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1999/613/EC:

- ★ **Commission Decision of 10 September 1999 amending Commission Decisions 92/260/EEC and 93/197/EEC with regard to the animal health conditions for the temporary admission and imports into the Community of registered horses from United Arab Emirates ⁽¹⁾ (notified under document number C(1999) 2795) 12**

I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 1957/1999
of 14 September 1999
establishing the standard import values for determining the entry price of certain fruit and
vegetables**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables ⁽¹⁾, as last amended by Regulation (EC) No 1498/98 ⁽²⁾, and in particular Article 4 (1) thereof,

- (1) Whereas Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto;

- (2) Whereas, in compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 15 September 1999.

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

Done at Brussels, 14 September 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 337, 24.12.1994, p. 66.

⁽²⁾ OJ L 198, 15.7.1998, p. 4.

ANNEX

to the Commission Regulation of 14 September 1999 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	052	62,5
	060	49,8
	999	56,1
0707 00 05	628	125,1
	999	125,1
0709 90 70	052	67,1
	999	67,1
0805 30 10	388	65,4
	524	77,2
	528	71,7
	999	71,4
0806 10 10	052	90,3
	064	49,3
	400	232,8
	999	124,1
0808 10 20, 0808 10 50, 0808 10 90	388	59,3
	400	53,0
	508	20,3
	512	61,8
	528	45,5
	800	180,8
	804	79,0
	999	71,4
0808 20 50	052	83,4
	064	45,4
	388	46,9
	720	88,4
	999	66,0
0809 30 10, 0809 30 90	052	104,0
	999	104,0
0809 40 05	052	46,7
	064	46,2
	624	184,9
	999	92,6

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2645/98 (OJ L 335, 10.12.1998, p. 22). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1958/1999**of 14 September 1999****fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs ⁽¹⁾, as last amended by Commission Regulation (EC) No 1516/96 ⁽²⁾, and in particular Article 5(4) thereof,

Having regard to Council Regulation (EEC) No 2777/75 of 29 October 1975 on the common organisation of the market in poultrymeat ⁽³⁾, as last amended by Commission Regulation (EC) No 2916/95 ⁽⁴⁾, and in particular Article 5(4) thereof,

Having regard to Council Regulation (EEC) No 2783/75 of 29 October 1975 on the common system of trade for ovalbumin and lactalbumin ⁽⁵⁾, as last amended by Commission Regulation (EC) No 2916/95, and in particular Article 3(4) thereof,

- (1) Whereas Commission Regulation (EC) No 1484/95 ⁽⁶⁾, as last amended by Regulation (EC) No 1532/1999 ⁽⁷⁾, fixes detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin;

- (2) Whereas it results from regular monitoring of the information providing the basis for the verification of the import prices in the poultrymeat and egg sectors and for egg albumin that the representative prices for imports of certain products should be amended taking into account variations of prices according to origin; whereas, therefore, representative prices should be published;

- (3) Whereas it is necessary to apply this amendment as soon as possible, given the situation on the market;

- (4) Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Poultrymeat and Eggs,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is hereby replaced by the Annex hereto.

Article 2

This Regulation shall enter into force on 15 September 1999.

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

Done at Brussels, 14 September 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 282, 1.11.1975, p. 49.

⁽²⁾ OJ L 189, 30.7.1996, p. 99.

⁽³⁾ OJ L 282, 1.11.1975, p. 77.

⁽⁴⁾ OJ L 305, 19.12.1995, p. 49.

⁽⁵⁾ OJ L 282, 1.11.1975, p. 104.

⁽⁶⁾ OJ L 145, 29.6.1995, p. 47.

⁽⁷⁾ OJ L 178, 14.7.1999, p. 17.

ANNEX

ANNEX I

CN code	Description	Representative price EUR/100 kg	Security referred to in Article 3(3) EUR/100 kg	Origin (¹)
0207 14 10	Boneless cuts of fowls of the species <i>gallus domesticus</i> , frozen	190,7	35	01
		195,9	32	02
		283,2	5	03
		283,2	5	04
1602 32 11	Preparations uncooked of Fowls of the species <i>gallus domesticus</i>	206,8	24	01
		204,2	25	02

(¹) Origin of imports:

01 Brazil

02 Thailand

03 Chile

04 Argentina.'

COMMISSION REGULATION (EC) No 1959/1999
of 14 September 1999
fixing the export refunds on poultrymeat

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2777/75 of 29 October 1975 on the common organization of the market in poultrymeat ⁽¹⁾, as last amended by Commission Regulation (EC) No 2916/95 ⁽²⁾, and in particular Article 8(3) thereof,

- (1) Whereas Article 8 of Regulation (EEC) No 2777/75 provides that the difference between prices on the world market for the products listed in Article 1(1) of that Regulation and prices for those products within the Community may be covered by an export refund;
- (2) Whereas it follows from applying these rules and criteria to the present situation on the market in poultrymeat that the refund should be fixed at an amount which would permit Community participation in world trade

and would also take account of the nature of these exports and their importance at the present time;

- (3) Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Poultrymeat and Eggs,

HAS ADOPTED THIS REGULATION:

Article 1

The list of product codes for which, when they are exported, the export refund referred to in Article 8 of Regulation (EEC) No 2777/75 is granted, and the amount of that refund shall be as shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 15 September 1999.

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

Done at Brussels, 14 September 1999.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 282, 1.11.1975, p. 77.

⁽²⁾ OJ L 305, 19.12.1995, p. 49.

ANNEX

to the Commission Regulation of 14 September 1999 fixing the export refunds on poultrymeat

Product code	Destination of refund ⁽¹⁾	Amount of refund
		EUR/100 units
0105 11 11 9000	01	1,40
0105 11 19 9000	01	1,40
0105 11 91 9000	01	1,40
0105 11 99 9000	01	1,40
0105 12 00 9000	01	3,30
0105 19 20 9000	01	3,30
		EUR/100 kg
0207 12 10 9900	02	25,00
	03	25,00
0207 12 90 9190	02	25,00
	03	25,00
0207 12 90 9990	02	25,00
	03	25,00
0207 14 20 9900	04	8,00
0207 14 60 9900	04	8,00
0207 14 70 9190	04	8,00
0207 14 70 9290	04	8,00

⁽¹⁾ The destinations are as follows:

01 All destinations except the United States of America,

02 Angola, Saudi Arabia, Kuwait, Bahrain, Qatar, Oman, the United Arab Emirates, Jordan, Yemen, Lebanon, Iraq and Iran,

03 Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan and Ukraine,

04 All destinations except the United States of America, Bulgaria, Poland, Hungary, Romania, Slovakia, the Czech Republic, Slovenia, Croatia, Bosnia and Herzegovina, Yugoslavia, the Former Yugoslav Republic of Macedonia, Lithuania, Estonia and Latvia, Switzerland and those of 03 above.

NB: The product codes and the footnotes are defined in amended Commission Regulation (EEC) No 3846/87.

COMMISSION DIRECTIVE 1999/82/EC**of 8 September 1999****amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products ⁽¹⁾, as last amended by Directive 93/39/EEC ⁽²⁾, and in particular Article 2(a)(1) thereof,

(1) Whereas Commission Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies ⁽³⁾ defines specified risk materials, provides for their elimination at source and prohibits their import into the Community;

(2) Whereas, prior to being marketed, all medicinal products, whether they originate in the Community or are imported from third countries, are subject to an approval procedure in the context of which the treatment process of any raw material is evaluated, in conformity with the provisions of the Annex to Directive 75/318/EEC;

(3) Whereas this approval procedure applies to all medicinal products to be placed on the market in the Community, notwithstanding the origin of the product or the raw materials contained therein; whereas, thereby, the compliance with Community law of medicinal products, starting materials and intermediate products which are imported into the Community to be used in the manufacture of medicinal products is systematically controlled and checked;

(4) Whereas on 21 April 1999, the Committee for Proprietary Medicinal Products of the European Agency for the Evaluation of Medicinal Products adopted an updated Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products;

(5) Whereas, in drafting this updated Note for Guidance, the Committee for Proprietary Medicinal Products of the European Agency for the Evaluation of Medicinal Products took into account all relevant Opinions of the

Scientific Committee on Medicinal Products and Medical Devices, as well as the Scientific Steering Committee and additional scientific considerations which apply to the specific field of medicinal products;

(6) Whereas, the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products will have to be regularly updated and modified by the Committee for Proprietary Medicinal Products of the European Agency for the Evaluation of Medicinal Products, taking into account the latest scientific developments;

(7) Whereas the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates are published by the European Commission in Volume 3 of its publication 'The rules governing medicinal products in the European Union';

(8) Whereas this Note for Guidance is considered to be adequate to assure that the risk of transmitting Animal Spongiform Encephalopathy via medicinal products is minimised since manufacturers of medicinal products are obliged under Directive 75/318/EEC to take into account the relevant Community guidelines in assembling the dossier for application for marketing authorisation;

(9) Whereas it contributes to the clarity of the legal situation and ensures the highest reasonable level of protection of public health to amend the Annex to Directive 75/318/EEC to expressly make compliance with the above Note for Guidance binding with regard to all marketing authorisations for medicinal products and to provide for an appropriate phasing-in period for already existing marketing authorisations;

(10) Whereas the measures provided for in this Directive are in conformity with the opinion of the Standing Committee for Medicinal Products for Human Use,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 75/318/EEC is hereby amended as shown in the Annex.

⁽¹⁾ OJ L 147, 9.6.1975, p. 1.

⁽²⁾ OJ L 214, 24.8.1993, p. 22.

⁽³⁾ OJ L 216, 8.8.1997, p. 95.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 January 2000.
2. Member States shall take the necessary measures to ensure that:
 - applications for marketing authorisations for medicinal products lodged as from 1 July 2000 comply with the criteria set out in the Annex to this Directive,
 - all marketing authorisations for medicinal products meet the criteria of the Annex to this Directive not later than 1 March 2001.
3. When the Member States adopt the provisions set out in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such references shall be adopted by the Member States.

4. The Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the third day following its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 September 1999.

For the Commission

Karel VAN MIERT

Member of the Commission

ANNEX

A new paragraph C.a is inserted in Part 2 of the Annex to Directive 75/318/EEC:

‘C.a Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

The applicant must demonstrate that the medicinal product is manufactured in accordance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the European Commission in Volume 3 of its publication “The rules governing medicinal products in the European Union”.’

COMMISSION DIRECTIVE 1999/83/EC

of 8 September 1999

amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products ⁽¹⁾, as last amended by Directive 93/39/EEC ⁽²⁾, and in particular Article 2(a)(1) thereof;

- (1) Whereas it is possible to replace results of pharmacological and toxicological tests or clinical trials by detailed references to published scientific literature if it can be demonstrated that the constituent(s) of a medicinal product have a well-established medicinal use, with recognised efficacy and an acceptable level of safety in accordance with point 8(a) and (b) of Article 4(2), of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ⁽³⁾;
- (2) Whereas Article 1(2) of Directive 75/318/EEC provides that where pursuant to point 8(a) and (b) of Article 4(2), of Directive 65/65/EEC references to published data are submitted (bibliographical applications), the provisions of Directive 75/318/EEC shall apply 'in like manner';
- (3) Whereas the increased speed of innovation and publication of innovation as well as the increasingly stringent requirements foreseen by Community pharmaceutical legislation for new medicinal products make it necessary to define the conditions applicable to bibliographic applications more closely and to determine more exactly the meaning of 'in like manner' in Article 1(2) of Directive 75/318/EEC;
- (4) Whereas it must be ensured that the possibility of submitting 'bibliographical applications' does not discourage innovative companies to publish results of their research as quickly as possible;
- (5) Whereas it is therefore necessary to lay down a more detailed common understanding of the conditions for 'bibliographical applications' and in particular the

meaning of 'well established use' pursuant to point 8(a) and (b) of Article 4(2), of Directive 65/65/EEC;

- (6) Whereas it is in particular necessary to clarify that 'bibliographic reference' to other sources of evidence (postmarketing studies, epidemiological studies, studies conducted with similar products, etc.) and not just tests and trials may serve as a valid proof of safety and efficacy of a product if an applicant explains and justifies the use of these sources of information satisfactorily;
- (7) Whereas the rules laid down in this Directive are to a large extent in line with current administrative practice in the majority of Member States;
- (8) Whereas this amendment may help in solving practical problems Member States are facing concerning the authorisation of old medicinal products;
- (9) Whereas the measures provided for in this Directive are in conformity with the opinion of the Standing Committee for Medicinal Products for Human Use,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 75/318/EEC is hereby amended as shown in the Annex.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 March 2000.
2. When the Member States adopt the provisions set out in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.
3. The Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

⁽¹⁾ OJ L 147, 9.6.1975, p. 1.

⁽²⁾ OJ L 214, 24.8.1993, p. 22.

⁽³⁾ OJ 22 of 9.2.1965, p. 369/65.

Article 3

This Directive shall enter into force on the third day following its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 September 1999.

For the Commission

Karel VAN MIERT

Member of the Commission

ANNEX

1. In Part 3 of the Annex to Directive 75/318/EEC a new Section I is inserted.

1. Well-established medicinal use

For the purpose of demonstrating, pursuant to Article 4(8)(a)(ii) of Directive 65/65/EEC, that the constituent(s) of a medicinal product have a well established use, with an acceptable level of safety, the following specific rules shall apply:

- (a) Factors which have to be taken into account in order to establish a "well established medicinal use" of constituents of medicinal products are the time over which a substance has been used, quantitative aspects of the use of the substance, the degree of scientific interest in the use of the substance (reflected in the published scientific literature) and the coherence of scientific assessments. Therefore different periods of time may be necessary for establishing "well established use" of different substances. In any case, however, the period of time required for establishing a "well established medicinal use" of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the EU.
- (b) The documentation submitted by the applicant should cover all aspects of the safety assessment and must include or refer to a review of the relevant literature, taking into account pre- and postmarketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, should be communicated.
- (c) Particular attention must be paid to any missing information and justification must be given why demonstration of an acceptable level of safety can be supported although some studies are lacking.
- (d) The Expert report must explain the relevance of any data submitted which concern a product different from the product intended for marketing. A judgement must be made whether the product studied can be considered as similar to the product which will be granted a marketing authorisation in spite of the existing differences.
- (e) Post-marketing experience with other products containing the same constituents is of particular importance and applicants should put a special emphasis on this issue.'

2. In Part 4 of the Annex to Directive 75/318/EEC a new section I is inserted:

1. Well established medicinal use

For the purpose of demonstrating, pursuant to Article 4(8)(a)(ii) of Directive 65/65/EEC, that the constituent(s) of a medicinal product have a well established use, with recognised efficacy, the following specific rules shall apply:

- (a) Factors which have to be taken into account in order to establish a "well established medicinal use" of constituents of medicinal products are the time over which a substance has been used, quantitative aspects of the use of the substance, the degree of scientific interest in the use of the substance (reflected in the published scientific literature) and the coherence of scientific assessments. Therefore different periods of time may be necessary for establishing "well established use" of different substances. In any case, however, the period of time required for establishing a "well established medicinal use" of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the EU.
 - (b) The documentation submitted by the applicant should cover all aspects of the efficacy assessment and must include or refer to a review of the relevant literature, taking into account pre- and postmarketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, should be communicated.
 - (c) Particular attention must be paid to any missing information and justification must be given why demonstration of efficacy can be supported although some studies are lacking.
 - (d) The Expert report must explain the relevance of any data submitted which concern a product different from the product intended for marketing. A judgement must be made whether the product studied can be considered as similar to the product which will be granted a marketing authorisation in spite of the existing differences.
 - (e) Post-marketing experience with other products containing the same constituents is of particular importance and applicants should put a special emphasis on this issue.'
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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 10 September 1999

amending Commission Decisions 92/260/EEC and 93/197/EEC with regard to the animal health conditions for the temporary admission and imports into the Community of registered horses from United Arab Emirates

(notified under document number C(1999) 2795)

(Text with EEA relevance)

(1999/613/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and imports from third countries of equidae⁽¹⁾, as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Articles 15(a) and 16 thereof,

- (1) Whereas the health conditions and veterinary certification for the temporary admission and imports of registered horses among others from the United Arab Emirates are laid down respectively in Commission Decision 92/260/EEC⁽²⁾, as last amended by Decision 1999/228/EC⁽³⁾; and Commission Decision 93/197/EEC⁽⁴⁾, as last amended by Decision 1999/252/EC⁽⁵⁾;
- (2) Whereas following a second Commission veterinary inspection mission to the United Arab Emirates the animal health situation appears to be under the satisfactory control of the veterinary services and in particular the movement of equidae and their health status are sufficiently controlled;
- (3) Whereas African horse sickness has never been reported in the United Arab Emirates and vaccination against this disease is prohibited for more than one year; whereas moreover a series of serological surveys have been carried out over the entire territory of the country and

the satisfactory results have been communicated to the Member States and the Commission;

- (4) Whereas the conditions for imports of equidae into the country concerned are at least as strict as the conditions for imports of equidae into the Community; whereas therefore the country should be considered at low risk of incursion of African horse sickness from outside;
- (5) Whereas the animal health conditions and veterinary certification must be adopted according to the animal health situation of the third country concerned; whereas the present case relates only to registered horses to be temporarily or permanently imported from the United Arab Emirates;
- (6) Whereas Commission Decisions 92/260/EEC and 93/197/EEC must be amended accordingly;
- (7) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Commission Decision 92/260/EEC is amended as follows:

1. The first indent in paragraph (d) of Chapter III of the animal health certificate E in Annex II is replaced as follows:

- ‘— either
- the country of dispatch, in an isolation centre⁽³⁾
- or
- the United Arab Emirates (AE), in designated premises under official veterinary supervision⁽³⁾’.

⁽¹⁾ OJ L 224, 18.8.1990, p. 42.

⁽²⁾ OJ L 130, 15.5.1992, p. 67.

⁽³⁾ OJ L 83, 27.3.1999, p. 77.

⁽⁴⁾ OJ L 86, 6.4.1993, p. 16.

⁽⁵⁾ OJ L 96, 10.4.1999, p. 31.

2. The fourth indent in paragraph (i) of Chapter III of the animal health certificate E in Annex II is replaced by the following:

— a test for African horse sickness as described in Annex D to Council Directive 90/426/EEC either

— on two occasions, carried out on samples of blood taken with an interval of between 21 and 30 days on ...⁽⁵⁾ and on ...⁽⁵⁾, the second of which must have been taken within 10 days of export⁽³⁾, either with negative reactions, if it has not been vaccinated⁽³⁾⁽⁴⁾, or without increase in antibody count, if it has been vaccinated⁽³⁾⁽⁴⁾

or

— on one occasion, carried out on a sample of blood taken within 10 days of export on ...⁽⁵⁾ with negative reaction, if it is to be dispatched from the United Arab Emirates (AE)⁽³⁾⁽⁴⁾;

3. 'United Arab Emirates (AE)' is added in the order of the ISO country code to the list of third countries in the last indent of paragraph (d) of Chapter III of the animal health certificates A, B, C, D and E in Annex II.

Article 2

Chapter III of the animal health certificate E in Annex II of Decision 93/197/EEC is amended as follows:

1. Paragraph (d) is replaced by the following:

'(d) during the three months immediately preceding the exportation (or since birth, if the animal is less than three months old, or since entry, if it was imported directly from the European Community during the previous three months) it has been resident on holdings under veterinary supervision in the country of dispatch

and it has been kept in an approved isolation centre, protected from vector insects, either

— during the 40 days prior to dispatch⁽³⁾,

or

— during 30 days prior to dispatch from the United Arab Emirates (AE)⁽³⁾;

2. Paragraph (k) is replaced by the following:

'(k) it was subjected to a test for African horse sickness as described in Annex D to Council Directive 90/426/EEC either

— on two occasions, carried out on samples of blood taken with an interval of between 21 and 30 days on ...⁽⁴⁾ and on ...⁽⁴⁾, the second of which must have been taken within 10 days of export⁽³⁾, either with negative reactions, if it has not been vaccinated⁽³⁾, or without increase in antibody count, if it has been vaccinated⁽³⁾

or

— on one occasion, carried out on a sample of blood taken within 10 days of export on ...⁽⁴⁾ with negative reaction, if it is to be dispatched from the United Arab Emirates (AE)⁽³⁾;

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 10 September 1999.

For the Commission

Franz FISCHLER

Member of the Commission