

Frequently asked questions – Import and Coding

Import Directive

1. What legislation do I need to refer to?

The Human Fertilisation and Embryology Act 1990 (as amended – the Act) incorporates the requirements further to the passing of Regulations through Parliament in February 2018 (The Human Fertilisation and Embryology (Amendment) Regulations 2018, as well as The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and 2020.

2. When do the new Regulations come into force?

The initial Regulations came into force from 1 April 2018. The EU exit amending regulations come into force at 11pm on 31 December 2020

3. What is an Importing Tissue Establishment (ITE)?

An importing Tissue Establishment is any UK clinic which is importing gametes or embryos from a third country supplier and has been provided with a certificate from the HFEA.

4. What is a third country supplier?

A third country supplier was initially from 1 April 2018, a country that is outside of the EEA and Gibraltar for the purposes of importing gametes or embryos into the UK.

After 11pm on 31 December 2020, whether or not a country is a ‘third country’ relative to a licensed centre will depend on the centre’s location and the date:

For centres in Great Britain (GB) (i.e. in England, Scotland, Wales) between 11pm on 31 December 2020 and 11pm on 30 June 2021, countries in the European Economic Area (EEA) and Gibraltar were not third countries, nor was Northern Ireland (NI). All other countries were third countries.

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.

5. What do clinics do about one-off imports?

If there has once been a one-off import from a particular third country supplier for a particular patient under a one-off ITE import certificate authorisation, there can be no further imports for a particular patient from that supplier again unless the UK clinic enters into a third party agreement with the supplier and gets an ITE import certificate from the HFEA authorising multiple imports from the third country supplier. A one-off under the Regulations is literally a one-off.

6. How do UK clinics apply for a certificate from the HFEA?

The ITE import certificate application form is held in the licensing applications function in the centre-restricted area of the Clinic Portal, please use this online form to apply for a certificate.

7. Do UK clinics need an ITE import certificate from the HFEA to import from other EU countries?

If a UK clinic imported from an EU or EEA state, then an ITE import certificate was not required when the certification scheme was introduced in 2018.

Between 1 January 2021 and 30 June 2021, centres in Great Britain and Northern Ireland still did not need an ITE import certificate to import gametes and embryos from an EU or EEA country.

This situation changed on 30 June 2021, after which centres in Great Britain need an ITE import certificate to import gametes and embryos from countries in the EU and EEA, whereas centres in Northern Ireland do not.

8. What about gamete and embryo transports between Northern Ireland and Great Britain?

After 1 January 2021, centres in Great Britain will not need an ITE import certificate to receive gametes and embryos from a centre in Northern Ireland. Centres in Northern Ireland will however remain in the EEA regulatory zone after 31 December 2020, while centres in Great Britain will be outside this zone and will be in a 'third country' relative to Northern Ireland. Therefore from 31 December 2020, centres in Northern Ireland will require ITE import certificate authorisation to receive gametes and embryos from centres in Great Britain.

9. Do UK centres need a separate certificate for each third country supplier?

No. When the UK centre applies for import authorisation, they complete Annex A of the application form for each third country supplier. The authorisation for the third country supplier, if approved, is added to the ITE import certificate provided to the centre. Third country suppliers are added sequentially to the ITE import certificate as they are applied for and approved.

10. Do the UK centres need third party agreements with the third country supplier if they are importing from that supplier on a regular basis?

Yes. This type of importing relationship involves regular imports and should be considered a multiple imports relationship. Written import / third party agreements with such TCSs, as well as the other documents required to support an application for a multiple imports authorisation, ensure that such a multiple imports relationship complies with the quality and safety standards defined in the HF&E Act 1990 (as amended). Patient and donor safety will therefore be protected.

11. Do the UK centres need third party agreements with the third country supplier if they are importing on a one-off basis?

No. No written agreement is required with the third country supplier in the case of one-off imports. Where a clinic will be undertaking more than one import from a supplier or doing regular imports from a third country supplier, a third party agreement will be required. The third party agreement is a prerequisite to the UK clinic applying for an ITE import certificate from the HFEA for ongoing or repeated imports. It is not however a prerequisite for an ITE import certificate to authorise a one off import.

12. What sections of the Code of Practice are Regulations on import referenced in?

Changes were made to the Code of Practice Guidance Note 16 on Imports and Exports to discuss the ITE import certification scheme in 2018. However recent changes due to the end of the transition period and EU exit have been accounted for by the issue of revised versions of General Directions 0006, which regulates imports and exports of gametes and embryos. Specifically, 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. The General Directions are all available on the clinic portal at:

<https://portal.hfea.gov.uk/knowledge-base/directions/>. Revisions to the HFEA Code of Practice are planned in 2021 to account for all these changes.

13. What General Directions do clinics need to refer to for importing of gametes and embryos into the UK from outside of the EU, EEA and Gibraltar?

If planning imports from outside the EEA, clinics in Northern Ireland need to refer to Schedule 4 of General Direction 0006(NI) version 1, while clinics in GB need to refer to Schedule 1 of General Direction 0006(GB) version 9.

14. Can an ITE import certificate be revoked or suspended?

The HFEA may suspend or revoke the ITE import certificate, in part or in full, if, in particular, inspections or other control measures demonstrate that such the ITE or a TCS no longer meet the requirements of the HFE Act or the HFEA Code of Practice.

15. Will the ITE import certificate expire?

The certificate life will be tied to the licence length and will be renewed as part of the licence renewal process. If inspections associated with the licence renewal find non compliance in an ITE's import relationship with a third country supplier, the certificate may be revoked or suspended, in part or in full, depending on the non compliance found.

Coding Directive

1. What legislation do I need to refer to for the EU Directive on Coding?

The Human Fertilisation and Embryology Act 1990 (as amended – the Act) incorporated the requirements further to the passing of Regulations through Parliament in February 2018 (The Human Fertilisation and Embryology (Amendment) Regulations 2018, then subsequently (The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and 2020).

2. When do the new Regulations come into force?

The original regulation come into force from 1 April 2018. The EU exit amendment regulations are active from 11pm on 31 December 2020. The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or tissue establishments) within the EEA regulatory zone. Thus after 11pm on 31 December 2020, clinics in Northern Ireland must continue to use the SEC in the normal way, while clinics in Great Britain no longer have to use the SEC though they can continue to if they so choose, and must continue to use it if an alternative system to ensure traceability is not used.

3. What is the Single European Code (SEC)?

The SEC is applied to the movement of donor gametes and embryos between licensed clinics (or tissue establishments) within the EEA regulatory zone. The SEC is the unique identifier for tissues and cells *distributed* in the EU. It is made up of the following (six) features.

Donation identification sequence			Product identification sequence		
*ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
XI	000123 HFEA Licensed Centre number	00000000XX456 the Clinic's donor registration 'number' and a donation event-specific identifier, which together function as a unique donation number or code	E0000059 1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	001 If sperm, for example, is distributed to more than one TE	20181231 Date of expiry of consent, for example, 31 December 2018
SEC XI00012300000000XX456 E000005900120181231					

*Note that Northern Ireland has been assigned the country code XI from 11pm on 31 December 2020. Clinics in UK used GB as a country code up until this date and any clinics in GB continuing to use the SEC should use GB as a country code.

4. What is the purpose of the SEC?

The SEC enables the recipient tissue establishment to trace the distributing tissue establishment if there is an issue (now or in the future) relating to the quality or safety of the gametes or embryos, for example if a child develops a genetic condition associated with the use of donor sperm.

5. Who does the SEC apply to?

The SEC applies to all HFEA licensed clinics in the UK that are distributing donated gametes and embryos between clinics, for use in treatment by others besides the gamete providers. After 11pm on 31 December 2020, clinics in Northern Ireland must continue to use the SEC in the normal way, while clinics in Great Britain no longer have to use the SEC though they can continue to if they so choose, and must continue to use it if an alternative system to ensure traceability is not used.

6. What sections of the Code of Practice is the SEC referenced in?

The SEC is discussed in Code of Practice Guidance Note 15 on Procuring, processing and transporting gametes and embryos, and Guidance Note 19 on Traceability.

Recent changes in the requirements to use the SEC related to the end of the transition period and EU exit, have been implemented primarily through revised versions of General Direction 0013, specifically General Direction 0013(NI) for clinics in Northern Ireland and General Direction 0013(GB) for clinics in Great Britain. These revised versions supersede all guidance in the HFEA Code of Practice, which will be updated in 2021 to reflect the new requirements.

There is also some reference to the SEC in the revised versions of General Directions 0006, specifically, General Direction 0006(GB) version 9 (active from 11pm on 30 June 2021 onwards), and General Direction 0006(NI) version 1.

7. What General Directions do clinics need to refer to when applying the SEC?

Clinics in Northern Ireland should refer to the recently released General Directions 0013(NI) and General Directions 0006(NI) version 1. Clinics in Great Britain should refer to the recently released General Directions 0013(GB) and General Directions 0006(GB) version 9. These revised versions supersede all guidance in the HFEA Code of Practice, which will be updated in 2021 to reflect the new requirements.

8. What licence conditions have been changed because of the changes to the use of the SEC?

Standard licence conditions T100 and T101 have also been amended for clinics in Great Britain to reflect the changes brought in by the SEC.