# Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance)

*Article 2*

**Requirements for the procurement of human tissues and cells**

1 With the exception of partner donation of reproductive cells for direct use, Member States shall ensure that the procurement of human tissues and cells is accredited, designated, authorised or licensed only when the requirements in paragraphs 2 to 12 are met.

2 Procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured or a tissue establishment authorised for procurement.

3 The tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the same organisation or establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors set out in Annex I.

4 The tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for tissue/cell procurement, unless they are employed by the same establishment or organisation, specifying the type(s) of tissues and/or cells and/or test samples to be procured and the protocols to be followed.

5 There shall be standard operating procedures (SOPs) for the verification of:

a donor identity;

b the details of donor or donor family consent or authorisation;

c the assessment of the selection criteria for donors as detailed in Article 3;

d the assessment of the laboratory tests required for donors as detailed in Article 4.

There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue establishment or, in the case of direct distribution of tissues and cells, to the clinical team responsible for their application or, in the case of tissue/cell samples, to the laboratory for testing, in accordance with Article 5 of this Directive.

6 Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with Article 5.

7 Procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in Annex IV, section 1.3, and with due regard to relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for tissue and cell procurement.

8 Procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy.

9 Where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively.

10 The procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements specified in Article 5.

11 A unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material. The coded data shall be entered in a register maintained for the purpose.

12 Donor documentation shall be maintained in accordance with section 1.4 of Annex IV.