Official Journal of the European Union

L 237

English edition

Legislation

Volume 61

20 September 2018

Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

Corrigenda

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notice concerning the entry into force of the Protocol to the Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part, to take account of the accession of the Republic of Croatia to the European Union

The Protocol to the Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part, to take account of the accession of the Republic of Croatia to the European Union [1] entered into force on 1 August 2018, the procedure provided for in Article 4.2 of the Protocol to the Framework Agreement having been completed on 24 July 2018.

[1] OJ L 161, 26.6.2018, p. 3.

COUNCIL DECISION (EU) 2018/1252

of 18 September 2018

on the signing, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the People's Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 12 March 2018, the Council authorised the Commission to open negotiations on a mutually agreed solution with China in connection with the WTO dispute settlement proceedings DS492 European Union — *Measures affecting Tariff Concessions on Certain Poultry Meat Products*.

(2) The negotiations have been concluded and an Agreement in the form of an Exchange of Letters between the European Union and China ('the Agreement') was initialled on 18 June 2018.

(3) The Agreement should be signed on behalf of the Union, subject to its conclusion at a later date,

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union of the Agreement in the form of an Exchange of Letters between the European Union and the People's Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products is hereby authorised, subject to the conclusion of the said Agreement ([1]).

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([1]) The text of the Agreement will be published together with the decision on its conclusion.

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2018/1253

of 28 June 2018

correcting Delegated Regulation (EU) 2016/2374 establishing a discard plan for certain demersal fisheries in South-Western waters

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC ([1]), and in particular Articles 15(6) and 18(1) and (3) thereof,

Whereas:

(1) Regulation (EU) No 1380/2013 aims to progressively eliminate discards in all Union fisheries through the introduction of a landing obligation for catches of species subject to catch limits.

(2) In order to implement the landing obligation, Article 15(6) of Regulation (EU) No 1380/2013 empowers the Commission to adopt discard plans by means of a delegated act on the basis of joint recommendations developed by Member States in consultation with the relevant Advisory Councils.

(3) Commission Delegated Regulation (EU) 2016/2374 ([2]) established a discard plan for certain demersal fisheries in South-Western waters following a joint recommendation submitted by Belgium, France, the Netherlands, Portugal and Spain (The South Western Waters Group) in 2016.

(4) On 2 June 2017 Belgium, France, the Netherlands, Portugal and Spain have submitted a new joint recommendation suggesting a number of amendments to the discard plan. Based on that, the Commission adopted Delegated Regulation (EU) 2018/44 amending Delegated Regulation (EU) 2016/2374 ([3]).

(5) On 26 October 2017 the South Western Waters Group communicated to the Commission the existence of a textual error in the Annex to Delegated Regulation (EU) 2018/44 as regards the description of hake fisheries subject to the landing obligation. According to the current version of that Annex, hake fisheries carried out in ICES (International Council for the Exploration of the Seas) divisions VIIIc and IXa with bottom trawls and seines are subject to the landing obligation if the total hake landings in the period 2014/2015 exceeded 5 % of all landed species and more than 5 metric tons. That condition however is no longer applicable.

(6) There is therefore a need to correct Delegated Regulation (EU) 2016/2374 as amended by Delegated Regulation (EU) 2018/44.

(7) Since the textual error in the Annex to Delegated Regulation (EU) 2016/2374 has been introduced by Delegated Regulation (EU) 2018/44, and in order to avoid any discontinuity and legal uncertainty in the application of the landing obligation, this Regulation should enter into force on the day following that of its publication and should apply retroactively from the date of application of Delegated Regulation (EU) 2018/44,

([1]) OJ L 354, 28.1.2013, p. 22.
([2]) Commission Delegated Regulation (EU) 2016/2374 of 12 October 2016 establishing a discard plan for certain demersal fisheries in South-Western waters (OJ L 352, 23.12.2016, p. 33.)
([3]) Commission Delegated Regulation (EU) 2018/44 of 20 October 2017 amending Delegated Regulation (EU) 2016/2374 establishing a discard plan for certain demersal fisheries in South-Western waters (OJ L 7, 12.1.2018, p. 1.)

HAS ADOPTED THIS REGULATION:

Article 1

In the fourth column of the table '3. Hake (*Merluccius merluccius*) fisheries' of the Annex to Delegated Regulation (EU) 2016/2374 the text:

'Vessels which fulfil the following cumulative criteria:

1. Use mesh size larger or equal to 70 mm

2. Total hake landings in the period 2014/2015 ([1]) consist of: more than 5 % of all landed species and more than 5 metric tons.'

is replaced by the following:

'Use mesh size larger or equal to 70 mm'.

Article 2

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

It shall apply from 1 January 2018.

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

Done at Brussels, 28 June 2018.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1254

of 19 September 2018

concerning the denial of authorisation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 as a feed additive belonging to the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Riboflavin (vitamin B2) was authorised without a time limit by Directive 70/524/EEC as a feed additive belonging to the group of vitamins, pro-vitamins and chemically well-defined substances having similar effect, for all animal species. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of riboflavin, with a purity of minimum 80 %, produced by the genetically modified strain *Bacillus subtilis* KCCM-10445, as a feed additive for all animal species. The applicant requested that the additive be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) In 2010, in accordance with Article 7(3)(f) of Regulation (EC) No 1831/2003 and Article 3 of Commission Regulation (EC) No 378/2005 ([3]), the applicant sent samples of the feed additive, in a form in which the feed additive was intended to be placed on the market, to the Reference Laboratory under Regulation (EC) No 1831/2003 ('the Reference Laboratory'). In 2013, in accordance with Article 3(3) of Regulation (EC) No 378/2005, the applicant supplied the Reference Laboratory with new samples to replace those expired.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 December 2013 ([4]) that neither the production strain nor its recombinant DNA ('rDNA') was detected in the final product having regard to the information provided by the applicant and that therefore, the final product did not raise any safety concern with regard to the genetic modification of the production strain. It was also concluded that the additive did not have an adverse effect on animal health, human health or the environment.

(6) However, the Commission was informed by the Reference Laboratory that, in the context of an official control performed by a national competent authority, the presence of viable cells and of rDNA from the production strain was detected in some reference samples of the additive by a national laboratory competent for official controls. Those reference samples consisted of a first set submitted to the Reference Laboratory in 2010 together with the application for authorisation and an updated set submitted to the Reference Laboratory in 2013. Such detection resulted from the use of a polymerase chain reaction ('PCR') analysis method developed by a national laboratory competent for official controls in accordance with Article 11(2) of Regulation (EC) No 882/2004 of the European Parliament and of the Council ([5]).

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).
([4]) EFSA Journal 2014;12(1):3531.
([5]) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

(7) The Commission and the Reference Laboratory informed the applicant on those findings and gave him the opportunity to provide a suitable method of analysis both for the detection of rDNA and for the presence of viable cells from the production strain in order to proceed to further analysis of various samples of the additive. For that purpose, the applicant requested several laboratories, established both in China and in a Member State, to perform new analyses of the samples. The results of those analyses were negative as regards the detection of both rDNA and viable cells from the specific production strain. However, it appeared that the new analyses carried out by the applicant did not concern the samples submitted in 2010 to the Reference Laboratory.

(8) In parallel, at the request of the Commission and the Reference Laboratory, further analyses of the samples of the additive were carried out by a national laboratory competent for official controls. On its basis, it was concluded that viable cells from the production strain were present in the samples of 2010 and that rDNA from the production strain was present in the samples of 2010 and 2013. That laboratory sent samples to another national laboratory competent for official controls for further analysis, which confirmed the presence of rDNA from the production strain in the samples of 2010 and 2013. Those results were obtained through the use of a PCR analysis method developed by a national laboratory competent for official controls in accordance with Article 11(2) of Regulation (EC) No 882/2004.

(9) In 2015, in order to resolve the divergence of results, it was agreed between the Commission and the Reference Laboratory on one hand and the applicant on the other hand that each of them would request an independent laboratory accredited for a PCR method to perform further analysis of the additive. For that purpose, the samples of 2010 and 2013 would be used and the applicant was invited to provide, among others, samples in the form in which the additive was placed on the market at that time. It was agreed that both the analytical methods used by the applicant and by the national laboratories competent for official controls would be shared and used.

(10) However, the applicant subsequently refused to have the samples submitted in 2010 and 2013 analysed and to provide samples corresponding to the additive placed on the market in 2015. The applicant refused to further cooperate with the Commission and the Reference Laboratory as long as a 'unified analysis standard' method for the detection of rDNA in riboflavin was not established under Union legislation.

(11) Under Regulation (EC) No 1831/2003, the burden is on the applicant to adequately and sufficiently demonstrate that the additive satisfies the conditions for authorisation laid down in that Regulation, its implementing measures ([1]) and applicable Authority's guidance ([2]), in particular through the submission of relevant samples of the additive, all information related to the genetic modification of the production strain, the PCR-based method used, the protocol for extraction of the DNA and other relevant data allowing the Authority to determine the absence of rDNA or viable cells from the production strain.

(12) On the basis of those data indicating the presence of viable cells and rDNA from the production strain in the additive, in August 2016 the Commission requested the Authority to deliver a new opinion on the safety of riboflavin (80 %) produced by the genetically modified strain *Bacillus subtilis* KCCM-10445 as a feed additive for all animal species.

(13) In order to undertake its assessment, the Authority requested the applicant to provide supplementary information and data, related in particular to the method of analysis for the detection of the presence of viable cells of the production strain in the additive. Such supplementary information and data was submitted by the applicant. The Authority also requested the Reference Laboratory to provide further information and data concerning the analyses performed by the national laboratories competent for official controls, which was also furnished.

(14) The Authority concluded in its opinion of 7 March 2018 ([3]) that the new data provided by the national laboratory competent for official controls show that reference samples of the additive contain viable cells and/or DNA from the production strain. The production strain *Bacillus subtilis* KCCM-10445 carries four antimicrobial resistance genes, three of them introduced by genetic modifications. Therefore, the Authority concluded that the additive poses a risk for the target species, consumers, users and the environment due to the potential for the spread of viable cells and DNA of a genetically modified strain-harbouring genes coding for resistance to antimicrobials of human and veterinary importance.

([1]) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

([2]) In particular, Guidance for the preparation of dossiers for nutritional additives (EFSA Journal 2012;10(1):2535) and Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use (EFSA Journal 2011;9(6):2193).

([3]) EFSA Journal 2018;16(3):5223.

(15) Consequently, it has not been established that riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 does not have an adverse effect on animal health, human health or the environment, when used as a feed additive belonging to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'.

(16) As referred to in Article 7(3)(i) of Regulation (EC) No 1831/2003, an additive falling within the scope of the Union legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms should be subject to an authorisation granted in accordance with that legislation. Such authorisation has not been granted for the genetically modified strain *Bacillus subtilis* KCCM-10445 detected in the additive.

(17) The assessment of riboflavin (80 %) produced by the genetically modified strain *Bacillus subtilis* KCCM-10445 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are therefore not satisfied.

(18) Accordingly, the authorisation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 as a feed additive belonging to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', should be denied. As explained to the applicant on the occasion of exchanges with the Commission which took place after the adoption of the Authority's opinion of 7 March 2018, the denial of authorisation of the additive set out in this Implementing Regulation is without prejudice to the possibility of submitting a new application for authorisation in accordance with Regulation (EC) No 1831/2003.

(19) Therefore, the additive riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 and feed containing it should be withdrawn from the market as soon as possible. For practical reasons, however, a limited period should be allowed for the withdrawal from the market of the existing stocks of the additive and feed containing riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445, in order to enable operators to comply properly with the withdrawal obligation while taking into account legitimate factors relevant to the matter under consideration.

(20) In particular, as riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 represents a significant part of the Union market concerning riboflavin to be used in feed, any risk of adverse effects on animal health or welfare due to an undersupply of animals with riboflavin should be avoided by providing the operators sufficient time to adapt to the situation.

(21) In addition, the time and resources needed to retrieve and withdraw from the market premixtures containing the additive riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445, and further down in the feed chain feed materials and compound feed produced with that additive or those premixtures, should be considered. Such practical constraints for withdrawing the products from the market are even more acute for feed intended for non-food producing animals, as this type of feed usually involves higher inclusion rates of riboflavin, longer shelf life and more complex destruction methods. Therefore, the time periods for the withdrawal from the market of the respective feed products concerned should be provided accordingly.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Denial of authorisation

The authorisation of riboflavin (80 %) produced by Bacillus subtilis KCCM-10445 as a feed additive belonging to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' ('the additive') is denied.

Article 2

Withdrawal from the market

1. Existing stocks of the additive referred to in Article 1 shall be withdrawn from the market by 10 November 2018.

2. Existing stocks of premixtures produced with the additive referred to in paragraph 1 shall be withdrawn from the market by 10 January 2019.

3. Feed materials and compound feed intended for food-producing animals, which have been produced with the additive referred to in paragraph 1 or with premixtures referred to in paragraph 2 before 10 January 2019 shall be withdrawn from the market by 10 April 2019.

4. Feed materials and compound feed intended for non-food producing animals, which have been produced with the additive referred to in paragraph 1 or with premixtures referred to in paragraph 2 before 10 January 2019 shall be withdrawn from the market by 10 July 2019.

Article 3

Entry into force

This Regulation shall enter into force on 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, 19 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

DECISIONS

COUNCIL DECISION (EU) 2018/1255

of 18 September 2018

appointing three members and four alternate members, proposed by the Slovak Republic, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Slovak Government,

Whereas:

(1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ([1]), (EU) 2015/190 ([2]) and (EU) 2015/994 ([3]) appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020. On 17 February 2017, by Council Decision (EU) 2017/312 ([4]), Mr Radoslav ČUHA was replaced by Mr Miroslav BENKO as an alternate member.

(2) Three members' seats on the Committee of the Regions have become vacant following the end of the term of office of Mr Pavol FREŠO, Mr Augustín HAMBÁLEK and Mr István ZACHARIAŠ.

(3) Four alternate members' seats on the Committee of the Regions have become vacant following the end of the term of office of Mr Martin BERTA, Mr Tibor MIKUŠ, Mr Miroslav BENKO and Mr Richard TAKÁČ,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

(a) as members:

— Mr Juraj DROBA, *Chairman of Bratislava Self-Governing Region*,

— Mr Rastislav TRNKA, *Chairman of Košice Self-Governing Region*,

— Mr József BERÉNYI, *Vice-Chairman of Trnava Self-Governing Region*;

(b) as alternate members:

— Ms Erika JURINOVÁ, *Chairman of Žilina Self-Governing Region*,

— Mr Jaroslav BAŠKA,*Chairman of Trenčín Self-Governing Region*,

— Mr Ján BELJAK, *Member of Banská Bystrica Regional Parliament*,

— Mr Jozef VISKUPIČ, *Chairman of Trnava Self-Governing Region*.

([1]) Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).
([2]) Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).
([3]) Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).
([4]) Council Decision (EU) 2017/312 of 17 February 2017 appointing two members and two alternate members, proposed by the Slovak Republic, of the Committee of the Regions (OJ L 45, 23.2.2017, p. 12).

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

COUNCIL DECISION (EU) 2018/1256

of 18 September 2018

appointing an alternate member, proposed by the Federal Republic of Germany, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the German Government,

Whereas:

(1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ([1]), (EU) 2015/190 ([2]) and (EU) 2015/994 ([3]) appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.

(2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Sven AMBROSY,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

— Mr Oliver SCHENK, *Chef der Staatskanzlei und Staatsminister für Bundes- und Europaangelegenheiten (Freistaat Sachsen)*.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([1]) Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).
([2]) Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).
([3]) Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2018/553 of 3 April 2018 concerning the classification of certain goods in the Combined Nomenclature

(Official Journal of the European Union L 92 of 10 April 2018)

On page 1, in recital 5:

for: 'The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,',

read: 'The Customs Code Committee has not delivered an opinion within the time limit laid down by its Chair,'.

Corrigendum to Commission Implementing Regulation (EU) 2018/659 of 12 April 2018 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae

(Official Journal of the European Union L 110 of 30 April 2018)

In Annex III to the Regulation, Part 1, Sections A, B and D are replaced with the following:

Section A

MODEL 1 – Model health certificate for imports of consignments of semen of equidae collected in accordance with Directive 92/65/EEC after 30 September 2014 and dispatched from an approved semen collection centre of origin of the semen

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. Person responsible for the load in EU Name Address Postal code Tel.	
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 Semen centre ☐ Name Approval number Address Postal code	I.12. Place of destination Semen centre ☐ Holding ☐ Name Approval number Address Postal code	
I.13. Place of loading	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) **05 11 99 85**	
	I.20. Quantity	
I.21.	I.22. Number of packages	
I.23. Seal/Container No	I.24.	
I.25. Commodities certified for: Artificial reproduction ☐		
I.26. For transit through EU to third country ☐ Third country ISO code	I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species (Scientific name) Donor identity Date of collection Quantity		

COUNTRY **Equine semen – Section A**

II. Health information	II.a. Certificate reference No	II.b.

Part II: Certification

I, the undersigned, official veterinarian, of the exporting country ([2]) ..... hereby
(*name of exporting country*)

certify that:

II.1. The semen collection centre ([3]), in which the semen described above was collected, processed and stored for export to the Union is approved and supervised by the competent authority in accordance with the conditions of Chapters I(I)(1) and I(II)(1) of Annex D to Directive 92/65/EEC ([4]);

II.2. During the period commencing 30 days prior to the date of first collection of the semen described above until the date the fresh or chilled semen was dispatched or until the 30 days storage period for frozen semen elapsed, the semen collection centre:

II.2.1. was situated in the exporting country or, in the case of regionalisation according to Article 13 of Directive 2009/156/EC ([5]), in that part of the territory of the exporting country which was:

— not considered to be infected with African horse sickness in accordance with Article 5(2)(a) and (b) of Directive 2009/156/EC,

— free from Venezuelan equine encephalomyelitis for a period of at least 2 years,

— free from glanders and dourine for a period of at least 6 months;

II.2.2. fulfilled the conditions for a holding laid down in Article 4(5) of Directive 2009/156/EC and in particular:

([1]) *either* [II.2.2.1. following a case of a disease mentioned below not all the animals of species susceptible to that disease located in the holding were slaughtered or killed and the holding has been free:

— from any type of equine encephalomyelitis for a period of at least 6 months, beginning on the day on which the equidae suffering from the disease are slaughtered,

— from equine infectious anaemia (EIA) for at least the period required to obtain a negative result in an agar gel immunodiffusion test (AGID or Coggins test) carried out on samples taken after the infected animals were slaughtered on two occasions 3 months apart from each of the remaining animals,

— from vesicular stomatitis (VS) for a period of at least 6 months from the last recorded case,

— from rabies for a period of at least one month from the last recorded case,

— from anthrax for a period of at least 15 days from the last recorded case,]

([1]) *or* [II.2.2.1. following a case of a disease mentioned below all the animals of species susceptible to that disease located in the holding have been slaughtered or killed and the premises disinfected, and the holding was free for a period of at least 30 days from any type of equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and rabies or 15 days in the case of anthrax, beginning on the day on which following the destruction of the animals the disinfection of the premises was satisfactorily completed;]

II.2.3. contained only equidae which were free of clinical signs of equine viral arteritis and contagious equine metritis,

II.3. Prior to entering the semen collection centre the donor stallions and any other equidae located in the centre:

COUNTRY **Equine semen – Section A**

II. Health information	II.a. Certificate reference No	II.b.

II.3.1. were continuously resident for a period of 3 months (or since entry if they were directly imported from a Member State of the Union during the 3 months period) in the exporting country or, in the case of regionalisation in accordance with Article 13 of Directive 2009/156/EC, in that part of the territory of the exporting country which was during that period:

— not considered to be infected with African horse sickness in accordance with Article 5(2)(a) and (b) of Directive 2009/156/EC,

— free from Venezuelan equine encephalomyelitis for a period of at least 2 years,

— free from glanders and dourine for a period of at least 6 months;

([1]) *either* [II.3.2. originated from the country of export which was on the day of admission into the centre free from vesicular stomatitis (VS) for a period of at least 6 months,]

([1]) *or* [II.3.2. were subjected to a virus neutralisation test for vesicular stomatitis (VS) carried out with a negative result at a serum dilution of 1 in 32 or a VS ELISA carried out with a negative result in accordance with the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE on a blood sample taken ([6]) within 14 days prior to entering the centre;]

II.3.3. originated from holdings which on the day of admission onto the centre fulfilled the requirements of point II.2.2;

II.4. The semen described above was collected from donor stallions which:

II.4.1. did not show any clinical sign of an infectious or contagious disease at the time of admission onto the semen collection centre and on the day the semen was collected;

II.4.2. were kept for a period of at least 30 days prior to the date of semen collection in holdings where no equine animal has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period;

II.4.3. were not used for natural mating during a period of at least 30 days prior to the date of first semen collection and between the dates of the first sample referred to in points II.4.5.1, II.4.5.2 and/or II.4.5.3 and until the end of the collection period;

II.4.4. underwent the following tests, which meet at least the requirements of the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE, carried out in a laboratory which is recognised by the competent authority and has the tests referred to hereinafter included in its accreditation equivalent to that provided for in Article 12 of Regulation (EC) No 882/2004 ([7]), as follows:

([8]) [II.4.4.1. for equine infectious anaemia (EIA), an agar-gel immuno-diffusion test (AGID or Coggins test) or an enzyme-linked immunosorbent assay (ELISA) for equine infectious anaemia with a negative result;]

II.4.4.2. for equine viral arteritis (EVA),

([1]) *either* [II.4.4.2.1. a serum neutralisation test with a negative result at a serum dilution of one in four;]

([1]) *and/or* [II.4.4.2.2. a virus isolation test, polymerase chain reaction (PCR) or real-time PCR with a negative result on an aliquot of the entire semen of the donor stallion;]

II.4.4.3. for contagious equine metritis (CEM), an agent identification test carried out on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than 7 days at least from the penile sheath (prepuce), the urethra and the fossa glandis;

COUNTRY **Equine semen – Section A**

II. Health information	II.a. Certificate reference No	II.b.

The samples were in no case taken earlier than 7 days (systemic treatment) or 21 days (local treatment) after antimicrobial treatment of the donor stallion and were placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory where they were subjected with a negative result to a test for:

([1]) *either* [II.4.4.3.1. the isolation of *Taylorella equigenitalis* after cultivation under microaerophilic conditions for a period of at least 7 days, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport;]

([1]) *and/or* [II.4.4.3.2. the detection of genome of *Taylorella equigenitalis* by PCR or real-time PCR, carried out within 48 hours after taking the specimens from the donor animal;]

II.4.5. were subjected with the results specified in point II.4.4 in each case to at least one of the test programmes detailed respectively in points 1.6(a), (b) and (c) of Chapter II of Annex D to Directive 92/65/EEC as follows:

([9]) [II.4.5.1. The donor stallion was continuously resident on the semen collection centre for a period of at least 30 days prior to the date of the first collection and during the period of collection of the semen described above, and no equidae on the semen collection centre came during that time into direct contact with equidae of lower health status than the donor stallion.

The tests described in point II.4.4 were carried out on samples taken ([6]) from the donor stallion at least once a year at the beginning of the breeding season or prior to the first collection of semen intended for imports into the Union of fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the first semen collection.]

([9]) [II.4.5.2. The donor stallion was resident on the semen collection centre for a period of at least 30 days prior to the date of the first collection and during the period of collection of the semen described above, but left the semen collection centre under the responsibility of the centre veterinarian for a continuous period of less than 14 days, and/or other equidae on the semen collection centre came into direct contact with equidae of a lower health status.

The tests described in point II.4.4 were carried out on samples taken ([6]) from the donor stallion at least once a year at the beginning of the breeding season or prior to the date of the first collection of semen intended for imports into the Union of fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the first semen collection,

and during the period of collection of the semen intended for imports into the Union of fresh, chilled or frozen semen the donor stallion was subjected to the tests described in point II.4.4, as follows:

(a) for equine infectious anaemia, one of the tests described in point II.4.4.1 was last carried out on a sample of blood taken ([6]) not more than 90 days prior to the collection of the semen described above;

(b) for equine viral arteritis, one of the tests described

([1]) *either* [in point II.4.4.2 was last carried out on a sample taken ([6]) not more than 30 days prior to the date of the collection of the semen described above;]

([1]) *or* [in point II.4.4.2.2 was carried out on an aliquot of the entire semen of the donor stallion taken ([6]) not more than 6 months prior to the date of the collection of the semen described above and a blood sample taken ([6]) from the donor stallion during the 6 months period reacted with a positive result in a serum neutralisation test for equine viral arteritis at a serum dilution of more than one in four;]

COUNTRY **Equine semen – Section A**

II. Health information	II.a. Certificate reference No	II.b.

(c) for contagious equine metritis, the test described in point II.4.4.3 was last carried out on three specimens (swabs) taken ([6]) not more than 60 days prior to the date of the collection of semen described above

([1]) *either* [on two occasions;]

([1]) *or* [on a single occasion and subjected to a PCR or real-time PCR.]]

([9]) [II.4.5.3. The donor stallion does not meet the conditions set out in points 1.6(a) and (b) of Chapter II of Annex D to Directive 92/65/EEC and the semen is collected for imports into the Union of frozen semen.

The tests described in points II.4.4.1, II.4.4.2 and II.4.4.3 were carried out on samples taken ([6]) from the donor stallion at least once a year at the beginning of the breeding season,

and the tests described in points II.4.4.1 and II.4.4.3 were carried out on samples taken ([6]) from the donor stallion during the storage period of the semen of a minimum period of 30 days from the date of the collection of the semen and before the semen is removed from the semen collection centre, not less than 14 days and not more than 90 days after the collection of the semen described above,

and ([1]) *either* [the tests for equine viral arteritis described in point II.4.4.2 were carried out on samples taken ([6]) during the storage period of the semen of a minimum period of 30 days from the date of the collection of the semen and before the semen is removed from the semen collection centre or used, not less than 14 days and not more than 90 days after the date of the collection of the semen described above.]

([1]) *or* [the non-shedder state of a donor stallion seropositive for equine viral arteritis was confirmed by virus isolation test, PCR or real-time PCR carried out with a negative result on samples of an aliquot of the entire semen of the donor stallion taken ([6]) twice a year at an interval of at least 4 months and the donor stallion has reacted with a positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis.]

II.4.6. underwent the testing provided for in points II.3.2 ([1]) and II.4.5 on samples taken on the following dates:

Identification of semen	Test programme	Start date ([6])		Date of sampling for health tests ([6])					
		Donor residence	Semen collection	VS ([1]) II.3.2	EIA II.4.4.1.	EVA II. 4.4.2.		CEM II.4.4.3.	
						Blood sample	Semen sample	1. sample	2. sample

COUNTRY **Equine semen – Section A**

II. Health information	II.a. Certificate reference No	II.b.

([1]) *either* [II.5. No antibiotics were added to the semen;]

([1]) *or* [II.5. The following antibiotic or combination of antibiotics was added to produce a concentration in the final diluted semen of not less than ([10]):

.....

..... ;]

II.6. The semen described above was:

II.6.1. collected, processed, stored and transported under conditions which comply with the requirements of Chapters II(I)(1) and III(I) of Annex D to Directive 92/65/EEC;

II.6.2. sent to the place of loading in a sealed container in accordance with point 1.4 of Chapter III(I) of Annex D to Directive 92/65/EEC and bearing the number indicated in Box I.23.

Notes

Part I:

Box I.11.: The place of origin shall correspond to the semen collection centre of the semen origin.

Box I.22.: The number of packages shall correspond to the number of containers.

Box I.23.: The identification of container and seal number shall be indicated.

Box I.28.: The donor identity shall correspond to the official identification of the animal.

The date of collection shall be indicated in the following format: dd/mm/yyyy.

Part II:

Guidance for the completion of the table in point II.4.6.

Abbreviations:

VS	Vesicular stomatitis (VS) testing if required in accordance with point II.3.2
EIA-1	Equine infectious anaemia (EIA) testing first occasion
EIA-2	EIA testing second occasion
EVA-B1	Equine viral arteritis (EVA) testing on blood sample first occasion
EVA-B2	EVA testing on blood sample second occasion
EVA-S1	EVA testing on semen sample first occasion
EVA-S2	EVA testing on semen sample second occasion
CEM-11	Contagious equine metritis (CEM) testing first occasion first sample
CEM-12	CEM testing first occasion second sample taken 7 days after CEM-11
CEM-21	CEM testing second occasion first sample
CEM-22	CEM testing second occasion second sample taken 7 days after CEM-21

Instructions:

For each semen identified in column A in correspondence with Box I.28, the test programme (points II.4.5.1, II.4.5.2 and/or II.4.5.3) shall be specified in column B, and columns C and D shall be completed with the dates required.

COUNTRY **Equine semen – Section A**

II. Health information	II.a. Certificate reference No	II.b.

The dates when samples were taken for laboratory testing prior to the first collection of the semen described above as required in points II.4.5.1, II.4.5.2 and II.4.5.3, shall be entered in the upper line of columns 5 to 9 of the table, this being the boxes marked with EIA-1, EVA-B1 or EVA-S1 and CEM-11 and CEM-12 in the example below.

The dates when samples were taken for repeat laboratory testing as required in accordance with point II.4.5.2. or II.4.5.3. shall be entered in the lower line of columns 5 to 9 in table , this being the boxes EIA-2, EVA-B2 or EVA-S2 and CEM-21 and CEM-22 in the example below.

Identification of semen	Test programme	Start date		Date of sampling for health tests					
		Donor residence	Semen collection	VS II.3.2.	EIA II.4.4.1.	EVA II.4.4.2.		CEM II.4.4.3.	
						Blood sample	Semen sample	1. sample	2. sample
A	**B**	**C**	**D**	**VS**	**EIA-1**	**EVA-B1**	**EVA-S1**	**CEM-11**	**CEM-12**
					EIA-2	**EVA-B2**	**EVA-S2**	**CEM-21**	**CEM-22**

([1]) Delete as necessary.

([2]) Imports of equine semen are authorised from a third country listed in column 2 of Annex I to Commission Implementing Regulation (EU) 2018/657 provided that the semen was collected in the part of the territory of the third country detailed in column 4 of that Annex from a donor stallion of the category of equidae indicated in columns 11, 12 or 13 of that Annex.

([3]) Only approved semen collection centres listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/equine/index_en.htm

([4]) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

([5]) Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).

([6]) Insert date in table in point II.4.6 (follow Guidance in Part II of the Notes).

([7]) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

([8]) The agar gel immunodiffusion test (AGID or Coggins test) or the ELISA for equine infectious anaemia are not required for donor equidae which have continuously resided in Iceland since birth, provided that Iceland has remained officially free of equine infectious anaemia and no equidae and their semen, ova and embryos have been introduced into Iceland from outside prior to and during the period the semen was collected.

([9]) Cross out the programmes that do not apply to the consignment.

([10]) Insert names and concentrations.

— The signature and the stamp must be in a different colour to that of the printing.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Section B

MODEL 2 – Model health certificate for imports of consignments of stocks of semen of equidae collected, processed and stored in accordance with Directive 92/65/EEC after 31 August 2010 and before 1 October 2014 and dispatched after 31 August 2010 from an approved semen collection centre of origin of the semen

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. Person responsible for the load in EU Name Address Postal code Tel.	
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 Semen centre ☐ Name / Approval number Address Postal code		I.12. Place of destination Semen centre ☐ Holding ☐ Name / Approval number Address Postal code	
I.13. Place of loading		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) **05 11 99 85**	
			I.20. Quantity
I.21.			I.22. Number of packages
I.23. Seal/Container No			I.24.
I.25. Commodities certified for: Artificial reproduction ☐			
I.26. For transit through EU to third country ☐ Third country / ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Donor identity	Date of collection	Quantity

COUNTRY **Equine semen – Section B**

II. Health information	II.a. Certificate reference No	II.b.

Part II: Certification

I, the undersigned, official veterinarian, of the exporting country ([2]) ..... hereby
(*name of exporting country*)

certify that :

II.1. The semen collection centre ([3]), in which the semen described above was collected, processed and stored for export to the European Union is approved and supervised by the competent authority in accordance with the conditions of Chapter I(I)(1) and Chapter I(II)(1) of Annex D to Directive 92/65/EEC,

II.2. during the period commencing 30 days prior to the date of first collection of the semen described above until the 30 days storage period for frozen semen elapsed, the semen collection centre:

II.2.1. was situated in the exporting country or, in the case of regionalisation according to Article 13 of Directive 2009/156/EC ([8]), in that part of the territory of the exporting country which was:

— not considered to be infected with African horse sickness in accordance with Article 5(2)(a) and (b) of Directive 2009/156/EC ([8]),

— free from Venezuelan equine encephalomyelitis for 2 years,

— free from glanders and dourine for 6 months;

II.2.2. fulfilled the conditions for a holding laid down in Article 4(5) of Directive 2009/156/EC ([8]) and in particular:

([1]) *either* [II.2.2.1. following a case of a disease mentioned below not all the animals of species susceptible to the disease located on the holding were slaughtered or killed and the holding has been free:

— from any type of equine encephalomyelitis for at least 6 months, beginning on the day on which the equidae suffering from the disease are slaughtered,

— from equine infectious anaemia for at least the period required to obtain a negative result in an agar gel immunodiffusion test (Coggins test) carried out on samples taken after the infected animals were slaughtered on two occasions 3 months apart from each of the remaining animals,

— from vesicular stomatitis for at least 6 months from the last recorded case,

— from rabies for at least one month from the last recorded case,

— from anthrax for at least 15 days from the last recorded case,]

([1]) *or* [II.2.2.1. following a case of a disease mentioned below all the animals of species susceptible to the disease located on the holding have been slaughtered or killed and the premises disinfected, the holding has been free for at least 30 days from any type of equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and rabies or 15 days in the case of anthrax, beginning on the day on which following the destruction of the animals the disinfection of the premises was satisfactorily completed;]

II.2.3. contained only equidae which were free of clinical signs of equine viral arteritis and contagious equine metritis,

II.3. Prior to entering the semen collection centre the donor stallions and any other equidae located in the centre:

COUNTRY **Equine semen – Section B**

II. Health information	II.a. Certificate reference No	II.b.

II.3.1. were continuously resident for 3 months (or since entry if they were directly imported from a Member State of the European Union during the 3 months period) in the exporting country or, in the case of regionalisation according to Article 13 of Directive 2009/156/EC ([8]), in that part of the territory of the exporting country which was during that period

— not considered to be infected with African horse sickness in accordance with Article 5(2)(a) and (b) of Directive 2009/156/EC ([8]),

— free from Venezuelan equine encephalomyelitis for at least 2 years,

— free from glanders and dourine for at least 6 months;

([1]) *either* [II.3.2. originated from the country of export which was on the day of admission into the centre free of vesicular stomatitis (VS) for at least 6 months,]

([1]) *or* [II.3.2. were subjected to a virus neutralisation test for vesicular stomatitis (VS) carried out with negative result at a serum dilution of 1 in 12 on a blood sample taken ([4]) within 14 days prior to entering the centre;]

II.3.3. originated from holdings which on the day of admission onto the centre fulfilled the requirements of point II.2.2;

II.4. The semen described above was collected from donor stallions, which:

II.4.1. have not shown any clinical sign of an infectious or contagious disease at the time of admission onto the centre and on the day the semen was collected;

II.4.2. have been kept for 30 days prior to the date of semen collection on holdings where no equine animal has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period;

II.4.3. have not been used for natural mating during at least 30 days prior to the date of first semen collection and between the dates of the first sample referred to in points II.4.5.1, II.4.5.2 and/or II.4.5.3 and until the end of the collection period;

II.4.4. have undergone the following tests, which meet at least the requirements of the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE, carried out on samples taken in accordance with one of the programmes specified in point II.4.5 in a laboratory recognised by the competent authority:

([1]) ([5]) *either* [II.4.4.1. an agar-gel immuno-diffusion test (Coggins test) for equine infectious anaemia (EIA) with negative result;]

([1]) ([5]) *or* [II.4.4.1. an ELISA for equine infectious anaemia (EIA) with negative result;]

and ([1]) *either* [II.4.4.2. a serum neutralisation test for equine viral arteritis (EVA) with negative result at a serum dilution of one in four;]

([1]) *or* [II.4.4.2. a virus isolation test for equine viral arteritis (EVA) carried out with negative result on an aliquot of the entire semen of the donor stallion;]

COUNTRY **Equine semen – Section B**

II. Health information	II.a. Certificate reference No	II.b.

and II.4.4.3. an agent identification test for contagious equine metritis (CEM) carried out on two occasions on samples collected with an interval of 7 days by isolation of *Taylorella equigenitalis* after a cultivation of 7 to 14 days from pre-ejaculatory fluid or a semen sample and from genital swabs taken at least from the penile sheath, urethra and urethral fossa with negative result in each case;

II.4.5. have been subjected with the results specified in II.4.4. in each case to at least one of the test programmes ([6]) detailed in points II.4.5.1, II.4.5.2 and II.4.5.3 as follows:

II.4.5.1. The donor stallion was continuously resident on the semen collection centre for at least 30 days prior to the date of the first collection and during the period of collection of the semen described above, and no equidae on the semen collection centre came during that time into direct contact with equidae of lower health status than the donor stallion.

The tests described in point II.4.4 have been carried out on samples taken ([4]) prior to the first semen collection and at least 14 days following the date of the commencement of the residence period of at least 30 days.

II.4.5.2. The donor stallion was resident on the semen collection centre for at least 30 days prior to the date of the first collection and during the period of collection of the semen described above, but has left the centre under the responsibility of the centre veterinarian for a continuous period of less than 14 days, or other equidae on the collection centre came into direct contact with equidae of lower health status.

The tests described in point II.4.4 have been carried out on samples taken ([4]) prior to the date of the first semen collection of the breeding season or collection period in the year the semen described above was collected and at least 14 days following the date of the commencement of the residence period of at least 30 days,

and the test described in point II.4.4.1 for equine infectious anaemia was last carried out on a sample of blood taken ([4]) not more than 90 days before the semen described above was collected;

and ([1]) *either* [one of the tests described in point II.4.4.2 for equine viral arteritis was last carried out on a sample taken ([4]) not more than 30 days before the semen described above was collected,]

([1]) *or* [a virus isolation test for equine viral arteritis was carried out with negative result on an aliquot of the entire semen of the donor stallion taken ([4]) not more than 6 months before the semen described above was collected and a blood sample taken on the same date ([4]) reacted positive in a serum neutralisation test for equine viral arteritis at a serum dilution of more than one in four,]

and the test described in point II.4.4.3 for contagious equine metritis was last carried out on samples taken ([4]), not more than 60 days before the semen described above was collected.

II.4.5.3. The tests described in point II.4.4 have been carried out on samples taken ([4]) prior to the date of the first semen collection of the breeding season or collection period in the year the semen described above was collected,

and the tests described in point II.4.4 have been carried out on samples taken ([4]) between 14 and 90 days after the collection of the semen described above.

COUNTRY **Equine semen – Section B**

II. Health information	II.a. Certificate reference No	II.b.

II.4.6. have undergone the testing provided for in points II.3.2 ([1]) and II.4.5 on samples taken on the following dates:

Identification of semen	Test programme	Start date ([4])		Date of sampling for health tests ([4])					
		Donor residence	Semen collection	VS ([1]) II.3.2	EIA II.4.4.1.	EVA II. 4.4.2.		CEM II.4.4.3.	
						Blood sample	Semen sample	1. sample	2. sample

([1]) *either* [II.5. No antibiotics were added to the semen;]

([1]) *or* [II.5. The following antibiotic or combination of antibiotics was added to produce a concentration in the final diluted semen of not less than ([7]):

.....

..... ;]

II.6. The semen described above was:

II.6.1. collected, processed, stored and transported under conditions which comply with the requirements of Chapters II(I)(1) and III(I) of Annex D to Directive 92/65/EEC;

II.6.2. sent to the place of loading in a sealed container in accordance with point 1.4 of Chapter III(I) of Annex D to Directive 92/65/EEC and bearing the number indicated in Box I.23.

Notes

Part I:

Box I.11.: The place of origin shall correspond to the semen collection centre of the semen origin.

Box I.22.: The number of packages shall correspond to the number of containers.

Box I.23.: The identification of container and seal number shall be indicated.

Box I.28.: The donor identity shall correspond to the official identification of the animal.

The date of collection shall be indicated in the following format: dd/mm/yyyy.

COUNTRY **Equine semen – Section B**

II. Health information	II.a. Certificate reference No	II.b.

Part II:

Guidance for the completion of the table in point II.4.6.

Abbreviations:

VS	Vesicular stomatitis (VS) testing if required in accordance with point II.3.2
EIA-1	Equine infectious anaemia (EIA) testing first occasion
EIA-2	EIA testing second occasion
EVA-B1	Equine viral arteritis (EVA) testing on blood sample first occasion
EVA-B2	EVA testing on blood sample second occasion
EVA-S1	EVA testing on semen sample first occasion
EVA-S2	EVA testing on semen sample second occasion
CEM-11	Contagious equine metritis (CEM) testing first occasion first sample
CEM-12	CEM testing first occasion second sample taken 7 days after CEM-11
CEM-21	CEM testing second occasion first sample
CEM-22	CEM testing second occasion second sample taken 7 days after CEM-21

Instructions:

For each semen identified in column A in correspondence with Box I.28, the test programme (II.4.5.1., II.4.5.2. and/or II.4.5.3.) must be specified in column B, and columns C and D must be completed with the dates required.

The dates when samples were taken for laboratory testing prior to the first collection of the semen described above as required in II.4.5.1., II.4.5.2. and II.4.5.3., are entered in the upper line of columns 5 to 9 of the table, this being the boxes marked with EIA-1, EVA-B1 or EVA-S1 and CEM-11 and CEM-12 in the example below.

The dates when samples were taken for repeat laboratory testing as required in accordance with II.4.5.2. or II.4.5.3. are entered in the lower line of columns 5 to 9 in table , this being the boxes EIA-2, EVA-B2 or EVA-S2 and CEM-21 and CEM-22 in the example below.

Identification of semen	Test programme	Start date		Date of sampling for health tests					
		Donor residence	Semen collection	VS II.3.2.	EIA II.4.4.1.	EVA II.4.4.2.		CEM II.4.4.3.	
						Blood sample	Semen sample	1. sample	2. sample
A	**B**	**C**	**D**	**VS**	**EIA-1**	**EVA-B1**	**EVA-S1**	**CEM-11**	**CEM-12**
					EIA-2	**EVA-B2**	**EVA-S2**	**CEM-21**	**CEM-22**

([1]) Delete as necessary.

([2]) Imports of equine semen are authorised from a third country listed in column 2 of Annex I to Commission Implementing Regulation (EU) 2018/657 provided the semen was collected in the part of the territory of the third country detailed in column 4 of that Annex from a donor stallion of the category of equidae indicated in columns 11, 12 or 13 of that Annex.

COUNTRY **Equine semen – Section B**

II. Health information	II.a. Certificate reference No	II.b.

([3]) Only approved semen collection centres listed in accordance with Article 17(3)(b) of Council Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/equine/index_en.htm

([4]) Insert date in table in point II.4.6 (follow Guidance in Part II of the Notes)

([5]) The agar gel immunodiffusion test (Coggins test) or the ELISA for equine infectious anaemia are not required for donor equidae which have continuously resided in Iceland since birth, provided that Iceland has remained officially free of equine infectious anaemia and no equidae and their semen, ova and embryos have been introduced into Iceland from outside prior to and during the period the semen was collected.

([6]) Cross out the programmes that do not apply to the consignment.

([7]) Insert names and concentrations.

([8]) OJ L 192, 23.7.2010, p. 1.

— The signature and the stamp must be in a different colour to that of the printing.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Section D

MODEL 4 – Model health certificate for imports of consignments of semen of equidae collected, processed and stored in accordance with Directive 92/65/EEC after 30 September 2014 and of consignments of stocks of semen of animals of the equine species collected, processed and stored in accordance with Directive 92/65/EEC after 31 August 2010 and before 1 October 2014 or before 1 September 2010 and dispatched after 31 August 2010 from an approved semen storage centre

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. Person responsible for the load in EU Name Address Postal code Tel.	
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 Semen centre ☐ Name Approval number Address Postal code		I.12. Place of destination Semen centre ☐ Holding ☐ Name Approval number Address Postal code	
I.13. Place of loading		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. No(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code) **05 11 99 85**	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24.	
I.25. Commodities certified for: Artificial reproduction ☐			
I.26. For transit through EU to third country ☐ Third country ISO code		I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species (Scientific name) Donor identity Date of collection Quantity			

COUNTRY **Equine semen – Section D**

II. Health information	II.a. Certificate reference No	II.b.

Part II: Certification

I, the undersigned official veterinarian of the exporting country ([2]) ....., hereby
(name of exporting country)

certify that:

II.1. The centre ([3]) described in Box I.11 at which the semen to be exported to the Union was stored:

([1]) *either* [II.1.1. meets the conditions laid down in Chapter I(I)(1) and is operated and supervised in accordance with the conditions laid down in Chapter I(II)(1) of Annex D to Directive 92/65/EEC ([4]);]

([1]) *or* [II.1.1. meets the conditions laid down in Chapter I(I)(2) and is operated and supervised in accordance with the conditions laid down in Chapter I(II)(2) of Annex D to Directive 92/65/EEC;]

II.2. The semen to be exported to the Union:

II.2.1. has been collected, processed and stored for a minimum period of 30 days immediately following collection in an approved semen collection centre ([5]) operated and supervised in accordance with Chapters I(I)(1) and I(II)(1) of Annex D to Directive 92/65/EEC, which is

([1]) *either* [located in the exporting country;]

([1]) *or* [located in ..... ([2]), and has been imported to the exporting country under conditions at least as strict as for imports of semen of animals of the equine species into the Union in accordance with Directive 92/65/EEC;]

II.2.2. was moved to the centre described in Box I.11 under conditions at least as strict as described in:

([1]) *either* [Model 1 in Section A of Part 1 of Annex III to Regulation (EU) 2018/657 ([6]);]

([1]) *or* [Model 2 in Section B of Part 1 of Annex III to Regulation (EU) 2018/657 ([6]);]

([1]) *or* [Model 3 in Section C of Part 1 of Annex III to Regulation (EU) 2018/657 ([6]);]

([1]) *or* [Model 1 in Section A of Part 2 of Annex II to Decision 2010/471/EU ([6]);]

([1]) *or* [Model 2 in Section B of Part 2 of Annex II to Decision 2010/471/EU ([6]);]

([1]) *or* [Model 3 in Section C of Part 2 of Annex II to Decision 2010/471/EU ([6]);]

([1]) *or* [Commission Decision 96/539/EC ([6]);]

II.2.3. was stored under conditions which satisfy the terms of Annex D to Directive 92/65/EEC;

II.2.4. sent to the place of loading in a sealed container in accordance with point 1.4 of Chapter III(I) of Annex D to Directive 92/65/EEC and bearing the number indicated in Box I.23.

Notes

Part I:

Box I.11.: The place of origin shall correspond to the semen storage centre of semen dispatch.

Box I.17.: The serial number of the individual official document(s) or health certificate(s) that accompanied the semen described above from the approved semen collection centre of its origin to the described above semen storage centre shall be indicated. The original(s) of this/these document(s) or certificate(s) or the officially endorsed copy/copies of thereof must be attached to this certificate.

COUNTRY **Equine semen – Section D**

II. Health information	II.a. Certificate reference No	II.b.

Box I.22.: The number of packages shall correspond to the number of containers.

Box I.23.: The identification of container and seal number shall be indicated.

Box I.28.: The donor identity shall correspond to the official identification of the animal.

The date of collection shall be indicated in the following format: dd/mm/yyyy.

Part II:

([1]) Delete as necessary.

([2]) Imports of equine semen are authorised from a third country listed in column 2 of Annex I to Commission Implementing Regulation (EU) 2018/657 provided that the semen was collected in the part of the territory of the third country detailed in column 4 of that Annex from a donor stallion of the category of equidae indicated in column 11, 12 or 13 of that Annex.

([3]) Only approved semen collection or storage centres listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/equine/index_en.htm

([4]) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

([5]) Only approved semen collection centres listed in accordance with Article 11(4) and Article 17(3)(b) of Directive 92/65/EEC on the Commission websites:

https://ec.europa.eu/food/animals/live_animals/approved-establishments_en;
http://ec.europa.eu/food/animal/semen_ova/equine/index_en.htm

([6]) The original(s) of the document(s) or the health certificate(s) or the officially endorsed copy/copies thereof that accompanied the semen described above from the approved semen collection centre of the semen origin to the centre of the semen dispatch described in Box I.11 must be attached to this certificate.

— The signature and the stamp must be in a different colour to that of the printing.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN