Legistation of traecability of gametes and embryos in UE

Law and Ethics

Professor: Gianni Baldini

Student: Amra Mahmutbegovic

The Treaty of the Functioning of the European Union – article 168

DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 31 March 2004

on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

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)

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)

Definitions

‘cells’ means individual human cells or a collection of human cells when not bound by any form of connective tissue;

‘human application’ means the use of tissues or cells on or in a human recipient and extracorporal applications;

Standard Operating Procedures’ (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

‘partner donation’ means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

‘critical’ means potentially having an effect on the quality and/or safety of or having contact with the cells and tissues;

‘organisations responsible for human application’ means a health care establishment or a unit of a hospital or another body which carries out human application of human tissues and cells.

Requirements for accreditation,designation,authorisation or licensing of tissue establishments

- ORGANISATION AND MANAGEMENT
- PERSONEL
- EQUIPMENT AND MATERIALS
- FACILITIES/ PREMISES
- DOCUMENTATION AND RECORDS
- QUALITY REVIEW

Requirements for the authorisation of tissue and cell preparation processes at the tissue establishments

RECEPTION AT THE TISSUE ESTABLISHMENT

PROCESSING

STORAGE AND RELEASE OF PRODUCTS

DISTRIBUTION AND RECALL

FINAL LABELLING FOR DISTRIBUTION

EXTERNAL LABELLING OF SHIPPING CONTAINER

What is the exact scope of traceability?

- ‘traceability’ means the ability :

✓to locate and identify the tissue/cell during any step:

a. procurement
b. processing,
c. testing and storage,
d. distribution to the recipient or disposal

✓ to identify the donor and the tissue establishment or the manufacturing facility receiving,processing or storing the tissues

✓To identify the recipient

Traceability

- 1. Tissue establishments shall have effective and accurate systems to uniquely identify and label cells/tissues received and distributed.

- 2. Tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, in an appropriate and readable storage medium.

ANNEX VI

Information on the minimum donor/recipient data set to be kept as required in Article 9

A. BY TISSUE ESTABLISHMENTS

Donor identification

Donation identification that will include at least:

— Identification of the procurement organisation or Tissue establishment

— Unique Donation ID number

— Date of procurement

— Place of procurement

— Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased)

Product identification that will include at least:

— Identification of the tissue establishment

— Type of tissue and cell/product (basic nomenclature)

— Pool number (if applicable)

— Split number (if applicable)

— Expiry date

— 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

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

(a) Identification of the supplier tissue establishment

(b) Identification of the clinician or end user/facility

(c) Type of tissues and cells

(d) Product identification

(e) Identification of the recipient

(f) Date of application

The tissues and cells intended for human application in the EU must be traceable from donor to recipient, and vice versa.

A unique identifier called the Single Europe code (SEC), together with its accompanying documentation, allows for this traceability and provides information on the main characteristics of tissues and cells for human use.

Users can retrieve relevant information on tissue and cell products through a publicly accessible IT platform.

The Commission encourages national participation in the WHO's NOTIFY Library - a website where experts from across the globe share information on selected and documented adverse outcomes associated with the donation, processing or clinical use of human organs, blood, tissues and cells..

Format of the SEC

DONATION IDENTIFICATION SEQUENCE (DIS)			PRODUCT IDENTIFICATION SEQUENCE			
TE code		Unique Donation number	Product code		Split number	Expiry date
ISO country identifier	TE number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character **E = EUTC** **A = ISBT128** **B = Eurocode**	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters

The "Single European Code" or "SEC" is a unique identifier that consists of two parts, a donation identification sequence, essentially indicating the origin of the tissue or cells, and a product identification sequence, essentially classifying the type of tissue or cells.

- Commission Directive (EU) 2015/565 amended Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells and was published on 9 April 2015
- Directive 2006/86/EC as amended ('The Directive') thus lays down the obligation for tissue establishments to affix a "Single European Code" or "SEC" on tissues and cells distributed for clinical application in the EU.

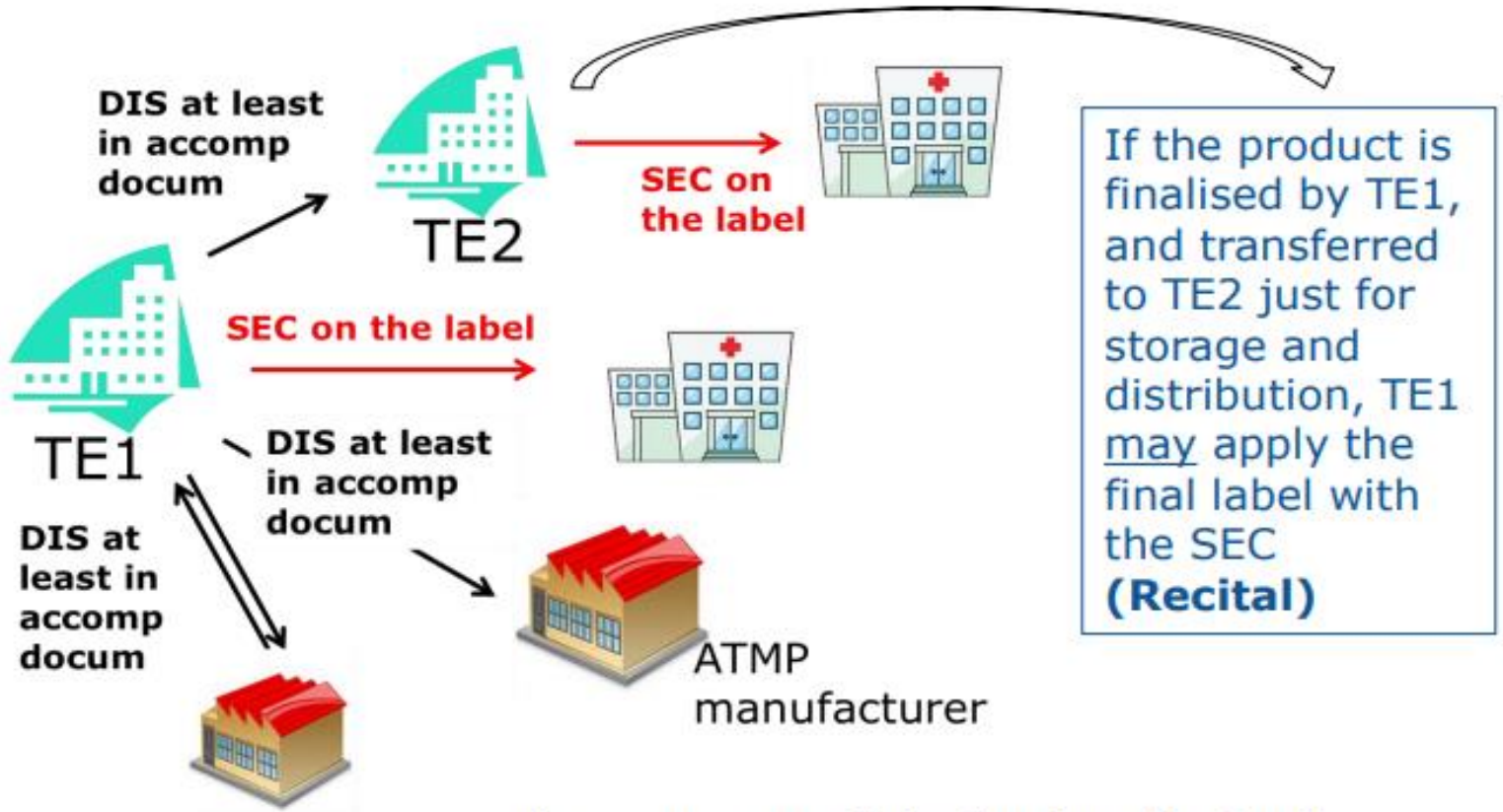
In which circumstances SEC could be avoid?

The following situations are excluded from the application of the SEC:

- ✓reproductive cells from partner donation;
- ✓tissues and cells distributed directly for immediate transplantation to the recipient
- ✓tissues and cells imported into the Union in case of emergency authorised directly by the competent authority or authorities, as referred to in Article 9(3)b of Directive 2004/23/EC.
- ✓tissues and cells that remain within the same centre;
- ✓tissues and cells that are imported into the Union, when these tissues and cells remain within the same centre from importation to application

European coding system (application of SEC)

- The SEC shall be applied to **all T&C distributed** for human application.
- For the **other situations where tissues and cells are released for circulation**, as a minimum the donation identification sequence (DIS) shall be applied at least in the accompanying documentation



If the product is finalised by TE1, and transferred to TE2 just for storage and distribution, TE1 may apply the final label with the SEC **(Recital)**

SEC = Single European Code

DIS = donation identification sequence

European coding system

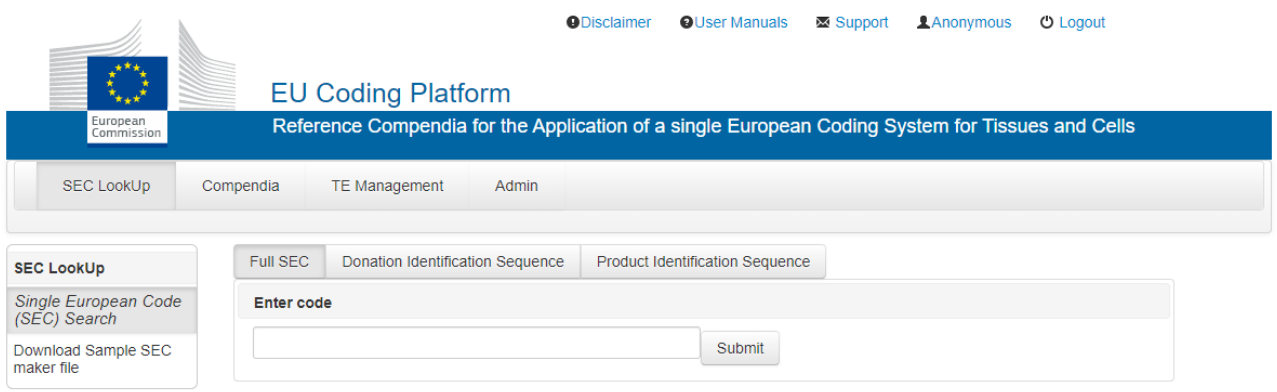
1. A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells.

2. Paragraph 1 shall not apply to partner donation of reproductive cells.

Directive 2006/86/EC
***Annex VII* - Information contained in the European Coding System**

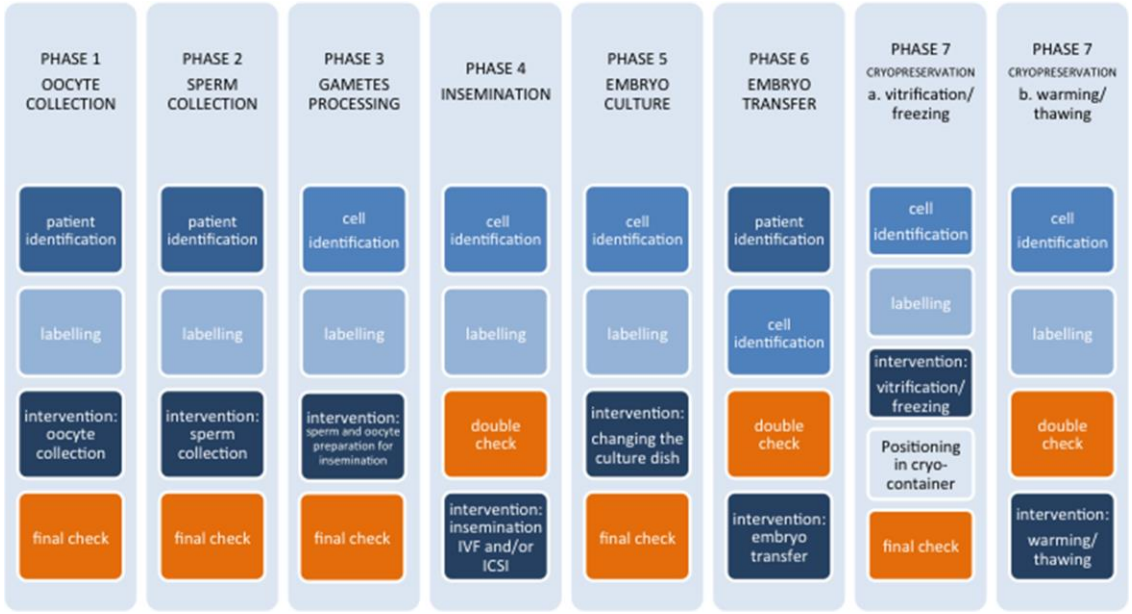
(a) Donation identification
- Unique ID number
- Identification of the tissue establishment

(b) Product identification
- Product code (basic nomenclature)
- Split number (if applicable)
- Expiry date



Practical implications

- ✓ ethical and legal issues in the international transaction of donor sperm and eggs are discussed
- ✓ **legislative and ethical "contradiction" by the local health authority** in permitting import of donor gametes, due to varying policies on donor reimbursement in different countries
- ✓ **lack of clear and coherent internationally-binding legislation** and regulatory guidelines overseeing the exchange of donor gametes across international borders
- ✓ case of "frozen-egg donation" from abroad, patients must rightfully be informed that current **cryopreservation technology is still sub-optimal**

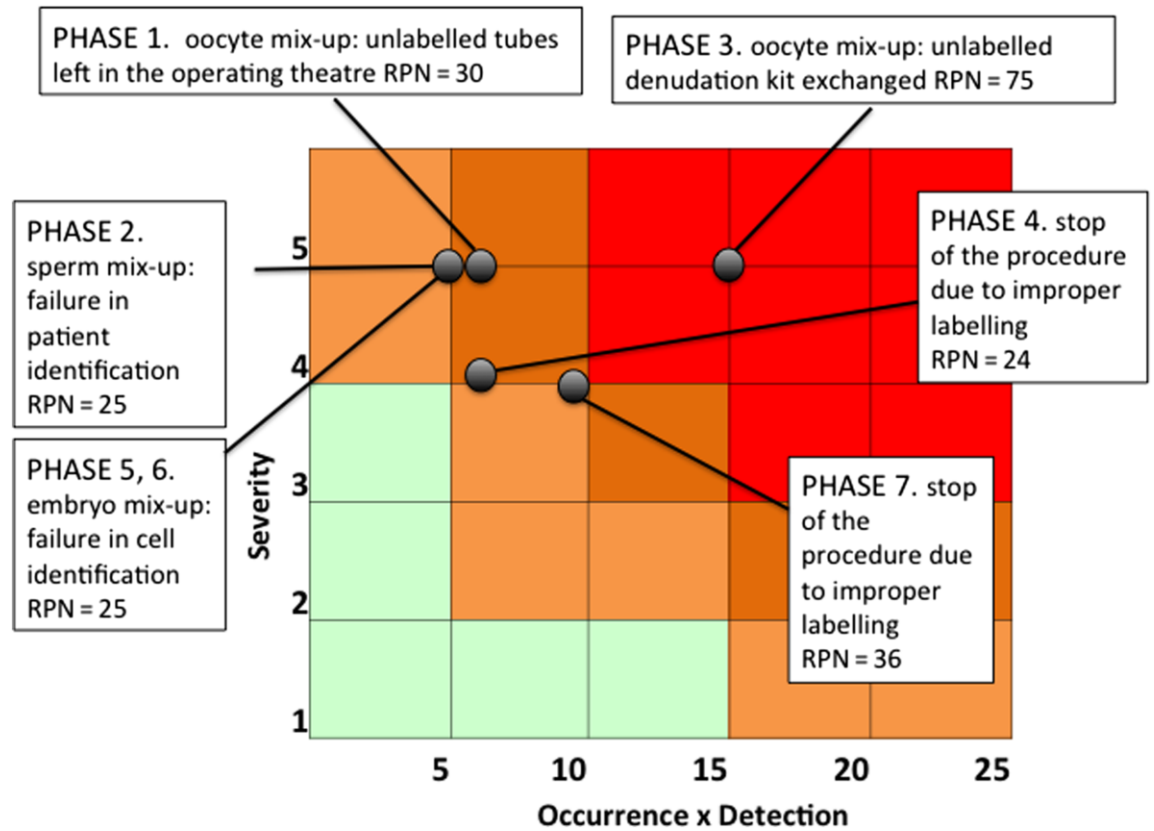


Comprehensive protocol of traceability during IVF: the result of a multicentre failure mode and effect analysis FREE

L. Rienzi ✉, F. Bariani, M. Dalla Zorza, E. Albani, F. Benini, S. Chamayou, M.G. Minasi, L. Parmegiani, L. Restelli, G. Vizziello, A. Nanni Costa,
on the behalf of the Italian Society of Embryology, Reproduction and Research (SIERR), Italy

Author Notes

Human Reproduction, Volume 32, Issue 8, August 2017, Pages 1612–1620,
https://doi.org/10.1093/humrep/dex144
Published: 31 May 2017 **Article history** ▾



Bologna court upholds couple's right to donor gametes!

I. At least 99 children conceived from one sperm donor developed Elephant Man's Disease.

II. The country had no law on traceability of donor gametes.

III. Possibility of creating of so-called "Abraham effect," (hundreds of siblings being generated from a single donor