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European Union - Chapter 4(D) Blood Products

Last Modified:

Chapter 4(D) Health Certificate for Treated Blood Products (from Animals other than Equidae) For Technical Purposes

Advisory regarding commercial documents e.g. company certificates of origin or analysis: The EU has indicated that consignments of blood products will be rejected if accompanied by commercial documents containing more specific information than the below certificates. APHIS strongly recommends that exporters not include commercial documents (or other paper work) with the consignments that make any claims regarding the origin of the blood products or about other information addressed in these certificates. The pre-lined out versions below contain the most specific assurances APHIS can provide for these consignments.

This certificate is only available from APHIS for blood products from Artiodactyla, Perrissodactyla, Proboscidea, Suidae, Tayassuidae, and avian animals.

Please select the appropriate certificate below based upon the species of origin and treatment method.

Options I though V below are for materials exported in new or sterilized bags or bottles:

- Blood Products Derived from Bovine, Ovine, and/or Caprine Animals (or Mixtures of Products containing both bovine/ovine/caprine materials and also materials from other ruminants)
 - A. Other than fetal bovine serum (FBS) and derivatives: The following certificate is for products derived from bovine, ovine, and/or caprine animals- except for fetal bovine serum (FBS):

```
Heat treatment (65C for 3 hours)

Dispatch to EU - May 2019

Irradiation

Dispatch to EU - May 2019

pH treatment

Dispatch to EU - May 2019

Heat treatment (80C)

Dispatch to EU - May 2019
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B. Fetal bovine serum (FBS) and derivatives: The following version may be used only for consignments containing only fetal bovine serum and/or the derivatives of fetal bovine serum. No other animal origin materials may be included in the production of the certified materials.

```
Heat treatment (65C for 3 hours)

Dispatch to EU - May 2019

Irradiation

Dispatch to EU - May 2019

pH treatment

Dispatch to EU - May 2019

Heat treatment (80C)

Dispatch to EU - May 2019
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II. Blood Products Derived from Ruminants other than Bovine, Ovine, and/or Caprine Animals

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Heat treatment (65C for 3 hours)

Dispatch to EU - May 2019

Irradiation

Dispatch to EU - May 2019

pH treatment

Dispatch to EU - May 2019

Heat treatment (80C)
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Dispatch to EU - May 2019

III. Blood Products Derived from Artiodactyla, Perrissodactyla, and/or Proboscidea Animals Other than Ruminants

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Heat treatment (65C for 3 hours)

Dispatch to EU - May 2019

Irradiation

Dispatch to EU - May 2019

pH treatment

Dispatch to EU - December 2022

Heat treatment (80C)

Dispatch to EU - May 2019
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IV. Blood Products Derived from Suidae/Tayassuidae Animals (includes Pigs)

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Heat treatment (65C for 3 hours)

<u>Dispatch to EU</u> - May 2019

Irradiation
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Dispatch to EU - September 2021

Heat treatment (80C)

Dispatch to EU - May 2019

V. Blood products from Avian Animals

Heat treatment (65C for 3 hours)

Dispatch to EU - May 2019

Irradiation

Dispatch to EU - May 2019

Heat treatment (70C)

Dispatch to EU - May 2019

VI. Other

The below versions should be utilized when:

- 1. Blood products are shipped in bulk containers rather than new or sterilized bags or bottles: and/or
- 2. Blood products derived from two or more of the following groups of animals are certified on the same 4D certificate:
 - o Artiodactyla, Perrissodactyla, Proboscidea Animals (includes Ruminants);
 - Suidae/Tayassuidae Animals (includes Pigs)
 - Avian Animals
- 3. Blood products treated in different ways (e.g. some products are processed using
 - heat treatment, an others with irradiation) are certified on the same 4D certificate
- 4. Consignments only transiting or being stored in the EU
- 5. Blood products shipped in bulk containers (when the inner most packaging of the blood products is not new or sterilized bags or bottles): In the case of blood products that are shipped in bulk containers, the certificate should be lined out as noted in the versions above, except Section II.8 should be lined out as follows:

II.8. the products were:

(2) either [packed in new or sterilised bags or bottles,]

⁽²⁾or [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,] and

the outer packaging or containers bear labels indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION';

To utilize these versions, the inappropriate text must be lined out prior to endorsement. The text must be lined-out consistent with the pertinent versions above.

<u>Dispatch to EU</u> - May 2019 Transit EU - May 2019

Print