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I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EEC) No 3895/91

of 11 December 1991

laying down rules for the description and presentation of special wines

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the proposal from the Commission,

Having regard to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organization of the market in wine⁽¹⁾, as last amended by Regulation (EEC) No 1734/91⁽²⁾, and in particular Article 72 (1) thereof,

Whereas Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽³⁾, as last amended by Commission Directive 91/72/EEC⁽⁴⁾, provides for the introduction of the principle of the compulsory indication of the actual alcoholic strength of all alcoholic beverages; whereas, on the other hand, Article 10a thereof provides for the determination, by specific provisions, of detailed rules governing the indication of the alcoholic strength by volume on the labelling of products falling within CN code 2204;

Whereas the description of liqueur wines, semi-sparkling wines and aerated semi-sparkling wines is not regulated by Council Regulation (EEC) No 2392/89 of 24 July 1989 laying down general rules for the description and presentation of wines and grape musts⁽⁵⁾, as last amended by Regulation (EEC) No 2356/91⁽⁶⁾, nor by Council Regulation (EEC) No 3309/85 of 18 November 1985 laying down general rules for the description and presentation of sparkling wines and aerated sparkling wines⁽⁷⁾, as last

amended by Regulation (EEC) No 2357/91⁽⁸⁾; whereas specific rules should be laid down for the indication of the alcoholic strength by volume on the labelling of such wines;

Whereas the use of lead-based capsules to cover the closing devices of containers in which wines or grape musts are marketed should be banned, in order to avoid, firstly, any risk of contamination, in particular by accidental contact with those products, and, secondly, any risk of environmental pollution from waste containing lead from the aforementioned capsules; whereas, however, provision should be made for a period of adjustment for the manufacturers and users of these capsules and, with this in view, the ban in question should be applied only from 1 January 1993 onwards;

Whereas Council Regulation (EEC) No 1627/86 of 6 May 1986 laying down rules for the description of special wines with regard to the indication of alcoholic strength⁽⁹⁾ should be repealed,

HAS ADOPTED THIS REGULATION:

Article 1

1. The description on the labelling of liqueur wines, semi-sparkling wines and aerated semi-sparkling wines, as referred to in Annex I to Regulation (EEC) No 822/87 and Article 2 of Regulation (EEC) No 2391/89⁽¹⁰⁾, shall include the actual alcoholic strength by volume.

2. The actual alcoholic strength by volume shall be indicated in accordance with the conditions laid down in the implementing provisions.

⁽¹⁾ OJ No L 84, 27. 3. 1987, p. 1.

⁽²⁾ OJ No L 163, 26. 6. 1991, p. 6.

⁽³⁾ OJ No L 33, 8. 2. 1979, p. 1.

⁽⁴⁾ OJ No L 42, 16. 2. 1991, p. 27.

⁽⁵⁾ OJ No L 232, 9. 8. 1989, p. 13.

⁽⁶⁾ OJ No L 216, 3. 8. 1991, p. 1.

⁽⁷⁾ OJ No L 320, 29. 11. 1985, p. 9.

⁽⁸⁾ OJ No L 216, 3. 8. 1991, p. 2.

⁽⁹⁾ OJ No L 144, 29. 5. 1986, p. 4.

⁽¹⁰⁾ Council Regulation (EEC) No 2391/89 of 24 July 1989 defining certain products in the wine sector falling within CN codes 2009 and 2204, and originating in third countries (OJ No L 232, 9. 8. 1989, p. 10).

Article 2

Lead-based capsules or foils shall not be used to cover the closing devices on liqueur wines, semi-sparkling wines or aerated semi-sparkling wines.

Article 3

1. Regulation (EEC) No 1627/86 is hereby repealed.

2. References to the repealed Regulation shall be understood to be references to this Regulation and are to be interpreted in accordance with the table of equivalence set out in the Annex hereto.

Article 4

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

Article 2 shall apply from 1 January 1993.

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

Done at Brussels, 11 December 1991.

For the Council

The President

P. BUKMAN

ANNEX

Regulation (EEC) No 1627/86	This Regulation
Article 1	Article 1
Article 2	—
Article 3	Article 4

COUNCIL REGULATION (EEC) No 3896/91

of 16 December 1991

amending for the third time Regulation (EEC) No 823/87 laying down special provisions relating to quality wines produced in specified regions

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS REGULATION:

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas the first indent of Article 6 (1) of Regulation (EEC) No 823/87 ⁽⁴⁾, as last amended by Regulation (EEC) No 3577/90 ⁽⁵⁾, defines the principle that quality wines produced in a specified region, hereinafter called 'quality wines psr', may be made only from grapes harvested within the specified region whose name they bear; whereas in order better to harmonize the conditions of competition between the specified regions in the production of quality wines, derogations from the above principle should be permitted only during a transitional period expiring on 31 December 1995, even in the case of authorizations granted pursuant to current rules;

Whereas certain regions of the territory of the former German Democratic Republic and of the United Kingdom have recently been defined for the production of quality wines; whereas the minimum natural alcoholic strength should be established for quality wines psr coming from those regions;

Whereas, taking into account the repute of certain sparkling quality wines psr or quality liqueur wines psr and the fact that the names of the regions in which those wines originate are sufficiently distinctive, it is not necessary to supplement their sales description with a specific term traditionally used;

Whereas in order to allow the producers of certain table wines who describe their wines by the name of a specific region to adapt to the rules of this Regulation, the date appearing in Article 15 (4) third subparagraph of Regulation (EEC) No 823/87 should be extended until 31 August 1993,

Article 1

Regulation (EEC) No 823/87 is hereby amended as follows:

1. In Article 6:

(a) paragraph 2 shall be replaced by the following:

'2. Notwithstanding the first indent of paragraph 1, in the case of a traditional practice governed by special provisions of the Member State of production, that Member State may permit, until 31 December 1995 at the latest, by means of express authorizations and subject to appropriate control, that a quality wine psr be obtained by adjusting the basic product of that wine by adding one or more wine-sector products which do not originate in the specified region whose name is borne by the wine, provided that:

- this type of added wine-sector product is not produced in that specified region with the same characteristics as products not originating therein,
- this adjustment is consistent with the oenological practices and definitions referred to in Regulation (EEC) No 822/87,
- the total volume of added wine-sector products which do not originate in the specified region does not exceed 10 % of the total volume of products used which originate in the specified region. However, the Commission may, in accordance with the procedure laid down in Article 83 of Regulation (EEC) No 822/87, authorize the Member States to allow in exceptional cases a percentage of added products higher than 10 but not more than 15 %;

(b) the second subparagraph of paragraph 5 shall be replaced by the following:

'They shall include in particular the definition of areas in the immediate proximity of a specified region, account being taken in particular of the geographical situation and administrative structures.'

2. In the first subparagraph of Article 7 (2), the first indent shall be replaced by the following:

- 6,5 % vol in zone A with the exception of the specified regions Mosel-Saar-Ruwer, Ahr,

⁽¹⁾ OJ No C 84, 28. 3. 1991, p. 9 and amendment forwarded on 13 December 1991.

⁽²⁾ OJ No C 305, 25. 11. 1991.

⁽³⁾ OJ No C 191, 22. 7. 1991, p. 45.

⁽⁴⁾ OJ No L 84, 27. 3. 1987, p. 59.

⁽⁵⁾ OJ No L 353, 17. 12. 1990, p. 23.

Mittelrhein, Sachsen, Saale-Unstrut, Moselle luxembourgeoise, England and Wales, in which the said alcoholic strength shall be 6 % vol.;

3. In Article 15:

(a) paragraph 2 shall be replaced by the following:

'2. Without prejudice to any additional terms which may be allowed by national laws, and subject to Community and national provisions on the wines in question being observed, the specific terms traditionally used which are referred to in the first subparagraph of paragraph 1 shall be the following:

(a) Germany:

the following terms accompanying an indication of the origin of the wine:

- "Qualitätswein",
- "Qualitätswein mit Prädikat", together with one of the following terms: "Kabinett", "Spätlese", "Auslese", "Beerenauslese", "Trockenbeerenauslese" or "Eiswein";

(b) France:

"appellation d'origine contrôlée", "appellation contrôlée", "appellation d'origine vin délimité de qualité supérieure", "vin doux naturel";

(c) Italy:

"Denominazione di origine controllata", "Denominazione di origine controllata e garantita", "vino dolce naturale";

(d) Luxembourg:

"Marque nationale" followed by the words "Appellation contrôlée" together with the name of the specified region "Moselle luxembourgeoise";

(e) Greece:

"Ονομασία προελεύσεως ελεγχόμενη (appellation d'origine contrôlée)",

"Ονομασία προελεύσεως ανωτέρας ποιότητας (appellation d'origine de qualité supérieure)",

"οίνος γλυκός φυσικός (vin doux naturel)";

(f) Spain:

"Denominación de origen", "Denominación de origen calificada", "vino generoso", "vino generoso de licor", "vino dulce natural";

(g) Portugal:

"Denominação de origem", "Denominação de origem controlada", "Indicação de proveniência regulamentada", "vinho generoso", "vinho doce natural".;

(b) in the last subparagraph of paragraph 3 the terms 'and Greek quality wines psr other than quality sparkling wines psr' shall be deleted;

(c) in the third subparagraph of paragraph 4, '31 August 1991' shall be replaced by '31 August 1993';

(d) paragraph 7 shall be supplemented by the following subparagraph:

'Notwithstanding the second indent of the first subparagraph and unless such an option is precluded by the legislation of the Member States concerned, it shall be possible to market wines bearing only the name of the respective specified region where such wines are, in accordance with the Community and national provisions applicable to them, entitled to one of the names of the following specified regions:

(a) France:

- "Champagne";

(b) Italy:

- "Asti"
- "Marsala";

(c) Greece:

- "Σάμος (Samos)";

(d) Spain:

- "Cava"
- "Jerez", "Xérès" or "Sherry";

(e) Portugal:

- "Madeira" or "Madère"
- "Porto" or "Port".;

Article 2

This Regulation shall enter into force on the third day following 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, 16 December 1991.

For the Council

The President

H. VAN DEN BROEK

COUNCIL REGULATION (EEC) No 3897/91

of 16 December 1991

amending for the third time Regulation (EEC) No 2392/89 laying down general rules for the description and presentation of wines and grape musts

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organization of the market in wine ⁽¹⁾, as last amended by Regulation (EEC) No 1734/91 ⁽²⁾, and in particular Article 72 (1) thereof,

Having regard to the proposal from the Commission,

Whereas in order to allow the producers of certain table wines who designate their wines by the name of a specific region to adapt to the rules of this Regulation the date appearing in Article 4 (4), last subparagraph, of Regulation (EEC) No 2392/89 ⁽³⁾, as last amended by Regulation (EEC) No 2356/91 ⁽⁴⁾, should be extended to 31 August 1993;

Whereas Article 13 (3), second subparagraph, (b) of Regulation (EEC) No 2392/89 provides, until 31 August 1991, the possibility for the Member States to allow a quality wine psr to bear the name of a given geographical unit which is smaller than a specified region, provided that at least 85 % of the quantity of grapes used are picked in that unit, the remainder coming from grapes picked in another geographical unit of the specified region; whereas experience has shown that this transitional period is too short to allow certain Member States to establish larger units; whereas this period should be extended;

Whereas Article 37 (1) (e) of Regulation (EEC) No 2392/89 lays down a prohibition on covering the closing device of wine bottles with capsules containing lead; whereas in order to align the terms in which that prohibition is expressed on those of Resolution No 7 approved on 6 September 1991 in Paris by the International Vine and Wine Office, the abovementioned provision should be amended;

Whereas experience has shown that it is important to provide that the geographical name designating a specified region must be sufficiently precise to avoid any possibility of confusion;

Whereas the use of brand names for the labelling of wines and grape musts is governed by Article 40 (2) and (3) of

Regulation (EEC) No 2392/89; whereas, with a view to providing effective protection for geographical names used for the description of wine-sector products, these provisions prohibit, for the description and presentation of such products, the use of brand names which contain wording that is identical to a geographical name used to describe a table wine, a quality wine psr or an imported wine, unless the product described by the brand name in question is entitled to such a name; whereas the application of these provisions has shown that there are well-known brand names corresponding to the identity of the original holder or of the original provider of the name, which have been registered and used for at least 25 years before the date of official recognition of the geographical name; whereas such brand names should be allowed to continue to be used,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 2392/89 shall be amended as follows:

1. in the last subparagraph of paragraph 4 (4), '31 August 1991' shall be replaced by '31 August 1993';
2. the following subparagraph shall be added to Article 5 (1) (f) and to Article 14 (1) (e):

'This does not apply to the use of the name of the variety "Barbera" in relation to the name of the specified region "Conca de Barberà".';

3. point (b) of the second subparagraph of Article 13 (3) shall be replaced by the following:

'(b) the name of a geographical unit as referred to in paragraph 1 where the wine is obtained from a mixture of grapes, grape musts, new wines still in fermentation or, until 31 August 1995, wines originating in the geographical unit the name of which is to be used for the designation, with a product obtained in the same specified region but outside that unit, provided that at least 85 % of the quality wine psr concerned is obtained from grapes picked in the geographical unit whose name it bears';

⁽¹⁾ OJ No L 84, 27. 3. 1987, p. 1.

⁽²⁾ OJ No L 163, 26. 6. 1991, p. 6.

⁽³⁾ OJ No L 232, 9. 8. 1989, p. 13.

⁽⁴⁾ OJ No L 216, 3. 8. 1991, p. 1.

4. the following point (f) shall be added to Article 20 (2):

'(f) a brand name, in accordance with the conditions laid down in Article 40.';

5. the following subparagraph shall be added to Article 27 (2):

'In addition, the description may be supplemented by the indication of a brand name, in accordance with the conditions laid down in Article 40.';

6. Article 37 (1) (e) shall be replaced by the following:

'(e) have a closing device which is not covered with a capsule made on the basis of lead.';

7. Article 40 shall be amended as follows:

- (a) the following subparagraph shall be added to paragraph 1:

'The geographical name designating a specified region must be sufficiently precise and familiarly linked to the area of production so that, taking account of the existing situations, confusion may be avoided.';

- (b) the second subparagraph to paragraph 3 shall be replaced by the following:

'Moreover, the holder of a well-known registered brand name for a wine or a grape must which

contains wording that is identical to the name of a specified region or the name of a geographical unit smaller than a specified region may, even if he is not entitled to use such a name pursuant to paragraph 2, continue to use that brand name where it corresponds to the identity of its original holder or of the original provider of the name, provided that the brand name was registered at least 25 years before the official recognition of the geographical name in question by the producer Member State in accordance with Article 1 (3) of Regulation (EEC) No 823/87 as regards quality wines psr and that the brand name has actually been used without interruption.

Brand names complying with the conditions of the first and second subparagraphs may not be invoked against the use of the names of geographical units used to describe a quality wine psr or a table wine.'.

Article 2

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

With regard to Article 1:

- point 3 shall apply from 1 September 1991,
- point 6 shall apply from 1 January 1993.

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

Done at Brussels, 16 December 1991.

For the Council

The President

H. VAN DEN BROEK

COUNCIL REGULATION (EEC) No 3898/91

of 16 December 1991

amending Regulation (EEC) No 358/79 on sparkling wines produced in the Community

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS REGULATION:

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas the provisions relating to the maximum sulphur dioxide contents of sparkling wines referred to in Article 12 (3) of Regulation (EEC) No 358/79 ⁽⁴⁾, as last amended by Regulation (EEC) No 1735/91 ⁽⁵⁾, should be reviewed on the basis of experience gained;

Whereas the first indent of Article 6 (1) of Regulation (EEC) No 823/87 of 16 March 1987 laying down special provisions relating to quality wines produced in specified regions ⁽⁶⁾, as last amended by Regulation (EEC) No 3896/91 ⁽⁷⁾, defines the principle that quality wines produced in a specified region, hereinafter called 'quality wines psr', may be made only from grapes harvested within the specified region whose name they bear, whilst making provision for derogations to that principle during a transitional period expiring on 31 December 1995; whereas a similar provision shall also be made for quality sparkling wines produced in specific regions (quality sparkling wines psr);

Whereas experience dictates that the rules on the production of sparkling wines should refer not only to quality sparkling wines of the aromatic type but also to quality sparkling wines of the aromatic type produced in specified regions (quality sparkling wines psr of the aromatic type);

Whereas the quality sparkling wines of the aromatic type and the quality sparkling wines psr must be obtained from vine varieties that are listed in the Annex to Regulation (EEC) No 358/79; whereas that list should be supplemented by certain varieties which, on the basis of experience gained, are appropriate for making quality sparkling wines of the aromatic type or quality sparkling wines psr of the aromatic type,

(1) OJ No C 84, 28. 3. 1991, p. 10, and amendment forwarded on 13 December 1991.

(2) OJ No C 305, 25. 11. 1991.

(3) OJ No C 191, 22. 7. 1991, p. 45.

(4) OJ No L 54, 5. 3. 1979, p. 130.

(5) OJ No L 163, 26. 6. 1991, p. 9.

(6) OJ No L 84, 27. 3. 1987, p. 59.

(7) See page 3 of this Official Journal.

Article 1

Regulation (EEC) No 358/79 is hereby amended as follows:

1. Article 12 (3) and (4) shall be replaced by the following:

'3. The Commission shall submit to the European Parliament and Council before 1 April 1992 a report, based on experience acquired, on maximum sulphur dioxide contents, accompanied, where appropriate, by proposals, on which the Council shall act in accordance with the procedure referred to in Article 43 (2) of the Treaty before 1 September 1992.

4. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 83 of Regulation (EEC) No 822/87;'

2. in Article 14a:

(a) paragraph 2 shall be replaced by the following:

'2. Notwithstanding the first indent of paragraph 1, in the case of a traditional practice governed by special provisions of the Member State of production, that Member State may permit, until 31 December 1995 at the latest, by means of express authorizations and subject to appropriate control, that a quality sparkling wine psr be obtained by adjusting the basic product of that wine by adding one or more wine-sector products which do not originate in the specified region whose name is borne by the wine, provided that:

— this type of added wine-sector product is not produced in that specified region with the same characteristics as products not originating therein,

— this adjustment is consistent with the oenological practices and definitions referred to in Regulation (EEC) No 822/87,

— the total volume of added wine-sector products which do not originate in the specified region does not exceed 10 % of the total volume of products used which originate in the specified region. However the Commission may, in accordance with the procedure laid down in Article 83 of Regulation (EEC) No 822/87, authorize the Member State to allow in

exceptional cases a percentage of added products higher than 10 %, but not more than 15 %;

- (b) the second subparagraph of paragraph 4 shall be replaced by the following:

'They shall include in particular the definition of areas in immediate proximity to a specified region, account being taken in particular of the geographical situation and administrative structures.';

3. Article 16 (4) shall be replaced by the following:

'4. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 83 of Regulation (EEC) No 822/87.';

4. in Article 18:

- (a) the first subparagraph of paragraph 1 shall be replaced by the following:

'1. Quality sparkling wines of the aromatic type may be produced only by using, as sole constituents of the cuvée, grape musts or grape musts in fermentation obtained from the vine varieties listed in the Annex. The same shall apply to quality sparkling wines psr of the aromatic type, provided that these varieties are recognized as suitable for the production of quality wines psr in the specified region whose name the quality sparkling wines psr bear.';

- (b) paragraphs 3 and 4 shall be replaced by the following:

'3. Notwithstanding the first subparagraph of Article 15 (2), quality sparkling wines of the aromatic type and quality sparkling wines psr of the aromatic type shall, when kept at a temperature of 20 °C in closed containers, have an excess pressure of not less than 3 bars.

4. Notwithstanding Article 17, the duration of the process of making quality sparkling wines of the aromatic type and quality sparkling wines psr of the aromatic type may not be less than one month.';

5. Article 22 shall be replaced by the following:

'Article 22

All sparkling wines covered by Article 2 that met the requirements of this Regulation in force at the time when

they were produced but the production conditions or analytical characteristics of which no longer meet the requirements of this Regulation as a result of amendments thereto may be held for sale, put on the market or exported until stocks are exhausted.'

6. The Annex shall be replaced by the following:

'ANNEX

List of the varieties of vine from which quality sparkling wines of the aromatic type and quality sparkling wines psr of the aromatic type may be obtained:

Aleatico N
 Ασύρτικο (Assyrtiko)
 Bourboulenc
 Brachetto N
 Clairette
 Colombard
 Freisa N
 Gamay
 Gewürztraminer
 Girò N
 Γλυκέρυθρα (Glykerithra)
 Huxelrebe
 Macabeu
 Malvasia (all)
 Mauzac blanc and rosé
 Monica N
 Μοσχοφίλερο (Moschofilero)
 Müller-Thurgau
 Muscats (all)
 Parellada
 Perle
 Picpoul
 Poulsard
 Prosecco
 Ροδίτης (Roditis)
 Scheurebe.'

Article 2

This Regulation shall enter into force on the third day following 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, 16 December 1991.

For the Council
 The President
 H. VAN DEN BROECK

COUNCIL REGULATION (EEC) No 3899/91

of 16 December 1991

amending for the sixth time Regulation (EEC) No 3309/85 laying down general rules for the description and presentation of sparkling wines and aerated sparkling wines

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organization of the market in wine ⁽¹⁾, as last amended by Regulation (EEC) No 1734/91 ⁽²⁾, and in particular Article 72 (1) thereof;

Having regard to the proposal from the Commission,

Whereas experience indicates a need to specify that for the purpose of informing the consumers of sparkling and aerated sparkling wines of the product type as determined by the residual sugar content only the information required under Community rules is permitted on the labelling;

Whereas for the purposes of consumer information it should be specified that packages containing bottles of sparkling or aerated sparkling wine put up for sale should have labelling meeting the requirements of the Community rules; whereas, however exceptions may be made in the case of specific packages containing small quantities of those wines;

Whereas experience has shown that it is important to provide that the geographical name designating a specified region for a quality sparkling wine psr must be sufficiently precise to avoid any possibility of confusion;

Whereas the use of brand names for the labelling of sparkling and aerated sparkling wines is governed by Article 13 (2) of Regulation (EEC) No 3309/85 ⁽³⁾, as last amended by Regulation (EEC) No 2357/91 ⁽⁴⁾; whereas for the sake of effective protection of geographical names used for the description of one of these products, those provisions prohibit, for the description and presentation of such a product, the use of brand names containing words identical to a geographical name used to describe another wine unless that sparkling wine is entitled to that name; whereas the application of these provisions has shown that there are well-known brand names corresponding to the identity of the original holder or of the original provider of the name, which have been registered and used for at least 25 years before the

date of official recognition of the geographical name in question by the producer Member State; whereas such brand names should be allowed to continue to be used,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 3309/85 is hereby amended as follows:

1. the second indent of Article 2 shall be replaced by the following:

— packaging means protective wrappings, such as paper, straw envelopes of all kinds, cartons and cases, used in the transport of one or more containers and/or for presenting them with a view to sale to the final consumer;

2. in Article 5 (3):

(a) the third indent of the first subparagraph shall be replaced by the following:

— “extra dry”, “extra trocken” or “extra seco”,
if the residual sugar content is between 12 and 20 g/l;

(b) the following final subparagraph shall be added:

‘No information other than that specified in the first and third subparagraphs may be used on the labelling to indicate the product type as determined by the residual sugar content.’;

3. in Article 10 (1), the second subparagraph shall be replaced by the following:

‘The closing device referred to in the first and second indents of point (a) of the first subparagraph may not be covered by a capsule or foil manufactured on the basis of lead.’;

4. Article 11 (2) shall be replaced by the following:

‘2. Where containers containing a product referred to in Article 1 (1) are presented for sale to the final consumer in a package it must be labelled in accordance with the provisions of this Regulation.

The arrangements for avoiding excessive strictness in the case of special packagings containing small quantities of

⁽¹⁾ OJ No L 84, 27. 3. 1987, p. 1.

⁽²⁾ OJ No L 163, 26. 6. 1991, p. 6.

⁽³⁾ OJ No L 320, 29. 11. 1985, p. 9.

⁽⁴⁾ OJ No L 216, 3. 8. 1991, p. 2.

the products referred to in Article 1 (1), on their own or with other products, shall be adopted under the procedure laid down in Article 83 of Regulation (EEC) No 822/87.';

5. Article 13 shall be amended as follows:

- (a) paragraph 1 shall be supplemented by the following subparagraph:

'The geographical name designating a specified region for a quality sparkling wine psr must be sufficiently precise and familiarly linked to the area of production so that, taking account of the existing situations, confusion may be avoided;'

- (b) the following paragraph shall be added:

'3. Notwithstanding paragraph 2 (b), the holder of a well-known registered brand name for a product referred to in Article 1 (1) which contains wording that is identical to the name of a specified region or the name of a geographical unit smaller than a specified region may, even if he is not entitled to use such a name pursuant to paragraph 2,

continue to use that brand name where it corresponds to the identity of its original holder or of the original provider of the name, provided that the brand name was registered at least 25 years before the official recognition of the geographical name in question by the producer Member State in accordance with Article 1 (3) of Regulation (EEC) No 823/87 as regards quality wines psr and that the brand name has actually been used without interruption.

Brand names complying with the conditions of the first subparagraph may not be invoked against the use of the name of geographical units used to describe a quality wine psr.'

Article 2

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

Article 1 (3) shall apply as from 1 January 1993.

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

Done at Brussels, 16 December 1991.

For the Council
The President
H. VAN DEN BROEK

COUNCIL REGULATION (EEC) No 3900/91

of 16 December 1991

suspending Common Customs Tariff duties for products covered by Regulation (EEC) No 3833/90 and originating in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Regulation (EEC) No 3835/90 ⁽⁴⁾ applies tariff preferences to Bolivia, Colombia, Ecuador and Peru in order to help these countries halt the growth in the production of, and trade in, cocaine, which threaten their social integrity and so damage their economies that their development is at risk;

Whereas the application of Regulation (EEC) No 3835/90 was extended until 31 December 1992 by Regulation (EEC) No 3587/91 ⁽⁵⁾;

Whereas it has been established that the countries of the Central American isthmus are being increasingly used as a staging post on the route of narcotic drugs from the Andean region to North America;

Whereas the illegal cultivation of poppies and cannabis and the production of drugs and other psychotropic substances in the countries of the Central American isthmus is expanding alarmingly;

Whereas the growing trade in, and cultivation of, drugs threatens the economic and social stability of the countries of the Central American isthmus;

Whereas Article 4 (1) of the Cooperation Agreement of 12 November 1985 between the European Economic Community, of the one part, and the countries parties to the General Treaty on Central American Economic Integration (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua) and Panama ⁽⁶⁾, of the other part, of which the

overall purpose is to help resolve the problems of the Central American isthmus, which have, in particular, been worsened by the effects of the current economic recession, provides that the Contracting Parties shall undertake to promote the harmonious development, diversification and qualitative improvement of their trade, with a view to maximizing such trade;

Whereas the countries of the Central American isthmus are today engaged in the consolidation of peace and democracy, which calls for the mobilization of all their economic resources and backing from the international community;

Whereas the Community has been constant in its support for peace and development in the Central American isthmus;

Whereas the Heads of State of Central America and Panama, meeting at Puntarenas on 15 December 1990, appealed to the Community to extend to their countries the tariff preferences granted to Bolivia, Colombia, Ecuador and Peru;

Whereas this appeal was backed by the Governments of Colombia and Ecuador in the San Andrés Declaration of 15 January 1991;

Whereas the ministerial meeting between the Community and the Central American countries, Panama and the cooperating countries (Colombia, Mexico and Venezuela) held in Managua on 18 and 19 March 1991 dealt constructively with this matter at the urgent request of the Central American Ministers;

Whereas the Community considers it necessary to continue to support peace and democratization in Central America and Panama in the present period of consolidation and therefore, in order to increase these countries' export earnings and their growth, to grant them exceptional, temporary assistance by extending to their agricultural exports generalized tariff preferences similar to those granted to Bolivia, Colombia, Ecuador and Peru; whereas these concessions should be granted to them for the same period, without prejudice to the annual nature of the Community's system of generalized tariff preferences,

⁽¹⁾ OJ No C 194, 25. 7. 1991, p. 17.

⁽²⁾ Opinion delivered on 12 December 1991 (not yet published in the Official Journal).

⁽³⁾ Opinion delivered on 15 October 1991 (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 370, 31. 12. 1990, p. 126.

⁽⁵⁾ OJ No L 341, 12. 12. 1991, p. 1.

⁽⁶⁾ OJ No L 172, 30. 6. 1986, p. 2.

HAS ADOPTED THIS REGULATION:

Article 1

Subject to Article 2 (2) of this Regulation, Common Customs Tariff duties shall be totally suspended until 31 December 1992 for products listed in the Annex to this Regulation and originating in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama. Without prejudice to the levying of any supplementary duties that may apply, Article 1 (4) and Articles 7 to 12 of Regulation (EEC) No 3833/90 ⁽¹⁾ shall apply to those countries and to the products listed in the Annex to this Regulation.

Article 2

1. Regulation (EEC) No 3833/90 shall continue to apply to products originating in countries mentioned in Article 1 and not listed in the Annex to this Regulation, but in Annex II to Regulation (EEC) No 3833/90.
2. Regulation (EEC) No 3833/90 shall continue to apply to products falling within Chapter 3 of the Common Customs Tariff originating in Panama.

Article 3

This Regulation shall enter into force on 1 January 1992.

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

Done at Brussels, 16 December 1991.

For the Council
The President
H. VAN DEN BROEK

⁽¹⁾ OJ No L 370, 31. 12. 1990, p. 86.

ANNEX

List of products covered by Article 1 ⁽¹⁾ ⁽²⁾

CN Code	Description
CHAPTER 3 except 0301	Fish and crustaceans, molluscs and other aquatic invertebrates
0409 00 00	Natural honey
CHAPTER 6 except 0601	Live trees and other plants, bulbs, roots and the like; cut flowers and ornamental foliage
0708	Leguminous vegetables, shelled or unshelled, fresh or chilled
0709 60 99	Other vegetables, fresh or chilled: other
0709 90 90	Other
0710 all codes except 0710 80 10	Vegetables (uncooked or cooked by steaming or boiling in water), frozen
0803 00 90	Bananas, including plantains, dried
0804 30 00	Pineapples
0804 50 00	Guavas, mangoes and mangosteens
1604	Prepared or preserved fish; caviar and caviar substitutes prepared from fish eggs
1803	Cocoa paste, whether or not defatted
1804	Cocoa butter, fat and oil
1806	Chocolate and other food preparations containing cocoa
2001	Vegetables, fruit, nuts and other edible parts of plants, prepared or preserved by vinegar or acetic acid
2004	Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, frozen
2005	Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, not frozen
2007	Jams, fruit jellies, marmalades, fruit or nut purée and fruit or nut pastes, being cooked preparations, whether or not containing added sugar or other sweetening matter
2008	Fruit, nuts and other edible parts of plants, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included
2009	Fruit juices (including grape must) and vegetable juices, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter
2101	Extracts, essences and concentrates, of coffee, tea or maté and preparations with a basis of these products or with a basis of coffee, tea or maté; roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof

⁽¹⁾ Notwithstanding the rules for the interpretation of the combined nomenclature, the wording for the description of the goods shall be considered as having no more than an indicative value, the preferential scheme being determined, within the context of this Annex, by the coverage of the CN codes. Where ex CN codes are indicated, the preferential scheme is to be determined by application of the CN code and the corresponding description taken together.

⁽²⁾ Agricultural products which, under standard procedure, enjoy exemption from, or the total temporary suspension of, Common Customs Tariff duty are listed only *pro memoria*.

CN Code	Description
2106 except 2106 90 30, 2106 90 51, 2106 90 55, 2106 90 59	Food preparations not elsewhere specified or included
2204 except 2204 10 11 to 2204 30 10	Wine of fresh grapes, including fortified wines; grape must other than that of heading No 2009
2208 except 2208 40 90, 2208 90 11 and 2208 90 19	Undenatured ethyl alcohol of an alcoholic strength by volume of less than 80 % vol; spirits, liqueurs and other spirituous beverages; compound alcoholic preparations of a kind used for the manufacture of beverages
2401 2402	Unmanufactured tobacco; tobacco refuse: Cigars, cheroots, cigarillos and cigarettes, of tobacco or of tobacco substitutes:
0805 30 90 0805 40 00	Citrus fruit, fresh or dried: Limes Grapefruit
0807 10 10 0807 10 90 0807 20 00	Melons (including watermelons) and papaws (papayas), fresh Watermelons Other Papaws (papayas)
0810 90 80	Other fruit, fresh
0811	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter
CHAPTER 9	Coffee, tea, maté and spices, excluding products falling within CN codes 0905 00 00 and 0907 00 00
1201 1202 1207 1209 1211 1214	Soya beans, whether or not broken Ground-nuts, not roasted or otherwise cooked, whether or not shelled or broken Other oil seeds and oleaginous fruits, whether or not broken Seeds, fruit and spores, of a kind used for sowing Plants and parts of plants (including seeds and fruits), of a kind used primarily in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes, . . . Swedes, mangolds, fodder roots, . . .
1301 1302	Lac; natural gums, resins, gum-resins and balsams Vegetable saps and extracts; pectic substances, . . .
1504 except code 1504 30 11	Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified
1519	Industrial monocarboxylic fatty acids; acid oils from refining; industrial fatty alcohols
1520	Glycerol (glycerine), whether or not pure; glycerol waters and glycerol lyes

COMMISSION REGULATION (EEC) No 3901/91

of 18 December 1991

laying down certain detailed rules on the description and presentation of special wines

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organization of the market in wine ⁽¹⁾, as last amended by Regulation (EEC) No 1734/91 ⁽²⁾, and in particular Article 72 ⁽⁵⁾ thereof,Whereas Council Regulation (EEC) No 3895/91 ⁽³⁾ provides that the alcoholic strength is to be indicated on the labelling of liqueur wines, semi-sparkling wines and aerated semi-sparkling wines and that closing devices on bottles containing such wines may no longer be covered by a capsule or foil made from lead as from 1 January 1993; whereas detailed rules of application should be laid down along the lines of the rules adopted for the description of wines, grape must and sparkling wines;Whereas the provisions of this Regulation are to replace those of Commission Regulation (EEC) No 1069/87 of 15 April 1987 laying down detailed rules as regards the indication of alcoholic strength on the labelling of special wines ⁽⁴⁾; whereas those provisions must accordingly be repealed;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Wine,

HAS ADOPTED THIS REGULATION:

Article 1

1. The actual alcoholic strength by volume indicated on the labelling of liqueur wines, semi-sparkling wines and aerated semi-sparkling wines shall be expressed as a unit or half-unit percentage by volume.

⁽¹⁾ OJ No L 84, 27. 3. 1987, p. 1.

⁽²⁾ OJ No L 163, 26. 6. 1991, p. 6.

⁽³⁾ See page 1 of this Official Journal.

⁽⁴⁾ OJ No L 104, 16. 4. 1987, p. 14.

The actual alcoholic strength by volume indicated may not be more than 0,8 % vol more or less than the strength determined by analysis.

2. The figure expressing the actual alcoholic strength by volume shall be followed by the symbol '% vol' and may be preceded by the words 'actual alcoholic strength' or 'actual alcohol', or the abbreviation 'alc.'. It shall be indicated on the labelling in lettering which is not less than 3 mm high.

Article 2

Liqueur wines, semi-sparkling and aerated semi-sparkling wines which:

(a) were put up before 1 May 1988 in containers of a nominal value of 60 litres or less with labelling:

— on which the actual alcoholic strength by volume is not indicated in accordance with Article 1 but is indicated in accordance with the national provisions applicable before that date,

or

— on which the alcoholic strength is not indicated and did not have to be indicated under the national provisions in force before that date;

or

(b) were put up before 1 January 1993 in bottles with closing devices covered by a capsule or foil made from lead,

may be kept for sale, put on the market or exported until all the stocks concerned have been disposed of.

Article 3

Regulation (EEC) No 1069/87 is hereby repealed.

Article 4

This Regulation shall enter into force on the third day following 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, 18 December 1991.

For the Commission

Ray MAC SHARRY

Member of the Commission

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 11 December 1991

designating the Community reference laboratories for testing certain substances for residues

(91/664/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues ⁽¹⁾, and in particular Article 8 (2) thereof,

Having regard to the proposal from the Commission,

Whereas coordination between the national reference laboratories responsible in the Member States for the examination of animals and their meat for the presence of residues must be assigned to highly specialized laboratories possessing the installations and equipment necessary for this type of analysis;

Whereas the Council, in its Decision 89/187/EEC ⁽²⁾, determined the powers and conditions of operation of the Community reference laboratories provided for in Directive 86/469/EEC;

Whereas, in accordance with Article 8 (2) of Directive 86/469/EEC, it is important to designate at this point the Community reference laboratories for testing certain substances for residues,

Whereas reference laboratories are eligible for Community aid according to the conditions referred to in Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽³⁾,

HAS ADOPTED THIS DECISION:

Article 1

The following laboratories are hereby designated Community reference laboratories:

- (a) for the residues included in Annex I, groups A. I and A. II, of Directive 86/469/EEC:

Rijksinstituut voor de Volksgezondheid en Milieuhygiëne

Antonie van Leeuwenhoeklaan 9

NL-3720 Bilthoven;

- (b) for the residues included in Annex I, group A. III. (a), of Directive 86/469/EEC, with the exception of sulphonamides:

Laboratoire des Médicaments vétérinaires

(CNEVA-LMV)

La Haute Marché, Javené

F-35133 Fougères;

⁽¹⁾ OJ No L 275, 26. 9. 1986, p. 36.

⁽²⁾ OJ No L 66, 10. 3. 1989, p. 37.

⁽³⁾ OJ No L 224, 18. 8. 1990, p. 19.

- (c) for the residues included in Annex I, group A.III. (b), of Directive 86/469/EEC, and the residues of beta-agonists and sulphonamides:

Bundesgesundheitsamt

Thielallee 88—92

D-1000 Berlin 33;

- (d) Directive 86/469/EEC:

Istituto Superiore di Sanità

via Regina Elena 299

I-00161 Roma.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11 December 1991.

For the Council

The President

P. BUKMAN

COUNCIL DECISION

of 11 December 1991

designating a Community Coordinating Institute for foot-and-mouth disease vaccines and laying down its functions

(91/665/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease ⁽¹⁾, as amended by Directive 90/423/EEC ⁽²⁾, and in particular Article 14 thereof,

Having regard to the proposal from the Commission,

Whereas Article 14 (1) of Directive 85/511/EEC authorizes Member States to retain reserves of antigens and to designate establishments for the packaging and storage of ready-to-use vaccines for emergency vaccination;

Whereas, pursuant to Article 14 (3) of that Directive, the Commission is required in particular to make proposals for the setting-up of at least two Community reserves of foot-and-mouth disease vaccines;

Whereas Article 14 (2) of that same Directive provides for the designation of a specialized institute responsible for carrying out checks on foot-and-mouth disease vaccines and cross-immunity checks, as well as providing for the institute's powers to be determined,

HAS ADOPTED THIS DECISION:

Article 1

Coordination of the control of foot-and-mouth disease vaccines used within the Community shall be carried out by the 'Centraal Diergeneeskundig Instituut, Lelystad, Nederland', hereinafter referred to as the 'Community Coordinating Institute'.

Article 2

The functions of the Community Coordinating Institute shall be:

1. to coordinate the methods of control carried out by the national laboratories on foot-and-mouth disease antigens and vaccines intended for use in accordance with Articles 13 (3) and 14 (1) of Directive 85/511/EEC;

2. to coordinate the control of foot-and-mouth disease vaccines by national laboratories in each Member State specifically by:

- (a) at regular intervals or at the request of the Institute or the Commission, receiving representative samples of batches of foot-and-mouth disease vaccines intended for use in the Community, including those produced in third countries for use either in the Community or in Community-supported vaccination campaigns, and testing such vaccines for safety and potency;
- (b) carrying out comparative studies to ensure that safety and potency testing in each Member State is carried out by comparable methodology;
- (c) testing, by means of cross-immunity assays in live cattle, the efficacy of existing vaccines against important new field strains of foot-and-mouth disease virus and communicating the results of such assays without delay to the Commission and the Member States;
- (d) gathering data and information on the control procedures and the vaccine tests and the periodic transmission of such information to the Commission and the Member States;

3. (a) to implement the necessary arrangements for further training of experts in vaccine verification and testing with a view to harmonizing such techniques;
- (b) to organize an annual meeting where representatives of the national laboratories may review vaccine control and testing techniques and the progress of coordination;

4. (a) to check antigen submitted for the Community foot-and-mouth disease vaccine reserves, as set up in accordance with Decision 91/666/EEC ⁽³⁾, for potency, safety and compliance with veterinary technical supply conditions;
- (b) to carry out routine potency testing of antigen stored in the Community foot-and-mouth disease vaccine reserves;

⁽¹⁾ OJ No L 315, 26. 11. 1985, p. 11.

⁽²⁾ OJ No L 224, 18. 8. 1990, p. 13.

⁽³⁾ See page 21 of this Official Journal.

- (c) to check the sterility of vaccine produced from the Community antigen reserves when needed, in accordance with the European Pharmacopoeia;
5. (a) in cooperation with appropriate Community experts, to assist and advise the Commission in ensuring that institutes which produce foot-and-mouth disease vaccines meet the necessary minimum safety requirements and in particular those laid down in accordance with Article 3 (2) of Council Decision 89/531/EEC of 25 September 1989 designating a reference laboratory for the identification of foot-and-mouth disease virus and determining the functions of that laboratory ⁽¹⁾;
- (b) in cooperation with appropriate Community experts, to assist the Commission in reviewing the list of establishments and laboratories authorized to manipulate the virus in connection with vaccine production, in accordance with Article 13 (2) of Directive 85/511/EEC;
6. in cooperation with the suppliers of antigen and the reference laboratory for the identification of the foot-and-mouth disease virus, to review strains stored in the Community reserves and to assist in selecting suitable new strains to be adapted to tissue culture for future vaccine production;
7. to store important seed virus strains other than those held in Community foot-and-mouth disease vaccine reserves;
8. at the request of the Commission, and taking account of scientific and technological developments, to carry out research into the efficacy and innocuity of vaccines, which is necessary or useful for their monitoring, in conformity with detailed conditions to be determined under the procedure provided for in Article 16 of Directive 85/511/EEC;
9. to collaborate with the reference laboratory for the identification of the foot-and-mouth disease virus in all relevant aspects of foot-and-mouth disease, including the publishing of an annual bulletin on the respective activities of the Community Coordinating Institute and the said laboratory and the training of veterinarians concerned in the clinical diagnosis and epidemiology of foot-and-mouth disease.

Article 3

1. The Community Coordinating Institute shall operate according to recognized conditions of strict disease security as indicated in 'Minimum standards for institutes working with foot-and-mouth disease virus *in vitro* and *in vivo*' — European Commission for the control of foot-and-mouth disease — 26th session, Rome, April 1985.

2. The Community Coordinating Institute shall formulate and recommend the disease security measures to be taken by national laboratories in accordance with the standards referred to in paragraph 1, particularly as regards monitoring of foot-and-mouth disease vaccines, except for those tasks which Article 3 (2) of Decision 89/531/EEC assigns to the reference laboratory for the identification of foot-and-mouth disease virus.

Article 4

The rules to be followed with regard to funding shall be adopted in accordance with Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽²⁾, as amended by Decision 91/133/EEC ⁽³⁾.

Article 5

The Community Coordinating Institute shall be appointed for a period of 5 years as from 1 January 1992.

Before that period expires, the Council, acting by a qualified majority on a proposal from the Commission, shall decide whether the said period should be continued or whether this Decision should be amended.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 11 December 1991.

For the Council
The President
P. BUKMAN

⁽¹⁾ OJ No L 279, 28. 9. 1989, p. 32.

⁽²⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽³⁾ OJ No L 66, 13. 3. 1991, p. 18.

COUNCIL DECISION

of 11 December 1991

establishing Community reserves of foot-and-mouth disease vaccines

(91/666/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease ⁽¹⁾, as amended by Decision 90/423/EEC ⁽²⁾, and in particular Article 14 thereof,

Having regard to the proposal from the Commission,

Whereas by 1 January 1992 all Member States must have discontinued routine vaccination against foot-and-mouth disease in their territory;

Whereas, however, in view of the high density of susceptible species in some parts of the Community, it is necessary to provide for the possibility of emergency vaccination in a limited area, in circumstances where slaughter of the entire herd may not be sufficient to eliminate the virus;

Whereas Community reserves of foot-and-mouth disease vaccine should be established, based on stocks of concentrated inactivated antigen capable of being quickly converted into vaccine for emergency use;

Whereas the antigen should be stored at four separate locations; whereas facilities for formulation, bottling and distribution must also be provided;

Whereas the criteria for the supply and storage of antigen and its conversion into vaccine should be established;

Whereas the national institutes responsible for maintaining the reserve of antigen should cooperate with the Community Coordinating Institute for foot-and-mouth disease vaccines designated by Decision 91/665/EEC ⁽³⁾ in order to ensure the potency, safety and stability of the antigen, and vaccines produced therefrom, and to ensure that the quantity and sub-types kept are appropriate to the risk, on the basis, in particular, of information supplied by the reference laboratory for the identification of foot-and-mouth disease virus designated by Decision 89/531/EEC ⁽⁴⁾;

Whereas Article 14 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽⁵⁾, as

amended by Decision 91/133/EEC ⁽⁶⁾, provides that the establishment of a Community reserve of foot-and-mouth disease vaccines may be eligible for Community aid,

HAS ADOPTED THIS DECISION:

Article 1

The establishment of Community reserves of foot-and-mouth disease vaccine shall consist of:

- the supply of concentrated inactivated antigen by establishments designated by Member States,
- the storage, in reserves, of the antigen referred to in the first indent,
- the guarantee of rapid formulation, bottling and distribution by establishments designated by Member States.

Article 2

For the purposes of this Decision the following definitions shall apply:

1. antigen banks: appropriate premises, such as those designated in Article 3 (1), for the storage of Community reserves of concentrated inactivated antigen for the production of foot-and-mouth disease vaccine;
2. Community Coordinating Institute for foot-and-mouth disease vaccine (CCI): the institute designated by Decision 91/665/EEC.

Article 3

1. Antigen banks shall be established at:

- the Institute for Animal Health, Pirbright (United Kingdom),
- the Laboratoire de pathologie bovine du centre national d'études vétérinaires et alimentaires, Lyon (France),
- Bayer AG, Cologne (Germany),
- the Istituto Zooprofilattico Sperimentale di Brescia (Italy).

2. The amounts and sub-types of antigen to be held in the antigen banks shall be as laid down in Annex I.

⁽¹⁾ OJ No L 315, 26. 11. 1985, p. 11.

⁽²⁾ OJ No L 224, 18. 8. 1990, p. 13.

⁽³⁾ See page 19 of this Official Journal.

⁽⁴⁾ OJ No L 279, 28. 9. 1989, p. 32.

⁽⁵⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽⁶⁾ OJ No L 66, 13. 3. 1991, p. 18.

3. The antigen shall be distributed between the antigen banks in such a way as to ensure that, in the event of technical problems which result in deterioration of the antigen in one of the said banks, the availability of antigen for vaccine production is guaranteed by the other antigen banks.

Article 4

The functions and duties of the antigen banks shall be:

- (a) to store the Community reserves of concentrated inactivated foot-and-mouth disease virus antigens in such a way as to maintain their usefulness for the production of a safe and potent vaccine for emergency use against foot-and-mouth disease, including the keeping of adequate records of the conditions under which the antigen is stored;
- (b) to liaise with the CCI for the purposes of:
 - (i) checking incoming batches of antigen for stability, potency and safety;
 - (ii) testing batches of stored antigen for stability, potency and safety at intervals to be determined under the procedure laid down in Article 10, following an opinion from the Scientific Veterinary Committee;
 - (iii) advising on the need for replacement of an antigen if tests indicate that its potency is inadequate;
- (c) to deliver concentrated inactivated antigen to establishments designated for the formulation, bottling and distribution of the vaccine, at the request of the Commission or a Member State under the conditions provided for in the second and third subparagraphs of Article 13 (3) of Directive 85/511/EEC, for use in the Member State or third country in which the vaccine is to be used.

Article 5

1. The establishments which are to supply the quantities and sub-types of antigens mentioned in Annex I and, without prejudice to Article 13 of Directive 85/511/EEC, those which are to ensure the formulation, production, bottling and distribution of the foot-and-mouth disease vaccine produced from the antigen shall be designated in accordance with the procedure laid down in Article 10 of this Decision.

2. For the purposes of paragraph 1, the Commission shall issue a call for tenders, taking into account the following criteria in particular:

- (a) the technical requirements concerning the supply of antigens, in accordance with Annex II;
- (b) the supply and delivery of the specified quantity to the antigen bank in a form suitable for long-term storage in liquid nitrogen, or other storage methods recognized, under the procedure laid down in Article 10 after obtaining the opinion of the Scientific Veterinary

Committee, as giving at least equivalent stability, including the provision of separate replicates suitable for routine testing;

- (c) a guarantee that any antigen supplied will meet the safety and stability requirements defined for vaccine by the European Pharmacopoeia, as well as the required potency (6 PD 50/dose) when tested as specified for vaccine;
- (d) the reagents and materials to be used in the formulation of the vaccine;
- (e) a guarantee that the vaccine supplied complies fully with the European Pharmacopoeia;
- (f) supply of the vaccine, within a given time and at a guaranteed rate of delivery, in bottles of suitable size, labelled in the language or languages of the country in which the vaccine is to be used;
- (g) compliance by the establishment which supplies an antigen with the 'minimum standards for laboratories working with foot-and-mouth disease virus *in vitro* and *in vivo*' — European Commission for the control of foot-and-mouth disease — 26th session, Rome, April 1985, on the basis, where necessary, of a report by experts acting under the procedure laid down in Article 10;
- (h) quoted costs for the supply of the antigen or the provision of the service, as appropriate.

Article 6

The antigen banks, the establishments supplying the antigen and the establishments carrying out formulation and bottling shall operate under strict conditions of hygiene and safety, in accordance with the generally accepted standards for good manufacturing practice in Europe, which shall be monitored by the CCI.

Article 7

Detailed arrangements for the implementation of this Decision shall be adopted under the procedure laid down in Article 10, in particular as regards:

- the distribution of antigen reserves between antigen banks,
- general procedures for replacing antigen reserves,
- the rules to be followed, should Decision 90/424/EEC be invoked, in making available to third countries vaccines produced from antigens to be replaced in accordance with the second indent,
- any derogations, after obtaining the opinion of the Standing Veterinary Committee, from the figure of 6 PD 50/dose laid down in Article 5 (2) (c) for new vaccines.

Article 8

Commission veterinary experts may, in collaboration with the competent authorities of the Member States, carry out on-the-spot inspections to verify whether or not the establishments and antigen banks are operating in accordance with this Decision.

The Commission shall inform the Member States of the outcome of such inspections.

The Member State in whose territory the inspections are carried out shall provide the experts with all the assistance required for the accomplishment of their task.

General rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 10.

Article 9

Annexes I and II may be supplemented or amended in accordance with the procedure laid down in Article 10.

Article 10

1. Where the procedure laid down in this Article is to be followed, the chairman of the Standing Veterinary Committee set up by Decision 68/361/EEC ⁽¹⁾, hereinafter referred to as 'the Committee', shall refer the matter without delay to the Committee either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a

proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

4. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within 15 days of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, except where the Council has decided against the measures by a simple majority.

Article 11

The Council, acting by a qualified majority on a proposal from the Commission, shall review this Decision before 1 January 1995.

Article 12

This Decision is addressed to the Member States.

Done at Brussels, 11 December 1991.

For the Council
The President
P. BUKMAN

⁽¹⁾ OJ No L 255, 18. 10. 1968, p. 23.

ANNEX I

Quantities and sub-types of antigen to be held in the antigen banks

Potent, well-tested vaccine strains corresponding to:

- O₁ European strain
- O₂ Middle East strain
- A₅ European strain
- A₂₄ South American strain
- A Middle East strain
- C₁ European strain
- ASIA₁
- SAT₂
- SAT₁

A recent type A strain like A/87 Argentina should be included in the collection of strains.

The above strains shall be kept in quantities sufficient to provide at least five million doses of each sub-type. Each dose should have an observed potency of 6 PD50 in cattle, when tested according to the European Pharmacopoeia.

ANNEX II

Technical requirements for supply of concentrated inactivated monovalent foot-and-mouth disease virus antigen and its formulation into vaccine

1. Availability of concentrated inactivated antigen suitable for storage in liquid nitrogen, or by a method giving at least equivalent stability.
2. Availability of antigen corresponding to each of the sub-types specified in Annex I. The antigen must also be suitable for the preparation of oil emulsion vaccines for pigs, in which case $\frac{1}{6}$ of a dose volume must protect at least 5 out of 10 pigs if challenged by intrapodal injection of 1 000 ID50.
3. Full information should be provided on the tests conducted by the producer on seed virus, cells and other materials used in the production.

Samples of each master seed virus must be submitted to the CCI for confirmatory tests of identity and purity.

Samples of the cells used to produce the virus should be submitted to the CCI.

4. The manufacture and quality of antigen must be consistent with the generally accepted standards for good manufacturing practice in Europe.

The vaccines to be produced on the basis of the antigen must comply with the requirements of the European Pharmacopoeia. In addition:

- (a) the antigen shall have been inactivated before concentration using a first order inactivant. For each batch of antigen the kinetics of inactivation must be followed and documented by the producer. The range of inactivation must be such that the batch as a whole is free from infective virus, and the safety margin should be in the range of about 3 log₁₀ (based on extrapolation); and

- (b) the mixture of virus preparation/inactivant must have been transferred to a second sterile container when half of the inactivation time has elapsed in such a manner as to prevent contamination; an equivalent method could, however, be acceptable; and
- (c) subsequent processing of the antigen should be carried out in a non-contaminated environment (FMD virus free). Polyethyleneglycol (PEG) precipitation, polyethyleneoxide (PEO) precipitation, ultrafiltration or a combination of these are permitted methods for the concentration of inactivated antigen; and
- (d) before and during the performance of innocuity tests, the inactivated antigen should be stored in a sealed container, in a quarantine area, outside the restricted (high-security) area; and
- (e) the concentrated product containing the inactivated antigen should be in a volume at least 100 times less than that used for formulation of conventional vaccines. The producer must indicate the number of vaccine doses per volume unit of concentrated material; and
- (f) the main bulk of the inactivated antigen should be supplied in containers suitable for storage over liquid nitrogen and divided into volumes to be agreed between the producer and the CCI.

In consultation with, and under the supervision of, the CCI, the producer must also provide 20 representative samples containing at least 1 mg each of concentrated 146S antigen for periodic *in vitro* and *in vivo* tests; and

- (g) the producer must provide relevant information about the antigen and its formulation into vaccine for consideration by the CCI.
5. (a) On receipt, each batch of concentrated inactivated antigen will be checked by the CCI for possible residual infective virus *in vitro* and in cattle using the method prescribed for vaccine in the European Pharmacopoeia; and
- (b) potency of the vaccines prepared from the concentrated antigen will be tested by the CCI. Vaccines will be formulated according to the prescription of the producer. Vaccines for pigs will be formulated as oil emulsions. For cattle, aluminium-hydroxide-, saponin- or oil-adjuvanted vaccines may be used. Any batches found to be unsatisfactory when tested immediately upon reconstitution following deposit in the antigen bank will be rejected and be replaced at the producer's expense. The cost of testing the replacement batch will be met by the producer;
- (c) components of the concentrated antigen must not interfere with the preparation and stability of the oil-emulsion vaccines.
6. The antigen as provided by the producer should have an expected stability of at least five years.
7. (a) The concentration and quality of the vaccine adjuvants will be agreed with the CCI.
- (b) The producer should also specify the expected shelf-life of the product after formulation into vaccine. This shelf-life should be at least four months.
8. Vaccines which have exceeded their expiry date must not be used; this date can be checked and if necessary reviewed by the CCI.
9. Formulated vaccines must be kept under cool temperature conditions as specified in the European Pharmacopoeia. Care should be taken to maintain the correct temperature during distribution, until administered.
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