



EUROPÄISCHE KOMMISSION

Brussels, 29/04/2009
C/2009/3375

Dear Mr President,

I would like to thank the German Bundestag 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 that the German Bundestag has no concerns regarding the legal basis of the proposal. The Commission moreover agrees that, in accordance with the second sentence of Article 152(5) of the Treaty, donation and medical use of organs lies within the exclusive competence of the Member States and therefore does not come under the legislative competence of the Community.

The Commission takes note of the concerns of the German Bundestag regarding the financial and administrative burdens on Member States. The Commission would like to invite the German Bundestag to closer examine the Impact Assessment and its Annexes which accompanies the proposal. The aforementioned documents adequately address the financial and bureaucratic implications. Having said that the Commission would like to point out to the German Bundestag that the approach followed in the proposal is essentially a framework one, being sufficiently flexible so as to respect national specificities and avoid additional red tape.

The Commission also takes note of the German Bundestag's concerns regarding Article 18 of the draft Directive. The Commission nevertheless would like to draw the attention of the German Bundestag to Recital 19 of the proposal. As the German Bundestag itself notes, the actual formation of the administrative structures is the responsibility of each individual Member State. This could potentially mean that Germany would not have to create additional new administrative structures or go through double authorisation procedures, as long as the existing ones comply with the requirements of the proposed Directive.

I hope that these explanations are useful for the German Bundestag and remain available to provide any further information.

Margot WALLSTRÖM

Vizepräsidentin der europäischen Kommission

Herrn Dr. Norbert Lammert
Der Präsident des Deutschen Bundestages