les conditions différentes en vigueur dans les États membres, tout en organisant un échange d'organes au niveau européen en prenant les précautions nécessaires en matière de sécurité, de qualité et de solidarité. Tout le monde aura à y gagner, étant donné que l'offre d'organes n'en sera que plus grande, ce qui permettra de mieux répondre aux besoins des patients.

M. Claes se félicite du sérieux avec lequel la commission des Affaires sociales du Sénat a mené la discussion sur la proposition de directive. Il évoque l'audition qui a fourni beaucoup d'informations utiles et permis de répondre à de nombreuses questions posées par les membres de la commission. Toute cette procédure a débouché sur la proposition d'avis rédigée par les deux rapporteurs.

L'intervenant propose cependant de compléter encore ledit avis sur certains points:

— au point *a)*, compléter le premier alinéa par la phrase suivante:

« Par ailleurs les donneurs sont de plus en plus âgés: 25 % des donneurs ont plus de 65 ans. »

— ajouter un point *g)* rédigé comme suit:

« *g)* Sensibilisation du corps médical

Les médecins actifs dans le secteur de la transplantation voient régulièrement des patients mourir faute d'avoir pu bénéficier d'une transplantation. Chaque médecin a pour mission première de sauver la vie des patients et, lorsqu'il n'y parvient pas, il le ressent toujours comme un échec dans une plus ou moins grande mesure. Il existe pourtant une étape suivante, où le patient décédé peut faire office de donneur.

Le Sénat demande s'il est possible d'insérer dans la directive une disposition portant explicitement sur la sensibilisation des médecins. »

— ajouter un point *h)* rédigé comme suit:

« *h)* Protection des donneurs vivants

Il est essentiel de protéger les donneurs vivants. L'article de la proposition de directive y relatif est composé de trois volets: le consentement éclairé, les critères de sélection et le registre.

Le Sénat demande que l'on évite une hyper-régulation trop stricte. L'évaluation d'un donneur vivant peut se révéler très complexe et doit dès lors être adaptée à la situation concrète. Des normes trop strictes risquent donc d'avoir un effet néfaste. »

Mme Van Ermen se rallie à l'avis et aux ajouts proposés. Elle souligne qu'il est parfaitement possible à l'heure actuelle, par exemple, de transplanter un rein provenant d'un donneur de 70 ans chez un patient de 25 ans.

M. Elsen pense aussi que la proposition d'avis complétée correspond à ce que les différents experts ont déclaré au cours de l'audition. À ses yeux, c'est surtout la transparence dans le contexte européen qui est un élément capital. Il souligne également l'importance de la « balance nationale », dont le but est de veiller à l'équilibre entre, d'une part, les organes mis à la disposition des patients étrangers et, d'autre part, les organes provenant de donneurs étrangers.

La commission approuve ces ajouts.

V. VOTES

La proposition de loi ainsi amendée est adoptée à l'unanimité des 9 membres présents.

Confiance a été faite aux rapporteurs pour la rédaction du présent rapport.

Les rapporteurs,
Dirk CLAES.
Jacques BROTCHI.

La présidente,
Nahima LANJRI.

Bulgarie: *Narodno Sabranie*

Evaluation

of the subsidiary check on the Commission proposal for the Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation

Procedures:

Question 1 Which parliamentary committees were involved in the subsidiarity check and how?

The Health Care Committee of the Parliament adopted an opinion on the Commission proposal.

The European Affairs Committee adopted a report which contains assessment of the implementation of the subsidiarity principle and represents the position of the National Assembly.

Question 2 Was the plenary involved?

No, according to the Rules of Organisation and Procedure of the National Assembly the European Affairs Committee of Parliament takes final decisions on European issues.

Question 3 At which level the final decision was taken and who signed it?

The report on the Commission proposal was adopted by the European Affairs Committee of Parliament and signed by its chairman.

Question 4 Which administrative services of your parliament were involved and how (please specify)?

The Directorate for EU Affairs prepared an expert opinion on the proposal which includes an assessment of the implementation of the subsidiarity principle.

Question 5 Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

Yes, Government has placed at the disposal of the National Assembly its framework position on the Commission proposal.

Question 6 In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

Not relevant

<u>Question 7</u> Did you consult your regional parliaments with legislative powers?

Not relevant.

<u>Question 8</u> Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

No.

<u>Question 9</u> What was the chronology of events?

1. Government has placed at the disposal of the National Assembly its framework position on the Commission proposal containing assessment of the implementation of the subsidiarity principle.
2. The Directorate for EU Affairs of the National Assembly prepared an expert opinion on the Commission proposal which includes also an assessment of the implementation of the subsidiarity principle.
3. The Health Care Committee of the Parliament adopted an opinion on the Commission proposal.
4. Using all above mentioned documents and after hearing representatives of the Ministry of Healthcare, the Committee on European Affairs has adopted a report which contains assessment of the implementation of the subsidiarity principle and represents the position of the National Assembly.

<u>Question 10</u> Did you cooperate with other national parliaments in the process? If so, by what means?

Yes, informal contacts have been established with representatives of other national parliaments.

<u>Question 11</u> Did you publicise your findings? If so, by what means?

Yes, on the internet site of the National Assembly and in the news bulletin "Evrovesty" "Euronews".

<u>Question 12</u> Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No procedural changes with regard to the subsidiarity check mechanism has been introduced since September 2008.

<u>Findings:</u>

<u>Question 1</u> Did you find any breach of the principle of subsidiarity?

The Draft Directive unifies quality and safety standards of human organs transplantation in the EU Member States and will facilitate trans-border exchange. It will lead to standardization of collecting data on organs, donors and recipients and will create a mechanism of providing this information. These objectives and trans-border organ exchange in particular cannot be met effectively at national level and a regulation at EU level is required. The proposal does

not regulate the ways of obtaining donor permission in procuring organs and does not contain regulations about the clinical evaluation regarding organ compatibility and transplantation. They are subject to the national legislation of the Member States. Therefore the proposal complies with Article 152 , Para 5, sentence 2 of the Treaty establishing the European Community, according to which the measures implementing high quality and safety standards of organs and substances of human origin do not have to affect national regulations concerning donors and the medical use of organs and blood. That is why it can be said that the proposal does not breach the principle of subsidiarity.

<u>Question 2</u> Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Not necessary.

<u>Question 3</u> Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

Yes, the Commission's justification was founded satisfactory.

<u>Question 4</u> Did you encounter any specific difficulties during this subsidiarity check?

No.

<u>Question 5</u> Any other comments?

No.

Cyprus: *Vouli ton Antiprosopon*

ANSWERS TO THE QUESTIONNAIRE OF THE COSAC SECRETARIAT CONCERNING THE EXERCISE ON THE COMMISSION PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL ON STANDARDS OF QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION

Procedure:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The examination was undertaken exclusively by the Parliamentary Committee on European Affairs. The Parliamentary Committee on European Affairs had a meeting on the 20th January 2009 in order to examine the said proposal.

2. Was your plenary involved?

The plenary of the House of Representatives was not involved in this exercise, but this does not preclude the possibility of the plenary being involved in future proceedings and / or when the mechanism of subsidiarity control, as provided in the Lisbon Treaty, actually enters into force.

3. At which level the final decision was taken and who signed it?

The decision was taken and approved unanimously by the Parliamentary Committee on European Affairs.

4. Which administrative services of your parliament were involved and how?

The European Affairs Service of the House of Representatives was involved with the exercise on a technocratic level. The European Affairs Service prepared a report regarding the compliance of the proposal with the principles of subsidiarity and proportionality.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

The competent bodies of the executive power, the Ministry of Health, were invited to express their opinion and/or views on the proposal at the meeting of the Parliamentary Committee on European Affairs on the 20th January 2009.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

There is no bicameral parliament in Cyprus.

7. Did you consult your regional parliaments with legislative powers?

There are no regional parliaments in Cyprus.

8. Did you consult any non-governmental organizations, interest groups, external experts or other stakeholders?

Yes. Representatives of the National Bioethics Commission of the Republic of Cyprus and the ***Paraskevaidion Transplant Centre*** took part in the meeting of the Parliamentary Committee of European Affairs and expressed their views and opinions.

9. What was the chronology of events?

On the 16th December 2008, the legislative proposal, accompanied by material concerning the principle of subsidiarity and proportionality and the explanatory note of the COSAC Secretariat concerning the matter, were distributed to the members of the Parliamentary Committee on European Affairs.

The documents were also accompanied by a letter from the president of the Parliamentary Committee on European Affairs, explaining the requirements of the task before the Committee. The European Affairs Service examined the legislative proposal and submitted a report offering its recommendations to the Parliamentary Committee regarding the compliance of the proposal with the principles of subsidiarity and proportionality.

At the meeting of the 20th January 2009, the Parliamentary Committee on European Affairs taking into account the material before it, submitted both by the COSAC Secretariat and the European Affairs Service, examined the legislative proposal in question on the basis of the criteria set out under the Lisbon Treaty concerning the principles of subsidiarity and proportionality.

Representatives from the Ministry of Health, the National Bioethics Commission of the Republic of Cyprus and the ***Paraskevaidion*** Transplant Center were invited by the European Affairs Committee to take part in the meeting and express their views on the proposal.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

No.

11. Did you publicise your findings? If so, by what means?

No.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No. However, in the future, it is possible that the Parliamentary Committee on European Affairs will, first, notify the competent sectoral parliamentary 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 subsidiarity principle, the President and the Plenary of the House of Representatives could also be notified. The findings of the Committee may also be transmitted to the government. The abovementioned procedure is currently under consideration by the House of Representatives.

Findings:

13. Did you find any breach of the principle of subsidiarity?

The Committee found that the proposal is not in breach with the principle of subsidiarity.

14. Did you adopt a reasoned opinion on the Proposal? (if so, please enclose a copy)

No.

15. Did you find the Commission's justification with regard to the principle subsidiary satisfactory?

The Commission's justification concerning the principle of subsidiarity was found to have been satisfactory.

16. Did you encounter any specific difficulties during the examination?

The Committee felt that the time available to the national parliaments would not be sufficient if, during the time frame provided, the proper procedure were to be followed, during which more interested parties and the competent sectoral parliamentary committees would be invited to express their opinion on the matter at hand.

17. Any other comments?

No.

Czech Republic: *Poslanecká Sněmovna*

Evaluation of the COSAC 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

Procedures:

1. **Which parliamentary committees were involved in the subsidiarity check and how?**

The Committee for European Affairs so far. It discussed the proposal preliminary at the meeting held on 18 December 2008 and it decided to submit the proposal for deliberation to the Committee on Health Care that will deliberate the proposal at its next session.
The Committee for European Affairs has finally deliberated the proposal at its session on 22 January 2009 after hearing the Government's preliminary position presented by the Deputy Minister of Health Care, MUDr. Markéta Hellerová, and the rapporteur's report. The proposal was assessed based on its legal basis, its compliance with international agreements and on the basis of its likely economic and legal effects. The draft conclusions contained in the rapporteur's report were submitted to discussion and finally were adopted by a large majority of the members of the Committee.
The result of the deliberation was a Committee resolution (see the enclosed annex). According to Article 109 (4) of the Rules of Procedure, a resolution of the Committee for European Affairs is deemed to be the position of the Chamber of Deputies.

2. Was the plenary involved?

No.

3. At which level the final Decision was taken and who signed it?

The final resolution was taken by the Committee for European Affairs and it was signed by its Vice-chairperson, Mr. Jan Bauer, by the Committee Rapporteur, Mr. Jozef Kochan, and by the Committee Verifier, Mr. Josef Šenfeld.

4. Which administrative services of your parliament were involved and how (please specify)?

The Parliamentary Institute of the Office of the Chamber of Deputies provided expert assistance to the Committee for European Affairs and especially to the Member of Parliament, who was appointed by the Committee as rapporteur.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

The government provided the Committee for European Affairs with the regular Government's preliminary position on the proposal without any particular reference to the principle of subsidiarity.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

No.

7. Did you consult your regional parliaments with legislative powers?

-

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

No.

9. What was the chronology of events?

The draft Directive was received by the Chamber of Deputies on 11 December 2008. The Committee for European Affairs started to deliberate the document on 18 December 2008. The deliberation continued and finished at the Committee´s meeting on 22 January 2009. The deliberation of this proposal by the Committee on Health Care has not yet taken place.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

There has been a standard form of cooperation with other national parliaments especially through our representative in Brussels.

11. Did you publicise your findings? If so, by what means?

Each resolution of the Committee is publicised on its website. No special type of publication was used in this case.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No, not so far. There is a debate on the introduction of the procedural changes in connection with the ratification of the Lisbon Treaty.

Findings:

13. Did you find any breach of the principle of subsidiarity?

No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Yes. See the enclosed annex.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

The Committee for European Affairs did not find it unsatisfactory.

16. Did you encounter any specific difficulties during this subsidiarity check?

No.

17. Any other comments?

-

Parliament of the Czech Republic
CHAMBER OF DEPUTIES
2009
5th electoral term

373rd

RESOLUTION

of the Committee for European Affairs
from its 46th session held on 22 January 2009

on the Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation [16521/08, COM(2008) 818 final]

The Committee for European Affairs after hearing the report of MUDr. Markéta Hellerová and after hearing the report of the rapporteur, Mr Jozef Kochan, and after deliberating the matter

a p p r o v e s **the position annexed to this resolution.**

Josef Šenfeld	Jozef Kochan	Jan Bauer
Committee Verifier	Committee Rapporteur	Committee Vice-Chairman

Annex to Resolution No. 373

DOCUMENT 16521/08

Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation

COM(2008) 818 final, 16521/08
Interinstitutional file 2008/0238/COD

- **Legal basis:**
  Article 152(4) of the EC Treaty

- **Date of transmission to the Council of the EU:**
  8 December 2008

- **Date of transmission to the Chamber of Deputies via the Committee for European Affairs:**
  11 December 2008

- **Date of deliberation in the Committee for European Affairs:**
  18 December 2008 (first round)

- **Procedure:**
  Co-decision

- **Preliminary position of the Government [pursuant to Article 109a(1) of the Rules of Procedure of the Chamber of Deputies]:**
  Dated 19 December 2008, delivered to the Committee for European Affairs on 7 January 2009 via the ISAP system.

- **Conformity with the principle of subsidiarity:**
  The proposal complies with the principle of subsidiarity.

- **Background and subject:**

At this time, organ transplantation is the most effective procedure in end stage renal failure and the only treatment available for end stage failure of organs such as the liver, lungs, and heart.[1] Even at this time, however, the main problem shared by all European countries is a lack of organs. The differing approaches and standards used in each of the Member States for organs and donors are also a problem.

The Commission has decided to respond in a number of ways to the fast pace of development of this medical treatment and to the differences between each of the Member

[1] In Europe, almost 40,000 patients are on waiting lists. The mortality rate of patients waiting for a heart, liver or lung transplant is usually in the range of 15 – 30 percent.

States. First it adopted the *Communication on organ donation and transplantation of 31 May 2007,*[2] in which it assessed what activities should be undertaken at the Community and Member State level to help increase the number of organ donors in the whole EU and ensure the quality and safety of these procedures.

Based on this Communication, it was decided that new Community legislation on organ donation and transplantation would be adopted along with an action plan for the same area. However, since the very beginning, some of the Member States have been of the opinion that it would be more appropriate to adopt the action plan first, evaluate its functionality, and only then, if appropriate, agree to the legislative proposal. It is planned that the first evaluation of the proposed action plan accompanying this proposal for the directive will be performed sometime in 2012.

Article 152(4)(a) of the EC Treaty makes it possible to address the problems with the mentioned legislation at the Community level. This provision gives the European Parliament and the Council the authority to adopt through co-decision according to Article 251 of the EC Treaty harmonised healthcare measures setting high standards of quality and safety for organs and substances of human origin. On this basis, the Community has, among other things, adopted guidelines on quality and safety standards for blood in 2003 and on quality and safety standards for tissues and cells in 2004.

The first of these legal instruments is *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells.*[3]

The purpose of adopting the mentioned directive was to ensure a higher level of protection of donation, procurement, testing, preservation, storage, and distribution of human tissues and cells intended for human applications and for the preparation of products for use on humans. For this reason, this directive sets the standards for each one of the steps in the human tissues and cells application process. [4]

The main objective of the set of directives[5] on standards of quality and safety for blood was to contribute to the general trustworthiness of the quality of donated blood and blood components, to achieve self-sufficiency at the Community level, and to increase trustworthiness in the safety of transfusion chains between Member States.

As blood and blood components, human tissues and cells and organs or tissues and cells of animal origin are governed by other provisions, they are explicitly excluded from the scope of the proposed legislation. It is necessary, however, to mention the existence of these provisions also for the reason that they use the same legal basis as the proposed directive and

[2] SEC(2007) 705.

[3] Transposition period until 7 April 2006

[4] There exist two additional technical implementing directives to this directive: Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells; and Commission Directive 2006/86/ES of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

[5] Blood and blood derivatives are at this time governed by Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC.

make use of a similar structure, which can help in particular in checking compliance with the principles of subsidiarity and proportionality.

Another initiative by the Community in this area is the *Action Plan on Organ Donation and Transplantation (2009 – 2015): Strengthened Cooperation between Member States*, which has been mentioned numerous times. This document, however, is being addressed by the European Affairs Committee as a separate point and, as such, is being analysed separately.

- **Content and impact:**

The objective of the proposed directive is to ensure that human organs used for transplantation in the EU comply with the same quality and safety requirements during all the phases of the process.[6] To ensure that this objective is met, the directive imposes the obligation on the Member States to establish or appoint a national authority to ensure compliance with the requirements of the directive and to establish a system for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria.[7]

The discussed legislative proposal also deals with the protection of organ donors. It does so because most donors are often also tissue and cell donors – these donors would then be granted certain guarantees in the area of tissues or blood and other guarantees in connection with organ donation. The provisions to protect the living donor include the due evaluation of the health of the donor and comprehensive information about the risk prior to donation, the introduction of registers for living donors to follow up their health, and measures to ensure the altruistic and voluntary donation of organs by living donors. This provision is also tied to the action plan, which has a supplementary function in the creation of these instruments.

The proposed directive further imposes on the Member States the obligation to introduce national quality programmes laying down standard operating procedures and the rules ensuring traceability of organs from donation to transplantation or disposal. In the area of organ transport, the Member States shall ensure the fulfilment of requirements both on the entities involved in the transport of the organs and on the organ container used for the transport.

The directive should also serve to facilitate both cooperation between Member States and cross-border exchanges. Such cooperation should take place mainly between bodies established on the basis of this directive to take responsibility for its implementation. A register of procurement organisations and transplantation centres will also be established and reports on their activities drawn up.

The presented legislative proposal also contains provisions governing the exchange of organs with third countries and allowing Member States to establish written agreements with European organ exchange organisations, granting to them the competencies that would otherwise be the competencies of the national authority responsible for administering the directive.

[6] Thus, the matter concerns not only use, but also donation, procurement, testing, transport, and preservation.
[7] Recommendation Rec(2004)19 of the Committee of Ministers of the Council of Europe to the Member States on criteria for the authorisation of organ transplantation facilities.

Position of the Czech Republic

In the Czech Republic, the national transplantation system is at a good level and complies with most of the provisions of the presented proposal. The Transplantation Coordination Centre, established by the Ministry of Health on the basis of the *Transplantation Act,*[8] already exists in the Czech Republic as an organisational unit of the state. In fact, it is planned for the Transplantation Coordination Centre to become the authorised body for the area of organ donation and transplantation as mentioned in the directive.

Although in the framework of its Presidency the Czech Republic is not openly counting on concluding all negotiations, its ambition is to make as much progress in them as possible. Therefore, discussion of the presented proposal has already been put on the agenda of the Working group on public health.

Subsidiarity checks on acts of European law

For the period of Czech Presidency of Council of the European Union, the Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation was chosen for a subsidiarity check. The subsidiarity check on this proposal was decided at the Meeting of the COSAC Chairpersons on 7 July 2008. This decision was then confirmed at the XL Conference of Community and European Affairs Committees of Parliaments of the European Union, which was held in Paris on 3 – 4 November 2008.

The European Commission adopted the presented proposal on 8 December 2008, the date on which the eight-week deadline for national parliaments to perform the check began to run. This deadline ends on 9 February 2009.

The legal basis contained in the establishing Treaties for adopting this directive, as described hereinabove, is sufficient and allows for the adoption of the proposal for the directive.

- **Anticipated timeframe for deliberation in the EU bodies:**

In the European Parliament, the document under discussion was forwarded to the Environment, Public Health and Food Safety Committee; Legal Affairs Committee; and the Civil Liberties, Justice and Home Affairs Committee. So far, none of the mentioned committees have included the document in their meeting agendas.

- **Conclusion:**

The Committee for European Affairs

1. t a k e s i n t o a c c o u n t the Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation;

[8] Act No. 285/2002 Coll., of 30 May 2002, on organ and tissue donation, procurement and transplantation and on changes to certain acts.

2. states that the presented proposal is not in breach with the principles of subsidiarity and proportionality at this time;

3. requests the Government to inform the Committee of subsequent developments of the deliberation of this proposal;

4. resolves to forward this document, together with its resolution and Government's position, to the Healthcare Committee for information.

Josef Šenfeld	Jozef Kochan	Jan Bauer
Committee Verifier	Committee Rapporteur	Committee Vice-Chairman

Czech Republic: *Senát*

THE PARLIAMENT OF THE CZECH REPUBLIC

SENATE

Evaluation of the COSAC 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

Procedures:

1. **Which parliamentary committees were involved in the subsidiarity check and how?**

The committee responsible – Committee on EU Affairs – invited all the members of the Committee on Health and Social Policy to discuss the proposal at a joint meeting held on 7 January 2009.

2. Was the plenary involved?

Yes, the plenary deliberated on the Proposal and approved the final resolution on 8 January 2009.

3. **At which level the final decision was taken and who signed it?**

The final decision was approved by the plenary session and signed by the President of the Senate.

4. **Which administrative services of your parliament were involved and how (please specify)?**

European Union Unit and EU Committee advisor

5. **Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?**

No. The government delivered standard Explanatory Memorandum without any particular reference to the compliance with the above mentioned principle.

6. **In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?**

No.

7. **Did you consult your regional parliaments with legislative powers?**

There are no regional parliaments in the Czech Republic.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
No.

9. What was the chronology of events?

11 December 2008:	Receipt of the Proposal by the Senate
22 December 2008:	Receipt of the draft Government Explanatory Memorandum
7 January 2009:	Debate in Committee on EU Affairs
8 January 2009:	Debate in the plenary session
13 January 2009:	Submission of translated resolution to COSAC and the Commission together with the questionnaire

10. Did you cooperate with other national parliaments in the process? If so, by what means?
Cooperation by means of standard procedures through permanent representatives of national parliaments in Brussels and consultation of the IPEX web pages.

11. Did you publicise your findings? If so, by what means?
Not in any special way. The resolution of the Senate has been published on the Senate and IPEX web pages and forwarded to the government.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No adaptations have been made, but they are being considered. Changes to the Rules of Procedure of the Senate, or draft Act on the Principles of Conduct and Relations between both Chambers and in their External Relations – as the case may be – are envisaged. They are aimed at strengthening the link between parliamentary scrutiny and Government responsibility in EU affairs, especially in sensitive issues like the transfer of competences (*passerelle*, flexibility clause). The proposed changes were approved by the Senate and are currently prepared for debate by the designated bodies of the Chamber of Deputies.

<u>Findings:</u>

13. Did you find any breach of the principle of subsidiarity?
No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
Yes, reasoned opinion of conformity with the principle (copy enclosed).

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?
Yes.

16. Did you encounter any specific difficulties during this subsidiarity check?
The date of the issue just before the Christmas Holidays put a strain on planning of debates on the proposal due to the parliamentary schedule. To assure that the deadline is kept, the specialized committee was not formerly asked for an opinion but was instead invited to the meeting of the Committee on EU Affairs.

17. Any other comments?
No.

13 January 2009

T H E P A R L I A M E N T O F T H E C Z E C H R E P U B L I C
S E N A T E

7th term

88th RESOLUTION

OF THE SENATE

Delivered on the 3rd session held on 8 January 2009

Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation
(Senate Press no. N 026/07)

The Senate

I.

Welcomes the proposal of the Commission since it is of the opinion that a common European standard of quality and safety of organs embedded in a harmonized legal framework will contribute to further development of transplantation medicine in the EU;

II.

1. **Notes** that the Proposal sets only minimal framework conditions necessary to achieve compatibility of functioning of national coordination systems in the area of transplantations and organ donation, thus it is compatible with principles of subsidiarity and proportionality;

2. **Recommends** the Government, with regard to the high quality of transplantation medicine and above-average number of organ donations in the Czech Republic, to take part in all activities aimed at sharing of knowledge and expertise in this field;

III.

1. **Requests** the Government to inform the Senate about the way this position was taken into account and to provide the Senate with information on further proceeding of negotiations;
2. **Authorises** the President of the Senate to forward this resolution to the European Commission**.**

Přemysl Sobotka
sign manual
President of the Senate

Soňa Paukrtová
sign manual
Senate Verifier

Denmark: *Folketing*

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The European Affairs Committee and the Committee on Health

2. Was the plenary involved?

No

3. At which level the final decision was taken and who signed it?

The European Affairs Committee following a consultation of the Committee on Health

4. Which administrative services of your parliament were involved and how (please specify)?

The EU Secretariat of the Danish Parliament elaborated a draft proposal on the basis of the views expressed by the MP's.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

Yes, the Government provided on 15 January 2009 a subsidiarity memorandum assessing the proposal's compliance with the principle of subsidiarity. This is a standard procedure for all EU draft legislation.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

7. Did you consult your regional parliaments with legislative powers?

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

No

9. What was the chronology of events?

The proposal was first examined by the Committee on Health, which submitted its views to the European Affairs Committee on 4 January 2009. Hereafter the European Affairs Committee conducted the final check on whether the proposals complied with the principle of subsidiarity on 6 January 2009.
Finally the opinion was submitted to the European Commission on 12 February 2009.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

No

11. Did you publicise your findings? If so, by what means?

Yes the findings were published on the Danish Parliament's website on 13 February 2009.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No

Findings:

13. Did you find any breach of the principle of subsidiarity?

No

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Yes an opinion was adopted and submitted to the Cosac-secretariat and the European Commission.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

Yes

16. Did you encounter any specific difficulties during this subsidiarity check?

No

17. Any other comments?

No.

FOLKETINGET

The European Affairs Committee and the Committee on Health
The EU-Secretariat of the Folketing

Date: 12 February 2009

Opinion adopted by the
European Affairs Committee of the Danish Parliament

On the Commission's 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

At the request of COSAC, the European Affairs Committee of the Danish Parliament has conducted an assessment of whether 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" complies with the principle of subsidiarity.

It is the assessment of a majority of the European Affairs Committee and the Committee on Health, composed of the Liberal Party, the Social Democrats, the Conservatives, the Socialist People's Party, the Social-Liberal Party and Ms. Pia Christmas-Møller (Non-attached Member), that the objectives of the Directive can best be attained through regulation at the European level, and that the proposal therefore complies with the principle of subsidiarity.

A minority composed of the Danish People's Party furthermore holds the view that the subsidiarity principle can be regarded as respected given that the directive seeks to resolve a concrete problem within the area and that the purpose of the directive is minimum harmonisation as described by the Minister of Health in his answer to question no. S 891 and S 1034 (Session of the Folketing 2008-2009)

Finally a minority composed of the Red-Green Alliance has expressed the view that they find that the proposal does not comply with the principle of subsidiarity. The Red-Green Alliance's Member of the Health Committee has handed in the following minority statement:

Minority opinion:

"It emerges clearly from the Government's explanatory note that the proposal for a Directive "on standards of quality and safety of human organs intended for transplantation" does not

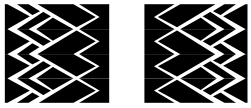
provide any guarantees for high standards in the field. That is why Member States preserve the right to maintain and introduce stricter measures at a national level.
Hence it follows that the directive does not guarantee that the exchange of human organs and substances of human origin, blood and blood derivatives across borders will be facilitated.

When the Government finds the proposal in compliance with principle of subsidiarity, it simply underlines the fact that the principle has no real substance".

Estonia: *Riigikogu*

RIIGIKOGU

PARLIAMENT OF ESTONIA
EUROPEAN UNION AFFAIRS COMMITTEE



COSAC Secretariat

10. February 2009 No 2.1-3/ **283**

Dear Messrs,

Based on the proposals from national parliaments, the COSAC Chairpersons in their meeting on 7 July 2008 in Paris agreed to carry out the second subsidiarity check of 2008 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 characterization of human organs. This decision was confirmed by the XL COSAC Meeting on 3-4 November 2008 in Paris

In order to facilitate the complication of the response we have structured it in the form of answers to the question in the aide-mémoire

1. Which parliamentary committees were involved in the subsidiarity check and how?
A: The Social Affairs Committee and the European Union Affairs Committee of Riigikogu were involved.

2. Was the plenary involved?
A: No the plenary was not involved.

3. At which level the final decision was taken and who signed it?
A: The final decision was taken by European Union Affairs Committee and was signed by the Chairman of the Committee

4. Which administrative services of your parliament were involved and how (please specify)?
A: There were no administrative services of our parliament involved.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
A: Yes, the Government provided its position with an explanatory memorandum (included)

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
A: Estonia has unicameral system.

7. Did you consult your regional parliaments with legislative powers?
A: There are no regional parliaments in Estonia.

8. Did you consult any non-governmental organizations, interest groups, external experts or other stakeholders?

A: No we did not.

9. What was the chronology of events?
A: 1) In December The European Union Affairs Committee asked the ministry of Social Affairs to present the Proposal for a COUNCIL DIRECTIVE of the European Parliament and the Council on standards of quality and safety for the donation, procurement, testing, preservation, transport and characterization of human organs to the Government.
2) On the 29 of January 2009 the Government presented its position regarding the Proposal to Riigikogu and the Social Affairs Committee gave their opinion to the European Union Affairs Committee on that subject.
3) European Union Affairs Committee gave its position on that matter on 9of February.

10. Did you cooperate with other national parliaments in the process? If so, by what means?
A. No we did not cooperate with other national parliaments.

11. Did you publicize your findings? If so, by what means?
A. The positions of the Committees are public (we put the minutes on the Riigikogu web).

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
A: No it has not.

Findings:

13. Did you find any breach of the subsidiarity principle?

A: No, we did not.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
A: Just the decision/ position. We will enclose a copy of an extract from explanatory memorandum.

15. Did you find the Commission's justification with regard to the subsidiarity principle satisfactory?
A: Yes we did.

16. Did you encounter any specific difficulties during the examination?
A: No we did not.

17. Any other comments?
A: We would like to point out that the timing was not appropriate due to the holydays in December and for further arrangements please try to avoid scheduling subsidiarity checks on the period of holidays.

Yours sincerely,

Ester Tuiksoo
Vice-Chairman of the European Union Affairs Committee
Riigikogu

Assessment of subsidiarity and proportionality

According to Article 2 of the Treaty on European Union, the principle of subsidiarity has to be followed in achieving the objectives of the Union. Subsidiarity principle is one of the central principles of the EU and it is based on the idea that higher social units (in the given case, the Community) should take upon themselves only the tasks lower social units (the member states) are not able to carry out. This reflects the principle of the EU that political decisions should always be made as close to the citizens as possible, i.e. at the lowest possible administrative and political level. Thus, except in the areas that fall within the exclusive competence of the EU, the principle of subsidiarity means that the EU will take action only if it is more effective to apply a legal act at the EU level than it can be possibly done at the national level.

Before submitting a draft act the Commission always has to assess whether the act complies with the principle of subsidiarity and at the same time justify the distribution of competences. Pursuant to Article 5 of the Treaty establishing the European Community, both conditions of Article 5(2) have to be fulfilled for the application of **subsidiarity requirement**:

1. measures for achieving the objective of the proposed act are not adequate at the level of member states (necessity criterion);

2. the objectives of the act are better achieved through Community action (criterion of effectiveness).

Besides that, the "prohibition of excess" has to be taken into account, according to which it is necessary to see that the measures of the Community would be **proportional**, i.e. would not exceed the level necessary for achieving the objectives of the Treaties.

Article 152 (4)a) of the Treaty establishing the European Community gives the Council and the Parliament the right to adopt at the Community level health measures setting high standards quality and safety of organs and substances of human origin, blood and blood derivatives.

The main objective of this directive is guaranteeing the safety and quality of organs and a high level of human health protection, and indirectly also to contribute to combating organ trafficking. The aim is to ensure that the organs used for transplantation in the EU would correspond to common quality and safety requirements, and in this way the directive should facilitate organ exchange between the Member States. The Commission considers the cooperation between the Member States in organ exchange significant help to smaller member states and to patients whose condition is severe or who need careful matching. In its explanatory memorandum the Committee highlights three main problems the directive focuses on solving – organ shortage, the quality and safety of organ transplantation and the exchange of organs between the Member States. The Commission finds that although most Member States have already adopted quality and safety standards of organ transplantation, many states still have to reach an agreement on them. Also, the exchange of organs between the Member States already exists today, but not all states are involved.

Thus the issues involve several Member States, and this directive establishing common standards of quality and safety and facilitating the exchange of organs would most probably contribute to improving the availability of organs. Also one can agree with the Commission that the directive will be of significant help to smaller Member States and patients whose condition is severe or who need careful matching.

The elaboration of this directive and applying common action plan will probably also increase the number of donated organs, which will bring significant benefit to the patients and economy of expenditures for national health systems.
In addition, the Community action in this sphere will contribute to achieving the objectives stipulated in the Treaty by creating a platform for mutual sharing of experience through reporting and exchange of information.

Proceeding from the fact that establishing standards of quality and safety for human organs meant for transplantation and purposeful cooperation will significantly contribute to improving the availability of organs, it can be said that it is not possible to achieve this objective adequately at the level of individual Member States and it is more useful to do it at the Community level. Thus the draft act meets the requirement of subsidiarity.

According to Article 152(4)a) of the Treaty, the Member States have the right to maintain and introduce more stringent measures, regardless of whether the Community adopts and plans to apply any measures and what these measures shall be like. The draft directive establishes for the Member States the obligation to appoint competent authority, adopt national quality programme and introduce several internal rules, but a Member State will maintain the right to decide on the contents of the internal rules and regulations, the pattern and content of the procedure for obtaining the agreement of the donor etc. Thus, keeping in mind the nature and extent of Community action, the draft act is consistent with securing the aim of the measure and observing the requirements of the Treaty, leaving adequate scope for national decision and taking into account the established national arrangements and the organisation and working of legal systems. In conclusion it can also be said that the draft directive does not contradict the principle of proportionality.

On the basis of the above, we are of the opinion that the adoption of the proposed draft act is in conformity with the principles of subsidiarity and proportionality.

Finland: *Eduskunta*

The subsidiarity check under the provisions of Protocol 2 on the Application of the Principles of Subsidiarity and Proportionality as attached to the Treaty of Lisbon on the Proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation

The answers of Eduskunta, Parliament of Finland

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

As the procedure took place during the Christmas break of the eduskunta, the normal future subsidiarity check procedure in the sector committees did not take place. The test was only handled by the Grand Committee.

2. Was the plenary involved?

No

3. At which level the final decision was taken and who signed it?

The decision was taken by the working sub-committee of the Grand Committee.

4. Which administrative services of your parliament were involved and how (please specify)?

EU-secretariat

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

We received a draft version of the government's communication of the EU legislation according to our national EU scrutiny procedure.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber? -

7. Did you consult your regional parliaments with legislative powers? –

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders? No.

9. What was the chronology of events? -

10. Did you cooperate with other national parliaments in the process? No.

11. Did you publicise your findings? If so, by what means? No.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how. No.

Findings:

13. Did you find any breach of the principle of subsidiarity?

No. The shortage of suitable organs is a problem in all the Member States. Efficient use of transplantations requires organ exchange across borders between the Member States. The Commission proposal ensures the high quality and safety for patients at EU level and enhances the mutual trust between national authorities and safety of their transplantation system. These results could not be achieved as effectively by national measures.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory? Yes.

16. Did you encounter any specific difficulties during this subsidiarity check? No.

17. Any other comments? -

France: *Assemblée nationale*

Paris, le 2 février 2009

Evaluation du test de subsidiarité sur la proposition de directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation

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Assemblée nationale française – Commission chargée des affaires européennes

1. Quelles commissions parlementaires ont été impliquées dans le test de subsidiarité et de quelle manière ?

Réponse : La Commission de l'Assemblée nationale chargée des affaires européennes a procédé, seule, au test de subsidiarité lors de la séance du mercredi 28 janvier, dont le compte rendu est ci-joint.

2. La séance plénière a-t-elle été impliquée ?

Réponse : Il n'y a pas eu de débat en séance publique.

3. A quel niveau la décision finale a-t-elle été prise et qui l'a paraphée ?

La décision de la Commission chargée des affaires européennes a été tacitement confirmée par la Commission des affaires culturelles, familiales et sociales, qui ne s'en est pas saisie.

4. Quels services administratifs de votre Parlement ont été impliqués et de quelle manière (merci de préciser) ?

Réponse : un membre du secrétariat de la Commission de l'Assemblée nationale chargée des affaires européennes a assuré le secrétariat des deux députés désignés co-rapporteurs.

5. Votre gouvernement a-t-il fourni des informations relatives au respect du principe de subsidiarité par la proposition de directive ?

Réponse : Les deux co-rapporteurs ont rencontré le cabinet de la ministre de la santé, en présence du service compétent (la Direction générale de la santé) et de l'organisme national concerné (l'Agence de biomédecine).

6. En ce qui concerne les parlements bicaméraux : avez-vous conduit le test de subsidiarité en coordination avec l'autre chambre ?

Réponse : Les procédures des deux assemblées sont indépendantes.

7. Avez-vous consulté les parlements régionaux de votre pays qui disposeraient de pouvoirs législatifs ?

Réponse : Cette question ne concerne pas la France.

8. Avez-vous consulté des organisations non gouvernementales, des groupes d'intérêt, des experts extérieurs ou d'autres parties prenantes ?

Réponse : Les consultations intervenues sont toutes mentionnées en réponse à la question 5.

9. Selon quelle chronologie le test a-t-il été conduit au sein de votre Parlement?

Réponse : La réunion de la Commission chargée des affaires européennes a eu lieu le 28 janvier 2009.

10. Avez-vous coopéré avec d'autres parlements nationaux ? Si oui, par quels moyens ?

Réponse : Au fur et à mesure de leur transmission par les autres parlements nationaux, les résultats du test ont été communiqués au secrétariat de la Commission chargée des affaires européennes par la représentation permanente de l'Assemblée nationale à Bruxelles. De plus, le site IPEX a été consulté.

11. Avez-vous publié vos conclusions ? Si oui, par quels moyens ?

Réponse : Les réunions de la Commission chargée des affaires européennes font chacune l'objet d'un compte-rendu public, directement accessible sur le site *Internet* de l'Assemblée nationale.

12. Votre Parlement a t-il adopté de nouvelles procédures de contrôle du principe de subsidiarité depuis septembre 2008 ? Si oui, merci de préciser comment ces nouvelles mesures ont été introduites ?

Réponse : A la suite de la loi constitutionnelle n° 2008-724 du 23 juillet 2008 de modernisation des institutions de la Ve République, qui concerne également les procédures d'examen parlementaire des questions européennes, une révision du Règlement de l'Assemblée nationale est en cours. Elle sera adoptée au cours des prochains mois.

Conclusions:

13. Avez-vous découvert un quelconque manquement au principe de subsidiarité ?

Réponse : La Commission chargée des affaires européennes n'a pas conclu dans le sens d'un manquement au principe de subsidiarité.

14. Avez-vous adopté un avis motivé sur la proposition de directive ? (Si oui, veuillez joindre une copie) ?

Réponse : La Commission chargée des affaires européennes a adopté les conclusions indiquées au compte-rendu ci-joint de sa réunion du 28 janvier.

15. Avez-vous trouvé les justifications de la Commission sur le respect du principe de subsidiarité satisfaisantes ?

Réponse : Aucune intervention n'a abordé ce point.

16. Avez-vous rencontré des difficultés spécifiques pendant l'examen ?

Réponse : Le respect de l'échéance du 6 février a imposé aux deux co-rapporteurs d'entamer sans délai leurs travaux dès la publication de la proposition de directive, puisque les travaux des assemblées parlementaires comme des ministères et des grandes administrations publiques se sont interrompus, comme toujours en cette période, en raison des fêtes de fin d'année.

17. Avez-vous d'autres observations ?

Réponse : Pas d'autre observation.

Commission chargée des affaires européennes

mercredi 28 janvier 2009

16 h 15

Compte rendu n° 86

Présidence de M. Pierre Lequiller Président

COMMISSION CHARGEE DES AFFAIRES EUROPEENNES

Mercredi 28 janvier 2009

Présidence de M. Pierre Lequiller, Président de la Commission

La séance est ouverte à seize heures quinze

I. Communication de MM. Jérôme Lambert et Didier Quentin sur le test de subsidiarité organisé dans le cadre de la COSAC sur la proposition de directive relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation (E 4173)

M. Jérôme Lambert, co-rapporteur. « Cet examen au titre de la subsidiarité et de la proportionnalité intervient dans le cadre informel décidé en liaison avec la Commission européenne, avant l'entrée en vigueur des dispositions donnant explicitement cette compétence aux parlements nationaux, lesquelles figurent dans le traité de Lisbonne.

Ce test concerté de subsidiarité sur la proposition de directive relative aux transplantations d'organes a été décidé par la COSAC des 3 et 4 novembre dernier, qui s'est déroulée à Paris lors de la présidence française.

La Commission européenne a présenté sa proposition de directive le 9 décembre et c'est le 10 décembre, le lendemain, que le délai de huit semaines imparti aux parlements nationaux pour se prononcer sur les éventuelles atteintes aux principes de subsidiarité et de proportionnalité a commencé à courir.

Ce délai, déjà bref, est raccourci par l'interruption des travaux due aux fêtes de fin d'année. La dernière fois, la Commission avait présenté sa proposition en juillet, peu de temps avant

l'interruption du mois d'août. Il conviendrait qu'à l'avenir, elle tienne mieux compte de tels éléments.

C'eût été, en l'espèce, d'autant plus nécessaire que la question des dons et transplantations d'organes est très délicate puisqu'elle met en jeu le plus profond des convictions de chacun. C'est un dossier sensible où les choix sont, en définitive, assez peu simples.

Le contexte est, en outre, difficile, marqué par une pénurie d'organes avec une estimation de 56.000 patients en attente de transplantation pour les pays de l'Union européenne. S'agissant de la France, 360 décès en liste d'attente sont intervenus en 2007. Ces personnes étaient dans l'espoir de bénéficier d'un don.

Après consultation tant de l'Agence de biomédecine, organisme national compétent, que de la Direction générale de la santé, il apparaît que la proposition de la Commission ne porte pas atteinte au principe de subsidiarité ni non plus au principe de proportionnalité.

En ce qui concerne la question de *la subsidiarité*, il faut préalablement remarquer que la Communauté européenne dispose d'une compétence claire en la matière, prévue à l'article 152 du traité. D'une part, elle peut adopter des mesures fixant des normes élevées de qualité et de sécurité des organes et substances d'origine humaine sans que ces mesures empêchent un Etat membre de maintenir ou d'établir des mesures de protection plus strictes. D'autre part, il est prévu que l'action de la Communauté dans le domaine de la santé publique respecte pleinement les responsabilités des Etats membres en matière d'organisation et de fourniture de services de santé et de soins médicaux et, qu'en particulier, les mesures ne doivent pas porter atteinte aux dispositions nationales relatives aux dons d'organes ou à leur utilisation à des fins médicales.

Le traité de Lisbonne n'apporte aucune modification de fond à ces éléments.

C'est d'ailleurs sur la même base juridique que sont déjà intervenus plusieurs textes sur le sang et les composants sanguins ainsi que les tissus et les cellules.

M. Didier Quentin, co-rapporteur. J'insiste également sur les délais. La présente proposition a été diffusée avant la « trêve des confiseurs », la précédente l'avait été avant celle des « baigneurs ». La Commission européenne doit modifier ses pratiques.

Pour ce qui concerne le texte proposé, il n'y a pas matière à réserve ni sur la subsidiarité, ni sur la proportionnalité.

Sur le premier point, on doit ajouter cinq précisions.

D'une part, les différences actuelles de niveau entre les Etats membres peuvent justifier une intervention communautaire au regard des objectifs du haut niveau de protection de la santé fixés par le traité. Néanmoins, il ne faut pas méconnaître que les échanges de greffons sont extrêmement peu nombreux d'un Etat à l'autre. C'est le résultat de la faiblesse de la durée de conservation des organes, même lorsqu'il ne s'agit pas d'organes vitaux.

D'autre part, la proposition de directive ne comprend pas la totalité des actions souhaitées par la Commission européenne en la matière, puisqu'une partie d'entre elles est prévue dans le plan d'action sur le don et la transplantation d'organes (2009-2015), qui propose des actions prioritaires dans le cadre de la compétence communautaire d'encouragement à la coopération entre les Etats membres et d'appui à leurs actions.

Dans ces circonstances, le texte proposé s'en tient au plus important avec, notamment, un programme national de qualité dans chaque Etat membre, l'obligation de prévoir une autorité nationale de contrôle des prélèvements et des greffes, des règles précises pour les organismes d'obtention comme pour les centres de transplantation, l'obligation de caractériser les organes et les donneurs afin d'éviter les transmissions de pathologie, une traçabilité entre donneur et receveur, un système de notification des incidents et réactions indésirables, ainsi que le cadre de l'échange d'informations entre les autorités compétentes des Etats membres et celui des échanges avec les pays tiers, pour éviter les trafics. Ces précautions d'ordre éthique et vital sont nécessaires, notamment dans les relations avec quelques pays très peu développés.

De plus, la proposition permet aux Etats qui coopèrent déjà entre eux dans le cadre des trois organismes existants, *Scandiatransplant*, pour l'Europe du Nord, *Eurotransplant,* pour certains pays d'Europe continentale, et *UKtransplant*, pour les îles britanniques, de poursuivre ces coopérations.

En outre, la proposition de directive respecte bien les compétences des Etats membres sur les éléments bioéthiques, à savoir le consentement et les autorisations préalables à l'obtention d'un organe. Le principe de subsidiarité va d'ailleurs assez loin en la matière puisqu'il rend, en pratique, impossible la mise en œuvre d'une carte européenne de donneur en dépit de l'intérêt que l'on peut lui porter *a priori*.

Enfin, la proposition de directive fixe, du point de vue de la France, un cadre administratif et sanitaire incontestable et d'autant plus acceptable qu'il est proche de celui déjà en vigueur en France. Celui-ci est d'ailleurs le résultat de plusieurs années de travail au sein d'un groupe d'experts.

En ce qui concerne le principe de *proportionnalité*, la proposition n'appelle pas non plus d'observation.

Il convient d'être uniquement vigilant sur le statut de la liste des données servant à caractériser les organes. Cette liste doit être indicative et non impérative, de manière à éviter tout risque de difficulté pour les Etats qui voudraient aller au-delà.

D'une manière générale, il doit d'ailleurs être clair que l'adoption de la future directive ne doit entraîner aucune régression dans aucun Etat membre. Les niveaux d'excellence atteints par certains ne sauraient, en effet, être remis en cause.

M. Jérôme Lambert. Ces conclusions positives, selon lesquelles les principes de subsidiarité et de proportionnalité sont respectés, rejoignent celles des commissions de certains parlements nationaux, notamment de Slovénie, de Lituanie, du Portugal, d'Italie et de Chypre. Au Royaume-Uni, la Chambre des Communes a demandé quelques précisions complémentaires. Il est en tout état de cause difficile de dresser, à l'heure actuelle, un bilan précis car les examens, notamment lorsqu'ils exigent l'intervention d'une commission permanente à côté de la Commission des affaires européennes, ne sont pas encore achevés.

M. Didier Quentin. A titre complémentaire, pour la France, il faut signaler l'intérêt de la carte de donneur d'organes et de tissus humains, que l'on peut directement obtenir auprès de l'Agence de biomédecine, qui a succédé à l'Etablissement français des greffes.

M. Jérôme Lambert. Cette carte facilite les procédures. Si, dans notre pays, tout le monde est présumé donneur, car il n'existe qu'un registre national des refus, en pratique, la famille

des personnes décédées est toujours consultée et il est considéré qu'elle peut faire part d'un refus. »

Conformément à la proposition des rapporteurs, la Commission *a adopté*, au regard de la subsidiarité et de la proportionnalité, les conclusions suivantes sur la proposition de directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation COM (2008) 818 final :

« *La Commission chargée des affaires européennes considère que la proposition de directive n'est pas, à ce stade et en l'état des informations dont elle a pu disposer, contraire aux principes de subsidiarité et de proportionnalité*. »

France: *Sénat*

SÉNAT

R É P U B L I Q U E
F R A N Ç A I S E

COMMISSION DES AFFAIRES EUROPÉENNES

Paris, le 4 février 2009

EXAMEN DE LA PROPOSITION DE DIRECTIVE RELATIVE AUX NORMES DE QUALITE ET DE SECURITE DES ORGANES HUMAINS

REPONSE AU QUESTIONNAIRE DE LA COSAC

I. Procédure :

1. Quelles commissions parlementaires ont été impliquées dans le test de subsidiarité et de quelle manière ?

Dans le cas du Sénat, c'est la commission des affaires européennes, dont les travaux ont un caractère transversal et qui a pour mission générale de suivre les travaux conduits par les institutions de l'Union, qui examine les textes européens au regard de la subsidiarité et de la proportionnalité dans le cadre du dialogue avec la Commission européenne.

Au cours de la réunion du 3 février 2009, la commission des affaires européennes a donc naturellement examiné la proposition de directive au regard du principe de subsidiarité, sur la base du rapport du président de la commission, M. Hubert Haenel.

2. La séance plénière a-t-elle été impliquée ?

Non.

3. A quel niveau la décision finale a-t-elle été prise et qui l'a paraphée ?

La décision finale a été prise par l'ensemble des membres de la commission des affaires européennes, qui se sont prononcés unanimement.

4. Quels services administratifs de votre parlement ont été impliqués et de quelle manière (merci de préciser) ?

L'analyse technique de la proposition de directive au regard du principe de subsidiarité a été conduite par les fonctionnaires du secrétariat de la commission des affaires européennes du Sénat.

5. Votre gouvernement a-t-il fourni des informations relatives au respect du principe de subsidiarité par la proposition de la directive ?

Non

6. En ce qui concerne les parlements bicaméraux : avez-vous conduit le test de subsidiarité en coordination avec l'autre chambre ?

Non

7. Avez-vous consulté les parlements régionaux de votre pays qui disposeraient de pouvoirs législatifs ?

Non

8. Avez-vous consulté des organisations non gouvernementales, des groupes d'intérêt, des experts extérieurs ou d'autres parties prenantes ?

Non

9. Selon quelle chronologie le test a-t-il été conduit au sein de votre Parlement ?

Le test a été conduit au cours d'une réunion de la commission des affaires européennes dont l'ordre du jour était en partie consacré au dialogue avec la Commission européenne sur le principe de subsidiarité. Outre le rapport oral du président de la commission, les membres de la commission ont pu prendre connaissance de l'analyse complète (note de cinq pages ci-jointe) du texte au regard du principe de subsidiarité, réalisée préalablement. Les conclusions ont été adoptées par les sénateurs membres de la commission à l'issue de l'exposé du président.

10. Avez-vous coopéré avec d'autres parlements nationaux ? Si oui, par quels moyens ?

Nous nous sommes informés des positions prises par certains autres parlements.

11. Avez-vous publié vos conclusions ? Si oui, par quels moyens ?

Les observations que la commission des affaires européennes du Sénat adopte au cours de ses réunions sont publiées de deux manières :

– après leur adoption, sur le site Internet du Sénat, sur les pages consacrées aux questions européennes ainsi que sur le site IPEX ;

– dans « les Actualités de la commission des affaires européennes ». Cette publication, qui paraît environ une fois par mois, rend compte de l'ensemble des débats et auditions menées par les sénateurs au sein de la commission et présente l'analyse des textes européens soumis au Sénat.

12. Votre parlement a-t-il adopté de nouvelles procédures de contrôle du principe de subsidiarité depuis septembre 2008 ? Si oui, merci de préciser comment ces nouvelles mesures ont été introduites.

Non

II. <u>Conclusions</u> :

13. Avez-vous découvert un quelconque manquement au principe de subsidiarité ?

Non

14. Avez-vous adopté un avis motivé sur la proposition de directive (Si oui, veuillez en joindre une copie) ?

Non

15. Avez-vous trouvé les justifications de la Commission sur le respect du principe de subsidiarité satisfaisantes ?

La commission des affaires européennes du Sénat a regretté que « *la Commission se contente, pour légitimer sa proposition au regard de la subsidiarité, d'une de ses formules-type qui ne démontrent rien* » et a donc estimé que la Commission européenne ne fournissait pas de véritable justification au regard de la subsidiarité.

16. Avez-vous rencontré des difficultés spécifiques pendant l'examen ?

Non

17. Avez-vous d'autres observations ?

Non

SÉNAT

COMMISSION
DES
AFFAIRES
EUROPÉENNES

RÉPUBLIQUE
FRANÇAISE

Paris, le 26 janvier 2009

CONTRÔLE DE SUBSIDIARITÉ

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Proposition de directive du Parlement européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation

(Texte retenu pour le test de subsidiarité organisé en vue de la prochaine COSAC)

1) Objet du texte

La proposition de directive vise à mettre en place un cadre communautaire permettant de garantir des normes de qualité et de sécurité identiques pour tous les organes humains utilisés à des fins de transplantation. Cette nouvelle législation concernerait toutes les phases du processus de transplantation : don, obtention, contrôle, conservation, transport et utilisation. Elle devrait faciliter les échanges d'organes entre les États membres.

2) Base juridique

La proposition se fonde sur l'article 152 du traité instituant la Communauté européenne qui fixe les objectifs et l'action de la Communauté en matière de santé publique.

Selon cet article, la Communauté doit assurer un niveau élevé de protection de la santé humaine, étant entendu que la réalisation des objectifs repose pour l'essentiel sur les politiques sanitaires des États membres. Elle a pour mission d'encourager la coopération entre États membres en matière de santé publique. Son action vient compléter les politiques nationales. Le principe de subsidiarité trouve donc pleinement à s'appliquer dans le domaine de la santé publique.

La proposition se fonde plus particulièrement sur le paragraphe 4, point a) de l'article 152 :

« Le Conseil […] contribue à la réalisation des objectifs visés au présent article en adoptant :

a) des mesures fixant des normes élevées de qualité et de sécurité des organes et substances d'origine humaine, du sang et des dérivés du sang ; ces mesures ne peuvent empêcher un État membre de maintenir ou d'établir des mesures de protection plus strictes ; »

Ce point s'applique donc directement à l'objet de la proposition de directive. Il faut préciser également que la Communauté européenne a déjà adopté des directives établissant des normes de qualité et de sécurité pour le sang en 2003 et pour les tissus et les cellules en 2004.

Il faut savoir que l'article 152 dispose également en son paragraphe 5 que « *l'action de la Communauté dans le domaine de la santé publique respecte pleinement les responsabilités des États membres en matière d'organisation et de fournitures de services de santé et de soins médicaux* » et que « *en particulier, les mesures visées au paragraphe 4, point a), ne portent pas atteinte aux dispositions nationales relatives aux dons d'organes et de sang ou à leur utilisation à des fins médicales* ». Ce paragraphe, auquel la proposition de directive ne fait pas référence, est intéressant : il apparaît comme une garantie supplémentaire pour les États membres dans le cadre de l'application du principe de subsidiarité. Toutefois, il semble introduire une contradiction au sein de l'article 152 car comment le Conseil peut-il adopter des normes élevées de qualité et de sécurité concernant les organes sans affecter les législations nationales en cette matière ? Il suggère en tout cas que la marge de manœuvre communautaire en matière de dons d'organes est étroite.

3) Motivation

Dans l'exposé des motifs de la proposition de directive, la Commission remarque qu'il existe des divergences entre États membres en ce qui concerne les exigences en matière de qualité et de sécurité des organes humains utilisés à des fins de transplantation. Des échanges d'organes transfrontaliers sont pratiqués mais limités en raison de ces divergences. Au-delà, la Commission constate que le taux de don et la disponibilité d'organes diffèrent considérablement d'un État membre à l'autre. Il s'ensuit une situation de pénurie d'organes dans de nombreux pays, dont l'une des conséquences est le trafic d'organes humains par des organisations criminelles.

Dans ce contexte, l'objectif de la Commission est d'augmenter le nombre de dons d'organes et de renforcer les échanges transfrontaliers au sein de l'Union européenne. La mise en place de normes de qualité et de sécurité communes doit permettre de constituer au niveau européen un vaste « réservoir » de donneurs qui étendra les possibilités de compatibilité pour les receveurs. Cette nouvelle situation devrait être particulièrement profitable aux receveurs nécessitant un appariement rare et aux petits États membres.

L'intervention communautaire paraît donc justifiée sur le principe.

Il est regrettable cependant que la Commission ne consacre pas véritablement de développements à la question de la subsidiarité en tant que telle. Comme trop souvent, elle se contente d'énoncer une formule-type pour justifier l'intervention de la Communauté : « *Étant donné que l'objectif de la présente directive, à savoir l'établissement de normes de qualité et de sécurité des organes humains destinés à la transplantation, ne peut être réalisé de manière suffisante par les États membres et peut donc, en raison des dimensions de l'action, être mieux réalisée au niveau communautaire, la Communauté peut prendre des mesures, conformément au principe de subsidiarité* ».

4) Contenu

Selon le principe de subsidiarité, la Communauté ne doit intervenir que « *dans la mesure où* » son action est réellement nécessaire. Il faut donc examiner si la proposition de directive ne va pas plus loin que nécessaire.

Les principales mesures de la directive sont contenues dans les chapitres II et III qui portent respectivement sur la qualité et la sécurité des organes et la protection du donneur et du receveur.

a) <u>la qualité et la sécurité des organes</u>

La directive prévoit que chaque État membre établisse un **programme national de qualité** définissant des règles et des procédures normalisées pour chaque étape de la chaîne de transplantation. La responsabilité et le suivi de ce programme doivent être confiés à une autorité nationale qui sera compétente par ailleurs pour toutes les questions relatives à l'obtention et la transplantation d'organes. La création d'une telle autorité n'est pas obligatoire ; les États ont la possibilité de simplement désigner un organisme national déjà investi d'une partie ou de la totalité de ces questions (Chapitre IV – article 18).

Les règles et procédures inscrites dans les programmes nationaux devront être conformes aux exigences fixées par la directive. Celles-ci prévoient que :

- l'obtention des organes doit être pratiquée dans des organismes (hôpital, clinique) bénéficiant d'une organisation adéquate, d'un personnel qualifié et d'installations et de matériel appropriés ;

- une caractérisation des organes, c'est-à-dire la collecte d'informations et de données médicales pertinentes sur l'organe et le donneur, doit être effectuée. Cette démarche doit permettre de conduire une évaluation adéquate des risques pour le receveur et d'optimiser l'attribution des organes. Un modèle de formulaire de 4 pages figurant en annexe de la directive détaille les informations requises ;

- le transport des organes doit s'effectuer de telle manière que l'intégrité de l'organe soit garantie et la durée du transport réduite au maximum. De plus, un étiquetage mentionnant un certain nombre d'informations utiles est exigé sur les conteneurs utilisés pour le transport d'organes ;

- la transplantation des organes s'effectue dans un « centre de transplantation » agréé par l'autorité nationale compétente qui définit précisément les activités de transplantation que le centre est autorisé à conduire ;

- un système de traçabilité des organes, du donneur au receveur et inversement, doit être mis en place par les États membres. Grâce à ce système, il doit être possible d'identifier un donneur et les dons et organes qui lui associés, dans les limites fixées par la législation relative au traitements des données à caractère personnel. Les informations pourront être conservées pendant une période de 30 ans minimum.

- un système de notification des évènements et des réactions indésirables graves après transplantation, liés ou intervenus pendant l'obtention, le contrôle ou le transport des organes, doit être mis en place par les États membres ;

- Le personnel intervenant dans la chaîne qui va du don à la transplantation doit être qualifié et avoir suivi à cet effet une formation appropriée.

b) <u>la protection du donneur et du receveur</u>

La directive fixe comme principes en la matière :

- le caractère volontaire du don d'organes humains par les donneurs vivants ou décédés et l'absence de toute rémunération liée à ce don ;

- l'interdiction de toute publicité visant offrir ou obtenir des organes humains dans le but d'en retirer un gain financier ou un avantage comparable ;

- l'information des donneurs vivants sur la nature, le risque et les conséquences de leur don éventuel ;

- le respect du droit de protection des données à caractère personnel dans le cadre des activités de transplantation d'organes, tel que prévu par la législation européenne.

Il est important de noter que la Commission ne propose aucune mesure visant à modifier les pratiques existantes au sein des États membres en matière de consentement à donner un organe. Elle souligne à juste titre que cette question fait appel en effet à des préoccupations éthiques, culturelles propres à chaque pays.

*

Outre ces mesures, la directive détaille le rôle de l'autorité désignée par chaque État membre pour traiter des questions relatives au don et à la transplantation d'organes humains. A cet égard, il est intéressant de noter du point de vue de la subsidiarité que la Commission, tout en affichant sa préférence pour une organisation unique, considère toutefois que, « *en fonction de la répartition des compétences au sein des États membres, diverses instances locales, régionales, nationales et/ou internationales peuvent s'associer pour coordonner le don, l'attribution et/ou la transplantation, dans la mesure où le cadre établi garantit l'identification des responsabilités, la coopération et l'efficacité* ».

La proposition de directive organise enfin les échanges d'organes avec des pays tiers selon les mêmes principes et autorise les États membres à déléguer à des organisations européennes d'échange d'organes (telles que Eurotransplant) les tâches et missions normalement dévolues à l'autorité nationale désignée.

Au final, il apparaît que les mesures proposées sont respectueuses des législations nationales et ne donne pas lieu à une intervention communautaire qui irait au-delà de ce qui est nécessaire.

5) Conclusion

La proposition de directive ne porte pas atteinte au principe de subsidiarité. On peut toutefois regretter de la part de la Commission l'absence d'une véritable justification sur ce point.

Germany: *Bundestag*

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?
Three committees of the German Bundestag were involved in the subsidiarity check: Committee on Health (lead committee) and the Committee on Legal Affairs and the Committee on the Affairs of the European Union, both participating in advisory capacity (committee asked for an opinion).

2. Was the plenary involved?
Yes. The final decision of the German Bundestag on the proposal's compliance with the subsidiarity principle was taken by the plenary. It was prepared by the named committees and communicated to the plenary within (reasoned) statements. On that basis the plenary took its final vote.

3. At which level the final decision was taken and who signed it?
The decision of the plenary based on the lead committee's recommendation for a decision. It was signed by the president of the German Bundestag, Prof. Dr. Norbert Lammert.

4. Which administrative services of your parliament were involved and how?
The deliberation and decision process was supported by the administrative units of the involved committees (Secretariats), by the division PA 1 – Europe and by the Parliamentary Secretariat of the German Bundestag.
The division PA 1- Europe supported the lead committee with a notation on the proposal's compliance with the subsidiarity principle and further information on the legal framework of the subsidiarity check. The named notation was distributed to all involved committees and their members.
The Secretariat of the Committee on Health prepared and organized the deliberation and decision process of the lead committee and prepared the committee's recommendation for a decision and report to the plenary which included the votes of the two other involved committees. In cooperation with the Parliamentary Secretariat it finally coordinated the information of the EU institutions.
The Secretariat of the Committee on Legal Affairs prepared and organized the deliberation and decision process of the Committee on Legal Affairs.
As the responsible division for the Bundestag's COSAC-membership, the Secretariat of the Committee on the Affairs of the European Union was in charge with the general coordination of the subsidiarity check. It distributed all relevant information (subject, procedure, responsibilities, deadline, schedule) on the COSAC subsidiarity check to the involved committees and other administrative entities, examined the proposal and provided a draft statement as basis for committee deliberations and the voting in the committee and communicated the decision to the lead committee. Finally, it sent the German Bundestag's vote and the questionnaire to the COSAC Secretariat.
Please refer also to question 9.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

The Federal Ministry on Health was invited to the involved committees and heard by each of them during their deliberation process. Moreover, the Ministry provided written reports on the proposal of the directive.

6. In case of bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
There was no cooperation with the Bundesrat.

7. Did you consult your regional parliaments with legislative powers?
Federal State parliaments were not involved.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
No.

9. What was the chronology of events?
The German Bundestag basically worked with its usual scrutiny procedure on EU documents.

- referral of the proposal to the German Bundestag
- notation on subsidiarity questions (provided by division PA 1 – Europa)
- deliberation and decision of the involved committees
- Committee on Health: recommendation for a decision and report to the plenary
- deliberation and decision of the plenary (final vote)
- transmission of the German Bundestag' decision to the EU institutions by the president of the German Bundestag
- transmission of the questionnaire to the COSAC Secretariat

Special attention was given to the strict time frame foreseen in the Protocol on the application of the principles of subsidiarity and proportionality as annexed to the draft Treaty of Lisbon.
The Committee on Health and the Committee on the Affairs of the European Union have, after completion of the subsidiarity check, reserved their right to continue their deliberations on the content of the proposal.

10. Did you cooperate with other national parliaments in the process? If so, by what means?
Since the discussion on the proposal was held intensively in the German Bundestag, the Secretariat of the Committee on the Affairs of the European Union got in touch on working level with the responsible administrative entities of the French Assemblée nationale and the British House of Commons in order to receive information on the deliberation process in their parliaments. There was, however, no formal cooperation. A short summary of the Committee on Health and the decision of the Bundestag will be published on the IPEX website.

11. Did you publicise your findings?
No.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008?
Since September 2008 no procedural changes have been taken or set into force.

Findings:

13. Did you find any breach of the principle of subsidiarity?
Concerning the principle of subsidiarity the German Bundestag in its final vote required clarifications on certain aspects, especially regulations on national health care administration.
Wording of the German Bundestag's final vote:

> "The German Bundestag has examined the EU Commission's 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; Council document 16521/08 –as regards the choice of legal basis and the subsidiarity principle. There are no concerns regarding the choice of legal basis. Regarding compliance with the subsidiarity principle, the Bundestag sees a need for clarification on certain points. It is not possible to reach a final conclusion on whether the Proposal for a Directive satisfies the principle of proportionality, as it does not contain any detailed information on the likely financial and administrative burden for the Member States"

14. Did you adopt a reasoned opinion on the Proposal?
No. A letter of the President of the German Bundestag was sent, however, to the EU institutions, stating that there were no concerns regarding the legal basis but that concerning the principle of subsidiarity clarifications on certain aspects are necessary and that there were concerns with regard to the principle of proportionality (final vote).

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?
Please refer to question 13.

16. Did you encounter any specific difficulties during this subsidiarity check?
The proposal's original (English) version and its translation into German were not completely coherent, especially Art. 19 created problems for the check and the final decision on the principle of subsidiarity.
Since the content of the health care related proposal is very complex it was to some extent difficult to differentiate between questions of subsidiarity and content.

17. Any other comments?
The committees – in full knowledge of the scope of the subsidiarity checking mechanism foreseen in the Treaty of Lisbon – decided to include observations on proportionality in their (reasoned) statements.

Germany: *Bundesrat*

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

   The Committee on European Union Questions is the Bundesrat's lead committee for deliberations on draft EU legislation and other EU documents. The Committee on EU Questions deliberates on the basis of recommendations from the sector-specific committees. The draft directive was also examined by the Health Committee, the Home Affairs Committee and the Committee on Cultural Affairs.

2. Was the plenary involved?

   On the basis of discussions in the committees, the Bundesrat adopted an Opinion on the draft directive in the plenary session on 13th February 2009.

3. At which level the final decision was taken and who signed it?

   See answer to question 2.

4. Which administrative services of your parliament were involved and how (please specify)?

   The office of the Committee on EU Questions compiled the recommendations of the Bundesrat's sector-specific committees into a text that served as the basis for the vote in the Bundesrat's plenary session.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

   The federal government transmitted a written report on the draft directive prior to deliberations in the committees, noting that in the ensuing procedure the proposed provisions should be scrutinised in the light of the requirements of the subsidiarity principle and the principle of proportionality. In the course of deliberations in the committees the federal government explained its interim assessment of the draft directive.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

   The offices of the respective lead committees informed each other about the progress of deliberations.

7. Did you consult your regional parliaments with legislative powers?

   It is incumbent upon the regional government in each federal state to ensure that the regional parliament is consulted.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

   Generally speaking interested parties, such as non-governmental organisations, are consulted directly by the federal states.

9. What was the chronology of events?

   The German version of the draft directive was transmitted to the Bundesrat on 8th December 2008 by the Commission and on 16th December 2008 by the German federal government. The Secretary-General of the Bundesrat, acting on behalf of the President of the Bundesrat, allocated the draft directive to three sector-specific committees for deliberations parallel to discussions in the Committee on European Union Questions, which was the lead committee (c.f. question 1). Deliberations were not started until after the Christmas recess. The committees involved met in the week of 26th – 30th January 2009 and adopted their recommendations for a Bundesrat Opinion. The draft directive was examined in the Committee on EU Questions on 30th January 2009. The Committee on European Union Questions adopted its recommendation to the Bundesrat for an Opinion on the basis of the Health Committee's recommendations. The Home Affairs Committee and the Committee on Cultural Affairs recommended taking cognizance of the draft directive.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

    There was no cooperation with other national parliaments. The results of deliberations in other parliaments, where available, were consulted via the IPEX system. Information on the progress of deliberations and the outcome of deliberations in the Bundesrat were also entered promptly into the IPEX system.

11. Did you publicise your findings? If so, by what means?

    The Bundesrat's resolutions are public and are freely available via the Internet.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

    The Bundesrat is currently still examining the question of whether the procedure needs to be adapted in the light of the early warning system envisaged in the Lisbon Treaty.

Findings:

13. Did you find any breach of the principle of subsidiarity?

    In the Bundesrat's view, it is also important when scrutinising respect for the subsidiarity principle to examine whether the European Community is actually competent to adopt the measure being considered. With that caveat, the Bundesrat emphasises that with reference to human organs pursuant to Article 152 Sub-section 4 Point a TEEC, the European Community is 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 Sub-section 5 Sentence 2 TEEC. On several points the draft directive steps outside this clear framework delineating competences and thus encroaches in an inadmissible manner on the intrinsic competences of the Member States.
Furthermore, the Bundesrat is also of the opinion that in particular the provisions stipulated in the draft directive on the establishment and designation of competent authorities, on procurement organisations and transplantation centres, as well as on organisations for organ exchange are not covered by the provisions on competences comprised in Article 152 TEEC. In the Bundesrat's opinion this also applies to the provisions in Article 4 Sub-section 2 Point b, Article 13, 14, 15 Sub-section 1 and Article 17 of the draft directive. The Bundesrat takes the view that a directive on the quality and safety of human organs should only contain provisions on the utilisation of test procedures to detect infectious diseases or tumours (risk assessment, conservation, transportation and ensuring traceability of organs, as well as notification of any serious undesirable post-transplantation incidents).

Furthermore the Bundesrat believes 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.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

The Bundesrat adopted the appended Opinion on the draft directive on 13th February 2009.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

The Bundesrat did not object to the Commission's justification with regard to the principle of subsidiarity.

16. Did you encounter any specific difficulties during this subsidiarity check?

No.

17. Any other comments?

The Bundesrat transmitted its Opinion on the draft directive directly to the Commission. 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.

Bundesrat Drucksache **964/08** (Beschluss) 13.02.09

Beschluss
des Bundesrates

Vorschlag für eine Richtlinie des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe
KOM(2008) 818 endg.; Ratsdok. 16521/08

Der Bundesrat hat in seiner 854. Sitzung am 13. Februar 2009 gemäß §§ 3 und 5 EUZBLG die folgende Stellungnahme beschlossen:

1. Der Bundesrat unterstützt grundsätzlich die Absicht der Kommission, durch grundlegende Qualitäts- und Sicherheitsanforderungen bei der Spende von Organen zu Transplantationszwecken ein hohes Schutzniveau für Patientinnen und Patienten in der EU zu gewährleisten und dem Organmangel sowie dem Organhandel entgegenzuwirken.

2. Der Bundesrat betont im Anschluss an seine Stellungnahme vom 21. September 2007, vgl. BR-Drucksache 419/07 (Beschluss), erneut, dass die Gemeinschaft hinsichtlich menschlicher Organe gemäß Artikel 152 Absatz 4 Buchstabe a EGV nur zum Erlass von Mindeststandards ermächtigt ist. Die Spende und die medizinische Verwendung von menschlichen Organen sind gemäß Artikel 152 Absatz 5 Satz 2 EGV der gemeinschaftlichen Zuständigkeit vollständig entzogen. Der Richtlinienvorschlag überschreitet diesen klaren Kompetenzrahmen in mehreren Punkten und greift so unzulässigerweise in die originäre Zuständigkeit der Mitgliedstaaten ein.

3. Der Bundesrat ist der Auffassung, dass insbesondere die im Richtlinienvorschlag vorgesehenen Regelungen über die Schaffung und Benennung zu-ständiger Behörden, über Beschaffungsorganisationen und Transplantationszentren sowie Organisationen zum Organaustausch nicht von der Kompetenznorm des Artikels 152 EGV gedeckt sind. Dies gilt ebenso für die in Artikel 4 Absatz 2 Buchstabe b, Artikel 13, 14, 15 Absatz 1 und Artikel 17 getroffenen Regelungen. Eine Richtlinie über die Qualität und Sicherheit von menschlichen Organen darf sich ausschließlich auf die Anwendung von Testverfahren zum Nachweis von Infektions- bzw. Tumorerkrankungen (Risikobewertung), Konservierung, Beförderung und Sicherstellung der Rückverfolgbarkeit von Organen sowie die Meldung etwaiger schwerer unerwünschter Zwischenfälle nach der Transplantation erstrecken.

4. Der Bundesrat betont, dass in Deutschland, wie in anderen Mitgliedstaaten mit leistungsfähigen Transplantationssystemen, hohe Standards für Qualität und Sicherheit gelten, die ständig weiterentwickelt werden. In den bestehenden europäischen Transplantationsverbünden gibt es bereits gut funktionierende Systeme zum Austausch von Organen.
Der Bundesrat befürchtet, dass die Schaffung einzelstaatlicher Aufsichtsbehörden sowie die Zulassung von Einrichtungen und Genehmigung von Programmen zur Organbeschaffung und -transplantation - so wie im Richtlinien-vorschlag vorgesehen - einen erheblichen

bürokratischen Mehraufwand mit sich bringen werden und sich nachteilig auf bestehende leistungsfähige Organisationsstrukturen auswirken könnten.

5. Der Bundesrat steht einem uneingeschränkten grenzüberschreitenden Organaustausch kritisch gegenüber. Die vorhandenen bzw. neu einzurichtenden Verbünde müssen hinsichtlich der Transportwege so geschaffen sein, dass keine unvertretbare Verlängerung der Ischämiezeiten eintritt, da diese maßgeblich zu einer Verschlechterung der Überlebensrate nach der Transplantation führen kann.

Soweit Mitgliedstaaten noch nicht über ausgebaute Transplantationssysteme einschließlich dafür entwickelter Datenerfassungssysteme verfügen, hält es der Bundesrat für vordringlich, diese Mitgliedstaaten im Rahmen der verstärkten Zusammenarbeit unter Berücksichtigung der jeweils spezifischen Problemlage bei der Organisation ihrer Transplantationssysteme zu unterstützen.

6. Der Bundesrat hält es für verfrüht, Systeme für einen Organaustausch zwischen den einzelnen Mitgliedstaaten zu regeln. Zum jetzigen Zeitpunkt würden solche Regelungen durch zusätzlichen bürokratischen Aufwand zu einer Verteuerung und weiteren Verknappung bei der Organspende führen und damit letztlich die notwendige Versorgung der auf eine Organtransplantation angewiesenen Patienten beeinträchtigen.
Der Bundesrat bezweifelt, dass Systeme für einen Organaustausch den allgemeinen Organmangel ursächlich beheben können.

7. Der Bundesrat hält die Maßnahmen im Sinne des Aktionsplans der Kommission zur verstärkten Zusammenarbeit zwischen den Mitgliedstaaten zum Wissens- und Erfahrungsaustausch und zur Unterstützung von Mitgliedstaaten mit noch nicht ausreichend entwickelten Transplantationssystemen sowie Maßnahmen zur Öffentlichkeitsarbeit, wie sie in der Mitteilung der Kommission an das Parlament und den Rat - Organspende und Organtransplantation - Maßnahmen auf EU-Ebene - niedergelegt sind, für vorrangig. Er verweist hierzu auf seine Stellungnahme vom 21. September 2007 (vgl. BR-Drucksache 419/07 (Beschluss)).

8. Das deutsche Transplantationsgesetz verbietet ausdrücklich jeglichen Handel mit Organen. Dem internationalen Organhandel sollte vorgebeugt werden, indem gerade die osteuropäischen Staaten im Aufbau ihrer Gesundheitssysteme gefördert und Maßnahmen aller Mitgliedstaaten unterstützt werden, die der Verringerung des Organmangels dienen. Eine qualitative und quantitative Analyse der Problematik, mit deren Hilfe die Kommission einen ordnungs-politischen Regelungsanspruch geltend machen könnte, steht weiterhin aus.

9. Der Bundesrat bittet die Bundesregierung unter Hinweis auf Artikel 152 EGV erneut, sich für eine umfassende Analyse des Organspendepotenzials in den Mitgliedstaaten, Maßnahmen zur Unterstützung von Mitgliedstaaten mit noch nicht ausreichend entwickelten Transplantationssystemen und Maßnahmen zur Öffentlichkeitsarbeit einzusetzen. Auf dieser Basis können Strategien zur Erkennung und Meldung potenzieller Organspender gefördert werden, die wesentlich zur Verminderung des Organmangels beitragen. Erst dann kann gegebenenfalls der Organaustausch zwischen den Mitgliedstaaten wirksam eingesetzt werden. Hierfür bietet sich im Übrigen die schrittweise Ausweitung der Aktivitäten von Eurotransplant an.
10. Der Bundesrat übermittelt diese Stellungnahme direkt an die Kommission.

Greece: *Vouli Ton Ellinon*

HELLENIC PARLIAMENT

Evaluation of the subsidiarity check

answers to the questionnaire by the Hellenic Parliament.

The Hellenic Parliament proceeded to a subsidiarity check on the Commission Proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation according to the conclusions of the XL COSAC meeting.

Procedures:

1. *Which parliamentary Committees were involved in the subsidiarity check and how?*

   The Special Standing Committee for European Affairs, and the Standing Committee for Social Affairs which is competent for health issues. The two Committees held a joint meeting which was concluded by the adoption of an opinion.

2. *Was the Plenary involved?*

   No

3. *At which level the final decision was taken and who signed it?*

   The final decision, as mentioned above, was taken by the majority of the involved Committees members.

4. *Which administrative services of your parliament were involved and how?*

   The advisors of the Chairperson of the Committee for European Affairs, the Directorate for European Relations (Department for European Affairs, which provides secretarial support to the Committee for European Affairs) and the

Directorate of Parliamentary Committees. The above mentioned services collected and distributed the background documents, contacted the Ministry and the Hellenic Transplantation Organization, drafted an opinion proposal, and finally took care of other organizational details of the joint meeting.

5. *Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?*

   Yes. 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 Organization participated in the Committees' joint meeting.

6. *In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?*

   The Hellenic Parliament consists of one chamber.

7. *Did you consult your regional parliaments with legislative powers?*

   We do not have any regional parliaments.

8. *Did you consult any non-governmental organizations, interest groups, external experts or other stakeholders?*

   As above mentioned, the Hellenic Transplantations Organization (HTO) responded to our call for specialized advice.

9. *What was the chronology of events*

   We received the translated text of the proposal by the European Commission on December 8, 2008 and the written remarks by the Ministry of Health at January 12th, 2009. At the same time the directive proposal and all the accompanying documents and relevant communications were distributed to the Committees' members. On the January 27th 2009, the Speaker of the Hellenic Parliament convened a joint meeting of the aforementioned committees for February 3, 2009 (according to article 41B "Opinions on legislative acts of the European Union" of the Standing Orders of the Hellenic Parliament).

10. *Did you cooperate with other national Parliaments in the process of opinion?*

We viewed (through IPEX) the contributions of Parliaments having already dealt with the subject.

11. *Did you publicize your findings? If so by what means?*

    Apart form the broadcasting of the joint meeting by the Hellenic Parliament's TV channel, the opinion of the committees was published on the IPEX website (related dossier 2008/0238) and was distributed to all members of our Parliament.

12. *Has your Parliament introduced any procedural changes with regard to the subsidiarity check mechanism since September 2008? If so, please specify how.*

    There hasn't been any change since last September.

Findings:

13. *Did you find any breach of the subsidiarity principle?*

    No (see attached Opinion).

14. *Did you adopt a reasoned opinion on the Proposal?*

    The majority of the Committees' members adopted an opinion summarizing the conformity of the proposal with the subsidiarity principle. [With the exception of the Communist Party (8%) all the other parties (4) took a positive position].

15. *Did you find the Commission's justification with regard to the subsidiarity principle satisfactory?*

    Yes.

16. *Did you encounter any specific difficulties during the examination?*

    No.

HELLENIC PARLIAMENT

JOINT SESSION

- **STANDING COMMITTEE FOR SOCIAL AFFAIRS**
- **SPECIAL STANDING COMMITTEE ON EUROPEAN AFFAIRS**

On Tuesday, February 3, 2009 at 13.00hs, the aforementioned committees of the Hellenic Parliament convened at a Joint Session in order to adopt an

OPINION

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) final,

in accordance to:

- The decision made during the 37th Conference of Presidents and of Committees on European Affairs (COSAC) in Berlin, in May 2007, by means of which all parliaments of member-states are encouraged to proceed to 2 subsidiarity and proportionality controls per year,

- The decision made during the Conference of Presidents of Committees on European Affairs (COSAC) in Paris, on July 7 2008, which was reiterated as well during the Conference of Committees on European Affairs on November 3 and 4, concerning the selection of the aforementioned proposal for a Directive for conducting control on observing the proportionality and subsidiarity principle.

The members of the aforementioned Committees, having considered,

- The Communication from the Commission "Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States" [COM(2008) 819 final]

- Commission staff working document accompanying 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 and the Communication from the Commission "Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States - Summary of the impact assessment" [SEC(2008) 2957]

- The publications by the Directorate General for Health and Consumer Protection of the Commission (DG SANCO) "Key facts and figures on EU organ donation and transplantation" and "Useful EU information on organ donation and transplantation"

- The Commission's Communication to the European Parliament and the Council "Organ Donation and Transplantation: Policy Actions at EU level" COM (2007) 275 final

- Commission staff working document - Accompanying document to the Communication from the Commission to the European Parliament and the Council - Organ donation and transplantation: policy actions at EU level - Summary of the Impact Assessment *[SEC(2007) 705]*

- The oral rapport by the Deputy Minister for Health and Social Solidarity mr. Georgios Papageorgiou and the representative of the National Organisation for Transplantations mrs. Athina Gombou

Concluded to the following ascertainments:

- The proposal for a Directive complements our country's existing legal framework with useful – concerning the health of both organ donors and of recipients-quality standards and safety rules during the whole procedural chain conducting the transplantation process, whereas it does not in any case touch upon legal aspects related to the moral side of the issues, such as the absence of any kind of profiteering , the anonymisation, the protection of personal data, which, at the present case, are repeated as well in the draft directive. Neither does it enter into requirements relating to organ procurement consent granting and authorization process, the selection of which remains in the authority and jurisdiction of member-states (article 14).

- Given the increased demand for human organs intended for transplantation and the limited supply of donors and organs, forcing patients to resort outside state borders in order to find solution to their problem, the establishment of a common pan-european frame on safety and implementation of high quality standards, as well as the setting up of a network for cooperation and information exchange between the European states' competent authorities are deemed as absolutely necessary in order to guarantee for a high level of public health.

- **The proposal for a Directive does not in any way infringe upon the subsidiarity principle**, since in the case in question the Union takes action within its limits of jurisdiction. Article 152 of the Treaty on the European Union stipulates explicitly that: *Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health.*

  Moreover, the selection of a Directive as legal means leaves member-states with room to take further measures towards that direction if desired, whereas there is a possibility for selection of penalties applicable in case of legislation infringement.

  It is noteworthy that the proposal for a Directive completes the legal frame already established by means of the respective Directive concerning human tissues and cells (2004/23), which has been transposed into Greek law by the Presidential Decree 26/24.3.08.

- **The proposal is also consistent with the proportionality principle**, since the outmost good of health and prolongation of life impose the undertaking of any possible action.

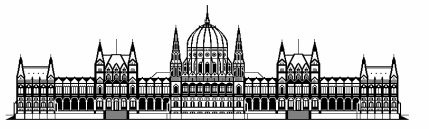
For all the reasons mentioned above, the Committees on Social Affairs and European Affairs of the Hellenic Parliament,

Call the Government

- To support the proposal for a Directive at the Council, and,

- Should it be adopted and its implementation proceed at a national level, to be accompanied by strict penalties against offenders, as well as by public awareness measures, with a view to, on the one hand minimize cases of human organ trafficking and of uncontrolled organ removal or transplantation and, on the other hand to strengthen the sense of trust of potential donors, so that their number is increased.

Hungary: *Országgyűlés*



Hungarian National Assembly
Committee on European Affairs

Answers to the COSAC questionnaire concerning the subsidiarity check

of the Proposal for Directive of the European Parliament and of the Council
on standards of quality and safety of human organs intended for transplantation
COM (2008) 818, 2008/238/COD

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?
   Only the Committee on European affairs was involved. Since the ordinary autumn session of the Parliament usually finishes in the second half of December, the 8-week timeframe made it not possible to involve any other committee.

2. Was the plenary involved?
   No. The plenary is involved in the procedure if a breach of the principle of subsidiarity is found by the Committee on European Affairs. If that was the case, the plenary should decide on the motion of the Committee on European Affairs within fifteen days.

3. At which level the final decision was taken and who signed it?
   The final decision was taken by the Committee on European Affairs since the breach of subsidiarity was not found. The decision was signed by the Chairperson of the Committee on European Affairs.

4. Which administrative services of your parliament were involved and how (please specify)?
   Generally, subsidiarity check is carried out by the Committee on European Affairs. At this stage there has been cooperation with the permanent representatives in Brussels.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
   At this stage there has been no information provided by the government on the Proposal.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
   The Hungarian National Assembly is a unicameral parliament.

7. Did you consult your regional parliaments with legislative powers?
   No, in Hungary there are no regional parliaments.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
   No, the advisors at the Secretariat of the Committee on European Affairs examined the Proposal thoroughly and presented their findings in a paper. No further external expertise were used.

9. What was the chronology of events?
   The first language versions of the Proposal were published on 8 December 2008, the official 8-week period started on 10 December 2008.

   The members of the Committee and the experts of the political groups were informed through email by the adoption of the Proposal and the launch of the subsidiarity check on the following days.

   The advisors of the Secretariat started the examination of the draft and their preliminary findings were sent to the Members of the Committee by the end of December.

   The proposal was discussed by the Committee on European Affairs on its meeting of 24 February.

10. Did you cooperate with other national parliaments in the process? If so, by what means?
    Yes, the Committee on European Affairs cooperated through the permanent representatives in Brussels.

11. Did you publicise your findings (e.g. in a special press release)?
    No special press release was published, but the minutes of the Committee meeting and a short memo summarizing the main discussion points were published on the website of the Committee.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
    There have been no changes introduced.

Findings:

13. Did you find any breach of the subsidiarity principle?
    No breach of subsidiarity was found by the Committee on European Affairs.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
    A reasoned opinion was not adopted but the minutes of the Committee meeting and a short memo summarizing the main points of the profound discussion were published on the website of the Committee.

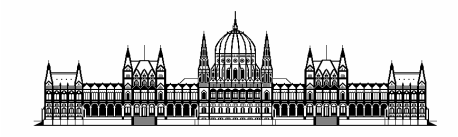
15. Did you find the Commission's justification with regard to the subsidiarity principle satisfactory?
    The Committee on European Affairs finds that the justification with regard to the subsidiarity and proportionality principles are rather formal and only reflect the relevant wording of the EC-Treaty without any further explanation.

The Explanatory Memorandum does not refer to the subsidiarity principles and the recital 23 of the Preamble does not go beyond the wording of 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.
The Committee considers that the Proposal includes only a formal justification.

16. Did you encounter any specific difficulties during the subsidiarity check?
The Committee holds that the timing does not contribute to the effective intra- and inter parliamentary works, since the large part of 8 weeks period falls between the ordinary sessions of parliaments.

17. Any other comments?
The Committee expects the Commission to provide more detailed justification with regard to the subsidiarity principle in its forthcoming legislative proposals.

Budapest, 24 February 2009.



Hungarian National Assembly
Committee on European Affairs

Reasoned opinion concerning the subsidiarity check

of the Proposal for Directive of the European Parliament and of the Council
on standards of quality and safety of human organs intended for transplantation
COM (2008) 818, 2008/238/COD

Following the thorough examination of the proposal by the secretariat of the Committee on European Affairs and the experts of the political groups, the Committee on European Affairs discussed the proposal on its meeting of 24 February 2009.

The Committee on European Affairs finds 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 Explanatory Memorandum does not refer to the subsidiarity principles and the recital 23 of the Preamble does not go beyond the wording of 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.

The Committee considers that the Proposal includes only a formal justification, but it concludes that the breach of subsidiarity was not found since the scope of the envisaged harmonisation seem to comply with the provisions of the EC-Treaty and respects the relevant competence of the Member States.

Ireland: *Houses of the Oireachtas*

Joint Committee on European Scrutiny

Evaluation of the subsidiarity check – COSAC questionnaire

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The subsidiarity check with regard to 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 was conducted by the Joint Committee on European Scrutiny (JCES). As this is the parliamentary committee with the primary responsibility for subsidiarity checks and the scrutiny of EU legislative proposals, there were no other committees involved.

2. Was the plenary involved?

As the Lisbon Treaty has not been ratified, and procedures for the implementation of Protocol 2 of the Treaty have not been decided, the plenary was not involved. The subsidiarity check was undertaken by the JCES acting as a committee of the Houses of the Oireachtas.

3. At which level the final decision was taken and who signed it?

The check and the reasoned opinion were finalised and subsequently adopted by the JCES acting as a committee of the Houses of the Oireachtas.

4. Which administrative services of your parliament were involved and how (please specify)?

The Office of the Parliamentary Legal Advisor and the Secretariat of the JCES, including policy advisors, were involved in facilitating and administering the subsidiarity check.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

At the request of the JCES, information was provided by the Department of Health and Children, the Government department with primary responsibility.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

As the JCES is a joint committee of the Houses of the Oireachtas it includes members of both the Dáil and the Seanad. Therefore, both Houses were involved simultaneously in the subsidiarity check.

7. Did you consult your regional parliaments with legislative powers?

There are no such regional parliaments in Ireland. Local authorities were not consulted.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

It was not considered necessary to consult such external bodies.

9. What was the chronology of events?

The draft proposal was first considered by the JCES on 16 December 2008. At this meeting, it was agreed to seek the views of the relevant Government department (Department of Health and Children) and the views of the Parliamentary Legal Advisor. On the basis of the submissions received, a policy advice note and draft reasoned opinion were prepared. The JCES adopted its reasoned opinion on 27 January 2009.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

Given the timeline involved coupled with the recess of the parliament for the Christmas period, it did not prove possible for the JCES to consult widely other national parliaments on this occasion. However, the JCES is of the opinion 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 'orange card' procedures contained in the Lisbon Treaty. It believes that COSAC is the most appropriate vehicle for this very important co-ordination and cooperation. That said, the JCES is doubtful whether the eight-week period provided for in the Protocol on the Application of the Principles of Subsidiarity and Proportionality for the submission of reasoned opinions by national parliaments is sufficient to allow full and effective consultation among the parliaments.

11. Did you publicise your findings? If so, by what means?

The reasoned opinion was posted on the website of the JCES.

12. Has your parliament introduced any procedural changes with regard to the subsidiarity check mechanism since September 2008? If so, please specify how.

No procedural changes have been introduced since September 2008. Under the subsidiarity check mechanism as foreseen in the Lisbon Treaty, each House of the Oireachtas will have an independent vote. Each House has yet to decide how, if the Lisbon Treaty comes into force, it wishes to carry out the subsidiarity monitoring function.

Findings:

13. Did you find any breach of the subsidiarity principle?

No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Yes, copy attached.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

The JCES found the Commission's justification to be incomplete with regard to the subsidiarity principle. It appears that the Commission did not complete all the elements of the detailed statement as required under the Protocol on the Principles of Subsidiarity and Proportionality. In particular information is lacking as regards the 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. The JCES is of the opinion that 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 or national parliaments are not in the position to take similar effective action in a specific policy area.

16. Did you encounter any specific difficulties during this subsidiarity check?

The last subsidiarity check was undertaken during the lead-in to the summer recess period. At the time, the JCES suggested that COSAC 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. While acknowledging that the Christmas recess is generally shorter than the summer recess, the JCES would repeat its observation in that regard.

17. Any other comments?

The JCES remains of the opinion that the subsidiarity check highlights the need for the national parliaments to develop an agreed definition and interpretation of the principle of subsidiarity. If the Lisbon Treaty is ultimately ratified, national parliaments will need to work closely together and must work 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' mechanism to be triggered. The JCES believes that there needs to be a focused, result orientated discussion at COSAC on the meaning of subsidiarity so that national parliaments can come to a common understanding.

Joint Committee on European Scrutiny

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): Compliance with the Principle of Subsidiarity

Reasoned Opinion

The Oireachtas Joint Committee on European Scrutiny concludes that 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 appears to comply with the principle of subsidiarity. This conclusion has been reached for the following reasons:

- the legal basis stated in the proposal would appear to be in order;

- the envisaged enlargement of the donor pool and establishment of common quality and safety standards can be achieved most appropriately at the EU level as opposed to the national, regional or local level.

However, the Oireachtas Joint Committee on European Scrutiny also considers there is an administrative deficiency in the submitted proposal. The explanatory memorandum contains no specific reference to compliance with the principles of subsidiarity and proportionality. This makes it more difficult to appraise compliance with the principles, indicating that the European Commission has not fulfilled its obligations under the 'Protocol on the Application of the Principles of Subsidiarity and Proportionality'.

The Oireachtas Joint Committee on European Scrutiny therefore recommends 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.

Oireachtas Joint Committee on European Scrutiny
Dublin, 27 January 2009

Italy: *Camera dei Deputati*

Questionnaire on the subsidiarity check on the Commission proposal for the Directive on standards of quality and safety of human organs intended for transplantation

1. Which parliamentary committees were involved in the subsidiarity check and how?
The Committee on EU policies issued an opinion to the Committee on social affairs which could adopt a final document on the proposal within the framework of the general scrutiny procedure

2. Was the plenary involved?
No.

3. At which level the final decision was taken and who signed it?
Just in view of the participation to the COSAC subsidiarity check the bureau of the Committee on EU policies decided to forward its opinion to the COSAC secretariat.
Under the Rules of Procedure of the Italian Chamber the final position on the proposal should be taken by the Committee on social affairs (within the framework of the general scrutiny procedure)

4. Which administrative services of your parliament were involved and how (please specify)?
The Department on EU Affairs provided the information and documentation for the scrutiny of the proposal. The Research service provided documentation for the assessment of the impact of the proposal on the Italian legal order.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
Not yet

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
No

7. Did you consult your regional parliaments with legislative powers?
No

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
No

9. What was the chronology of events?
On 20 January the Committee on EU Policies started the scrutiny; it issued an opinion on 21 January.
See also the information in the IPEX dossier:
http://www.ipex.eu/ipex/cms/home/Documents/dossier_COD20080238/pid/35024?matrix=1232638411043

10. Did you cooperate with other national parliaments in the process? If so, by what means?
The Department for EU affairs provided the Committee on EU Policies with information on the scrutiny in other NPs retrieved by the IPEX web site.

11. Did you publicise your findings? If so, by what means?
Publication of the minutes of the meetings of the Committee on EU Policies and of the opinion adopted.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No yet.

Findings:

13. Did you find any breach of the principle of subsidiarity?
No. Conversely, the opinion considers that the Commission proposal fully complies with the principles of subsidiarity and proportionality as the objectives of the proposal cannot be sufficiently achieved at national level.
In particolar this assessment is based on the fact that the shortage in available organs, the new quality and safety challenges related to the transplantation of human organs as well as the differencies in donation rates and transplantation activity between the Member States, requires an action at EU level.
In fact only an action at EU level would allow to exploit the considerable potential to increase the availability of organs in Europe.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
No

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?
No. The opinion noted that the motivations given in the Preamble to the Proposal and in the explanatory report in respect of subsidiarity and proportionality are not clear, but simply reiterate conventional protocols
Therefore, the opinion expressly stated the need for the European Commission to include in the Preamble and in the explanatory report a more specific and detailed justification of the legislative measure being proposed therein;

16. Did you encounter any specific difficulties during this subsidiarity check?
See answer 15.

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)

OPINION APPROVED BY THE COMMITTEE ON EU POLICIES OF THE ITALIAN CHAMBER OF DEPUTIES

The Committee on EU Policies,

Having considered 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);

Recognising that its consideration of the Proposal constitutes a verification of subsidiarity by national Parliaments, as promoted by the Conference of Community and European Affairs Committees of Parliaments of the European Union (COSAC);

Noting that, pursuant to Article 4 of Law 11/2005, once the Houses of Parliament have begun considering proposed EU acts, the Government may proceed, within its scope of competence, to frame related Community and European Union acts only after the conclusion of the consideration process, and in any case not before 20 days have passed, having apprized the Council of Ministers of the European Union of its intention to submit the proposal to Parliamentary scrutiny;

Having ascertained that the purpose of the Proposal is to strengthen coordination and cooperation among Member States in matters concerning the donation and transplantation of organs with reference to three priority objectives, viz.: to improve the quality and safety of organs in Europe, to increase the availability of organs and to make the mechanisms for transplant operations more effective and accessible;

Being fully agreeable both to the Proposal as framed and to the accompanying action plan (2009-2015) for organ donations and transplantation, with reference to the necessity of assuring, through the adoption of harmonised regulations, quality and safety for patients at an EU level and safeguards for donors, and of facilitating cooperation among Member States and to encourage cross-border exchanges by eliminating obstacles and regulatory vacuums that have hitherto aggravated the scarcity of organs and lengthened patient waiting lists;

Having also evaluated the possibility of transposing some of the ten priority actions contained in the aforementioned plan of action into binding pieces of legislation;

Recognising that the legal basis for the proposal, which is Article 152 Section 4a) of the EC Treaty, appears to be both appropriate and sufficient for the adoption of the measures envisaged in the proposal;

Judging the proposal to comply with the principle of subsidiarity and proportionality for the following reasons:

- the intervention of the European Community appears necessary to facilitate the exchange of organs, an objective that cannot be guaranteed by the action of individual Member States in view of the scarcity of organs, the waiting list of around 56,000 patients

and the considerable differences in donation rates and availability from one European country to the next;

- the European Community's action clearly produces value added with respect to action carried out by single Member States, since the introduction of binding Europe-wide measures that set out high standards of quality and safety in the use of blood, organs and substances of human provenance and promote cooperation among Member states seems to be the only way of bringing about a significant increase in the exchange of organs among them;

Having noted, however, that the motivations given in the Preamble to the Proposal and in the accompanying report in respect of subsidiarity and proportionality are not clear, but simply reiterate conventional protocols;

Emphasizing the need for a detailed evaluation of the impact that the implementation of the directive would have on the structures and procedures in place in the Italian system, with particular regard to those regulated by Law 91/1999 (Regulations relating to the procurement and transplantation of organs and tissues),

Does herewith express itself

FAVOURABLE

With the following conditions

1) that the appropriate Committee shall make reference in the final document to the need for the European Commission to include in the Preamble and in the accompanying report a more specific and detailed motivation of the legislative measure being proposed therein;

2) that the appropriate Committee shall make reference in the final document to the need for the Government to carry out a detailed evaluation of the impact that the Directive, as proposed by the European Commission, would have on the Italian system, with particular reference to possible administrative and financial costs arising from the upgrading of the national structures and procedures for the procurement and transplantation of organs.

Italy: *Senato della Repubblica*

Replies of the Italian Senate to the COSAC Questionnaire on subsidiarity compliance check on the proposal on standards of quality and safety of human organs intended for transplantation

To COSAC Secretariat (secretariat@cosac.eu).

Procedures:
1. Which parliamentary committees were involved in the subsidiarity check and how?
The European Affairs Committee gave with an advisory remit and the Health Committee as the Committee having jurisdiction over the subject matter.

2. Was the plenary involved?
No.

3. At which level the final decision was taken and who signed it?
The European Affairs Committee issued an opinion on 4 February 2009, within the 8 weeks time, but no formal decision has been made by the Senate as yet. Senate Rules of procedure state that if the Committee having jurisdiction over the subject matter (the Health Committee in this case) does not issue its "final" decision within 15 days counting from the date when the opinion of the European Affairs Committee is issued, then the opinion of the European Affairs Committee should be considered the final decision of the Senate. In such case, the European Affairs Committee shall take another vote on the opinion, but only to "upgrade" it to. The vote is taken by simple majority, with the presence of the majority of members (15 out of 29).
All opinions issued by Senate committees scrutinising EU business are signed by the rapporteurs.

4. Which administrative services of your parliament were involved and how (please specify)?
The European Affairs Office followed the scrutiny of the proposal and prepared documentation on it. The Secretariats of EU Affairs Committee and Health Committee were involved too.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
No.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
No.

7. Did you consult your regional parliaments with legislative powers?
No.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
No.

9. What was the chronology of events?
The European Affairs Committee started consideration on 21 January 2009 and issued an opinion on 3 February 2009.
Consideration in the Health Committee started on 3 February 2009.

10. Did you cooperate with other national parliaments in the process? If so, by what means?
No.

11. Did you publicise your findings? If so, by what means?
Yes. As usual, a summary report of the sittings was published on the Senate website the day following the Committee meetings. The papers adopted and the opinion issued are attached to the reports of the sittings.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No.

Findings:
13. Did you find any breach of the principle of subsidiarity?
15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

On the issue of compliance with the subsidiarity principle, the European Affairs Committee stated the following:
1. acknowledges that, as per Article 152 of the EC Treaty, the proposal for a directive 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;
2. believes however 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 mentioned above, 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 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";

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
Yes. A copy is attached.

16. Did you encounter any specific difficulties during this subsidiarity check?
No.

17. Any other comments?
The Committee's consideration of the proposal has shown that an opinion issued by a Senate committee may not always be considered a "reasoned opinion" under to the Protocol on subsidiarity. All opinions issued include compliance assessment with the subsidiarity and

proportionality principles, and also an assessment of the substance of the proposal. It is very difficult to issue a neat opinion on just one of these aspects without considering the other.

OPINION OF THE 14TH COMMITTEE

ON COMMUNITY ACT NO. 26

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)

The 14th Committee, European Union Policies,

upon concluding its consideration of the Community Act above,

whereas the proposal for a directive under scrutiny deals with a context marked by stark imbalance between supply and demand and the shortage of available organs feeds the proliferation of illegal trafficking, the proposal abates such risk by establishing transplantation authorities and centres and laying down conditions for organ reception and traceability;

whereas the proposal aims to combine in a harmonious and balanced fashion the need to quickly procure organs with the need to ensure high safety and quality standards, following the guidelines of the Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union, held on 17-18 September 2003, and the Council conclusions on organ donation and transplantation of 6 December 2007;

whereas in the working paper attached to the proposal the Commission emphasizes that Article 152 of the EC Treaty, which provides the legal basis for the proposal, may be construed to reconcile a measure of the European Union in the field of organ donation and transplantation with the subsidiarity principle, in that the Union manifestly can and must implement binding measures setting high quality and security standards;

whereas the working paper shows that the European Commission, for the purposes of achieving a high level of human health protection in the field of organs intended for transplantation while complying with the proportionality principle, has chosen a specific action plan to be implemented alongside a "flexible" directive, including non-detailed framework measures providing for the adoption of national legislation dealing with the crucial aspects of organ donation and transplantation;

expresses the following comments:

a) regarding compliance with the subsidiarity principle, the Committee

1. acknowledges that, as per Article 152 of the EC Treaty, the proposal for a directive 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;

2. believes however 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 mentioned above, 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 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";

b) regarding compliance with the proportionality principle, the Committee,

in consideration of the sensitive nature of the subject, expresses appreciation for the decision of the Commission to introduce, alongside the tool of the action plan, a "flexible", non prescriptive, directive, rather than a "rigorous" directive laying down, like directive 94/33 on tissue and cells, detailed regulation of quality and safety systems to be adopted in the member States; the Committee therefore hopes that the final text of the directive will fully comply with such flexibility criteria and shall confine itself to framework provisions, stopping short of an overly detailed regulation, especially with regard to Article 4 on the "National Quality Programmes" that member States will be called to adopt;

c) regarding the substance of the proposal, the Committee,

1. recalls that Italy sets a veritable example in terms of safety standards for human organs intended for transplantation. This renders all the more necessary a reference to Article 152.4(a) of the EC Treaty, in order to enable our country to keep its regulations in place, where it is more rigorous than the standards envisaged in the directive;
2. underlines that the "bad publicity" relating to the tragic phenomenon of organ trafficking, engenders dangerous scaremongering, which translates into a psychological obstacle to donation. Following this consideration, softer and more cautious wording should be used in paragraph 5 of the introduction to the proposal for a directive. It is therefore necessary and appropriate to amend the directive, and particularly the whereases, in order to specify most clearly that donation takes place between the living and that in most cases it involves relatives by blood or the inner family, for which there obviously is no anonymity requirement;
3. urges to consider whether measures should be introduced, at national or European level, to provide organ donors with welfare measures, in terms of social security, health assistance and insurance;
4. believes that the present training of organ transplantation staff based on the mere specifics of the work, should be complemented by a system of assessment and certification, ensuring that the training process has indeed produced an improvement of knowledge and skills;
5. believes that the establishment of a "European observatory" is highly desirable, also in view of the migration flows of third-country nationals, to ensure appropriate health checks in relation to organ exchange and transplantation and timely information to member States on the presence of pathogenic agents uncommon or rare in Europe in live or deceased donors;
6. finally believes that, during scrutiny of the proposal for a directive, consideration should be given to donor's and receiver's age standards, so as to keep abreast of the changes occurred over the last few years in terms of health and average life expectancy.

Latvia: *Saeima*

REPUBLIC OF LATVIA SAEIMA
EUROPEAN AFFAIRS COMMITTEE

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Riga, February 4, 2009
No. 9/17- 2-n/18-(2008)

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On the subsidiarity and proportionality check

The participants of the COSAC Chairpersons meeting on 7 July 2008 in Paris agreed to carry out the 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.

Accordingly, the Saeima (Parliament) of the Republic of Latvia has carried out a subsidiarity and proportionality check concerning the final version of the Proposal for a Directive of the European Parliament and the Council COM (2008) 818 on standards of quality and safety of human organs for transplantation.

On 4 February 2009 the given issue was examined and final decision was taken by the Saeima European Affairs Committee. The Saeima European Affairs Committee's initial assessment about observance of subsidiarity and proportionality principles is as follows: the European Commission has chosen an adequate framework for developing legislative acts. Taking into consideration the above-mentioned, the Saeima European Affairs Committee considers that the final wording of the Proposal for a Directive of the European Parliament and the Council COM (2008) 818 on standards of quality and safety of human organs for transplantation complies with the principles of subsidiarity and proportionality.

In order to facilitate the compilation of the replies, we have structured our reply in the form of answers to the questions posed in the aide-mémoire prepared by the COSAC Secretariat.

Annex: A copy in English (three pages) of the opinion of the Saeima European Affairs Committee on the subsidiarity and proportionality check for the final wording of the Proposal for a Directive of the European Parliament and the Council COM (2008) 818 on standards of quality and safety of human organs for transplantation.

Sincerely,
Vaira Paegle

Vaira Paegle
Chairperson of the Saeima
European Affairs Committee

Opinion of the Saeima European Affairs Committee on the subsidiarity and proportionality check for the final wording of the Proposal for a Directive of the European Parliament and the Council COM (2008) 818 on standards of quality and safety of human organs for transplantation

Procedure:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The Saeima European Affairs Committee and Public Health Subcommittee of the Social and Employment Matters Committee considered the proposal.

2. Was the plenary involved?

The given issue has not been on the agenda of Saeima plenary meetings.

3. At which level the final decision was taken and who signed it?

Final decision was taken by Saeima European Affairs Committee and covering letter signed by Chairperson of the Saeima European Affairs Committee.

4. Which administrative services of your parliament were involved and how (please specify)?

The Saeima European Affairs Committee and Public Health Subcommittee of the Social and Employment Matters Committee. Other administrative services of the Saeima were not involved in the scrutiny process.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

On the part of the Latvian government, the Ministry for Health was involved in the scrutiny process. Ministry for Health provided opinion regarding the observation of the principles of subsidiarity and proportionality in the given item.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

Latvia has a unicameral parliament.

7. Did you consult your regional parliaments with legislative powers?

Since the given proposal does not lie within the competence of Latvian local governments, local governments were not consulted on this issue.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

In view of the specific nature of the issue, other external actors were not involved in the examination.

9. What was the chronology of events?

On 10 December 2008, the Saeima European Affairs Committee transmitted a letter to the Ministry of Health of the Republic of Latvia and Public Health Subcommittee of the Social and Employment Matters Committee with a request to assess the compatibility of the given proposal with the principles of subsidiarity and proportionality.

On 29 January 2009, the Saeima European Affairs Committee received the opinion of the Latvian Ministry of Health regarding the observation of the principles of subsidiarity and proportionality in the given proposal. And on 30 January 2009, the Saeima European Affairs Committee received the opinion of the Saeima Social and Employment Matters Committee.

On 4 February 2009 the issue was examined and final decision was taken by the Saeima European Affairs Committee.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

While preparing its opinion on subsidiarity and proportionality check the Saeima European Affairs Committee did not directly cooperate with other EU national parliaments. European Affairs Committee followed subsidiarity and proportionality checks in other EU parliaments through IPEX and Permanent Representative to the EU of the Parliament of Latvia.

11. Did you publicise your findings? If so, by what means?

The conclusions were not published; however, a press release on the last meeting of the European Affairs Committee during which the subsidiarity and proportionality check was discussed was prepared and sent to the Latvian news agencies.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

Parliament has not introduced any procedural changes regarding to subsidiarity check mechanism since September 2008.

Findings:

13. Did you find any breach of the principle of subsidiarity?

Breaches of the subsidiarity and proportionality principles were not detected.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Taking into account the fact that no breaches of the subsidiarity and proportionality principles were detected, the Saeima opinion on the given item was not adopted.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

The justification put forward by the European Commission is satisfactory.

16. Did you encounter any specific difficulties during this subsidiarity check?

No.

17. Any other comments?

The Saeima European Affairs Committee's initial assessment about observance of subsidiarity and proportionality principles is as follows: the European Commission has chosen an adequate framework for developing legislative acts. Taking into consideration the above-mentioned, the Saeima European Affairs Committee considers that the final wording of the Proposal for a Directive of the European Parliament and the Council COM (2008) 818 on standards of quality and safety of human organs for transplantation complies with the principles of subsidiarity and proportionality; and the regulation of the said issue falls within the competence of the European Commission.

The European Affairs Committee also concluded that, while discussing the text of the said draft legislative act, it will be necessary to evaluate the conformity of its norms to the principles of subsidiarity and proportionality. Cause Article 152(5) of the EC Treaty proclaim that "measures referred to in [Article 152(4)(a)] shall not affect national provisions on the donation or medical use of organs".

Lithuania: *Seimas*

REPORT TO COSAC

**BY THE COMMITTEE ON EUROPEAN AFFAIRS
OF THE SEIMAS OF THE REPUBLIC OF LITHUANIA**

ON THE SUBSIDIARITY CHECK OF THE COMMISSION PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL ON STANDARDS OF QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION

6 February 2009

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

Two parliamentary committees were involved in the subsidiarity check: the Committee on European Affairs and one specialised committee, i.e. the Committee on Health Affairs. The specialised committee submitted its expert conclusions to the Committee on European Affairs, which took the final decision.

2. Was the plenary involved?

No.

In accordance with the provisions of the Statute (Rules of Procedure) of the Seimas, the plenary shall be involved for the adoption of reasoned opinion in cases when non-compliance with the principle of subsidiarity has been established by the Committee on European Affairs. The matter shall be finished without involvement of the plenary in cases when European Affairs Committee (after obtaining opinion of specialised committee) concludes that draft legislative proposal does not violate the principle of subsidiarity.

3. At which level the final decision was taken and who signed it?

The final decision was taken by the Committee on European Affairs and signed by the Chairman of the committee.

4. Which administrative services of your parliament were involved and how (please specify)?

The Legal Department of the Office of the Seimas was asked to submit an conclusion on the compliance of the proposal with the principle of subsidiarity.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

Yes.

The Ministry of Health of the Republic of Lithuania was commissioned to draft, in cooperation with other responsible institutions, the Governments' position on the proposal for the Directive. The position also contains the primary opinion on whether the proposal concerning the legal act of the European Union is in conformity with the principle of subsidiarity.

The National Bureau on Transplantation under the Ministry of Health of the Republic of Lithuania was invited to submit its opinion on the compliance of the proposal with the principle of subsidiarity.

In addition, the European Law Department under the Ministry of Justice was asked to present its expert opinion.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

Not relevant.

7. Did you consult your regional parliaments with legislative powers?

Not relevant.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

No. However some interest groups are represented in the National Bureau on Transplantation which was invited to submit its opinion.

9. What was the chronology of events?

The subsidiarity check organised through the COSAC is conducted following the usual control mechanism of the principle of subsidiarity provided for in Article 180[6] of the Seimas Statute, with the exception of one aspect: the procedure is initiated by the Committee on European Affairs rather than by a specialised committee, which is responsible, within its competence, for proper and timely control of the principle of subsidiarity, as generally provided in 180[6](1) of the Seimas Statute.

10 December 2008 **The Committee on European Affairs initiated the subsidiarity check at the Seimas. The Committee informed the responsible specialised committee (Committee on Health Affairs) in writing and requested its conclusion. The Committee also applied in**

writing to the Legal Department of the Seimas and the European Law Department under the Ministry of Justice with the request to present their expert opinion on the compliance of the Commission proposal with the principle of subsidiarity. Two members of the Committee on European Affairs were nominated as reporters.

30 December 2008 **The European Law Department under the Ministry of Justice submitted its opinion to the Committee on European Affairs. The Lisbon Treaty and consequently Protocol 2 of the Treaty has not been enforced yet. In the opinion of the Department, however, the laid down criteria may be a useful common denominator for the assessment of the Commission's draft legislative acts. In this context the Department raised the doubts if the Commission has provided sufficient and proper justification in terms of the qualitative and quantitative criteria.**

9 January 2009 **The Legal Department of the Office of the Seimas issued its legal conclusion. Based on the conclusion, there is no obvious conflict with the principle of subsidiarity. There might be some doubt though as to Article 24 of the Directive (sanctions).**

14 January 2009 **The Committee on Health Affairs held a meeting and issued its conclusion. The specialised committee decided that there is no possible breach of the principle of subsidiarity.**

28 January 2009 **The Committee on European Affairs debated the issue at its meeting. No possible breach of the principle of subsidiarity was found.**

10. Did you cooperate with other national parliaments in the process? If so, by what means?

The information about the decision taken by other Parliaments of the EU Member States provided by the permanent representatives of national parliaments in Brussels was presented to the drafters of the committee conclusion.

11. Did you publicise your findings? If so, by what means?

No.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No.

Findings:

13. Did you find any breach of the principle of subsidiarity?

No. The Committee on European Affairs adopted the final conclusion finding no possible breach of the principle of subsidiarity.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

No, see answer to the question No 2.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

Yes.

16. Did you encounter any specific difficulties during this subsidiarity check?

No.

17. Any other comments?

The European Affairs Committee is of the opinion that the Commission's draft legislative act complies with the subsidiarity principle while it notes that the legislative proposal may undergo significant modifications in the course of consideration by the EU institutions. Therefore, the Committee will follow closely the debate on this issue in the EU institutions.

Luxembourg: *Chambre des Députés*

Luxembourg, le 5 février 2009

mb/af

Mme Androulla Vassiliou
Commissaire de la Santé
Commission Européenne
D. G. Health and Consumers
B-1049 Bruxelles

Concerne: Proposition de directive du Parlement Européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation COM (2008) 818 final du 8 décembre 2008 - Test de subsidiarité

Madame le Commissaire,

J'ai l'honneur de vous faire parvenir ci-joint l'avis émis par la Commission de la Santé et de la Sécurité sociale de la Chambre des Députés en vue du test de subsidiarité sur la proposition de directive mentionnée sous rubrique.

Copie de la présente est adressée au Secrétariat de la COSAC.

Veuillez agréer, Madame le Commissaire, l'expression de ma considération très distinguée.

Lucien Weiler
Président de la Chambre des Députés

Proposition de directive

du Parlement Européen et du Conseil relative aux normes de qualité et de sécurité des organes humains destinés à la transplantation
COM (2008) 818 final du 8 décembre 2008

Avis de la Commission de la Santé et de la Sécurité sociale

en vue du test de subsidiarité conduit dans le cadre de la COSAC

Lors de sa réunion du 17 juillet 2008, la Conférence des Présidents de la COSAC a décidé de conduire le second test de subsidiarité de 2008 sur la proposition de directive du Parlement européen et du Conseil relatif aux normes de qualité et de sécurité pour le don, l'obtention, le contrôle, la conservation, le transport et la caractérisation des organes humains destinés à la transplantation.

Par lettre du Président de la Chambre des Députés du 9 décembre 2008, la Commission de la Santé et de la Sécurité sociale a été informée qu'il lui appartient d'émettre endéans un délai de 8 semaines à partir du 10 décembre 2008 un avis motivé sur la question de savoir si elle considère cette proposition comme étant conforme au principe de subsidiarité et au principe de proportionnalité.

La Commission de la Santé et de la Sécurité sociale a examiné la proposition de directive dans ses réunions des 15 et 29 janvier 2009, en présence des experts gouvernementaux. Le contenu de la directive peut être résumé en trois grands volets.

En premier lieu, la proposition de directive prévoit l'établissement de règles de sécurité et des exigences techniques médicales afin de garantir la qualité des organes destinés à la transplantation et de neutraliser les risques inhérents à l'utilisation d'organes à des fins thérapeutiques. Il s'agit en l'occurrence principalement de la mise en place d'un système de traçabilité de tous les organes, du don à la réception et inversement, et de mesures visant à mettre en évidence des incidents indésirables graves intervenus au cours de la transplantation.

Ensuite, la directive prévoit des règles protectrices du donneur et du receveur, règles se vérifiant principalement par le caractère volontaire et non rémunéré du don et par la garantie du respect de la protection des données.

Enfin la directive prévoit l'établissement d'une autorité nationale compétente dans tous les Etats membres aux fins de favoriser la coopération européenne dans ce domaine, comme dans le cas du sang, des tissus et des cellules.

En ce qui concerne les exigences médicales et techniques que la proposition de directive tend à généraliser au plan européen, il y a lieu de préciser que celles-ci sont dans une très large mesure actuellement déjà remplies au Luxembourg, étant entendu que les critères de qualité des organes transplantés se trouvent vérifiés en permanence dans le cadre des échanges transfrontaliers d'organes. L'organisme compétent au Luxembourg est « Luxtransplant », agréé en tant que service national de coordination en application du

règlement grand-ducal du 24 janvier 1984 et qui gère notamment le prélèvement de reins, ceci en étroite coopération avec « Eurotransplant ».

Les règles de protection préconisées par la proposition de directive sont également déjà ancrées dans notre législation nationale. Dans la mesure où notre législation a consacré le principe du consentement présumé au don d'organes, l'exigence du caractère volontaire du don est censée satisfaite par le fait que le donneur présumé a la possibilité de manifester et de documenter sa vie durant son opposition à donner ses organes. Par ailleurs, les normes légales luxembourgeoises consacrent également le caractère non rémunéré du don et la protection des données.

En ce qui concerne le troisième volet de la directive, il est entendu que le Luxembourg ne dispose à l'heure actuelle pas d'une autorité compétente au sens de la directive, de sorte que le moment venu la transposition de ce texte communautaire impliquera la mise en place d'une cellule hautement spécialisée auprès de la Direction de la Santé.

La Commission de la Santé et de la Sécurité sociale considère qu'en prenant l'initiative de cette proposition de directive, la Commission européenne répond en principe à un besoin évident d'harmonisation des critères de qualité et de sécurité de tous les organes humains utilisés à des fins de transplantation dans l'Union européenne. Elle estime que cette proposition de directive est conforme au principe de subsidiarité, alors qu'il est évident que la simple coexistence de législations nationales protectrices ne suffit pas pour garantir cette harmonisation au plus haut niveau possible. De par le caractère hautement sensible et complexe de la matière, les objectifs poursuivis par l'intervention de la Commission européenne ne peuvent être réalisés de manière suffisante par les Etats membres. Ils impliquent donc l'adoption de règles comportant des éléments communs applicables au niveau transnational. Par ailleurs, la Commission de la Santé et de la Sécurité sociale considère que le principe de proportionnalité se trouve également respecté, alors que le caractère contraignant des règles et mesures proposées par la directive est à qualifier d'approprié par rapport aux objectifs à attendre. En d'autres termes, les mesures prévues par la proposition de directive n'excèdent pas ce qui est nécessaire pour atteindre ces objectifs.

Dans la mesure où le Luxembourg dispose déjà d'une législation hautement protectrice, il n'éprouvera à cet égard pas de difficultés majeures pour assumer la transposition de la future directive.

La Commission de la Santé et de la Sécurité sociale a toutefois relevé la question de savoir si l'initiative de la Commission européenne ne risque pas de faire du moins partiellement double emploi avec les mécanismes de coopération déjà développés par le Conseil de l'Europe dans ce même domaine pour éliminer les lacunes juridiques existant dans certains pays. En effet, il s'avère qu'au sein du Conseil de l'Europe le processus d'harmonisation des critères de sécurité qui s'imposent pour la transplantation d'organes est également en cours ; dans cette optique, il ne peut pas être exclu que la présente initiative communautaire puisse potentiellement faire obstacle à une réglementation paneuropéenne harmonisée.

La Commission de la Santé et de la Sécurité sociale considère que la perspective d'une harmonisation sur une plus large échelle ne devrait pas être négligée tout en concédant que le Conseil de l'Europe ne dispose a priori pas des instruments juridiques qui permettraient de rendre directement contraignantes et applicables ses résolutions et propositions dans ce domaine.

Dans la mesure où la présente proposition de directive se trouve tout à fait au début de la procédure d'instruction par les différents organes communautaires et que les implications sur les différentes législations nationales restent à examiner en détail, la Commission de la

Santé et de la Sécurité sociale souhaite que le risque potentiel de voir cette initiative communautaire se révéler contreproductive par rapport aux évolutions au niveau du Conseil de l'Europe ne soit pas négligée au cours de cette instruction et que, le cas échéant, les dispositions appropriées soient prises pour éliminer ce risque et pour coordonner les démarches des deux enceintes européennes dans ce domaine. La Commission de la Santé et de la Sécurité soclale a d'ailleurs été informée qu'à l'occasion des premières concertations au niveau communautaire les représentants d'autres Etats-Membres, dont la France, ont partagé le même souci et sont intervenus en ce sens.

The Netherlands: *States-General*

STATES GENERAL OF THE NETHERLANDS

Evaluation of the subsidiarity check under the provisions of Protocol 2 on the Application of the Principles of Subsidiarity and Proportionality as attached to the Treaty of Lisbon on the Proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation

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Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?
Three parliamentary committees were involved:
- the Temporary Joint Committee on the Subsidiarity Check;
- the committee on Health, Welfare and Sports/Youth and Family of the Senate;
- the committee on Health, Welfare and Sports of the House of Representatives.

2. Was the plenary involved?
The final decision was taken by the plenary of both Houses.

3. At which level the final decision was taken and who signed it?
Both Houses adopted the reasoned opinion on the subsidiarity check; it was co-signed by the Presidents of both Houses.

4. Which administrative services of your parliament were involved and how (please specify)?
The staffs of the above mentioned parliamentary committees and the European Affairs-staff of the House of Representatives were involved. The personal assistant of the rappoteur of the House of Representatives, who was specially appointed for this occasion, was also involved. The staff of the Temporary Joint Committee on the Subsidiarity Check drafted a request to the responsible committees of both Houses for an opinion on the compliance with the principles of subsidiarity and proportionality. The staff of the involved committee of the Senate drafted the advice of that committee. The advice of the involved committee in the House of Representatives was drafted by the personal assistant of the rapporteur, in cooperation with the committee's staff and the EU-staff.
The staff of the Temporary Joint Committee drafted the letter of both Houses of parliament.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

Government provided a so-called fiche on the proposal to both Houses of Parliament 27 January 2009. By that time both committees had already given their preliminary opinion to the Temporary Joint Committee on the Subsidiarity Check

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
Yes, Dutch parliament enforces a specific procedure on the subsidiarity check, which includes involvement of (the responsible committees of) both Houses.

7. Did you consult your regional parliaments with legislative powers?
No.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
The rapporteur of the House of Representatives consulted ngo's and some stakeholders.

9. What was the chronology of events?

December 11, 2008	request for an opinion on the compliance with the principles of subsidiarity and proportionality from the Temporary Joint Committee on the Subsidiarity Check to the responsible committees of both Houses;
January 27, 2009	opinion of the committee Health, Welfare and Sports/Youth and Family of the Senate to the Joint committee;
January 28, 2009	opinion of the committee Health, Welfare and Sports of the House of Representatives to the Joint committee;
February 5, 2009	draft-joint reasoned opinion of both Houses sent to the plenaries of both Houses by the Joint committee;
February 10, 2009	adoption of the draft-joint reasoned opinion by the Senate;
February 12, 2009	adoption of the draft-joint reasoned opinion by the House of Representatives;
February 12, 2009	joint reasoned opinion sent to the Commission, the Council, the European Parliament, Dutch government and the Cosac-secretariat.
(February 24, 2009	courtesy translation (in English) of the reasoned opinion sent to the Cosac-secretariat)

10. Did you cooperate with other national parliaments in the process? If so, by what means?
There was no specific cooperation with other national parliaments during the process.

11. Did you publicise your findings? If so, by what means?
The findings were published as an official parliamentary publication under registration number 31 805.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No.

Findings:

13. Did you find any breach of the principle of subsidiarity?

Both Houses of the States General consider the chosen legal basis for the proposed directive to be adequate for the intended objective. They are not yet convinced, however, that the proposed measures fulfil the requirements of subsidiarity and proportionality in the EC Treaty. They will therefore defer a final assessment of this subject until they have received an adequate response from the European Commission to the comments and questions set out in the enclosure and have had the opportunity to consult stakeholders about the proposed measures.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
See the response to question 13 and the annex to this questionnaire.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?
Not for the time being, see the response to question 13 and the annex to this questionnaire.

16. Did you encounter any specific difficulties during this subsidiarity check?
Due to recess of both Houses of Parliament the subsidiarity check could not be concluded within the time frame of eight weeks

17. Any other comments?
The responsible committee in the House of Representatives appointed a rapporteur, who drafted a draft-opinion for the committee.

ANNEX TO THE COSAC-QUESTIONNAIRE

The Vice-President of the European Commission
Mrs M. Wallström
B – 1049 BRUSSELS
Belgium

COURTESY TRANSLATION

date: 12 February 2009
subject: *Subsidiarity check on the proposal for a directive on standards of quality and safety of human organs intended for transplantation (COM(2008)818)*
reference: *142983.02u/YTB/FB*

Dear Mrs Wallström,

In accordance with the procedures adopted by them, the two Houses of the States General of the Kingdom of the Netherlands have checked 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) by reference to the principles of subsidiarity and proportionality. In doing so they have applied Article 5 of the EC Treaty and Protocol 30 to the Treaty of Amsterdam on the application of the principles of subsidiarity and proportionality. Both Houses of the States General would inform the European Commission that this procedure has not yet been completed.

Both Houses of the States General consider the chosen legal basis for the proposed directive to be adequate for the intended objective. They are not yet convinced, however, that the proposed measures fulfil the requirements of subsidiarity and proportionality in the EC Treaty. They will therefore defer a final assessment of this subject until they have received an adequate response from the European Commission to the comments and questions set out in the enclosure and have had the opportunity to consult stakeholders about the proposed measures.

The two Houses of the States General therefore look forward to receiving a reply from the European Commission as quickly as possible.

Yours sincerely,

Yvonne E.M.A. Timmerman-Buck
President of the Senate
of the States General

Gerdi A. Verbeet
President of the House of Representatives
of the States General

An identical letter has been sent to the presidents of the Council of the European Union and the European Parliament and to the Dutch government and the secretariat of COSAC.

QUESTIONS TO THE EUROPEAN COMMISSION FROM BOTH HOUSES OF THE STATES GENERAL OF THE KINGDOM OF THE NETHERLANDS CONCERNING THE SUBSIDIARITY AND PROPORTIONALITY OF 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)

Legal basis

The European Commission has based the proposal for a directive on Article 152 (4) (a) of the EC Treaty. It appears to both Houses of the States General of the Kingdom of the Netherlands that the chosen legal basis is adequate for the intended objective, namely to adopt standards of quality and safety of human organs intended for transplantation. This legal basis is also in keeping with Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[9] and with the legal basis of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC of the Council.

Subsidiarity

In view of the subsidiarity requirements, action on the part of the Community is justified only if (1) the objective(s) of the proposed action cannot be sufficiently achieved by the Member States and (2) the objective(s) can be better achieved by the European Union.

The two Houses of the States General note that organ donation and transplantation have transnational aspects. All the Member States are involved in organ donation and transplantation. Around one fifth of the organs donated within the countries that participate in Eurotransplant are exchanged between the countries concerned. Seven countries (Austria, Belgium, Croatia, Germany, Luxembourg, Slovenia and the Netherlands) are at present affiliated to Eurotransplant for the exchange of organs and apply strict quality and safety rules in this connection. Countries not affiliated to Eurotransplant also exchange organs, either within Eurotransplant or otherwise. The Commission has supplied figures with this proposal showing that there is a shortage of 56,000 organs in Europe. No European country whatever has a surplus of organs.

The European Commission considers that the present European measures are necessary because (1) the differences in quality between the organs have, in its view, become too great and the measures to prevent this are insufficient, partly because not all countries participate in Eurotransplant, and (2) it is necessary to combat the high volume of organ trafficking by criminal groups. The proposed measures are thus intended to help achieve the objectives of the proposed directive, namely to increase the number of donations, provide better accessibility and more efficient transplantation systems and ensure compliance with quality and safety standards.

As regards the subsidiarity of the proposed measures, the two Houses of the States General have a number of questions and comments. It follows that they both defer making a final

[9] Transposed into Dutch law in the Body Material (Safety and Quality) Act and various other laws (Parliamentary Papers 30338)

assessment until these questions and comments have been adequately answered by the European Commission.

1. The States General wonders whether the survey of how transplantation systems etc. operate in practice dating from some seven years ago is still sufficiently relevant to serve as a basis for the measures now proposed. They would request the European Commission to comment on this.
2. The directive and the underlying documents still provide insufficient information about the figures on which the proposal is based. Can the European Commission provide more clarity about the figures on which the proposal is based? How many organs are exchanged annually between non-Eurotransplant countries and Eurotransplant countries? Can the Commission explain how this legislation would benefit quality?
3. At present, the professional groups of transplant physicians, transplant surgeons and tissue typing experts, united in the European Society for Organ Transplantation (ESOT) (as well as at global level), are already responsible for exchanging information about best practices and adequate courses for fundamental, translational and clinically applied research. The international exchange of organs in the Netherlands takes place under the auspices of Eurotransplant, which covers an optimal geographic area as an unduly long cold ischemia time (organ too long in transit) adversely affects the quality of the organ. Improvement of the existing cooperation within Eurotransplant and in the context of the agreements within the Council of Europe would be a possibility. It should be noted in this connection that the latter agreements have the disadvantage that they cannot be compulsorily implemented (Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS N°. 186)). The States General requests the European Commission to address the question of the extent to which the above-mentioned cooperation could help to achieve the objectives of the proposal for a directive.
4. It was submitted in the previous point that Eurotransplant covers an optimal geographic area as an unduly long cold ischemia time (organ too long in transit) adversely affects the quality of the organ. Shortening the cold ischemia time is of greater importance than achieving a better match, given the present quality of immunosuppressants. This does not apply to highly sensibilised patients. As it is nowadays already possible to transplant across blood group incompatibility, organ exchanges are becoming less important. Does the European Commission agree with this analysis and, if so, how does this affect the added value of the European action proposed in the draft directive?
5. Is the Commission able to be more specific about the extent to which the quality of organs differs from country to country, in particular about the differences in quality between Eurotransplant and non-Eurotransplant countries?
6. Does the European Commission agree with the States General that the quality of organs and the safety of organ donation depend to a great extent on cultural attitudes and the level of care in the various European countries? A clear example has been given by the Dutch government[10], namely non-heart-beating organ donations and the use of marginal organs. Some European countries do not accept these organs. Mention should also be made in this connection of live organ donation (living related donors and living unrelated donors). This is a form of organ donation that achieves very good results. The statutory rules on consent for such donation differ from country to country in Europe. Can the European Commission indicate whether achievement of the objectives of the

[10] Views of the Dutch government dated 10 December 2008, Parliamentary Paper 22.112, 750.

proposed directive can nonetheless be guaranteed by means of the measures now proposed and, if so, to what extent?

7. It is insufficiently clear from the directive and the related documents what effect the directive will have on the practice relating to non-heart-beating donors. This is of importance to the Netherlands as it has a relatively large number of non-heart-beating donations. Can the Commission provide more information about this?
8. Does the European Commission agree with the States General that the following factors determine to a large extent the number of organs available, namely donation demand, ideological views (affecting intrinsic motivation), organisation, logistical aspects and care providers' familiarity with the practice of organ donation. If so, how does this affect the added value of the European action proposed in the draft directive?
9. A second reason which the Commission puts forward for common action is the high volume of organ trafficking by criminal groups. The two Houses of the States General consider that this is not adequately explained in the directive and the underlying documents. Can the Commission provide further information and support this with figures?

Proportionality

The two Houses of the States General are not yet convinced that the proposed measures are proportional. Before making a definite assessment, they request the European Commission to provide further clarification and explanation in respect of the following questions:

1. With a view to the proportionality requirement the European Commission has opted for what is known as a 'flexible directive', without detailed policy measures. Can the European Commission provide more evidence than is presently given in the directive and the related impact assessment of why the directive would be more effective in achieving the objectives (increase in the number of donations, better accessibility, more efficient transplantation systems and compliance with quality and safety standards) than the present practice.
2. Nor is it sufficiently clear to either House of the States General what would happen if there were to be no new European legislation. What would be the consequences for the different countries? The Commission does not deal with this point at all in the proposal. Could the European Commission provide more clarity about this, and distinguish in particular between the effects on the Eurotransplant countries and the non-Eurotransplant countries?
3. There is some concern in the States General that European supervision of procedures on the transfer of information about the characteristics and traceability of organs and about serious adverse events will cause delay in the process. The two Houses of the States General request the European Commission to allay this concern by providing convincing reasons.
4. It is still insufficiently clear from the directive and the related documents what the effects will be of any innovations in the field of organ donation and transplantation. Can the Commission indicate how these matters will be dealt with in the future?
5. In assessing the proposal the British government has come to the conclusion that the quality and safety regulations proposed by the Commission are more far-reaching than is clinically necessary. What is the Commission's reaction to this assessment?
6. Organ trafficking. This point has already been dealt with in point 9 under the heading 'subsidiarity'.

Poland: *Sejm*

Warsaw, January 23rd, 2009

Answers on the following questions concerning subsidiarity check on the "Proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)" adopted by European Union Affairs Committee of the Sejm of the Republic of Poland on 23rd January 2009.

1. Which parliamentary committees were involved in the subsidiarity check and how?
In subsidiarity check the European Union Affairs Committee (EUAC) was involved, which is a specialized body of the Sejm, that gives opinions on behalf of the whole Chamber on the European Union matters.

2. Was the plenary involved?
No, it was not.

3. At which level the final decision was taken and who signed it?
The final decision was taken on the level of the European Union Affairs Committee of the Sejm of the Republic of Poland. The opinion concerning subsidiarity check on the "Proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)" was signed by Mr Andrzej Grzyb, the Chairman of the EUAC.

4. Which administrative services of your parliament were involved and how (please specify)?
In subsidiarity check the following administrative bodies of the Chancellery of the Sejm were involved:
- The European Union Division in the European Union Affairs Bureau, as a competent section to organize and coordinate works of the EUAC meetings,
- The Bureau of Research of the Chancellery of the Sejm, which prepared expertise on the subsidiarity check.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
No, the government did not provide any written information.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
No. we did not. The European Union Affairs Committee of the Sejm and The European Union Affairs Committee of the Senate worked separately.

7. Did you consult your regional parliaments with legislative powers?
No, we didn't consult. In Poland, regional parliaments do not exist.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
No, we did not consult.

9. What was the chronology of events?
The document was analysed at two stages First of all this document was the subject of the agenda of the meeting of the European Union Affairs Committee on 9th January 2009. The Committee considered the draft legislative act (COM(2008) 818) under article 6 of the *Act of 11 March 2004 on co-operation of the Council of Ministers with the Sejm and the Senate in matters related to Republic of Poland's membership in the European Union (Co-operation Act)*. After discussion the conclusion was that the EUAC did not raise any remarks. Afterwards, at the EUAC meeting on 23rd January 2009 the opinion concerning subsidiarity check was adopted. The opinion of the EUAC was held in accordance with the Protocol (No 2) on the Application of the principles of Subsidiarity and Proportionality to the treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, on the "Proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)".

10. Did you cooperate with other national parliaments in the process? If so, by what means?
No, we did not cooperate with other national parliaments in the process.

11. Did you publicise your findings? If so, by what means?
The Committee's opinion was forwarded to the government and was published on the website of the EUAC. Additionally, the transcript of the EUAC meeting is available on the website of the Sejm.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No, Sejm did not introduce any procedural changes referring to subsidiarity check mechanism. However this matter falls within the domain of EUAC's interests.

Findings:

13. Did you find any breach of the principle of subsidiarity?
No, the Committee did not find any breach of the subsidiarity principle.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
"The European Union Affairs Committee of the Sejm of the Republic of Poland:
1. acknowlegdes the 'Proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)' in conformity with subsidiarity check.
2. does not raise any remarks to the proposal for a directive referred to point 1 and to the relevant government's draft position."

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

The European Union Affairs Committee found THE Commission's justification satisfactory. The written opinion of the Bureau of Research of the Chancellery of the Sejm, was also positive but there was one remark. In the opinion of the Bureau of Research the proposal for the legislative act of the EU has not contained the substantive justification of the compliance of the 'proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)' with the subsidiarity principle.

16. Did you encounter any specific difficulties during this subsidiarity check?
No, there was no specific difficulties.

17. Any other comments?
No, we do not have any other comments.

Opinion No. 30
of the European Union Affairs Committee of
the Sejm of the Republic of Poland
on the 'Proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)'
adopted at the 90th sitting on 23 January 2009

The European Union Affairs Committee of the Sejm of the Republic of Poland:

1. acknowlegdes the 'Proposal for a Council Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008) 818)' in conformity with subsidiarity check.
2. does not raise any remarks to the proposal for a directive referred to point 1 and to the relevant government's draft position.

Chairman

/-/ Andrzej Grzyb

Poland: *Senat*

SENATE OF THE REPUBLIC OF POLAND

Report on the subsidiarity check under the Treaty of Lisbon on the proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation, COM(2008) 818

At the sitting on 3rd February 2009 the Senate's European Union Affairs Committee carried out a subsidiarity check following the procedure agreed by the COSAC. The check was completed and the conclusions formulated as follows:

Procedures:

1. **Which parliamentary committees were involved in the subsidiarity check and how?**

Two parliamentary committees were involved in the subsidiarity check in the Senate of the Republic of Poland: the European Union Affairs Committee and the Health Committee.

At the first sitting concerning the subsidiarity check the European Union Affairs Committee discussed the procedures regarding the subsidiarity check, as well as approved the working agenda, the sectoral committees to give opinions on the said proposal and the choice of the experts.

The Health Committee joined the EU Affairs Committee at the second sitting concerning the subsidiarity check. After a discussion the EU Affairs Committee, with the co-operation of the Health Committee, came to the conclusion that the above-mentioned proposal complies with the principle of subsidiarity.

2. **Was the plenary involved?**

No.

3. **At which level the final decision was taken and who signed it?**

The decision was taken by the European Union Affairs Committee and signed by the chairman of the Committee.

4. **Which administrative services of your parliament were involved and how (please specify)?**

The Information and Documentation Bureau (seeking external experts and concluding agreements with them), the European Union Unit (preparing a sitting, drafting an opinion, making a report).

5. **Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?**

The government's written position on the proposed directive, submitted to the parliament, included their opinion on the compliance with the subsidiarity and proportionality principles. A government's official took part in the Committee's sitting and provided the senators with additional information.

6. **In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?**

No.

7. **Did you consult regional parliaments with legislative powers?**

No. There are no regional parliaments or any similar bodies in Poland.

8. **Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?**

Yes, the Committee was provided with an external expertise prepared by an independent expert on internal medicine and clinical transplantology.

9. **What was the chronology of events?**

- ***10 December 2008**, the European Commission published all linguistic versions of the Proposal for a Directive*
- ***18 December 2008** – the sitting of the European Union Affairs Committee*

- *discussing the procedures regarding the subsidiarity check*
- *approving the working agenda*
- *appointing the sectoral committees to give opinions on the said proposal*
- *choosing the experts*

- ***3 February 2009** – the joint sitting of the European Union Affairs Committee and the Health Committee.*

- *hearing the opinions of the government representatives*
- *hearing the opinions of the Committee experts*
- *discussion*
- *adopting an opinion on the basis of the tabled motions*

- *Preparing and forwarding the report to the COSAC secretariat (before 6 February).*

10. **Did you cooperate with other national parliaments in the process? If so, by what means?**

No.

11. **Did you publicise your findings? If so, by what means?**

Yes, a report on the subsidiarity check has been publicised on the website of the European Union Affairs Committee and in the IPEX network.

12. **Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.**

In the present subsidiarity check the same procedure was applied as in the previous tests. Before the possible entry into force of the Treaty of Lisbon, a selection system of documents has to be worked out to seek those legislative proposals which may raise doubts about their

compliance with the subsidiarity principle. It will make therefore necessary for an experienced team of parliamentary staff to specify precise selection criteria.

Findings:

13. Did you find any breach of the principle of subsidiarity?

The European Union Affairs Committee came to the conclusion that the proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation does not breach the subsidiarity principle.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

No.

15. Did you find the Commission's justification with regard to the subsidiarity principle satisfactory?

Yes.

16. Did you encounter any specific difficulties during the examination?

No.

17. Any other comments?

The possible entry into force of the Treaty of Lisbon will make it necessary to make amendments both in the so-called "cooperative act", which deals with the cooperation between the government and the Sejm and the Senate in matters related to Poland's EU membership, and the rules of procedure of each chamber. It will be also indispensable to formulate a new legal basis to enable the Sejm and the Senate to exercise their newly acquired powers resulting from the Protocol on the application of principles of subsidiarity and proportionality. Changes will have to be introduced to the rules of procedure of the Sejm and the Senate to make it clear whether the opinions on the compliance with the subsidiarity principle - because of their special status - should be adopted by the plenary of each chamber or their authorised EU committees. Legal expert opinions on possible changes in this respect are being prepared now.

SENATE OF THE REPUBLIC OF POLAND
THE EUROPEAN UNION AFFAIRS COMMITTEE

Warsaw, February 5, 2009

Mr. Ludek Sefzig
Chairman of the Committee on European Affairs
Senate

Mr. Petr Krill
Vice-chairman of the Committee on European Affairs
Chamber of Deputies

Dear Colleagues,

The participants of the COSAC Chairperson meeting on 7 July 2008 in Paris agreed to carry out the subsidiarity check on the Proposal for the Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation.

With this in view, the European Union Affairs Committee of the Senate of the Republic of Poland at the sitting on 3rd February 2009 conduct a subsidiarity check concerning the final version of above-mentioned EU proposal following the procedure agreed by the COSAC. The European Union Affairs Committee, with the co-operation of the Health Committee, has come to the conclusion that the proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation does not breach the subsidiarity principle.

We have prepared our reply in the form of answers to the questions posed in the aide-mémoire prepared by the COSAC Secretariat.

Please find enclosed the report on the subsidiarity check on the proposal for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation COM(2008) 818.

Yours sincerely,

Edmund Wittbrodt
Chairman of the European Union Affairs Committee

ul. Wiejska 6, 00-902 Warszawa, Poland, tel. (+48.22) 694-27-15, fax (48.22) 694-19-26, e-mail: ksue@nw.senat.gov.pl

Portugal: *Assembleia da República*

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The European Affairs Committee (EAC), which coordinates the scrutiny procedure, and the Committee on Health, responsible for the matter in question.

2. Was the plenary involved?

No, there was no need for it, since no breach of the subsidiarity principle was found.

3. At which level the final decision was taken and who signed it?

The final decision was taken by the European Affairs Committee, and the report was signed by both the rapporteur and the Chairman of the European Affairs Committee.

4. Which administrative services of your parliament were involved and how (please specify)?

Besides the Committees mentioned above, the translation unit was also involved.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

No.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

n.a.

7. Did you consult your regional parliaments with legislative powers?

According to the Law 43/2006, dated 25 August, ***Monitoring, assessment and Pronouncement by the Portuguese Parliament within the scope of the process of constructing the European Union,*** *the Legislative Assemblies of the autonomous regions shall be consulted when the proposal being analysed refers to a matter that falls within the responsibility of the said assemblies. It was not the case for this subsidiarity check.*

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

No.

9. What was the chronology of events?

The European Commission published all the linguistic versions of the ***Proposal for the Directive of the European Parliament and the Council on standards of quality and safety of human organs for transplantation*** *on 10 December 2008.*

On 11 December, the EAC sent the proposal to the Committee on Health, responsible for the matter, asking for its reasoned opinion, which was adopted on 20 January 2009.

The final report was adopted by the European Affairs Committee on 27 January 2009.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

The work being done in other Parliaments was followed closely not only through the findings being uploaded to IPEX, but also via the network of national Parliaments' representatives to the EU based in Brussels.

11. Did you publicise your findings? If so, by what means?

The findings were published on IPEX.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

There were no changes in recent times, because the Law that sets out the powers of the Parliament regarding EU affairs, approved in 2006, already contains the procedures to deal with the subsidiarity check mechanism.

Findings:

13. Did you find any breach of the principle of subsidiarity?

No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

Yes. You can find herewith the copies of both the opinions from the EAC and the Committee on Health.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

This issue was not discussed by the EAC.

16. Did you encounter any specific difficulties during this subsidiarity check?

None of the Committees involved mentioned any specific difficulty.

17. Any other comments?

ASSEMBLEIA DA REPÚBLICA

European Affairs Committee

Opinion

Proposal for a Directive of the European Parliament and the Council on quality and safety standards for human organs intended for transplant (COM 818 final)

I – Preliminary Note

In compliance with the requirements of Law 43/2006, of 25 August 2006, on s*upervision, consideration and pronouncement by the Assembly of the Republic within the scope of the process of constructing the European Union*, the Parliamentary Committee for Health has drawn up a report on the following matter:

Proposal for a Directive of the European Parliament and the Council on quality and safety standards for human organs intended for transplant (COM 818 final)

II – Analysis

A) National and community framework

1 – The Parliamentary Committee for Health starts its report by outlining the national and community framework for the subsidiarity test in relation to the Draft Directive in question.

2 – It explains that, in this particular case, the aim is specifically to produce a report on whether the Draft Directive complies with the principle of subsidiarity. The Assembly of the Republic has powers to adopt a resolution denouncing non-compliance with the principle of subsidiarity to the European institutions, under the terms of Article 3 of Law 43/2006.

3 – The report also points out that, at European level, these questions are regulated by Article 5 of the TEU.
This provision is complemented by the Additional Protocol to the Treaty of Amsterdam, on the application of the principles of subsidiarity and proportionality, which lays down that in order for the principle of subsidiarity to be complied with, community action needs to meet two requirements:

- "***the objectives of the proposed action cannot be sufficiently achieved by Member States' action in the framework of their national constitutional system and can therefore be better achieved by action on the part of the Community***"

On the principle of proportionality, the additional protocol establishes that:

- ***"the form of Community action shall be as simple as possible, consistent with satisfactory achievement of the objective of the measure and the need for effective enforcement. The Community shall legislate only to the extent necessary"***

B) On the content of the Draft Directive

1 – The report in question recalls that Article 152 of the TEU confers powers on the institutions of the European Union to adopt health measures with a view to establishing quality and safety standards for the different stages of procurement, treatment and use of organs and substances of human origin, blood and blood derivatives.

2 – It also states that the Draft Directive is the outcome of several years' work in this field, which has included holding conferences and conducting research.

3 – It notes the importance of considering the growing need and demand for transplant organs. Accordingly, adoption of rules which permit improved access to transplant organs, in safe conditions, reducing the difficulties of access, will contribute to reduction in illegal trafficking.

4 – This Draft Directive is therefore intended to set a number of rules, at community levels, governing quality and safety in this field.

III – Conclusions

1 – The draft directive deals with matters where deep-level coordination is essential between member States. The quality and safety requirements for organ transplants should be high and duly guaranteed by the relevant national authorities.

2 – It is therefore necessary that absolute reliability be assured in the procedures in each country in order to cement confidence in the quality and safety of organs received in each member State through cross-border arrangements. The existence of common rules at community level is necessary for this purpose.

3 – When the ***principle of subsidiarity*** is applied (the purpose of this report), clear advantages appear to be found in setting community level regulations, subsequently transposed into national legal systems.

4 – Likewise, the proposed rules do not appear to exceed the limits set by the ***principle of proportionality***, as they leave to member States the regulation of penalties and the rules on consent.

4 – This Proposal for a Directive therefore complies with the above principles.

Opinion

The European Affairs Committee is of the opinion that, in relation to the document in question, the process of scrutiny has been concluded.

Assembly of the Republic, 26 January 2009

The Rapporteur — The Chairman of the Committee

Regina Bastos — Vitalino Canas

ASSEMBLEIA DA REPÚBLICA

Committee on Health

REPORT

Proposal for a Directive of the European Parliament and the Council on quality and safety standards for human organs intended for transplant (COM 818 final)

1 – THE NATIONAL AND COMMUNITY FRAMEWORK

The Parliamentary Committee for Health received from the European Affairs Committee, on 11 December, a request for its opinion on the subsidiarity test for the **Proposal for a Directive of the European Parliament and the Council on quality and safety standards for human organs intended for transplant (COM 818 final)**. This process is part of a simultaneous exercise of scrutiny of the draft legislation from the European Commission decided on at the COSAC held in Paris on 7 July last year.

The consultation process at the Assembly of the Republic on draft European legislation, together with other forms of intervention by the Portuguese parliament, is regulated by Law 43/2006, of 15 August 2006. In this particular case, the specific purpose of the process is to produce a report on whether the draft directive conforms to the principle of subsidiarity. The Assembly of the Republic may adopt a resolution denouncing non-compliance with the principle of subsidiarity to the European institutions, and in urgent cases the opinion of the European Affairs Committee is sufficient for this purpose (Article 3 of Law 43/2006). It is this committee, after liaising with the relevant committees in respect of the subject matter, which is responsible for delivering an opinion on compliance with this principle.

At European level, this question is regulated by Article 5 of the **Treaty Establishing the European Community**, which lays down that:

"The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein.

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty."

This provision is complemented by the Additional Protocol to the Treaty of Amsterdam, **on the application of the principles of subsidiarity and proportionality**. This establishes that in order for the principle of subsidiarity to be complied with, community action must meet two requirements: *"the objectives of the proposed action cannot be sufficiently achieved by Member States' action in the framework of their national constitutional system and can therefore be better achieved by action on the part of the Community."*

These conditions are met, according to the same additional protocol, when there are transnational aspects which cannot be satisfactorily regulated by the actions of the member States, when the absence of community action significantly damages their interests, or when such action offers evident advantages in relation to the actions of member States.

With regard to the principle of proportionality, the same document establishes that *"the form of Community action shall be as simple as possible, consistent with satisfactory achievement of the objective of the measure and the need for effective enforcement. The Community shall legislate only to the extent necessary."*

This is the community framework on this matter.

It is therefore with some surprise that this committee notes that, according to the letter received from the European Affairs Committee, the subsidiarity test in question is supposedly being conducted in accordance with the protocol on the same issues attached to the Treaty of Lisbon. It is common knowledge that the Treaty of Lisbon has never come into force, having been rejected in a referendum by the people of the Republic of Ireland, the only electorate permitted to pronounce on the matter, given that in every other country, including in Portugal, despite the undertakings given by all political parties, governments and parliaments denied the people this opportunity.

In view of the efforts of governments and European institutions to bypass the democratic will of the Irish people, it is no surprise that attempts are made to apply provisions which are not and never will be in force; nonetheless, these attempts are vehemently repudiated.

2 – ON THE CONTENT OF THE DRAFT DIRECTIVE

Article 152 of the European Community Treaty, introduced by the Treaty of Amsterdam, grants powers to the institutions of the European Union to adopt health measures with a view to establishing quality and safety standards for the various stages in the procurement, treatment and application of organs and substances of human origin, blood and blood derivatives.

These matters have been regulated by a number of directives, namely, in the case of blood and its derivatives, directives 2002/98/EC, 2004/33/EC and 2005/62/EC, and, in the case of human tissues and cells, directives 2994/23/EC, 207/17/EC and 2006/86/EC.

Internally, legislation has already been enacted on the transplantation of organs and tissues and on the transposition of these directives. This has included Law 12/93, of 22 April 1993, and Law 22/2007, of 29 June 2007, and the Parliamentary Committee for Health is currently engaged in line-by-line discussion of draft law 200/X, setting rules on the transplanting of human cells and tissues.

The draft directive is the outcome of several years' work on this matter, including a conference in Venice in 2003 on the safety and quality of organ donations and transplantation in the European Union, and a study of the legal requirements in the various member States, which uncovered the existence of discrepancies between them.

In the meantime, this matter is of increasing importance in view of the growing need and demand for transplant organs. The shortage of organs means there are now 56 000 patients on waiting lists, with a mortality rate of between 15% and 30%. This situation has created an environment in which illegal organ trafficking has flourished, and it is accordingly considered that the adoption of rules permitting improved access in safe conditions to transplant organs, reducing the difficulties of access, will help to reduce the illegal trade. The possibility of increasing cross-border exchanges of transplant organs, by means of common rules, thereby improving the general availability of organs, will also increase the chances of compatibility between donors and recipients.

This draft directive is therefore intended to set a number of quality and safety rules at community level, in particular:

- The existence of common standards on the procurement, transport and use of human organs;
- The requirement of an effective national quality programme;
- Oversight of procurement conditions, through authorization of procurement organizations;
- Specification of the information necessary and required for a correct assessment of transplant risks, in particular in the pre-transplant assessment;
- The setting of effective rules on the transport of organs;
- Guaranteeing the traceability of organs, from donation to reception, and also creation of a system for detecting serious adverse reactions and incidents, which also communicates, given the frequency of multiple donations, with the system for human tissue and cells;
- Appropriate qualification and training requirements for personnel involved in the process;

- Respect for fundamental rights and for the provisions of the Convention on Human Rights and Biomedicine, namely the principles of voluntary and non-remunerated donation, altruism and donor/recipient solidarity, and the guarantee of anonymity;
- The existence of a single national authority responsible for transplantation.

3 – CONCLUSIONS

The draft directive deals with matters where deep-level coordination is essential between member States. Indeed, the quality and safety requirements for organ transplants should be high and duly guaranteed by the relevant national authorities. There are clear advantages for potential transplantees in extending the available supply of donations, in particular because of the greater probability of a compatible donor being found.

It is therefore necessary that absolute reliability be assured in the procedures in each country in order to cement confidence in the quality and safety of organs received in each member State through cross-border arrangements. In actual fact, the existence of common rules at community level is necessary to this process.

Applying the criteria of the principle of subsidiarity, we find that, even though it is possible for rules to be set gradually by each member State on its own account, there appear to be clear advantages in regulating these questions at community level, for subsequent transposition into internal legal systems. Likewise, the limits set by the principle of proportionality appear not to have been exceeded, insofar as it is left to member States to regulate the penalties and the rules on consent, an issue which draws on ethical principles which vary appreciably from country to country.

4 – OPINION

The Parliamentary Committee for Health is of the opinion that the **Proposal for a Directive of the European Parliament and the Council on quality and safety standards for human organs intended for transplant (COM 818 final)** complies with the principles of subsidiarity and proportionality as established in the additional Protocol regulating their effect, attached to the Treaty of Amsterdam.

The Member of Parliament,	The Chairperson,
(signed)	(signed)
(Bernadino Soares)	(Maria de Belém Roseira)

Slovenia: *Državni zbor*

REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY
Committee on EU Affairs

Response to COSAC Subsidiarity Check on the Proposal for the Directive of the European Parliament and the Council on standards of quality and safety on human organs intended for transplantion

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?
The Committee on Health adopted an opinion on the issue at its meeting held on 21 January 2009. Taking this opinion into account, the Committee on EU Affairs took a position thereon at its meeting on 23 January 2009.

2. Was the plenary involved?
No.

3. At which level the final decision was taken and who signed it?
The final decision was taken by the Committee on EU Affairs and was signed by its Chairperson.

4. Which administrative services of your parliament were involved and how (please specify)?
The Legislative and Legal Service (delivering the opinion - legal view), staff of the Committee on Health and of the Committee on EU Affairs (delivering the opinion - expertise and general information)

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
Yes, verbal communication at the meeting of the Committee on Health held on 21 January 2009.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
The Committee on Health and the Committee on EU Affairs received a joint opinion by the Commission for International Relations and European Affairs and the

Commission for Social Care, Labour, Health and the Disabled of the National Council of the Republic of Slovenia. This opinion was presented by a Member of the Council at the meeting of the Committee on Health on 21 January as well as at the meeting of the Committee on EU Affairs on 23 January 2009.

7. Did you consult your regional parliaments with legislative powers?
No.

8. Did you consult any NGOs, interest groups, external experts or other stakeholders?
No.

9. What was the chronology of events?

12 December 2008: the Committee on EU Affairs decides to send the Proposal for the Directive to the Committee on Health and to the Legislative and Legal Service;
15 January 2009: the Legislative and Legal Service delivers an opinion on the Proposal for the Directive;
16 January 2009: receipt of the joint opinion by the Commission for International Relations and European Affairs and of the Commission for Social Care, Labour, Health and the Disabled of the National Council of the Republic of Slovenia;
21 January 2009: the Committee on Health delivers its opinion;
23 January 2009: the Committee on EU Affairs takes a position;
26 January 2009: final submission to COSAC

10. Did you cooperate with other national parliaments in the process? If so, by what means?
No.

11. Did you publicise your findings? If so, by what means?
No.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No.

Findings:

13. Did you find any breach of the principle of subsidiarity?
No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclosed a copy.)
Yes.

15. Did you find the Commission's justification with regard to the principle of subsidiarity check satisfactory?
Yes.

16. Did you encounter any specific difficulties during this subsidiarity check?
No.

17. Any other comments?
No.

26 January 2009

REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY
Committee on EU Affairs

No: 008-19/08-8/
Date: 23 January 2009

Committee on EU Affairs

At its 7th meeting of 23 January 2009, discussing item 6 "Reasoned opinion regarding compliance with the principle of subsidiarity in 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", the Committee on EU Affairs adopted the following

DECISION:

Having regard to the opinion of the Committee on Health of 21 January 2009 and the opinion of the Legislative and Legal Service of 15 January 2009, the Committee on EU Affairs hereby establishes that 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* complies with the principle of subsidiarity as required by the *Protocol on the application of the principles of subsidiarity and proportionality* annexed to the *Treaty on European Union* and the *Treaty on the Functioning of the European Union*.

Darja Lavtižar Bebler
Chair

Cc:
- Council of the President of the National Assembly
- Committee on Health

REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY

Committee on Health

No:
Ljubljana: 21 January 2009

COMMITTEE ON EU AFFAIRS

By *mutatis mutandis* application of Article 154h(2) of the Rules of Procedure of the National Assembly of the Republic of Slovenia (Official Gazette of the Republic of Slovenia No. 35/2002, 60/2004, 64/2007), the Committee on Health - as the **working body responsible** - adopted the following

O P I N I O N

regarding compliance with the principle of subsidiarity under the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, in 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

At its 4th meeting of 12 December 2008, the Committee on EU Affairs - discussing item 7 on the agenda - called upon the Committee on Health to deliver a reasoned opinion as to whether 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 complied with the principle of subsidiarity as required by the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union.

The Committee on Health carried out a subsidiarity check in relation to the said proposal at its 1st regular meeting of 21 January 2009.

Mr. Matevž Frangež, Deputy Chair of the Committee on EU Affairs and initiator of the above procedure, explained that COSAC each year adopts a decision whereby all Member States' national parliaments carry out at least two subsidiarity checks per year on jointly selected draft legislative acts. Thus, at their meeting in Paris in July 2008, the committee chairmen decided to carry out a 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. The proposal was published in all EU official languages on 10 December 2008, together with an eight-week deadline to carry out the check. Such deadline is provided by the above Protocol on the application of the principles of subsidiarity and proportionality of the Lisbon Treaty. The implementation of the subsidiarity check for one of the "pilot projects" should anticipate the actual functioning and cooperation of parliaments in such area, particularly when the Lisbon Treaty will have entered into force.

Considering that the purpose of such checks is to increase the involvement of national parliaments in the preliminary procedure, in accordance with hitherto practice the Committee on EU Affairs decided at its 4th meeting of 12 December 2008 that the proposed Directive and the relevant materials prepared by the COSAC Secretariat be forwarded to the working body responsible - i.e. the Committee on Health - and to the Legislative and Legal Service, asking them to deliver reasoned opinions as to whether the proposal complies with the principle of subsidiarity as provided by the Protocol. Upon taking note of the opinion on the Committee on EU Affairs, its expert service will draw up a report to be sent to the COSAC Secretariat. Based on the reports received by the national parliaments, COSAC will hold a debate on possible violations of the principle of subsidiarity in the above proposal and on the success of the checks at its meeting in May 2009.

In the new institutional structure under the Lisbon Treaty, greater significance is attributed to Member States' national parliaments. In recent years, in fact, the complex issue of their involvement in EU decision-making has been constantly in the centre of discussions, mainly for two reasons. First, in relation to the increasing number of legislative acts adopted at Community level that need to be transposed into national legislations and, second, in relation to the constantly underlined "democratic deficit" on the side of EU institutions.

The new Article 12 of the Treaty on European Union points out that national parliaments contribute actively to the good functioning of the Union, particularly by seeing to it that the principle of subsidiarity is respected in accordance with the procedures provided for in the Protocol on the application of the principles of subsidiarity and proportionality. In accordance with the principle of subsidiarity " in areas which do not fall within its exclusive competence, the Community takes action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States at the national, regional or local levels and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community". Ensuring the respect of such principle means preventing that the Union interferes in areas that are not within its competence but are left within the competence of the Member States.

Mr. Samo Kutoš from the Legislative and Legal Service drew up a written opinion in which he delivered a general definition of the principle of subsidiarity and proportionality and the Service's position on public health and subsidiarity and on subsidiarity in the proposed Directive. Despite certain concerns of, mainly, formal nature, the Legislative and Legal Service assessed that the proposal complied with the principle of subsidiarity.

An opinion on the proposed Directive was also delivered by the National Council, more precisely by the Commission for Social Care, Labour, Health and the Disabled and the Commission for International Relations and European Affairs. Their opinion was presented by Mr. Peter Požun, Member of the National Council. Both Commissions find that the standards of quality and safety of human organs intended for transplantation in Slovenia -

based on the provisions of the Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act (Official Gazette of the Republic of Slovenia No.: 12/00, 61/07) and the related implementing regulations - are high. According to the Act, the competent non-profit national institution is the Institute for Transplantation of Organs and Tissues - Slovenia Transplant.

The Commissions further establish that Slovenia is one of Europe's advanced countries in such area and is actively involved in its development at the EU level. With 20 donors per million inhabitants it is also above the European average. Particular mention was made of Article 11 of the Directive dealing with reporting systems for serious adverse events and reactions, which is considered insufficiently defined in the sense of a basic uniformity of procedures applied in such events. For that reason it will not ensure the same level of security in all EU Member States. In Slovenia, such issue is very well regulated - special protocols on traceability of organs intended for transplantation were introduced on the basis of the law as early as 2000. Authorisation for exercising control was given to Slovenia Transplant which performs such function with due care and diligence. The National Council Commissions establish that the proposed Directive is not inconsistent with the principle of subsidiarity, yet call upon the Slovenian Government and the Ministry of Health to commit themselves in any further procedures regarding the proposal that Article 11 be reconsidered to better ensure the functioning of the reporting systems for serious adverse events and reactions.

According to the representative of the Ministry of Health Mr. Janez Remškar, the draft position of the Republic of Slovenia on the proposed Directive is underway and will be sent - based on the Act on Cooperation between the National Assembly and the Government regarding EU Affairs - to the National Assembly. Considering that legislation concerning the quality and safety of human organs intended for transplantation differs from country to country, coordination at the EU level would be recommended. The Ministry of Health assesses that the proposal complies with the principle of subsidiarity.

The members of the Committee stressed in the debate that considering all the presented opinions, the proposed Directive enshrines all the above principles. The issue under consideration is a highly sensitive issue where Slovenia has achieved remarkable results and its legislation is well developed.

Following the debate, the Committee on Health adopted the following opinion:

The Committee on Health establishes that 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 complies with the principle of subsidiarity under the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union.

The rapporteur at the meeting of the competent working body will be the member of the committee Mr. Anton Colariˇ.

Hedvika Staniˇ Igliˇar
Committee Secretary

Ljubo Germiˇ
Chair

REPUBLIC OF SLOVENIA
NATIONAL ASSEMBLY

Legislative and Legal Service

No: 008-19/08-8/
Date: 15 January 2009

COMMITTEE ON EU AFFAIRS

Subject: Opinion regarding compliance with the principle of subsidiarity in 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

On 12 December 2008, the Legislative and Legal Service of the National Assembly of the Republic of Slovenia was called upon by the Committee on EU Affairs to prepare a reasoned opinion as to whether the proposed Directive (hereinafter: the proposal) complied with the principle of subsidiarity as required by the Protocol on the application of the principles of subsidiarity and proportionality (hereinafter: the Protocol), annexed to the Treaty on European Union and the Treaty establishing the European Community (TEC).

About the principle of subsidiarity and proportionality
The principle of subsidiarity and proportionality is enshrined in Article 5(2) of TEC; according thereto, in areas which do not fall within its exclusive competence, the Community takes action (e.g. adopts legislative acts) only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States at the national, regional or local levels (negative criterion or necessity test) and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community (positive criterion or value-added test). The positive and the negative criteria must be met cumulatively. The principle of subsidiarity is defined in the third paragraph of the same article: any action by the Community shall not go beyond what is necessary to achieve the objectives of the Treaties. The manner to apply (implement) such principle is defined in Article 5 of the Protocol: any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principle of subsidiarity. This statement should contain some assessment of the proposal's financial impact. In the case of a directive, it should also contain information on the implications for the rules to be put in place by Member States. The reasons for concluding that a Union objective can be better achieved at Union level should be substantiated by qualitative and, wherever possible, quantitative indicators. Last but not least, Article 5 of the Protocol requires that proposals should take

account of the need for any financial or administrative burden to be minimised and commensurate with the objective to be achieved.
In addition to the general provision on the principle of subsidiarity enshrined in Article 5 of the TEC, this principle is further specified in the Treaty's provisions concerning specific fields, such as public health which is regulated in Title XIII of the TEC.

Public health and subsidiarity
The only article under Title XIII is Article 152. In paragraph 1, it provides that a high level of human health protection must be ensured in the definition and implementation of all Community policies and activities (known as *mainstreaming*). In the second and third subparagraphs of the same paragraph, particular emphasis is placed on the flight against the major health scourges and on the fight against drugs. The second subparagraph of paragraph 2 defines for the first time the principle of subsidiarity, providing that (primarily) Member States, in liaison with the Commission, coordinate among themselves their policies and programmes in the above areas. Paragraph 3 deals with international cooperation.
For the proposal under discussion, the most relevant paragraph is paragraph 4: point (a) thereof provides that in the codecision procedure under Article 251 of TEC, (legislative) measures are adopted, *inter alia*, that set high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. Point (a) also includes a limitation in terms of subsidiarity, providing that these measures do not prevent any Member State from maintaining or introducing more stringent protective measures. An additional limitation in the sense of the principle of subsidiarity is found in paragraph 5 of Article 152, stating that Community action in the field of public health fully respects the responsibilities (i.e. competences) of the Member States for the organisation and delivery of health services and medical care. The specific limitation of Community competences is in the provision stating that measures referred to in paragraph 4(a) do not affect national provisions on the donation or medical use of organs and blood. The provisions of paragraphs 4(a) and 5 should be read together in order to make sense. An interpretation whereby paragraph 5 would exclude organ donation from EU regulations is not possible as it could literarily mean that the standards of quality referred to in paragraph 4(a) do not apply to the donation of organs. These provisions thus need to be read in the sense that the standards of quality adopted by the EU indeed apply also to the donation of organs. Other issues on organ donation that do not affect standards, however, remain within the competence of the Member States. In practice, this relates to, for example, admissibility of donation among relatives, form of consent (see below), etc.
Article 152(4)(a) already served as a basis for the adoption of Directive 2002/98 on blood and blood components and Directive 2004/23 on human tissues and cells, as well as certain implementing acts. The proposal under discussion also relates to the third field of Article 152(4)(a).

Subsidiarity in the proposal
The elements of the statement on subsidiarity and proportionality are indicated in the explanatory memorandum of the proposal. Data on the expected financial impacts of the proposal and the requirement to minimise costs are specified in the "Legislative financial statement"; the latter is - according to the Legislative and Legal Service - appropriate. Particular attention is drawn to the fact that financial impacts are indicated in figures, thereby meeting the requirement for quantitative assessment.
The main part of the assessment of compliance with the principle of subsidiarity is the assessment of the negative and positive criteria, also known as comparative efficiency test,

i.e. the assessment whether a Community objective is better achieved at Community level rather than at national level. The fulfilment of criteria is a topic dealt with under the section "The added value of the Directive", assessing the fulfilment of, in particular, the positive criterion. Particularly important is the last part of the section "Facilitating cooperation between Member States and cross-border exchanges": paragraph 27 contains the objective of ensuring a high level of quality and safety throughout the 'organ transplantation chain' in *all* Member States, bearing in mind the freedom of movement of citizens and the need to enhance the cross-border exchange of organs. This should convince the European citizens that the same standards as those in their own country apply in all Member States. The necessity of cross-border exchange is justified in paragraph 28 by the fact that to cover the needs of all the patients on the waiting lists, a large donor pool is important, particularly for the most sensitive patients. Paragraphs 29-31 explain the mechanisms whereby the proposal achieves such objectives. Particular mention needs to be made of paragraph 24 of the explanatory memorandum, explicitly stating - in accordance with subsidiarity - that the proposed Directive does not deal with certain sensitive ethical issues concerning the consent for organ donation.

To the opinion of the Legislative and Legal Service, the explanatory memorandum in principle complies with the requirement for explaining the proposal in terms of subsidiarity. Likewise, subsidiarity is observed in the provisions referring to transnational elements of organ transplantation within the EU in accordance with the proposal's objectives. Chapter II of the proposal deals with organisations and procedures (procurement, traceability, transport, reporting, etc.) which should ensure standards of quality and safety as defined in more detail in Chapter III. The exchanges of information among the Member States and with third countries are regulated by Chapter IV and V, respectively. Chapter VI (General Provisions) contains the same provisions ad most directives. Thus, the proposal contains mainly provisions that are obviously intended to establish the same standards of quality and safety in all Member States, which is indeed in line with Article 152(4)(a).

The Legislative and Legal Service assesses that the regulation of organ donation in the proposal needs more consideration. As stated above, Article 152(5) explicitly prohibits that EU legislative measures affect national provisions on the donation of organs. In such context, attention needs to be drawn to Articles 13 and 14 of the proposal that - apparently contrary to the said provision - regulate the donation of organs. Article 13 contains - as indicated by the title - principles governing organ donation, whereby Member States must ensure that donations of human organs from deceased and living donors are voluntary and unpaid (paragraph 1), that advertising organ donation for financial gain is prohibited (paragraph 2), and that procurement of organs is carried out on a non-profit basis (paragraph 3). Pursuant to Article 14, procurement may only be carried out after compliance with all mandatory consent or authorisation requirements in force in the Member State concerned. This second provision is drawn up so that it does not prejudice the competence of the Member State, linking procurement explicitly to *national* requirements and conditions instead of those posed by the Directive as such. Therefore, Article 14 does not prejudice the competences of the Member States.

An outstanding issue is, however, whether the mandatorily unpaid and non-profit organ donation provided by Article 13 interferes with the prohibition of regulating donation pursuant to paragraph 5 as explained above. The issue arises in particular in relation to a similar provision enshrined in Directive 2004/23 on blood and blood components: Article 12(1) thereof stipulates that Members States merely "endeavour" to ensure unpaid donations of blood. The second subparagraph of Article 12(1) provides for the possibility of compensations in certain cases. On the contrary, Article 13 of the proposal *commits* the Member States to unpaid donations.

As a reply to any such concern, the Legislative and Legal Service points out that the very significance of the term "donation" excludes the possibility of financial gain as this would instead mean "trading". Likewise, it underlines one of the basic principles of EU law, namely that the Union is committed to the respect of human rights as deriving from constitutional traditions of the Member States and human rights' treaties. This principle has been pursued by the European Court of Justice ever since the *Nold v. Commission* case (1974 ECR 491). Furthermore, it draws attention to Article 6 of the TEU which reiterates the principle from the *Nold* ruling (paragraph 1) and explicitly refers to the European Convention on Human Rights (paragraph 2). The Convention has been signed by all EU Member States, which means that it is a part of their "domestic" law. In terms of the proposed Directive, particularly important is paragraph 16 of the preamble referring to the Convention on Human Rights and Biomedicine. The latter is based on the European Convention on Human Rights, which means that it is also subject to Article 6(2) of the TEU. According to paragraph 16, the said Convention explicitly requires voluntary and unpaid donation. In more detail, this issue is regulated by Article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the transplantation of organs and tissues of human origin. According to paragraph 1 thereof, the human body and its parts (i.e. also organs) should not give rise to financial gain. Although its second sentence allows the possibility of compensation, this only applies for loss of earnings and expenses and not for donation. Paragraph 2 of the same Article prohibits advertising with a view of financial gain. The provision of Article 13 of the proposed Directive thus complies, *mutatis mutandis*, with the provision of Article 21 of the Additional Protocol. Since the latter - based on Article 6(2) of the TEU and the above Court ruling - is a part of EU and Member States' law in terms of protection of human rights, the prohibition under Article 13 merely reiterates a norm already existing in Member States' law; therefore, it does not prejudice their competences contrary to the principle of subsidiarity.

Likewise important is the reference to the EU Charter of Fundamental Rights in paragraph 16 of the preamble. Similarly to the Additional Protocol, the third indent of Article 3(2) of the Charter prohibits making the human body and its parts a source of financial gain. Given the failed ratification of the Treaty Establishing the Constitution for Europe and the unfinished ratification of the Lisbon treaty, however, the Charter is not a legally binding act. Nevertheless, in the Case C-540/03 (*European Parliament v. Council* [2006] ECR I-5769) the European Court stressed that the Charter recognises human rights as resulting from the constitutional traditions common to the Member States, from the treaties and legal acts under primary or secondary Community law, conferring the latter the power of interpretation in establishing which norms on human rights constitute a part of Community law. Since the non-profit use of the human body and its parts, including organs, is enshrined in the Charter, the principle of non-profitability is also a constituent part of Community law and needs to be respected by the Member States.

The Legal and Legislative Service thus assesses that in terms of content Article 13 is not in contravention of the principle of subsidiarity, yet in order to satisfy formal (procedural) requirements more properly, the proposal could contain a more detailed and explicit explanation of the issues under consideration. Paragraph 23 of the preamble does feature a general reference to the principle of subsidiarity, as provided by Article 5(2) of the TEC, but contains no reference to or analysis of compliance with Article 152(5) specifying subsidiarity in public health and, more precisely, organ donation. Likewise, no such analysis is found in the explanatory memorandum. It would be recommended the proposal contained - among the initial paragraphs - a special paragraph on the proposal's compliance with the principle of subsidiarity under Article 152 of the TEC. It would be likewise recommended that it contained, in addition, an interpretation of the relation between Article 152(5) and the proposal, namely between Article 13 of the proposal and individual national provisions in the

sense of explaining in more detail which Member States' national provisions are affected by Article 13 and which are not (comp. the interpretation in paragraph 12 of the preamble of Directive 2004/23). Since the preamble is used as an interpreting tool for applying EU secondary legislation, the above recommended modifications could significantly improve the legal clarity of the proposal.
Notwithstanding the above formal (procedural) comments, the mentioned drawbacks are not such that they could undermine the substantial adequacy of the proposal. The Legislative and Legal Service thus assesses that the proposal **complies** with the principle of subsidiarity.

Samo Kutoš
Senior Adviser III

Božo Strle
Head of Service

Cc:
- Committee on Health

Slovenia: *Državni svet*

Proposal
for a Directive of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?

The Commission for Social Care, Labour, Health and the Disabled the Commission for International Relations and European Affairs held a joint session.

2. Was the plenary involved?

No.

3. At which level the final decision was taken and who signed it?

At the commissions level. It was signed jointly by the presidents of the two above-mentioned commissions.

4. Which administrative services of your parliament were involved and how (please specify)?

Secretariat of the above mentioned Commissions and technical departments that are normally in charge of the preparation and conduct of meetings of working bodies.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?

Yes. Ministry of Health and the Institute for Transplantation of Organs and Tissues of the Republic of Slovenia (Slovenija - Transplant) were invited to the joint session to present their assessment of the compliance of the proposal with the principles of subsidiarity, together with a draft position of the Republic of Slovenia on the proposal.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?

Not in these particular case.

7. Did you consult your regional parliaments with legislative powers?

There are no regional parliaments in Slovenia.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

No.

9. What was the chronology of events?

The proposal was received on 8 December 2008. The Chairmen of the before mentioned Commissions decided to call a Joint Commission Meeting which was held on 12 January 2009. Ministry of Health and the Institute for Transplantation of Organs and Tissues of the Republic of Slovenia were asked to attend the Joint Commission Meeting and present their assessment of the compliance of the proposal with the principles of subsidiarity, together with a draft position of the Republic of Slovenia. Both Commissions adopted the joint opinion that respective proposal is in compliance with the principle of subsidiarity.
The joint opinion was sent to the EU Affairs Committee of the National Assembly and the Government.

10. Did you cooperate with other national parliaments in the process? If so, by what means?

No.

11. Did you publicise your findings? If so, by what means?

It was published on the internet page of the National Council.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.

No.

Findings:

13. Did you find any breach of the principle of subsidiarity?

No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

No.

16. Did you encounter any specific difficulties during this subsidiarity check?

No.

17. Any other comments?

Sweden: *Riksdag*

SVERIGES RIKSDAG

KAMMARKANSLIET

PM 2009-02-04

3. Evaluation of the subsidiarity check

To facilitate the evaluation of the subsidiarity check during the Czech Presidency, national parliaments are, on behalf of the French Presidency, kindly asked to reply to the following questions and send their answers to the COSAC Secretariat (secretariat@cosac.eu).

Procedures:

1. Which parliamentary committees were involved in the subsidiarity check and how?
   The Committee on Health and Welfare.

2. Was the plenary involved?
   No.

3. At which level the final decision was taken and who signed it?
   At a regular meeting of the Committee on Health and Welfare. The decision was noted in an abstract of the Committee record. The record was immediately checked by the Committee through the Chair of the Committee.

4. Which administrative services of your parliament were involved and how (please specify)?
   The secretariat of the Committee (see chronology of events) and the secretariat of the Chamber (coordination of measures and of the evaluation).

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
   Yes, oral information from a State secretary at a Committee meeting.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
   Not applicable.

7. Did you consult your regional parliaments with legislative powers?
   Not applicable.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
   No.

9. What was the chronology of events?
   The 16th of December: A presentation about the subsidiarity check to the Committee was made by a committee official. A majority of the Committee decided that the Committee should participate in the subsidiarity check. The Committee secretariat updated IPEX.
   The 22nd of January: An oral presentation was made to the Committee by a committee official about subsidiarity, the initiatives from the Commission and a memorandum from the Government Offices.
   The 27th of January: A state secretary provided oral information to the Committee about the Government offices subsidiarity check. The Committee carried out a preliminary scrutiny.
   The 29th of January: The Committee arrived at a decision on subsidiarity. The decision was noted in an abstract of the Committee record. The record was immediately checked and sent for translation. The secretariat of the Committee updated IPEX.

10. Did you cooperate with other national parliaments in the process? If so, by what means?
    The secretariat of the Committee consulted IPEX for available information. Also, e-mail correspondence with an official in another parliament, which was very useful.

11. Did you publicise your findings? If so, by what means?
    The findings were noted in a section in the record from the Committee meeting and the findings were published on IPEX.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
    No.

Findings:

13. Did you find any breach of the principle of subsidiarity?
    No.

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
    No. However, the Committees findings concerning the principle of subsidiarity were noted in a Committee record. See annex.

15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?
    Yes.

16. Did you encounter any specific difficulties during this subsidiarity check?
The subsidiarty check in the Committee was carried out smothly. However, the Christmas recess caused a higher number of meetings in the Committee. Also, it would have been difficult to involve the Plenary, because the Riksdag is in recess this week.

17. Any other comments?
It has been instructive for both the Committee and the secretariat of the Committee.

ANNEX

SVERIGES RIKSDAG

Committee on Health and Welfare

Extract from

MINUTES **COMMITTEE MEETING 19 Sep 2008**
DATE Thursday 29 January 2009
TIME 9.30-9.55 am

- - - -

§ 3 Subsidiarity control

Continued consideration of the trial regarding subsidiarity control of the Commission's proposal for a Directive on standards of quality and safety of organs of human origin intended for transplantation COM (2008) 818.

The Committee on Health and Welfare is participating in the trial initiated by COSAC regarding subsidiarity control of the Commission's above-mentioned proposal. The objective of the draft Directive is to ensure that organ donation and transplantation in the EU will meet common fundamental requirements in regard to quality and safety. The proposal covers the whole process, that is to say donation, acquistion, control, storage, transport and use. Improved quality is intended to increase patient safety and the legitimacy of the activities concerned, and in addition organ availabilty is expected to improve in various ways, including facilitation of the exchange of organs between member states by means of a common regulatory framework.

While considering this matter the Committee received information from the Government Offices in background brief 2008/09:FPM 60 and by way of the visit of State Secretary Karin Johansson of the Ministry of Health and Social Affairs on 27 January 2009.

Initially, the Committee notes that the Community, on the basis of Article 152 point 4 a in the EC treaty, has the possibility of adopting measures of health promotion in order to set high standards of quality and safety with regard to organs and substances of human origin, blood

and blood derivatives. The Committee takes note of previously adopted directives on the quality and safety of blood and blood components and directives on human tissue and cells.

The objective of the Commission's draft Directive is to set standards of quality and safety for organs of human origin intended for transplantation. The Committee is of the opinion that there is added value in the adoption at EU level of common minimum levels of the kind now being considered. Admittedly such provisions may be decided at national level, but a common minimum level cannot be ensured in this way. The objective of the Commission's measure cannot therefore be adequately achieved at member state level alone.

To sum up, it is the Committee's view that the draft Directive does not contravene the principle of subsidiarity.

The member of the Left Party is not party to the decision.

This paragraph approved as correct with immediate effect.

- - - -

SECRETARY OF THE MINUTES: Mattias Andersson

APPROVED 29 January 2009

Kenneth Johansson

This excerpt certified as correct:

Mattias Andersson

Submitted to the Secretariat of the Chamber on 29 January 2009

United Kingdom: *House of Commons*

COSAC SUBSIDIARITY CHECK ON THE DRAFT DIRECTIVE ON STANDARDS OF QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION (16521/08 (COM(08) 818))

Response of the European Scrutiny Committee of the United Kingdom House of Commons to the COSAC questionnaire of 8 December 2008

Procedures

1. Which parliamentary committees of the House of Commons were involved in the subsidiarity check and how?

- *The European Scrutiny Committee of the House of Commons considered the draft Directive in accordance with its usual procedure for the scrutiny of EU documents.*

2. Was the plenary involved?

- *No.*

3. At which level was the final decision taken and who signed it?

- *The final decision has not yet been taken. The interim decision was taken by the European Scrutiny Committee.*

4. Which administrative services of your parliament were involved?

- *The Clerks of the Committee and the Legal Adviser.*

5. Did your Government provide any information on the compliance of the proposal with the principle of subsidiarity?

- *Yes and has been asked for further information on the question.*

6. In case of a bicameral system, did you coordinate with the other chamber?

- *No*.

7. Did you consult regional parliaments with legislative powers?

- *They had the opportunity to comment on the document.*

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?

- *No.*

9. What was the chronology of events?

- *The draft Directive was deposited in the UK Parliament on 15 December 2008. The European Scrutiny Committee considered the document on 14 January2009 and decided its response to the COSAC ˇ uestionnaire on the same day.*

10 Did you cooperate with other national parliaments in the process?

- *No.*

11. Did you publicise your findings?

- *Yes, in a published Report to the House of Commons.*

12. Has your parliament introduced any procedural changes to its subsidiarity check mechanism since September 2008?

- *No.*

Findings

13. Did you find any breach of the subsidiarity principle?

- *We shall not reach a final decision on the question until we have considered the further information for which we have asked the Government. We have 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.*

- *We have also asked the Government to comment on 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 provision on the donation or medical use of organs.*

14. Did you adopt a reasoned opinion on the proposal?

- *See response to question 13.*

15. Did you find the Commission's justification on compliance with the principle of subsidiarity satisfactory?

- *See response to question 13.*

16. Did you encounter any specific difficulties during the examination?

- *No.*

17. Any other comments?

- *No.*

Quality and safety of human organs for transplantation

(a) (30265) 16521/08 COM(08) 818	Draft Directive on standards of quality and safety of human organs intended for transplantation
+ ADDs 1–2	Commission staff working documents: impact assessment and summary of assessment
(b) (30266) 16545/08 COM(08) 819	Commission Communication: *Action Plan on Organ Transplantation (2009–12): Strengthened cooperation between Member States*
+ ADDs 1–2	Commission staff working documents :impact assessment and summary of assessment

Legal base	(a) Article 153(4(a) EC; co-decision; QMV (b) —
Document originated	(Both) 8 December 2008
Deposited in Parliament	(Both) 15 December 2008
Department	Department of Health
Basis of consideration	EM of 17 December 2008
Previous Committee Report	None
To be discussed in Council	No date set
Committee's assessment	Legally and politically important
Committee's decision	(Both) Not cleared; further information requested

Legal background

(a) Article 5 of the EC Treaty establishes the principle of "subsidiarity". It requires the Community, in matters not within its exclusive competence, to take action only if the objectives of the proposed action cannot be sufficiently achieved by the Member States and can be better achieved by the Community.

(b) Article 152(1) of the EC Treaty requires action by the Community on public health to complement national policies and to be directed to the improvement of public health and the prevention of illness and disease. Article 152(2) requires the Community to encourage cooperation between Member States to improve public health. Article 152(4)(a) authorises the Council to adopt measures setting standards of quality and safety for human organs, blood and other substances of human origin. Article 152(5) requires Community action to pay full respect to the responsibilities of the Member States for the organisation and delivery of health services and medical care; it says that:

> "In particular, measures referred to in [Article 152(4)(a)] shall not affect national provisions on the donation or medical use of organs".

The COSAC subsidiarity check

(c) The Conference of European Affairs Committees of the national parliaments of the Member States (COSAC) was established in 1989. It exists to consider matters of common interest to the national parliaments. For example, COSAC has decided to make two "subsidiarity checks" a year in order to improve understanding of the provisions of Protocol 2 to the Lisbon Treaty (Protocol on the application of the principles of subsidiarity and proportionality).

(d) COSAC agreed that the second check in 2008 should be made on document (a), the draft Directive on quality and safety standards of human organs intended for transplantation. Each chamber of the national parliaments has been invited to complete its check within eight weeks of the publication of the draft Directive in all the official languages of the EU on 8 December 2008. If the chamber considers that the proposal does not comply with the principle of subsidiarity, it is invited to send the Commission, the European Parliament, the Council and COSAC a copy of a written opinion giving the reasons. COSAC will evaluate the results of the subsidiarity check at its meeting in May 2009.

The Commission's previous Communication

(e) In June 2007, we considered a Communication by the Commission on organ donation and transplantation.[11] It suggested ways in which the EC and Member States might help increase the supply of organs and improve the quality and safety of transplantation. The Commission advocated the preparation of an Action Plan to encourage cooperation between Member States and EC legislation to establish basic principles of safety and quality.

(f) In our report to the House on the document, we recognised the potential benefits of cooperation between Member States to disseminate best practice and agree common standards for the safety and quality of donated organs. But we endorsed the Government's view that vigilance would be needed to ensure that Community action was consistent with the principle of subsidiarity. We also drew attention to the need to ensure that the proposed Directive was compatible with the requirement in Article 152(5) that the measure should not affect national provisions on the donation or medical use of organs.

Document (a) — the draft Directive

(g) The draft Directive takes account of the Commission's consultations with regulators, national experts, hospitals, patients' organisations and others since the publication of the 2007 Communication.

(h) In its explanatory memorandum on the draft Directive, the Commission notes that there is an acute shortage of organs for transplantation. More than 56,000 people in the EU are on transplant waiting lists. The exchange of organs across the borders of the Member States is common. For example, the countries which are members of "Eurotransplant" (Austria, Belgium, Germany, Luxembourg, the Netherlands and Slovenia) exchange about 20% of all the organs transplanted in that area each year (about 3,300 organs a year). Cross-border exchanges are particularly important for countries with a small population or where there is difficulty in finding a good match between an organ and potential recipients.

(i) There are currently significant differences in Member States' standards of quality and safety for donation and transplantation. Transplants can transmit infectious diseases and other illnesses. In the Commission's view, common EU-wide standards are necessary to protect

[11] (28686) 9834/07: see HC 41–xxvii (2006–07), chapter 6 (27 June 2007).

donors and recipients from infection, increase trust in the systems for donation and transplantation and facilitate cross-border exchanges of organs.

(j) Community action in a similar medical field has already shown benefits. In 2002, the Council adopted a Directive setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.[12] And in 2004, the Council adopted a Directive setting quality and safety standards for human tissues and cells.[13]

(k) Document (a) sets out rules which are intended to ensure high standards of quality and safety for human organs for transplantation. Section 4 of the Commission staff working document at ADD 1 provides an extensive explanation of why the Commission believes that the measure is consistent with the principle of subsidiarity.

(l) The draft Directive applies to the donation, procurement, testing, "characterisation", preservation, transport and transplantation of human organs.[14] It requires Member States to ensure that:

— there is a national quality programme to ensure compliance with the requirements of the Directive (for example, national rules to ensure that organs are traceable at all stages from donation to transplantation or disposal);

— the donation of organs takes place in a "procurement organisation" (that is, in a hospital or other body authorised by the national competent body to procure organs in specialised facilities which minimise risks of contamination);

— the information listed in the Annex to the Directive is collected on all donated organs and donors;

— the bodies involved in the transportation of organs have written rules to ensure the integrity of the organ during transit, that transit time is minimised, and that shipping containers are labelled with specified identification information;

— transplantation tales place in a "transplantation centre" (that is, a hospital or other organisation authorised by the national competent body to conduct transplants);

— all organs can be traced from donor to recipient and vice versa and that the relevant data is kept for a minimum of 30 years;

— systems are established both to report, investigate, and register serious adverse events or reactions which threaten the health of the recipient or donor and to recall any organ associated with a serious adverse event or reaction;

— donations from deceased and living donors are voluntary and unpaid;

— advertising the availability of, or demand for, organs for financial gain is prohibited;

— living donors are provided with all necessary information in advance of the donation;

— personal data is protected in conformity with the existing EC legislation on data protection;

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12 Directive 2002/98/EC: OJ No. L 33, 8.2.03, p.30.

13 Directive 2004/23/EC: OJ No. L 102, 7.4.04, p.48.

14 "Characterisation" means the collection of the information on the donor which is needed to minimise risks to the recipient and optimise organ allocation.

— exchanges of organs with third countries are authorised by Member States' competent authorities; and

— there are effective, proportionate and dissuasive penalties for the infringement of the national legislation to give effect to the Directive.

(m) The draft Directive requires Member States to designate a competent authority or authorities. Competent authorities are, for example, to establish and keep up-to-date the national plan; grant, suspend or withdraw authorisations of procurement organisations and transplantation centres; and supervise exchanges of organs with other Member States and third countries.

(n) Finally, the draft Directive makes provision for the issue of detailed rules on the up-dating and transmission of the information about donors and recipients collected in accordance with the Annex; on the traceability of organs; and on the reporting of serious adverse events and reactions. These measures would be made in accordance with the Community's "regulatory procedure with scrutiny" procedure.[15] Accordingly, the Commission would make proposals for measures to a Committee comprising representatives of the Member States. The Commission would subsequently put the proposals to the European Parliament and the Council for decision.

Document (b) — the Action Plan for 2009–15

(o) The Commission strongly advocates the benefits of Member States sharing their experience of and expertise in organ donation and transplantation. The aim of the Action Plan proposed by the Commission is to strengthen cooperation through the identification and development of common objectives and guidelines; jointly-agreed indicators and benchmarks; regular reporting; and the identification of best practice.

(p) The Action Plan sets out the following 10 priority actions:

- promote the role of transplant donor coordinators in every hospital where there is potential for organ donation;
- promote Quality Improvement Programmes in every hospital where there is potential for organ donation;
- exchange best practice on organ donation by living donors and support an EU-register of living donors;
- improve the knowledge of doctors, nurses, other health workers and patients' organisations about organ donation and improve their communication skills;
- facilitate the identification of organ donors and cross-border donation;
- improve organisational arrangements so as the encourage and facilitate organ donation and transplantation;
- promote EU-wide agreements on, for example, the mobility within the EU of transplant patients who are citizens of the Member States;
- facilitate the exchange of organs between national authorities;

[15] Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC: OJ No. L 184, 17.7.99, p.23 and OJ No. L 200, 22.7.06, p.11.

- improve the evaluation of the results of transplants; and
- promote a common accreditation system for organ donation and transplant programmes.

(q) The Commission says that each Member State should decide for itself what needs to be done to achieve these objectives. It proposes that every Member State should produce its own Set of Priority Actions for discussion with other Member States. In 2012, the Commission will evaluate and report on the implementation of the EC Action Plan.

The Government's views on documents (a) and (b)

(r) In her Explanatory Memorandum of 17 December 2008, the Minister for Public Health at the Department for Health (Dawn Primarolo) tells us that, in England, Wales and Northern Ireland, the Human Tissues Act 2004:

— established the Human Tissues Authority to regulate the removal, storage and use of human organs;

— prohibited commercial dealings in human material for transplantation;

— placed restrictions on transplants involving living donors; and

— provided for the supply of information on transplant operations.

The Human Tissues (Scotland) Act 2006 makes provision for the regulation of organ donation and transplantation in Scotland.

(s) The Minister notes that, if the proposed Directive (document (a)) were adopted, the Acts of 2004 and 2006 might need consequential amendment. The role of NHS Blood and Transplant (NHSBT) would also need consideration. (NHSBT's job is to provide the NHS with supplies of human blood, organs and associated services and to encourage people to donate blood, organs and tissues.)

(t) The Minister says that the UK is keen to work with the Commission and other Member States to raise the profile of organ donation, identify appropriate strategies and strengthen donation frameworks so as to enable more people to benefit from transplants. She agrees with the Commission that common minimum standards of quality and safety would help reduce the risk of the transmission of disease. She says, however, that the Government will argue strongly that the standards should be kept to the minimum necessary to ensure safety and quality and should neither go beyond what is clinically justified nor be overly bureaucratic. Accordingly, the Government's negotiating objective will be to ensure that the Directive provides enough flexibility for decisions about the quality of organs to be informed by clinical judgement. The ratio of risk to benefit for donated organs for transplantation is different from the ratio for tissues and cells. In determining whether an organ should be accepted for transplantation, the potential recipient and his or her doctors have an important part to play in deciding where, in that particular case, the balance should be struck between the potentially life-saving benefits of the transplant, on the one hand, and the risks of the transmission of disease or the failure of the transplantation, on the other.

(u) As to the compliance of the proposed Directive with the principle of subsidiarity, the Minister tells us that:

> "The Government accepts that the establishment of a clear framework for setting the standard for safety and quality of organs donated for transplant across the EU will require action at Community level. However, we will continue to argue for minimum levels of detail in the proposal that will not go beyond what is necessary to achieve this objective. The UK Government will not support an overly burdensome Directive that might prove a disincentive to organ donation and transplantation."

(v) Commenting on the proposed Action Plan (document (b)), the Minister says that the Government welcomes the opportunity to work with the Commission to develop a framework for Member States to share expertise and cooperate with each other to increase both organ donation and access to transplantation.

Conclusion

(w) Article 152 of the EC Treaty appears to be internally inconsistent. On the one hand, Article 152(4)(a) expressly authorises the Council to adopt measures setting standards of quality and safety for human organs. On the other hand, Article 152(5) says that the measures referred to in Article 152(4)(a) "shall not affect national provisions on the donation of or medical use of organs". The Minister tells us that the Human Tissues Act 2004 and the Human Tissues (Scotland) Act 2006 make national provision on those matters. It is not readily apparent, therefore, that the draft Directive is compliant with Article 152(5). We should be grateful for the Minister's comments on the matter.

(x) The Minister also tells us that the Government will not support a Directive which is unduly burdensome, that the standards it sets should be the minimum necessary to ensure the safety and quality of organ donation and transplantation, and that the Government will try to ensure that the Directive is sufficiently flexible to allow decisions about the quality of organs to be informed by clinical judgement. It is not clear if the Government objects to the provisions of the Directive on any of those grounds. We should be grateful, therefore, if the Minister would tell us the specific provisions, if any, about which the Government has reservations or to which it will seek to amendments.

(y) In October 2008, we published the report on our inquiry into *Subsidiarity, National Parliaments and the Lisbon Treaty*.[16] It contains a chapter on the application of the principle of subsidiarity. One of the main findings of our inquiry — and one supported by the oral evidence to us from, among others, the Vice-President of the Commission, Commissioner Margot Wallström — is that it is largely a question of political judgement whether a legislative provision does or does not comply with the principle of subsidiarity.

(z) It could be argued, for example, that the Commission has not provided sufficient information to show that Article 12 of the draft Directive is compliant. The Article says that:

> **"Member States should ensure that personnel directly involved in the chain from donation to the transplantation or disposal of organs are qualified to perform their tasks and are provided with the relevant training, as specified in the national quality programmes".**

It is not readily apparent that action for those purposes by the Member States would not sufficiently achieve the objectives of the Directive. On the other hand, the absence of such a justification at this stage does not mean that the Commission

[16] HC 263 (2007–08), 8 October 2008.

might not be able to produce a persuasive case for Article 12 or, at any rate, a justification which was not unreasonable. There are, as we said in the report on our inquiry, no objective criteria for deciding compliance with the principle of subsidiarity. We should be grateful if the Minister would tell us whether the Government considers the Article to be compliant and the reasons.

(aa) Meanwhile, we do not see sufficient grounds to recommend the House to approve the sending of a written opinion to the Commission, the European Parliament and the Council arguing that the Directive does not comply with the principle of subsidiarity.

(bb) The Council's negotiations on the draft Directive have only just begun. We should be grateful to the Minister for progress reports on them. We shall keep document (a) under scrutiny pending receipt of the progress reports and the other information for which we have asked the Minister.

(cc) It is conceivable that the Council's discussions of the draft Directive will affect the contents of the Action Plan. We shall, therefore, also keep document (b) under scrutiny while we await the further information for which we have asked.

United Kingdom: *House of Lords*

EUROPEAN UNION COMMITTEE

16521/08: Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation

Procedures:

1. **What was the procedure used to conduct the subsidiarity check?**
   The Social Policy and Consumer Affairs Sub-Committee of the House of Lords' EU Committee took a position on the issue at its meeting of 29th January 2009. It had previously undertaken an inquiry into the Commission's Communication, "Organ donation and transplantation: policy actions at EU level" (COM (2007) 275, 30 May 2007).

   a. Which committees were involved?
   Social Policy and Consumer Affairs Sub-Committee of the EU Committee.

   b. Was the plenary involved?
   The plenary was not involved in the subsidiarity check itself, but a debate was a held in the plenary (14 November 2008) on the Report, *"Increasing the supply of donor organs within the European Union"* which the Committee published further to the inquiry referred to in paragraph 1.

   c. Which administrative services of your parliament were involved?
   The Committee Office

   d. What was the chronology of events?
   2 July 2008: Publication of Committee's Report (paragraph 1.a.)
   14 November 2008: Plenary Debate on Committee's Report
   8 December 2008: Proposal adopted by the Commission
   10 December 2008: Translation into official EU languages completed
   12 December 2008: Contacted Devolved Assemblies
   17 December 2008: Government Explanatory Memorandum submitted
   January 2009: Staff analysis of the proposals
   20 January 2009: Receipt of information from National Assembly of Wales
   20 January 2009: Receipt of notification from Northern Ireland Assembly that it would not be participating in the Check
   28 January 2009: Receipt of response from the Scottish Parliament
   29 January 2009: Consideration in Social Policy Sub-Committee
   29 January 2009: Letter to Government
   6 February 2009: Final submission to COSAC.

e. Did your government provide any information as part of the scrutiny process?

Government Explanatory Memorandum dated 17 December 2008. The Government also gave evidence to the inquiry referred to in paragraph 1.

f. In case of a bicameral system, did you coordinate with the other chamber?

Yes

g. Did you consult regional parliaments with legislative powers?

Yes. The Welsh Assembly, Northern Ireland Assembly and Scottish Parliament were all consulted.

h. Did you make use of any external expertise?

Not in relation to the subsidiarity check itself. In the course of its inquiry (see paragraph 1), the Committee took evidence and advice from a range of experts and stakeholders in the field.

2. Did you cooperate with other national parliaments in the process? If so, by what means (the COSAC Secretariat, IPEX, permanent representatives of national parliaments in Brussels)?

Cooperation through permanent representatives of national parliaments in Brussels. The Committee's report (see paragraph 1.b.) was circulated to other national parliaments.

3. Did you publicise your findings (e.g. in a special press release)?

The findings of the subsidiarity check were not publicised, but a press release was issued upon publication of the report (see paragraph 1.b.)

4. Has your parliament lately adapted its procedures with regard to subsidiarity check mechanism as foreseen in the Treaty of Lisbon; or is it planning to do so?

It is planning to do so and has used this exercise as a "pilot" project.

Findings:

5. Did you find any breach of the subsidiarity principle?

No.

6. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)

No.

7. Did you find the Commission's justification with regard to the subsidiarity principle satisfactory?

No. We considered that it lacks clarity and we would disagree with the Commission's assertion that the Community has an obligation to act.

8. Did you encounter any specific difficulties during the examination?

Our Committee did not encounter any specific difficulties. The regional parliaments with legislative powers did, however, find that the limited timetable of the Subsidiarity Check prevented them from considering the subsidiarity aspects of the Directive in the detail that they would have wished.

9. Any other comments?
No.