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COMMISSION OF THE EUROPEAN COMMUNITIES

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AVIS DU COMITE DES EVALUATIONS D'IMPACT

**COMMUNICATION FROM THE COMMISSION
ORGAN DONATION AND TRANSPLANTATION: POLICY ACTIONS AT EU
LEVEL**

**{COM(2007) 275 final
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Brussels, 28 February 2007
D(2007)1918

Opinion

Title **Impact Assessment on: Communication on organ donation and transplantation**

(draft version of 24 January 2007)

Lead DG **DG SANCO**

Impact Assessment Board Opinion

(A) Context

This impact assessment concerns a draft communication that explores options for EU action on the basis of Article 152 of the Treaty, which enables the European Parliament and Council to adopt health measures setting high standards of quality and safety of blood, blood components, organs and substances of human origin. The Community has already adopted Directives of the Parliament and the Council on quality and safety standards for blood in 2003 and for Tissues and Cells in 2004. However, it was recognized during the discussions leading to adoption of the Tissues and cells Directive that organs need a different approach, and this communication is following up on that.

(B) Positive aspects

The IA report explains well the importance of and cost effectiveness of organ donation in general.

(C) Main recommendations for improvements

The recommendations below are listed in order of descending importance. Some more technical comments will be transmitted directly to the author DG.

General recommendation: This is an elaborate IA report when it comes to describing the background and merits of organ donation in general, but the problem definition and objectives should focus on the specific EU context while the expected impacts/contribution from the policy options considered should be clarified.

(1) The IA report should focus on the EU dimension and more clearly justify the case for EU action. The IA report explains the general benefits and problems of organ donation from a public health perspective. But in order to justify EU action in respect of the subsidiarity principle, the impact assessment should give more specific justifications for EU action, for instance by explaining to what extent organ waste and organ interchange is affected by differences in the national legal frameworks. This EU-specific angle should appear throughout the IA report, in the problem definition, objectives, and policy options.

(2) The linkage between the three objectives needs further clarification. Whereas the main driver of this initiative seems to be the shortage of organs, the impact assessment identifies additional policy goals concerning quality standards and organ trafficking. Although these goals are related, the IA should make clarify better the links between them, including whether there are (potential) trade-offs between these goals, and if this is the case what the hierarchy between them is.

(3) The IA report should clarify the preferred option and assess its expected impacts. The preferred option should be spelled out more clearly to avoid that it is presented as an unstructured set of individual actions. It should be made clear how the preferred option will contribute to increased organ availability and achieving the other 2 objectives. Insofar as this is possible (and with regard to the principle of proportionate analysis), the benefits of the options should be quantified and contrasted with the degree of intervention.

(D) Procedure and presentation

The problem definition is too long, which does not add to clarity. It should be shortened especially by moving some of the medical background information and the detailed descriptions of national systems to an annex.

(1)

(2)

IAB scrutiny process

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