EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Brussels, 06 February 2007
SANCO C6 CT/gcs D (2007) 360045

Summary Table of
Responses from Competent Authorities:
Questionnaire on the transposition and implementation of the European Tissues and Cells regulatory framework

In preparation of the first meeting of competent authorities on tissues and cells which the Commission convenes in order to exchange experiences in the transposition of the Directives into their national law, competent authorities were invited to complete a questionnaire covering the transposition and implementation of the Tissues and Cells regulatory framework. This table presents responses regarding the situation from the Member States and EEA countries as of 7 February 2007.

1. NAME OF COMPETENT AUTHORITY

Member State	Competent Authority
BE - Belgique / België	Federal Agency for Medicinal products and Health products
BU - Bulgaria	Executive Agency for Transplantation
CZ - Česká Republika	Ministry of Health
DK - Denmark	Danish Medicines Agency
DE - Deutschland	Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines
EE - Eesti	State Agency of Medicines
EL - Elláda	1) Ministry of Health and Social Solidarity**,** 2) Hellenic Transplant Organisation 3) National Independent Authority for medically Assisted Reproduction
ES - España	Organización Nacional de Trasplantes – National Transplant Organization (ONT)

Commission européenne, B-1049 Brussels – Belgium. Telephone : (32.2) 299 11 11
Office : F101 – 07 87. telephone : direct line (32.2) 295 40 72

E-mail: Caroline.Trouet@ec.europa.eu

Member State	Competent Authority
FR - France	Minisètre de la santé – direction générale de la santé – bureau 3C
IE - Ireland	Irish Medicines Board
IT - Italia	Centro Nazionale Trapianti, Centro Nazionale Sangue, Regioni (Regional Health Authorities)
CY - Kypros	Medical and public health services, Ministry of Health
LV - Latvija	Health Statistics and Medical Technologies State Agency
LT - Lietuva	National Bureau on Transplantation
LU - Luxembourg	Ministère de la Santé
HU - Magyarország	- National Public Health and Medical Officer's Service (NPHMOS) (in Hungarian: Állami Népegészségügyi és Tisztiorvosi Szolgálat) - The National Chief Medical Officer's Office (in Hungarian: Országos Tisztifőorvosi Hivatal) on the central level, and the regional offices of the NPHMOS on regional level
MT - Malta	Director General Health, Ministry for Health, the Elderly and Community care
NL - Nederland	Minister of Health, Welfare and Sport
AT - Österreich	Federal Ministry of Health and Women
PL - Polska	National Centre of Tissue and Cell Banking
PT - Portugal	Autoridade para os Serviços de Sangue e da Transplantação
RO - Romania	National Transplant Agency
SI - Slovenija	Ministry of Health, Directorate of Public Health
SK - Slovensko	Ministry of Health

Member State	Competent Authority
FI - Suomi/Finland	National Agency for Medicines
SE - Sverige	National Board of Health and Welfare Medical Products Agency
UK - United Kingdom	Human Fertilisation and Embryology Authority (HFEA) – deals with gametes and embryos Human Tissue Authority *(The two organisations provided 2 separate reports: Regular font – HFEA; Italics – Human Tissue Authority)*

EEA/EFTA countries

Iceland	Ministry of Health and Social Security
Norway	Norwegian Directorate of Health and Social Affairs (authorisations) Norwegian Board of Health (inspections)
Liechtenstein	Kontrollstelle für Arzneimittel

2. TRANSPOSITION

Member State	2004/23	2006/17	2006/86	Comment
BE - Belgique / België	No	No	No	Transposition is expected to be completed by end of 2007
BU- Bulgaria	Yes	Yes	Yes	There are two regulations in actual law concerning some of the requirements of Directive 2006/86/EC (One for adverse reactions and events and one for requirements for accreditation, designation, authorisation or licensing of tissue establishments)
CZ - Česká Republika	No	No	No	All Directives will be transposed into one law according to Czech national standards. In the Czech Republic, all Directives have to be transposed as a law and a decree.
DK - Denmark	Yes	Yes	Yes	- Transposition is expected to be completed by early 2007

Member State	2004/23	2006/17	2006/86	Comment
			(main parts)	- Transposition for the reporting of serious adverse incidents and reactions is planned to be completed by April 2007
DE - Deutschland	Yes (main parts)	Yes (partially)	Yes (main parts)	Transposition is expected to be completed by May 2007
EE - Eesti	No	No	No	- Transposition is expected to be completed by 31/07/2007 - Directive 2004/23/EC has been partly transposed into national law
EL - Elláda	No	No	No	Transposition is expected to be completed by end of April 2007
ES - España	Yes	Yes	Yes	
FR - France	voir commentaire ci-dessous	voir commentaire ci-dessous	voir commentaire ci-dessous	2004/23/EC: La transposition des dispositions de niveau législatif est en voie d'achèvement (elles ont été votées par le parlement français et leur promulgation est imminente). Les dispositions de la directive qui ne sont pas de niveau législatif (décrets ou arrêtés) figurent déjà pour la plupart dans la réglementation nationale française. Il reste un nombre limité de mesures qui restent encore à transposer. La transposition de ces mesures est en cours. 2006/17/EC: Les principales dispositions de cette directive sont déjà transposées en droit interne. Certains textes nationaux en cours d'actualisation (arrêtés de bonnes pratiques notamment) intégreront les précisions complémentaires apportées par la directive sur certains points. La transposition devrait pouvoir s'achever à la fin de l'année 2007. 2006/86/EC: Les principales dispositions de cette directive sont déjà transposées en droit interne. Certains textes nationaux en cours d'actualisation (décrets et arrêtés de bonnes pratiques) intégreront les précisions complémentaires apportées par la directive sur certains points. La transposition devrait pouvoir s'achever à la fin de l'année 2007
IE - Ireland	Yes	Yes	No	Transposition is expected to be completed by 31/08/2007
IT - Italia	No	No	No	Transposition is expected to be completed by end of 2007 (2004/23/EC will be transposed in Spring 2007)

Member State	2004/23	2006/17	2006/86	Comment
CY - Kypros	No	No	No	- 2004/23 and 2006/17 is expected to be transposed by March 2007 - 2006/86/EC is expected to be transposed by December 2007
LV - Latvija	No	No	No	- 2004/23/EC and 2006/17/EC will be transposed by 01/03/2007 - 2006/86/EC will be transposed by 01/01/2008 - The Ministry of Health of the Republic of Latvia has drafted the Regulations of the Cabinet of Ministers for transposition of the requirements of the Directives 2004/23/EC and 2006/17/EC (these Regulations are expected to be adopted by 01.03.2007.) According to the draft Regulations the Competent Authority is responsible for implementation and application of the Directives 2004/23/EC and 2006/17/EC
LT - Lietuva	Yes Partially	No	No	Directives will be transposed by 01/03/2007
LU - Luxembourg	No	No	No	- When the 2004/23/CE will be transposed, the other related directives of the Commission will be automatically transposed - As Luxembourg has no specific legislation concerning tissue establishment, we cannot give any accreditation neither give an authorization license. - For the time being, there is one company which is involved in the harvesting of bones (femoral heads) in Luxembourg and Belgium for further treatment (devitalisation) abroad (Germany and France) - The Ministry of Health has been following this specific activity for ten years - In the view of a future possible accreditation, we have checked the procedures applied by this company and required that they stick to all relevant requirements set up in the directives (procedures for harvesting, consent, laboratory testing, traceability, storage etc)
HU - Magyarország	Yes	No	No	- Transposition of 2006/17/EC is expected to be completed by April 2007 - Transposition of 2006/86/EC is expected to be completed by July 2007
MT - Malta	Yes	Yes	No	Transposition will be completed by 30/06/2007
NL - Nederland	No	No	No	- Transposition will be completed by 01/05/2007 - Both Upper and Lower House agreed upon the Act already, but it sill needs to be published, etc.

Member State	2004/23	2006/17	2006/86	Comment
AT - Österreich	No	No	No	- Transposition will be completed by 01/07/2007 - Tissues and cells are medicinal products in Austria and therefore are governed by the Austrian Medicines Act (AMA) including the manufacturing authorisation (MIA) of tissue establishments. - 11 tissue establishments including 6 stem cell banks received such a MIA according to the AMA before 2006. - Procurement is not regulated yet (see above) and will also be enforced by the future CA.
PL - Polska	Yes	Yes	Yes	
PT - Portugal	Yes Partially	No	No	- Directive 2004/23/EC and 2006/17/EC are expected to be transposed by the end of 04/2007 - Directive 2006/86/EC is expected to be transposed by 12/2007 - The CA was created Dec 2006. New legislation transposing the directives 2004/23/EC, 2006/17/EC is waiting for approval from the Government
RO - Romania	Yes	No	No	Transposition will be completed by 31/12/2007
SI - Slovenija	No	No	No	2004/23/EC is expected to be transposed by 30/09/2007 2006/17/EC is expected to be transposed by 31/03/2008 2006/86/EC is expected to be transposed by 31/03/2008
SK - Slovensko	Yes	Yes	No	Transposition will be completed by 01/09/2007 at the latest
FI - Suomi/Finland	No	No	No	- For 2004/23/EC: The bill for amending the Act on the Medical Use of Human Organs and Tissues has been approved by parliamentary committee and it will be discussed in the Parliament plenary for final approval on 31 January 2007 - For 2006/17/EC & 2006/86/EC: The parliamentary proceedings with the proposal for the Act are in progress. Other regulations and administrative provisions necessary to comply with the Tissue Directives can be given after the Act has been approved. The Act and other regulations and administrative provisions are expected to enter into force simultaneously, within few months.
SE - Sverige	No	No	No	- All three directives will be transposed into one national law. - The Medical products agency and the National Board of Health and Welfare will issue separate Regulations which are binding for the Tissue Establishments and for the Health care facilities as users of the tissues, cells and products

Member State	2004/23	2006/17	2006/86	Comment
				- Proposal for an Act is planned to be ready in the fall of 2007 - The Tissue act and the Regulations will enter into in December 2007 according to current plan.
UK - United Kingdom	No	No	No	- All directives to be transposed by 7 April 2007. A regulatory framework has been in place in the UK since 1 August 1991, the Human Fertilisation & Embryology Act 1990. Many of the provisions in the Act mirror those in the Directive. The Act will be amended to bring the provisions of the Directive fully into UK law. - UK has applied the one year derogation in Article 31(2) of the Mother Directive, as a domestic legislative framework was in place when the Mother Directive was adopted in 2004.
	Yes	*No*	*No*	*-For 2004/23/EC: The Human Tissue Act (2004) established a regulatory body to license and inspect (amongst other things) tissue establishments storing tissue for transplantation. Section 46 of this Act (Power to give effect to Community Obligations) was included to enable the Directives to be implemented via the HT Act. The HTA was designated one of the two UK Competent Authorities for the EUTCD. Draft transposition regulations have been published for consultation and the final version is currently being drafted. Formal transposition will occur in April 2007.* *- For 2006/17/EC: The HTA has powers to issue Directions to establishments it licenses. HTA issued Directions in April 2006 which summarised the requirements of Directive 2004/23/EC and Directive 2006/17/EC which requires establishments to meet the standards of these two Directives which will be implemented from 7 April 2007. Formal transposition will occur in April 2007.* *- For 2006/86/EC: HTA directions summarising the requirements of Directive 2006/86/EC will be published in April. Formal transposition will take place from 7 April 2007.*

EEA/EFTA countries

Iceland	No	No	No	- Transposition is expected 3rd quarter of 2007 - Transposition has taken so long time due to workload, shortage of expertise in this field at the Ministry and backlog in translation of EU Directives
Norway	Yes	No	No	- 2006/17/EC will be transposed as soon as possible (currently awaiting the decision of the EEA Committee) - 2006/86/EC is expected to be transposed by 01/09/2007
Liechtenstein	No	No	No	-For 2004/23, the draft of the law has passed the first reading in the parliament. The second and

			.	third reading is expected to take place in the first third of 2007 - Directives 2006/17 and 2006/86 are still not part of the EEA Agreement

3. NUMBER OF TISSUE ESTABLISHMENTS

Member State	Number	Accreditation	Types of tissue establishments for accreditation
BE - Belgque / België	104	- All tissue establishments have been authorised or designated, except a commercial one	- Reproductive cells & tissues: 18 - Musculo-skelettal system: 7 - Beta-pancreatic cells: 2 - Stemcells: 3 - Hematopoietic stemcells: 9 - Hepatocytes: 1 - Keratinocytes: 3 - Amniotic membrane: 4 - Skin: 4 - Cord blood: 4 - Femoralhead: 16 - Ophtalmic tissue: 5 - Ossicular bone: 4 - Blood vessels: 3 - Cardiac valves: 1
BU- Bulgaria	7	All establishments have been accredited	- Department of Tissue banking to Emergency Hospital "N.I.Pirogov"-Sofia-bone and skin bank: Authorised, accreditation is a separate process and still not accredited. - "Tissue bank Osteocentre Bulgaria"-Sofia-bone and skin bank: Authorised, accreditation is a separate process and still not accredited. - "Cytonet Sofia-Tissue bank"-hepatocyte cell bank: Authorised, accreditation is a separate process and still not accredited. - Department of Eye banking"-Hospital "Queen Jovanna"-Sofia: Authorised, accreditation is a separate process and still not accredited. - Department of cord blood banking to "Malinov" Hospital Sofia:

Member State	Number	Accreditation	Types of tissue establishments for accreditation
			Authorised, accreditation is a separate process and still not accredited - Department of cord blood banking to "Saint Lazar" Hospital Sofia: Authorised, accreditation is a separate process and still not accredited - Tissue bank "Bulgen"-HPC cord blood bank: Authorised, accreditation is a separate process and still not accredited.
CZ - Česká Republika	25	All establishments have been accredited (except reproductive cells: sperms – no accreditation)	- Eye tissue banks: 2 - Bone tissue banks: 16 - Cell tissue banks: 4 - Specialised tissue banks (Cardiovascular tissue): 1 - Multi-tissue banks: 2
DK - Denmark	100	Full accreditation will be achieved by April 2007	- The number of types of tissue establishments will become available once accreditation process is completed
DE - Deutschland	400-600	- Not all establishments have been accredited - Within three months after filing an application for manufacturing authorisation, the respective tissue manufacturing or tissue donation site will be provided with a manufacturing authorisation by the competent authority of the respective German Land, following an on-site inspection by the competent authority of the respective German Land under consultation with the Paul-Ehrlich-Institut, which sends an expert to the on-site inspection - Marketing authorisation for a specific tissue preparation medicinal product prepared and banked in a tissue establishment (which already obtained manufacturing authorisation) will be granted by the Paul-Ehrlich-Institut marketing authorisation following an evaluation of the marketing authorisation application	- See below for existing types of tissue establishments (The total number already accredited is presently unknown, but it will be available soon) <u>Types of tissues establishments</u> bones, ligaments, (blood) stem cells, umbilical cord blood, heart valves, pancreatic islet cells, hepatocytes, dura mater, skin, fascia lata, collagenmembrane, spongiosa, amniotic membrane

Member State	Number	Accreditation	Types of tissue establishments for accreditation
		- It is known that additional tissue establishments will file for a manufacturing and/or marketing authorisation. The approval process will be completed in 2007	
EE - Eesti	NA	The process of accreditation will be completed when Estonia has transposed the directives and laid down requirements for all tissue establishments	- Reproductive cells: 3
EL - Elláda	3	- Not all establishments have been accredited - Approval process will be completed after the transposition of Directive into the national law	1) Human Tissue Bank-NCSR Demokritos, Authorised ISO 9001/2000 (bone, dura matter, skin, tendons (not yet accredited) 2) Hellenic Cord Blood Bank-IBEAA Authorised (NETCORD-FACT) application 3) Cornea Bank – AXEPA Hospital of Salonica (not yet accredited)
ES - España	270	All establishments have been accredited	- CORNEA: 29 - PIEL: 15 - T. VALVULAR: 14 - T. VASCULAR: 18 - T. OSTEO-TENDINOSO: 67 - CELULAS Y CULTIVOS C.: 8 - MEMBRANA FETAL: 9 - OTROS TEJIDOS: 10
FR - France	**1) secteur des tissus et des cellules** 44 Banques de Tissus autorisées 43 Unités de thérapie cellulaire autorisées Total : 87 établissements	Yes, all establishments have been accredited	- Cornées: 21 (par site) - Peau: 14 (par site) - Têtes fémorales/ os massifs/ fascia-lata: 43 (par site) - Tendons: 6 (par site) - Volets crâniens: 5 (par site) - Valves/ artères: 28 (par site) - Membranes amniotiques: 13 (par site) - Parathyroïdes: 8 (par site) - CSH: 34 (par site)

Member State	Number	Accreditation	Types of tissue establishments for accreditation
	autorisés 2) **<u>secteur des gamètes et de l'AMP</u>** 215 centres d'AMP clinico-biologiques autorisés (soit 108 centres de fécondation in vitro et 107 laboratoires de préparation du sperme vue d'insémination)		- CMN (cellules mononucléées): 16 (par site) - Lymphocytes: 13 (par site) - Kératinocytes: 2 (par site) - Cellules souches mesenchymateuses: 1 (par site) - Cellules dendritiques: 2 (par site) - Macrophages: 1 (par site) - Chondrocytes: 1 (par site) - Vaccins autologues (culture de cellules tumorales de différentes origines): 1 (par site) - Centres de fécondation in vitro: 107 (par site) - Laboratoires de préparation du sperme n vue d'insémination): 108 (par site)
IE - Ireland	Approximately 20	Accreditation process will be completed by end of August 2007. Inspection process has started. Compliance will be assessed prior to issue of authorisation.	- Haemopoeitic Stem Cells: 6 - Bone: 1 - Fertility Clinics: 8 - Eye, heart valve, and directed cord blood donations: 1 - Skin: 2 - Cord blood for private use: 1 - None of the establishments have received accreditation yet - Others are likely to apply in the cord blood industry
IT - Italia	- 31 tissue banks - 105 haematopoietic stem cell centres - 16 cord blood banks	- All establishments received authorisation to operate by regional authorities, but not all have been inspected and certified by CNT (Centro Nazionale Trapianti) - For tissue banks, first round of inspections is already completed and second inspections started in 2006 - For HPC centres, preliminary certifications for all centres (on basis of document review) will be completed by the end of 2007	- Bone (CNT inspection): 6 (1 in process) - Cornea (CNT inspection): 13 - Skin (CNT inspection) : 5 - Valves and vessels (CNT inspection): 5 (1 in process) - Haematopoietic stem cells (Regional authorisation): 105 - Cord blood banks (Regional authorisation): 16

Member State	Number	Accreditation	Types of tissue establishments for accreditation
CY - Kypros	Approximately 10 establishments	Approval process will be completed by December 2007	No accreditation granted
LV - Latvija	4 tissue establishments and 36 procurement organisations	- Not all establishments are accredited - The establishments and procurement organisations are designated by Regulations of the Cabinet of Ministers	- In the draft Regulations of the Cabinet of Ministers tissue establishments are not classified according to the different types of tissues and cells - 4 establishments received accreditation
LT - Lietuva	4	Not all establishments have been accredited	Cornea bank (1)
LU - Luxembourg	0	Not Applicable	Not Applicable
HU - Magyarország	about 18-22 tissue establishments	All tissue establishments have been authorised or designated	- Musculoskeletal Tissue Banks,1 keratinocyta labor: 4 - Cornea banks: 2 - Amnion membrane: 1 - Limbal stem cells: 1 - Cord blood storage: 2 - stem cell (all centers performing hemopoietic stem cell transplantation): 5 - Reproductive cell banks (plus all authorities performing In Vitro Fertilization): 2 - Heart valves (all authorities performing heart transplantation/surgery): 3 - Vascular grafts (all authorities performing heart transplantation/surgery): 3
MT - Malta	Estimated that there may be less than five establishments	Approval process is expected to be carried out by mid-2008	No tissue establishments have received accreditation or authorisation yet
NL - Nederland	200 (purely estimation)	- Not all establishments have been accredited - The date of completion depends on when the Act enters into force and when tissue establishments will apply for accreditation	Yes

Member State	Number	Accreditation	Types of tissue establishments for accreditation
AT - Österreich	83	Accreditation process will be completed by 2009	TE in hospitals in Austria - Bone: 43 - Cornea: 22 - Homografts: 9 - Others: 2 - Stem cells: 9
PL - Polska	40	Not all establishments have been accredited, but the approval process will be completed by the end of 2007	- Bone: 3 - Heart valve bank: 3 - Cornea bank: 2 - Skin bank: 2 - Stem cells: 10 - Reproductive cells: 20
PT – Portugal	40-45	Approval process will be completed by end of 2008 (licensed by the new CA)	- Stem cells (8 license) - Ophthalmic tissue (13 license) - Cardiac valves (4 license) - Muskulo-skeletal - Cord blood - Reproductive cells - These establishments have been licensed by the previous authority: Health Ministry
RO – Romania	25	All tissue establishments have been accredited	- Bones, tendons: 4 - Skin: 5 - Stem cells: 3 - Reproductive cells: 8 - Pancreatic cells: 2 - Heart valves, vessels: 1 - Cornea: 1

Member State	Number	Accreditation	Types of tissue establishments for accreditation
SI - Slovenija	None yet. There are 15 procurement organisations and organisations responsible for human application	- Establishments will be accredited in 2007 and 2008	Not applicable
SK - Slovensko	19	- All existing tissue establishments have received authorisation by the Ministry of Health in the past. According to the Law 282/2006 Z.z.implementing Directive 2004/23/EC. - All these tissue establishments need to be re-authorised by 01/04/2007	- Multi-tissue banks: 3 - Eye banks: 2 - Private cord blood bank: 1 - HPC banks: 6 - Assisted reproduction centres: 7
FI - Suomi/Finland	About 60 (estimate)	- No tissue establishments has been accredited according to the tissue directive - According to the proposal, deadline for applications is 1 September 2007, and NAM has to make the decision on the authorisation within six months after that date	-
SE - Sverige	- Total number is unknown yet - A questionnaire has been sent to all County Councils to verify the exact number	- According to the Biobanks act all establishments dealing with human material of any kind are registered and thus known - Currently in the process of sorting out those tissue establishments that are included in the directive as they deal with tissues and cells intended for human application - All tissue establishments will be approved by the time EC directive has been transposed into national law and regulations by the National Board of Health and Welfare and the Medical Products Agency - There are some research laboratories (they can be public or owned by Pharma) dealing with human	At the present, there are a number of separate well known tissue establishments as follows: - Cornea banks: 5 - Heart valve/ vascular banks: 3 - Skin banks: 1-2 - Combined bank for cornea, heart valves, vascular tissue and ossicles (hörselben): 1 - Femoral head banks: may be as many as >80 - Banks for in vitro fertilization: some 15 separate establishments, which can be, 1) for partner donation only, 2) for sperm donation, and 3) for ovum donation - Swedish cord blood bank (altruistic and voluntary for allogeneic

Member State	Number	Accreditation	Types of tissue establishments for accreditation
		tissues and cells that may be on the verge of human application. Sweden is actively looking for such instances	use) at Drottning Silvias hospital for children in Göteborg
UK - United Kingdom	Approximately 191 reproductive cell establishments	- Accreditation process will be completed by 7 April 2007. - 91 establishments are already licensed under existing regulatory framework (the Human Fertilisation & Embryology Act 1990). - The remaining 100 establishments to be licensed in accordance with the Directive by 7th April 2007.	- 91 reproductive cell establishments have received accreditation as of 20 December, 2006
	117 main establishments and 110 satellite establishments associated with these main sites	*- We have licensed 117 tissue establishments (linked to 110 smaller satellite sites) but believe there are a small number of establishments (we estimate this may be up to about 10) that process tissue without storing are not licensed currently but will be licensed from April 2007* *- The statutory position in the UK is that tissues or cells that are processed and/or stored for more than 48 hours must be held under the authority of a licence* *- The Designated Individual (Responsible Person) at the storage establishment must have third party agreements with any organisation that procures, tests, processes, preserves or distributes material on their behalf*	*- Cord blood: 4* *- More than one type of tissue: 22* *- Heamopoeitic stem cells: 33* *- Muscoskeletal: 30* *- Skin: 11* *- Cardiovascular: 4* *- Ocular: 9* *- Other: 4*

EEA/EFTA countries

Iceland	2	- Accreditation process will be completed after the transposition of the Directives 2004/23/EC, 2006/17/EC and 2006/86/EC	- IVF clinic: 1 - LSH (State and University hospital – bone/skin)

Norway	Approximately 60	- Accreditation process will be completed by end of 2007	-
Liechtenstein	1	- The establishment has been accredited - Please note that Liechtenstein is part of the European Economic Area, but also part of the Customs Union with Switzerland. At the moment we have only one license issued under this Customs Union.	Cornea: 1

4. PREPARATION PROCESSES

Member State	Tissues and Cell preparation processes
BE - Belgique / België	- The authorisation of the tissue and cell preparation process is planned to take place
BU- Bulgaria	1. Procurement of bone and skin from deceased and living donors. 2. Processing, labelling, storage and release of bone allograft products and skin. 3. Distribution of bone allografts and skin for human application. 4. Procurement of HPC stem cells from cord blood, bone marrow and peripheral circulation 5. Processing, labelling, storage and distribution of human corneas. 6. Procurement, processing, storage and release of human hepatocytes.
CZ - Česká Republika	- Ocular tissue: Cornea (optisol storage +4C, Organ culture); Sclera (deep freezing -80C, freeze-drying) - Skin: hypothermic storage +4C, cryopreservation with storage at -80c or liquid nitrogen, freeze-drying,, keratinocyte culture - Musculoskeletal tissue: Bone (deep freezing -80C, freeze-drying), Osteochondral grafts and menisci (hypothermic storage +4C, cryopreservation with storage at -80C or liquid nitrogen, chondrocyte culture) - Fascia lata or other fascia (deep freezing -80C, freeze-drying) - Ligaments and tendons (deep freezing -80C, cryopreservation with storage at -80C or liquid nitrogen, freeze-drying) - Cardiovascular tissue: Heart valves, vessels, arteries and veins (hypothermic storage +4C, cryopreservation with storage in liquid nitrogen) - Foetal membranes (Deep freezing -80C, Cryopreservation with storage at -80C or liquid nitrogen, freeze-drying) - Haematopoietic tissue (Hypothermic storage +4C, cryopreservation with storage at -80C or liquid nitrogen) - Reproductive cells and tissues (cryopreservation with storage at -80C or liquid nitrogen) - Endrocrine cells and tissues (cryopreservation with storage in liquid nitrogen)

Member State	Tissues and Cell preparation processes
DK - Denmark	- Type of tissue and cell processes for accreditation is still under consideration - Input from CA meeting welcome
DE - Deutschland	procurement, separation, concentration, selection, manipulation, modification, cleaning, cutting, preparation, cultivation, cryo-conservation, sterilisation, irradiation denaturation, inactivation, demineralisation, quality testing, virological and microbiological testing procedures, packaging, transport and storage
EE - Eesti	Reproductive cells, hematolocical services (includes blood preparations), neurosurgery, cornea transplantation
EL - Elláda	1) Tissue preparation in Demokritos-human tissue bank: biochemical process, lyphilization, radiosterilazation, collection, storage 2) Hellenic cord blood bank: collection and storage of cord blood stem cells for allogenic transplantation 3) cornea for human application
ES - España	**-**
FR - France	**Tissus autorisés** : cornées : 50 procédés autorisés (ces procédés sont mis en oeuvre dans 20 banques de tissus): membranes amniotiques utilisées en ophtalmologie : 9 procédés autorisés (ces procédés sont mis en oeuvre dans 9 banques de tissus) **evaluation en cours** : os (cryoconservation , viro-inactivation) : 60 procédés en cours d'évaluation (ces procédés sont mis en oeuvre dans 32 banques de tissus) **objectifs pour 2007/2008** : evaluation des vaisseaux, des valves et de la peau **Cellules (hors cellules reproductrices)** : **objectifs pour 2007**: evaluation des cellules souches hématopoiétiques à but de reconstruction du tissus hématopoiétique : 200 procédés en attente d'autorisation (ces procédés sont mis en oeuvre dans 30 banques de tissus) **Cellules reproductrices** : 1)sperm preparation for IVI 2)IVF 3)ICSI 4)sperm donation 5)oocyte donation 6)germinal tissue cryopreservation 7)embryocryopreservation

Member State	Tissues and Cell preparation processes
IE - Ireland	For example : - Stem cells: procurement, processing, testing and cryopreservation - Gametes: IVF, ICSI, cryopreservation, assisted Hatching, spearm preparation, etc.
IT - Italia	Cryopreservation, freezing (without cryoprotectant), lyophilisation, demineralization, glycerolization (skin), Cornea – cold preservation, cornea – preservation in organ culture medium, antibiotic decontamination, gamma irradiation sterilisation, Graft cutting and shaping, cell selection, cell depletion
CY - Kypros	Not determined due to the fact that the legal framework has not been established
LV - Latvija	-
LT - Lietuva	Working on the matter
LU - Luxembourg	Not Applicable
HU - Magyarország	- Musculoskeletal tissue grafts preparation and preservation (the list is enclosed) - Corneal tissue preparation and preservation - Amniotic membrane preparation and preservation - Limbal stem cell preparation and preservation - Cord blood preparation and preservation - Stem cell preparation and preservation - Heart valves, vascular grafts
MT - Malta	The Ministry for Health, the Elderly and Community Care in Malta still has not established such a list
NL - Nederland	Establishments apply for a accreditation for processing as such. Processing is more or less defined as all operations carried out during preparation, manipulation and preservation of human tissues and cells
AT - Österreich	- Bone, Cornea, Skin, Ligaments - Cells derived from endodermal, ectodermal and mesenchymal origin including stem cells derived from cord blood, bone marrow and peripherial blood
PL - Polska	- Frozen, radiation sterilized bone grafts (granules, chips, wedges, struts, massive) - Lyophilized, radiation sterilized bone grafts

Member State	Tissues and Cell preparation processes
	- Frozen, radiation sterilized menisci - Frozen, radiation sterilized tendons - Frozen, radiation sterilized ligaments - Fresh, radiation sterilized cartilage - Frozen, radiation sterilized skin - Frozen, radiation sterilized acellular dermis - Frozen, radiation sterilized amnion - Frozen, radiation sterilized pericardium - Frozen, radiation sterilized fascia - Frozen heart valves - Cultured cornea - Cultured keratinocytes - Cultured chondrocytes - Frozen stem cells
PT - Portugal	-
RO - Romania	No processes accredited yet
SI - Slovenija	- The list of tissue and cell preparation processes will be adapted to the needs of our patients, self sufficient procurement program and financial possibilities of our state. Therefore it is not strictly foreseen yet. Nevertheless some activities and development in this particular area are in progress. - Cryopreservation, storage and preparation for application of: haematopoietic stem cells from marrow, peripheral blood and cord blood, cornea, amniotic membrane, skin, bones and tendons, femoral heads, hondrocytes, osteoblasts, keratinocytes, ear ossicles, heart valves, arteries
SK - Slovensko	- Skin: aseptic procurement, cryopreservation, glycerol preservation - Amnion: asceptic procurement, cryopreservation, freeze drying, glycerol preservation - Bone: massive grafts and femoral heads: aseptic procurement, cryopreservation - Cancellous bone: aseptic procurement, morselization, deep freezing, deminerlized cancellous bone chips - Cornea: 2 types of preservation (Optisol, organ culture) - HPCs, Cord Blood: cell separation, concentration, cryopreservation - Cardiovascular tissue: cryopreservation - Reproductive tissue: cropreservation - In vitro cell cultures: keratinocytes, chondrocytes, osteoblasts, limbal stem cells
FI - Suomi/Finland	-

Member State	Tissues and Cell preparation processes
SE - Sverige	- Sweden intends to accredit most cell preparation processes. - The full list is unavailable at present time
UK - United Kingdom	Reproductive cells: donation, procurement, testing, processing, storage, & distribution
	- Currently we license the storage of tissue intended for transplantation, this means that we currently license most establishments carrying out any type of cell preparation or processing *- Following the transposition of the directive into UK law, the HTA will regulate any processing of tissue*

EEA/EFTA countries

Iceland	-
Norway	- Bone marrow for transplantation – both autologous and allogenic - Stem cells from cord blood for transplantation - Stem cells for growth of cartilaginous tissue - Stem cells for transplantation into the heart - Preparation of bone tissue - Preparation of corneas - Preparation of skin cells - Procedures for sperm and oocytes connected to IVF,ICSI,MESA,PESA,TESA,IVM - Isolation and preparation of pancreatic islets
Liechtenstein	Not applicable

5. DIRECT DISTRIBUTION

Member State	Cells for direct distribution	Accreditation
BE – Belgique / België	Not regulated	- No suppliers accredited, designated, authorised or licensed for direct distribution for immediate transplantation - No agreement to the direct distribution for immediate transplantation to the recipients

Member State	Cells for direct distribution	Accreditation
BU – Bulgaria	HPC stem cells	No suppliers accredited and no agreement given for direct distribution
CZ – Česká Republika	None	- No suppliers accredited - No agreement given for direct distribution
DK – Denmark	- The situation may occur on a random basis, for certain specialised stem cells; but it might also be relevant for some other cell types. - However since the Directives do not specify the specific type of tissue or cell, Denmark has taken the position that it is more relevant to implement an effective control system, with direct consultation to our Agency for the authorisation, to assist the rapid distribution of the tissue/ cells, for immediate transplantation elsewhere.	- No suppliers accredited - No agreement given for direct distribution
DE – Deutschland	None (not applicable according to the German Law)	No suppliers accredited and no agreement given for direct distribution (not applicable to the German Law)
EE – Eesti	NA	No suppliers accredited and no agreement given for direct distribution
EL – Elláda	Processed tissues, cord blood stem cells	No suppliers accredited and no agreement given for direct distribution
ES – España	Corneas, HP	Suppliers have been accredited
FR – France	Sont concernées les cellules hématopoïétiques prélevées dans la moelle osseuse et transplantées sans une phase de préparation, de transformation et de conservation dans une banque de tissus. Ce n'est pas le cas des cellules hématopoïétiques issues du sang de cordon ou du sang périphérique qui doivent être préparées dans une banque de tissus autorisée à les préparer et à les distribuer.	- Aucun demandeur n'a été autorisé (le terme de "demandeur" n'est pas approprié) : en effet, le prélèvement et la greffe de cellules hématopoïétiques prélevées dans la moelle osseuse ne peuvent être réalisés que dans des établissements de santé autorisés. Les établissements qui vont être autorisés à prélever des cellules hématopoïétiques issues de la moelle osseuse seront de fait autorisés à les distribuer La loi française qui transpose cette disposition prévoit que les établissements de santé autorisés à prélever des cellules hématopoïétiques issues de la moelle osseuse peuvent distribuer des cellules hématopoïétiques issues de la moelle osseuse non transformées en vue d'une greffe immédiate. Un décret décline par ailleurs les conditions médico-techniques d'autorisation des établissements de santé qui prélèvent des cellules y compris bien entendu les

Member State	Cells for direct distribution	Accreditation
		cellules hématopoïétiques prélevées dans la moelle osseuse. - Il ne sera pas donné d'autorisation de distribution en tant que telle (voir explication ci-dessus)
IE – Ireland	Allogeneic stem cells from International Bone Marrow Registry will be distributed directly from our National Blood Centre for immediate transplantation	No suppliers accredited and no agreement given for direct distribution
IT – Italia	Bone marrow, peripheral blood stem cells are allowed direct distribution	No suppliers accredited and no agreement given for direct distribution
CY – Kypros	Haematopoetic Stem cells	No suppliers accredited and no agreement given for direct distribution
LV – Latvija	The draft Regulations of Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" do not define which types of tissues/cells may be distributed directly	No suppliers accredited and no agreement given for direct distribution
LT – Lietuva	Bone marrows	Suppliers have been accredited (3 suppliers received approval) Have not given agreement to direct distribution
LU – Luxembourg	Not applicable	Not applicable
HU – Magyarország	Hemopoietic stem cells for allogeneic usage	- 6 suppliers received approval for direct distribution for immediate transplantation - Agreements to direct distribution have been given in case of all allogeneic stem cell transplantation (among them 135 unrelated transplantations)
MT – Malta	No agreement has been reached with regards to suppliers	No agreements given
NL – Nederland	X	No suppliers accredited (not yet anyway) and no agreement given for direct distribution
AT – Österreich	Issue of direct distribution will be defined in an ordinance	No suppliers accredited and no agreement given for direct distribution
PL – Polska	- Stem cells of bone marrow, stem cells of circulating	- All suppliers received accreditation

Member State	Cells for direct distribution	Accreditation
	blood, reproductive cells	- One agreement granted for for direct distribution
PT – Portugal	Probably stem cells (not defined yet)	No suppliers accredited and no agreement given for direct distribution
RO – Romania	Bones, tendons, skin, corneas, heart valves, reproductive cells	- 26 suppliers received accreditation - One agreement given in 2006 to direct distribution for immediate transplantation
SI – Slovenija	HSC Haematopoietic Stem Cells from unrelated bone marrow donors (UBMD)	- 1 supplier received accreditation (International accreditation (BMDW) only) - 28 agreements given for direct distribution (only UBMD)
SK – Slovensko	In vitro cell cultures, bone marrow (directed donations), reproductive cells	- Accreditation for suppliers for direct distribution are not yet granted from the competent authority - Agreements to direct distribution have not been granted yet, but will follow once new authorisations are given
FI – Suomi/Finland	Not defined yet	No suppliers accredited and no agreement given for direct distribution
SE – Sverige	- Hematopoetic stem cells (currently 7 centres for transplantation of Hematopoetic stem cells) - Swedish cord blood bank (altruistic and voluntary for allogeneic use) at Drottning Silvias hospital for children in Göteborg - It is possible that there will be direct distribution from this tissue establishment to health care facilities where hematopoetic stem cell transplantation is carried out - Some of the cells used are procured locally from donors that are related to the recipient, but an increasing number of transplantations are made with matched unrelated donors via registers in other countries. We have been informed that many donors are in Germany, but donors from third party countries (USA for example) are also being used	- Suppliers not yet accredited - No agreement for direct distribution given yet - Sweden is considering accreditation of establishments to deliver and receive haematopoetic stem cells according to special rules rather than having to authorize every single import or export - Some of the stem cells come from non- EU countries (the US and Others)
UK – United Kingdom	Not applicable to reproductive cells	Not applicable to reproductive cells

Member State	Cells for direct distribution	Accreditation
	Following the transposition of the directives into UK law, tissues and cells may be directly distributed in exceptional and rare cases where the Authority is satisfied that it is necessary for clinical reasons, eg bone marrow for lifesaving transplantation. We have worked hard to advise the sector of the benefits of only procuring and distributing via a Designated Individual (Responsible Person) at a storage establishment as this person will already have quality management systems in place to ensure that the requirements (particularly with regard to traceability and testing) of the Directive are met. Representatives of the licensed sector have endorsed this approach.	*No suppliers accredited and no agreement given for direct distribution*

EEA/EFTA countries

Iceland	-	No supplier in the country and no agreement given for direct distribution
Norway	-	No supplier in the country and no agreement given for direct distribution
Liechtenstein	Not applicable	No supplier in the country and no agreement given for direct distribution

6. INSPECTIONS

Member State	System for inspections	Inspections conducted	Officials & authorities
BE -Belgique / België	- Yes, inspection system in place - Procurement of human tissues and cells may also be inspected by the same system	4 inspections conducted in 2006	- Inspections carried out by members of the staff of the Public Agency or Ministry of Health - Granting accreditation and inspecting done by different authority
BU – Bulgaria	- Yes, system for organising inspections/control measures in place	14 inspections conducted	- Inspectors (mainly physicians) from Department "Development and control on transplantation" in Executive Agency for Transplantation

Member State	System for inspections	Inspections conducted	Officials & authorities
			- Granting accreditation and inspecting done by different authority
CZ - Česká Republika	- In the Czech Republic, tissues and cells establishment are inspected before obtaining an authorisation/ license/ agreement from the competent authority - If the authorisation/agreement is broken then the inspection follows	25 inspections conducted	- Granting accreditation and inspecting done by same authority
DK - Denmark	- Yes, The control measures for the procurement of tissue/cells, as required by the Directives, are the direct responsibility of the tissue establishments in Denmark - During our inspection programme of tissue establishments, we shall verify their quality systems and procedures to confirm the procurement centre complies with the requirements of the Directive - In addition, throughout 2007 our Agency plans to inspect several procurement facilities, with the co-operation of the tissue establishment and our National Board of Health.	20 conducted at the time of reporting	- The officials performing the inspection of tissue establishments are qualified professional inspectors, representing the designated Competent Authority, the Danish Medicines Agency - They are highly proficient in the auditing of medicinal product and blood facilities and have received training as to the systems, practices and regulatory requirements of tissue establishments - Granting accreditation and inspecting done by same authority
DE - Deutschland	- Yes, controlled through the following activities: 1. Notification of competent authority about the procurement sites and the manufacturing site 2. Manufacturing authorisation and inspections if possible done by competent authorities	- Inspections have been carried out for a number of years already - The exact number of inspections already conducted is not available	- The competent authority of the German Land is responsible for GMP inspections of manufacturing sites and tissue/cell donation sites. This is done under consultation of the Paul-Ehrlich-Institut which sends an expert to the on-site inspection. Thus, inspections are carried out by civil servants or other official employees of the competent authority of the respective German Land. - Granting accreditation and inspecting done by different authority.
EE - Eesti	No system in place for inspections	None	- State Agency of Medicines

Member State	System for inspections	Inspections conducted	Officials & authorities
			- Granting accreditation and inspecting done by same authority
EL - Elláda	No system in place yet	None	- ISO 9001/2000 for tissue bank - NETCORD-FACT
ES - España	- Inspection system in place - Inspections under responsibility of the Regional Health Authorities was every 4 years, but shall be every 2 years after Directive implementation	All authorised centres have been updated at least once before being authorised	- General inspectors belonging to Health Care Regional Authority carry out inspections - Granting accreditation and inspecting done by different authority
FR - France	System for inspections exist in the form of: - inspections - autorisations - rapports d'activité	- **pour les banques de tissus et de cellules** : 87 - **pour les activités portant sur les cellules reproductrices** : il y a des inspections réalisées par les services des agences régionales de l'hospitalisation mais leur nombre n'a pas été recensé	**Pour les activités portant sur les tissus et les cellules (hors cellules reproductrices)**, les inspecteurs sont des agents de l'Agence française de sécurité sanitaire des produits de santé. Ils sont désignés par cette agence. **Pour les activités portant sur les cellules reproductrices**, les inspecteurs sont des médecins ou des pharmaciens inspecteurs en santé publique qui exercent leurs fonctions dans les services des agences régionales de l'hospitalisation. - Granting accreditation and inspecting done by different authority
IE - Ireland	- Yes, a system is in place for organising inspections and control measures - Procurement of tissues and cells can be performed by the following means: a) Procurement can take place in a site attached to tissues establishments in Irish territory; b) Procurement can take place in a site attached to a tissue establishment outside of Irish territory. - For procurement sites attached to a tissue establishment in Irish territory we will inspect	11 inspections have been conducted to date	- Blood and tissue inspectors from Irish Medicines Board (CA) who have been empowered with responsibilities of Article 7.4 of 2004/23/EC conducts the inspections - Granting accreditation and inspecting done by same authority

Member State	System for inspections	Inspections conducted	Officials & authorities
	procurement during the tissue establishment inspection and will appear on the tissue establishments' authorisation. If a number of procurement sites are attached to a tissue establishment then inspections will be performed on a selection of procurement sites. - For procurement sites not attached to tissue establishment in Irish territory we will inspect all sites offering the procurement of tissues and cells. Each procurement site has to be authorised individually.		
IT - Italia	- Yes, inspections of tissue establishments incorporate a thorough review of procurement procedures, procurement staff training, procurement documentation and procedures and documentation for donor selection, testing and acceptance - To date, no procurement site has been inspected, but we may conduct some on a random or selected basis in the future	- 30 + 3 re-inspections - 105 self-declaration questionnaires for preliminary certification of HSC centres	- A team with at least one (usually 2) CNT inspectors – these are CNT staff with relevant past experience of tissue banking/or training provided by CNT in inspection – together with at least one assistant inspector who is a tissue bank expert from a field of tissue banking that is different from the bank being inspected and working in a different geographical region. - Experts have been trained by CNT inspectors. For HPC centres that apply for a JACIE inspection, CNT will send one inspection – the inspection will be joint but the post-inspection reporting and certifications will be managed separately - Granting accreditation and inspecting done by same authority
CY - Kypros	- No system in place for organising inspections and control measures - No control measures in place for procurement of human tissues and cells	No inspections conducted	Granting accreditation and inspecting done by same authority
LV - Latvija	- No system of inspection in place - The draft regulations of the Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" provide that Health Statistics and Medical Technologies State Agency will assess tissue	No inspections conducted	- The draft Regulations of the Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" state that Health Statistics and Medical Technologies State Agency is the competent authority for the transposition and implementation of the tissues and cells regulatory framework. - Granting accreditation and inspecting done by different authority

Member State	System for inspections	Inspections conducted	Officials & authorities
	establishments systematically, but not less than twice a year. It will inspect devices, which have been used for tissues and cells donation, storage, preservation and distribution, as well as all the documentation, procedures and actions, which are related to tissue establishment requirements.		
LT - Lietuva	No inspection system in place	None	- State Health Care Accreditation Agency Under The Ministry of Health of The Republic of Lithuania - National Bureau on transplantation
LU - Luxembourg	Not applicable	Not applicable	Not applicable
HU - Magyarország	- System for inspection in place - According to Government Decree No. 96/2003. (VII. 15.) on the general conditions of providing health services and on operation permits, health service providers are allowed to operate holding a permit issued by the health authority (NPHMOS regional offices). The health authority controls the fulfilment of all the conditions included in the permit. In case of the breach of the conditions, the operation permit may be suspended or revoked, and sanctions may be imposed	- Inspections have already taken place - Minimum of one examination per year is obligatory, but the health authority may conduct inspections any time.	- Inspections are carried out by qualified personnel of the regional offices of the NPHMOS - Granting authorisation and inspecting done by same authority
MT - Malta	No such systems are yet in place	No inspections conducted	- The necessary regulatory structure is still being set up. The inspectorate is likely to consist of medical and other professionals proficient in the area. It is not excluded that foreign expertise will be drafted in the initial stages - Granting accreditation and inspecting done by same authority
NL - Nederland	- System for inspection in place	50+/- (based on the old	- Inspectors carry out inspections

Member State	System for inspections	Inspections conducted	Officials & authorities
	- The Inspectorate inspects on regular basis establishments were the procurement of human tissue and cells occur	legislation)	- Granting accreditation and inspecting done by different authority
AT - Österreich	- System for inspections is in place - No control measures in place for procurement of human tissues and cells yet	11 according to the AMA	- Before 2006, biologist of Ministry of Health and Women conducted inspections - Granting accreditation and inspecting done by different authority
PL - Polska	- Yes, system for inspection is in place - Control measures: 1) an information about the number of employees and their qualifications; 2) possession of rooms and equipment that correspond with the professional and sanitary requirements (a list of rooms and equipment), 3) presentation of a project of the quality assurance system. - These information is reported to the competent authority at the first step to get the accreditation (according to Art 26 of Polish "Transplantation act"). They are also reviewed during inspections - Procurement of human tissues and cells is allowed exclusively to health care institutions, forensic medicine departments and anatomical pathology departments of medical academies and universities that have a medical faculty and medical R & D units - Procurement and transplantation of tissues and cells are not allowed for tissue establishments. Procurement organizations and transplantation teams are controlled by POLTRANSPLANT.	No inspections yet	- Granting accreditation and inspecting done by same authority

Member State	System for inspections	Inspections conducted	Officials & authorities
PT - Portugal	- No system in place for organising inspections	No inspections conducted yet	Technicians, representing the CA will carry out inspections
RO – Romania	No system in place	No inspections conducted yet	- The accreditation of the tissue establishments is done by the Ministry of Health at the proposal of the National Transplant Agency. The inspections are done by the National Transplant Agency together with the Estate's Sanitary Inspection, both belonging to the Ministry of Health.
SI - Slovenija	- No system in place for inspections - Every procurement procedure of human body parts has to be reported to national Institute for transplantation of organs and tissues of the R of Slovenija according to the Act on removal and transplantation of human body parts for the purposes of medical treatment act (ZOPDCT, 2000)	No inspections conducted	- Governmental inspectors, but not yet authorised for tissue and cell establishments - Granting accreditation and inspecting done by same authority
SK - Slovensko	- Inspections according to new Directives are in a phase of preparation - Inspections according to previous regulations have been performed	No inspections according to the Directive conducted yet	- Granting accreditation and inspecting done by different authority
FI - Suomi/Finland	- No system in place for inspections - Legislation in force regulates consent of the donor, non-profit nature of procurement, intended use of **organs and tissues**, register keeping etc. (primarily **ethical aspects**) and the supervising authority is the National Authority for Medicolegal Affairs - The amendments to the Act will cover the role of NAM as supervising authority for tissue establishments (procurement).	No inspections conducted	- NAM inspectors and officers (expertise on safety and quality aspects of the field to be inspected) - According to the proposal for the Act, Granting accreditation and inspecting done by same authority

Member State	System for inspections	Inspections conducted	Officials & authorities
SE - Sverige	- No inspections in place that is specifically for human tissues and cells - At the present time tissue establishments have to comply with the regulations of the National Board of Health and Welfare on how to prevent disease transmission with tissues cells and organs (SOSFS 1994:4) - The Board of Health and Welfare and its Board dealing with organs and tissues as well as all the tissue establishments are very active in efforts to procure tissues according to the Swedish Transplant act.	- None yet - There is already a possibility to inspect tissue banks according other Swedish acts and regulations by the Board of Health and Welfare but no inspections according to the directive have yet been carried out	- It has not yet been decided. It maybe be by officials of the National Board of Health and Welfare or by officials at one or other of the six regional branches of the Board. Similarly by the Medical Products Agency. There are no regional branches of that authority. - Accreditation will most probably be by the National authorities, not by the regional branches.
UK - United Kingdom	Yes, licensing and inspection system is in place	- Inspections have been taking place under existing framework since 1991 - Inspections will also assess compliance against Directive from 7 April 2007	- Only inspectors who are employees of HFEA Regulation Department carry out inspections - Same authority grants accreditation and inspects establishments
	- Yes, system for inspection in place *- Currently the Authority licenses the storage of tissue and cells for the purpose of transplantation. If the storage establishment relies on a third party to procure tissue or cells then we require that the establishment has a third party agreement with procurers ensuring that they meet the standards set out in 2006/17/EC. We require that establishments are compliant with this requirement by 05/04/07. From April 2007, import of tissues and cells for transplantation will need to be done under the auspices of a licence or a third party agreement with a licensed establishment.*	*The HTA has developed a two tier risk based approach to inspections. This is supported by the UK Government's recommendations about how regulation can be improved. We perform both phase I and phase II inspections.* *A **phase I inspection** is a detailed desk based evaluation of a self assessment compliance*	*- The Authority is employing professional inspectors with a range of experience in: quality management systems; inspections, law and science. These full time inspectors will be supported by specialist assessors trained by the HTA who are scientists and medical practitioners currently working in the regulated sector. Their role is to provide sector specific scientific and technical advice. The full time professional inspectors will make the licensing decisions.* *- Same authority grants accreditation and inspects establishments*

Member State	System for inspections	Inspections conducted	Officials & authorities
		report submitted on-line via the HTA website by the Designated Individual (Responsible Person), the Licence Holder and the relevant staff involved in the work of the establishment. The compliance report contains two application forms (Designated Individual and Licence Holder application forms), establishment contextual information and eighteen standards. The application form for the Designated Individual includes a summary of their qualifications and evidence about their experience working with tissues and cells. They also have to demonstrate the extent of their understanding of the role and a statement to say why they believe they are suitable for the role. There is a shorter application form for the Licence Holder. The eighteen standards are divided into four themes: • *consent* • *governance and quality systems*	

Member State	System for inspections	Inspections conducted	Officials & authorities
		• *premises, facilities and equipment* • *disposal of tissues* *The Directions summarising the first two Directives map across onto these standards. A* ***phase II inspection*** *always involves a site visit to the establishment which may lead to a change in the licence. We are currently inspecting high risk establishments and a selection of low risk establishments* *- We have undertaken* ***117 phase I inspections*** *since April 2006* *- We have undertaken* ***6 phase II inspections*** *so far and have another twelve planned for January-March 2007.*	

EEA/EFTA countries

Iceland	- Yes, inspection system in place - Professional supervision/surveillance of the Directorate of Health for procurement	No inspections have been conducted	- Specially trained inspectors - Granting accreditation and inspecting done by different authority
Norway	Yes, inspection system in place	No inspections have been conducted	- Norwegian Board of Health/ County Medical Officers of Health - Granting accreditation and inspecting done by different authority

Liechtenstein	- Yes, inspection system in place - Procurement of human tissues/cells are controlled through inspections	1 inspection conducted	- Liechtenstein does not have its own inspector. The country has an agreement with Switzerland to carry out inspections in FL - Granting accreditation and inspecting done by different authority

7. IMPORT & EXPORT

Member State	Measures to verify quality of imported tissues and cells
BE - Belgique / België	The tissue establishment importing the tissue is responsible for verifying equivalency
BU – Bulgaria	Regulation N13/15.04.2004 of the requirements for quality and safety of tissues and cells that are imported in Republic of Bulgaria, promulgated in SG N39/12.05.2004
CZ - Česká Republika	- No procedure for verification in place, except for hemotopoietic cells - For hemotopoietic tissues (BM, RBSC and CB) – only registries in BMDW (Bone Marrow Donors Worldwide) association are contacted
DK - Denmark	- The tissue establishment is required, by our national implementation of the European Regulations, to have systems in place to verify their receipt of imported tissues/cells comply with all the regulatory requirements of these Directives - Our inspection activities will focus on the auditing of the systems and procedures of a tissue establishment, and their effectiveness to achieve this requirement. An information sheet, in English, to clarify this activity, is in preparation, so it is known more fully to the organisations outside Europe who wish to export to Denmark
DE - Deutschland	- For the import of human material and active ingredients of tissue preparation medicinal products, an import authorisation and certificate has to be obtained from the competent authority of the German Land. - This authorisation is granted following an on-site inspection by the German Land authority under consultation of the Paul-Ehrlich-Institut, which sends an expert to the on-site inspection.
EE - Eesti	Information unavailable
EL - Elláda	No procedure of verification in place
ES - España	Questionnaire must be filled out by the tissue establishment origin of the tissues/cells
FR - France	**A) Pour les tissus et les cellules non reproductrices** Deux moyens de contrôle sont mis en place :

	<u>1) L'autorisation de l'activité d'importation</u> L'encadrement de l'activité d'importation et d'exportation des tissus et des cellules a été définie par un décret de 2000. Cette activité est soumise à une autorisation délivrée par l'Agence française de sécurité sanitaire des produits de santé. Cette agence délivre cette autorisation : - aux seuls demandeurs qui sont des banques de tissus autorisés ; - au vue des éléments à fournir dans le dossier de demande d'autorisation qui comprend des informations sur : - le produit biologique de départ (tissus et cellules prélevés) et les produits annexes utilisés - le procédé de préapration - le contrôle de la qualité du produit fini - la sécurité virale - les données sur les données cliniques et non-cliniuqes - l'indication thérapeutique Ces éléments permettent à l'Agence de vérifier : - la nature des produits concernés - les fournisseurs concernés - les procédés de préparation, de conservation et de transformation des produits cédés par chaque fournisseur ; - elle vérifie également que les produits fournis ont été prélevés ou collectés dans le respect de règles de sanitaire au moins aussi exigeantes que celles prévues par la réglementation nationale L'Agence française de sécurité sanitaire des produits de santé peut demander toute information complémentaire au demandeur qu'elle estime nécessaire et elle sollicite l'avis de l'Agence de la biomédecine avant de se prononcer sur la demande d'autorisation d'importation/exportation. Ces dispositions sont en cours de modifications dans le cadre de la transposition des directives et les critères permettant d'exiger un niveau équivalent de qualité et de sécurité sont en cours d'élaboration. **<u>2) Les inspections</u>** Il s'agit : - soit de l'inspection des fournisseurs étrangers (déplacement des inspecteurs de l'afssaps à l'étranger) - soit de l'inspection du distributeur français dans le cadre des demandes d'autorisations d'importation. Deux procédures sont en place en matière d'inspections : l'inspection des établissements et l'inspection du procédé. **B) Pour les cellules reproductrices** Les déplacements transfrontaliers concernent seulement les embryons mais un décret est actuellement en cours d'élaboration sur l'activité d'importation et d'exportation de gamètes.
IE - Ireland	Inspections shall be carried out in Tissue Establishments who import from third countries. The Tissue Establishments must provide appropriate documentation to prove that the tissues/cells comply with the requirements of 2004/23/EC

IT - Italia	The banks or the Regional Centres have the responsibility to verify standards of tissues and cells to be imported. Some international musculo-skeletal banks are included in a CNT list of approved centres but banks importing from them must nonetheless guarantee equivalent safety and quality. During tissue establishment inspections, any importation events are reviewed to verify the adequacy of the review of safety and quality
CY - Kypros	No procedures in place for verification
LV - Latvija	- Import and export of human tissues and cells may be performed by concluding an international contract - The draft Regulations of Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" set the requirements for safety and quality of human tissue and cells which apply also in a case of tissues and cells import
LT - Lietuva	- Permit to import are given only by National Bureau on Organ transplantation; - Conditions under which tissues and cells may be imported/exported are laid down in amendment of Health care ministry
LU - Luxembourg	-
HU - Magyarország	- Under Section 15/B of Decree of the Minister of Health No. 18/1998. (XII.27.), tissues and cells may only be imported from third countries where conditions similar to the Hungarian legislation are applicable. The National Chief Medical Officer's Office is responsible for collecting the necessary documents to prove this - In practice, none of the tissue banks of any Member State imports tissues from a third country - For stem cell transplantation we are following the standards of the World Marrow Donor Association. There is an accreditation system in use for the registries and laboratories
MT - Malta	No such procedures are established yet
NL - Nederland	Most tissues and cells need to be imported by a tissue establishment
AT - Österreich	No system in place yet to verify quality of imports
PL - Polska	Not regulated yet
PT - Portugal	No procedures are implemented yet
RO – Romania	The tissues and cells are allowed to be imported only from tissue establishments agreed by the National Transplant Agency, after having checked the accreditations and standards of those establishments.
SI - Slovenija	No procedure in place yet
SK - Slovensko	- No importation is provided so far.

	- Eventual importation/exportation in the future will need approval from the competent authority and will need to conform to Art 9.1. of the Directive 2004/23/EC
FI - Suomi/Finland	Existing provisions (quality, safety and traceability) have been specified in the proposal.
SE - Sverige	- The existing tissue establishments work in close collaboration with the European Association of Tissue banks and cornea banks and follow their guidelines. There is a limited exchange of corneas and heart valves with some other EU – countries and non EU countries (Norway**)** - In the Act and the Regulations it will be stated that the Tissue Establishments only interact, import from or export to, Establishments which have been accredited in the EU - We have to consider how to verify that equivalent standards for safety are met by Establishments in third countries. Norway actually is such a third country
UK - United Kingdom	- Imports/Exports only permitted under written direction (licence) from HFEA - Control system already in place under existing regulatory framework.
	Currently we require that all licensed establishments ensure that any tissues or cells imported from a third country meet the standards of quality and safety set out in 2004/23/EC and 2006/17/EC, particularly with regards to traceability. We require that establishments comply with this by 7 April 2007. From April, import of tissues and cells for transplantation will need to be done under the auspices of a licence or a third party agreement with a licensed establishment unless authorised for direct distribution.

EEA/EFTA countries

Iceland	None
Norway	The tissue establishment will verify imported material. The competent authority will verify that tissue establishments have proper procedures in place for this task.
Liechtenstein	Information not available

8. SERIOUS ADVERSE EVENTS AND REACTIONS

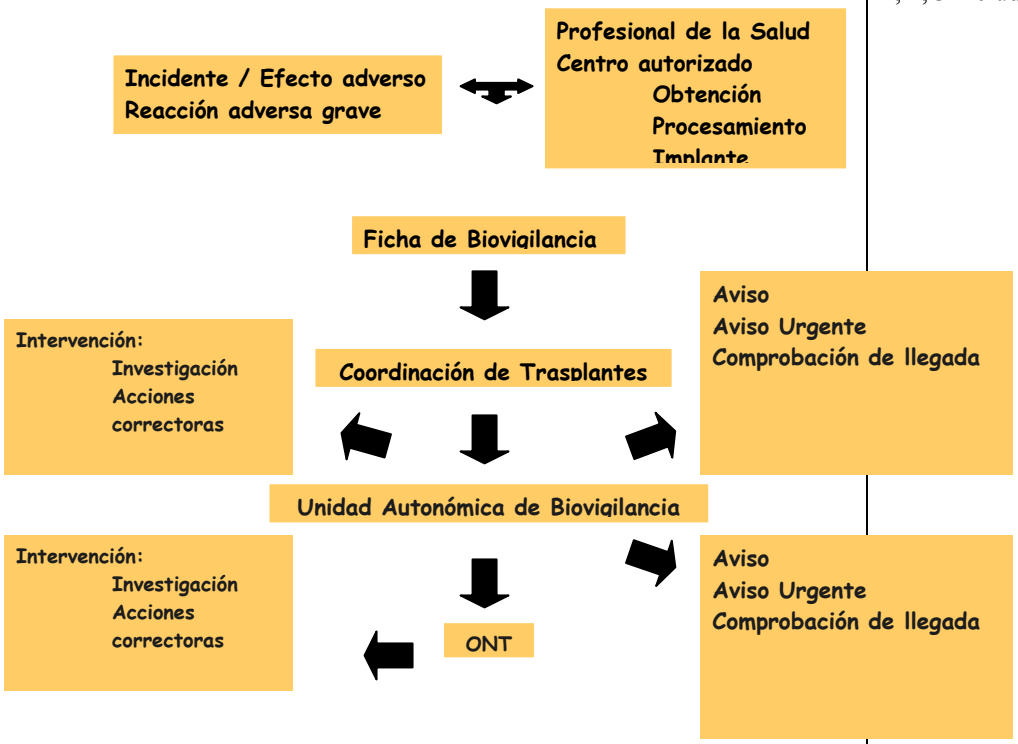
***Serious adverse <u>events</u>**

1. The administration or the use of tissues/cells that did not fulfil the safety and quality requirements
2. A near miss: the distribution of tissues/cells that did not fulfil the safety or quality requirements at that time (but that was not administered or used)

3. The release of tissues/cells (even if not distributed) that did not fulfil the release requirements, due to a procedural problems of the release process (e.g. informatics)

****Serious adverse <u>reactions</u>**
1. Serious adverse reactions in the recipient which may be linked to the quality and safety of tissues and cells
2. Serious adverse reactions that cannot be attributed to the quality and safety of tissues and cells
3. Serious adverse reactions in the donor which may influence the quality and safety of tissues and cells
4. Serious adverse reactions in the donor that do not influence the quality and safety of tissues and cells

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
BE - Belgique / België	Not in place yet, but system is ready to start as soon as the directives are transposed in Belgian legislation (end of 2007) or sooner if possible	- 1, 2, 3 are proposed to be part of national definition - Additional definition 'an event that might put the life of a donor in danger' added	- 1, 3, 4 are proposed to be part of national definition - Inclusion of 2 is to be discussed
BU – Bulgaria	There is a new Regulation concerning the issue-will be done to the end of February 2007	- 1, 2, 3 included	- 1, 2, 3, 4 included
CZ - Česká Republika	No reporting system in place	Not applicable	Not applicable
DK - Denmark	- No, the procedural system for the reporting of serious adverse events and reactions is presently in development. It is expected to be in place early 2007.	- Will become known early 2007	- Will become known early 2007
DE - Deutschland	- Yes, Currently, the system for reporting adverse reactions is described in the German Drug Law (“Arzneimittelgesetz”) which is fully compliant with Directive 2001/83/EC. - It is currently pursued to further adapt the German legislation by adopting the Tissue Act (“Gewebegesetz”) in order to meet all the requirements laid down in Directive 2004/23/EC.	- 1, 3 included - 2 not included	- 1 included - 2,3,4 not included
EE - Eesti	No reporting system in place	- Not available	- Not available
EL - Elláda	No reporting system in place	- 1 included	1, 2, 3, 4 included

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
		- 2,3 excluded	
ES – España		1, 2, 3 included	1, 2, 3, 4 included
FR - France	La biovigilance s'applique à l'ensemble des activités portant sur les éléments et produits d'origine humaine depuis l'étape du prélèvement ou de la collecte jusqu'à leur utilisation. Le dispositif de biovigilance repose sur 3 pôles : 1) L'Agence française de sécurité sanitaire des produits de santé	Les évènements indésirables sont des incidents qui se sont produits à une étape de mise en œuvre du procédé (préparation ,qualification, stockage ,etc…) pouvant entraîner des effets	Les réactions indésirables sont définies comme des manifestations cliniques innatendues chez le donneur ou le receveur (reaction allergique par exemple).

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
	➢ Cette agence définit les orientations, anime et coordonne les actions des différents intervenants et veille au respect des procédures. Elle réalise le bilan d'activité de la biovigilance à l'attention des différents intervenants. ➢ Elle est destinataire des déclarations d'incident ou d'effet indésirables ainsi que des rapports de synthèse adressés par les correspondants locaux ; elle prend les mesures conservatoires qui s'imposent ainsi que les mesures appropriées visant à prévenir ou faire cesser les incidents ou effets indésirables. 2) <u>les correspondants locaux de biovigilance</u> Toutes les structures publiques et privées, autres que les cabinets libéraux, qui collectent et prélèvent préparent, conservent distribuent, importent et exportent des cellules, tissus, organes ou qui administrent ou greffent des produits d'origine humaine doivent disposer d'un correspondant local de biovigilance. Les correspondants sont chargés de la transmission des déclarations de tous les incidents et effets indésirables à l'AFSSAPS, de la réalisation des enquêtes et investigations nécessaires à la recherche de l'imputabilité de l'incident et de l'information des autres correspondants locaux concernés. Les correspondants n'ont pas la responsabilité de prendre des mesures conservatoires, mission qui incombe exclusivement à l'AFSSAPS. Les professionnels de santé qui exercent dans une structure ne disposant pas de correspondant (notamment en libéral) ont également l'obligation de signaler et de déclarer à l'AFSSAPS les incidents et effets indésirables. 3) <u>La commission nationale de biovigilance</u> Cette instance, dont le secrétariat est assuré par l'AFSSAPS, a essentiellement un rôle de réflexion et de conseil, notamment sur les mesures à adopter afin d'éviter que les incidents ne se reproduisent ; elle procédera au bilan de ces informations. Elle pourra être consultée par le ministre chargé de la santé et aura la faculté de faire appel à des experts. Un dispositif analogue s'applique aux activités d'assistance médicale à la	indésirables sur le donneur ou le receveur. (contamination microbiologique) Les évènements indésirables graves sont des incidents qui se produisent avec une fréquence anormale et qui peuvent susciter des effets indésirables graves chez le donneur ou le receveur (événemnt liè à un problème d'inctivation virale) - 1 included (examples: serological screening of the donor : not done or incomplete, high percentage of non viable cells) - 2, 3 included - Additionally: a) Perte accidentelle avant la greffe d'un greffon autologue (réctions indésirables graves chez le patient déjà conditionné pour la greffe) b) Mauvaise qulaité d'un produit annexe découverte après la délivrance ou la distribution de ce produit Contamination bactérienne ou fongique d'un greffon découverte après la greffe	Les réactions indésirables graves sont définies comme des reactions pouvant entrainer la mort ou mettre en danger la vie du patient ou générer chez lui des problèmes de santé graves (réactions neutologqiues par exemple) - 1 included (failure or delayed graft function; Risk of infectious disease (viral or bacterial infection)) - 2 included - 3 included (Detection of a CJD few years after the procurement) - 4 included (hypocalcaemia entailed in the donor after HSC collection) - Additionally: a) Adverse reaction which occur with an abnormal frequency, b) adverse reaction possibly linked to the ancillary product

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
	procréation et de don de gamètes , mais dans ce cas le pivot central du dispositif est l'Agence de biomédecine à qui les coordonnateurs de centres transmettent les fiches de déclaration d' incidents et effets indésirables.		
IE - Ireland	Yes, An initial report form for SARs/SAEs is available on the IMB website. Once a report is sent to the IMB, it is reviewed in-house. Further information is requested e.g. actions taken etc. All information is logged in Excel Spreadsheet. A database is to be developed.	- 1,2 included - 3 excluded	- 1, 3 included - 2,4 excluded
IT - Italia	- Yes, there is a local system of reporting to Regional Transplant Centres - Tissue establishments must have systems in place to report serious adverse reactions to Regional Transplant Centres. Their procedures are checked during inspections by CNT. The CNT national guidelines for tissue banking are under revision. The new version will include instructions for reporting of adverse events and reactions following the requirements of Directive 2006/86/EC	- The term 'serious adverse events' is not specifically defined	- 1 included, but the term 'serious adverse reactions' is not specifically defined
CY - Kypros	No reporting system in place	Not determined	Not determined
LV - Latvija	No reporting system in place	- 1, 2, 3 included - In the draft Regulations of the Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" serious adverse event is defined as untoward occurrence related to the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or a threat to life, disabling or incapacitating conditions for patients or which	- 1, 3 included - 2,4 excluded In the draft Regulations of the Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" serious adverse event is defined as untoward occurrence related to the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or a threat to life, disabling or incapacitating

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
		might result in a prolonged hospitalization	conditions for patients or which might result in a prolonged hospitalization
LT - Lietuva	No reporting system in place	1, 2, 3 included	1, 2, 3, 4 included
LU - Luxembourg	Not applicable	Not applicable	Not applicable
HU - Magyarország	- Reporting system in place - Under Section 15/A of Decree of the Minister of Health No. 18/1998. (XII.27.), the NPHMOS regional office must be informed by the health service provider (e.g. tissue bank) about any adverse events that may affect the quality and safety of tissues and cells. The regional office is responsible for taking the necessary measures - There are two types of possible complications in case of transplantated tissues and cells: a) transferred infection b) transferred tumour. In case of any of the two, the normal procedure for nosocomial infection shall be followed: it shall be reported to the hospital hygienic doctors and the National Public Health and Medical Officers' Service.	- 1, 2, 3 included - Addition definition 'seropositivity' added	1, 2, 3, 4 included
MT - Malta	No system in place	-	-
NL - Nederland	- Reporting system in place - The Inspectorate has to be informed. (the system is partly already electronically). Depending on the report the Inspectorate can take immediate measures. Besides that there is an optional system in place were all adverse reactions and events can be reported, so statistics can give more detailed results, etc.	- 1, 2, 3 included	- 1, 2 included - Information regarding 3,4 unavailable
AT - Österreich	No reporting system in place	Not applicable	Not applicable
PL - Polska	- In case of SAR, transplantation team has an obligation to report to tissue establishment. Tissue establishment must report SAR and SAE to NCTCB. - For tissues and somatic cells by National Center of Tissue and Cell Banking - For stem cells (blood marrow, circulating blood) by Pol transplant	- 1, 2, 3 included	1,2,3,4 included

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
PT - Portugal	No reporting system in place	Not defined yet	- Not fully defined yet - 1,2 included
RO – Romania	No reporting sytsem in place	The terms "serious adverse effects and serious adverse reactions" are not yet defined in the Romanian legislation, an official regulation is now in legislative process to be approved on this issue.	The terms "serious adverse effects and serious adverse reactions" are not yet defined in the Romanian legislation, an official regulation is now in legislative process to be approved on this issue.
SI - Slovenija	- No reporting system in place - Governmental mandatory system of reporting adverse events or reactions is in preparation	1, 2, 3 included	1, 2, 3, 4 included
SK - Slovensko	Yes, all serious adverse events/reactions shall be reported to the competent authority and corrective actions shall be taken	1,2, 3 included	- 1,2, 3, 4 included - Additional items 'disease transmission, serious infection' added
FI - Suomi/Finland	- No reporting system in place - Specified regulations and administrative provisions concerning procedures and notification of serious adverse events and reactions will be given after the Act has been approved	All serious adverse events mentioned shall be notified according to the proposal	All serious adverse reactions linked to the quality and safety of tissues and cells (points 1 and 3) shall be notified according to the proposal
SE - Sverige	Serious adverse reactions and events can always be reported according to Regulations by the Board (SOSFS 2005:12) and SOSFS 2001:12, but not necessarily in a way as in the directive	1,2,3 included	- 1,3 included - 2,4 not included

Member State	Reporting system	*Definition of serious events	**Definition of serious reactions
UK - United Kingdom	- Yes, Reports of all adverse events/reactions are in place since 2004 - Verbal report must be made within 12 hours of discovery of incident, followed by a written report within 24 hours.	- 1, 2, 3 included - Additional definition 'any incident (or near miss) that may impact of the quality and/or safety of reproductive cells' added	- 1,2,3,4 included - Additional definition 'any incident (or near miss) that may impact of the quality and/or safety of reproductive cells' added
	- Yes, Currently establishments inform us of any adverse events and reactions that occur by e-mail. We also have a system for issuing regulatory alerts to our establishments and other competent authorities – please see annex 1- regulatory alert. *- We are currently working with representatives from the sector and other regulators to develop an online reporting system. In April we will put in place an online reporting system for serious adverse events and reactions – please see annex 2 - project initiation document. We have defined an adverse event or reaction as it is defined in 2004/23/EC.* *- During the 2005 to 2006 period, 41 of the licensed tissue establishments reported adverse events or reactions, 27 of these establishments reported more than 1 adverse event or reaction, and 17 of the establishments reported more than 3. We are currently conducting a more detailed analysis of these reports.*	*- 1 included* *- 2 excluded* *- When the new reporting system is in place, we will collect information on a wide range of serious adverse events and reactions* *- (information unavailable for 3)*	*- 1, 3 included* *- 2, 4 excluded* *- When the new reporting system is in place, we will collect information on a wide range of serious adverse events and reactions*

EEA/EFTA countries

Iceland	- Reporting system is in place - Registration of events at the Directorate of Health	- 1, 3 included - 2 excluded	- 1 included - 3,4 excluded
Norway	No reporting system in place	1, 2, 3 included	- 1, 3 included - 2, 4 included, but in another context
Liechtenstein	Liechtenstein is part of the vigilance system of Switzerland. - Information regarding ADRs is unavailable at this time. Discussions about this topic are just beginning to take place	Information not available yet	Information not available yet

9. TESTING REQUIREMENTS

Member State	Minimum tests required
BE - Belgique / België	- Anti-HIV1 & 2 (serological test) - HbsAg; Anti-HBc (serological test) - Anti-HCV (serological test) - Syphilis screening (serological test)
BU – Bulgaria	- HIV 1 & 2 (Serological-CE) - HBsAg (Serological-CE) - Anti HBc (Serological-CE) - HCV (Serological-CE) - Treponema Pallidum (Serological-CE)
CZ - Česká Republika	- HIV 1&2 (Anti HIV 1&2, HIV 1Ag) - Hep B (ABsAg) - Hep C (Anti HCV) - Syphilis (RRR, TPHA)
DK - Denmark	- HIV 1& 2 - Hep B, C og - Syphilis (Serological, and NAT where relevant)
DE - Deutschland	- HIV 1& 2, HCV (serological, NAT test) - HBV (serological (HBs and anti-HBc) - Treponema pallidum (serological test) - HTLV I/II (serological, if indicated – i.e. high risk donors) - CMV, parvovirus B19 (serological if indicated – i.e. cord blood stem cells)
EE - Eesti	Not available
EL - Elláda	HIV, CMV, HbV (serological, rarely NAT) Epstein Bar-etc
ES - España	HIV 1 & 2: always

Member State	Minimum tests required
	Hepatitis B: always Hepatitis C: always Syphilis: always HBs Ag. Anti. Hbc: always Anticuerpos AntiHVC (En casos de progenitores hematopoyéticos se requerirá además PCR): always
FR - France	- Hepatitis B (Serological detection: HBs antigen, HBc antibody) - HIV (Serological detection: HIV1/2 antibody detected with two different tests, and P24 antigen or NAT RNA HIV-1) - Hepatitis C (Serological detection: Antibody detection) - HTLV1/2 (Antibody detection) Other: For cells: in these cases a positive result can lead to tissues or cells graft depending on the benefit risk ratio for the recipient - Syphilis (Serological detection) - CMV (not obliged for reproductive cells) (serological detection) - EBV (not obliged for reproductive cells) (serological detection) - Toxoplasma (not obliged for reproductive cells) (serological detection) For tissues: in these cases a positive result can lead to tissues or cells graft depending on the benefit risk ratio for the recipient - Syphilis (serological detection)
IE - Ireland	- HIV 1 & 2: Anti-HIV 1 & 2 (serological) - Hep B: HBsAg, Anti HBc (serological) - Hep C: Anti-HCV-Ab (serological) - Syphilis: (serological) - All as per Directive
IT - Italia	- HIV 1 & 2 (serological) - HCV (seriological) - HBV (Surface antigen; Anti-core not previously required put performed by most banks – now being introduced in revised national guidelines) - Syphilis - HTLV – I & II (serological – required for donors coming from endemic areas) - CMV IgM (for skin, heart valve & vessel and amniotic membrane donors) - Toxoplasma IgM (for amniotic membrane donors) - Living tissue donors (retesting at 180 days post donation, unless NAT testing is performed for HBV, HCV and HIV at least 7 days after donation)

Member State	Minimum tests required
CY - Kypros	Not determined
LV - Latvija	- Antibodies against HIV 1 & 2: anti-HIV 1 &2 - HBV marker: HBs Ag, anti HBc - Antibodies against C hepatitis: anti-HCV-ab - Antibodies against syphilis agent: Specifics test - These types of laboratory tests for living and deceased donors are provided in the draft Regulations of the Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs"
LT - Lietuva	- HIV 1 and 2 (Serological (EIA, MEIA)) - Hepatitis B, C (Serological (EIA, MEIA)) - Syphilis (Serological (RPR, TPHP))
LU - Luxembourg	Not applicable
HU – Magyarország	- HIV 1,2-AB: serology - HBsAg: serology - HBcoreAg: serology - HCV, lues: serology
MT - Malta	HIV 1 & 2: serological Hepatitis B: serological Hepatitis C: serological
NL - Nederland	As soon as the Directive will enter into force, the exact same tests as required by the Directive are required. In practise most parties use a list on which also rhesus D testing is mentioned. This is not compulsory.
AT - Österreich	- HbsAG, HbcAb, HCV-Ab (Serological) - HIV-1/2-Ab, HTLV-1/2-Ab (Serological) - Treponema pallidum (Serological) - CMV, Parvovirus B19 Ab, EBV (Serological - optional with different rationals depending on the kind of tissues or cells) - HBV, HCV, HIV (NAT) - The combination of determination of infectious markers is different for each kind of tissues or cells

Member State	Minimum tests required
PL - Polska	- HIV-1, -2 (serological) - Hep B (serological) - Hep C (serological) - T. pallidum (serological)
PT - Portugal	- Hepatitis C (Serological. Some perform also NAT tests) - Hepatitis B – Hbs Ag and anti Hbc (Serological. Some TE perform also NAT tests) - HIV1/2 (Serological. Some TE perform also NAT tests) - HTLV1,2 & syphilis (Serological. Some TE perform also NAT tests)
RO – Romania	HIV, Hepatitis C, Hepatitis B, CMV, Lues, Toxoplasma, Epstein Barr virus (serological and NAT test)
SI - Slovenija	- HBsAg, anti-HBc (serological) - Anti-HCV (serological) - Anti-HIV 1, 2 (serological) - Anti-Treponema pallidum (serological) - If necessary: anti-CMV, anti-HBs, anti-toxoplasmosis, EPsteinBarr (serological)
SK - Slovensko	- HIV 1, 2: Anti HIV 1&2 & p24Ag testing (CMIA method)) - HBSAg, HBc (Anti HBc): CMIA (chemiluminescent microparticle immunoassay) - HCB: Anti HCV (CMIA method) - Syphilis: Syphacard (R reagine test), TPPA (aglutin.r.)
FI - Suomi/Finland	At least the minimum set defined in the Directive 2006/17/EC
SE - Sverige	Anti HIV, HBsAg, Anti HBc, HCV, CMV, Toxoplasma (in cardiac transplantation), and EBV (Lues tests are not performed regularly in Sweden)
UK - United Kingdom	- HIV 1 & 2 (Anti-HIV 1 & 2 - Serological & NAT) - Hep B (HBsAg, Anti-HBc - Serological & NAT) - Hep C (Anti-HCV-Ab - Serological & NAT) - Syphilis (serological) - Chlamydia (serological)

Member State	Minimum tests required
	- HIV 1 & 2 (Anti-HIV 1 & 2 - Serological or NAT) *- Hep B (HBsAg, Anti-HBc - Serological or NAT)* *- Hep C (Anti-HCV-Ab - Serological or NAT)* *- Syphilis (serological)*

EEA/EFTA countries

Iceland	HIV, Hepatitis C
Norway	For sperm (living donors only): Hepatitis B and C, HTLV, HIV, Treponema pallidum, gonorrhea, Chlamydia For organs: HIV, Hepatitis, infection/ septicaemia
Liechtenstein	The country does not have donors. According to national legislation, the minimal requirements are: - HIV 1 & 2, HBV, HCV (serological) - Additional HTLV 1&2 and CMV for cellsuspensions and tissues rich in leucocytes

10. PRIVATE AUTOLOGOUS CORD BLOOD BANKING

Member State	Provisions on cord blood banking	Private blood banking
BE - Belgique / België	- No specific provisions on cord blood banking (a specific set of quality criteria has been published by the Superior Health Council)	- Private autologous cord bank cannot apply for an authorisation
BU – Bulgaria	- No specific provisions on cord blood banking	- Private autologous cord bank can apply for authorisation
CZ - Česká Republika	- Yes, the same provisions as other haemotopoetic cells	- Private autologous cord banks can apply for authorisation - The Czech system is based on equal access for both private and public banks to the accreditation process
DK - Denmark	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
DE - Deutschland	- Yes, specific provisions on cord blood banking exist - Cord blood banking underlies the provisions of the German Drug	- Private autologous cord blood banks can apply for authorisation - In case of allogeneic or autologous cord blood products, a manufacturing

Member State	Provisions on cord blood banking	Private blood banking
	Law and the Transfusion Act. In addition, the national "Guideline for the transplantation of (allogeneic) stem cells from cord blood" has specific provisions. According to the national "Guideline on hemotherapy", basically the requirements of the guideline named above ato autologous cord blood cells in cord blood banks as far as organization, production and storage of stem cell preparations from cord blood are concerned.	authorization is required - In addition, for banked allogeneic cord blood preparations a marketing authorization is needed (German Drug Law).
EE - Eesti	No specific provisions on cord blood banking	Private autologous cord banks cannot apply for authorisation
EL - Elláda	No specific provisions on cord blood banking	-
ES - España	Yes, specific provisions on cord blood banking exist	Private autologous cord banks can apply for authorisation
FR - France	oui dans l'arrêté relatif aux régles de bonnes pratiques concernant les cellules hématopoiétiques	En France , il y a 2 types d'autorisation : ➢ La première concerne l'autorisation des établissements qui préparant les tissus et les cellules ➢ La deuxième concerne l'autorisation des tissus et des cellules après évaluation de leurs procédés de préparation. Tout organisme public ou privé pouvant solliciter une autorisation de banque auprés de l'AFSSAPS, les banques de sang de cordon autologues pourraient être autorisées mais aucune autorisation en ce sens n'a été déposée auprès de l 'AFSSAPS. Pour ce qui concerne l'autorisation du produit en tant que tel, il conviendrait que la finalité thérapeutique en soit clairement démontrée. Or cette finalité n'est pas clairement démontrée aujourd'hui. Enfin, le débat éthique sur la constitution de telles banques qui portent notamment atteinte au principe de solidarité se poursuit**.**
IE - Ireland	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
IT - Italia	- Yes, specific provisions on cord blood banking exist (Ordinanza Ministero Salute 13 aprile 2006 "Misure urgenti in materia di	Private autologous cord banks cannot apply for authorisation

Member State	Provisions on cord blood banking	Private blood banking
	cellule staminali da cordone ombelicale")	
CY - Kypros	- No specific provisions on cord blood banking - In the draft legislation submitted to the Cyprus Parliament, there are special conditions for private cord banking	Private autologous cord blood banks can apply for authorisation
LV - Latvija	No specific provisions on cord blood banking	Private autologous cord banks cannot apply for authorisation
LT - Lietuva	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
LU - Luxembourg	Not applicable	Not applicable
HU – Magyarország	- Yes, specific provisions on cord blood banking exists - Decree of the Minister of Health No. 60/2003. (X. 20.) ESzCsM, Annex 2., Title "Minimum conditions of cell and tissue transplantation" on the professional minimum requirements needed for providing health services determines the minimum requirements of cord blood procurement as follows: 1. During the procurement of cord blood cells, provisions on blood donors shall be applied for the examination of pregnant women. During the collection, processing, transport, storage and application of cord blood, the provisions on bone marrow transplantation shall be applied. 2. Procurement of cord blood can exclusively be executed by healtcare providers or obstetrical care units disposing certification of compliance according to Section 124. of Act CLIV of 1997 on health care. 3. If processing and storage of cord blood cells do not take place at the health care provider executing the procurement, the procurement of cord blood can be executed based on a contract between the organisation executing processing and storage and the service provider. Authority permits for the procedure required by a piece of legislation shall compose the annex of the contract.	Private autologous cord banks can apply for authorisation

Member State	Provisions on cord blood banking	Private blood banking
MT - Malta	No specific provisions on cord blood banking	Private autologous cord banks cannot apply for authorisation
NL - Nederland	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
AT - Österreich	Yes, guideline on cord blood banking exists	Private autologous cord banks can apply for authorisation
PL - Polska	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
PT - Portugal	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
RO – Romania	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
SI - Slovenija	- No specific provisions on cord blood banking - Cord blood banking can only be public institutions	Private autologous cord banks cannot apply for authorisation
SK - Slovensko	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
FI - Suomi/Finland	No specific provisions on cord blood banking	Only non-profit activity is allowed, i.e. according to national law it is not allowed to charge e.g. parents for storage of cord blood
SE - Sverige	- No specific provisions yet but will have in the proposed regulation - There is one national cord blood bank	Private autologous cord banks cannot apply for authorisation
UK - United Kingdom	Not applicable	Not applicable
	No specific provisions on cord blood banking	*- Private autologous cord banks can apply for authorisation* *- Please note that legislation in the UK prohibits commercial dealings in human material for transplantation.*

EEA/EFTA countries

Iceland	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation

Norway	No specific provisions on cord blood banking	Private autologous cord banks can apply for authorisation
Liechtenstein	- Yes, provisions on cord blood banking exists (The principles of GMP and JACIE Standards for Hematopoietic Cell Collection, Processing and Transplation)	There is no autologous cord blood bank in FL

11. SANCTIONS

Member State	Incidences of withdrawal/suspension	Penalties
BE - Belgique / België	No incident yet	- Penalties were already laid down in existing legislation (Law of June 13 1986 concerning procurement an transplantation of organs (includes tissues and cells) and Royal Decree of April 15, 1988 concerning tissue banks). Violation concerning procurement or transplantation by a medical doctor in a hospital: punished with imprisonment of three to six months and a fine of 500 to 5000 BEF or with one of those punishments alone (art 17. &1). *(actually 750 € to 7.500 €)* - Violation concerning communication of identity of donor and receptor or concerning rules or conditions for procurement, storage, preparation, import, transportation, distribution and delivery of organs, tissues and cells (art 17. &2): punished with imprisonment of eight days to six months and a fine of 100 to 500 BEF or with one of those punishments alone). *(actually 750 € to 7.500 €)* - Violation concerning the law: punished with imprisonment of three months to one year and a fine of 1000 to 10000 BEF or with one of those punishments alone (art 17. &1). *(actually 1.500 € to 15.000 €)* In case of recidivism within five years of the sentence the punishment may be doubled.
BU – Bulgaria	No incident yet	Chapter seven "Administrative penal provisions" from Bulgarian "Organs, tissues and cells transplantation act": 1. Punishment by a fine of 10 000 to 30 000 BGN for those tissue banks which carry out activity in transplantation in violation of the provisions of Bulgarian "Organs, tissues and cells transplantation act"; 2. Suspending of activity and revoking the authorisation of tissue bank by Executive Director of EAT. 3. According to low inspections are performed every year for every authorised tissue bank.
CZ - Česká Republika	No, there has been times when accreditations/ authorisation have been delayed due to default, but once the duties were	No penalties have been laid down

Member State	Incidences of withdrawal/suspension	Penalties
	fulfilled, authorisation was given	
DK - Denmark	No incident yet	Yes, there would be fines depending on the nature of infringement
DE - Deutschland	No incident yet	- Yes, Penalties have been laid down - Imprisonment and/or fines according to the provisions of the German Drug Law and the Transfusion Act
EE - Eesti	No incident yet	No penalties have been laid down
EL - Elláda	No incident yet	No penalties have been laid down
ES - España	No incident yet	- Yes, penalties have been laid down **- "(RD):** Sin perjuicio de otra normativa que pudiera resultar de aplicación, las infracciones cometidas contra lo dispuesto en este real decreto y sus disposiciones de desarrollo tendrán la consideración de infracción en materia de sanidad, según lo previsto en el capítulo VI del título I de la Ley 14/1986, de 25 de abril, General de Sanidad, y de las demás disposiciones que resulten de aplicación. En las infracciones en materia de utilización de ficheros que contengan datos personales se estará a lo dispuesto en el Título VII de la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de datos de carácter persona"
FR - France	Yes, accreditation has been revoked or suspended (ex: BT Moselle Tutogen)	Yes, penalties have been laid down **1) Tissus et cellules (hors cellules reproductrices)** Actuellement, il existe en droit national une disposition permettant le retrait ou la suspension des autorisations d'établissements de tissus et des autorisations de produits. Il existe aussi des dispositions pénales en cas de non respect des dispositions sur la conservation et transformation de tissus ou de préparations de thérapie cellulaire par un établissement de tissus non autorisé, sur l'autorisation des produits et sur l'importation et l'exportation. **2) Cellules reproductrices** Il existe également pour ce secteur des sanctions administratives à l'encontre de tout établissement de santé ou laboratoire qui encourent le retrait temporaire ou définitif de son autorisation en cas de violation des prescriptions législatives et réglementaires applicables à l'AMP ou au cas où le volume d'activité ou la qualité des résultats de la structure autorisée sont jugés insuffisants. Par ailleurs, le directeur général de l'**ABM** peut retirer l'agrément au praticien en cas de violation par ce dernier des prescriptions législatives et réglementaires applicables à l'assistance médicale à la procréation ou de violation des conditions fixées par l'agrément. Le retrait de l'agrément peut également intervenir en cas de volume d'activité ou de qualité

Member State	Incidences of withdrawal/suspension	Penalties
		des résultats jugés insuffisants au regard des critères fixés par le directeur général de l'**ABM**, après avis de son conseil d'orientation .En cas d'urgence, l'agrément peut, à titre conservatoire, être suspendu pour une durée maximale de trois mois. Enfin,des dispositions pénales sanctionnent les infractions commises dans le cadre de l'AMP.
IE - Ireland	No incident yet	Yes, Fines and Imprisonment (Part 4 if S.I. 158 of 2006 – European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006)
IT - Italia	Yes, accreditation has been revoked or suspended	Not yet, proposals currently under discussion
CY - Kypros	No incident yet	- No penalties laid down yet - In the draft legislation submitted to the Cyprus Parliament, there are special penalties proposed which include fines up to 10,000 CY pound and/or 2 years of imprisonment
LV - Latvija	No incident yet	- No penalties for infringements of the national provisions adopted pursuant to the Directive have been laid down - The draft Regulations of the Cabinet of Ministers "Storage, preservation and distribution of human tissues and organs" provide that the competent authority may revoke the accreditation of a tissue establishment if inspections or control measures demonstrate that such an establishment does not comply with the requirements of these Regulations. Furthermore, the Criminal Law of the Republic of Latvia provides that for a medical practitioner who commits unlawful removal of tissues or organs from a living or dead human being in order to use them for medical purposes, the applicable sentence is deprivation of liberty for a term not exceeding five years, with or without deprivation of the right to engage in the practice of medical treatment for a period not exceeding five years.
LT - Lietuva	No incident yet	Not in place
LU - Luxembourg		Not applicable
HU – Magyarország	Yes, accreditations, designations, authorisations or licenses have already been revoked or suspended	- Yes, penalties have been laid down - According to Government Decree No. 96/2003. (VII. 15.) on the general conditions of providing health services and on operation permits, health service providers are allowed to operate holding a permit issued by the health authority (NPHMOS regional offices). In case of infringements, the operation permit may be suspended or revoked, and the following sanctions may be imposed: fines, OR in the most serious cases, criminal procedure may be initiated and penal sanctions may be applied by the courts

Member State	Incidences of withdrawal/suspension	Penalties
MT - Malta	No incident yet	- No penalties have been laid down - In view of the fact that accreditation and licensing has not yet started, no penalties have yet been determined
NL - Nederland	No incident yet	- Yes, penalties have been laid down - The limit is that the establishment can be closed or loose its accreditation
AT - Österreich	No incident yet	There will be penalties in the transponed law and there are penalties in the current AMA.
PL - Polska	No incident yet	- Yes, all those who disseminate notices about payable sales, purchases of cells, tissues and organs or about an agency for payable sales or purchases of cells, tissues and organs with the aim of transplanting them shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of up to one year. 1. All those who with the purpose of acquiring financial benefits buy or sell other people's cells, tissues or organs, run an agency for the purchase and sale of cells, tissues or organs or take part in transplantations of recovered in defiance of the regulations of the present act cells, tissues or organs that originate from living donors or human dead bodies, shall be liable to a penalty of imprisonment of up to three years. 2. All offenders who have a fixed income source through perpetration of the crime stated in paragraph 1 shall be liable to a penalty of imprisonment of up to five years. All those who perform activities, which the regulations in the Act provide for tissue and cell banks, without having the required permission shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of up to one year. All those who without having the required permission recover cells, tissues or organs for transplantations or transplant these shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of up to three years.
PT – Portugal	No incident yet	Not defined yet
RO – Romania	No incident yet	- Penalties have been laid down as listed below: **- Law nr.95/2006** "concerning the reform in the health field" - Title VI "Performing of harvesting and the transplant of organs, tissues and cells of human origin with a therapeutic purpose" **ART. 154** The organization and harvesting of organs, tissues and/or cells of human origin, for transplant, in other conditions than the ones mentioned in the present title, constitute an infringement and are punished according to the penal law. **ART. 155** The harvesting or transplant of organs and/or tissues and/or cells of human origin without a consent given in the conditions of the present title, constitute an infringement and are punished by jail from 5 to 7 years. **ART. 156** The deed of the person that ordered or made the harvesting and by it they compromise a forensic necropsy,

Member State	Incidences of withdrawal/suspension	Penalties
		solicited in the law conditions, constitutes an infringement and is punished by jail from 1 to 3 years. **ART. 157** (1) It is an infringement and is punished by jail from 3 to 5 years the deed of the person that donates organs and/or tissues and/or cells of human origin so as to obtain material gains or of other kind for themselves or others. (2) The determination in bad faith or the constraint of a person to donate organs and/or tissues and/or cells of human origin is an infringement and is punished by jail from 3 to 10 years. (3) The advertising in favor of a person to obtain organs and/or tissues and/or cells of human origin as well as the publication and broadcast of some ads concerning the donation of organs and/or tissues and/or cells of human origin to obtain material gains or of other kind for themselves, the family or third parties juridical or natural persons, is an infringement and is punished by jail from 2 to 7 years. **ART. 158** (1) The organization and/or harvesting of organs, tissues and/or cells of human origin, for transplant, to obtain material gains for the donor or organizer, is a infringement of traffic of organs and/or tissues and/or cells of human origin and is punished by jail from 3 to 10 years. (2) The same punishment is also applied to the buying of organs, tissues and/or cells of human origin, so as to re-sell them to obtain a profit. (3) The attempt is punished. **ART. 159** The import or export of organs, tissues, cells of human origin, without a special authorization issued by the National Transplant Agency is an infringement and is punished by jail from 3 to 10 years.
SI - Slovenija	No incident yet	- Not penalties for infringements of the national provisions adopted pursuant to the Directive - Between 2.000,00 and 20.000,00 EUR according to the Act on removal and transplantation of human body parts for the purposes of medical treatment act (ZOPDCT, 2000)
SK - Slovensko	No incident yet	Not yet
FI - Suomi/Finland	No incident yet	- Proposal complies with the Directive concerning penalties - Fines can be imposed on those who act against the national legislation
SE - Sverige	No incident yet	No penalties have been laid down
UK - United Kingdom	No incident yet	- Penalties have been laid down - In addition to loss of licence, if prosecution not deemed appropriate, on conviction following a prosecution for breach of the requirements imposed by the Directive a term of imprisonment not exceeding 2 years, a fine or both. On summary conviction a term of imprisonment not exceeding 3 months or a fine

Member State	Incidences of withdrawal/suspension	Penalties
	No incident yet, however we have taken significant regulatory action by issuing an establishment with Special Directions to prevent the distribution of stem cells. See the annex 1 - regulatory alert.	*- Penalties have been laid down* *- Currently it is an offence to store tissues and cells for the purpose of transplantation without a licence. A breach of the licensing requirements could lead to a fine or a prison sentence of up to 3 years.*

EEA/EFTA countries

Iceland	No incident yet	No penalties have been laid down
Norway	No incident yet	- No penalties for infringements of the national provisions adopted pursuant to the Directive have been laid down - Fines and/or imprisonment up to 3 years
Liechtenstein	Not yet	No penalties have been laid down

12. COMMENTS

Member State	Comments
BE - Belgique / België	No technical difficulties
BU – Bulgaria	- We did not have difficulties in the transposition of the Directives. - I suggest some administrative and legislative measures about non altruistic private Autologous cord blood banking donation. We have some difficulties with this very fast growing sector in our country.
CZ - Česká Republika	Not enough time for transposition of the Directives
DK - Denmark	- A comprehensive list of the contact points for all Member States, for the notification of serious quality defects or recalls (i.e. a rapid alert system), would be beneficial for all parties - An indication of the type of cell preparation processes to be authorised by the national authority would be beneficial to all parties

Member State	Comments
	- Illustrative examples of the type of cells/tissues that may be directly supplied to a transplantation centre would be informative for all parties (Article 6.5, Dir. 2004/23/EC) - Some clarification from the Commission on the regulatory status of lymphocytes, with reference to the Tissues Establishments Directives, would be beneficial - The Standards of quality and safety expected for imports shall be equivalent to the ones laid down in this Directive. Some feedback on the early experiences of Member States (e.g. when declarations are stated for compliance with other country requirements) would be of interest
DE - Deutschland	The authorization of the procurement process by the competent authorities is critically discussed among the health care establishments.
EE - Eesti	Work overload for the national authorities
EL - Elláda	Since our national law for transplantation generally covers organs and tissues/cells together, we have encountered difficulties to adopt the details of the Directives in it
ES - España	- Common id system - Transnational Trazability and Biovigilance - Import/ Export rules and requirements
FR - France	1) La difficulté pour les juristes réside parfois dans l'appréciation du niveau de texte requis pour la transposition (décret ou arrêté) : il s'agit en effet de textes très techniques et qui de plus présentent des enjeux de sécurité sanitaire importants. 2) Par ailleurs, nous souhaitons appeler à nouveau l'attention de la commission sur le fait que les conditions d'autorisation des procédés de préparation des tissus et des cellules telles que prévues dans la directive 2006/86/EC ne nous paraissent pas suffisants pour garantir la qualité et la sécurité des tissus et des cellules qui sont encadrés par cette directive. La directive 2004/23/CE prévoit dans son article 6-2 que les autorités compétentes autorisent les procédés de préparation des tissus et cellules conformément aux exigences visées à l'article 28, point g). Cet article 28 g) renvoie à la comitologie le soin de définir les exigences requises pour autoriser les procédés de préparation des tissus et des cellules. La directive 2006/86/EC est notamment prise en application de l'article 28 point g) comme l'attestent ses visas. Or ce texte ne définit en aucune façon le contenu et la nature des données qui vont permettre aux autorités compétentes des Etats membres de se prononcer sur la qualité, la sécurité et l'efficacité d'un procédé. Les dispositions prévues en matière de procédés mettent en place un système d'assurance qualité validé permettant une bonne mise en œuvre des procédés par les opérateurs. Elles ne permettent pas aux autorités compétentes d'apprécier les normes de qualité, de sécurité et d'efficacité des tissus ou des cellules qui vont résulter de la mise en œuvre de ces procédés comme prévu dans les considérants 13 et 14 et à l'article 6 de la directive. Or, il nous semble toujours indispensable que ces procédés de préparation soient évalués dans les différents Etats membres sur la base d'exigences communes en termes de données et d'informations à fournir par les demandeurs de l'autorisation traduisant des exigences techniques également communes. Ceci est indispensable pour garantir un mode d'évaluation homogène des procédés de préparation. En l'absence de précisions à ce sujet, les

Member State	Comments
	produits vont être évalués dans chaque pays de l'Union selon des normes différentes, ce qui, dans un secteur où les échanges internationaux sont nombreux , ne permet pas de garantir le même niveau de qualité et de sécurité des produits aux patients quelle que soit leur origine. 3) Nous nous interrogeons sur le niveau de qualification à requérir pour la personne responsable 4) La codification n'est pas pertinente pour les gamètes (cette exigence est d'autant moins pertinente que la circulation des gamètes est très limitée au sein de l'UE)
IE - Ireland	- Testing requirements for reproductive cells. 'Testing at time of Donation' Guidance on this requirement should be provided. - Difficulty in interpreting air quality requirements as they are not as specified in EU Guide to GMP Annex I. (Grade A with minimum Grade D background?) - Procurement sites that supply tissue establishments outside of our territory. How should these be managed?
IT - Italia	- Delays in the transposition process itself - Some resistance from the HSC professional community who see JACIE accreditation as the way forward – now largely resolved - Lack of clarity regarding the place of DLI (blood or tissues and cells directive). We are managing under the tissues and cells directive. - Some confusion regarding coding – should we proceed to put a national system in place or wait for the Commission's system?
CY - Kypros	- The Directive 2004/23/EC did not lay down the specific technical requirements which were later defined by the 2006/17/EC and 2006/86/EC, making it difficult for the regulators to draft the national law - The draft legislation submitted to the Cyprus Parliament was challenged by the private companies providing cord blood banking resulting in the delay of its approval - The lack of extended expertise in a very highly specialised area made it difficult to draft the regulation and is expected to hinder its effective implementation
LV - Latvija	-
LT - Lietuva	Lithuanian biggest problem is shortage of human resources.
LU - Luxembourg	The draft of the law transposing the directive is blocked at the "Chambre des Députés"
HU – Magyarország	- The current system determined national minimum requirements and controls their existence. The comparison of these minimum requirements on an international level would be useful. - The detailed control should be performed through (international) professional bodies, because small countries do not have enough (independent) competent persons to perform controls appropriately. - The main difficulty of the transposition of Directive 2004/23/EC was that the provisions of this framework directive are too broad and thus it was not easy to formulate the corresponding provisions in national law in an exact and enforceable manner.

Member State	Comments
	- From a legal point of view, interpretation and consequently the transposition of certain provisions caused some difficulties e.g. in Directive 2006/17/EC the following articles: - Article 1 (e) "standard operating procedures" (SOPs): it is not absolutely clear on which level such procedures are meant to be adopted – in national legislation or by the competent authorites or by the individual organisations. - Article 2 paragraph 7 says: "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." Transposition of the second half of this provision is problematic as it is not mentioned which international regulations are meant here, those referred to in paragraph (6) of the Preamble or others, and therefore what exact references are expected here from Member States in their transposing national legislation. - Article 6 "Requirements for direct distribution to the recipient of specific tissues and cells": clarification of the definition of 'specific' tissues and cells might be useful, i.e. whether certain exact types of tissues and cells are meant here, or it is in the Member States' discretion to define what is 'specific'.
MT - Malta	A major problem encountered is the setting up of a regulatory structure, especially with regards to limited human resources and lack of expertise in inspecting and regulating tissue establishment
NL - Nederland	- Apparently Germany has placed the scope of the Directive under pharmacy legislation. This puts certain (tissue) establishments in the Netherlands in a difficult position. To export human tissue to Germany they will need to prove they fulfil the requirements of the German legislation. However under Dutch law they can not apply for a license under pharmacy legislation, because in The Netherlands that type of legislation does not apply to these products. - Also we heard that apparently England will apply the rules that strict, that companies are thinking to move to the Netherlands. How do we deal with these differences?

AT - Österreich	- Diverse grown systems of various tissues and cells to be harmonised within one MS
	- Infectious marker tests not validated for cadaveric plasma or serum
	- Growth and maintenance media
	  - contents
	  - origin of ingredients
	  - kind of proteins and their potential transmission of infectious diseases
	  - production
	  - manufacturer
	  - procedures
	  - quality systems
	  - marketing authorisation

Member State	Comments
	- Import (from third countries) of tissues and cells : - safety issues - epidemiological aspects - procurement environment - processing enviroment - transport (not only for imported tissues and cells) - traceability to the donor - vigilance – international reporting system (may be solved by EUSTITE project with WHO)
PL - Polska	No Comment
PT - Portugal	- The existing national organization has to be changed, because it was neither sufficient nor efficient enough to carry out all measures defined by the directives. - Accreditation/license, Inspections, control measures, and bio vigilance system imply a different and solid organization as well as more human and financial resources. - These meetings, exchanging expertises and different experiences in the field can be quite useful for countries like Portugal that still have a long way ahead.
SI - Slovenija	-
SK - Slovensko	The process of the re-authorization of the tissue establishments will probably need more time because the criteria for both accreditation of the tissue establishments and for accreditation of tissues/cells preparation processes were included in the Directive 2006/86/EC, which will be implemented last
FI - Suomi/Finland	Short transposition period of the Commission Directives
SE - Sverige	Sweden has encountered some difficulties
UK - United Kingdom	- As indicated in the report for the HFEA's sister competent authority (the Human Tissue Authority), EU Directives can only be implemented in the UK by statutory legislation - in the case of reproductive cells, secondary legislation amending the existing regulatory framework the Human Fertilisation & Embryology Act 1990. The delay in publishing the two supporting Commission Directives meant that the UK was unable to formally begin the process of amending the primary legislation until October 2006 when the text of the final Commission Directive (2006/86/EC) was published. - The issue of import and export is one that the UK believes Commission should consider. In the case of reproductive cells, the UK has long had a control system in place to ensure that all gametes and embryos coming into the UK for use in treatment had been handled to the same standards applicable to UK establishments. The import/export controls applied equally to imports from EU Member States as they did to non-EU countries. The UK is concerned that variance across the Union in implementing the provision of the Directives means that the UK is unable to take the position of automatically

Member State	Comments
	assuming that gametes and embryos from other Members States have been handled to Directive standards. The UK is unable to accept gametes and embryos from other Member States where it cannot be confident that the Tissue Directive standards have been applied in full. Equally, the UK does not permit payment for the donation of gametes and will also feel unable to accept gametes or embryos from other Members States where it has evidence to believe that financial inducements have been paid to the donor.
	- The Human Tissue Authority was set up to implement the Human Tissue Act (2004) which set out statutory responsibility for HTA to license and inspect establishment storing tissue for transplantation (human application). However European community law currently requires that directives are transposed into law via statutory legislation. In the UK we have already transposed the 2004/23/EC and 2006/17/EC via directions issued under the HT Act (2004) to our licence holders. The requirement to produce new legislation means altering licensing systems currently in place within the UK and creating an additional administrative burden for the licensed sector. *- The delay in publication of 2006/83/EC has caused difficulties for the regulated sector and left some unsure of the actions they will need to take in order to comply with the directives.* *- There has been a lack of clarity in the directives on certain areas, particularly on annual reporting and registers. Neither the information required nor the timelines for the reporting of the information was made clear.* *- The Authority has already issued one regulatory alert which may have affected other competent authorities in Europe. However a list of all competent authorities in Europe was not available to allow us to distribute this alert to all authorities.*

EEA/EFTA countries

Iceland	-
Norway	- There have been some discussions on the scope of the directives, for example are pancreatic islets covered, are skin products covered? - It would be of great help if the commission could give information on borderline questions on their web-site. - There are also some problems in implementing the specifications for premises and air quality in some of the tissue establishments. The problems mainly arise in established institutions for reproductive treatment.
Liechtenstein	No difficulties have been encountered so far. (In Liechtenstein we have only one establishment using cornea from Switzerland)