HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Guide to
# Non-Routine Import/Export of Tissues and Cells for Human Application Involving Countries Outside the European Economic Area

## 1 SCOPE

This guide is issued by the Health Products Regulatory Authority (HPRA) to provide guidance on the non-routine import or export of tissues and cells for human application to or from countries outside the European Economic Area (EEA) by an authorised tissue establishment in Ireland. Routine import or export of tissues and cells is covered in a separate guideline, 'Guide to routine import/export of tissues and cells', available on the 'Publications and Forms' section of www.hpra.ie.

## 2 DEFINITIONS

### 2.1 Import of tissues or cells for human application

Import of tissues or cells for human application is defined as receipt of tissues/cells from countries outside the EEA (i.e. third countries). This is a prescribed activity which tissue establishments must be authorised to perform.

Please note that the import of tissues and cells for human application from third countries (routine or non-routine) can **only** be performed by tissue establishments authorised for the purposes of this activity by the HPRA.

### 2.2 Import of tissues or cells for human application 'on a non-routine basis'

Authorised tissue establishments in Ireland can be additionally authorised by the HPRA for the import of tissues/cells from organisations outside the EEA 'on a non-routine basis'. This specific activity can be listed on the tissue establishment authorisation granted by the HPRA.

This means that these tissue establishments may import tissues/cells from an organisation outside the EEA on a once-off basis (e.g. at the patient's request).

The tissue establishment authorisations of those tissue establishments authorised for the activity of import on a non-routine basis have two specific special conditions with which they must comply:

(i) The Responsible Person (or delegated individual) of the tissue establishment must notify the HPRA in writing, prior to the non-routine importation of tissues or cells from countries outside the EEA, specifying:
- the type of tissues or cells to be imported
- the name and address of the tissue establishment or organisation from which the tissues or cells are to be imported

- the tissues or cells code or reference number

(ii) The Responsible Person (or delegated individual) of the tissue establishment must provide evidence to the HPRA to confirm that tissues or cells which are to be imported into the European Community are tested in conformity with the requirements of S.I. 158 of 2006, including any additional tests which may be necessary for specific tissues or cells, types of donors or epidemiological situations.

In order to comply with these conditions, tissue establishments intending to import tissues or cells from third countries must complete the 'Notification of non-routine import/export of tissues or cells for human application' form.

The import arrangements will not have been previously assessed by the HPRA on inspection and will therefore be followed up at the next routine inspection of the tissue establishment.

## 2.3 Export of tissue or cells for human application

Export of tissues or cells for human application is defined as sending tissues or cells to countries outside the EEA (i.e. third countries). This is a prescribed activity which tissue establishments must be authorised to perform.

Please note that the export of tissues and cells for human application to third countries (routine or non-routine) can **only** be performed by tissue establishments authorised for the purposes of this activity by the HPRA.

## 2.4 Export of tissue or cells for human application 'on a non-routine basis'

Tissue establishments in Ireland can be authorised by the HPRA for the export of tissues or cells to organisations outside the EEA 'on a non-routine basis'. This specific activity is listed on the tissue establishment authorisation granted by the HPRA to those tissue establishments.

This means that these tissue establishments may export tissues or cells to an organisation outside the EEA on a once-off basis (e.g. at the patient's request).

The tissue establishment authorisations of those tissue establishments authorised for the activity of export on a non-routine basis have a specific special condition with which they must comply:

The Responsible Person (or delegated individual) of the tissue establishment must notify the HPRA in writing, prior to the non-routine export of tissues or cells to countries outside the EEA, specifying:
- the type of tissues or cells to be exported
- the name and address of the tissue establishment or organisation to which the tissues or cells are to be exported
- the tissues or cells code or reference number

In order to comply with this condition, tissue establishments intending to export tissues or cells from third countries must complete the 'Notification of non-routine import/export of tissues or cells for human application' form.

The arrangements of such exports will not have been previously assessed by the HPRA on inspection, and will therefore be followed up at the next routine inspection of the tissue establishment.

### 2.5 Who should complete the notification form

The 'Notification of non-routine import/export of tissues or cells for human application' form **must** be completed prior to non-routine imports or exports by tissue establishments authorised for this activity. The form must be signed by the individual completing the form and by the tissue establishment's Responsible Person.

## 3 NOTES ON THE COMPLETION OF THE NOTIFICATION FORM

Following are some brief guidance notes on the completion of the 'Notification of non-routine import/export of tissues or cells for human application' form.

### Section 3.1 Total number of units of tissues or cells to be imported or exported

In this instance, the 'number of units' means the number of primary containers used to package the tissues or cells, for example:

| Tissues or cells | One unit equals: |
|---|---|
| Assisted reproduction technology | One vial/straw of partner sperm or one straw containing embryos (e.g. 4 vials/straws of partner sperm and 3 straws containing embryos would be a total of 7 units of tissues/cells to be imported) |
| Skeletal tissues | One individually packaged graft (e.g. one femoral head, one unit of demineralised bone, one container of bone chips, one femoral strut, one osteochondral allograft, one individually packaged tendon or part of tendon) |
| Haematopoietic stem cells | One single bag or container of cells |
| Ocular tissues | One individually packaged or contained graft (e.g. one valve, one package containing one or more lengths of vessel) |
| Skin | One container of skin, regardless of the area of skin it contains |
| Amniotic membrane | One container of tissue, regardless of the area of tissue it contains |

### Section 3.2 Type of tissues or cells to be imported or exported

Please provide a description of each unit of tissues or cells to be imported, e.g. 'straw containing 2 embryos' or 'unit of stem cells'. Please also provide the assigned code or reference number used for traceability purposes.

## 4 FURTHER INFORMATION

Please e-mail any queries to compliance@hpra.ie.

HPRA
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