[F1ANNEX VI

Minimum data to be kept in accordance with Article 9(2)

Textual Amendments

F1 Substituted by Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (Text with EEA relevance).

A.BY TISSUE ESTABLISHMENTS

(1) Donor identification

(2) Donation identification that will include at least:

— Identification of the procurement organisation (including contact details) or the tissue establishment
— Unique donation number
— Date of procurement
— Place of procurement
— Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased)

(3) Product identification that will include at least:

— Identification of the tissue establishment
— Type of tissue and cell/product (basic nomenclature)
— Pool number (in case of pooling)
— Split number (if applicable)
— Expiry date (if applicable)
— Tissue/cell status (i.e. quarantined, suitable for use, etc.)
— Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety.
— Identification of the facility issuing the final label

(4) Single European Code (if applicable)

(5) Human application identification that will include at least:

— Date of distribution/disposal
— Identification of the clinician or end-user/facility

B. BY ORGANISATIONS RESPONSIBLE FOR HUMAN APPLICATION

(1) Identification of the supplier tissue establishment

(2) Identification of the clinician or end-user/facility

(3) Type of tissues and cells

(4) Product identification

(5) Identification of the recipient

(6) Date of application

(7) Single European Code (if applicable)]