Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (Text with EEA relevance)

Article 6

Notification of serious adverse events

1 Member States shall ensure that:

a procurement organisations and tissue establishments have procedures in place to retain the records and to notify tissue establishments without delay of any serious adverse events that occur during procurement which may influence the quality and/or safety of human tissues and cells;

b organisations responsible for human application of tissues and cells have procedures in place to notify tissue establishments without delay of any serious adverse events that may influence the quality and safety of the tissues and cells;

c tissue establishments provide to the organisation responsible for human application information about how that organisation should report serious adverse events to them that may influence the quality and safety of the tissues and cells.

2 In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the competent authority.

3 Member States shall ensure that tissue establishments:

a have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse events as referred to in paragraph 1(a) and (b);

b have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

4 Member States shall ensure that:

a the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex IV;

b tissue establishments evaluate serious adverse events to identify preventable causes within the process;

c tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex IV.