

Commission Implementing Decision of 18 July 2012 amending  
Implementing Decision 2011/630/EU as regards animal health  
requirements relating to bluetongue and Simbu viruses (notified under  
document C(2012) 4882) (Text with EEA relevance) (2012/415/EU)

COMMISSION IMPLEMENTING DECISION

of 18 July 2012

amending Implementing Decision 2011/630/EU as regards animal  
health requirements relating to bluetongue and Simbu viruses

(notified under document C(2012) 4882)

(Text with EEA relevance)

(2012/415/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species<sup>(1)</sup>, and in particular the first subparagraph of Article 10(2) and Article 11(2) thereof,

Whereas:

- (1) Commission Implementing Decision 2011/630/EU of 20 September 2011 on imports into the Union of semen of domestic animals of the bovine species<sup>(2)</sup> lays down the list of third countries from which Member States are to authorise imports of semen of domestic animals of the bovine species and additional guarantees as regards specific animal diseases to be provided by certain third countries listed in Annex I thereto. It also lays down certification requirements for the imports of such semen into the Union.
- (2) The model animal health certificate in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU includes the animal health requirements for imports into the Union of semen of domestic animals of the bovine species collected, processed and stored in accordance with Directive 88/407/EEC, as amended by Council Directive 2003/43/EC<sup>(3)</sup>.
- (3) The current animal health requirements for bluetongue in the model health certificate in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU provide that donor animals must fulfil the import conditions for bovine semen laid down in the Bluetongue Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). That Chapter recommends a whole range of risk mitigating measures aiming at either protecting the mammalian host from exposure to the infectious vector or at inactivating the virus by antibodies. In the interest of

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legal certainty, it is appropriate that that model health certificate sets out clearly the relevant requirements and the guarantees to be provided by the exporting third country, depending on the epidemiological situation.

- (4) In addition, the OIE has laid down a chapter on Surveillance for arthropod vectors of animal diseases in the Terrestrial Animal Health Code. Those recommendations do not include the monitoring of ruminants for antibodies to Simbu viruses, such as the Akabane and Aino viruses of the *Bunyaviridae* family, which in the past was considered an economical method for determining the distribution of bluetongue competent vectors until more information on the spread of those diseases became available.
- (5) Also, the OIE does not list Akabane and Aino diseases in the Terrestrial Animal Health Code. Consequently, the requirement for annual testing for those diseases to prove the absence of the vector should be deleted from Annex I to Implementing Decision 2011/630/EU and from the model health certificate in Section A of Part 1 of Annex II thereto.
- (6) Implementing Decision 2011/630/EU should therefore be amended accordingly.
- (7) To avoid any disruption of trade, the use of animal health certificates issued in accordance with Implementing Decision 2011/630/EU in its version prior to the amendments introduced by this Decision should be authorised during a transitional period subject to certain conditions.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

The Annexes to Implementing Decision 2011/630/EU are amended in accordance with the Annex to this Decision.

*Article 2*

For a transitional period until 30 June 2013, Member States shall authorise imports of semen and stocks of semen from third countries which are accompanied by an animal health certificate issued not later than 31 May 2013 in accordance with the model set out in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU before the amendments introduced by this Decision.

*Article 3*

This Decision shall apply from 1 January 2013.

*Article 4*

This Decision is addressed to the Member States.

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Done at Brussels, 18 July 2012.

*For the Commission*

John DALLI

*Member of the Commission*

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## ANNEX

1. Annex I is replaced by the following:

‘ANNEX I List of third countries or parts thereof from which Member States shall authorise imports of semen of domestic animals of the bovine species

The certificate to be used for imports from Canada is set out in Commission Decision 2005/290/EC of 4 April 2005 on simplified certificates for the importation of bovine semen and fresh pig meat from Canada and amending Decision 2004/639/EC (only for the semen collected in Canada) laid down in accordance with the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products, as approved by Council Decision 1999/201/EC. The certificates to be used for imports from Switzerland are set out in Annex D to Directive 88/407/EEC, with the adaptations set out in point 4 of Chapter VII(B) of Appendix 2 of Annex 11 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products as approved by Decision 2002/309/EC, Euratom of the Council, and of the Commission as regards the Agreement on Scientific and Technological Cooperation of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation.’

ISO Code	Name of the third country	Remarks	Description of the territory (if appropriate)	Additional guarantees
AU	Australia			The additional guarantee concerning testing set out in point II.5.4.1 of the certificate in Section A of Part 1 of Annex II is compulsory.
CA	Canada			
CH	Switzerland			
CL	Chile			
GL	Greenland			
HR	Croatia			
IS	Iceland			
NZ	New Zealand			
PM	Saint Pierre and Miquelon			
US	United States			The additional guarantee set out in point II.5.4.1 of the certificate in Section A of Part 1 of Annex II is compulsory.

2. In Part 1 of Annex II, Section A is replaced by the following:

### SECTION A

**Model 1 — Animal health certificate applicable to imports and transits of semen of domestic animals of the bovine species collected, processed and stored in**



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COUNTRY		Bovine semen — Section A	
II. Health information		II.a. Certificate reference No	II.b.
Part II: Certification	I, the undersigned official veterinarian, hereby certify that :		
	II.1.	..... (name of exporting country) <sup>(2)</sup>	
	was free from rinderpest and foot-and-mouth disease during the 12 months immediately prior to collection of the semen for export and until its date of dispatch to the Union and no vaccination against these diseases has taken place during the same period.		
	II.2.	The centre <sup>(3)</sup> described in Box. I.11. at which the semen to be exported was collected:	
		II.2.1. meets the conditions laid down in Chapter I(1) of Annex A to Directive 88/407/EEC;	
		II.2.2. is operated and supervised in accordance with the conditions laid down in Chapter II(1) of Annex A to Directive 88/407/EEC.	
	II.3.	The centre at which the semen to be exported was collected was free from rabies, tuberculosis, brucellosis, anthrax and contagious bovine pleuropneumonia during 30 days prior to the date of collection of the semen to be exported and the 30 days after collection (in the case of fresh semen until the day of dispatch to the Union).	
	II.4.	The bovine animals standing at the semen collection centre:	
		II.4.1. come from herds which satisfy the conditions of paragraph 1(b) of Chapter I of Annex B to Directive 88/407/EEC;	
		II.4.2. come from herds or were born to dams which comply with the conditions of Chapter I.1(c) of Annex B to Directive 88/407/EEC, or were tested at the age of at least 24 months in accordance with Chapter II.1(c) of Annex B to that Directive;	
		II.4.3. underwent the tests required in accordance with paragraph 1(d) of Chapter I of Annex B to Directive 88/407/EEC in the 28 days preceding the quarantine isolation period;	
		II.4.4. have satisfied the quarantine isolation period and testing requirements laid down in paragraph 1(e) of Chapter I of Annex B to Directive 88/407/EEC;	
		II.4.5. have undergone, at least once a year, the routine tests referred to in Chapter II of Annex B to Directive 88/407/EEC.	
	II.5.	The semen to be exported was obtained from donor bulls which:	
		II.5.1. satisfy the conditions laid down in Annex C of Directive 88/407/EEC;	
	<sup>(1)</sup> either [II.5.2. have remained in the exporting country for at least the last six months prior to collection of the semen to be exported;]		
	<sup>(1)</sup> or [II.5.2. have remained in the exporting country for at least 30 days prior to the collection of the semen since entry and they were imported from ..... <sup>(2)</sup> during the period of less than six months prior to the collection of the semen and satisfied the animal health conditions applying to donors of the semen which is intended for export to the European Union;]		
	<sup>(1)</sup> either [II.5.3. were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the semen;]		
	<sup>(1)</sup> or [II.5.3. were kept during a bluetongue virus seasonally free period in a seasonally free zone for at least 60 days prior to, and during collection of the semen;]		
	<sup>(1)</sup> or [II.5.3. were kept in a vector-protected establishment for at least 60 days prior to, and during collection of the semen;]		
	<sup>(1)</sup> or [II.5.3. were subjected to a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of semen;]		
	<sup>(1)</sup> or [II.5.3. were subjected to an agent identification test for bluetongue virus, carried out in accordance with the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals with negative results on blood samples taken at commencement and final collection for this consignment of semen and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during collection for this consignment of semen;]		
	II.5.4. were resident in the exporting country,		
	<sup>(1)</sup> either [II.5.4.1. which according to official findings is free from epizootic haemorrhagic disease (EHD);]		

ANNEX

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COUNTRY		Bovine semen — Section A
II. Health information	II.a. Certificate reference No	II.b.
<p>(<sup>1</sup>) (<sup>5</sup>) or [II.5.4.1. in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and were subjected with negative results in each case to:</p> <p>(<sup>1</sup>) either [on two occasions not more than 12 months apart a serological test (<sup>4</sup>) carried out in an approved laboratory on samples of blood taken prior to and not less than 21 days following collection for this consignment of semen;]]</p> <p>(<sup>1</sup>) or [a serological test (<sup>4</sup>) for the detection of antibody to the EHDV group, carried out on samples taken at intervals of not more than 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of semen.]]</p> <p>(<sup>1</sup>) or [an agent identification test (<sup>4</sup>) carried out in approved laboratories on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during collection for this consignment of semen.]]</p> <p>II.6. The semen to be exported was collected after the date on which the centre was approved by the competent national authorities of the exporting country;</p> <p>II.7. The semen to be exported was processed, stored and transported under conditions which satisfy the terms of Directive 88/407/EEC.</p> <p><b>Notes</b></p> <p><b>Part I:</b></p> <p>Box I.6: <i>Person responsible for the load in EU:</i> this box is to be filled in only if it is a certificate for transit commodity.</p> <p>Box I.11: <i>Place of origin</i> shall correspond to the semen collection centre listed in accordance with Article 9(2) of Directive 88/407/EEC on the Commission website:  <a href="http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm">http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm</a> and where the semen was collected.</p> <p>Box I.22: number of packages shall correspond to the number of containers.</p> <p>Box I.23: identification of container and seal number shall be indicated.</p> <p>Box I.26: fill in according to whether it is a transit or an import certificate.</p> <p>Box I.27: fill in according to whether it is a transit or an import certificate.</p> <p>Box I.28: <i>Species:</i> select amongst "<i>Bos taurus</i>", "<i>Bison bison</i>" or "<i>Bubalus bubalis</i>" as appropriate.  <i>Donor identity</i> shall correspond to the official identification of the animal.  <i>Date of collection</i> shall be indicated in the following format: dd/mm/yyyy.  <i>Approval number of the centre</i> shall correspond to the approval number of the semen collection centre indicated in Box I.11 where the semen was collected.</p> <p><b>Part II:</b></p> <p>(<sup>1</sup>) Delete as necessary.</p> <p>(<sup>2</sup>) Only third countries listed in Annex I to Implementing Decision 2011/630/EU.</p> <p>(<sup>3</sup>) Only semen collection centres listed in accordance with Article 9(2) of Directive 88/407/EEC on the Commission website:  <a href="http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm">http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm</a></p> <p>(<sup>4</sup>) Standards for EHD virus diagnostic tests are described in the Bluetongue Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.</p> <p>(<sup>5</sup>) Compulsory for Australia, Canada and the United States.</p> <p>— The signature and the stamp must be in a different colour to that of the printing.</p>		

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COUNTRY		Bovine semen — Section A	
II. Health information	II.a. Certificate reference No	II.b.	
Official veterinarian			
Name (in capital letters):		Qualification and title:	
Date:		Signature:	
Stamp:			



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- (1) OJ L 194, 22.7.1988, p. 10.
- (2) OJ L 247, 24.9.2011, p. 32.
- (3) OJ L 143, 11.6.2003, p. 23.

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