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.