ANNEX VI

SPECIAL RULES ON RESEARCH, FEEDING AND COLLECTION AND DISPOSAL

CHAPTER I

SPECIAL RULES ON SAMPLES FOR RESEARCH AND OTHER PURPOSES

Section 1

Research and diagnostic samples

1. Operators shall ensure that consignments of research and diagnostic samples are accompanied by a commercial document, which must specify:

(a) the description of the material and the animal species of origin;

(b) the category of the material;

(c) the quantity of the material;

(d) the place of origin and the place of dispatch of the material;

(e) the name and the address of the consignor;

(f) the name and the address of the consignee and/or user.

2. Users that handle research and diagnostic samples shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.

3. Any subsequent use of research and diagnostic samples for purposes other than those referred to in point 38 of Annex I shall be prohibited.

4. Unless they are kept for reference purposes, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:

(a) as waste by incineration or co-incineration;

(b) in case of the animal by-products or derived products referred to in Article 8 (a)(iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No 1069/2009 which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves[(1)] and subsequent disposal as waste or wastewater in accordance with relevant Union legislation;

(c) by pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.

5. Users that handle research and diagnostic samples shall keep a register of consignments of such samples.

The register shall include the information referred to in point 1 and the date and method of disposal of the samples and of any derived products.

6. By way of derogation from points 1, 4 and 5, the competent authority may accept the handling and disposal of research and diagnostic samples for educational purposes under other conditions which ensure that no unacceptable risks for public or animal health arise.

(**1**) CEN TC/102 – Sterilisers for medical purposes – EN 285:2006 + A2:2009 – Sterilization - Steam Sterilisers - Large Sterilisers, reference published in OJ C 293, 2.12.2009, p. 39.

Status:
Point in time view as at 08/03/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, Division Section 1.