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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	ANNEXES to the COMMISSION DELEGATED REGULATION (EU) .../... supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs

Delegations will find attached document C(2019) 4058 final ANNEXES 1 to 8.

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ANNEXES 1 to 8

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs

ANNEX I

DIAGNOSTIC METHODS

Part 1

Infection with *Brucella abortus, B. melitensis* and *B. suis*

1. Serological tests for bovine, ovine, caprine and camelid animals:
   (a) buffered *Brucella* antigen tests;
   (b) complement fixation test (CFT);
   (c) indirect enzyme-linked immunosorbent assay (I-ELISA);
   (d) fluorescence polarisation assay (FPA);
   (e) competitive enzyme-linked immunosorbent assay (C-ELISA).
2. Serological tests for porcine animals:
   (a) buffered *Brucella* antigen tests;
   (b) complement fixation test (CFT);
   (c) indirect enzyme-linked immunosorbent assay (I-ELISA);
   (d) fluorescence polarisation assay (FPA);
   (e) competitive enzyme-linked immunosorbent assay (C-ELISA).
3. Brucellin skin test (BST) for ovine, caprine and porcine animals

Part 2

Infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*)

1. Tuberculin skin tests:
   (a) the single intradermal tuberculin test (SITT);
   (b) the comparative intradermal tuberculin test (CITT).
2. Test available for blood samples:
   (a) gamma-interferon assay.

Part 3

Surra (*Trypanosoma evansi*)

Serological tests:

(a) enzyme-linked immunosorbent assay (ELISA) for trypanosomiasis;

(b) card agglutination test for trypanosomiasis (CATT) at a serum dilution of 1:4.

Part 4

Enzootic bovine leukosis

Serological tests:

(a) tests for blood samples:
   (i) agar gel immuno-diffusion test (AGID);
   (ii) blocking enzyme-linked immunosorbent assay (B-ELISA);

(iii) indirect enzyme-linked immunosorbent assay (I-ELISA).

(b) test for milk samples:

(i) indirect enzyme-linked immunosorbent assay (I-ELISA).

Part 5

Infectious bovine rhinotracheitis / infectious pustular vulvovaginitis

	Methods:
Non-vaccinated bovine animals	BoHV-1 I-ELISA[a]
	gB B-ELISA[b]
Bovine animals vaccinated with a gE-deleted vaccine	gE B-ELISA[c]

[a] enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies against BoHV-1 whole virus.

[b] ELISA for the detection of antibodies against BoHV-1-gB protein. When referred to tests for the detection of antibodies against whole BoHV-1, this method may also be used.

[c] ELISA for the detection of antibodies against BoHV-1-gE protein.

Part 6

Bovine viral diarrhoea

1. Direct methods:

(a) real-time reverse transcription-polymerase chain reaction (real-time RT-PCR);

(b) bovine viral diarrhoea virus (BVDV) antigen detection enzyme-linked immunosorbent assay (ELISA).

2. Serological tests:

(a) indirect enzyme-linked immunosorbent assay (I-ELISA);

(b) blocking enzyme-linked immunosorbent assay (B-ELISA).

Part 7

Infection with Aujeszky's disease virus

	Methods:
Porcine animals	Aujeszky's disease virus (ADV) ELISA[a]
Porcine animals less than 4 months old born to dams vaccinated with a gE-deleted vaccine	gE ELISA[b]

[a] ELISA for the detection of antibodies against whole ADV, ADV-gB protein or ADV-gD protein. For batch control of ADV-gB kits and ADV-gD kits or whole ADV kits, Community reference serum ADV 1, or sub-standards, must be scored positive at a dilution of 1:2.

[b] ELISA for the detection of antibodies against ADV-gE protein. For batch control, Community reference serum ADV 1, or sub-standards, must be scored positive at a dilution of 1:8.

Part 8

Dourine

Complement fixation test for dourine, at a serum dilution of 1:5.

Part 9

Equine infectious anaemia

Serological tests:

(a) agar gel immuno-diffusion test (AGID);

(b) enzyme-linked immunosorbent assay (ELISA) for equine infectious anaemia.

Part 10

Venezuelan equine encephalomyelitis

1. Serological tests:

   (a) virus isolation test for Venezuelan equine encephalomyelitis;

   (b) haemagglutination inhibition test for Venezuelan equine encephalomyelitis;

2. Direct method:

   reverse transcription-polymerase chain reaction (RT-PCR) for the detection of Venezuelan equine encephalomyelitis virus genome.

ANNEX II

MINIMUM PRE-MOVEMENT REQUIREMENTS AS REGARDS INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX (*M. BOVIS, M. CAPRAE* AND *M. TUBERCULOSIS*) IN CAPRINE, CAMELID AND CERVID ANIMALS

Part 1

Minimum requirements for a pre-movement programme as regards infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in caprine animals

1. The pre-movement surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in an establishment for the purpose of movement to another Member State of kept caprine animals as referred to in Article 15(3) must at least include the following elements:

   (a) post-mortem inspection of all slaughtered caprine animals from the establishment;

   (b) post-mortem examination of fallen stock of all caprine animals older than 9 months, unless impossible for logistical reasons or not necessary for scientific reasons;

   (c) an annual animal health visit carried out by a veterinarian;

   (d) annual testing of all caprine animals kept on the establishment for breeding purposes, with negative results.

2. By way of derogation from paragraph 1, the annual testing provided for in point 1(d) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection as negligible in the Member State or zone, and the following conditions are fulfilled:

   (a) the pre-movement surveillance programme referred to in paragraph 1 has been carried out on the establishment for at least 24 months, and infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in caprine animals kept on the establishment has not been reported during this period;

   (b) the establishment is situated in a Member State or zone thereof free from infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in its bovine animal population.

3. If infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in caprine animals kept on the establishment has been reported, such animals may be moved to another Member State only when all caprine animals older than 6 weeks kept on the establishment have been tested, with negative results. These tests must be carried out on samples collected no earlier than 42 days after the removal of the last confirmed case and of the last animal which tested positive using a diagnostic method.

Part 2

Minimum requirements for a pre-movement programme as regards infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in camelid animals

1. The pre-movement surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in an establishment for the purpose of movement to another Member State of kept camelid animals as referred to in Article 23(1)(e) must at least include the following elements:

   (a) post-mortem inspection of all slaughtered camelid animals from the establishment;

   (b) post-mortem examination of fallen stock of camelid animals older than 9 months, unless impossible for logistical reasons or not necessary for scientific reasons;

   (c) an annual animal health visit carried out by a veterinarian;

   (d) annual testing of all camelid animals kept on the establishment for breeding purposes, with negative results.

2. By way of derogation from paragraph 1, the annual testing provided for in point 1(d) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection as negligible in the Member State or zone, and the following conditions are fulfilled:

   (a) the pre-movement surveillance programme referred to in paragraph 1 has been carried out on the establishment for at least 24 months and infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in camelid animals kept on the establishment has not been reported during this period;

   (b) the establishment is situated in a Member State or zone thereof free from infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in its bovine animal population;

3. If infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in camelid animals kept on the establishment has been reported, such animals may be moved to another Member State only when all camelid animals older than 6 weeks kept on the establishment have been tested, with negative results. These tests must be carried out on blood samples collected no earlier than 42 days after the removal of the last confirmed case and of the last animal which tested positive using a diagnostic method.

Part 3

Minimum requirements for a pre-movement programme as regards infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in cervid animals

1. The pre-movement surveillance programme to detect infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in an establishment for the purpose of movement to another Member State of kept cervid animals as referred to in Article 26(1)(e) must at least include the following elements:

   (a) post-mortem inspection of all slaughtered cervid animals from the establishment;

   (b) post-mortem examination of fallen stock of cervid animals older than 9 months, unless impossible for logistical reasons or not necessary for scientific reasons;

   (c) an annual animal health visit carried out by a veterinarian;

   (d) annual testing of cervid animals kept on the establishment for breeding purposes, with negative results.

2. By way of derogation from paragraph 1, the annual testing provided for in point 1(d) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection as negligible in the Member State or zone, and the following conditions are fulfilled:

   (a) the pre-movement surveillance programme referred to in paragraph 1 has been carried out on the establishment for at least 24 months, and infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in cervid animals kept on the establishment has not been reported during this period;

   (b) the establishment is situated in a Member State or zone thereof free from infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in its bovine animal population;

3. If infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) in cervid animals kept on the establishment has been reported, such animals may be moved to another Member State only when all cervid animals older than 6 weeks kept on the establishment have been tested on two occasions, with a minimum interval of 6 months, for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*), with negative results. The first test must be performed on cervid animals or samples collected from cervid animals no earlier than 6 months after the removal of the last confirmed case and of the last animal which tested positive using a diagnostic method.

ANNEX III

MINIMUM PRE-MOVEMENT REQUIREMENTS AS REGARDS INFECTION WITH *BRUCELLA ABORTUS, B. MELITENSIS* AND *B SUIS* IN PORCINE ANIMALS

1. The pre-movement surveillance programme to detect infection with *Brucella abortus, B. melitensis* and *B suis* in an establishment for the purpose of movement to another Member State of kept porcine animals, as referred to in Article 19(1)(f)(ii), must at least include the following elements:

   (a) an annual animal health visit carried out by a veterinarian;

   (b) if porcine animals are kept on the establishment for breeding, an annual immunological survey carried out in the porcine population of that establishment, using one of the diagnostic methods listed in Part 1(2) of Annex I, with at least a capacity to demonstrate with a 95% level of confidence the absence of infection with *Brucella abortus*, *B. melitensis* and *B. suis* with a target prevalence of 10%.

2. By way of derogation from point 1, the animal health visit referred to in point 1(a) and the survey provided for in point 1(b) does not have to be required if the competent authority, based on a risk assessment, considers the risk of infection with *Brucella abortus, B. melitensis* and *B. suis* as negligible in the Member State or zone thereof, and the following conditions are fulfilled:

   (a) infection with *Brucella abortus, B. melitensis* and *B. suis* has not been reported in the kept porcine population for the last five years;

   (b) infection with *Brucella abortus, B. melitensis* and *B. suis* has not been reported in the population of wild animals of listed species for the past 5 years, and during that period of time, wild boars have been included in the targeted animal population for surveillance as provided for in Article 4 of [C(2019)4056 Commission Delegated Regulation (EU) 2019/… of … supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases];

   (c) the Member State or zone thereof is free from infection with *Brucella abortus, B. melitensis* and *B. suis* in its bovine, ovine and caprine populations.

3. If infection with *Brucella abortus*, *B. melitensis* and *B. suis* in porcine animals kept on the establishment has been reported, such animals may be moved to another Member State only when all porcine animals kept on the establishment have been subjected to a test on two occasions, with negative results. The first test must be carried out on samples collected no earlier than 3 months after the removal of the infected animals and the animals which tested positive using one of the diagnostic methods provided for in Part 1(2) of Annex I. The second test must be carried out on samples collected no earlier than 6 months and no later than 12 months after the first test.

ANNEX IV

TESTING OF DUCKS AND GEESE FOR HIGHLY PATHOGENIC AVIAN INFLUENZA

During the week prior to the time of loading for dispatch, ducks and geese must have tested negative in a virological examination for highly pathogenic avian influenza, either by virus isolation or by molecular testing at a level which gives 95 % confidence of detecting infection at 5 % prevalence.

ANNEX V

REQUIREMENTS FOR TESTING CONSIGNMENTS OF LESS THAN 20 HEADS OF POULTRY OTHER THAN RATITES OR LESS THAN 20 HATCHING EGGS OF POULTRY OTHER THAN RATITES

1. Consignments of less than 20 heads of poultry other than ratites or less than 20 hatching eggs of poultry other than ratites must have tested negative in accordance with point 2 for the following disease agents for the relevant listed species:

   (a) infection with *Salmonella* Pullorum, *S.* Gallinarum and *S. arizonae*;

   (b) avian mycoplasmosis (*Mycoplasma gallisepticum and M. meleagridis)*.

2. Testing:

   (a) for breeding poultry, productive poultry and poultry intended for slaughter, the animals must have tested negative in serological and/or bacteriological tests for the diseases under point 1 within 21 days preceding the time of loading for dispatch;

   (b) for hatching eggs and day-old chicks, the flock of origin must have tested negative in serological tests and/or bacteriological tests for the diseases under point 1 within 21 days preceding the time of loading for dispatch at a level which gives 95% confidence of detecting infection at 5% prevalence;

   (c) if the animals have been vaccinated against infection with any serotype of Salmonella or Mycoplasma, only bacteriological testing must be used. The confirmation method must be capable of differentiating between live vaccinal strains and field strains.

ANNEX VI

CRITERIA FOR VACCINES AGAINST INFECTION WITH NEWCASTLE DISEASE VIRUS

Live attenuated vaccines against infection with Newcastle disease virus must be prepared from a Newcastle disease virus strain for which the master seed has been tested and shown to have an intracerebral pathogenicity index (ICPI) of:

(a) less than 0,4 if not less than 10^7 EID_{50} (50% Embryo Infectious Dose) are administrated to each bird in the ICPI test; or

(b) less than 0,5 if not less than 10^8 EID_{50} are administered to each bird in the ICPI test.

ANNEX VII

VALIDITY OF ANTI-RABIES VACCINATION AND RISK-MITIGATING MEASURES FOR DISEASES OTHER THAN RABIES

Part 1

Validity of anti-rabies vaccinations for dogs, cats, ferrets and other carnivores

The validity requirements for vaccination against infection with rabies virus referred to in Articles 53(b)(i), 55(b)(i) and 58(1)(c) are those set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council[1].

Where no anti-rabies vaccine is authorised in a Member State for carnivores other than dogs, cats and ferrets, anti-rabies vaccination carried out in accordance with Article 10(1) of Directive 2001/82 must be deemed valid.

Part 2

Risk-mitigating measures for diseases other than rabies

1. The risk-mitigating measures for infestation with *Echinococcus multilocularis* referred to in Articles 53(b)(ii) and 55(b)(ii) are those laid down in Delegated Regulation (EU) 2018/772[2] in combination with Commission Implementing Regulation (EU) 2018/878[3].

2. By way of derogation from paragraph 1, the treatment referred to in Article 58(1)(d) of canidae other than dogs against infestation with *Echinococcus multilocularis* must be carried out and documented no earlier than 48 hours prior to entry into a Member State or zone thereof listed in the Annex to Regulation (EU) 2018/878.

3. The risk-mitigating measures for diseases other than infection with rabies virus and infestation with *Echinococcus multilocularis* referred to in Articles 53(b)(ii) and 55(b)(ii) are the preventive health measures applicable to the relevant species of carnivores adopted in accordance with Article 19(1) of Regulation (EU) No 576/2013.

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1 Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

2 Commission Delegated Regulation (EU) 2018/772 of 21 November 2017 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to preventive health measures for the control of *Echinococcus multilocularis* infection in dogs and repealing Delegated Regulation (EU) No 1152/2011 (OJ L 130, 28.5.2018, p. 1).

3 Commission Implementing Regulation (EU) 2018/878 of 18 June 2018 adopting the list of Member States, or parts of the territory of Member States, that comply with the rules for categorisation laid down in Article 2(2) and (3) of Delegated Regulation (EU) 2018/772 concerning the application of preventive health measures for the control of *Echinococcus multilocularis* infection in dogs (OJ L 155, 19.6.2018, p. 1).

ANNEX VIII

INFORMATION TO BE CONTAINED IN ANIMAL HEALTH CERTIFICATES AND NOTIFICATIONS

Part 1

Information to be contained in the animal health certificate for terrestrial animals and hatching eggs moved to another Member State

1. The animal health certificate for the kept terrestrial animals referred to in Article 143(1) of Regulation (EU) 2016/429 and in Article 71(1) of this Regulation moved to another Member State must contain at least the following information:

   (a) the name and address of the consignor and the consignee;

   (b) the name and address of the establishment of dispatch, and

      (i) where the establishment of dispatch is an approved establishment, the unique approval number of that establishment; or

      (ii) where the establishment of dispatch is a registered establishment, the unique registration number of that establishment;

   (c) the name and address of the establishment of destination, and

      (i) where the establishment of destination is an approved establishment, the unique approval number of that establishment; or

      (ii) where the establishment of destination a registered establishment, the unique registration number of that establishment;

   (d) the species and category of animals and identification, where required;

   (e) information on the animal health situation and additional guarantees in relation to:

      (i) the Member State or zone of origin;

      (ii) the establishment and flock of origin of the animals, including test results where applicable;

      (iii) the animals to be dispatched, including test results or vaccinations where applicable;

   (f) the date and place of issue and period of validity of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.

2. The animal health certificate for hatching eggs referred to in Article 161(1) of Regulation (EU) 2016/429 and in Article 72 of this Regulation moved to another Member State must contain at least the following information:

   (a) the name and address of the consignor and the consignee;

   (b) the name and address of the establishment of dispatch, and

      (i) where the establishment of dispatch is an approved establishment, the unique approval number of that establishment; or

      (ii) where the establishment of dispatch is a registered establishment, the unique registration number of that establishment;

   (c) the name and address of the establishment of destination, and,

(i) where the establishment of destination is an approved establishment, the unique approval number of that establishment; or

(ii) where the establishment of destination a registered establishment, the unique registration number of that establishment;

(d) the category of hatching eggs;

(e) information allowing identification of hatching eggs:

(i) the species and identification, where required, of the animals from which they originate;

(ii) the marking applied on the hatching eggs, where required;

(ii) the place and date of their collection;

(f) information on the animal health situation and additional guarantees in relation to:

(i) the Member State or zone thereof of origin;

(ii) the establishment and flock of origin, including test results where applicable;

(iii) the animals from which hatching eggs were collected, including test results where applicable;

(iv) the hatching eggs to be dispatched;

(g) the date and place of issue and the period of validity of the animal health certificate and the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.

3. The animal health certificate for wild terrestrial animals referred to in Article 155(1)(c) of Regulation (EU) 2016/429 moved to another Member State must contain at least the following information:

(a) the name and address of the consignor and the consignee;

(b) the place where animals were captured and loaded for dispatch;

(c) the place of destination, and

(i) where the place of destination is the habitat, the place where animals are intended to be unloaded; or

(ii) where the establishment of destination is a registered establishment, the unique registration number of that establishment;

(d) the species and category of animals;

(e) the date and place of issue and period of validity of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.

Part 2

Information in the notification of movements for certain terrestrial animals for which animal health certificate is not required

The notification for moving bumble bees from approved environmentally isolated production establishments to another Member State must contain at least the following information:

(a) the name and address of the consignor and the consignee;

(b) the name, address and unique approval number of the establishment of dispatch;

(c) the name and address of the establishment of destination, and

  (i) where the establishment of destination is an approved establishment, the unique approval number of that establishment; or

  (ii) where the establishment of destination is a registered establishment, the unique registration number of that establishment;

(d) the species, category and quantity and size of colonies;

(e) the date of dispatch.