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Legislation

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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.

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EN

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Corrigenda

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 538/95

of 6 March 1995

amending Regulation (EC) No 519/94 on common rules for imports from certain third countries

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

Whereas Council Regulation (EC) No 519/94 of 7 March 1994 on common rules for imports from certain third countries and repealing Regulations (EEC) No 1765/82, (EEC) No 1766/82 and (EEC) No 3420/83 [1], introduced certain quantitative quotas, listed in Annex II to that Regulation, applicable to the People's Republic of China;

Whereas, in accordance with Article 2 of the Act of Accession of Austria, Finland and Sweden, these quotas are applicable to the acceding countries, subject to and on the date of the entry into force of the Treaty concerning the accession of those acceding countries; whereas in accordance with Article 169 of the Act of Accession, the Community institutions may make the necessary adaptations to Community acts which have not been provided for in that Act;

Whereas the Council, in determining the level of the quotas referred to above, endeavoured to strike a balance between adequate protection of the Community industries concerned and the need to preserve traditional trade flows with the People's Republic of China, bearing in mind the various interests of the parties concerned;

Whereas, in the context of accession, that balance should be preserved by ensuring continuity in the acceding countries' traditional trade flows for the products concerned, without prejudice to the protection of the Community industry;

Whereas, to that end, it should be borne in mind that imports of the products concerned have developed in each of the acceding countries without the constraints imposed by quantitative restrictions; whereas imports recorded in 1993 — the most recent year for which full statistical records are available — may be considered as being representative of the pattern of traditional trade;

Whereas in these circumstances, the levels of quotas established on an annual basis pursuant to Regulation (EC) No 519/94 should be adjusted by additional of the quantities shown in the Annex to this Regulation, which are equivalent to imports recorded in 1993;

Whereas, in addition, the experience gained in applying and administering the 1994 quotas together with a review of the situation of the various Community producers based on available data concerning the main economic indicators, and in particular production, exports, imports, consumption and employment levels, suggest that some of these quotas could be increased and that the quota for gloves falling within CN code 4203 29 10 could be abolished; whereas such increases may be introduced while guaranteeing the necessary level of protection for the Community industry and ensuring a more appropriate volume of trade with China; whereas the same does not hold in respect of quotas imposed on footwear, which should not be increased beyond the quantities required by reason of the accession of the new Member States;

Whereas, however, Regulation (EC) No 519/94 had excluded from the application of any quantitative restrictions certain sports footwear involving special technology; whereas in-depth analysis of the sector shows that the range of such footwear may be freely imported without causing prejudice to the Community industry can be expanded; whereas the quotas covering the products falling within CN codes ex 6402 19 and ex 6403 19 should be abolished and the mention of the cif price condition appearing in the definition of the footwear involving special technology should be modified;

Whereas, therefore, the quantitative quotas introduced by Regulation (EC) No 519/94 should be modified as shown in the Annex to this Regulation;

[1] OJ No L 67, 10. 3. 1994, p. 89. Regulation as amended by Regulation (EC) No 1921/94 (OJ No L 198, 30. 7. 1994, p. 1).

Whereas the products in respect of which quotas are abolished by this Regulation should, however, be subject to prior Community surveillance;

Whereas Annex III to Regulation (EC) No 519/94 should therefore be amended to take account, *inter alia,* of certain amendments made to the combined nomenclature;

Whereas quotas should not apply to products en route for one of the acceding countries on 31 December 1994 where their destination cannot be changed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 519/94 shall be replaced by the Annex to this Regulation.

Article 2

The following amendments shall be made to Annex III to Regulation (EC) No 519/94:

1. 'Food preparations falling under HS/CN code .1901 90 90' shall be replaced by:

   'Food preparations falling within HS/CN codes: 1901 90 91
   1901 90 99';

2. the following product shall be added to the list of products originating in the People's Republic of China and subject to Community surveillance

   'Protective gloves falling within HS/CN code: 4203 29 10';

3. the text concerning footwear shall be replaced by the following:

'Footwear falling within HS/CN codes: 6402 19
ex 6402 99 (1)

6403 19
ex 6403 91 (1)

ex 6403 99 (1)

ex 6404 11

(1) (a) Footwear which is designed for a sporting activity and has, or has provision for the attachment of, spikes, sprigs, stops, clips, bars or the like, with a non-injected sole,

(b) Footwear involving special technology: shoes which have a cif price per pair of not less than ECU 9 for use in sporting activities, with a single- or multi-layer moulded sole, not injected, manufactured from synthetic materials specially designed to absorb the impact of vertical or lateral movements and with technical features such as hermetic pads containing gas or fluid, mechanical components which absorb or neutralize impact or materials such as low-density polymers.'

Article 3

Products en route for either Austria, Finland or Sweden on 31 December 1994 shall not be subject to the quotas listed in the Annex to this Regulation and may therefore be freely imported, where their destination cannot be changed.

Article 4

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 January 1995.

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

Done at Brussels, 6 March 1995.

For the Council

The President

A. JUPPÉ

ANNEX

'ANNEX II

List of quotas for certain products originating in China

Description	CN code	Quotas (annual basis)	Of which by reason of accession
Gloves falling within HS/CN codes	4203 29 91 4203 29 99	ECU 15 177 038	ECU 5 616 038
Footwear falling within HS/CN codes	ex 6402 99 (1)	39 151 481 pairs	4 151 481 pairs
	6403 51 6403 59	2 740 116 pairs	240 116 pairs
	ex 6403 91 (1) ex 6403 99 (1)	11 881 963 pairs	1 955 963 pairs
	ex 6404 11 (1)	18 228 780 pairs	1 378 780 pairs
	6404 19 10	31 897 716 pairs	2 845 716 pairs
Tableware, kitchenware of porcelain or china	6911 10	43 619 tonnes	3 893 tonnes
Ceramic tableware or kitchenware	6912 00	33 000 tonnes	2 377 tonnes
Glassware of a kind used for table, etc.	7013	14 210 tonnes	1 906 tonnes
Cas radios falling within HS/CN codes	8527 21 8527 29	2 238 899 units 251 664 units	138 899 units 19 587 units
Toys falling within HS/CN codes	9503 41 9503 49 9503 90	ECU 274 764 243 ECU 132 767 177 ECU 649 465 212	ECU 16 447 910 ECU 11 110 177 ECU 44 714 212

(1) Excluding:

(a) footwear which is designed for a sporting activity and has, or has provision for the attachment of, spikes, sprigs, stops, clips, bars or the like, with a non-injected sole;

(b) footwear involving special technology: shoes which have a cif price per pair of not less than ECU 9 for use in sporting activities, with a single- or multi-layer moulded sole, not injected, manufactured from synthetic materials specially designed to absorb the impact of vertical or lateral movements and with technical features such as hermetic pads containing gas or fluid, mechanical components which absorb or neutralize impact or materials such as low-density polymers.'

COMMISSION REGULATION (EC) No 539/95

of 10 March 1995

laying down the extent to which applications lodged on 6 and 7 March 1995 for certificates for the advance-fixing of the export refund for certain poultrymeat products may be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 437/95 of 28 February 1995 laying down detailed rules for granting a special refund for exports of poultrymeat sector products to certain third countries [1], and in particular Article 3 thereof,

Whereas the export refunds for poultrymeat are laid down by Commission Regulation (EC) No 442/95 [2];

Whereas Regulation (EC) No 437/95 lays down that refunds must be fixed in advance for control purposes;

Whereas pursuant to Article 3 of Regulation (EC) No 437/95, it may be decided to terminate the lodging of applications for advance-fixing certificates and to reduce the quantities applied for when the total quantity exceeds 40 000 tonnes; whereas, in view of the quantities for which advance-fixing certificates have been applied for, applications may be granted in full,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for certificates for the advance-fixing of the refund for products falling within CN codes 0207 21 10 and 0207 21 90 referred to in the Annex to Regulation (EC) No 442/95 and which must be exported under the conditions laid down in Regulation (EC) No 437/95, submitted on 6 and 7 March 1995, shall be granted in full.

Article 2

This Regulation shall enter into force on 13 March 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 45, 1. 3. 1995, p. 30.
[2] OJ No L 45, 1. 3. 1995, p. 42.

COMMISSION REGULATION (EC) No 540/95

of 10 March 1995

laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1], and in particular Articles 22 (1) third paragraph and 44 (1) third paragraph thereof,

Whereas a number of adverse reactions not described in the summary of products characteristics of the medicinal product may occur and be identified at any time of marketing of a medicinal product;

Whereas Articles 22 (1) and 44 (1) have already provided for reporting of suspected serious adverse reactions to medicinal products for human use and to veterinary medicinal products respectively;

Whereas innovative medicinal products deserve a close pharmacovigilance supervision in the interest of human and animal health, including unexpected, non-serious, suspected adverse reactions, whether arising in the Community or in a third country and reported to the holders of marketing authorizations by health professionals and also, in the veterinary sector, by other appropriate persons;

Whereas holders of marketing authorizations should where necessary apply for a variation to the marketing authorization when it is confirmed that suspected unexpected adverse reactions not classified as serious are due to the medicinal product in question;

Whereas the European Agency for the Evaluation of Medicinal Products (hereinafter referred to as 'the Agency') should be responsible for coordinating the activities of the Member States in the field of monitoring of adverse reactions to medicinal products (pharmacovigilance);

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committees on Human and Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The person responsible for placing the medicinal product on the market shall ensure that suspected unexpected adverse reactions to a medicinal product authorized in accordance with the provisions of Regulation (EEC) No 2309/93, which are not classified as serious, arising in the Community or in a third country, are reported to the competent authorities of all Member States and to the Agency.

Article 2

Unless other requirements have been laid down as a condition of granting the marketing authorization by the Community, suspected unexpected adverse reactions which are not serious shall be reported by the holder of the marketing authorization in a distinct and clearly identified section of the periodical reports referred to in Articles 22 (2) and 44 (2) of Regulation (EEC) No 2309/93 ('safety updates'). These safety updates shall consist of a line listing of individual case reports accompanied by an overall scientific evaluation including a narrative review of the nature and other relevant characteristics of reactions, with special attention to any change in frequency.

Article 3

Data should to be incorporated into the relevant safety update until the end of each period referred to in Articles 22 (2) and 44 (2) of Regulation (EEC) No 2309/93 ('data lock-point'). Safety updates shall be submitted to the competent authorities not later than 60 days after each data-lock point.

[1] OJ No L 214, 24. 8. 1993, p. 1.

Article 4

Unexpected, non-serious, suspected adverse reactions which, according to the assessment carried out by the holder of the marketing authorization, can be attributed to the medicinal product and requiring a change to the summary of products characteristics referred to in Article 4 (9) second paragraph of Council Directive 65/65/EEC [1], as last amended by Directive 93/39/EEC [2], and in Article 5 (9) second paragraph of Council Directive 81/851/EEC [3], as last amended by Directive 93/40/EEC, shall be dealt with in accordance with Commission Regulation (EC) No 542/95 of 10 March 1995, as last amended by Directive 93/40/EEC [4], concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93 [5], and with Commission Regulation (EEC) No 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization granted by a competent authority of a Member State [6].

Article 5

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, 10 March 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No 22, 9. 2. 1965, p. 369/65.
(2) OJ No L 214, 24. 8. 1993, p. 22.
(3) OJ No L 317, 6. 11. 1981, p. 1.
(4) OJ No L 214, 24. 8. 1993, p. 31.
(5) See page 15 of this Official Journal.
(6) See page 7 of this Official Journal.

COMMISSION REGULATION (EC) No 541/95

of 10 March 1995

concerning the examination of variations to the terms of a marketing authorization granted by a competent authority of a Member State

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 75/319/EEC of 20 May 1975, on the approximation of provisions laid down by law, regulations or administrative action relating to medicinal products [1], as last amended by Council Directive 93/39/EEC [2] of 14 June 1993, and in particular Article 15 thereof,

Having regard to Council Directive 81/851/EEC of 28 September 1981, on the approximation of legislation of the Member States relating to veterinary medicinal products [3], as last amended by Council Directive 93/40/EEC [4], and in particular Article 23 thereof,

Whereas, appropriate provisions should be adopted for the examination of variations to the terms of a marketing authorization of medicinal products which have benefited from the procedures of mutual recognition foreseen in Articles 7 and 7a of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [5], as last amended by Directive 93/39/EEC, in Article 9 (4) of Council Directive 75/319/EEC or in Articles 8, 8a and 17 (4) of Council Directive 81/851/EEC, and medicinal products for which there has been a referral to the procedures foreseen by Articles 13 and 14 of Directive 75/319/EEC or Articles 21 and 22 of Directive 81/851/EEC;

Whereas, these provisions should also apply to the examination of applications to vary the terms of a marketing authorization which had been considered within the scope of application of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high technology medicinal products, particularly those derived from biotechnology [6];

Whereas, it is appropriate to include a notification system or administrative procedures concerning minor variations for which it is necessary to precisely define minor variations;

Whereas, moreover, it is necessary to distinguish from amongst those variations which do not qualify as minor variations, those which must be considered to so fundamentally alter the marketing authorization, particularly from the point of view of the quality, safety or efficacy of a medicinal product, that a new application for a marketing authorization would be required;

Whereas, the provisions of this Regulation are in accordance with the opinion of the Standing Committee on Medicinal Products for Human use and the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Scope and definitions

Article 1

1. This Regulation lays down the procedure for the examination of applications for variations to the terms of a marketing authorization of medicinal products which have been considered within the scope of application of Directive 87/22/EEC, of medicinal products having benefited from the procedures of mutual recognition foreseen in Articles 7 and 7a of Directive 65/65/EEC, Article 9 (4) of Directive 75/319/EEC or Articles 8, 8a and 17 (4) of Directive 81/851/EEC, and medicinal products for which there has been a referral to the procedures foreseen by Articles 13 and 14 of Directive 75/319/EEC or Articles 21 and 22 of Directive 81/851/EEC.

2. This Regulation does not impede the marketing authorization holder(s) from taking provisional urgent safety restrictions in the event of risk to public or animal health. The holder(s) shall forthwith inform the national competent authorities. If the competent authorities have not raised any objections within 24 hours, the urgent safety restrictions may be introduced and the applications for this variation shall be submitted to the national competent authorities for the application of the procedures set out in Articles 6 and 7 of this Regulation.

Article 2

For the purposes of this Regulation, the following definitions shall apply:

1. Variation to the terms of a marketing authorization:

— for medicinal products for human use: an amendment to the contents of the documents referred to in Articles 4 and 4a of Directive 65/65/EEC, in the Annex of Directive 75/318/EEC and in Article 2 of

[1] OJ No L 147, 9. 6. 1975, p. 13.
[2] OJ No L 214, 24. 8. 1993, p. 22.
[3] OJ No L 317, 6. 11. 1981, p. 1.
[4] OJ No L 214, 24. 8. 1993, p. 31.
[5] OJ No 22, 9. 2. 1965, p. 369/65.
[6] OJ No L 15, 17. 1. 1987, p. 38.

Directive 75/319/EEC, such as they existed at the moment of the decision on the marketing authorization or after approval of any previous variations; except where a new application for a marketing authorization must be presented pursuant to Annex II of this Regulation;

— for veterinary medicinal products: an amendment to the contents of the documents referred to in Articles 5, 5a and 7 of Directive 81/851/EEC such as they existed at the moment of the decision on the marketing authorization or after approval of any previous variation; except where a new application for a marketing authorizaton must be presented pursuant to Annex II of this Regulation.

2. Reference Member State: the Member State which, for a given medicinal product, has produced the assessment report which served as the basis for the Community procedures foreseen in Article 1 of this Regulation or alternatively the Member State chosen in this respect by the authorization holder with a view to application of this Regulation.

3. Urgent safety restriction: an interim change to product information by the marketing authorization holder restricting the indication(s), and/or dosage, and/or target species of the medicinal product; or adding a contra-indication, and/or warning due to new information having a bearing on the safe use of the product.

Article 3

1 (a) A 'minor variation' (type I) means a variation as defined in Article 2 and listed in Annex I to this Regulation, provided the conditions for such variations laid down in the said Annex are met.

(b) A 'major variation' (or type II) means a variation as defined in Article 2 which cannot be deemed to be a type I variation within the meaning of the preceding paragraph.

2. For the purposes of this Regulation, transfer of marketing authorization to a new holder, except for the situations covered by point 3 of Annex I to this Regulation shall not be considered as a variation in the meaning of Article 2 (1).

Notification procedure for minor variations

Article 4

1. (a) To obtain a type I variation, an identical application shall be submitted simultaneously to the national competent authorities of the different Member States where the medicinal product has been authorized; it shall be accompanied by documents demonstrating that the conditions laid down in Annex I of this Regulation for the requested variation have been met and all documents amended as a result of the application.

(b) The abovementioned documents shall include the list of Member States concerned by the application for the variation and shall identify the reference Member State for the medicinal product under consideration.

2. The Member States concerned shall forthwith notify the reference Member State about the receipt of the application. The reference Member State shall inform the Member States concerned and the marketing authorization holder(s) about the date of the start of the procedure.

3. An application within the meaning of paragraph 1 shall not concern more than one variation in the marketing authorization. Where several variations are to be made to a single marketing authorization, an application shall be submitted within the meaning of paragraph 1 in respect of each variation sought; each such application shall contain a reference to the other application(s).

4. By derogation to paragraph 3, where a variation in the marketing authorization entails one or more further changes, a single application may cover all such consequential variations. The single application shall describe the relation between the main variation and its consequential variations.

5. To be valid, an application within the meaning of paragraph 1 shall be consistent with the provisions of this Article and accompanied by the relevant fees provided for this purpose by the applicable national regulations.

Article 5

1. If, within 30 days of the date of the start of the procedure, the national competent authority of the reference Member State has not sent to the marketing authorization holder, who submitted the application, the notification provided for in paragraph 2 of this Article, the variation requested is deemed accepted by all Member States which have received the application.

2. Where one of the national competent authorities concerned cannot accept the request for the variation, that authority shall send objective grounds for non-acceptance to the reference Member State within a period of 20 days following the date of the start of the procedure. The reference Member State shall send, before the end of the period foreseen in paragraph 1, a notification with grounds to the marketing authorization holder who has submitted the application;

(a) within 30 days of receipt of the said notification, the marketing authorization holder may amend on one occasion only the application in order to take due

account of the grounds set out in the notification. In that case the provisions of this present Article apply to the amended application and all applications foreseen by Article 4 are deemed to have been modified in the same sense ;

(b) if the marketing authorization holder does not amend the application as provided for in (a) above, all applications are deemed to have been rejected. The national competent authority of the reference Member State shall forthwith notify the refusal to the marketing authorization holder and to the other concerned national competent authorities.

3. Within 10 days of the end of the procedure mentioned in paragraph 2 of this Article, and in cases of divergent positions among the national competent authorities of the concerned Member States leading to a refusal, the marketing authorization holder may refer the matter to the Agency for application of Article 15, last paragraph, of Directive 75/319/EEC or Article 23, last paragraph, of Directive 81/851/EEC.

Approval procedure for major variations

Article 6

1. (a) To obtain a type II variation, an identical application shall be submitted simultaneously to the national competent authorities of the different Member States where the medicinal product has been authorized. It shall be accompanied by the relevant particulars and supporting documents referred to in Article 2 (1) of this Regulation.

The application must also be accompanied by :

— the supporting data relating to the variation applied for,

— all documents amended as a result of the application,

— an Addendum to or updating of existing expert report(s) to take account of the variation applied for ;

(b) The above mentioned documents shall include the list of Member States concerned by the application for the variation and shall identify the reference Member State for the medicinal product under consideration.

2. The Member States concerned shall forthwith notify the reference Member States about the receipt of the application. The reference Member State shall inform the Member States concerned and the marketing authorization holder(s) about the date of the start of the procedure.

3. An application within the meaning of paragraph 1 shall not concern more than one variation in the marketing authorization. Where several variations are to be made to a single marketing authorization, an application shall be submitted within the meaning of paragraph 1 in respect of each variation sought ; each such application shall contain a reference to the other application(s).

4. By derogation to paragraph 3, where a variation in the marketing authorization entails one or more further changes, a single application may cover all such consequential variations. The single application shall describe the relation between the main variation and its consequential variations.

5. To be valid an application within the meaning of paragraph 1 shall be consistent with the provisions of this Article and accompanied by the relevant fees provided for this purpose by the applicable national regulations.

Article 7

1. Within 60 days following the date of the start of the procedure, the national competent authority of the reference Member State shall prepare an assessment report and a draft decision which shall be addressed to the other national competent authorities concerned.

2. Within that period, the competent authority of the reference Member State may send the marketing authorization holder a single request for information supplementary to that already supplied pursuant to Article 6. It shall inform the other competent authorities concerned. In this case the period shall be extended by a further 60 days. This period may be extended for a period to be determined by the competent authority on its own initiative or upon request of the marketing authorization holder.

3. Within 30 days following receipt of the draft decision and the assessment report, the other national competent authorities concerned shall accept this draft decision and inform the national competent authority of the reference Member State to this effect.

4. Each national competent authority concerned by the application for the variation shall adopt a decision in conformity with the draft decision foreseen in the preceding paragraph. The national decisions shall take effect on the day agreed after discussion between the national competent authority of the reference Member State and the marketing authorization holder in consultation with the other national competent authorities concerned.

5. If within the period foreseen in paragraph 3, mutual recognition by one or more national competent authorities of the draft decision of the national competent authority of the reference Member State is not possible, reference shall be made to the provisions of Article 15, last paragraph, of Directive 75/319/EEC or Article 23, last paragraph, of Directive 81/851/EEC.

Article 8

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, 10 March 1995.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX I

MINOR VARIATIONS (TYPE I) TO A MARKETING AUTHORIZATION AS REFERRED TO IN ARTICLE 3 (1)

Introductory statements

A. By derogation, for medicinal products falling within the scope of Council Directives 89/342/EEC [1], or 89/381/EEC [2], or 90/677/EEC [3], or which had been considered as arising under List A of Directive 87/22/EEC, the procedure set out in Articles 6 and 7 of the present Regulation shall apply to the minor variations Nos 11, 12, 13, 14, 15, 16, 17, 24, 25 and 30 as referred to below.

B. Where a variation requires consequential updating of the product information (summary of product characteristics, labelling, package and/or leaflet), this is considered part of the variation and the time period for implementing the consequential update must be agreed with the competent authority at the time of the approval of the variation.

1. *Change in the content of the manufacturing authorization*

   Condition to be fulfilled : the new manufacturing authorization, approved by the supervising competent authority, must be submitted to the competent authority.

2. *Change in the name of the medicinal product (either invented name or common name)*

   Condition to be fulfilled : confusion with names of other existing medicinal products or INN (International Non-proprietary Name) name must be avoided ; when the name is a common name, the change has to be made in the following order : from common name to pharmacopoeial name or to INN.

3. *Change in the name and/or address of the marketing authorization holder (see Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC)*

   Condition to be fulfilled : the marketing authorization holder shall remain the same person.

4. *Replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients)*

   Condition to be fulfilled : Same functional characteristics, no change in dissolution profile for solid dosage forms.

5. *Deletion of a colorant or replacement of a colorant with another*

6. *Addition, deletion or replacement of a flavour*

   Condition to be fulfilled : Proposed flavour must be in accordance with Council Directive 88/388/EEC [4].

7. *Change in coating weight of tablets or change in weight of capsule shells*

   Condition to be fulfilled : No change in dissolution profile.

8. *Change in the qualitative composition of immediate packaging material*

   Conditions to be fulfilled : The proposed packaging material must be at least equivalent to the approved material on relevant properties, and the change does not relate to sterile products.

9. *Deletion of an indication*

   Conditions to be fulfilled : The continued safety in use of the medicinal product has not been the subject of concern from pharmacovigilance, pre-clinical safety or quality data. Justification must be given.

10. *Deletion of a route of administration*

    Condition to be fulfilled : The continued safety in use of the medicinal product has not been the subject of concern from pharmacovigilance, pre-clinical safety or quality data. Justification must be given.

[1] OJ No L 142, 25. 5. 1989, p. 14.
[2] OJ No L 181, 28. 6. 1989, p. 44.
[3] OJ No L 373, 31. 12. 1990, p. 26.
[4] OJ No L 184, 15. 7. 1988, p. 61.

11. *Change in the manufacturer(s) of active substance*

Condition to be fulfilled : the specifications, synthetic route and quality control procedures are the same as those already approved or a European Phamarcopoeia Certificate of suitability covering the active substance is submitted.

12. *Minor change of manufacturing process of the active substance*

Condition to be fulfilled : Specifications are not adversely affected ; no change in the physical properties, no new impurities or change in level of impurities which would require further qualifications in safety studies.

13. *Batch size of active substance*

Condition to be fulfilled : Batch data must show that the change does not affect consistency of production, or physical properties.

14. *Change in specifications of active substance*

Condition to be fulfilled : Specifications must be tightened or addition of new tests and limits.

15. *Minor changes in manufacture of the medicinal product*

Conditions to be fulfilled : Medicinal product specifications are not adversely affected ; the new process must lead to an indentical product regarding all aspects of quality, safety and efficacy.

16. *Change in the batch size of finished product*

Condition to be fulfilled : the change does not affect consistency of production.

17. *Change in specification of the medicinal product*

Condition to be fufilled : Specifications must be tightened or addition of new tests and limits.

18. *Synthesis or recovery of non-Pharmacopoeial excipients which had been described in the original dossier*

Conditions to be fulfilled : Specifications are not adversely affected, no new impurities or change in level of impurities which would require further qualification in safety studies, no change in physico-chemical properties.

19. *Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)*

Condition to be fulfilled : Specifications must be tightened or addition of new tests and limits.

20. *Extension of shelf life as foreseen at time of authorization*

Conditions to be fulfilled : Stability studies have been done to the protocol which was approved at the time of the issue of the marketing authorization ; the studies must show that the agreed end of shelf life specifications are still met ; the shelf life does not exceed five years.

21. *Change in shelf life after first opening*

Condition to be fulfilled : Studies must show that the agreed end of shelf life specifications are still met.

22. *Change in shelf life after reconstitution*

Condition to be fulfilled : Studies must show that the agreed end of shelf life specifications are still met for the reconstituted product.

23. *Change in the storage conditions*

Condition to be fulfilled : Stability studies have been done to the protocol which was approved at the time of issue of the marketing authorization. The studies must show that the agreed end of shelf life specifications are still met.

24. *Change in test procedure af active substance*

Condition to be fulfilled : Results of method validation show new test procedure to be at least equivalent to the former procedure.

25. *Change in the test procedures of the medicinal product*

Conditions to be fulfilled : Medicinal product specifications are not adversely affected ; results of method validation show new test procedure to be at least equivalent to the former procedure.

26. *Changes to comply with supplements to pharmacopoeias* (1)

Conditions to be fulfilled : change is made exclusively to implement the new provisions of the supplement.

27. *Change in test procedures of non-pharmacopoeial excipients*

Condition to be fulfilled : Results of method validation show new test procedure to be at least equivalent to the former test procedure.

28. *Change in test procedure of immediate packaging*

Condition to be fulfilled : Results of method of validation show new test procedure to be at least equivalent to the former test procedure.

29. *Change in test procedure of administration device*

Condition to be fulfilled : Results of method validation show new test procedure to be at least equivalent to the former test procedure.

30. *Change in pack size for a veterinary medicinal product*

Conditions to be fulfilled : Specifications of the medicinal product are not affected, the new size is consistent with the dosage regimen and duration of use as approved in the summary of product characteristics ; the change does not relate to parenteral preparations.

31. *Change in container shape*

Conditions to be fulfilled : No change in the quality and in the stability of the product in the container, no change in the container-product interactions.

32. *Change of imprints, bossing or other markings (except scoring) on tablets or printing on capsules*

Condition to be fulfilled : New markings do not cause confusion with other tablets or capsules.

33. *Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitative composition and mean mass*

Condition to be fulfilled : No change in dissolution profile.

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(1) In cases where the marketing authorization refers to the current edition of the phamarcopoeia, no notification is required provided the change is introduced within six months of adoption of the revised monograph.

ANNEX II

Changes to a marketing authorization leading to a new application as referred to in Article 2

Certains changes to a marketing authorization have to be considered to fundamentally alter the terms of this authorization and therefore cannot be considered as a variation in the meaning of Article 15 of Directive 75/319/EEC or in the meaning of Article 23 of Directive 81/851/EEC. For these changes, listed below, an application for a new marketing authorization must be made. This Annex is without prejudice to the provisions of Article 4 of Directive 65/65/EEC and Article 5 of Directive 81/851/EEC. When evaluating the application for a new marketing authorization, the competent authority shall also review whether the former marketing authorization should be withdrawn, in conformity with Community legislation.

Changes requiring a new application

1. *Changes to the active substance(s):*

   (i) addition of one or more active substance(s) including antigenic components for vaccines;

   (ii) deletion of one or more active substance(s) including antigenic components for vaccines;

   (iii) quantitative change to the active substance(s);

   (iv) replacement of the active substance(s) by a different salt/ester complex/derivative (with the same therapeutic moiety);

   (v) replacement by a different isomer, a different mixture of isomers, of a mixture by an isolated isomer (e.g. racemate by a single enantiomer);

   (vi) replacement of a biological substance or product of biotechnology with one of a different molecular structure; modification of the vector used to produce the antigen/source material, including a master cell bank from a different source;

   (vii) a new ligand or coupling mechanism for a radiopharmaceutical.

2. *Changes to the therapeutic indications* [1]:

   (i) addition of an indication in a different therapeutic area, either treatment, diagnosis or prophylaxis;

   (ii) change of the indication to a different therapeutic area, either treatment, diagnosis or prophylaxis.

3. *Changes to strength, pharmaceutical form and route of administration* [2]:

   (i) change of bioavailability;

   (ii) change of pharmacokinetics e.g. change in rate of release;

   (iii) addition of a new strength;

   (iv) change or addition of a new pharmaceutical form;

   (v) addition of a new route of administration.

4. *Other changes specific to veterinary medicinal products used in food-producing animals:*

   (i) addition or change of target species;

   (ii) shortening of the withdrawal period.

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[1] Therapeutic area is defined as the third level of the Anatomical Therapeutic Chemical (A.T.C./A.T.C. Vet) code.

[2] For parenteral administration, it is necessary to distinguish between intraarterial, intravenous, intramuscular, subcutaneous, and other routes. For administration to poultry, respiratory, oral, ocular (nebulization) routes used for vaccination are considered to be the equivalent routes of administration.

COMMISSION REGULATION (EC) No 542/95

of 10 March 1995

concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1], and in particular Articles 15 (4) and 37 (4) thereof,

Whereas, appropriate provisions should be adopted for the examination of variations to the terms of a marketing authorization of medicinal products which have been authorized in accordance with Regulation (EEC) No 2309/93;

Whereas, it is appropriate to include a notification system or administrative procedures concernng minor variations for which it is necessary to precisely define minor variations;

Whereas, moreover, it is necessary to distinguish from amongst those variations which do not qualify as minor variations, those which must be considered to so fundamentally alter the marketing authorization, particularly form the point of view of the quality, safety or efficacy of a medicinal product, that a new application for a marketing authorization would be required;

Whereas, the provisions of this Regulation are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use and the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Scope and definitions

Article 1

1. This Regulation lays down the procedure for the examination of applications for variations to the terms of a marketing authorization granted in accordance with Regulation (EEC) No 2309/93.

2. This Regulation does not impede the marketing authorization holder from taking provisional urgent safety restrictions in the event of risk to public or animal health. The holder shall forthwith inform the Agency. If the Agency has not raised any objections within 24 hours, the urgent safety restrictions may be introduced and the corresponding application for this variation shall be submitted without delay to the Agency for the application of the procedures set out in Articles 6 and 7 of this Regulation.

Article 2

For the purpose of this Regulation, the following definitions shall apply;

1. 'variation to the terms of a marketing authorization': an amendment to the contents of the documents referred to in Article 6 (1) and (2) or Article 28 (1) and (2) of Regulation (EEC) No 2309/93 such as they existed at the moment the decision on the marketing authorization has been adopted in accordance with Article 10 or Article 32 of that Regulation or after approval of any previous variations, except where a new application for a marketing authorization must be presented pursuant to Annex II to this Regulation.

2. 'Urgent safety restriction': an interim change to product information by the marketing authorization holder restricting the indication(s), and/or dosage, and/or target species of the medicinal product; or adding a contra-indication, and/or warning due to new information having a bearing on the safe use of the product.

Article 3

1. (a) A 'minor variation' (type I) means a variation as defined in Article 2 and listed in Annex I to this Regulation, provided the conditions for such variation laid down in the said Annex are met.

(b) A 'major variation' (type II) means a variation as defined in Article 2 which cannot be deemed to be a type I variation within the meaning of the preceding paragraph.

[1] OJ No L 214, 24. 8. 1993, p. 1.

2. For the purposes of this Regulation, transfer of marketing authorization to a new holder, except for the situations covered by the point 3 of Annex I to this Regulation, and changes to the maximum residue limit (MRL) shall not be considered as a variation in the meaning of Article 2 (1).

Notification procedure for minor variations

Article 4

1. To obtain a type I variation, the holder of the marketing authorization shall submit to the Agency an application, accompanied by documents demonstrating that the conditions laid down in Annex I to this Regulation for the requested variation are met, and all documents amended as a result of the application.

2. An application within the meaning of paragraph 1 shall not concern more than one variation in the marketing authorization. Where several variations are to be made to a single marketing authorization, an application shall be submitted within the meaning of paragraph 1 in respect of each variation sought; each such application shall contain a reference to the other application(s).

3. By derogation from paragraph 2, where a variation in the marketing authorization entails one or more further changes, a single application may cover all such consequential variations. The single application shall describe the relation between the main variation and its consequential variations.

4. To be valid an application within the meaning of paragraph 1 shall be consistent with the provisions of this Article and accompanied by the relevant fee provided for in the applicable Community regulation.

Article 5

1. If, within 30 days of receipt of a valid application as provided for in Article 4, the Agency has not sent the holder of the marketing authorization the notification provided for in paragraph 4, the variation applied for shall be deemed to have been accepted.

2. The Agency shall inform the Commission within the period referred to in the preceding paragraph of the variation to be made to the terms of the marketing authorization. The Commission shall, where necessary, amend the decision taken pursuant to Article 10 or Article 32 of Regulation (EEC) No 2309/93. The decision thus amended shall take effect retroactively from the day following the end of the period referred to in paragraph 1.

3. The Community Register of Medicinal Products provided for in Articles 12 and 34 of Regulation (EEC) No 2309/93 shall be updated as necessary.

4. Where the Agency is of the opinion that the application cannot be accepted, it shall send a notification to that effect to the holder of the marketing authorization within the period referred to in paragraph 1, stating the objective grounds on which its opinion is based:

(a) within 30 days of receipt of the said notification, the marketing authorization holder may amend the application in a way which takes due account of the grounds set out in the notification. In that case the provisions of paragraphs 1, 2 and 3 shall apply to the amended application.

(b) if the marketing authorization holder does not amend the application as provided for in (a) above, this application shall be deemed to have been rejected.

Approval procedure for major variations

Article 6

1. To obtain a type II variation, the holder of the marketing authorization shall send the Agency an application accompanied by the relevant particulars and supporting documents referred to in Article 2 (1) of this Regulation.

The application must also be accompanied by:

— the supporting data relating to the variation applied for,

— all documents amended as a result of the application,

— an Addendum to or updating of existing expert report(s) to take account of the variation applied for.

2. An application within the meaning of paragraph 1 shall not concern more than one variation in the marketing authorization. Where several variations are to be made to a single marketing authorization, an application shall be submitted within the meaning of paragraph 1 in respect of each variation sought; each such application shall contain a reference to the other application(s).

3. By derogation from paragraph 2, where a variation in the marketing authorization entails one or more further changes, a single application may cover all such consequential variations. The single application shall describe the relation between the main variation and its consequential variations.

4. To be valid an application within the meaning of paragraph 1 shall be consistent with the provisions of this Article and accompanied by the relevant fee provided for in the applicable Community regulation.

Article 7

1. The competent Committee of the Agency shall give its opinion within 60 days following receipt of a valid application as provided for in Article 6.

2. Within that period, the competent Committee may send the marketing authorization holder a single request for information supplementary to that already supplied

pursuant to Article 6. In this case, the period shall be extended by a further 60 days. This period may be extended, for a period to be determined by the competent Committee, on its own initiative or at the request of the marketing authorization holder.

Article 8

1. Where the competent Committee delivers a favourable opinion, the Agency shall so inform the marketing authorization holder and the Commission forthwith and shall send to the Commission the amendments to be made to the terms of the marketing authorization accompanied by the documents set out in Article 9 (3) and Article 31 (3) of Council Regulation (EEC) No 2309/93.

2. Where the competent Committee delivers an unfavourable opinion, the appeal procedure provided for in Article 9 (1) and (2) or Article 31 (1) and (2) of Regulation (EEC) No 2309/93 shall apply.

3. The decision varying the terms of the marketing authorization shall be adopted in accordance with the procedure laid down in Article 10 or Article 32 of Regulation (EEC) No 2309/93.

4. The Community Register of Medicinal Products provided for in Articles 12 and 34 of Regulation (EEC) No 2309/93 shall be updated as necessary.

Article 9

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, 10 March 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX I

MINOR VARIATIONS (TYPE I) TO A MARKETING AUTHORIZATION AS REFERRED TO IN ARTICLE 3 (1)

Introductory statements

A. By derogation, for medicinal products falling within the scope of Council Directives 89/342/EEC [1], or 89/381/EEC [2], or 90/677/EEC [3], or which had been considered as arising under List A of Regulation (EEC) 2309/93, the procedure set out in Articles 6 to 8 of the present Regulation shall apply to the minor variations Nos 11, 12, 13, 14, 15, 16, 17, 24, 25 and 30 as referred to below.

B. Where a variation requires consequential updating of the product information (summary of product characteristics, labelling, package and/or leaflet), this is considered part of the variation and the time period for implementing the consequential update must be agreed with the Agency at the time of the approval of the variation.

1. *Change in the content of the manufacturing authorization*

   Condition to be fulfilled : the new manufacturing authorization, approved by the supervising competent authority, must be submitted to the Agency.

2. *Change in the name of the medicinal product (either invented name or common name)*

   Condition to be fulfilled : confusion with names of other existing medicinal products or INN (International Non-proprietary Name) name must be avoided ; when the name is a common name, the change has to be made in the following order : from common name to pharmacopoeial name or to INN.

3. *Change in the name and/or address of the marketing authorization holder* (see Article 4a of Council Directive 65/65/EEC [4] or Article 5a of Council Directive 81/851/EEC) [5]

   Condition to be fulfilled : the marketing authorization holder shall remain the same person.

4. *Replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients)*

   Condition to be fulfilled : Same functional characteristics, no change in dissolution profile for solid dosage forms.

5. *Deletion of a colorant or replacement of a colorant with another*

6. *Addition, deletion or replacement of a flavour*

   Condition to be fulfilled : Proposed flavour must be in accordance with Council Directive 88/388/EEC [6].

7. *Change in coating weight of tablets or change in weight of capsule shells*

   Condition to be fulfilled : No change in dissolution profile.

8. *Change in the qualitative composition of immediate packaging material*

   Conditions to be fulfilled : The proposed packaging material must be at least equivalent to the approved material on relevant properties, and the change does not relate to sterile products.

9. *Deletion of an indication*

   Conditions to be fulfilled : The continued safety in use of the medicinal product has not been the subject of concern from pharmacovigilance, pre-clinical safety or quality data. Justification must be given.

10. *Deletion of a route of administration*

    Condition to be fulfilled : The continued safety in use of the medicinal product has not been the subject of concern from pharmacovigilance, pre-clinical safety or quality data. Justification must be given.

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[1] OJ No L 142, 25. 5. 1989, p. 14.
[2] OJ No L 181, 28. 6. 1989, p. 44.
[3] OJ No L 373, 31. 12. 1990, p. 26.
[4] OJ No 22, 9. 2. 1965, p. 369/65.
[5] OJ No L 317, 6. 11. 1981, p. 7.
[6] OJ No L 184, 15. 7. 1988, p. 61.

11. *Change in the manufacturer(s) of active substance*

Condition to be fulfilled : the specifications, synthetic route and quality control procedures are the same as those already approved or a European Pharmacopoeia Certificate of suitability covering the active substance is submitted.

12. *Minor change of manufacturing process of the active substance*

Condition to be fulfilled : Specifications are not adversely affected ; no change in the physical properties, no new impurities or change in level of impurities which would require further qualifications in safety studies.

13. *Batch size of active substance*

Condition to be fulfilled : Batch data must show that the change does not affect consistency of production, or physical properties.

14. *Change in specifications of active substance*

Condition to be fulfilled : Specifications must be tightened or new tests and limits added.

15. *Changes in manufacture of the medicinal product*

Conditions to be fulfilled : Medicinal product specifications are not adversely affected ; the new process must lead to an indentical product regarding all aspects of quality, safety and efficacy.

16. *Change in the batch size of finished product*

Condition to be fulfilled : The change does not affect consistency of production.

17. *Change in specification of the medicinal product*

Condition to be fulfilled : Specifications must be tightened or new tests and limits added.

18. *Synthesis or recovery of non-pharmacopoeial excipients which had been described in the original dossier*

Conditions to be fulfilled : Specifications are not adversely affected, no new impurities or change in level of impurities which would require further qualification in safety studies, no change in physico-chemical properties.

19. *Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)*

Condition to be fulfilled : Specifications must be tightened or addition of new tests and limits added.

20. *Extension of shelf life as foreseen at time of authorization*

Conditions to be fulfilled : Stability studies have been done to the protocol which was approved at the time of the issue of the marketing authorization ; the studies must show that the agreed end of shelf life specifications are still met ; the shelf life does not exceed five years.

21. *Change in shelf life after first opening*

Condition to be fulfilled : Studies must show that the agreed end of shelf life specifications are still met.

22. *Change in shelf life after reconstitution*

Condition to be fulfilled : Studies must show that the agreed end of shelf life specifications are still met for the reconstituted product.

23. *Change in the storage conditions*

Condition to be fulfilled : Stability studies have been done to the protocol which was approved at the time of issue of the marketing authorization ; the studies must show that the agreed end of shelf life specifications are still met.

24. *Change in test procedure af active substance*

Condition to be fulfilled : Results of method validation show new test procedure to be at least equivalent to the former procedure.

25. *Change in test procedures of the medicinal product*

Conditions to be fulfilled : Medicinal product specifications are not adversely affected ; results of method validation show new test procedure to be at least equivalent to the former procedure.

26. *Changes to comply with supplements to pharmacopoeias* (1)

Conditions to be fulfilled : Change is made exclusively to implement the new provisions of the supplement.

27. *Change in test procedures of non-pharmacopoeial excipients*

Condition to be fulfilled : Results of method validation show new test procedure to be at least equivalent to the former test procedure.

28. *Change in test procedure of immediate packaging*

Condition to be fulfilled : Results of method of validation show new test procedure to be at least equivalent to the former test procedure.

29. *Change in test procedure of administration device*

Condition to be fulfilled : Results of method validation show new test procedure to be at least equivalent to the former test procedure.

30. *Change in pack size for a veterinary medicinal product*

Conditions to be fulfilled : Specifications of the medicinal product are not affected, the new size is consistent with the dosage regimen and duration of use as approved in the summary of product characteristics ; the change does not relate to parenteral preparations.

31. *Change in container shape*

Conditions to be fulfilled : No change in the quality and in the stability of the product in the container, no change in the container-product interactions.

32. *Change of imprints, bossing or other markings (except scoring) on tablets or printing on capsules*

Condition to be fulfilled : New markings do not cause confusion with other tablets or capsules.

33. *Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitative composition and mean mass*

Condition to be fulfilled : No change in dissolution profile.

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(1) In cases where the marketing authorization refers to the current edition of the pharmacopoeia, no notification is required provided the change is introduced within six months of adoption of the revised monograph.

ANNEX II

Changes to a marketing authorization leading to a new application as referred to in Article 2

Certain changes to a marketing authorization have to be considered to fundamentally alter the terms of this authorization and therefore cannot be considered as a variation in the meaning of Articles 15 (4) or 37 (4) of Regualtion (EEC) No 2309/93. For these changes, listed below, an application for a new marketing authorization must be made. This Annex is without prejudice to the provisions of Article 4 of Directive 65/65/EEC as amended and Article 5 of Directive 81/851/EEC as amended.

When evaluating the application for a new marketing authorization, the Agency shall also review whether the former marketing authorization should be withdrawn, in conformity with Community legislation.

Changes requiring a new application

1. *Changes to the active substance(s):*

   (i) addition of one or more active substance(s) including antigenic components for vaccines;

   (ii) deletion of one or more active substance(s) including antigenic components for vaccines;

   (iii) quantitative change to the active substance(s);

   (iv) replacement of the active substance(s) by a different salt/ester complex/derivative (with the same therapeutic moiety);

   (v) replacement by a different isomer, a different mixture of isomers, of a mixture by an isolated isomer (e.g. racemate by a single enantiomer);

   (vi) replacement of a biological substance or product of biotechnology with one of a different molecular structure; modification of the vector used to produce the antigen/source material, including a master cell bank from a different source;

   (vii) a new ligand or coupling mechanism for a radiopharmaceutical.

2. *Changes to the therapeutic indications* [1]:

   (i) addition of an indication in a different therapeutic area, either treatment, diagnosis or prophylaxis;

   (ii) change of the indication to a different therapeutic area, either treatment, diagnosis or prophylaxis.

3. *Changes to strength, pharmaceutical form and route of administration* [2]:

   (i) change of bioavailability;

   (ii) change of pharmacokinetics e.g. change in rate of release;

   (iii) addition of a new strength;

   (iv) change or addition of a new pharmaceutical form;

   (v) addition of a new route of administration.

4. *Other changes specific to veterinary medicinal products to be administered to food-producing animals:*

   (i) addition or change of target species;

   (ii) shortening of the withdrawal period.

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[1] Therapeutic area is defined as the third level of the Anatomical Therapeutic Chemical (A.T.C./A.T.C. Vet) code.

[2] For parenteral administration, it is necessary to distinguish between intraarterial, intravenous, intramuscular, subcutaneous, and other routes. For administration to poultry, respiratory, oral, ocular (nebulization) routes used for vaccination are considered to be the equivalent routes of administration.

COMMISSION REGULATION (EC) No 543/95

of 10 March 1995

amending Regulation (EC) No 1904/94 as regards the countervailing charges to be imposed where the minimum price applicable to imports of dried grapes is not observed

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 426/86 of 24 February 1986 on the common organization of the market in products processed from fruit and vegetables [1], as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 9 (6) thereof,

Whereas Commission Regulation (EC) No 1904/94 [2], as amended by Regulation (EC) No 2462/94 [3], fixes the minimum import price applicable to dried grapes and the countervailing charges to be imposed where that price is not observed;

Whereas Article 2 (2) of Council Regulation (EEC) No 2089/85 of 23 July 1985 laying down general rules relating to the system of minimum import prices for dried grapes [4] provides that the maximum countervailing charge is to be determined on the basis of the most favourable prices applied on the world market for significant quantities by the most representative non-member countries; whereas the countervailing charges currently in force should be amended on the basis of the prices applied on the world market;

Whereas the measures provided for in this Regulation take account of the agrimonetary rules applicable from 1 February 1995 in accordance with Article 13 (2) of Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy [5], as last amended by Regulation (EC) No 150/95 [6];

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Products Processed from Fruit and Vegetables,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1904/94 is hereby replaced by the Annex to this Regulation.

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, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 49, 27. 2. 1986, p. 1.
[2] OJ No L 194, 29. 7. 1994, p. 18.
[3] OJ No L 263, 13. 10. 1994, p. 3.
[4] OJ No L 197, 27. 7. 1985, p. 10.
[5] OJ No L 387, 31. 12. 1992, p. 1.
[6] OJ No L 22, 31. 1. 1995, p. 6.

ANNEX

'ANNEX II

Countervailing charges

1. Currants falling within CN code 0806 20 11 :

(ECU per tonne)

Import price applied		Countervailing charge to be levied
less than	but not less than	
1 125,89	1 114,64	11,26
1 114,64	1 092,12	33,78
1 092,12	1 058,35	67,55
1 058,15	1 024,56	101,33
1 024,56		296,49

2. Currants falling within CN code 0806 20 91 :

(ECU per tonne)

Import price applied		Countervailing charge to be levied
less than	but not less than	
967,44	957,77	9,67
957,77	938,42	29,02
938,42	909,40	58,05
909,40	880,37	87,07
880,37		138,04

3. Dried grapes falling within CN codes 0806 20 12 and 0806 20 18 :

(ECU per tonne)

Import price applied		Countervailing charge to be levied
less than	but not less than	
1 177,86	1 166,09	11,78
1 166,09	1 142,53	35,34
1 142,53	1 107,19	70,67
1 107,19	1 071,86	106,01
1 071,86		348,46

4. Dried grapes falling within CN codes 0806 20 92 and 0806 20 98 :

(ECU per tonne)

Import price applied		Countervailing charge to be levied
less than	but not less than	
1 012,10	1 001,98	10,12
1 001,98	981,73	30,36
981,73	951,37	60,73
951,37	921,00	91,09
921,00		182,70'

COMMISSION REGULATION (EC) No 544/95

of 10 March 1995

opening an invitation to tender for the refund for the export of rye to all third countries

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 organization of the market in cereals [1], as last amended by the Act of Accession of Austria, Finland and Sweden,

Having regard to Council Regulation (EEC) No 1533/93 of 22 June 1993 laying down certain detailed rules for granting export rules under Council Regulation (EEC) No 1766/92 on the granting of exports on cereals and the measures to be taken in the event of disturbance on the market for cereals [2], as last amended by Commission Regulation (EC) No 3304/94 [3], and in particular Article 5 (2) thereof,

Whereas, in view of the current situation on the cereals market, an invitation should be opened in respect of rye to tender for the export refund provided for in Article 5 of Regulation (EEC) No 1533/93;

Whereas the detailed procedural rules governing invitations to tender are, as regards the fixing of the export refund, in Commission Regulation (EEC) No 1533/93; whereas the commitments on the part of the tenderer include an obligation to lodge an application for an export licence; whereas compliance with this obligation may be ensured by requiring tenderers to lodge a tendering security of ECU 12 per tonne when they submit their tenders;

Whereas it is necessary to specify the exact duration of validity of the licences issued under this tendering procedure; whereas the period of validity must correspond to the current requirements of the world market;

Whereas, in order to ensure that all those concerned are treated equally, it is necessary to lay down that the period of validity of the licences issued should be identical;

Whereas, in order to ensure the smooth operation of the tendering procedure, it is appropriate to prescribe a minimum quantity to be tendered for and a time limit and form for the communication of tenders submitted to the competent authorities;

Whereas 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

1. Tenders shall be invited for the export refund provided for in Article 5 of Regulation (EEC) No 1533/93.

2. The tendering procedure shall concern rye for export to all third countries.

3. The invitation shall remain open until 18 May 1995. During this period weekly awards shall be made, for which the quantities and the time limits for the submission of tenders shall be as prescribed in the notice of invitation to tender.

Article 2

A tender shall be valid only if it relates to an amount of not less than 1 000 tonnes.

Article 3

The security referred to in Article 6 of Regulation (EEC) No 1533/93 shall be ECU 12 per tonne.

Article 4

1. Notwithstanding Article 21 (1) of Commission Regulation (EEC) No 3719/88 [4], export licences issued under Article 9 (1) of Regulation (EEC) No 1533/93 shall, for the purpose of determining their period of validity, be deemed to have been issued on the day on which the tender was submitted.

2. Subject to the provisions of Article 1 of Commission Regulation (EC) No 1521/94 [5] export licences issued in connection with the invitation to tender pursuant to this Regulation shall be valid from their date of issue, as defined in paragraph 1, until the end of the fourth month following that of issue.

[1] OJ No L 181, 1. 7. 1992, p. 21.
[2] OJ No L 151, 23. 6. 1993, p. 15.
[3] OJ No L 341, 30. 12. 1994, p. 48.
[4] OJ No L 331, 2. 12. 1988, p. 1.
[5] OJ No L 162, 30. 6. 1994, p. 47.

Article 5

1. The Commission shall decide, pursuant to the procedure laid down in Article 23 of Regulation (EEC) No 1766/92 :

— to fix a maximum export refund, taking account in particular of the criteria laid down in Article 2 of Regulation (EEC) No 1533/93, or

— to make no award.

2. Where a maximum export refund is fixed, a contract shall be awarded to any tenderer whose tender indicates a rate of refund equal to or less than such maximum export refund.

Article 6

Tenders submitted must reach the Commission through the intermediary Member States, at the latest one and a half hours after expiry of the period for the weekly submission of tenders as specified in the notice of invitation to tender. They must be communicated in the form indicated in Annex I, to the telex or telefax numbers in Annex II.

If no tenders are received, Member States shall inform the Commission of this within the time limit indicated in the preceding paragraph.

Article 7

The time limits fixed for the submission of tenders shall correspond to Belgian time.

Article 8

This Regulation shall enter into force on the 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, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX I

Weekly tender for the refund for the export of rye to all third countries

(Regulation (EC) No 544/95)

(Closing date for the submission of tenders (date/time))

1	2	3
Number of tenderer	Quantity in tonnes	Amount of export refund in ECU per tonne
1		
2		
3		
etc.		

ANNEX II

The only numbers to use to call Brussels (DG VI-C-1 (Attention : Messrs Thibault and Brus)) are :

— telex : 22037 AGREC B
22070 AGREC B (Greek characters)

— telefax :
— 295 01 32,
— 295 25 15,
— 296 10 97.

COMMISSION REGULATION (EC) No 545/95

of 10 March 1995

amending Regulation (EC) No 2668/94 authorizing the Italian intervention agency to put up for sale by tender 148 000 tonnes of durum wheat for export in the form of durum wheat meal to Algeria

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 organization of the market in cereals [1], as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 5 thereof,

Whereas Commission Regulation (EEC) No 2131/93 [2], as amended by Regulation (EC) No 120/94 [3], lays down the procedure and conditions for the disposal of cereals held by intervention agencies;

Whereas Commission Regulation (EC) No 2668/94 of 31 October 1994 authorizing the Italian intervention agency to put up for sale by tender 148 000 tonnes of durum wheat for export in the form of durum wheat meal to Algeria [4], as last amended by Regulation (EC) No 490/95 [5], stipulates 23 February 1995 as the latest date for the submission of tenders; whereas this deadline should be extended and a new validity for the licences in respect of the quantities awarded from 1 March 1995 on, should be fixed;

Whereas Regulation (EC) No 2668/94 does not set a time limit for the removal of durum wheat from intervention stocks; whereas it is necessary to provide for one; whereas the successful tenderer is obliged to complete the customs export formalities for durum wheat meal equivalent to that which would be obtained from the cereals awarded within 45 days of the date of the award; whereas, therefore, the same time limit should be used for removal of the durum wheat from intervention stocks;

Whereas the Management Committee for Cereals has not delivered an opinion within the time limit set by its Chairman,

HAS ADOPTED THIS REGULATION:

Article 1

In the second subparagraph of Article 3 (2) of Regulation (EC) No 2668/94, '23 February 1995' is replaced by '27 April 1995'.

Article 2

Article 5 of Regulation (EC) No 2668/94 is replaced by the following:

'Article 5

1. No export refund shall be granted for exports carried out pursuant to this Regulation.

2. Customs export formalities for durum wheat meal equivalent to that which would be obtained from the cereals awarded must be completed within 45 days of the date of the award and not later than 31 January 1995.

3. In the case of the quantities awarded between 1 January and 28 February 1995, the customs export formalities for durum wheat meal equivalent to that which would be obtained from the cereals awarded must be completed within 45 days of the date of the award and not later than 31 March 1995.

4. In the case of the quantities awarded from 1 March 1995 on, the customs export formalities for durum wheat meal equivalent to that which would be obtained from the cereals awarded must be completed within 45 days of the date of the award and not later than 31 May 1995.

5. Export licences issued under this invitation to tender must bear the following entry in Section 22:

"Invitation to tender opened by Regulation (EC) No 2668/94 — Tender dated..."

6. Notwithstanding Article 9 of Commission Regulation (EEC) No 3719/88 [*], the rights deriving from the licence referred to in this Article shall not be transferable.

[*] OJ No L 331, 2. 12. 1988, p. 1.'

Article 3

Article 10 of Regulation (EC) No 2668/94 is replaced by the following:

'Article 10

The successful tenderer shall pay for the durum wheat before removing it and no later than 45 days following the date of the award at the price indicated in the tender. The payment due for each of the lots to be removed shall be indivisible.'

[1] OJ No L 181, 1. 7. 1992, p. 21.
[2] OJ No L 191, 31. 7. 1993, p. 76.
[3] OJ No L 21, 26. 1. 1994, p. 1.
[4] OJ No L 284, 1. 11. 1994, p. 45.
[5] OJ No L 49, 4. 3. 1995, p. 48.

Article 4

The second subparagraph of Article 11 (2) of Regulation (EC) No 2668/94 is replaced by the following:

'Notwithstanding Article 15 (2) of Commission Regulation (EEC) No 3002/92 (*), the amount of ECU 50 per tonne of durum wheat corresponding to the processed meal must be released within 15 working days of the date on which the successful tenderer submits proof that the primary requirement referred to in paragraph 4 has been met.

(*) OJ No L 301, 17. 10. 1992, p. 17.'

Article 5

This Regulation shall enter into force on 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, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION REGULATION (EC) No 546/95

of 10 March 1995

amending for the third time Regulation (EC) No 3146/94 adopting exceptional support measures for the market in pigmeat in Germany

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2759/75 of 29 October 1975 on the common organization of the market in pigmeat (1), as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 20 thereof,

Whereas, because of the outbreak of classical swine fever in certain production regions in Germany, exceptional support measures for the market in pigmeat were adopted for that Member State in Commission Regulation (EC) No 3146/94 (2), as last amended by Regulation (EC) No 321/95 (3);

Whereas, due to the continuation of the veterinary and commercial restrictions, it is appropriate to include old sows delivered in Bavaria in the buying-in scheme provided for by Regulation (EC) No 3146/94; whereas this amendment should apply from 24 February 1995 in order to reduce the economic losses to the producers concerned;

Whereas, due to several new outbreaks of classical swine fever in Bundesland Mecklenburg-Vorpommern, the veterinary and trade restrictions imposed by the German authorities have been enlarged to that area; whereas these restrictions make the trade in piglets which are in surplus in these regions impossible; whereas, it is therefore justified to include piglets originating from these regions in the exceptional support measures introduced by Regulation (EC) No 3146/94;

Whereas it is necessary to adjust the aid granted for the delivery of the animals to the present market situation taking into account the increase in market prices;

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 3146/94 is hereby amended as follows:

1. Article 1 is amended as follows:

(a) paragraphs 3, 4 and 5 are replaced by the following:

'3. As from 24 February 1995 producers may benefit on request, from an aid granted by the competent German authorities for the delivery to them of old sows falling under CN code 0103 92 11 weighing 160 kg or more on average per batch.

4. The aid granted:

— to the first 14 000 fattened pigs and old sows delivered in Bavaria,

— to the first 10 500 fattened pigs and to the first 1 050 piglets and young piglets delivered in Lower Saxony,

— to the first 8 400 piglets delivered in Mecklenburg-Vorpommern

is financed by the Community budget.

5. Germany is authorized to grant, in addition, at its own expense and on the terms laid down in this Regulation an aid for:

— the following 6 000 fattened pigs and old sows delivered in Bavaria,

— the following 4 500 fattened pigs and the following 450 piglets and young piglets delivered in Lower Saxony,

— the following 3 600 piglets delivered in Mecklenburg-Vorpommern.'

(b) The following paragraph is added:

'6. If the numbers in paragraphs 4 and 5 relating to fattened pigs and piglets delivered in Lower Saxony are reached, aid may be granted for a following 10 500 fattened pigs and a following 1 050 piglets on the terms laid down in paragraph 4 and for a following 4 500 fattened pigs and a following 450 piglets on the terms laid down in paragraph 5.'

2. In Article 2 'fattened pigs, piglets and young piglets' are replaced by 'fattened pigs, piglets, young piglets and old sows'.

3. Article 5 is amended as follows:

(a) in paragraph 1, 'ECU 144' and 'ECU 122' are replaced by 'ECU 147' and 'ECU 125'.

(1) OJ No L 282, 1. 11. 1975, p. 1.
(2) OJ No L 332, 22. 12. 1994, p. 23.
(3) OJ No L 37, 17. 2. 1995, p. 4.

(b) in paragraph 3, 'ECU 48', 'ECU 41', 'ECU 38' and 'ECU 33' are replaced by 'ECU 54', 'ECU 46', 'ECU 43' and 'ECU 37'.

(c) the following paragraph is added:

'4. The aid provided for in Article 1 (3), at farm-gate, shall be ECU 118 per 100 kilograms slaughtered weight for old sows weighing 160 kilograms or more on average per batch.

The buying-in price is calculated in accordance with the established slaughtered weight.

However if the animals are only weighed live, a coefficient of 0,78 is applied to the aid.'

4. The following phrase is added to Article 7:

'— the number and total weight of the old sows delivered.'

5. In the Annex, the following point is added:

'3. In Bundesland Mecklenburg-Vorpommern, the protection zones in the following Kreise:

Bad Doberan
Güstrow
Ostvorpommern
Nordvorpommern
Demlin
Müritz
Parchim'

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 from 24 February 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION REGULATION (EC) No 547/95

of 10 March 1995

on the issue of import licences for high-quality fresh, chilled or frozen beef and veal

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3071/94 of 12 December 1994 opening a Community tariff quota for high-quality fresh, chilled or frozen meat of bovine animals falling within CN codes 0201 and 0202 and for products falling within CN codes 0206 10 95 and 0206 29 91 (first half of 1995) (1), and in particular Article 2 thereof,

Whereas Commission Regulation (EC) No 3243/94 of 21 December 1994 laying down detailed rules for the application of import arrangements provided for by Council Regulations (EC) No 3071/94 and (EC) No 3073/94 for high-quality beef and frozen buffalo meat (2), as amended by Regulation (EC) No 498/95 (3), provides in Article 6, that applications for and the issue of import licences for the meat referred to in Article 1 (1) (d) thereof are to be effected in accordance with the provisions of Articles 12 and 15 of Commission Regulation (EEC) No 2377/80 of 4 September 1980 on special detailed rules for the application of the system of import and export licences in the beef and veal sector (4), as last amended by Regulation (EC) No 1084/94 (5);

Whereas Article 1 (1) (d) of Regulation (EC) No 3243/94 fixes the amount of high-quality fresh, chilled or frozen beef and veal originating in and imported from the United States of America and Canada which may be imported on special terms in the first half of 1995 at 5 200 tonnes;

Whereas it should be recalled that licences issued pursuant to this Regulation will, throughout the period of validity, be open for use only in so far as provisions on health protection in force permit,

HAS ADOPTED THIS REGULATION:

Article 1

1. All applications for import licences from 1 until 5 March 1995 for high-quality fresh, chilled or frozen beef and veal as referred to in Article 1 (1) (d) of Regulation (EC) No 3243/94 shall be met in full.

2. Applications for licences may be submitted, in accordance with Article 15 of Regulation (EEC) No 2377/80, during the first five days of April 1995 for 2 420 tonnes.

Article 2

This Regulation shall enter into force on 11 March 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

(1) OJ No L 325, 17. 12. 1994, p. 1.
(2) OJ No L 338, 28. 12. 1994, p. 62.
(3) OJ No L 50, 7. 3. 1995, p. 2.
(4) OJ No L 241, 13. 9. 1980, p. 5.
(5) OJ No L 120, 11. 5. 1994, p. 30.

COMMISSION REGULATION (EC) No 548/95

of 10 March 1995

laying down special measures concerning the application of Regulation (EC) No 231/95 in the pigmeat sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EEC) No 3444/90 of 27 November 1990 laying down detailed rules for granting private storage aid for pigmeat [1], as last amended by Regulation (EC) No 3533/93 [2], and in particular Article 11(b) thereof,

Whereas an examination of the situation has indicated a risk that there will be an excessively large number of applications for the private storage aid scheme introduced by Regulation (EC) No 231/95 [3]; whereas, therefore, it is necessary to suspend application of the Regulation and reject the applications in question,

HAS ADOPTED THIS REGULATION:

Article 1

1. Application of Commission Regulation (EC) No 231/95 is hereby suspended for the period 11 to 17 March 1995.

2. Applications submitted on 10 March 1995 for which acceptance decisions would have had to be taken during that period, are hereby rejected.

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, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 333, 30. 11. 1990, p. 2.
[2] OJ No L 321, 23. 12. 1993, p. 9.
[3] OJ No L 27, 4. 2. 1995, p. 9.

COMMISSION REGULATION (EC) No 549/95

of 10 March 1995

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], and in particular Article 4 (1) thereof,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the units of account on the conversion rates to be applied with the purposes of the common agricultural policy [2], as last amended by Regulation (EC) No 150/95 [3], and in particular Article 3 (3) thereof,

Whereas 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;

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

Whereas the derogation laid down in the second subparagraph of Article 1 of Council Regulation (EC) No 3311/94 of 20 December 1994 extending by one month the application of the agrimonetary arrangements in force on 31 December 1994 and fixing the agricultural conversion rates for the new Member States [4] should be applied,

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 11 March 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 337, 24. 12. 1994, p. 66.
[2] OJ No L 387, 31. 12. 1992, p. 1.
[3] OJ No L 22, 31. 1. 1995, p. 1.
[4] OJ No L 350, 31. 12. 1994, p. 1.

ANNEX

to the Commission Regulation of 10 March 1995 establishing the standard import values for determining the entry price of certain fruit and vegetables

(ECU/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 15	204	94,0
	212	95,6
	624	143,3
	999	111,0
0707 00 15	052	100,7
	053	166,9
	068	77,4
	204	55,2
	624	207,3
	999	121,5
0709 90 73	052	106,0
	204	94,2
	624	196,3
	999	132,2

(1) Country nomenclature as fixed by Commission Regulation (EC) No 3079/94 (OJ No L 325, 17. 12. 1994, p. 17). Code '999' stands for 'of other origin.'

COMMISSION REGULATION (EC) No 550/95

of 10 March 1995

fixing the import levies on cereals and on wheat or rye flour, groats and meal

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 organization of the market in cereals (1), as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Articles 10 (5) and 11 (3) thereof,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy (2), as last amended by Regulation (EC) No 150/95 (3),

Whereas the import levies on cereals, wheat and rye flour, and wheat groats and meal were fixed by Commission Regulation (EC) No 502/95 (4) and subsequent amending Regulations;

Whereas, in order to make it possible for the levy arrangements to function normally, the representative market rate established during the reference period from 9 March 1995, as regards floating currencies, should be used to calculate the levies;

Whereas it follows from applying the detailed rules contained in Regulation (EC) No 502/95 to today's offer prices and quotations known to the Commission that the levies at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies to be charged on products listed in Article 1 (1) (a), (b) and (c) of Regulation (EEC) No 1766/92 shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 March 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

(1) OJ No L 181, 1. 7. 1992, p. 21.
(2) OJ No L 387, 31. 12. 1992, p. 1.
(3) OJ No L 22, 31. 1. 1995, p. 1.
(4) OJ No L 321, 14. 12. 1994, p. 28.

ANNEX

to the Commission Regulation of 10 March 1995 fixing the import levies on cereals and on wheat or rye flour, groats and meal

(ECU/tonne)

CN code	Third countries (8)
0709 90 60	112,98 (2) (3)
0712 90 19	112,98 (2) (3)
1001 10 00	53,98 (1) (5) (11)
1001 90 91	104,00
1001 90 99	104,00 (9) (11)
1002 00 00	140,53 (6)
1003 00 10	109,67
1003 00 90	109,67 (9)
1004 00 00	119,83
1005 10 90	112,98 (2) (3)
1005 90 00	112,98 (2) (3)
1007 00 90	117,65 (4)
1008 10 00	55,90 (9)
1008 20 00	61,30 (4) (9)
1008 30 00	0 (5)
1008 90 10	(7)
1008 90 90	0
1101 00 11	193,63 (9)
1101 00 15	193,63 (9)
1101 00 90	193,63 (9)
1102 10 00	242,42
1103 11 10	124,97
1103 11 90	220,84
1107 10 11	198,26
1107 10 19	151,46
1107 10 91	208,35 (10)
1107 10 99	159,00 (9)
1107 20 00	183,13 (10)

(1) Where durum wheat originating in Morocco is transported directly from that country to the Community, the levy is reduced by ECU 0,7245/tonne.

(2) In accordance with Regulation (EEC) No 715/90 the levies are not applied to products imported directly into the French overseas departments, originating in the African, Caribbean and Pacific States.

(3) Where maize originating in the ACP is imported into the Community the levy is reduced by ECU 2,186/tonne.

(4) Where millet and sorghum originating in the ACP is imported into the Community the levy is applied in accordance with Regulation (EEC) No 715/90.

(5) Where durum wheat and canary seed produced in Turkey are transported directly from that country to the Community, the levy is reduced by ECU 0,7245/tonne.

(6) The import levy charged on rye produced in Turkey and transported directly from that country to the Community is laid down in Council Regulation (EEC) No 1180/77 (OJ No L 142, 9. 6. 1977, p. 10), as last amended by Regulation (EEC) No 1902/92 (OJ No L 192, 11. 7. 1992, p. 3), and Commission Regulation (EEC) No 2622/71 (OJ No L 271, 10. 12. 1971, p. 22), as amended by Regulation (EEC) No 560/91 (OJ No L 62, 8. 3. 1991, p. 26).

(7) The levy applicable to rye shall be charged on imports of the product falling within CN code 1008 90 10 (triticale).

(8) No levy applies to OCT originating products according to Article 101 (1) of Decision 91/482/EEC.

(9) Products falling within this code, imported from Poland or Hungary under the Agreements concluded between those countries and the Community and under the Interim Agreement between the Czech Republic, the Slovak Republic, Bulgaria and Romania and the Community and in respect of which EUR.1 certificates issued in accordance with amended Regulation (EC) No 121/94 or (EC) No 335/94 have been presented, are subject to the levies set out in the Annex to that Regulation.

(10) In accordance with Council Regulation (EEC) No 1180/77 this levy is reduced by ECU 6,569 per tonne for products originating in Turkey.

(11) The levy for the products falling within this code in accordance with Regulation (EC) No 774/94 is restricted under the conditions of this Regulation.

COMMISSION REGULATION (EC) No 551/95

of 10 March 1995

fixing the import levies on white sugar and raw sugar

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector [1], as last amended by Regulation (EC) No 283/95 [2], and in particular Article 16 (8) thereof,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy [3], as last amended by Regulation (EC) No 150/95 [4], and in particular Article 5 thereof,

Whereas the import levies on white sugar and raw sugar were fixed by Commission Regulation (EC) No 1957/94 [5], as last amended by Regulation (EC) No 537/95 [6];

Whereas it follows from applying the detailed rules contained in Commission Regulation (EC) No 1957/94 to the information known to the Commission that the levies at present in force should be altered to the amounts set out in the Annex hereto;

Whereas, in order to make it possible for the levy arrangements to function normally, the representative market rate established during the reference period from 9 March 1995, as regards floating currencies, should be used to calculate the levies,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies referred to in Article 16 (1) of Regulation (EEC) No 1785/81 shall be, in respect of white sugar and standard quality raw sugar, as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 March 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 34, 14. 2. 1995, p. 3.
[3] OJ No L 387, 31. 12. 1992, p. 1.
[4] OJ No L 22, 31. 1. 1995, p. 1.
[5] OJ No L 198, 30. 7. 1994, p. 88.
[6] OJ No L 54, 10. 3. 1995, p. 23.

ANNEX

to the Commission Regulation of 10 March 1995 fixing the import levies on white sugar and raw sugar

(ECU/100 kg)

CN code	Levy (3)
1701 11 10	38,27 (1)
1701 11 90	38,27 (1)
1701 12 10	38,27 (1)
1701 12 90	38,27 (1)
1701 91 00	48,26
1701 99 10	48,26
1701 99 90	48,26 (2)

(1) The levy applicable is calculated in accordance with the provisions of Article 2 or 3 of Commission Regulation (EEC) No 837/68 (OJ No L 151, 30. 6. 1968, p. 42), as last amended by Regulation (EEC) No 1428/78 (OJ No L 171, 28. 6. 1978, p. 34).

(2) In accordance with Article 16 (2) of Regulation (EEC) No 1785/81 this amount is also applicable to sugar obtained from white and raw sugar containing added substances other than flavouring or colouring matter.

(3) No import levy applies to OCT originating products according to Article 101 (1) of Decision 91/482/EEC.

COMMISSION REGULATION (EC) No 552/95

of 10 March 1995

altering the basic amount of the import levies on syrups and certain other products in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector [1], as last amended by Regulation (EC) No 283/95 [2], and in particular Article 16 (8) thereof,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy [3], as last amended by Regulation (EC) No 150/95 [4], and in particular Article 5 thereof,

Whereas the import levies on syrups and certain other sugar products were fixed by Commission Regulation (EC) No 425/95 [5], as last amended by Regulation (EC) No 524/95 [6];

Whereas it follows from applying the detailed rules contained in Regulation (EC) No 425/95 to the information known to the Commission that the basic amount of the levy on syrups and certain other sugar products at present in force should be altered;

Whereas, in order to make it possible for the levy arrangements to function normally, the representative market rate established during the reference period from 9 March 1995, as regards floating currencies, should be used to calculate the levies,

HAS ADOPTED THIS REGULATION:

Article 1

The basic amounts of the import levy on the products listed in Article 1 (1) (d) of Regulation (EEC) No 1785/81, as fixed in the Annex to amended Regulation (EC) No 425/95 are hereby altered to the amounts shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 March 1995.

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

Done at Brussels, 10 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 177, 1. 7. 1981, p. 4.
[2] OJ No L 34, 14. 2. 1995, p. 3.
[3] OJ No L 387, 31. 12. 1992, p. 1.
[4] OJ No L 22, 31. 1. 1995, p. 1.
[5] OJ No L 45, 1. 3. 1995, p. 3.
[6] OJ No L 53, 9. 3. 1995, p. 26.

ANNEX

to the Commission Regulation of 10 March 1995 altering the basic amount of the import levy on syrups and certain other products in the sugar sector

(ECU)

CN code	Basic amount per percentage point of sucrose content and per 100 kg net of the product in question (1)	Amount of levy per 100 kg of dry matter (1)
1702 20 10	0,4826	—
1702 20 90	0,4826	—
1702 30 10	—	55,20
1702 40 10	—	55,20
1702 60 10	—	55,20
1702 60 90 10 (2)	—	104,88
1702 60 90 90 (3)	0,4826	—
1702 90 30	—	55,20
1702 90 60	0,4826	—
1702 90 71	0,4826	—
1702 90 80	—	104,88
1702 90 99	0,4826	—
2106 90 30	—	55,20
2106 90 59	0,4826	—

(1) No import levy applies to OCT originating products according to Article 101 (1) of Decision 91/482/EEC.
(2) Taric code : Inulin syrup. For the purposes of classification under this subheading, 'Inulin syrup' means the immediate product obtained by hydrolysis of inulin or oligofructoses.
(3) Taric code : CN code 1702 60 90, other than inulin syrup.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 2 March 1995

amending Decision 94/85/EC drawing up a list of third countries from which the Member States authorize imports of fresh poultrymeat

(Text with EEA relevance)

(95/58/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat [1], as last amended by Directive 93/121/EC [2], and in particular Article 9 thereof,

Whereas Commission Decision 94/85/EC [3], as last amended by Decision 94/453/EC [4], established a list of third countries from which importation of fresh poultrymeat is authorized;

Whereas further written assurances have been received from several countries, in particular Namibia and Slovenia; whereas examination of these assurances has shown that these countries satisfy the requirements of the Community;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

In the Annex to Commission Decision 94/85/EC the following lines are inserted in accordance with the alphabetic order of the ISO-code:

' NA	Namibia	×	ostrich meat only:	
SI	Slovenia	×		',

Article 2

This Decision shall apply from 1 March 1995.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 2 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 268, 24. 9. 1991, p. 35.
[2] OJ No L 340, 31. 12. 1993, p. 39.
[3] OJ No L 44, 17. 2. 1994, p. 31.
[4] OJ No L 187, 22. 7. 1994, p. 11.

COMMISSION DECISION

of 2 March 1995

approving the programme for the eradication of Aujeszky's Disease in Austria

(Only the German text is authentic)

(95/59/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964, on animal health problems affecting intra-Community trade in bovine animals and swine [1], as amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 9 thereof,

Whereas an eradication programme was commenced in Austria for Aujeszky's Disease in 1986;

Whereas in accordance with Article 9 (2) of Directive 64/432/EEC the Commission has examined the programme; whereas it meets the criteria laid down in Article 9 (1) of the said Directive and can therefore be approved;

Whereas by letter dated 16 November 1994, Austria has submitted information on its eradication programme for Aujeszky's Disease;

Whereas the programme should allow Aujeszky's Disease to be eradicated from Austria in the future; whereas the situation concerning this disease in Austria shall be reviewed within two years;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme for the eradication of Aujeszky's Disease from Austria is hereby approved for a period of two years.

Article 2

Austria shall bring into force by 1 March 1995 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

This Decision shall enter into force on 1 March 1995.

Article 4

This Decision is addressed to the Republic of Austria.

Done at Brussels, 2 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No 121, 29. 7. 1964, p. 1977/64.

COMMISSION DECISION

of 6 March 1995

amending Decision 94/381/EC concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein

(Text with EEA relevance)

(95/60/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC [2], and in particular Article 10 (4) thereof,

Whereas cases of bovine spongiform encephalopathy (BSE) have been reported in the United Kingdom and some other Member States ; whereas scrapie is also known to exist in several Member States ;

Whereas the origin of BSE in cattle is considered to be from ruminant protein which contained agents of animal spongiform encephopathies, which had not been sufficiently processed to inactivate the infectious agents ; whereas the Scientific Veterinary Committee has stated that it is not possible at present to define processes which can guarantee total inactivation of the agents in the commercial rendering industry, in the light of recent studies ;

Whereas, in order to protect ruminant species from the risk that methods for the processing of protein may not completely inactivate these agents, the Commission has adopted Decision 94/381/EC of 27 June 1994 concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein [3] ;

Whereas, however, the BSE subgroup of the Scientific Veterinary Committee has evaluated the risk from certain animal products and by-products and has recommended that certain of these may be exempted from the provisions of Decision 94/381/EC ;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION :

Article 1

The following paragraph is added to Article 1 of Decision 94/381/EC :

'3. The prohibition mentioned in paragraph 1 shall not apply to :

— milk,

— gelatin,

— amino acids produced from hides and skins by a process which involves exposure of the material to a pH of 1 to 2 followed by a pH of > 11 followed by heat treatment at 140 °C for 30 minutes at 3 bar,

— dicalcium phosphate derived from defatted bones,

— dried plasma and other blood products.'

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 224, 18. 8. 1990, p. 29.
[2] OJ No L 62, 15. 3. 1993, p. 49.
[3] OJ No L 172, 7. 7. 1994, p. 23.

COMMISSION DECISION

of 6 March 1995

on a special financial contribution from the Community for the eradication of swine vesicular disease in Belgium

(Only the French and Dutch texts are authentic)

(95/61/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], as last amended by Commission Decision 94/370/EEC [2], and in particular Article 3 thereof,

Whereas outbreaks of swine vesicular disease occurred in Belgium in 1992 and 1993; whereas the appearance of this disease is a serious danger to the Community's pig population and, in order to eradicate the disease as rapidly as possible, the Community has the possibility of making good the losses caused;

Whereas, as soon as the presence of swine vesicular disease was officially confirmed, the Belgian authorities took appropriate measures which included the measures listed in Article 3 (2) of Decision 90/424/EEC; whereas these measures were notified by the Belgian authorities;

Whereas the conditions for Community assistance have been met;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

For outbreaks of swine vesicular disease which occurred in 1992 and 1993 Belgium may obtain Community financial assistance. The contribution by the Community shall be:

— 50 % of the costs incurred by Belgium in compensating owners for the slaughter and destruction, as appropriate, of pigs and pig products,

— 50 % of the costs incurred by Belgium for the cleaning, disinsectization and disinfection of holdings and equipment,

— 50 % of the costs incurred by Belgium in compensating owners for the destruction of contaminated feedingstuffs and contaminated equipment.

Article 2

1. The Community financial contribution shall be granted after supporting documents have been submitted.

2. Belgium must submit the documents referred to in paragraph 1 not later than six months after the notification of this Decision.

Article 3

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 6 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

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[1] OJ No L 224, 18. 8. 1990, p. 19.
[2] OJ No L 168, 2. 7. 1994, p. 31.

COMMISSION DECISION

of 6 March 1995

approving the programme for the eradication of infectious bovine rhinotracheitis in Austria

(Only the German text is authentic)

(Text with EEA relevance)

(95/62/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [1], as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 9 thereof,

Whereas an eradication programme was commenced in Austria for infectious bovine rhinotracheitis in 1990;

Whereas in accordance with Article 9 (2) of Directive 64/432/EEC the Commission has examined the programme; whereas it meets the criteria laid down in Article 9 (1) of the said Directive and can therefore be approved;

Whereas by letter dated 5 December 1994, Austria has submitted information on its eradication programme for infectious bovine rhinotracheitis;

Whereas the programme should allow infectious bovine rhinotracheitis to be eradicated from Austria in the future; whereas the situation concerning this disease in Austria shall be reviewed within two years;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The programme for the eradication of infectious bovine rhinotracheitis from Austria is hereby approved for a period of two years.

Article 2

Austria shall bring into force by 1 March 1995 the laws, regulations and administrative provisions for implementing the programme referred to in Article 1.

Article 3

This Decision shall enter into force on 1 March 1995.

Article 4

This Decision is addressed to the Republic of Austria.

Done at Brussels, 6 March 1995.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ No 121, 29. 7. 1964, p. 1977/64.

CORRIGENDA

Corrigendum to Commission Regulation (EC) No 406/95 of 27 February 1995 laying down detailed rules for the application in the poultrymeat sector of the arrangements provided for in Council Regulation (EC) No 774/94

(Official Journal of the European Communities No L 44 of 28 February 1995)

On page 10, in Article 1, paragraph 1, section (a), fifth line:

for: '... imported or exported ...',

read: '... imported ...'.