

16. Imports and exports

This guidance note contains:

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Reference to relevant HFEA Directions

 Refer to principles 7, 10 and 13

HFEA guidance

- Registering patients and donors ■
- Information for patients and donors
- Imports and exports decision tree
- General Directions: evidence of compliance ■
- Special Directions: imports or exports within the EEA and Gibraltar
- Special Directions: imports or exports outside the EEA and Gibraltar
- Notifying the HFEA about transfers ■

■ Section includes interpretation of mandatory requirements

Other legislation, professional guidelines and information



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

- 24 Directions as to particular matters
- (3) In relation to gametes or embryos that are not intended for human application, directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.
- (3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage –
- (a) between premises to which licences relate,
 - (b) between such premises and relevant third party premises,
 - (c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or
 - (d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4), in such circumstances and subject to such conditions as may be specified in directions.
- (3B) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of human admixed embryos in the course of their carriage to or from any premises.



Mandatory requirements (cont)

- (4) Directions may authorise any person to whom a licence applies to receive gametes, embryos or human admixed embryos from outside the United Kingdom or to send gametes, embryos or human admixed embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.
- (4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country, gametes or embryos intended for human application, the Authority shall—
- include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such imports or exports meet standards of quality and safety equivalent to those laid down in the Act, and
 - have regard to ensuring traceability.

Directions

0005 – Collecting and recording information for the HFEA

0006 – Import and export of gametes and embryos

For a copy of the relevant Directions visit www.hfea.gov.uk



HFEA guidance

Registering patients and donors



Interpretation of mandatory requirements

16A

Where a centre wishes to import gametes or embryos into the UK, or export them from the UK, the person responsible must ensure that:

- a donor information form is completed in respect of any donated gametes, and
- where the gametes are exported or imported for the use of a patient, that the patient is registered with the HFEA, and the relevant registration forms are completed.

Information for patients and donors

16.1 Before a patient or donor considers obtaining gametes or embryos from outside the UK, the centre should inform them that special criteria relating to UK standards must be met.

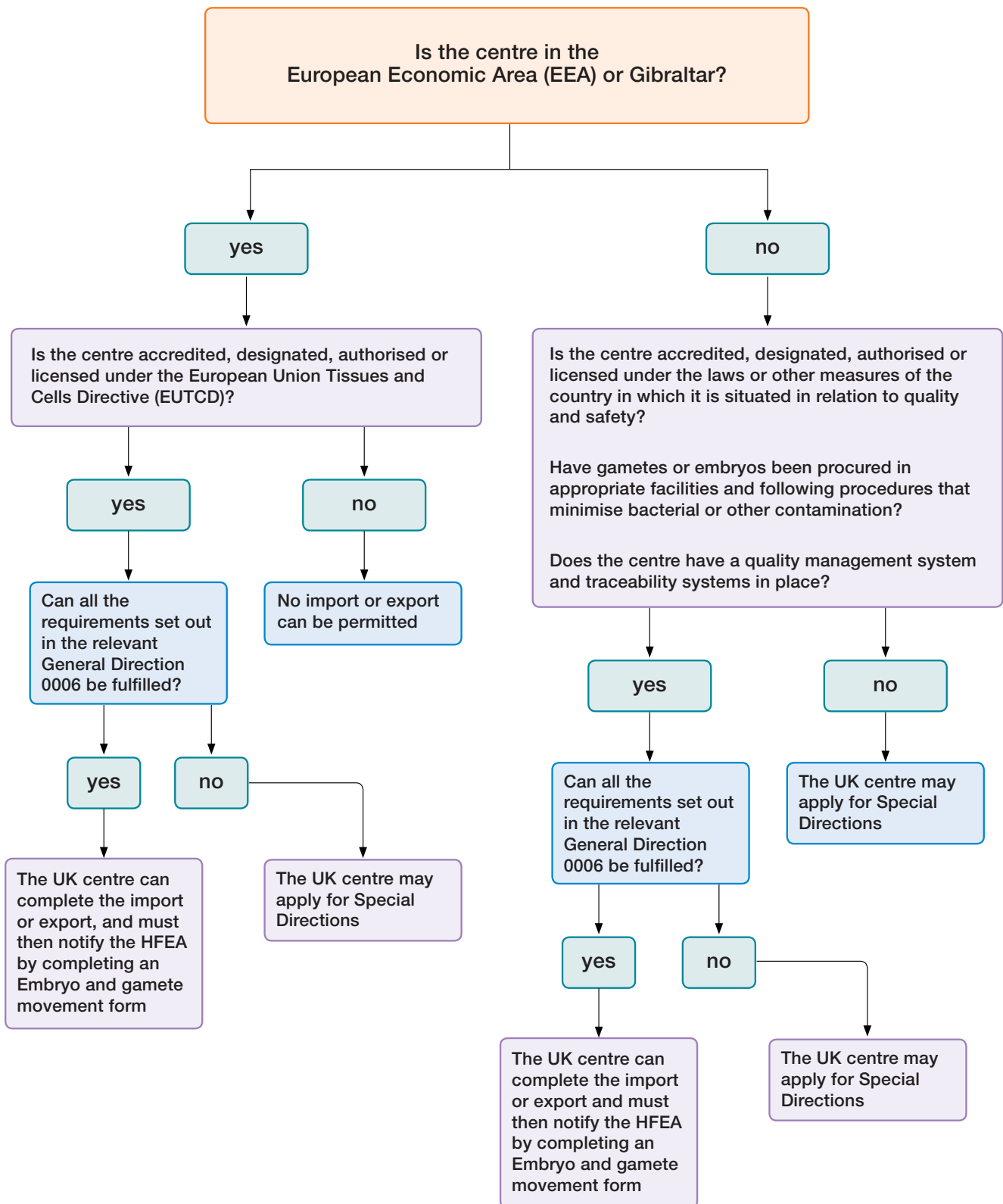
Imports and exports decision tree

16.2 The decision tree on the following page summarises what centres must consider when transferring gametes and embryos:

- within the European Economic Area (EEA) and Gibraltar, or
- outside the EEA and Gibraltar.



Imports and exports decision tree





General Directions: evidence of compliance



Interpretation of mandatory requirements

16B

a) Within the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from another EEA state or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that the receiving or sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

b) Outside the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that:

- (i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety
- (ii) the centre has appropriate quality management and traceability systems, and
- (iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

- 16.3** The systems referred to in the interpretation box above should include the traceability of all materials and equipment that could affect the quality and safety of the gametes or embryos. For transfers to or from centres within the EEA and Gibraltar, this evidence may include documented certification from the competent authority that the centre complies with the requirements of the EUTCD, is included in a national database of registered tissue establishments, or both.

See also guidance note:

- [19 - Traceability](#)
- [31 - Record keeping and document control](#)

Special Directions: imports or exports within the EEA and Gibraltar

- 16.4** An application to the HFEA for Special Directions should be made when patients wish to transfer gametes or embryos to or from an EEA centre that is accredited, designated, authorised or licensed in line with the EUTCD, but compliance with the other conditions in the relevant General Directions cannot be assured.
- 16.5** The HFEA has no power to issue Special Directions to allow imports to or exports from unaccredited tissue establishments within the EEA. Centres should tell patients that imports or exports of gametes or embryos are permitted only if the EEA centre has been accredited and licensed as complying with the requirements of the EUTCD.

Special Directions: imports or exports outside the EEA and Gibraltar

- 16.6** If compliance with all conditions in the relevant General Directions cannot be assured, then an application to the HFEA for Special Directions should be made.



See also:

- [Special Direction – Export of Embryos form](#)
- [Special Direction – Export of Gametes form](#)
- [Special Direction – Import of Embryos form](#)
- [Special Direction – Import of Gametes form](#)

You can find these forms at: www.hfea.gov.uk

Notifying the HFEA about transfers



Interpretation of mandatory requirements

16C

When transferring gametes or embryos to or from the UK under General Directions, the centre must complete the relevant transfer notification form. In this form, the person responsible must declare that they are satisfied that the centre to or from which the transfer is being made meets the requirements listed in the Directions. Completed forms must be returned to the HFEA no later than five working days after the transfer has taken place.

When transferring gametes or embryos under Special Directions, the person responsible must notify the HFEA within two working days.

See also:

- [Embryo and gamete movement – Out \(GO\) form](#)
- [Embryo and gamete movement – In \(GI\) form](#)
- Found on the Electronic Data Interchange (EDI) system



Other legislation, professional guidelines and information

For information on EEA countries and the relevant competent authorities there, you may find the following links useful:

- EEA countries – http://ec.europa.eu/external_relations/eea/
- list of EEA countries and competent authorities – http://ec.europa.eu/health/ph_threats/human_substance/documents/tissues_responses_en.pdf
- list of competent bodies for EUTCD – <http://www.iss.it/ecet/scie/cont.php?id=85&lang=2&tipo=23>

