



**Expert meeting on
EU CODING SYSTEM FOR TISSUES AND CELLS
Luxembourg 30 April 2004. Conclusions**

Introduction

The tissues and cells Directive, adopted by the Council of Ministers on 2 March 2004, will require the development of a series of technical requirements under its Article 28 (Point 1 below) for its implementation. It will also require the implementation of other requirements (point 2 below) in different areas by the Commission.

1. Technical Requirements and their adaptation to scientific and technical progress
(Article 28)

- Requirements for the accreditation, designation, authorisation or licensing of tissue establishments;
- Requirements for the procurement of human tissues and cells;
- Quality system, including training;
- Selection criteria for the donor of tissues and/or cells;
- Laboratory tests required for donors;
- Cell and/or tissue procurement procedures and reception at the tissue establishment;
- Requirements for the tissue and cell preparation process;
- Tissue and cell processing, storage and distribution;
- Requirements for the direct distribution to the recipient of specific tissues and cells.

2. Other requirements laid down in the Directive under the Comitology procedure
(Article 29):

- **EU Coding system (Article 25)**
- EU Register of tissue establishments (Article 10)
- EU System for import/export (Article 9)
- Guidelines for inspections (Article 7)
- Traceability at community level (Article 8)
- Traceability requirements for products and materials in contact with tissues and cells (Article 8)

All these requirements have to be carried out through the Comitology procedure.

Objectives of the meeting:

The Directive 2004/23/EC established in its Article 25 a requirement for an EU coding system for tissues and cells. The characteristics of this code have to be decided in the near future. The objective of the meeting was to analyse the existing coding systems for tissues and cells in place at the European level and to discuss the best and most feasible option to implement in compliance with this provision.

Conclusions of the meeting*:

1) Article 25 of Directive 2004/23/EC indicates the obligation for Member States to establish a system for the identification of human tissues and cells, in order to ensure their traceability. The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells. Therefore the EU code should constitute an important part of the traceability system and provide a description of the tissue and cell characteristics useful for professionals.

2) There are two main coding initiatives at the European level: ISBT 128 and EUROCODE. ISBT 128 already provides a comprehensive system for the identification and description of tissues and cells. EUROCODE is planning to do so but as yet provides codes for blood and blood products only. The experts presented a number of national experiences on the implementation of these codes for blood banking and traceability. ISBT 128 is being implemented in many European countries (UK, Scandinavia, the Netherlands, Belgium, Switzerland and Portugal among others) and also in the US, Eurocode is being implemented in Germany. The German authorities are considering the option to replace it with ISBT 128 in the future, after full implementation of Eurocode in Germany. The only experience of implementation for tissues and cells so far has been of ISBT 128. This has been implemented for a range of tissues in the UK, bone in Denmark, and for stem cells in the UK, Finland and the US.

3) The two codes have a lot of similarities and could be compatible. Both of them currently use bar codes as the means of transmitting information though both coding systems could also be applied to other electronic reading systems in the future (e.g. Radio Frequency Identification tags) as they become available and reliable. Both provide information on identification and on classification of blood; ISBT 128 provides similar for tissue and cells:

ISBT 128	EUROCODE
The International Council for Commonality in Blood Banking Automation, Inc (ICCBBA)	EUROCODE - IBL (International Blood Labelling Systems) e.V. (abbreviated: EUROCODE-IBLS)
Currently uses Bar codes Using Code 128.	Currently uses Bar codes Using Code 128.
Provides a donation numbering system that ensures globally unique identification;	Provides unique donation number (UDN) or unique bag number (UBN) that ensures globally unique identification;
an international product reference database for blood and blood products, tissues and haemopoietic stem cells;	Provides a product code tables and product code catalogue for blood and blood products.
A standard layout for the product label for blood and blood products and for tissues;	A standard layout for the product label for blood and blood products

Check digit to ensure correct computer entry when codes are entered manually (i.e. without scanning the barcode)	Check digit to ensure correct computer entry when codes are entered manually (i.e. without scanning the barcode)
Fee per year to cover costs of maintaining and updating the system (i.e. not for profit)	Fee per year to cover costs of maintaining and updating the system (i.e. not for profit)

However it was agreed that it is not the role of this working group to endorse any specific type of system at this stage, but to define in detail the characteristics that the code should have.

Once the specification has been agreed, it will be compared with existing systems and a strategy for development or adoption of a system could be agreed. Every effort should be made to ensure that the strategy adopted is complementary to any systems that are already in place in Europe and is not detrimental to wider global initiatives in this area.

4) The experts concluded that a European coding system will be a key element in the traceability system; however this system has to be complemented with the other measures laid down in the Directive 2004/23/EC. The coding system could not substitute for the role of the registers or the tissue establishments.

5) The meeting showed that existing systems in use for blood (where there is vast experience) are suitable for adaptation to tissues and cells. Tissues and cells present, however, particular challenges that require substantial adaptation of any existing system before they can be used for tissues. This emphasises the need for the new EU coding system.

6) The group of experts identified the basic information that the code should provide. There should be two different information areas covered by the code:

A) Donation identification that should include at least:

- Identification of the donation (unique number/code)
- Country of origin
- Establishment that issued the product
- Date of collection

Other information that the code could include:

- Donor identification
- Procurement organisation (if different from the supplying establishment)

B) Product identification should include at least:

- Type of tissue (basic Nomenclature)
- Expiration date

Other information that the code could include:

- Type of process (basic list)

- Status Code (Quarantine, fit for use...)

7) The experts agreed that an electronic means of transmitting the coded label information is the best solution but a bar code is the preferable option at the moment. The implementation of a bar code system will need lectures, computers and software. The cost will depend on which establishments will require the ability to read the code. The experts agreed that the first phase of the implementation should focus on tissue establishments, and in a second phase hospitals or health care establishments.

A flexible and progressive process for implementation should be designed. The experts discussed the possibility of allowing tissue banks to use an eye-readable code (a series of numbers or numbers and letters) without any barcode, at an early stage.

A basic scheme of the implementation could be as follows

FIRST PHASE	<u>Donation identification</u> <ul style="list-style-type: none"> • Identification of the donation (unique number/code) • Country of origin • Establishment that issue the product • Date of collection B) <u>Product identification</u> <ul style="list-style-type: none"> • Type of tissue (basic Nomenclature) • Expiration date 	Tissue establishments Eye-readable code and Bar code Or Eye-readable code only
SECOND PHASE	<u>Donation identification</u> <ul style="list-style-type: none"> • Identification of the donation (unique number/code) • Country of origin • Establishment that issue the product • Date of collection B) <u>Product identification</u> <ul style="list-style-type: none"> • Type of tissue (extended Nomenclature) • Expiration date • Type of process (basic list) • Status Code (Quarantine, fit for use...) 	Tissue establishments and Hospitals Eye-readable code and Bar code?

8) A Working group should be established, coordinated by the Commission and formed by a subgroup of the experts present at this meeting. The next tasks of the group will be:

- Design a flow chart of the process of coding from the donor to the recipient defining all steps and responsibilities.
- Complete the description of information that the code should provide, in particular:
 - o Donation number
 - o Code for the establishments
 - o Basic nomenclature for tissues and cells
 - o Basic list of processes.
- Conduct an options appraisal on the best means of establishing a system that meets the specification (to include cost, timescale, quality, global compatibility)

*** These conclusions represent the opinion of the experts present in the meeting and not necessarily the position of the European Commission**

Annex List of participants

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