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# Legislation

Contents





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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.

II *Acts whose publication is not obligatory*





[1] Text with EEA relevance

I

*(Acts whose publication is obligatory)*

# COUNCIL REGULATION (EC) No 1478/2000

## of 19 June 2000

## amending Regulation (EC) No 2866/98 on the conversion rates between the euro and the currencies of the Member States adopting the euro

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 123(5) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Central Bank [1],

Whereas:

(1) Council Regulation (EC) No 2866/98 of 31 December 1998 on the conversion rates between the euro and the currencies of the Member States adopting the euro [2] determines the conversion rates as from 1 January 1999 pursuant to Council Regulation (EC) No 974/98 of 3 May 1998 on the introduction of the euro [3].

(2) Council Decision 98/317/EC of 3 May 1998 in accordance with Article 121(4) of the Treaty [4] stipulated that Greece did not fulfil the necessary conditions for the adoption of the single currency.

(3) Pursuant to Council Decision 2000/427/EC of 19 June 2000 in accordance with Article 122(2) of the Treaty on the adoption by Greece of the single currency on 1 January 2001 [5] Greece now fulfils the necessary conditions, and the derogation of Greece should be abrogated with effect from 1 january 2001.

(4) The introduction of the euro in Greece requires the adoption of the conversion rate between the euro and the drachma,

HAS ADOPTED THIS REGULATION:

*Article 1*

In the list of conversion rates in Article 1 of Regulation (EC) No 2866/98, the following shall be inserted between the rates of the German mark and the Spanish peseta:

'= 340,750 Greek drachma.'

*Article 2*

This Regulation shall enter into force on 1 January 2001.

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

Done at Santa Maria da Feira, 19 June 2000.

*For the Council*

*The President*

J. PINA MOURA

[1] Opinion delivered on 16 June 2000 (not yet published in the Official Journal).
[2] OJ L 359, 31.12.1998, p. 1.
[3] OJ L 139, 11.5.1998, p. 1.
[4] OJ L 139, 11.5.1998, p. 30.
[5] See page 19 of this Official Journal.

# COMMISSION REGULATION (EC) No 1479/2000

## of 6 July 2000

## 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,

Whereas:

(1) Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral 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) 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 7 July 2000.

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

Done at Brussels, 6 July 2000.

*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 6 July 2000 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 | 50,2 |
| | 999 | 50,2 |
| 0707 00 05 | 052 | 96,5 |
| | 628 | 130,8 |
| | 999 | 113,7 |
| 0709 90 70 | 052 | 63,0 |
| | 999 | 63,0 |
| 0805 30 10 | 388 | 46,6 |
| | 524 | 72,7 |
| | 528 | 64,4 |
| | 999 | 61,2 |
| 0808 10 20, 0808 10 50, 0808 10 90 | 064 | 129,9 |
| | 388 | 78,2 |
| | 400 | 79,0 |
| | 508 | 84,4 |
| | 512 | 86,4 |
| | 528 | 88,2 |
| | 720 | 79,3 |
| | 804 | 89,1 |
| | 999 | 89,3 |
| 0808 20 50 | 388 | 99,7 |
| | 512 | 86,2 |
| | 528 | 83,5 |
| | 800 | 67,5 |
| | 999 | 84,2 |
| 0809 10 00 | 052 | 205,8 |
| | 064 | 123,9 |
| | 999 | 164,9 |
| 0809 20 95 | 052 | 268,0 |
| | 061 | 180,5 |
| | 066 | 130,3 |
| | 068 | 63,4 |
| | 400 | 235,7 |
| | 999 | 175,6 |
| 0809 40 05 | 624 | 281,7 |
| | 999 | 281,7 |

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2543/1999 (OJ L 307, 2.12.1999, p. 46). Code '999' stands for 'of other origin'.

# COMMISSION REGULATION (EC) No 1480/2000

## of 6 July 2000

## fixing, for June 2000, the specific exchange rate for the amount of the reimbursement of storage costs in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2038/1999 of 13 September 1999 on the common organisation of the markets in the sugar sector [1],

Having regard to Council Regulation (EC) No 2799/98 of 15 December 1998 establishing agrimonetary arrangements for the euro [2],

Having regard to Commission Regulation (EEC) No 1713/93 of 30 June 1993 establishing special detailed rules for applying the agricultural conversion rate in the sugar sector [3], as last amended by Regulation (EC) No 1642/1999 [4], and in particular Article 1(3) thereof,

Whereas:

(1) Article 1(2) of Regulation (EEC) No 1713/93 provides that the amount of the reimbursement of storage costs referred to in Article 8 of Regulation (EC) No 2038/1999 is to be converted into national currency using a specific agricultural conversion rate equal to the average, calculated *pro rata temporis*, of the agricultural conversion rates applicable during the month of storage. That specific rate must be fixed each month for the previous month. However, in the case of the reimbursable amounts applying from 1 January 1999, as a result of the introduction of the agrimonetary arrangements for the euro from that date, the fixing of the conversion rate should be limited to the specific exchange rates prevailing between the euro and the national currencies of the Member States that have not adopted the single currency.

(2) Application of these provisions will lead to the fixing, for June 2000, of the specific exchange rate for the amount of the reimbursement of storage costs in the various national currencies as indicated in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specific exchange rate to be used for converting the amount of the reimbursement of the storage costs referred to in Article 8 of Regulation (EC) No 2038/1999 into national currency for June 2000 shall be as indicated in the Annex hereto.

*Article 2*

This Regulation shall enter into force on 7 July 2000.

It shall apply with effect from 1 June 2000.

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

Done at Brussels, 6 July 2000.

*For the Commission*

Franz FISCHLER

*Member of the Commission*

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 349, 24.12.1998, p. 1.
[3] OJ L 159, 1.7.1993, p. 94.
[4] OJ L 195, 28.7.1999, p. 3.

*ANNEX*

**to the Commission Regulation of 6 July 2000 fixing, for June 2000, the exchange rate for the amount of the reimbursement of storage costs in the sugar sector**

| Specific exchange rate | | |
|---|---|---|
| EUR 1 = | 7,46092 | Danish kroner |
| | 336,660 | Greek drachma |
| | 8,31640 | Swedish kroner |
| | 0,628737 | Pound sterling |

# COMMISSION REGULATION (EC) No 1481/2000

## of 6 July 2000

## establishing the sugar forecast supply balance for 2000/01 for the Azores, Madeira and the Canary Islands provided for in Council Regulations (EEC) No 1600/92 and (EEC) No 1601/92

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1600/92 of 15 June 1992 concerning specific measures for the Azores and Madeira relating to certain agricultural products [1], as last amended by Regulation (EC) No 1257/1999 [2], and in particular Article 10 thereof,

Having regard to Council Regulation (EEC) No 1601/92 of 15 June 1992 concerning specific measures for the Canary Islands with regard to certain agricultural products [3], as last amended by Regulation (EC) No 1257/1999, and in particular Articles 3(4) and 7(2) thereof,

Whereas:

(1) Pursuant to Article 2 of Regulations (EEC) No 1600/92 and (EEC) No 1601/92, Commission Regulation (EEC) No 2177/92 [4], as last amended by Regulation (EC) No 1434/1999 [5], sets the forecast supply balance for sugar for the Azores, Madeira and the Canary Islands for the 1999/2000 marketing year. Pursuant to that Article 2 and on the basis of the forecasts, the supply balance for the 2000/01 marketing year under those arrangements should now be set, on the basis of the objective data provided by the Portuguese and Spanish authorities in line with local market requirements.

(2) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EEC) No 2177/92 is replaced, for the 2000/01 marketing year, by the Annex to this Regulation.

*Article 2*

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

It shall apply with effect from 1 July 2000.

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

Done at Brussels, 6 July 2000.

*For the Commission*

Franz FISCHLER

*Member of the Commission*

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[1] OJ L 173, 27.6.1992, p. 1.
[2] OJ L 160, 26.6.1999, p. 80.
[3] OJ L 173, 27.6.1992, p. 13.
[4] OJ L 217, 31.7.1992, p. 71.
[5] OJ L 166, 1.7.1999, p. 58.

*ANNEX*

**Quantities of sugar expressed in terms of tonnes of white sugar referred to in Article 1 of Regulation (EEC) No 2177/92 for the 2000/01 marketing year**

| Region | Quantity |
|---|---|
| Azores | 6 500 |
| Madeira | 8 000 |
| Canary Islands | 63 000 |

# COMMISSION REGULATION (EC) No 1482/2000

## of 6 July 2000

## supplementing the Annex to Regulation (EC) No 2301/97 on the entry of certain names in the Register of certificates of specific character provided for in Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs [1], and in particular Article 9(2)(b) thereof,

Whereas:

(1) In accordance with Article 8 of Regulation (EEC) No 2082/92, the Member States have forwarded to the Commission applications for the registration of certain names as denoting products of specific character.

(2) The names so registered are entitled to use the indication 'traditional speciality guaranteed' which is reserved for them.

(3) A number of objections concerning the names 'Leche certificada de Granja' and 'Traditional Farmfresh Turkey' have been sent to the Commission in accordance with Article 7 of the Regulation following the publication in the *Official Journal of the European Communities* of the main points of the applications for registration [2].

(4) The Commission asked the Member States, in accordance with Article 9(2) of Regulation (EEC) No 2082/92, to seek agreement between themselves. No agreement has been reached and it is therefore up to the Commission to decide on the registration of the names concerned.

(5) The protection referred to in Article 13(2) of the Regulation has been requested but consideration of the various observations in the abovementioned objections shows that the use of the names for similar products is lawful, recognised and economically significant.

(6) However, the names 'Leche certificada de Granja' and 'Traditional Farmfresh Turkey' are entitled to be entered in the Register of certificates of specific character and protected at Community level under Article 13(1) of Regulation (EEC) No 2082/92 as traditional specialities guaranteed. This does not prevent the names from continuing to be used in accordance with specifications other than those which are protected provided that the labelling does not bear the Community symbol or indication.

(7) Protection has been requested solely for the Spanish version of the name 'Leche certificada de Granja' and for the English version of the name 'Traditional Farmfresh Turkey'. Therefore, in accordance with Council Directive 79/112/EEC [3], as last amended by Commission Directive 1999/10/EC [4], on the labelling of foodstuffs, when these two products are marketed their labels must include in the other languages, immediately next to the name concerned, the words 'traditional Spanishstyle' or their equivalent for the former product and the equivalent of 'traditional Britishstyle' for the latter.

(8) As regards the name 'Traditional Farmfresh Turkey', in accordance with Directive 79/112/EEC on the labelling of foodstuffs the labelling and in particular the information intended for consumers must in no case lead to confusion with the terms laid down for indicating types of farming in Commission Regulation (EEC) No 1538/91 of 5 June 1991 introducing detailed rules for implementing Regulation (EEC) No 1906/90 on certain marketing standards for poultry [5], as last amended by Regulation (EC) No 1072/2000 [6].

(9) The Annex to this Regulation supplements the Annex to Commission Regulation (EC) No 2301/97 [7], as last amended by Regulation (EC) No 2419/1999 [8].

(10) The measures provided for in this Regulation are in accordance with the opinion of the Regulatory Committee on Certificates of Specific Character,

HAS ADOPTED THIS REGULATION:

*Article 1*

The names in the Annex hereto are added to the Annex to Regulation (EC) No 2301/97 and entered in the Register of certificates of specific character in accordance with Article 9(1) of Regulation (EEC) No 2082/92.

They shall be protected in accordance with Article 13(1) of that Regulation.

[1] OJ L 208, 24.7.1992, p. 9.
[2] OJ C 21, 21.1.1997, p. 15 and OJ C 405, 24.12.1998, p. 9.
[3] OJ L 33, 8.2.1979, p. 1.
[4] OJ L 69, 16.3.1999, p. 22.
[5] OJ L 143, 7.6.1991, p. 11.
[6] OJ L 119, 20.5.2000, p. 21.
[7] OJ L 319, 21.11.1997, p. 8.
[8] OJ L 291, 13.11.1999, p. 25.

When marketing 'Leche certificada de Granja' in languages other than Spanish:

— the label must include the expression 'traditional Spanish-style' in English (or its equivalent in the other languages).

When marketing 'Traditional Farmfresh Turkey' in languages other than English:

— the label must include an expression equivalent to: 'traditional British-style'.

*Article 2*

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

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

Done at Brussels, 6 July 2000.

*For the Commission*

Franz FISCHLER

*Member of the Commission*

*ANNEX*

— Leche certificada de Granja

— Traditional Farmfresh Turkey

# COMMISSION REGULATION (EC) No 1483/2000
## of 6 July 2000
## on the issue of import licences for garlic originating in China

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables [1], as last amended by Regulation (EC) No 1257/1999 [2],

Having regard to Commission Regulation (EC) No 1104/2000 of 25 May 2000 concerning a protective measure applicable to imports of garlic from China [3], and in particular Article 1(3) thereof,

Whereas:

(1) Pursuant to Commission Regulation (EEC) No 1859/93 [4], as amended by Regulation (EC) No 1662/94 [5], the release for free circulation in the Community of garlic imported from third countries is subject to presentation of an import licence.

(2) Article 1(1) of Regulation (EC) No 1104/2000, restricts the issue of import licences for garlic originating in China to a maximum monthly quantity in the case of applications lodged from 29 May 2000 to 31 May 2001.

(3) Given the criteria laid down in Article 1(2) of that Regulation and the import licences already issued, the quantity applied for on 3 July 2000 is in excess of the maximum quantity given in the Annex to that Regulation for the month of July 2000. It is therefore necessary to determine to what extent import licences may be issued in response to these applications. The issue of licences in response to applications lodged after 3 July 2000 and before 31 July 2000 should be refused,

HAS ADOPTED THIS REGULATION:

*Article 1*

Import licences applied for from 3 July 2000 pursuant to Article 1 of Regulation (EEC) No 1859/93 for garlic falling within CN code 0703 20 00 originating in China shall be issued for 0,638 % of the quantity applied for, having regard to the information available to the Commission on 5 July 2000.

For the abovementioned products applications for import licences lodged after 3 July 2000 and before 31 July 2000 shall be refused.

*Article 2*

This Regulation shall enter into force on 7 July 2000.

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

Done at Brussels, 6 July 2000.

*For the Commission*
Franz FISCHLER
*Member of the Commission*

[1] OJ L 297, 21.11.1996, p. 1.
[2] OJ L 160, 26.6.1999, p. 80.
[3] OJ L 125, 26.5.2000, p. 21.
[4] OJ L 170, 13.7.1993, p. 10.
[5] OJ L 176, 9.7.1994, p. 1.

# COMMISSION REGULATION (EC) No 1484/2000
## of 6 July 2000
## fixing the import duties in the rice sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice [1], as last amended by Regulation (EC) No 2072/98 [2],

Having regard to Commission Regulation (EC) No 1503/96 of 29 July 1996 laying down detailed rules for the application of Council Regulation (EC) No 3072/95 as regards import duties in the rice sector [3], as last amended by Regulation (EC) No 2831/98 [4], and in particular Article 4(1) thereof,

Whereas:

(1) Article 11 of Regulation (EC) No 3072/95 provides that the rates of duty in the Common Customs Tariff are to be charged on import of the products referred to in Article 1 of that Regulation; whereas, however, in the case of the products referred to in paragraph 2 of that Article, the import duty is to be equal to the intervention price valid for such products on importation and increased by a certain percentage according to whether it is husked or milled rice, minus the cif import price provided that duty does not exceed the rate of the Common Customs Tariff duties.

(2) Pursuant to Article 12(3) of Regulation (EC) No 3072/95, the cif import prices are calculated on the basis of the representative prices for the product in question on the world market or on the Community import market for the product.

(3) Regulation (EC) No 1503/96 lays down detailed rules for the application of Regulation (EC) No 3072/95 as regards import duties in the rice sector.

(4) The import duties are applicable until new duties are fixed and enter into force; whereas they also remain in force in cases where no quotation is available from the source referred to in Article 5 of Regulation (EC) No 1503/96 during the two weeks preceding the next periodical fixing.

(5) In order to allow the import duty system to function normally, the market rates recorded during a reference period should be used for calculating the duties.

(6) Application of Regulation (EC) No 1503/96 results in import duties being fixed as set out in the Annexes to this Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The import duties in the rice sector referred to in Article 11(1) and (2) of Regulation (EC) No 3072/95 shall be those fixed in Annex I to this Regulation on the basis of the information given in Annex II.

*Article 2*

This Regulation shall enter into force on 7 July 2000.

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

Done at Brussels, 6 July 2000.

*For the Commission*

Franz FISCHLER

*Member of the Commission*

[1] OJ L 329, 30.12.1995, p. 18.
[2] OJ L 265, 30.9.1998, p. 4.
[3] OJ L 189, 30.7.1996, p. 71.
[4] OJ L 351, 29.12.1998, p. 25.

*ANNEX I*

**Import duties on rice and broken rice**

*(EUR/t)*

| CN code | Duties [5] | | | | |
|---|---|---|---|---|---|
| | Third countries (except ACP and Bangladesh) [3] | ACP [1] [2] [3] | Bangladesh [4] | Basmati India and Pakistan [6] | Egypt [8] |
| 1006 10 21 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 23 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 25 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 27 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 92 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 94 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 96 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 10 98 | [7] | 69,51 | 101,16 | | 158,25 |
| 1006 20 11 | 154,31 | 49,67 | 72,82 | | 115,73 |
| 1006 20 13 | 154,31 | 49,67 | 72,82 | | 115,73 |
| 1006 20 15 | 154,31 | 49,67 | 72,82 | | 115,73 |
| 1006 20 17 | 242,01 | 80,36 | 116,67 | 0,00 | 181,51 |
| 1006 20 92 | 154,31 | 49,67 | 72,82 | | 115,73 |
| 1006 20 94 | 154,31 | 49,67 | 72,82 | | 115,73 |
| 1006 20 96 | 154,31 | 49,67 | 72,82 | | 115,73 |
| 1006 20 98 | 242,01 | 80,36 | 116,67 | 0,00 | 181,51 |
| 1006 30 21 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 23 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 25 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 27 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 42 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 44 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 46 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 48 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 61 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 63 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 65 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 67 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 92 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 94 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 96 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 30 98 | [7] | 133,21 | 193,09 | | 312,00 |
| 1006 40 00 | [7] | 41,18 | [7] | | 96,00 |

[1] The duty on imports of rice originating in the ACP States is applicable, under the arrangements laid down in Council Regulation (EC) No 1706/98 (OJ L 215, 1.8.1998, p. 12) and amended Commission Regulation (EC) No 2603/97 (OJ L 351, 23.12.1997, p. 22).

[2] In accordance with Regulation (EC) No 1706/98, the duties are not applied to products originating in the African, Caribbean and Pacific States and imported directly into the overseas department of Réunion.

[3] The import levy on rice entering the overseas department of Réunion is specified in Article 11(3) of Regulation (EC) No 3072/95.

[4] The duty on imports of rice not including broken rice (CN code 1006 40 00), originating in Bangladesh is applicable under the arrangements laid down in Council Regulation (EEC) No 3491/90 (OJ L 337, 4.12.1990, p. 1) and amended Commission Regulation (EEC) No 862/91 (OJ L 88, 9.4.1991, p. 7).

[5] No import duty applies to products originating in the OCT pursuant to Article 101(1) of amended Council Decision 91/482/EEC (OJ L 263, 19.9.1991, p. 1).

[6] For husked rice of the Basmati variety originating in India and Pakistan, a reduction of EUR/t 250 applies (Article 4a of amended Regulation (EC) No 1503/96).

[7] Duties fixed in the Common Customs Tariff.

[8] The duty on imports of rice originating in and coming from Egypt is applicable under the arrangements laid down in Council Regulation (EC) No 2184/96 (OJ L 292, 15.11.1996, p. 1) and Commission Regulation (EC) No 196/97 (OJ L 31, 1.2.1997, p. 53).

*ANNEX II*

**Calculation of import duties for rice**

| | Paddy | Indica rice | | Japonica rice | | Broken rice |
|---|---|---|---|---|---|---|
| | | Husked | Milled | Husked | Milled | |
| 1. Import duty (EUR/tonne) | (1) | 242,01 | 416,00 | 154,31 | 416,00 | (1) |
| 2. Elements of calculation: | | | | | | |
| (a) Arag cif price (EUR/tonne) | — | 309,42 | 274,00 | 421,63 | 310,48 | — |
| (b) fob price (EUR/tonne) | — | — | — | 390,01 | 278,86 | — |
| (c) Sea freight (EUR/tonne) | — | — | — | 31,62 | 31,62 | — |
| (d) Source | — | USDA | USDA | Operators | Operators | — |

(1) Duties fixed in the Common Customs Tariff.

# COMMISSION REGULATION (EC) No 1485/2000
## of 6 July 2000
## fixing the export refunds on rice and broken rice and suspending the issue of export licences

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ([1]), as last amended by Regulation (EC) No 2072/98 ([2]), and in particular the second subparagraph of Article 13(3) and (15) thereof,

Whereas:

(1) Article 13 of Regulation (EC) No 3072/95 provides that the difference between quotations or prices on the world market for the products listed in Article 1 of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) Article 13(4) of Regulation (EC) No 3072/95, provides that when refunds are being fixed account must be taken of the existing situation and the future trend with regard to prices and availabilities of rice and broken rice on the Community market on the one hand and prices for rice and broken rice on the world market on the other. The same Article provides that it is also important to ensure equilibrium and the natural development of prices and trade on the rice market and, furthermore, to take into account the economic aspect of the proposed exports and the need to avoid disturbances of the Community market with limits resulting from agreements concluded in accordance with Article 300 of the Treaty.

(3) Commission Regulation (EEC) No 1361/76 ([3]) lays down the maximum percentage of broken rice allowed in rice for which an export refund is fixed and specifies the percentage by which that refund is to be reduced where the proportion of broken rice in the rice exported exceeds that maximum.

(4) Article 13(5) of Regulation (EC) No 3072/95 defines the specific criteria to be taken into account when the export refund on rice and broken rice is being calculated.

(5) The world market situation or the specific requirements of certain markets may make it necessary to vary the refund for certain products according to destination.

(6) A separate refund should be fixed for packaged long grain rice to accommodate current demand for the product on certain markets.

(7) The refund must be fixed at least once a month; whereas it may be altered in the intervening period.

(8) It follows from applying these rules and criteria to the present situation on the market in rice and in particular to quotations or prices for rice and broken rice within the Community and on the world market, that the refund should be fixed as set out in the Annex hereto.

(9) For the purposes of administering the volume restrictions resulting from Community commitments in the context of the WTO, the issue of export licences with advance fixing of the refund should be restricted.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

*Article 1*

The export refunds on the products listed in Article 1 of Regulation (EC) No 3072/95 with the exception of those listed in paragraph 1(c) of that Article, exported in the natural state, shall be as set out in the Annex hereto.

*Article 2*

The issue of export licences with advance fixing of the refund is suspended.

*Article 3*

This Regulation shall enter into force on 7 July 2000.

([1]) OJ L 329, 30.12.1995, p. 18.
([2]) OJ L 265, 30.9.1998, p. 4.
([3]) OJ L 154, 15.6.1976, p. 11.

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

Done at Brussels, 6 July 2000.

*For the Commission*
Franz FISCHLER
*Member of the Commission*

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*ANNEX*

**to the Commission Regulation of 6 July 2000 fixing the export refunds on rice and broken rice and suspending the issue of export licences**

*(EUR/t)*

| Product code | Destination (1) | Amount of refunds |
|---|---|---|
| 1006 20 11 9000 | 01 | 95,00 |
| 1006 20 13 9000 | 01 | 95,00 |
| 1006 20 15 9000 | 01 | 95,00 |
| 1006 20 17 9000 | — | — |
| 1006 20 92 9000 | 01 | 95,00 |
| 1006 20 94 9000 | 01 | 95,00 |
| 1006 20 96 9000 | 01 | 95,00 |
| 1006 20 98 9000 | — | — |
| 1006 30 21 9000 | 01 | 95,00 |
| 1006 30 23 9000 | 01 | 95,00 |
| 1006 30 25 9000 | 01 | 95,00 |
| 1006 30 27 9000 | — | — |
| 1006 30 42 9000 | 01 | 95,00 |
| 1006 30 44 9000 | 01 | 95,00 |
| 1006 30 46 9000 | 01 | 95,00 |
| 1006 30 48 9000 | — | — |
| 1006 30 61 9100 | 01 | 119,00 |
| | 02 | 125,00 |
| | 03 | 130,00 |
| | 04 | 125,00 |
| | 05 | 125,00 |
| 1006 30 61 9900 | 01 | 119,00 |
| | 04 | 125,00 |
| 1006 30 63 9100 | 01 | 119,00 |
| | 02 | 125,00 |
| | 03 | 130,00 |
| | 04 | 125,00 |
| | 05 | 125,00 |
| 1006 30 63 9900 | 01 | 119,00 |
| | 04 | 125,00 |
| 1006 30 65 9100 | 01 | 119,00 |
| | 02 | 125,00 |
| | 03 | 130,00 |
| | 04 | 125,00 |
| | 05 | 125,00 |
| 1006 30 65 9900 | 01 | 119,00 |
| | 04 | 125,00 |
| 1006 30 67 9100 | 05 | 125,00 |
| 1006 30 67 9900 | — | — |
| 1006 30 92 9100 | 01 | 119,00 |
| | 02 | 125,00 |
| | 03 | 130,00 |
| | 04 | 125,00 |
| | 05 | 125,00 |
| 1006 30 92 9900 | 01 | 119,00 |
| | 04 | 125,00 |
| 1006 30 94 9100 | 01 | 119,00 |
| | 02 | 125,00 |
| | 03 | 130,00 |
| | 04 | 125,00 |
| | 05 | 125,00 |
| 1006 30 94 9900 | 01 | 119,00 |
| | 04 | 125,00 |
| 1006 30 96 9100 | 01 | 119,00 |
| | 02 | 125,00 |
| | 03 | 130,00 |
| | 04 | 125,00 |
| | 05 | 125,00 |
| 1006 30 96 9900 | 01 | 119,00 |
| | 04 | 125,00 |
| 1006 30 98 9100 | 05 | 125,00 |
| 1006 30 98 9900 | — | — |
| 1006 40 00 9000 | — | — |

(1) The destinations are identified as follows:
01 Liechtenstein, Switzerland, the communes of Livigno and Campione d'Italia,
02 Zones I, II, III, VI, excluding Turkey,
03 Zones IV, V, VII(c), Canada and Zone VIII excluding Suriname, Guyana and Madagascar,
04 Destinations mentioned in Article 34 of amended Commission Regulation (EEC) No 3665/87,
05 Ceuta and Melilla.

*NB:* The zones are those defined in the Annex to amended Commission Regulation (EEC) No 2145/92.

# COMMISSION REGULATION (EC) No 1486/2000

## of 6 July 2000

## fixing the rates of the refunds applicable to certain cereal and rice-products exported in the form of goods not covered by Annex I to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]), as last amended by Commission Regulation (EC) No 1253/1999 ([2]), and in particular Article 13(3) thereof,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ([3]), as amended by Regulation (EC) No 2072/98 ([4]), and in particular Article 13(3) thereof,

Whereas:

(1) Article 13(1) of Regulation (EEC) No 1766/92 and Article 13(1) of Regulation (EC) No 3072/95 provide that the difference between quotations of prices on the world market for the products listed in Article 1 of each of those Regulations and the prices within the Community may be covered by an export refund.

(2) Commission Regulation (EC) No 1222/94 of 30 May 1994 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds ([5]), as last amended by Regulation (EC) No 701/2000 ([6]), specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex B to Regulation (EEC) No 1766/92 or in Annex B to Regulation (EC) No 3072/95 as appropriate.

(3) In accordance with the first subparagraph of Article 4(1) of Regulation (EC) No 1222/94, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month.

(4) The commitments entered into with regard to refunds which may be granted for the export of agricultural products contained in goods not covered by Annex I to the Treaty may be jeopardised by the fixing in advance of high refund rates. Whereas it is therefore necessary to take precautionary measures in such situations without, however, preventing the conclusion of long-term contracts. Whereas the fixing of a specific refund rate for the advance fixing of refunds is a measure which enables these various objectives to be met.

(5) Now that a settlement has been reached between the European Community and the United States of America on Community exports of pasta products to the United States and has been approved by Council Decision 87/482/EEC ([7]), it is necessary to differentiate the refund on goods falling within CN codes 1902 11 00 and 1902 19 according to their destination.

(6) Article 4(5)(b) of Regulation (EC) No 1222/94 provides that, in the absence of the proof referred to in Article 4(5)(a) of that Regulation, a reduced rate of export refund has to be fixed, taking account of the amount of the production refund applicable, pursuant to Commission Regulation (EEC) No 1722/93 ([8]), as last amended by Regulation (EC) No 87/1999 ([9]), for the basic product in question, used during the assumed period of manufacture of the goods.

(7) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.

(8) The Management Committee for Cereals has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

*Article 1*

The rates of the refunds applicable to the basic products appearing in Annex A to Regulation (EC) No 1222/94 and listed either in Article 1 of Regulation (EEC) No 1766/92 or in Article 1(1) of Regulation (EC) No 3072/95, exported in the form of goods listed in Annex B to Regulation (EEC) No 1766/92 or in Annex B to amended Regulation (EC) No 3072/95 respectively, are hereby fixed as shown in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on 7 July 2000.

([1]) OJ L 181, 1.7.1992, p. 21.
([2]) OJ L 160, 26.6.1999, p. 18.
([3]) OJ L 329, 30.12.1995, p. 18.
([4]) OJ L 265, 30.9.1998, p. 4.
([5]) OJ L 136, 31.5.1994, p. 5.
([6]) OJ L 83, 4.4.2000, p. 6.
([7]) OJ L 275, 29.9.1987, p. 36.
([8]) OJ L 159, 1.7.1993, p. 112.
([9]) OJ L 9, 15.1.1999, p. 8.

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

Done at Brussels, 6 July 2000.

*For the Commission*
Erkki LIIKANEN
*Member of the Commission*

*ANNEX*

**to the Commission Regulation of 6 July 2000 fixing the rates of the refunds applicable to certain cereals and rice products exported in the form of goods not covered by Annex I to the Treaty**

*(EUR/100 kg)*

| CN code | Description of products (1) | Rate of refund per 100 kg of basic product | |
|---|---|---|---|
| | | In case of advance fixing of refunds | Other |
| 1001 10 00 | Durum wheat: | | |
| | – on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America | — | — |
| | – in other cases | — | — |
| 1001 90 99 | Common wheat and meslin: | | |
| | – on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America | — | — |
| | – in other cases: | | |
| | – – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2) | — | — |
| | – – in other cases | — | — |
| 1002 00 00 | Rye | 3,394 | 3,394 |
| 1003 00 90 | Barley | — | — |
| 1004 00 00 | Oats | 2,511 | 2,511 |
| 1005 90 00 | Maize (corn) used in the form of: | | |
| | – starch: | | |
| | – – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2) | 2,635 | 2,635 |
| | – – in other cases | 5,373 | 5,373 |
| | – glucose, glucose syrup, maltodextrine, maltodextrine syrup of CN codes 1702 30 51, 1702 30 59, 1702 30 91, 1702 30 99, 1702 40 90, 1702 90 50, 1702 90 75, 1702 90 79, 2106 90 55 (3): | | |
| | – – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2) | 1,292 | 1,292 |
| | – – in other cases | 4,030 | 4,030 |
| | – other (including unprocessed) | 5,373 | 5,373 |
| | Potato starch of CN code 1108 13 00 similar to a product obtained from processed maize: | | |
| | – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2) | 2,635 | 2,635 |
| | – in other cases | 5,373 | 5,373 |
| ex 1006 30 | Wholly-milled rice: | | |
| | – round grain | 11,938 | 11,938 |
| | – medium grain | 11,938 | 11,938 |
| | – long grain | 11,938 | 11,938 |
| 1006 40 00 | Broken rice | 2,770 | 2,770 |
| 1007 00 90 | Sorghum | — | — |

(1) As far as agricultural products obtained from the processing of a basic product or/and assimilated products are concerned, the coefficients shown in Annex E of amended Commission Regulation (EC) No 1222/94 shall be applied (OJ L 136, 31.5.1994, p. 5).

(2) The goods concerned are listed in Annex I of amended Regulation (EEC) No 1722/93 (OJ L 159, 1.7.1993, p. 112).

(3) For syrups of CN codes NC 1702 30 99, 1702 40 90 and 1702 60 90, obtained from mixing glucose and fructose syrup, the export refund may be granted only for the glucose syrup.

II

*(Acts whose publication is not obligatory)*

# COUNCIL

## COUNCIL DECISION

## of 19 June 2000

## in accordance with Article 122(2) of the Treaty on the adoption by Greece of the single currency on 1 January 2001

(2000/427/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 122(2), thereof,

Having regard to the proposal from the Commission [1],

Having regard to the report from the Commission [2],

Having regard to the report from the European Central Bank [3],

Having regard to the opinion of the European Parliament,

Having regard to the discussion of the Council, meeting in the composition of Heads of State or Government,

Whereas:

(1) The third stage of economic and monetary union (EMU) started on 1 January 1999. The Council, meeting in Brussels on 3 May 1998 in the composition of Heads of State or Government, decided that Belgium, Germany, Spain, France, Ireland, Italy, Luxembourg, the Netherlands, Austria, Portugal and Finland fulfilled the necessary conditions for adopting the single currency on 1 January 1999 [4].

(2) In accordance with paragraph 1 of the Protocol on certain provisions relating to the United Kingdom of Great Britain and Northern Ireland annexed to the Treaty, the United Kingdom notified the Council that it did not intend to move to the third stage of EMU on 1 January 1999. This notification has not been changed. In accordance with paragraph 1 of the Protocol on certain provisions relating to Denmark annexed to the Treaty and the Decision taken by the Heads of State or Government in Edinburgh in December 1992, Denmark has notified the Council that it will not participate in the third stage of EMU. Denmark has not requested that the procedure referred to in Article 122(2) of the Treaty be initiated.

(3) By virtue of Decision 1998/317/EC Greece and Sweden have a derogation as defined in Article 122 of the Treaty.

(4) The European Central Bank (ECB) was established on 1 July 1998. The European Monetary System has been replaced by an exchange rate mechanism, the setting-up of which was agreed by a resolution of the European Council on the establishment of an exchange-rate mechanism in the third stage of economic and monetary union of 16 June 1997 [5]. The procedures for an exchange-rate mechanism in stage three of economic and monetary union (ERM II) were laid down in the Agreement of 1 September 1998 between the ECB and the national central banks of the Member States outside the euro area laying down the operating procedures for an exchange rate mechanism in stage three of economic and monetary union [6].

(5) Article 122(2) of the Treaty lays down the procedures for abrogation of the derogation of the Member States concerned. According to that Article at least once every two years, or at the request of a Member State with a derogation, the Commission and the ECB shall report to the Council in accordance with the procedure laid down in Article 121(1) of the Treaty. Such reports have to be prepared in 2000. On 9 March 2000 Greece made such a request.

[1] Opinion delivered on 8 May 2000 (not yet published in the Official Journal).
[2] Opinion delivered on 5 May 2000 (not yet published in the Official Journal).
[3] Opinion delivered on 28 April 2000 (not yet published in the Official Journal).
[4] Council Decision 1998/317/EC of 3 May 1998 in accordance with Article 121(4) of the Treaty (Oj L 139, 11.5.1998, p. 30).
[5] OJ C 236, 2.8.1997, p. 5.
[6] OJ C 345, 13.11.1998, p. 6.

(6) National legislation in the Member States including the statutes of national central banks shall as necessary be adapted with a view to ensuring compatibility with Articles 108 and 109 of the Treaty and the Statute of the ESCB. The reports of the Commission and the ECB provide a detailed assessment of the compatibility of the legislation of Greece and Sweden with Articles 108 and 109 of the Treaty and the Statute of the ESCB.

(7) According to Article 1 of the Protocol on the convergence criteria referred to in Article 121 of the Treaty establishing the European Community, the criterion on price stability referred to in the first indent of Article 121 (1) of the Treaty means that a Member State has a price performance that is sustainable and an average rate of inflation, observed over a period of one year before the examination, that does not exceed by more than one and a half percentage points that of, at most, the three best performing Member States in terms of price stability. For the purpose of the criterion on price stability inflation will be measured by the harmonised indices of consumer prices (HICPs) defined in Council Regulation (EC) No 2494/95 [1]. In order to assess the price stability criterion a Member State's inflation has been measured by the percentage change in the arithmetic average of 12 monthly indices relative to the arithmetic average of 12 monthly indices of the previous period. In the one year period ending in March 2000 the three best performing Member States in terms of price stability were France, Austria and Sweden, with inflation rates of, respectively 0,9 %, 0,9 % and 0,8 %. A reference value calculated as the simple arithmetic average of the inflation rates of the three best performing Member States in terms of price stability plus 1,5 percentage points was considered in the reports of the Commission and the ECB. On this basis, the reference value in the one year period ending in March 2000 was 2,4 %.

(8) According to Article 2 of the Protocol on the convergence criteria referred to in Article 121 of the Treaty establishing the European Community, the criterion on the government budgetary position referred to in the second indent of Article 121(1) of the Treaty shall mean that at the time of the examination the Member State is not the subject of a Council decision under Article 104(6) of the Treaty that an excessive deficit exists.

(9) According to Article 3 of the Protocol on the convergence criteria referred to in Article 121 of the Treaty establishing the European Community, the criterion on participation in the exchange-rate mechanism of the European Monetary System referred to in the third indent of Article 121(1) of the Treaty means that a Member State has respected the normal fluctuation margins provided for by the exchange-rate mechanism (ERM) of the European Monetary System without severe tensions for at least the last two years before the examination. In particular, the Member State must not have devalued its currency's bilateral central rate against any other Member State's currency on its own initiative for the same period. Since 1 January 1999 the ERM II provides the framework for assessing the fulfilment of the exchange rate criterion. In assessing the fulfilment of this criterion in their reports, the Commission and the ECB have examined the two-year period ending in March 2000.

(10) According to Article 4 of the Protocol on the convergence criteria referred to in Article 121 of the Treaty establishing the European Community, the criterion on the convergence of interest rates referred to in the fourth indent of Article 121(1) of the Treaty means that, observed over a period of one year before the examination, a Member State has had an average nominal long-term interest rate that does not exceed by more than two percentage points that of, at most, the three best performing Member States in terms of price stability. For the purpose of the criteria on the convergence of interest rates, comparable interest rates on 10-year benchmark government bonds were used. In order to assess the fulfilment of the interest-rate criterion a reference value calculated as the simple arithmetic average of the nominal long-term interest rates of the three best performing Member States in terms of price stability plus two percentage points was considered in the reports of the Commission and the ECB. On this basis, the reference value in the one year period ending in March 2000 was 7,2 %.

(11) In accordance with Article 5 of the Protocol on the convergence criteria referred to in Article 121 of the Treaty establishing the European Community, the data used in the current assessment of the fulfilment of the convergence criteria will be provided by the Commission. For the preparation of this proposal the Commission provided data. Budgetary data were provided by the Commission after reporting by the Member States by 1 March 2000 in accordance with Council Regulation (EC) No 3605/93 of 22 November 1993 on the application of the Protocol on the excessive deficit procedure annexed to the Treaty establishing the European Community [2].

(12) The Greek domestic legislation, including the Statute of the national central bank, is compatible with Articles 108 and 109 of the Treaty and the Statute of the ESCB.

Regarding the fulfilment by Greece of the convergence criteria mentioned in the four indents of Article 121(1) of the Treaty:

— the average inflation rate in Greece in the year ending March 2000 stood at 2,0 % which is below the reference value,

[1] Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices (OJ L 257, 27.10.1995, p. 1).

[2] OJ L 332, 31.12.1993, p. 7. Regulation as amended by Council Regulation (EC) No 475/2000 (OJ L 58, 3.3.2000, p. 1).

— by virtue of Council Decision 2000/33/EC of 17 December 1999 abrogating the Decision on the existence of an excessive deficit in Greece [1], Greece is not the subject of a Council Decision on the existence of an excessive government deficit,

— Greece has been a member of the ERM and subsequently of ERM II during the last two years. In that period the Greek drachma (GRD) has not been subject to severe tensions and Greece has not devalued, on its own initiative, the GRD bilateral central rate against any other Member State's currency up to 1 January 1999 nor against the euro since then,

— in the year ending March 2000 the long-term interest rate in Greece was, on average, 6,4 % which is below the reference value.

Greece has achieved a high degree of sustainable convergence by reference to all four criteria.

Consequently, Greece fulfils the necessary conditions for the adoption of a single currency.

(13) The Council, acting by qualified majority on a proposal by the Commission, shall decide which Member States with a derogation fulfil the necessary conditions for the adoption of the single currency and abrogate the derogations of the Member States concerned,

HAS ADOPTED THIS DECISION:

*Article 1*

Greece fulfils the necessary conditions for the adoption of the single currency. The derogation in favour of Greece laid down in recital 4 of Decision 98/317/EC shall be abrogated with effect from 1 January 2001.

*Article 2*

This Decision is addressed to the Member States.

Done at Santa Maria da Feira, 19 June 2000.

*For the Council*

*The President*

J. PINA MOURA

[1] OJ L 12, 18.1.2000, p. 24.

# COMMISSION

## COMMISSION DECISION

**of 4 July 2000**

**establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease**

*(notified under document number C(2000) 1805)*

**(Text with EEA relevance)**

(2000/428/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease [1], as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Annex II, paragraph 3 thereof,

Whereas:

(1) It is necessary to lay down at Community level diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation of swine vesicular disease and a rapid differentiation from foot-and-mouth disease, in order that an improved control of both diseases can be ensured.

(2) Annex III of Council Directive 92/119/EEC lays down the functions and duties of the Community reference laboratory for swine vesicular disease in order to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease; these functions and duties include the organisation of periodic comparative tests and the supplying of standard reagents at Community level.

(3) Laboratory tests have been recently developed to ensure that swine vesicular disease is quickly diagnosed and distinguished from foot-and-mouth disease.

(4) The results of the most recent comparative tests performed at Community level suggest, in particular, that reliable tests have been developed to detect the antigen or the genome of swine vesicular disease virus and that these tests can successfully supplement the virus isolation test for the virological diagnosis of swine vesicular disease.

(5) The experiences gained in the control of swine vesicular disease in recent years have resulted in the identification of the most suitable sampling procedures and criteria for evaluation of the results of the laboratory tests for a proper diagnosis of this disease in different situations.

(6) The opinion and recommendations of the Scientific Committee on animal health and welfare on swine vesicular disease have been taken into account.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

*Article 1*

1. Member States shall ensure that the confirmation of swine vesicular disease and the differential diagnosis with foot-and-mouth disease are based on:

(a) the detection of clinical signs of disease;

[1] OJ L 62, 15.3.1993, p. 69.

(b) the detection of virus, antigen or genome in samples of epithelium tissue, vesicular fluid or faeces;

(c) the demonstration of a specific antibody response in serum samples,

in accordance with the procedures, sampling methods and criteria for evaluation of the results of laboratory tests laid down in the Manual annexed to this Decision.

2. However, the national diagnostic laboratories referred to in Annex II(5) to Directive 92/119/EEC may apply modifications to the laboratory tests referred to in the Manual annexed to this Decision or use different tests, provided that an equal sensitivity and specificity can be demonstrated.

The sensitivity and specificity of these modified or different tests must be evaluated in the framework of the periodic comparative tests organised by the Community Reference Laboratory for swine vesicular disease.

*Article 2*

This Decision shall apply from 1 October 2000.

*Article 3*

This Decision is addressed to the Member States.

Done at Brussels, 4 July 2000.

*For the Commission*

David BYRNE

*Member of the Commission*

*ANNEX*

# MANUAL OF DIAGNOSTIC PROCEDURES, SAMPLING METHODS AND CRITERIA FOR THE EVALUATION OF THE RESULTS OF LABORATORY TESTS FOR THE CONFIRMATION AND DIFFERENTIAL DIAGNOSIS OF SWINE VESICULAR DISEASE

## CHAPTER I

### *Introduction, objectives and definitions*

1. This Manual:

   (a) provides for guidelines and minimum requirements on diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for a proper diagnosis of swine vesicular disease. However, particular emphasis is also on the differential diagnosis with foot-and-mouth disease;

   (b) integrates the provisions of Annex II to Directive 92/119/EEC, and in particular of paragraphs 4, 7 and 8 of the said Annex;

   (c) is principally directed towards the authorities responsible for the control of swine vesicular disease. Therefore, emphasis is on the principles and applications of laboratory tests and evaluation of their results and not on detailed laboratory techniques.

2. For the purpose of this Manual the following definitions shall apply:

   (a) 'seropositive pig' means any pig whose serum has an antibody titre equal to or greater than the swine vesicular disease Reference Serum 4 referred to in Chapter X in the virus neutralisation test used by the National Laboratory;

   (b) 'singleton reactor' means any single seropositive pig in a holding which yields a positive result in serological tests for swine vesicular disease, but which has no history of contact with swine vesicular disease virus and from which there is no evidence of spread of infection to in-contact pigs. A seropositive pig is confirmed to be a singleton reactor if the conditions referred to in Chapter VIII(C) are fulfilled;

   (c) 'in-contact pigs' means the pigs which have direct contact, or have had direct contact within the last 28 days, with one or more seropositive pigs or with one or more pigs suspected to be infected with swine vesicular disease virus. In-contact pigs may be, or may have been, in the same pen or in adjacent pens if there is the possibility of pig-to-pig contact between pens.

## CHAPTER II

### *Guidelines for checks on pigs showing clinical signs of swine vesicular disease*

1. Member States shall ensure that when the presence of swine vesicular disease virus is suspected in a holding, a statistically significant number of pigs are checked by the official veterinarian as quickly as possible to detect the clinical signs of disease referred to in Chapter IX.

2. Member States shall ensure that when pigs show clinical signs suggesting swine vesicular disease or foot-and-mouth disease, differential diagnosis by means of appropriate sampling and laboratory investigations is carried out as quickly as possible, in accordance with the provisions referred to in Chapters IV, VII and VIII of this Manual.

## CHAPTER III

### *General procedures for sampling and transport of samples*

1. Any person entering or leaving pig holdings where there is a suspicion of swine vesicular disease must observe the strictest hygienic measures necessary to reduce the risk of contamination or spread of virus.

2. All pigs sampled must be uniquely marked in such a way that they can be identified for eventual re-sampling. It is recommended that the location of each pig sampled in the holding is recorded together with its unique identification mark, in particular if suspect pigs are sampled.

3. The samples must be sent to the laboratory accompanied by appropriate forms, which will include details of the history of the pigs sampled and the clinical signs observed, if any.

4. Since any vesicular condition in pigs may be foot and mouth disease, special precautions must be taken for the safe packaging of suspected samples. These precautions must be mainly designed to prevent breakage or leakage of containers and the risk of contamination but are also important to ensure that specimens arrive in a satisfactory state. If wet ice is put inside a package escape of water must be prevented. No containers with samples suspected to contain swine vesicular disease virus must be opened once they leave the infected premises and until they arrive to the laboratory.

5. Samples suspected to contain swine vesicular disease virus must only be analysed in a laboratory authorised to handle foot-and-mouth disease virus for diagnostic purposes, in accordance with Community legislation on the control of foot-and-mouth disease, unless foot-and-mouth disease has already been ruled out.

6. All samples can be transported at 4 °C if the anticipated transport time to the recipient laboratory is less than 48 hours, or otherwise they must be maintained at a temperature of not more than −20 °C.

7. For samples destined for the Community reference laboratory from Member States other than the United Kingdom the only permitted method of transport is by airfreight to London (Heathrow) or London (Gatwick) airports. Before shipment the laboratory must be informed by fax ((44-1483) 23 26 21) or e-mail of the details of airline flight, date, expected time of arrival and the airwaybill number so that the parcel can be located on arrival. The parcel must be addressed to:

   Institute for Animal Health, Pirbright Laboratory
   Community Reference Laboratory for swine vesicular disease
   Ash Road, Pirbright, Woking
   Surrey GU24 ONF
   United Kingdom, UK

   The following information must also be included on the label: 'Animal pathological material of no commercial value. Perishable. Fragile. To be collected at airport by addressee. Not to be opened outside the laboratory.'

   Authorised collection of consignments at the airport is made by personnel from the Community reference laboratory, under a special general import permit issued for this purpose by the United Kingdom Ministry of Agriculture, Food and Fisheries. This is a standing arrangement, a separate licence is not required for each importation. The hand carriage of suspected vesicular material into the United Kingdom by unauthorised personnel is not permitted. Courier companies must not be used.

8. Transportation of samples to the national laboratories must be in accordance with the instructions laid down by the competent authority of the Member States.

## CHAPTER IV

### *Sampling procedures in a holding with clinical suspect pigs*

1. When the presence of swine vesicular disease virus in a holding is suspected as clinical signs of disease have been observed, appropriate samples from representative groups of pigs showing these signs must be collected for disease confirmation and differential diagnosis with foot-and-mouth disease.

2. In these holdings the preferred samples for diagnosis are epithelium and vesicular fluid from unruptured or freshly ruptured vesicles collected from pigs showing the typical signs of disease, in which swine vesicular disease virus, its antigens or genome can be detected. It is recommended that about five or six of these pigs are sampled.

3. Even if fresh epithelial tissue and vesicular fluid in sufficient quantity (1g or more) are available, the following samples must also be collected:

   (a) blood samples from the suspected pigs and in-contact pigs for serological testing; and

   (b) faecal samples from suspected pigs and from the floor of their pen and of adjacent pens for virological testing.

4. The samples must be collected and transported in accordance with the following procedures:

   (a) for epithelium samples and vesicular fluid:

   — if possible, at least 1g of epithelium tissue from an unruptured or recently ruptured vesicle must be collected. It is recommended that pigs are sedated before samples are collected both to avoid injury to personnel as well as for pig welfare,

   — if transport to the national laboratory is carried out immediately (less than three hours), epithelial samples can be transported dry and kept refrigerated. However, if the time taken is likely to exceed three hours, the samples must be placed in a small volume of transport medium consisting of equal amounts of glycerol and 0,04 M phosphate buffer or other equivalent buffer (hepes), so that the pH is maintained in the optimal range for foot and mouth disease virus survival (pH from 7,2 to 7,6). The transport medium must contain antibiotics for additional anti-microbial activity. Suitable antibiotics and their concentration per ml final are:

     (i) penicillin 1 000 IU,

     (ii) neomycin sulphate 100 IU,

     (iii) polymyxin B sulphate 50 IU,

     (iv) mycostatin 100 IU,

   — if vesicular fluid can be collected from an unruptured vesicle, this must be kept undiluted in a separate container;

(b) for blood samples:

— blood samples can be collected for serological or virological tests. However, generally they are collected only from pigs suspected to have recovered from clinical or subclinical infection for antibody detection, as epithelium, vesicular fluid and faecal samples from pigs showing clinical signs of disease are more suitable for virus detection than blood samples. It is recommended that whole blood samples are taken using vacutainers with no anticoagulant and that the vacutainers are transported unopened;

(c) for faecal samples:

— faecal samples from the floor of premises suspected to contain, or to have contained, pigs infected with swine vesicular disease or faecal swabs and faecal samples from suspected live pigs must be placed in strong, leak-proof containers.

Containers of suspected samples must be disinfected on the outside before being transported to the laboratory. Suitable disinfectants are:

— sodium hydroxide (1:100 dilution),

— formalin (1:9 dilution of a solution of formalin containing a minimum of 34 % formaldehyde), and

— sodium hypochlorite (2 % available chlorine).

These disinfectants must be handled with care.

## CHAPTER V

### *Sampling procedures for swine vesicular disease serosurveillance*

1. When sero-surveillance is carried out with the following purposes:

(a) for surveillance in holdings where there is no evidence or suspicion that the disease might be present;

(b) for surveillance at the slaughterhouse, market, collecting centre or similar place by routine serological sampling;

(c) as non-discriminatory surveillance on pigs received from other Member States at the importing holding,

blood samples must be collected for serological testing from pigs in accordance either with the provisions laid down in the monitoring or eradication programmes or plans approved in the framework of Decision 90/424/EEC [1] or Directive 90/425/EEC [2], or, in the absence of these provisions, with the procedures established by the competent authority of the Member States.

2. When sero-surveillance is carried out with the following purposes:

(a) for surveillance of holdings located within the protection and surveillance zones, which have been established following confirmation of disease outbreaks in accordance with Annex II(7) and (8) to Directive 92/119/EEC; or

(b) for surveillance of the holdings referred to in Article 9 of Directive 92/119/EEC,

blood samples must be collected for serological testing from the pigs in accordance with the following scheme:

— in case of breeding holdings, a randomised sampling procedure must be carried out in such a way to detect 5 % prevalence of seroconversion with 95 % confidence;

— in case of holdings containing fattening pigs only, the sampling procedure must ensure that the total number of samples collected is at least equal to the number required to detect a prevalence of 5 % with 95 % confidence. In any case, the samples must be taken from as many random selected pens as possible;

— in case of mixed breeding and fattening holdings, each group of pigs living in separate premises must be sampled in such a way to detect a 5 % prevalence of seroconversion with 95 % confidence.

## CHAPTER VI

### *Further actions and re-sampling procedures in case of finding of seropositive pigs*

1. In case a single seropositive pig is detected on a holding following the surveillance referred to in Chapter V(1)(a) or V(2), the competent authority shall ensure that:

(a) if not already applied, the measures referred to in Article 4 of Directive 92/119/EEC are applied in this holding;

(b) a check is carried out in the holding in accordance with the provisions referred to in Chapter II(1);

[1] OJ L 224, 18.8.1990, p. 19.
[2] OJ L 224, 18.8.1990, p. 29.

(c) blood samples are collected for serological testing from:

— the suspect pig,

— in-contact pigs living in the same and in adjacent pens of the suspect pig; these pigs must be sampled in such a way to detect 50 % prevalence of seroconversion with 95 % confidence in the pen.

2. However, the competent authority may decide to lift the measures referred to in (1)(a) if:

(a) the epidemiological enquiry carried out in accordance with Article 8 of Directive 92/119/EEC suggests that swine vesicular disease has not been introduced in the holding;

(b) no clinical signs of swine vesicular disease have been detected in the holding; and

(c) the holding is not located in a surveillance or restriction zone established following a confirmed outbreak of disease or subject to other restrictions applied in relation to a confirmed outbreak of disease,

and provided that:

— no pigs are moved from the holding for intra-Community trade; and

— pigs from the holding in question are only moved to a slaughterhouse for immediate slaughter or to another holding from which no pigs are moved for intra-Community trade,

until the results of the further checks and serological tests indicate that swine vesicular disease can be definitely ruled out.

3. If the checks and the serological tests carried out in accordance with 1(b) and (c):

(a) give negative results or only the previously positive pig is confirmed positive (singleton reactor), swine vesicular disease can be ruled out. The measures referred to in 1(a) shall be lifted, unless the holding is located in a protection or surveillance zone established around an outbreak of disease where disease eradication measures must stay in force in accordance with Annex II(7) or (8) to Directive 92/119/EEC;

(b) indicate that more than one seropositive pig is present on the holding either swine vesicular disease must be confirmed or, if the conditions laid down in Annex II(4) of Directive 92/119/EEC are not fulfilled to confirm the presence of this disease, further samples must be taken from the holding in accordance with the sampling procedures referred to in (4).

4. In case more than one seropositive pig is detected on a holding following the sampling and the serological testing referred to in Chapter V(1)(a), (1)(c) or (2), but the conditions laid down in Annex II(4) to Directive 92/119/EEC are not fulfilled to confirm swine vesicular disease, the competent authority shall ensure that:

(a) the provisions referred to in Article 4 of Directive 92/119/EEC are applied or shall continue to apply;

(b) a check on the holding is carried out in accordance with the provisions referred to in Chapter II(1);

(c) blood samples for serological testing are further collected from the seropositive pigs and in-contact pigs in accordance with 1(c);

(d) blood samples for serological testing are collected from pigs in the other buildings of the holding in accordance with the procedure referred to in Chapter V(2);

(e) a sufficient number of faecal samples are collected for virological tests from:

— the seropositive pigs,

— the floor of the pens containing seropositive pigs and adjacent pens,

— random selected pens from other buildings on the holding.

Faecal samples collected in accordance with the first and the second indents above must be examined as soon as possible. In case these samples are negative but the results of the serological tests suggest that swine vesicular disease virus might have spread to others buildings, the faecal samples collected in accordance with the third indent above must also be examined;

If following these further checks and tests the conditions laid down in Annex II(4) of Directive 92/119/EEC are not fulfilled to confirm the presence of swine vesicular disease, the seropositive pigs shall be killed or slaughtered in accordance with the provisions referred to in Annex II(4)(d) of Directive 92/119/EEC. However, if further pigs have been found seropositive in addition to the ones already found seropositive following the previous sampling, the provisions and procedures laid down in (a), (b), (c), (d) and (e) shall be further applied *mutatis mutandis*.

5. Without prejudice to the measures referred to in Article 9 of Directive 92/119/EEC, in case one or more seropositive pigs are detected following the surveillance activities referred to in Chapter V(1)(b) or V(1)(c), the competent authority shall ensure that:

   (a) where necessary and feasible, appropriate further checks including collection of samples are carried out to confirm or rule out swine vesicular disease in the place where these pigs have been detected, taking into account the local situation;

   (b) the measures referred to in Article 4 of Directive 92/119/EEC are applied in the holding of origin of these pigs;

   (c) a check is carried out in the holding of origin of these pigs in accordance with the provisions referred to in Chapter II(1); and

   (d) blood samples are collected for serological testing from the pigs in the holding of origin of the seropositive pigs, in accordance with the provisions referred to in Chapter V(2).

6. However, the competent authority may decide to lift the measures referred to in 5(b) if:

   (a) the epidemiological enquiry carried out in accordance with Articles 4 and 8 of Council Directive 92/119/EEC suggests that swine vesicular disease has not been introduced in the holding;

   (b) no clinical signs of swine vesicular disease have been detected in the holding;

   (c) the holding is not located in a surveillance or restriction zone established following a confirmed outbreak of disease or subject to other restrictions applied in relation to a confirmed outbreak of disease,

   and provided that:

   — no pigs are moved from the holding for intra-Community trade, and

   — the pigs are only moved from the holding to a slaughterhouse for immediate slaugher or to another holding from which no pigs are moved for intra-Community trade,

   until the results of the further checks and serological tests carried out in the place where the seropositive pigs had been detected and in the holding of origin indicate that swine vesicular disease can be definitely ruled out.

## CHAPTER VII

### *Principles and applications of virological tests and evaluation of their results*

### A. **Detection of virus antigen**

1. An indirect sandwich ELISA has replaced the complement fixation test as the method of choice for the detection of swine vesicular disease viral antigen. The test is the same as that used for foot-and-mouth disease diagnosis. The tests for the two diseases must be performed at the same time, unless foot-and-mouth disease has already been ruled out. It is recommended in particular on samples of epithelium or fluid from vesicular lesions, in which both swine vesicular disease and foot-and-mouth disease viruses can be present at high titers in acutely infected pigs and detected in a few hours ([3]).

   Duplicate rows in multiwell ELISA plates are coated with rabbit antiserum to swine vesicular disease virus and to each of the seven serotypes of foot and mouth disease virus. These are the trapping sera. Test sample suspensions are added to each of the rows. Appropriate controls are also included. Homologous guinea-pig detection serum is added in the respective rows at the next stage followed by rabbit anti-guinea pig serum conjugated to an enzyme such as horse-radish peroxidase. Extensive washing is carried out between each stage to remove unbound reagents. A positive reaction is indicated if there is a colour reaction on the addition of chromogen and substrate. With strong positive reactions this will be evident to the naked eye, but results can also be read spectrophotometrically, in which case an absorbance reading 0,1 above background indicates a positive reaction.

2. Alternative monoclonal antibody-based ELISA systems, using selected monoclonal antibodies as trapping antibody and peroxidase-conjugated monoclonal antibodies as detecting antibody, may be used for swine vesicular disease antigen detection and for differential diagnosis with foot-and-mouth disease in epithelium samples, vesicular fluid or infected tissue culture.

3. A monoclonal antibody-based ELISA can be used to study antigenic variation among strains of swine vesicular disease virus. Tissue-culture grown viral antigens are trapped by a rabbit hyperimmune anti-serum to swine vesicular disease adsorbed to the solid phase. Appropriate panels of monoclonal antibodies are then reacted and the binding of monoclonal antibodies to field strains is compared to the binding of monoclonal antibodies to the parental strains. Similar binding indicates the presence of epitopes shared between the parental and the field strains.

([3]) Positive ELISA results are associated with the presence of at least $10^5$ $TCID_{50}$ (tissue culture infectious doses) of virus in the sample.

B. **Isolation and growth of virus**

1. As a routine, clarified suspensions of samples of epithelium, vesicular fluid or faeces suspected to contain swine vesicular disease virus must be inoculated onto sensitive cell cultures. If the quantity and quality of samples from vesicular lesions submitted for examination is insufficient for immediate examination by ELISA, the growth of virus in tissue culture will be necessary to amplify viral antigen.

2. To isolate and grow virus, clarified epithelial suspension is inoculated onto monolayer cultures of IB-RS-2 cells. Two dilutions of epithelial suspension, one high (1/500) and one low (1/10) should be used to avoid interference with virus growth by interferon, the release of which will interfere with the growth of swine vesicular disease virus. For virus isolation only antibiotics are added to maintenance medium. For differential diagnosis from foot-and-mouth disease virus, primary bovine thyroid cells, or baby hamster kidney cells (BHK-21) must also be inoculated.

3. If a cytopathic effect develops, the supernatant fluid must be harvested from positive cultures when the effect is complete and used in the ELISA for virus identification. Negative cultures must be inoculated on fresh tissue cultures at 48 or 72 hours and this blind passage examined up to 72 hours later. In the absence of cytopathic effect after a further blind passage the sample can be declared negative for the presence of live virus.

4. Suspensions of faecal samples can be processed as described in 1. As there is generally less virus in faeces than in epithelium, it is essential that in the absence of a cytopathic effect in the first two passages, a third blind passage is included.

5. The simultaneous inoculation of a porcine cell line and one of the above-mentioned tissue culture systems (preferably primary bovine thyroid cells) is a useful guide as to whether vesicular samples contain swine vesicular disease virus or foot and mouth disease virus, as the former will only grow in cells of porcine origin. However, foot-and-mouth disease virus isolates with a prolonged history of transmission between pigs may also preferentially grow in porcine cell culture systems.

C. **The polymerase chain reaction (PCR) for genome detection**

1. Nucleic acid recognition methods can be used to detect swine vesicular disease viral genome in clinical material using the PCR and to establish relationships between isolates of swine vesicular disease virus by determining the nucleotide sequence of part of the genome. Techniques using the PCR have been developed to improve the sensitivity of diagnosis. Slightly different reverse transcriptase-PCR procedures have been described using primers corresponding to highly conserved regions in the 1C and 1D genes.

2. The PCR technique is rapid (the results are usually available within 24 hours), detects all genotypes of swine vesicular disease virus, and is sufficiently sensitive for use on samples collected from cases of suspect clinical disease.

3. Where sub-clinical infection is suspected, or when samples are collected after the resolution of clinical disease or when processing faecal samples, enhanced RT-PCR techniques, like nested RT-PCR, immune-PCR, ELISA-PCR and more elaborate RNA extraction methods produce a detection system at least as sensitive, but considerably more rapid, than multiple passage on tissue culture.

4. By sequencing approximately 200 nucleotides within the 1D gene which codes for the major structural protein VP1, it is possible to group strains of swine vesicular disease virus according to their sequence homology, and epidemiologically relate strains causing disease in different regions or at different times.

D. **Evaluation of the results of virological tests**

The detection of antigens or genome of swine vesicular disease virus by means of ELISA and PCR has the same diagnostic value as virus isolation.

However, virus isolation must be considered as the reference test and must be used as confirmatory test when necessary, in particular if a positive ELISA or PCR result is not associated with:

(a) the detection of clinical signs of disease,

(b) the detection of seropositive pigs, or

(c) a direct epidemiological connection with a confirmed outbreak.

CHAPTER VIII

***Principles and applications of serological tests and evaluation of their results***

A. **Virus neutralization (VN) test**

1. The quantitative VN micro-test for swine vesicular disease virus antibody detection is performed with IB-RS-2 cells or an equivalent cell system in flat-bottomed tissue culture grade microtitre plates.

2. Virus is grown in IB-RS-2 cell monolayers and stored either at −20 °C after the addition of 50 % glycerol or at −70 °C without glycerol. The sera are inactivated at 56 °C for 30 minutes before testing.

B. **ELISAs**

1. The ELISA for detection of antibodies is a monoclonal antibody-based competitive ELISA. If the serum sample contains antibodies to swine vesicular disease virus, the binding of a selected peroxidase-conjugated monoclonal antibody to virus antigen will be inhibited.

   In this ELISA the swine vesicular disease viral antigen is trapped to the solid phase using monoclonal antibodies; then the sera samples are incubated at appropriate dilution, followed by the addition of the peroxidase-conjugated monoclonal antibody. Then, the inhibition of the monoclonal antibody binding is measured by means of a substrate and chromogen.

2. An indirect trapping ELISA using isotype-specific monocolonal antibodies to detect swine IgG or IgM specific for swine vesicular disease virus is helpful in assessing the time of infection in the pig or on the infected premise.

   In the isotype specific ELISA the viral antigen is trapped to the solid phase using an antigen-catching antibody. If the serum sample contains antibodies to swine vesicular disease virus, they are detected using an anti-pig IgG or an anti-pig IgM monoclonal antibody conjugated with peroxidase. Then, this binding is measured by means of a substrate and chromogen.

   The isotype-specific ELISA may also help in distinguishing singleton reactors from true positive pigs, as referred to in (C).

C. **Application of serological tests and evaluation of results**

1. The VN test and the ELISA are the recommended serological tests. Chapter X lists the reference sera, which are available from the Community reference laboratory in order that standardised serological tests are carried out in the Community.

   The VN test must be considered as the reference test, but has the disadvantage that it takes 2 to 3 days to complete and requires tissue culture facilities.

   The ELISA is more rapid and can be more easily standardised. The monoclonal antibody competition ELISA is the most reliable swine vesicular disease antibody ELISA described to date. It is recommended as a screening test on a large number of samples.

   However, the VN test must be used as confirmatory test when necessary, in particular after first detection of positive samples in a holding. Pigs positive by ELISA, but negative by VN test can be disregarded.

2. The presence of a singleton reactor [4] may be suspected where a single seropositive pig is detected and where the following criteria are met:

   (a) there are no clinical signs of disease on the holding;

   (b) there is no relevant history of clinical disease on the holding;

   (c) there is no history of contact with a known outbreak of disease.

3. A pig is confirmed singleton reactor when:

   (a) follow-up testing does not identify other seropositive pigs;

   (b) sampling performed on in-contact pigs after first detection of the singleton reactor does not reveal sero-conversion;

   (c) antibody titre on repeated sampling remains constant or declines.

[4] A small proportion of singleton reactors can be detected by any of the current serological tests for swine vesicular disease. The factors responsible for singleton reactors are unknown. Serological cross-reactivity with swine vesicular disease virus might arise due to infection with another, as yet unidentified, picornavirus or may be due to other non-specific factors present in the serum.

4. However, the following additional criteria and principles must also be considered for the confirmation of a singleton reactor:

   (a) singleton reactors occur at a prevalence of approximately 1 per 1 000 pigs;

   (b) sera from singleton reactors generally have the following profile:

   — low VN test antibody titre,

   — borderline positive in the monoclonal antibody-based competition ELISA,

   — exclusively IgM and no IgG in the swine vesicular disease isotype-specific ELISA [5].

CHAPTER IX

***Clinical signs and features of swine vesicular disease***

Swine vesicular disease is a contagious disease of pigs caused by an enterovirus of the picornaviridae family, which can be a sub-clinical, mild or severe vesicular condition depending on the strain of virus involved, the route and dose of infection, and the husbandry conditions under which the pigs are kept. Additional stress factors such as transport, mixing with other pigs and temperature extremes could also predispose to the development of clinical signs.

It is characterised by a mild fever and vesicles on the coronary band, the bulbs of the heel, skin of the limbs and less frequently the snout, lips, tongue and teats. The morbidity rate may be as high as 100 % but mortality is very low or nil.

Infection can develop in an inapparent or mild form showing only a transitory decline in the general appearance of pigs but leading to the development of virus neutralising antibodies in a few day [6].

Because of the subclinical or mild nature of the disease, it is often first suspected following serological tests for disease surveillance or export certification. Recent European outbreaks of swine vesicular disease have been characterised by less severe or no clinical signs, diagnosis frequently being dependent on serology.

However, clinical signs of swine vesicular disease are indistinguishable from those of foot-and-mouth disease. Any vesicular condition must be treated initially as suspected foot-and-mouth disease and differential diagnosis must be obtained as quickly as possible.

The incubation period of swine vesicular disease in individual pigs is usually between two and seven days, after which a transient fever of up to 41 °C may occur, but clinical signs may become evident in the holding after a longer period. Vesicles then develop on the coronary band, typically at the junction with the heel. These may affect the whole coronary band resulting in loss of the hoof. More rarely, vesicles may also appear on the snout, particularly on the dorsal surface, on the lips, tongue and teats, and shallow erosions may be seen on the knees. Affected pigs may be lame and off their feed for a few days.

Younger pigs are more severely affected, although mortality due to swine vesicular disease is very rare, in contrast with foot-and-mouth disease in young stock.

Nervous signs have been reported, but are unusual. Abortion is not a typical feature of swine vesicular disease. Cardiac failure due to multifocal myocarditis can be a feature of foot-and-mouth disease and encephalomyocarditis, especially in young piglets, but does not occur in swine vesicular disease.

Recovery is usually complete in two to three weeks, with the only evidence of infection being a dark, horizontal line on the hoof where growth has been temporarily interrupted.

Affected pigs may excrete virus from the nose and mouth and in the faeces up to 48 hours before the onset of clinical signs. Most virus is produced in the first seven days after infection, and virus excretion from the nose and mouth normally stops within two weeks. Virus can be isolated from the faeces for up to 20 days after infection, although it has been reported present for up to three months. It can persist for a considerable period of time in the necrotic tissue associated with ruptured vesicles and in the faeces.

[5] Specific IgG alone or both IgG and IgM are usually detected in serum samples from swine vesicular disease virus infected pigs, whereas sera from singleton reactors generally contain IgM only. Specific IgG will not be detected in serum samples from pigs infected with swine vesicular disease virus during the previous 10 to 14 days, although specific IgG should be detected in a second blood sample. However, recently infected pigs cannot be reliably distinguished from singleton reactors before their immune response switches from IgM to IgG production. See also Chapter IX and footnote 7.

[6] Specific IgM can be usually detected in the blood from two to three days post infection and disappear after about 30 to 50 days; specific IgG can be usually detected in the blood from 10 to 14 days post infection and last for some years. The Ig isotype can be determined by means of the ELISA described in Chapter VIII(B)(2).

CHAPTER X

***Swine vesicular disease reference sera***

| Reference serum | Origin | Comment ([7]) |
|---|---|---|
| 1 | Normal pig serum (NPS) | Negative control serum. |
| 2 | Serum collected 21 days post infection (dpi) from a pig infected with swine vesicular disease virus strain UKG 27/72 (neat) | Strong positive control serum. |
| 3 | A 1:10 dilution in NPS of a serum collected five dpi from a pig infected with swine vesicular disease strain Italy 8/94 | A low-positive serum from a pig soon after infection with a recent European isolate of swine vesicular disease virus. The serum has been diluted to give a low positive result in ELISA and VNT. |
| 4 | A 1:40 dilution of a serum collected 21 dpi from a pig infected with swine vesicular disease virus strain UKG 27/72 | A low-positive serum defining the lowest level of antibodies that EU National Reference Laboratories should consistently score positive by ELISA and virus neutralisation.<br>Equivalent to serum RS 01-04-94 ([8]) |
| 5 | Serum collected four dpi from a pig infected with swine vesicular disease virus strain UKG 27/72 (neat) | A low-positive serum from a pig soon after infection. |
| 6 | Serum collected five dpi from a pig infected with swine vesicular disease virus strain UKG 27/72 (neat) | A low-positive serum from a pig soon after infection. |

([7]) These comments relate to the testing of individual pigs. For sero-surveillance the sensitivity of the test used should be taken into account.
([8]) i.e. a serum with a titre sufficiently greater than the cut-off that it should always score positive by ELISA and VN test in repeated testing.