RIIGIKOGU
PARLIAMENT OF ESTONIA
EUROPEAN UNION AFFAIRS COMMITTEE

COSAC Secretariat

10. February 2009 No 2.1-3/ 235

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?

Lossi plats 1A, Tallinn
15165 Estonia
Tel +372 631 6463
Fax + 372 631 6484
EuroAC.staff@riigikogu.ee

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

Kristi Sõber tel. +3726316487; e-mail: kristi.sober@riigikogu.ee

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.