

Regulatory changes to imports and the ITE import certification scheme from 11pm on 31 December 2020 and from 11pm on 30 June 2021.

Regulatory changes

Imports to centres in Great Britain (GB) will be regulated by General Direction 0006(GB) version 8 (active between 11pm on 31 December 2020 and 11pm on 30 June 2021) and version 9 (active from 11pm on 30 June 2021 onwards), and to centres in Northern Ireland (NI) by General Direction 0006(NI) version 1. These directions incorporate changes to allow for those made in the HF&E Act 1990 (as amended) by the 2019 and 2020 EU exit amendments.

After 11pm on 30 June 2021, whether or not a country is a 'third country' relative to a licensed centre will depend on the centre's location :

- For centres in GB after 11pm on 30 June 2021, all countries outside of the United Kingdom (England, Scotland, Wales and Northern Ireland) are third countries including those in the EEA and Gibraltar.
- For centres in NI after 11pm on 31 December 2020, all countries outside of the EEA, including GB and Gibraltar, are third countries.

If a licensed centre is making an import from a third country supplier (TCS), it must have authorisation for the import, before undertaking it, via its importing tissue establishment (ITE) import certificate. The changes above have the following impacts on the ITE import certificate application process:

For licensed centres in GB, from 11pm on 31 December 2020, a third country is defined as any country outside of the UK and tissue establishments in those countries exporting to GB will be TCS. From 11pm 30 June 2021, this change acts for imports to GB from tissue establishments in the EEA and Gibraltar. Licensed centres in GB seeking to import from a TCS must have authority to do so from an ITE import certificate. NI is in the UK and licensed centres in NI are not TCS when transporting gametes and embryos to centres in GB, so ITE import certificate authorisation is not required by centres in GB for such transports.

For licensed centres in NI after 11pm on 31 December 2020, all countries outside of NI and the EEA will be third countries and tissue establishments in countries outside of NI and the EEA will be TCS. GB is a third country in relation to NI from 11pm on 31 December 2020. Licensed centres in NI seeking to import from a TCS, including those in GB, must apply for an ITE import certificate to authorise such imports. Imports to NI from the EEA will not be from third countries so will not require authorisation by an ITE import certificate.

Applying for an ITE import certificate

The form to make an application to issue or update an ITE import certificate has been revised to account for the regulatory changes discussed above.

The ITE import certificate application form is held in the licensing application function in the centre-restricted area of the Clinic Portal.

Applying for an ITE import certificate to authorise a one off import

Reference to a one-off import is to gametes or embryos imported from a TCS for the purposes of providing services to a particular (named) person or persons on one occasion only. All imports which are not one-off imports are by definition multiple imports.

If an ITE in GB or NI is applying for an ITE import certificate to authorise a one off import from a third country supplier (TCS), the following requirements must be met:

- A. All required information in the application form must be provided; i.e. all fields in the application form must be accurately completed (General Direction 0006(GB) version 9 and General Direction 0006(NI) v1, Annex C (A) – (E)).
- B. Documentary assurance must be provided that:
 - the TCS is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated;
 - the ITE has not previously import gametes or embryos from the TCS for use in treating particular (named) person or persons.

Applying for an ITE import certificate to authorise multiple imports

If an ITE in GB or NI is applying for an ITE import certificate to authorise multiple imports from a third country supplier (TCS), the following requirements must be met:

- A. Documentary assurance must be provided that the third country supplier is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated.
- B. All required information in the application form must be provided; i.e. all fields in the application form must be accurately completed (General Direction 0006(GB) version 9 and General Direction 0006(NI) v1, Annex C (A) – (E)).
- C. The three documents listed in General Direction 0006, v8, Annex C (F) (Documents i – iii) must be provided. These are listed in Audit tool A below, along with the specific requirements regarding the contents of the importing agreement / third party agreement between the ITE and TCS, as per General Direction 0006(GB) and 0006(NI), Annex A.

Audit tool A: Multiple imports authorisation additional requirements

For a multiple imports authorisation, centres must provide the information in Audit tool A

Document (i). A copy of the written agreement between the receiving centre and the TCS, which <u>must</u> include clauses in line with General Direction 0006(GB) and 0006(NI), Annex A including:		
	Compliant - evidence	Non compliant
i) <u>Detailed information</u> on the specifications of the receiving centre aimed at ensuring that the quality and safety standards of the HF&E Act 1990 (as amended) and Directive 2004/23/EC embedded within it, are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported tissues and cells meet those standards;		
The Quality and Safety Standards relate to:		
<ul style="list-style-type: none"> • Accreditation, designation, authorisation or licensing 		
<ul style="list-style-type: none"> • Traceability from the donor to the recipient and vice versa, and of relevant materials 		
<ul style="list-style-type: none"> • Imports are between accredited clinics and comply with the requirements of 2004/23/EC 		
<ul style="list-style-type: none"> • Notification of serious adverse events and reactions 		
<ul style="list-style-type: none"> • Donor compensation strictly limited to the expenses and inconveniences of donation, i.e. compliant with General Direction 0001 		
<ul style="list-style-type: none"> • Proper information and consent provided to donors before procurement: 		
<ul style="list-style-type: none"> • Data protection and confidentiality 		
<ul style="list-style-type: none"> • Donor selection and evaluation and the procurement process 		
<ul style="list-style-type: none"> • Quality management system 		
<ul style="list-style-type: none"> • The responsible person 		
<ul style="list-style-type: none"> • Staff qualifications, training and experience 		
<ul style="list-style-type: none"> • Tissue and cell reception 		
<ul style="list-style-type: none"> • Tissue and cell processing 		
<ul style="list-style-type: none"> • Premises, Equipment and Materials 		
<ul style="list-style-type: none"> • Tissue and cell storage conditions 		
<ul style="list-style-type: none"> • Labelling, documenting and packaging 		
<ul style="list-style-type: none"> • Distribution 		
<ul style="list-style-type: none"> • Third party relationships 		
<ul style="list-style-type: none"> • Coding of information about samples and the Single European Code 		
ii) A clause specifying that the TCS will provide the information set out Part B of		

Annex B to General Direction 0006 to the receiving centre (requirements detailed in Information Tool B below)		
iii) A clause ensuring that the TCS informs the receiving centre of any suspected or actual serious adverse events or reactions which may influence the quality and safety of gametes and embryos imported or to be imported by the receiving centre.		
iv) A clause ensuring that the TCS informs the receiving centre of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export gametes or embryos or other such decisions of non-compliance by the authority or authorities in the third country responsible for regulating tissue establishments in that country		
v) Clauses guaranteeing the rights of the HFEA to inspect the activities of the TCS, including on-site inspections, and the receiving centre to audit the TCS		
vi) The agreed conditions to be met for the transport of gametes and embryos from the TCS to the receiving centre		
vii) A clause ensuring that donor records relating to imported tissues and cells are kept by the TCS or subcontractor, in line with data protection legislation within the meaning of section 3(a) of the Data Protection Act 2018.		
viii) Provisions for the regular review and, where necessary, revision of the written agreement in order to reflect any changes in the standards required by the Human Fertilisation and Embryology Act 1990.		
ix) A list of all standard operating procedures of the TCS relating to the quality and safety of imported gametes and embryos		
Documents (ii) and (iii) are required by General Directions 0006(GB) and 0006(NI), Annex C, F (ii) and (ii)		
Document (ii). A detailed description of the flow of imported tissues and cells from their procurement to their reception at the ITE		
Document (iii). A copy of the TCS's export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority(s) authorising the TCS's activities including export. This documentation shall also include the contact details of the third country's authority or authorities concerned with regulating the third country supplier in that country.		

Information tool B

Receiving centres (ITEs) must have available and provide to the authority, on request, the documentation listed in Part B of Annex B to General Directions 0006(GB) and 0006(NI), as listed here in Audit Tool B. Note that this documentation and information is NOT part of the application process requirements, but can be requested by the HFEA at any time so must be held by the receiving centre. The written agreement between the receiving centre and the TCS should include that the TCS will provide the information set out in Part B of Annex B to General Direction 0006.

Requirements for documents to be supplied by the TCS on request, as per General Directions 0006(GB) and 0006(NI), Annex B		
	IN TPA	NOT in TPA
Are these documentary requirements covered in the TPA by a general clause, as per item ii) in Audit tool A.		
If a general clause is present, each of the items below does not need to be specified in the TPA		
i. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor/donor family, how consent is obtained from the donor/donor family and whether the donation was voluntary and unpaid or not;		
ii. Detailed information on the testing centre(s) used by the TCS and the tests performed;		
iii. Detailed information on the methods used during the processing of the gametes or embryos including details of the validation of critical processes;		
iv. 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 TCS;		
v. Detailed information on the conditions for release of gametes or embryos by the TCS;		
vi. Details of any sub-contractors used by the TCS including the name, location and activity undertaken;		
vii. A summary of the most recent inspection of the TCS by the third country regulatory authority or authorities including the date of the inspection, type of inspection and main conclusions;		
viii. A summary of the most recent audit of the TCS carried out by, or on behalf of, the receiving centre;		
ix. Any relevant national or international accreditation.		