Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells (Text with EEA relevance)

ANNEX I

Minimum requirements concerning the information and documentation to be provided by importing tissue establishment applicants when applying to be accredited, designated, authorised or licensed for the purpose of import activities

When applying for an accreditation, designation, authorisation or licence for the purpose of import activities, the importing tissue establishment applicant shall, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as a tissue establishment or importing tissue establishment, provide the most up-to-date information and, for part F, documentation on the following:

A. **General Information on the Importing Tissue Establishment (ITE)**

1. Name of the ITE (Company name).

2. Visiting address of the ITE.

3. Postal address of the ITE *(if different)*.

4. Status of the applicant ITE: It should be indicated if this is the first application for accreditation, designation, authorisation or licensing as an ITE or, where applicable, whether this is a renewal application. Where the applicant is already accredited, designated, authorised or licensed as a tissue establishment, the TE compendium code should be provided.

5. Name of the applying unit *(if different from the company name)*.

6. Visiting address of the applying unit.

7. Postal address of the applying unit *(if different)*.

8. Name of the site of reception of imports *(if different from the company name and applying unit)*.

9. Visiting address of the site of reception.

10. Postal address of the site of reception *(if different)*.

B. **Contact Details for the Application**

1. Name of contact person for the application.

2. Telephone number.

3. E-mail address.

4. Name of Responsible Person *(if different from contact person)*.

5. Telephone number.

6. E-mail address.

7. URL of ITE website *(if available)*.

C. **Details of Tissues and Cells to be Imported**

1. A list of the types of tissues and cells to be imported, including one-off imports of specific types of tissues or cells.

2. The product name *(where applicable, in accordance with the EU generic list)* of all types of tissues and cells to be imported.

3. The trade name *(if different to the product name)* of all types of tissues and cells to be imported.

4. The name of the third country supplier for each type of tissue and cell to be imported.

D. **Location of Activities**

1. A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by the third country supplier per type of tissue or cell.

2. A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by sub-contractors of the third country supplier per type of tissue or cell.

3. A list of all activities carried out by the ITE subsequent to import per type of tissue or cell.

4. The names of the third countries in which the activities prior to import take place per type of tissue or cell.

E. **Details of Third Country Suppliers**

1. Name of third country supplier(s) (company name).

2. Name of contact person.

3. Visiting address.

4. Postal address *(if different)*.

5. Telephone number including international dialling code.

6. Emergency contact number *(if different)*

7. E-mail address.

F. **Documentation to Accompany the Application**

1. A copy of the written agreement with the third country supplier(s).

2. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment.

3. A copy of the third country supplier's export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports. This documentation shall also include the contact details of the third country competent authority or authorities. In third countries where such documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier.

ANNEX II

Certificate of Accreditation, Designation, Authorisation or Licence to be issued by the competent authority or authorities to importing tissue establishments

Certificate of Accreditation, Designation, Authorisation or Licence of an Importing Tissue Establishment								
1. **Importing Tissue Establishment (ITE) Details**								
1.1 Name of ITE								
1.2 EU Tissue Establishment Compendium Code								
1.3 ITE Address and postal address *(if different)*								
1.4 Site of reception of imports *(if different from the above address)*								
1.5 Name of accreditation, designation, authorisation or licence holder								
1.6 Address of accreditation, designation, authorisation or licence holder								
1.7 Telephone number of accreditation, designation, authorisation or licence holder *(optional)*								
1.8 E-mail address of accreditation, designation, authorisation or licence holder *(optional)*								
1.9 URL of ITE website								
2. **Scope of Activities**								
2.1 Type of Tissues and Cells *(list below using categories of tissues and cells listed in the EU Tissue Establishment Compendium adding rows as necessary)*	Activities in third countries						Import Accreditation, Designation, Authorisation or Licence Status	
	Donation	Procurement	Testing	Preservation	Processing	Storage		
	3CS — Third country supplier *SC — Sub-contractor of third country supplier*						*G — Granted* *S — Suspended* *R — Revoked* *C — Cessation*	
2.2 One-off imports							☐	
2.3 Product name(s) of imported tissues and cells								
2.4 Any conditions placed on the import or clarifying remarks								

2.5	Third country or countries of procurement *(per tissue and cell import)*	
2.6	Third country or countries in which other activities take place *(if different)*	
2.7	Name and country of third country supplier(s) *(per tissue and cell import)*	
2.8	EU Member States in which imported tissues and cells will be distributed *(if known)*	
	3. Competent Authority (CA) Accreditation, Designation, Authorisation or Licence	
3.1	National accreditation, designation, authorisation or licence number	
3.2	Legal basis of accreditation, designation, authorisation or licence	
3.3	Date of expiry of accreditation, designation, authorisation or licence *(if any)*	
3.4	First accreditation, designation, authorisation or licence as ITE or renewal	First time ☐ Renewal ☐
3.5	Additional remarks	
3.6	Name of CA	
3.7	Name of CA Officer	
3.8	Signature of CA Officer *(electronic or otherwise)*	
3.9	Date of accreditation, designation, authorisation or licence	
3.10	CA Stamp	

ANNEX III

Minimum requirements concerning the documentation to be made available to the competent authority or authorities by tissue establishments intending to import tissues and cells from third countries

With the exception of one-off imports as defined in Article 2 of this Directive which have been exempted from these documentation requirements, the applicant importing tissue establishment shall make available and, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as an importing tissue establishment or tissue establishment, shall provide when requested by the competent authority or authorities the most up-to-date version of the following documents regarding the applicant and its third country supplier(s).

A. **Documentation relating to the importing tissue establishment**

1. A job description of the Responsible Person and details of his/her relevant qualifications and training record as laid down in Directive 2004/23/EC;

2. A copy of the primary label, repackage label, external package and transport container;

3. A list of relevant and up-to-date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code, reception and storage of imported tissues and cells at the importing tissue establishment, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

B. **Documentation relating to the third country supplier or suppliers**

1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not;

2. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres;

3. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure;

4. A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier;

5. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers;

6. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken;

7. A summary of the most recent inspection of the third country supplier by the third country competent authority or authorities including the date of the inspection, type of inspection and main conclusions;

8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment;

9. Any relevant national or international accreditation.

ANNEX IV

Minimum requirements concerning the contents of written agreements between importing tissue establishments and their third country suppliers

With the exception of one-off imports as defined in Article 2 of this Directive which have been exempted from these requirements, the written agreement between the importing tissue establishment and the third country supplier shall contain at least the following provisions.

1. Detailed information on the specifications of the importing tissue establishment aimed at ensuring that the quality and safety standards laid down in Directive 2004/23/EC

are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported tissues and cells are of equivalent standards of quality and safety;

2. A clause ensuring that the third country supplier provides the information set out in Annex III B to this Directive to the importing tissue establishment;

3. A clause ensuring that the third country supplier informs the importing tissue establishment of any suspected or actual serious adverse events or reactions which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;

4. A clause ensuring that the third country supplier informs the importing tissue establishment of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export tissue and cells or other such decisions of non-compliance by the third country competent authority or authorities, which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;

5. A clause guaranteeing the competent authority or authorities the right to inspect the activities of the third country supplier, including on-site inspections, should it wish to do so as part of its inspection of the importing tissue establishment. The clause should also guarantee the importing tissue establishment the right to regularly audit its third country supplier;

6. The agreed conditions to be met for the transport of tissues and cells between the third country supplier and importing tissue establishment;

7. A clause ensuring that donor records relating to imported tissues and cells are kept by the third country supplier or its sub-contractor, in line with EU data protection rules, for 30 years following procurement and that suitable provision is made for their retention should the third country supplier cease to operate;

8. Provisions for the regular review and, where necessary, revision of the written agreement including in order to reflect any changes in the requirements of the EU quality and safety standards laid out in Directive 2004/23/EC;

9. A list of all standard operating procedures of the third country supplier relating to the quality and safety of imported tissues and cells and a commitment to provide these on request.