Subsidiary Legislation made under s.29.

SAFETY OF IMPORTED HUMAN TISSUES AND CELLS REGULATIONS 2017

(LN. 2017/082)

Commencement **29.4.2017**

ARRANGEMENT OF REGULATIONS.

Regulation

Subsidiary 2017/082

SAFETY OF IMPORTED HUMAN TISSUES AND CELLS REGULATIONS 2017

This version is out of date

Minimum requirements concerning the documentation to be made available to the competent authority by tissue establishments intending to import tissues and cells from third countries.

Schedule 4

Minimum requirements concerning the contents of written agreements between importing tissue establishments and their third country suppliers.

SAFETY OF IMPORTED HUMAN TISSUES AND CELLS REGULATIONS 2017

In exercise of the power conferred upon him by section 29 of the Public Health (Human Tissues, Cells and Organs) Act 2009, as read with section 23(g)(i) of the Interpretation and General Clauses Act, and for the purposes of transposing into the law of Gibraltar Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells, the Minister has made the following Regulations–

Title and commencement.

1. These Regulations may be cited as the Safety of Imported Human Tissues and Cells Regulations 2017 and come into operation on 29 April 2017.

Scope.

2.(1) These Regulations shall apply to the import of-

(a) human tissues and cells intended for human application; and

(b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other European Union legislation.

(2) Where the human tissues and cells to be imported are intended for human applications where those products are not covered by other European Union legislation, these Regulations shall only apply to the donation, procurement and testing, which takes place outside of the European Union as well as to contributing to ensuring traceability from donor to recipient and vice versa.

(3) These Regulations shall not apply to-

(a) the import of tissues and cells referred to in Article 9(3)(a) of the principal Directive, which are directly authorised by the competent authority;

(b) the import of tissues and cells referred to in Article 9(3)(b) of the principal Directive, which are directly authorised in case of emergencies;

(c) blood and blood components as defined by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the

collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;

(d) organs or parts of organs, as defined in the principal Directive.

Interpretation.

3. In these Regulations-

"competent authority" means the competent authority designated under section 1B of the Public Health (Human Tissues, Cells and Organs) Act 2009;

"Directive 2006/86/EC" means Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells;

"emergency" means any unforeseen situation in which there is no practical alternative other than to urgently import tissues and cells from a third country into the European Union for immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import;

"importing tissue establishment" means a tissue bank or a unit of a hospital or another body established within the European Union which is a party to a contractual agreement with a third country supplier for the import into the European Union of tissues and cells coming from a third country intended for human application;

"one-off import" means the import of any specific type of tissue or cell which is for the personal use of an intended recipient or recipients known to the importing tissue establishment and the third country supplier before the importation occurs. Such an import of any specific type of tissue or cell shall normally not occur more than once for any given recipient. Imports from the same third country supplier taking place on a regular or repeated basis shall not be considered to be 'one-off imports';

"principal Directive" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement,

testing, processing, preservation, storage and distribution of human tissues and cells;

"third country supplier" means a tissue establishment or another body, established in a third country, which is responsible for the export to the European Union of tissues and cells it supplies to an importing tissue establishment. A third country supplier may also carry out one or more of the activities, which take place outside of the European Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the European Union.

Accreditation, designation, authorisation or licensing of importing tissue establishments.

4.(1) Without prejudice to regulation 2(3), the importing of tissues and cells from third countries shall only be undertaken by importing tissue establishments that are accredited, designated, authorised or licensed by the competent authority for the purposes of these activities.

(2) Importing tissue establishments undertaking the activities in subregulation (1) shall provide the information in Schedule 1 to the competent authority.

(3) The competent authority, having obtained the information set out in Schedule 1 and, having verified that the importing tissue establishment complies with the requirements of these Regulations, shall accredit, designate, authorise or license the importing tissue establishment to import tissues and cells, and indicate any conditions which apply such as any restrictions of the types of tissues and cells to be imported or the third country suppliers to be used.

(4) The competent authority shall issue the accredited, designated, authorised or licensed importing tissue establishment with the certificate set out in Schedule 2.

(5) Subject to subregulations (6) and (7), an importing tissue establishment shall not undertake any substantial changes to its import activities without the prior written approval of the competent authority.

(6) For the purposes of subregulation (5), the following shall be considered a substantial change-

(a) any changes to the type of tissues and cells imported;

(b) any changes to the activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells; or

(c) any changes to the third country suppliers that are used.

(7) Where an importing tissue establishment undertakes a one-off import of tissues or cells originating from a third country supplier not covered by its existing accreditation, designation, authorisation or licence, such an import shall not be considered as a substantial change if the importing tissue establishment is authorised to import the same type of tissues or cells from another third country supplier.

(8) The competent authority may suspend or revoke the accreditation, designation, authorisation, or licence, in part or in full, of an importing tissue establishment if, in particular, inspections or other control measures demonstrate that such an establishment no longer meets the requirements of these Regulations.

Inspections and other control measures.

5.(1) The competent authority shall, at least every 2 years, organise inspections and other control measures of-

(a) importing tissue establishments; and

(b) where appropriate, the third country supplies of the importing tissue establishments under paragraph (a).

(2) Importing tissue establishments shall carry out appropriate controls in order to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in the principal Directive.

(3) Inspections under subregulation (1) shall be carried out by officials representing the competent authority, who shall-

(a) be empowered to inspect importing tissue establishments and, where appropriate, the activities of any third country suppliers;

(b) evaluate and verify the procedures and activities carried out in importing tissue establishments and the facilities of third country suppliers that are relevant to ensuring the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in the principal Directive;

(c) examine any documents or other records that are relevant for this evaluation and verification.

(4) Upon a duly justified request from a Member State or the European Commission, the competent authority shall provide information on the results of inspections and other control measures relating to importing tissue establishments and third country suppliers.

(5) Subject to subregulation (6) and upon the importation of tissues and cells, if there is a duly justified request from a Member State into which imported tissues and cells are subsequently distributed, the competent authority shall consider whether to carry out inspections or other control measures on importing tissue establishments and the activities of any third country suppliers.

(6) The competent authority shall consult with the Member Stated which has made the request referred to in subregulation (5), and decide on the appropriate measures to take following the consultation.

(7) Where an on-site inspection takes place following a request under subregulation (5), the competent authority shall agree with the competent authority of the Member State making the request on whether and how the Member State making the request shall participate in the inspection.

(8) The final decision on the participation of a Member State under subregulation (7) is to be taken by the competent authority, and if the decision is to refuse participation this shall be explained to the Member State.

Applications for accreditation, designation, authorisation or licensing as an importing tissue establishment.

6. Importing tissue establishments, having taken measures under regulation 5(2) and ensuring that imported tissues and cells can be traced from the donor to the recipient and vice versa, shall apply for an accreditation, designation, authorisation or licence as an importing tissue establishment by-

(a) providing to the competent authority the required information and documentation as set out in Schedule 1;

(b) making available and, when requested by the competent authority, providing the documentation listed in Schedule 3.

Updated information.

7.(1) If an importing tissue establishment has planned any substantial changes to their import activities, in particular those substantial changes described in regulation 4(6), the importing tissue establishment shall seek the prior written approval of the competent authority.

(2) If an importing tissue establishment makes a decision to cease their import activities in part or in full, it shall inform the competent authority of the decision.

(3) Importing tissue establishments shall notify, without delay, the competent authority of any suspected or actual serious adverse events or reactions, reported to them by third country suppliers and which may influence the quality and safety of the tissues and cells they import.

(4) Pursuant to subregulation (3), the information laid out in Annexes III and IV to Directive 2006/86/EC shall be included in such notifications.

(5) The importing tissue establishment shall notify, without delay, the competent authority of-

(a) any revocation or suspension, in part or full, of a third country supplier's authorisation to export tissues and cells; and

(b) any other decision taken for reasons of non-compliance by the competent authority of the country in which the third country supplier is based and which may be relevant to the quality and safety of imported tissues and cells.

Written agreement.

8.(1) Importing tissue establishments shall have in place written agreements with third country suppliers where any of the of the following activities relating to tissues and cells to be imported are carried out outside of the European Union-

(a) donation;

(b) procurement;

(c) testing;

(d) processing;

(e) preservation;

(f) storage; or

(g) export to the European Union.

(2) Without prejudice to subregulation (3), the written agreement between the importing tissue establishment and the third country supplier shall specify the quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in the principal Directive.

(3) The written agreement shall include, as a minimum, the contents listed in Schedule 4.

(4) The written agreement shall establish the right of the competent authority to inspect the activities, including the facilities, of any third country suppliers during the duration of the written agreement and for a period of 2 years following its termination.

(5) Importing tissue establishments shall provide copies of written agreements with third country suppliers to the competent authority as part of their application for accreditation, designation, authorisation or licensing.

Register of importing tissue establishments.

9.(1) Importing tissue establishments shall keep a record of their activities, including the types and quantities of tissues and cells imported, and on their origin and destination.

(2) The record referred to in subregulation (1), shall also include the same information for any one-off imports carried out.

(3) The annual report referred to in Article 10(1) of the principal Directive shall include information about those activities.

(4) The competent authority shall include importing tissue establishments in the publicly accessible register of tissue establishments laid down in Article 10(2) of the principal Directive.

(5) Information on the accreditations, designations, authorisations or licences of importing tissue establishments shall also be made available through the network of registers referred to in Article 10(3) of the principal Directive.

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Public Health (Human Tissues, Cells and Organs)

Subsidiary 2017/082

SAFETY OF IMPORTED HUMAN TISSUES AND CELLS REGULATIONS 2017

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Schedule 1

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

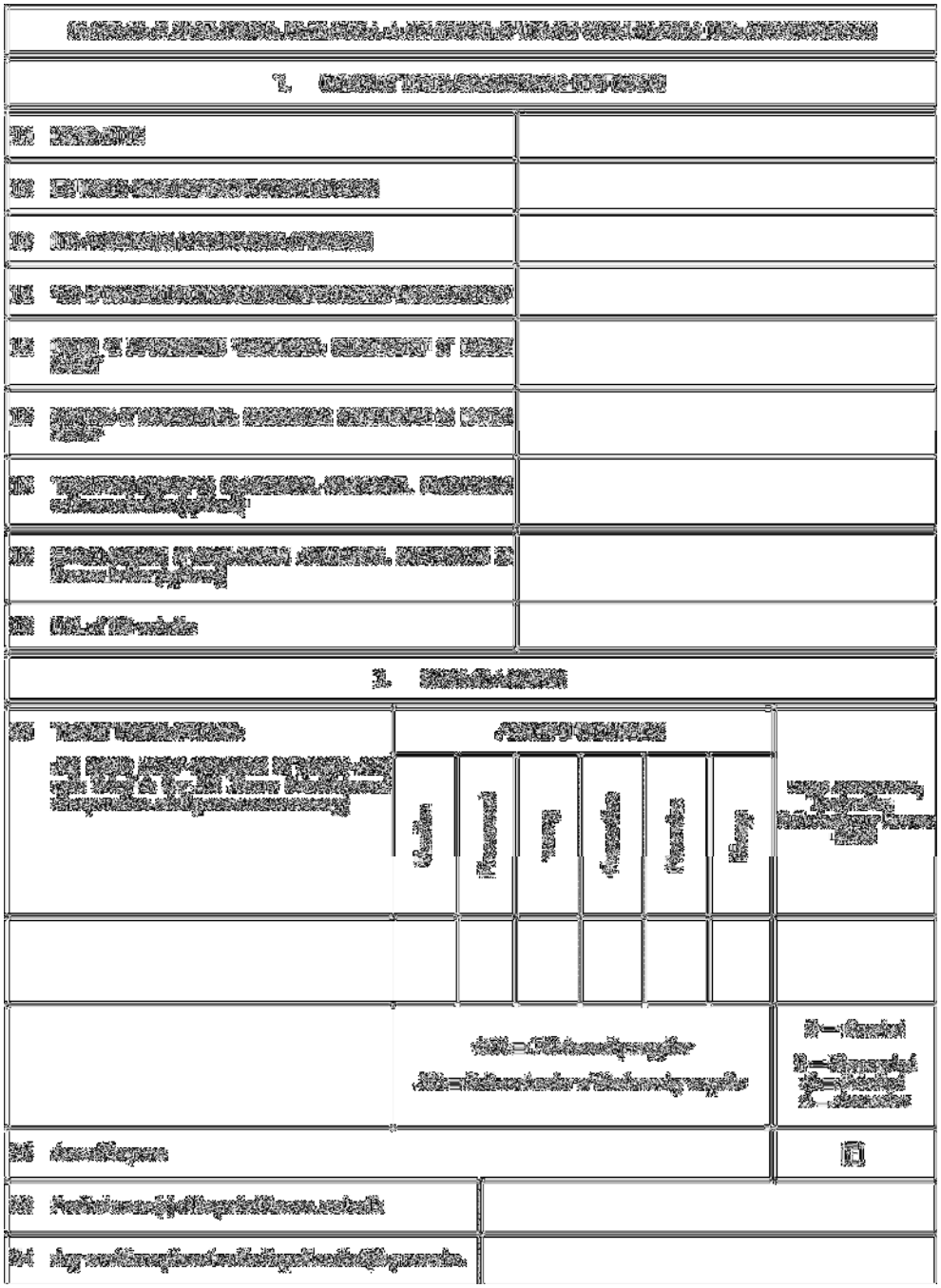
1. A copy of the written agreement with the third country supplier(s).

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 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. 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.

Schedule 2

Certificate of Accreditation, Designation, Authorisation or Licence to be issued by the competent authority to importing tissue establishments



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Schedule 3

Minimum requirements concerning the documentation to be made available to the competent authority by tissue establishments intending to import tissues and cells from third countries

With the exception of one-off imports which have been exempted from these documentation requirements, the applicant importing tissue establishment shall make available and, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as an importing tissue establishment or tissue establishment, shall provide when requested by the competent authority the most up-to-date version of the following documents regarding the applicant and its third country supplier(s).

A. Documentation relating to the importing tissue establishment

1. A job description of the Responsible Person and details of his/her relevant qualifications and training record as laid down in the principal Directive;

2. A copy of the primary label, repackage label, external package and transport container;

3. A list of relevant and up-to-date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code, reception and storage of imported tissues and cells at the importing tissue establishment, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

B. Documentation relating to the third country supplier or suppliers

1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not;

2. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres;

3. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure;

4. 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 third country supplier;

5. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers;

6. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken;

7. A summary of the most recent inspection of the third country supplier by the third country competent authority including the date of the inspection, type of inspection and main conclusions;

8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment;

9. Any relevant national or international accreditation.

Schedule 4

Minimum requirements concerning the contents of written agreements between importing tissue establishments and their third country suppliers

With the exception of one-off imports which have been exempted from these requirements, the written agreement between the importing tissue establishment and the third country supplier shall contain at least the following provisions.

1. Detailed information on the specifications of the importing tissue establishment aimed at ensuring that the quality and safety standards laid down in the principal Directive are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported tissues and cells are of equivalent standards of quality and safety;

2. A clause ensuring that the third country supplier provides the information set out in Schedule 3 part B to the importing tissue establishment;

3. A clause ensuring that the third country supplier informs the importing tissue establishment of any suspected or actual serious adverse events or reactions which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;

4. A clause ensuring that the third country supplier informs the importing tissue establishment of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export tissue and cells or other such decisions of non-compliance by the third country competent authority, which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;

5. A clause guaranteeing the competent authority the right to inspect the activities of the third country supplier, including on-site inspections, should it wish to do so as part of its inspection of the importing tissue establishment. The clause should also guarantee the importing tissue establishment the right to regularly audit its third country supplier;

6. The agreed conditions to be met for the transport of tissues and cells between the third country supplier and importing tissue establishment;

7. A clause ensuring that donor records relating to imported tissues and cells are kept by the third country supplier or its sub-contractor, in line with EU data protection rules, for 30 years following procurement and that suitable

provision is made for their retention should the third country supplier cease to operate;

8. Provisions for the regular review and, where necessary, revision of the written agreement including in order to reflect any changes in the requirements of the EU quality and safety standards laid out in the principal Directive;

9. A list of all standard operating procedures of the third country supplier relating to the quality and safety of imported tissues and cells and a commitment to provide these on request.