



EUROPEAN COMMISSION

Brussels, 27/04/2009
C/2009/2895

Dear Mr Rudiengaard,

The Commission would like to thank the Danish Parliament for its 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) 818}.

The Commission is pleased to note that the Danish Parliament concludes that the proposal in question complies with the principle of subsidiarity.

In particular the Commission is pleased to note that the Parliament acknowledges that the legal basis used is correct 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). The Danish Parliament moreover shares the Commissions' view namely that 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.

In relation to the minority statement the Commission would like to state the following: The legal base of the proposal in hand is in fact Article 152 and in particular, as stipulated in the citations, Article 152 (4)(a). Any Member State can have in place more rigorous quality and safety standards as long as they comply with the provisions of the proposed Directive. This proposed Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty. Moreover, it should be mentioned that Article 152 provides for minimum harmonisation, therefore enabling Member States to keep their current legislation and organisational structures as far as they comply with the provisions of the proposed Directive and of the Treaty.

The Commission hopes that these explanations are useful for the Danish Parliament and remains available to provide any further information.

Please note that the same letter will be transmitted to Mr Auken, Chairman of the European Affairs Committee of the Folketing.

Yours sincerely

Margot WALLSTRÖM
Vice-President of the European Commission

Mr. Preben Rudiengaard
Chairman of the Committee
on Health
Folketing



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Margot WALLSTRÖM
Vice-President of the European Commission

Mr. Svend Auken
Chairman of the European
Affairs Committee
Folketinget