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 I

GENERAL PROVISIONS

Article 1

Scope

1 This Directive shall apply to the import into the Union 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 Union legislation.

2 Where the human tissues and cells to be imported are intended to be used exclusively in manufactured products which are covered by other Union legislation, this Directive shall only apply to the donation, procurement and testing which takes place outside of the Union as well as to contributing to ensuring traceability from donor to recipient and vice versa.

3 This Directive shall not apply to:

a the import of tissues and cells referred to in Article 9(3)(a) of Directive 2004/23/EC which are directly authorised by the competent authority or authorities;

b the import of tissues and cells referred to in Article 9(3)(b) of Directive 2004/23/EC which are directly authorised in case of emergencies;

c blood and blood components as defined by Directive 2002/98/EC;

d organs or parts of organs, as defined in Directive 2004/23/EC.

Article 2

Definitions

For the purposes of this Directive, the following definitions apply:

(a) ‘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 Union for immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import;

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

(c) ‘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';

(d) 'third country supplier' means a tissue establishment or another body, established in a third country, which is responsible for the export to the 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 Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the Union.