II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 854/2013

of 4 September 2013

amending Annex I to Regulation (EU) No 206/2010 as regards animal health requirements for scrapie in the model of veterinary certificate for imports into the Union of ovine and caprine animals intended for breeding and production

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC [1], and in particular Article 13(1)(e) thereof,

Whereas:

(1) Commission Regulation (EU) No 206/2010 [2] lays down, *inter alia*, the veterinary certification requirements for the introduction into the Union of certain consignments of live animals or fresh meat. It provides that consignments of ungulates are to be introduced into the Union only, if they comply with certain requirements and they are accompanied by the appropriate veterinary certificate, drawn up in accordance with the relevant model set out in Part 2 of Annex I to that Regulation.

(2) The model certificate for imports into the Union of ovine and caprine animals for breeding is set out in Annex I to Regulation (EU) No 206/2010 as model "OVI-X". That model includes the guarantees for scrapie.

(3) Regulation (EC) No 999/2001 of the European Parliament and of the Council [3] lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine, and caprine animals. Chapter A of Annex VIII to that Regulation lays down the conditions for intra-Union trade in live animals, semen and embryos. In addition, Annex IX to that Regulation lays down the conditions for the importation of live animals, embryos, ova and products of animal origin into the Union.

(4) In the light of new scientific evidence, Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) No 630/2013 [4]. The amendments to Regulation (EC) No 999/2001 lift most of the restrictions with regards to atypical scrapie. They also further align to the World Organisation for Animal Health (OIE) standards the rules as regards classical scrapie relating to imports of live ovine and caprine animals to reflect a stricter approach.

(5) The model certificate "OVI-X" set out in Annex I to Regulation (EU) No 206/2010 should therefore be amended to reflect the requirements relating to imports of ovine and caprine animals laid down in Regulation (EC) No 999/2001, as amended by Regulation (EU) No 630/2013.

(6) Regulation (EU) No 206/2010 should therefore be amended accordingly.

[1] OJ L 139, 30.4.2004, p. 321.

[2] Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

[3] Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

[4] Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 179, 29.6.2013, p. 60).

(7) To avoid any disruption of imports into the Union of consignments of animals of the ovine and caprine species, the use of veterinary certificates issued in accordance with Regulation (EU) No 206/210 in its version prior to the amendments being introduced by this Regulation should be authorised during a transitional period subject to certain conditions.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In Part 2 of Annex I to Commission Regulation (EU) No 206/2010, the model veterinary certificate "OVI-X" is replaced by the text in the Annex to this Regulation.

Article 2

For a transitional period until 31 December 2013, Member States shall authorise imports into the Union of consignments of live ovine and caprine animals for breeding or production accompanied by a veterinary certificate which has been completed and signed in accordance with the model "OVI-X" set out in Part 2 of Annex I to Regulation (EU) No 206/2010 in its version before the date of entry into force of this Regulation, provided that the certificates were completed and signed before 1 December 2013.

Article 3

This Regulation shall enter into force on the the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 September 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

'Model OVI-X

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12.	
I.13. Place of loading Address Approval number		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24.	
I.25. Commodities certified for: Breeding ☐ Fattening ☐			
I.26.		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (scientific name)	Breed	Identification system	Identification number	Age	Sex

COUNTRY **Model OVI-X**

Part II: Certification

II.	Health information	II.a. Certificate reference number	II.b.

II.1. **Public Health Attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described in this certificate:

II.1.1. come from holdings which have been free from any official prohibition on health grounds, for the last 42 days in the case of brucellosis, for the last 30 days in the case of anthrax, for the last six months in the case of rabies, and, have not been in contact with animals from holdings which did not comply with these conditions;

II.1.2. have not received any stilbene or thyrostatic substances, oestrogenic, androgenic, gestagenic or β- agonist substances for purposes other than therapeutic or zootechnic treatment (as defined in Directive 96/22/EC).

II.2. **Animal Health attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described above meet the following requirements:

II.2.1. they come from the territory with code: ..... ([1]), which, at the date of issuing this certificate:

([2]) *either* [(a) has been free for 24 months from foot-and-mouth disease,]

([2]) *or* [(a) has been considered free from foot-and-mouth disease since ..... (dd/mm/yyyy), without having had cases/outbreaks after that date, and authorised to export these animals by Commission Implementing Regulation (EU) No .../..., of ..... (dd/mm/yyyy),]

(b) has been free for 12 months from rinderpest, Rift valley fever, peste des petits ruminants, sheep pox and goat pox, contagious caprine pleuropneumonia, and epizootic haemorrhagic disease, and for 6 months from vesicular stomatitis,

(c) where during the last 12 months, no vaccination against the diseases mentioned in points (a) and (b) has been carried out and imports of domestic cloven-hoofed animals vaccinated against these diseases are not permitted;]

([2]) *either* [(d) has been free for 24 months from bluetongue;]

([2])([7]) *or* [(d) has been free for 24 months from bluetongue, and the animals have reacted negatively to a serological test for the detection of antibody for bluetongue and epizootic haemorrhagic disease, carried out on two occasions on samples of blood taken at the beginning of the isolation/quarantine period and at least 28 days later, on ..... (dd/mm/yyyy) and on ..... (dd/mm/yyyy), the second of which must have been taken within 10 days before export;]

([2]) *or* [(d) has not been free for 24 months from bluetongue, and the animals have been vaccinated with an inactivated vaccine, at least 60 days before the date of dispatch to the Union, against all bluetongue serotype/s ... (insert serotype/s) which are those present in the source population as demonstrated through a surveillance programme ([9]) in an area with a 150 km radius around the holding(s) of origin described under box reference I.11., and the animals are still within the immunity period of time guaranteed in the specifications of the vaccine;]

II.2.2. they have remained in the territory described under point II.2.1. since birth, or for at least the last six months before dispatch to the Union and without contact with imported cloven-hoofed animals for the last 30 days;

II.2.3. they have remained since birth or at least 40 days in the holding(s) described under box reference I.11. before dispatch:

(a) in and around which, in an area with a 150 km radius, there has been no case/outbreak of epizootic haemorrhagic disease during the previous 60 days, and

(b) in and around which, in an area with a 10 km radius, there has been no case/outbreak of foot-and-mouth disease, rinderpest, Rift valley fever, bluetongue, peste des petits ruminants, sheep pox and goat pox, contagious caprine pleuropneumonia and vesicular stomatitis during the previous 40 days;

II.2.4. according to my knowledge and to the written declaration made by the owner, the animals:

(a) do not come from holdings, and have not been in contact with animals of a holding, in which the following diseases have been clinically detected:

(i) contagious agalactia of sheep or goats (*Mycoplasma agalactiae, Mycoplasma capricolum, Mycoplasma mycoides var. mycoides* large colony), within the last six months,

(ii) paratuberculosis and caseous lymphadenitis, within the last 12 months,

(iii) pulmonary adenomatosis, within the last three years, and

(iv) Maedi/Visna or caprine viral arthritis/encephalitis:

([2]) *either* [within the last three years,]

([2]) *or* [within the last 12 months, and all the infected animals were slaughtered and the remaining animals subsequently reacted negatively to two tests carried out at least six months apart,]

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II. Health information	II.a. Certificate reference number	II.b.

(b) are included in an official system for notification of these diseases, and

(c) have been free from clinical or other evidence of tuberculosis and brucellosis during the three years prior to export;

II.2.5. they are not animals to be killed under a national programme for the eradication of diseases, nor have they been vaccinated against the diseases referred to in point II.2.1.(a) and (b);

II.2.6. they originate:

([2])([3]) *either* [from the territory described under box reference I.8., which has been recognised as officially brucellosis-free;]

([2]) *or* [from the holding(s) described under box reference I.11., where, in respect of brucellosis (*Brucella melitensis*):

(a) all susceptible animals have been free from clinical or any signs of this disease for the last 12 months,

(b) a representative number of the domestic ovine and caprine animals over an age of six months are submitted each year to a serological test, ([4])]

([2])([5]) *either* [(c) all domestic ovine or caprine animals have not been vaccinated against this disease, save those vaccinated with Rev. 1 vaccine more than two years ago;

(d) the last two tests ([6]), separated by an interval of at least six months, carried out on ..... (dd/mm/yyyy) and on ..... (dd/mm/yyyy) on all domestic ovine and caprine animals over six months of age gave negative results, and]

([2]) *or* [(c) domestic ovine or caprine animals under the age of 7 months are vaccinated against this disease with Rev. 1 vaccine;

(d) the last two tests ([6]), separated by an interval of at least six months, carried out: on ..... (dd/mm/yyyy) and on ..... (dd/mm/yyyy) on all non-vaccinated domestic ovine and caprine animals over six months of age, and on ..... (dd/mm/yyyy) and on ..... (dd/mm/yyyy) on all vaccinated domestic ovine and caprine animals over 18 months of age gave negative results, and]

(e) there are only domestic ovine and caprine animals that comply with the above conditions and requirements;]

([2]) [II.2.7. the uncastrated rams have been kept continuously during the previous 60 days in a holding where no case of contagious epididymitis (*Brucella ovis*) has been diagnosed in the last 12 months and, these rams have undergone during the previous 30 days a complement fixation test to detect contagious epididymitis with a result of less than 50 IU/ml;]

II.2.8. they have been kept continuously since birth in a country where the following conditions are fulfilled:

(a) classical scrapie is compulsorily notifiable;

(b) an awareness, surveillance and monitoring system for classical scrapie is in place;

(c) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(d) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least the last seven years, and

([2]) *either* [II.2.8.1 they are animals intended for production and they are destined for a Member State other than those with a negligible risk status for classical scrapie approved in accordance with point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, or other than those which are listed in point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 as having an approved national scrapie control programme;]

([2]) *or* [II.2.8.1 they are animals intended for breeding and they are destined for a Member State other than those with a negligible risk status for classical scrapie approved in accordance with point 2.2 of section A of chapter A of Annex VIII to Regulation (EC) No 999/2001, or other than those which are listed in point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 as having an approved national scrapie control programme and:

([2]) *either* [they come from a holding or holdings that have complied with the requirements laid down in point 1.3 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

([2]) *or* [they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years;]]

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II. Health information	II.a. Certificate reference number	II.b.

(2) *or* [II.2.8.1 they are destined for a Member State with a negligible risk status for classical scrapie approved in accordance with point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, or for a Member State listed in point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 as having an approved national scrapie control programme, and:

(2) *either* [they come from a holding or holdings that have complied with the requirements laid down in point 1.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

(2) *or* [they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years;]]

II.2.9. they are/were (2) dispatched from their holding(s) of origin, without passing through any market,

(2) *either* [directly to the Union,]

(2) *or* [to the officially authorised assembly centre described under box reference I.13. situated within the territory described under point II.2.1.,]

and, until dispatched to the Union:

(a) they did not come in contact with other cloven-hoofed animals not complying with the health requirements as described in this certificate, and

(b) they were not at any place where, or around which within a 10 km radius, during the previous 30 days there has been a case/outbreak of any of the diseases referred to in point II.2.1.;

II.2.10. any transport vehicles or containers in which they were loaded were cleaned and disinfected before loading with an officially authorised disinfectant;

II.2.11. they were examined by an official veterinarian within 24 hours of loading and showed no clinical sign of disease;

II.2.12. they have been loaded for dispatch to the Union on ..... (dd/mm/yyyy) (8) in the means of transport described under box reference I.15. above that were cleaned and disinfected before loading with an officially authorised disinfectant and so constructed that faeces, urine, litter or fodder could not flow or fall out of the vehicle or container during transportation.

II.3. **Animal transport attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described above have been treated before and at the time of loading in accordance with the relevant provisions of Regulation (EC) No 1/2005, in particular as regards watering and feeding, and they are fit for the intended transport.

Notes

This certificate is meant for live domestic ovine animals (*Ovis aries*) and domestic caprine animals (*Capra hircus*) intended for breeding or production.

After importation the animals must be conveyed without delay to the holding of destination where they shall remain for a minimum period of 30 days before further movement outside the holding, except in the case of a dispatch to a slaughterhouse.

Part I:

— Box reference I.8.: Provide the code of territory as appearing in Part 1 of Annex I to Regulation (EU) No 206/2010.

— Box reference I.13.: The assembly centre, if any, must comply with the conditions for its approval, as laid down in Part 5 of Annex I to Regulation (EU) No 206/2010.

— Box reference I.15.: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the BIP of entry into the Union.

— Box reference I.19.: Use the appropriate HS code: 01.04.10 or 01.04.20.

— Box reference I.23.: For containers or boxes, the container number and the seal number (if applicable) should be included.

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II. Health information	II.a. Certificate reference number	II.b.

— Box reference I.28.: *Identification system*: The animals must bear:

An individual number which permits tracing of their premises of origin. Specify the identification system (such as tag, tattoos, brand, chip, transponder) and the anatomic place used in the animal.

An ear tag that includes the ISO code of the exporting country. The individual number must permit tracing of their premises of origin.

Species: Select amongst "*Ovis aries*" and "*Capra hircus*" as appropriate.

Age: (months).

Sex (M = male, F = female, C = castrated).

Part II:

([1]) Code of the territory as it appears in Part 1 of Annex I to Regulation (EU) No 206/2010.

([2]) Keep as appropriate.

([3]) Only for a territory appearing with the entry "**V**" in column 6 of Part 1 of Annex I to Regulation (EU) No 206/2010.

([4]) The representative number of animals to be tested for brucellosis must, for each holding, consist of:
all non-castrated male animals, which have not been vaccinated against brucellosis, over six months old,
all non-castrated male animals, which have been vaccinated against brucellosis, over 18 months old,
all animals brought onto the holding since the previous tests, and
25% of females which are sexually mature, within a minimum of 50 females.

([5]) This must be completed when the destination is a Member State or part of a Member State listed in one of the Annexes of Decision 93/52/EEC.

([6]) In accordance with Part 6 of Annex I to Regulation (EU) No 206/2010.
Where more than one holding of origin is involved the date of the most recent test on each holding must be clearly indicated.

([7]) Supplementary guarantees to be provided when required in column 5 "SG" of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry "**A**". Tests for Bluetongue and for Epizootic-haemorrhagic-disease in accordance with Part 6 of Annex I to Regulation (EU) No 206/2010.

([8]) Date of loading. Imports of these animals shall not be allowed when the animals were loaded either prior to the date of authorisation for exportation to the Union of the third country, territory or part thereof referred to in boxes I.7. and I.8., or during a period where restrictive measures have been adopted by the Union against imports of these animals from this third country, territory or part thereof.

([9]) Surveillance programme as laid down in Annex I to Commission Regulation (EC) No 1266/2007 (OJ L 283, 27.10.2007, p. 37).

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp: