ANNEX

INFORMATION TO BE PROVIDED ON THE DONATION OF CELLS AND/OR TISSUES

A.Living donors

1. The person in charge of the donation process shall ensure that the donor has been properly informed of at least those aspects relating to the donation and procurement process outlined in paragraph 3. Information must be given prior to the procurement.

2. The information must be given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the donor.

3. The information must cover: the purpose and nature of the procurement, its consequences and risks; analytical tests, if they are performed; recording and protection of donor data, medical confidentiality; therapeutic purpose and potential benefits and information on the applicable safeguards intended to protect the donor.

4. The donor must be informed that he/she has the right to receive the confirmed results of the analytical tests, clearly explained.

5. Information must be given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the tissue and/or cell procurement can be carried out.

B. Deceased donors

1. All information must be given and all necessary consents and authorisations must be obtained in accordance with the legislation in force in Member States.

2. The confirmed results of the donor's evaluation must be communicated and clearly explained to the relevant persons in accordance with the legislation in Member States.