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 (Text with EEA relevance)

CHAPTER II

OBLIGATIONS ON MEMBER STATES' AUTHORITIES

Article 3

Accreditation, designation, authorisation or licensing of importing tissue establishments

1 Without prejudice to Article 1(3), Member States shall ensure that all imports of tissues and cells from third countries are undertaken by importing tissue establishments accredited, designated, authorised or licensed by a competent authority or authorities for the purposes of these activities.

2 The competent authority or authorities, having obtained the information set out in Annex I to this Directive and, having verified that the importing tissue establishment complies with the requirements of this Directive, 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. The competent authority or authorities shall issue the accredited, designated, authorised or licensed importing tissue establishment with the certificate set out in Annex II to this Directive.

3 The importing tissue establishment shall not undertake any substantial changes to its import activities without the prior written approval of the competent authority or authorities. In particular, any changes to the type of tissues and cells imported, the activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells or the third country suppliers used shall be considered as substantial changes. 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 or suppliers.

4 The competent authority or authorities 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 this Directive.

Article 4

Inspections and other control measures

1 Member States shall ensure that the competent authority or authorities organise inspections and other control measures of importing tissue establishments and, where appropriate, their third country suppliers and that importing tissue establishments 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 Directive 2004/23/EC. The interval between inspections of any given importing tissue establishment shall not exceed 2 years.

2 Such inspections shall be carried out by officials representing the competent authority or authorities 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 Directive 2004/23/EC;

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

3 Member States shall, upon a duly justified request from another Member State or the Commission, provide information on the results of inspections and other control measures relating to importing tissue establishments and third country suppliers.

4 Member States into which tissues and cells are imported shall, upon a duly justified request from another Member State into which imported tissues and cells are subsequently distributed, consider carrying out inspections or other control measures on importing tissue establishments and the activities of any third country suppliers. The Member State in which the importing tissue establishment is located shall decide on the appropriate measures to take following consultation with the Member State which made such a request.

5 Where an on-site inspection takes place following such a request, the competent authority or authorities of the Member State in which the importing tissue establishment is located shall agree with the competent authority or authorities of the Member State which made such a request on whether and how the Member State which made such a request shall participate in the inspection. The final decision on any such participation shall rest with the Member State in which the importing tissue establishment is located. The reasons for any decision to refuse such participation shall be explained to the Member State which made such a request.