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I

(Acts whose publication is obligatory)

of 16 December 1999
on orphan medicinal products

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

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

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product; the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions; these medicinal products are called 'orphan';

(2) patients suffering from rare conditions should be entitled to the same quality of treatment as other patients: it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry; incentives for the development of orphan medicinal products have been available in the United States of America since 1983 and in Japan since 1993;

(3) in the European Union, only limited action has been taken so far, whether at national or at Community level, to stimulate the development of orphan medicinal products; such action is best taken at Community level in order to take advantage of the widest possible market and to avoid the dispersion of limited resources; action at Community level is preferable to uncoordinated measures by the Member States which may result in distortions of competition and barriers to intra-Community trade;

(4) orphan medicinal products eligible for incentives should be easily and unequivocally identified: it seems most appropriate to achieve this result through the establishment of an open and transparent Community procedure for the designation of potential medicinal products as orphan medicinal products;

(5) objective criteria for designation should be established; those criteria should be based on the prevalence of the condition for which diagnosis, prevention or treatment is sought; a prevalence of not more than five affected persons per 10 thousand is generally regarded as the appropriate threshold; medicinal products intended for a life-threatening, seriously debilitating or serious and chronic condition should be eligible even when the prevalence is higher than five per 10 thousand;

(6) a Committee composed of experts appointed by the Member States should be established to examine applications for designation; this Committee should also include three representatives of patients’ associations, designated by the Commission, and three other persons, also designated by the Commission, on a recommendation from the European Agency for the Evaluation of Medicinal Products (hereinafter referred to as ‘the Agency’); the Agency should be responsible for the adequate coordination between the Committee on orphan medicinal products and the Committee on proprietary medicinal products;

(7) patients with such conditions deserve the same quality, safety and efficacy in medicinal products as other patients; orphan medicinal products should therefore be submitted to the normal evaluation process; sponsors of orphan medicinal products should have the possibility of obtaining a Community authorisation; in order to facilitate the granting or the maintenance of a Community authorisation, fees to be paid to the Agency should be waived at least in part; the Community budget should compensate the Agency for the loss in revenue thus occasioned;

has been designated under the terms and conditions of this Regulation; (c) 'sponsor' means any legal or natural person, established in the Community, seeking to obtain or having obtained the designation of a medicinal product as an orphan medicinal product; (d) 'Agency' means the European Agency for the Evaluation of Medicinal Products.

Article 3

Criteria for designation

1. A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:

(a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment;

HAVE ADOPTED THIS REGULATION:

Article 1

Purpose

The purpose of this Regulation is to lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.

Article 2

Definitions

For the purposes of this Regulation:

(a) ‘medicinal product’ means a medicinal product for human use, as defined in Article 2 of Directive 65/65/EEC;

(b) ‘orphan medicinal product’ means a medicinal product designated as such under the terms and conditions of this Regulation;

(c) ‘sponsor’ means any legal or natural person, established in the Community, seeking to obtain or having obtained the designation of a medicinal product as an orphan medicinal product;

(d) ‘Agency’ means the European Agency for the Evaluation of Medicinal Products.

Article 3

Criteria for designation

1. A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:

(a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment;


and
(b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

2. The Commission shall adopt the necessary provisions for implementing this Article in the form of an implementing Regulation in accordance with the procedure laid down in Article 72 of Council Regulation (EEC) No 2309/93 (1).

Article 4
Committee for Orphan Medicinal Products
1. A Committee for Orphan Medicinal Products, hereinafter referred to as 'the Committee', is hereby set up within the Agency.

2. The task of the Committee shall be:
(a) to examine any application for the designation of a medicinal product as an orphan medicinal product which is submitted to it in accordance with this Regulation;
(b) to advise the Commission on the establishment and development of a policy on orphan medicinal products for the European Union;
(c) to assist the Commission in liaising internationally on matters relating to orphan medicinal products, and in liaising with patient support groups;
(d) to assist the Commission in drawing up detailed guidelines.

3. The Committee shall consist of one member nominated by each Member State, three members nominated by the Commission to represent patients’ organisations and three members nominated by the Commission on the basis of a recommendation from the Agency. The members of the Committee shall be appointed for a term of three years, which shall be renewable. They may be accompanied by experts.

4. The Committee shall elect its Chairman for a term of three years, renewable once.

5. The representatives of the Commission and the Executive Director of the Agency or his representative may attend all meetings of the Committee.

6. The Agency shall provide the secretariat of the Committee.

7. Members of the Committee shall be required, even after their duties have ceased, not to disclose any information of the kind covered by the obligation of professional secrecy.

Article 5
Procedure for designation and removal from the register
1. In order to obtain the designation of a medicinal product as an orphan medicinal product, the sponsor shall submit an application to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation is made.

2. The application shall be accompanied by the following particulars and documents:
(a) name or corporate name and permanent address of the sponsor;
(b) active ingredients of the medicinal product;
(c) proposed therapeutic indication;
(d) justification that the criteria laid down in Article 3(1) are met and a description of the stage of development, including the indications expected.

3. The Commission shall, in consultation with the Member States, the Agency and interested parties, draw up detailed guidelines on the required format and content of applications for designation.

4. The Agency shall verify the validity of the application and prepare a summary report to the Committee. Where appropriate, it may request the sponsor to supplement the particulars and documents accompanying the application.

5. The Agency shall ensure that an opinion is given by the Committee within 90 days of the receipt of a valid application.

6. When preparing its opinion, the Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall be adopted by a majority of two-thirds of the members of the Committee. The opinion may be obtained by written procedure.

7. Where the opinion of the Committee is that the application does not satisfy the criteria set out in Article 3(1), the Agency shall forthwith inform the sponsor. Within 90 days of receipt of the opinion, the sponsor may submit detailed grounds for appeal, which the Agency shall refer to the Committee. The Committee shall consider whether its opinion should be revised at the following meeting.

8. The Agency shall forthwith forward the final opinion of the Committee to the Commission, which shall adopt a decision within 30 days of receipt of the opinion. Where, in exceptional circumstances, the draft decision is not in accordance with the opinion of the Committee, the decision shall be adopted in accordance with the procedure laid down in Article 73 of Regulation (EEC) No 2309/93. The decision shall be notified to the sponsor and communicated to the Agency and to the competent authorities of the Member States.

9. The designated medicinal product shall be entered in the Community Register of Orphan Medicinal Products.

10. Each year the sponsor shall submit to the Agency a report on the state of development of the designated medicinal product.

11. To have the designation of an orphan medicinal product transferred to another sponsor, the holder of the designation shall make specific application to the Agency. In consultation with the Member States, the Agency and interested parties, the Commission shall draw up detailed guidelines on the form in which applications for transfer shall be made and the content of such applications and all the particulars of the new sponsor.

12. A designated orphan medicinal product shall be removed from the Community Register of Orphan Medicinal Products:

(a) at the request of the sponsor;

(b) if it is established before the market authorisation is granted that the criteria laid down in Article 3 are no longer met in respect of the medicinal product concerned;

(c) at the end of the period of market exclusivity as laid down in Article 8.

**Article 6**

**Protocol assistance**

1. The sponsor of an orphan medicinal product may, prior to the submission of an application for marketing authorisation, request advice from the Agency on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of the medicinal product, in accordance with Article 51(j) of Regulation (EEC) No 2309/93.

2. The Agency shall draw up a procedure on the development of orphan medicinal products, covering regulatory assistance for the definition of the content of the application for authorisation within the meaning of Article 6 of Regulation (EEC) No 2309/93.

**Article 7**

**Community marketing authorisation**

1. The person responsible for placing on the market an orphan medicinal product may request that authorisation to place the medicinal product on the market be granted by the Community in accordance with the provisions of Regulation (EEC) No 2309/93 without having to justify that the medicinal product qualifies under Part B of the Annex to that Regulation.

2. A special contribution from the Community, distinct from that provided for in Article 57 of Regulation (EEC) No 2309/93, shall be allocated every year to the Agency. The contribution shall be used exclusively by the Agency to waive, in part or in total, all the fees payable under Community rules adopted pursuant to Regulation (EEC) No 2309/93. A detailed report of the use made of this special contribution shall be presented by the Executive Director of the Agency at the end of each year. Any surplus occurring in a given year shall be carried forward and deducted from the special contribution for the following year.

3. The marketing authorisation granted for an orphan medicinal product shall cover only those therapeutic indications which fulfil the criteria set out in Article 3. This is without prejudice to the possibility of applying for a separate marketing authorisation for other indications outside the scope of this Regulation.

**Article 8**

**Market exclusivity**

1. Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to Regulation (EEC) No 2309/93 or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down in Articles 7 and 7a of Directive 65/65/EEC or Article 9(4) of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (1), and without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.

2. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5. The sponsor shall provide the Agency with the information necessary for that purpose.

3. By way of derogation from paragraph 1, and without prejudice to intellectual property law or any other provision of Community law, a marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if:

(a) the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the second applicant, or

(b) the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or

(c) the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.

4. The Commission shall adopt definitions of ‘similar medicinal product’ and ‘clinical superiority’ in the form of an implementing Regulation in accordance with the procedure laid down in Article 72 of Regulation (EEC) No 2309/93.

5. The Commission shall draw up detailed guidelines for the application of this Article in consultation with the Member States, the Agency and interested parties.

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Article 9

Other incentives

1. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Community and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings provided for in framework programmes for research and technological development.

2. Before 22 July 2000, the Member States shall communicate to the Commission detailed information concerning any measure they have enacted to support research into, and the development and availability of, orphan medicinal products or medicinal products that may be designated as such. That information shall be updated regularly.

3. Before 22 January 2001, the Commission shall publish a detailed inventory of all incentives made available by the Community and the Member States to support research into, and the development and availability of, orphan medicinal products. That inventory shall be updated regularly.

Article 10

General report

Before 22 January 2006, the Commission shall publish a general report on the experience acquired as a result of the application of this Regulation, together with an account of the public health benefits which have been obtained.

Article 11

Entry into force

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

It shall apply as from the date of adoption of the implementing Regulations provided for in Article 3(2) and Article 8(4).

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

Done at Brussels, 16 December 1999.

For the European Parliament
The President
N. FONTAINE

For the Council
The President
K. HEMILA
COMMISSION REGULATION (EC) No 142/2000
of 21 January 2000
establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

to the Commission Regulation of 21 January 2000 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

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COMMISSION REGULATION (EC) No 143/2000
of 21 January 2000
fixing the maximum export refund on wholly milled long grain rice in connection with the invitation to tender issued in Regulation (EC) No 2176/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

(1) Whereas an invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 2176/1999 (3);

(2) Whereas, Article 5 of Commission Regulation (EEC) No 584/75 (4), as last amended by Regulation (EC) No 299/95 (5), allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund; whereas in fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account; whereas a contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund;

(3) Whereas the application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1;

(4) 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

The maximum export refund on wholly milled long grain rice falling within CN code 1006 30 67 to be exported to certain third countries pursuant to the invitation to tender issued in Regulation (EC) No 2176/1999 is hereby fixed on the basis of the tenders submitted from 14 to 20 January 2000 at 254,00 EUR/t.

Article 2

This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission

Franz FISCHLER
Member of the Commission

COMMISSION REGULATION (EC) No 144/2000
of 21 January 2000
fixing the maximum export refund on wholly milled medium grain and long grain A rice in connection with the invitation to tender issued in Regulation (EC) No 2178/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

(1) Whereas an invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 2178/1999 (3);

(2) Whereas Article 5 of Commission Regulation (EEC) No 584/75 (4), as last amended by Regulation (EC) No 299/95 (5), allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund; whereas in fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account; whereas a contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund;

(3) Whereas the application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1;

(4) 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

The maximum export refund on wholly milled medium grain and long grain A rice to be exported to certain third countries pursuant to the invitation to tender issued in European Regulation (EC) No 2178/1999 is hereby fixed on the basis of the tenders submitted from 14 to 20 January 2000 at 170,00 EUR/t.

Article 2

This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission
Franz FISCHLER
Member of the Commission

COMMISSION REGULATION (EC) No 145/2000
of 21 January 2000
fixing the maximum export refund on wholly milled round grain, medium grain and long grain A rice in connection with the invitation to tender issued in Regulation (EC) No 2179/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

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

(1) Whereas an invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 2179/1999 (3);

(2) Whereas Article 5 of Commission Regulation (EEC) No 584/75 (4), as last amended by Regulation (EC) No 299/95 (5), allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund; whereas in fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account; whereas a contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund;

(3) Whereas the application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1;

(4) 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
The maximum export refund on wholly milled grain, medium grain and long grain A rice to be exported to certain third countries pursuant to the invitation to tender issued in Regulation (EC) No 2179/1999 is hereby fixed on the basis of the tenders submitted from 14 to 20 January 2000 at 152,00 EUR/t.

Article 2
This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission
Franz FISCHLER
Member of the Commission

COMMISSION REGULATION (EC) No 146/2000

of 21 January 2000

fixing the maximum export refund on wholly milled round grain rice in connection with the invitation to tender issued in Regulation (EC) No 2180/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

(1) Whereas an invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 2180/1999 (3);

(2) Whereas Article 5 of Commission Regulation (EEC) No 584/75 (4), as last amended by Regulation (EC) No 299/95 (5), allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund; whereas in fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account; whereas a contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund;

(3) Whereas the application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1;

(4) 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

The maximum export refund on wholly milled round grain rice to be exported to certain third countries pursuant to the invitation to tender issued in Regulation (EC) No 2180/1999 is hereby fixed on the basis of the tenders submitted from 14 to 20 January 2000 at 149,00 EUR/t.

Article 2

This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission

Franz FISCHLER

Member of the Commission

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(3) OJ L 267, 15.10.1999, p. 16.
COMMISSION REGULATION (EC) No 147/2000
of 21 January 2000
providing for the rejection of applications for export licences in relation to certain processed
products and cereal-based compound feedingstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,


Having regard to Commission Regulation (EC) No 1162/95 of 23 May 1995 laying down special detailed rules for the application of the system of import and export licences for cereals and rice (3), as last amended by Regulation (EC) No 1432/1999 (4), and in particular Article 7(3) thereof,

Whereas:
The quantity covered by applications for advance fixing of refunds on potato starch and maize products is of great importance and could give rise to speculation; whereas it has there-
fore been decided to reject all applications for export licences of such products made on 20 January 2000,

HAS ADOPTED THIS REGULATION:

Article 1
In accordance with Article 7(3) of Regulation (EC) No 1162/95, applications for export licences with advance fixing of refunds for products falling within CN codes 1102 20 10, 1103 13 10, 1104 23 10, 1108 11 00, 1108 12 00, 1108 13 00, 1702 30 51, 1702 30 99, 1702 90 50, 1702 90 79, 2309 10 11, 2309 10 13, 2309 10 31, 2309 10 33, 2309 10 51, 2309 90 31, 2309 90 33, 2309 90 41, 2309 90 43, 2309 90 51 and 2309 90 53 made on 20 January 2000 shall be rejected.

Article 2
This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission
Franz FISCHLER
Member of the Commission

(4) OJ L 166, 1.7.1999, p. 56.
COMMISSION REGULATION (EC) No 148/2000
of 21 January 2000
determining the extent to which applications lodged in January 2000 for import licences for certain poultrymeat products under the regime provided for in Council Regulation (EC) No 774/94 opening and providing for the administration of certain Community tariff quotas for poultrymeat and certain other agricultural products can be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,
Having regard to Commission Regulation (EC) No 1431/94 of 22 June 1994, laying down detailed rules for the application in the poultrymeat sector of the import arrangements provided for in Council Regulation (EC) No 774/94 opening and providing for the administration of certain Community tariff quotas for poultrymeat and certain other agricultural products (1), as last amended by Regulation (EC) No 2719/1999 (2), and in particular Article 4(4) thereof,
Whereas:
The applications for import licences lodged for the period 1 January to 31 March 2000 are greater than the quantities available and must therefore be reduced by a fixed percentage to ensure a fair distribution,

HAS ADOPTED THIS REGULATION:

Article 1
Applications for import licences for the period 1 January to 31 March 2000 submitted under Regulation (EC) No 1431/94 shall be met as referred to in the Annex.

Article 2
This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

<table>
<thead>
<tr>
<th>Group No</th>
<th>Percentage of acceptance of import certificates submitted for the period 1 January to 31 March 2000</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>5</td>
<td>2.75</td>
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of 21 January 2000
determining the extent to which applications lodged in January 2000 for import licences for certain
poultrymeat sector products pursuant to Regulation (EC) No 509/97 can be accepted

The Commission of the European Communities,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 509/97 of 20 March 1997 laying down procedures for applying in the poultrymeat sector the Interim Agreement on trade and accompanying measures between the European Community, the European Coal and Steel Community and the European Atomic Energy Community, of the one part, and the Republic of Slovenia, of the other part (1), as amended by Regulation (EC) No 1514/97 (2), and in particular Article 4(5) thereof,

Whereas:

(1) The applications for import licences lodged for the first quarter of 2000 are for quantities less than the quantities available and can therefore be met in full;

(2) The surplus to be added to the quantity available for the following period should be determined,

Has adopted this Regulation:

Article 1

1. Applications for import licences for the period 1 January to 31 March 2000 submitted pursuant to Regulation (EC) No 509/97 shall be met as referred to in Annex I.

2. During the first 10 days of the period 1 April to 30 June 2000 applications may be lodged pursuant to Regulation (EC) No 509/97 for import licences for the total quantities as referred to in Annex II.

Article 2

This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission
Franz FISCHLER
Member of the Commission

(2) OJ L 204, 31.7.1997, p. 16.
### ANNEX I

<table>
<thead>
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<th>Group No</th>
<th>Percentage of acceptance of import licences submitted for the period 1 January to 31 March 2000</th>
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<td>80</td>
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<td>90</td>
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### ANNEX II

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<th>Group No</th>
<th>Available quantities for the period 1 April to 30 June 2000</th>
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<td>80</td>
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<tr>
<td>90</td>
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<tr>
<td>100</td>
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COMMISSION REGULATION (EC) No 150/2000
of 21 January 2000
determining the extent to which applications lodged in January 2000 for import licences for certain egg sector products and poultrymeat pursuant to Regulations (EC) No 1474/95 and (EC) No 1251/96 can be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,
Having regard to Commission Regulation (EC) No 1474/95 (1) opening and providing for the administration of the tariff quotas in the egg sector and for egg albumin, as last amended by Regulation (EC) No 1323/1999 (2), and in particular Article 5(5) thereof,
Having regard to Commission Regulation (EC) No 1251/96 of 28 June 1996 opening and providing for the administration of tariff quotas in the poultrymeat sector and albumin (3), as last amended by Regulation (EC) No 1327/1999 (4) and in particular Article 5(5) thereof,
Whereas:
The applications for import licences lodged for the first quarter of 2000 are, in the case of certain products, for quantities less than or equal to the quantities available and can therefore be met in full, but in the case of other products the said applications are for quantities greater than the quantities available and must therefore be reduced by a fixed percentage to ensure a fair distribution.

HAS ADOPTED THIS REGULATION:

Article 1
1. Applications for import licences for the period 1 January to 31 March 2000 submitted pursuant to Regulations (EC) No 1474/95 and (EC) No 1251/96 shall be met as referred to in Annex I.

Article 2
This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission
Franz FISCHLER
Member of the Commission

### ANNEX I

<table>
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<th>Group No</th>
<th>Percentage of acceptance of import licences submitted for the period 1 January to 31 March 2000</th>
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### ANNEX II

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<tr>
<td>E2</td>
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<tr>
<td>E3</td>
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<td>P2</td>
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<td>P3</td>
<td>146,00</td>
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<tr>
<td>P4</td>
<td>200,00</td>
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COMMISSION REGULATION (EC) No 151/2000
of 21 January 2000

determining the extent to which applications lodged in January 2000 for licences for certain eggs
and poultry meat products under the regime provided for by the Interim Agreements concluded by
the Community with the Republic of Poland, the Republic of Hungary, the Czech Republic,
Slovakia, Romania and Bulgaria can be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 1899/97, of
29 September 1997, setting rules of application in the poultry-
meat and egg sectors for the arrangements covered by Council
Regulation (EEC) No 3066/95 and repealing Regulations (EEC)
No 2699/93 and (EC) No 1559/94 (1), as amended by Regulation
(EC) No 2719/98 (2) and in particular Article 4(3) thereof,

Whereas:
The applications for import licences lodged for the first quarter
of 2000 are, in the case of some products, for quantities less
than or equal to the quantities available and can therefore be
met in full, but in the case of other products the said applica-
tions are for quantities greater than the quantities available and
must therefore be reduced by a fixed percentage to ensure a fair
distribution,

HAS ADOPTED THIS REGULATION:

Article 1

1. Applications for import licences for the period 1 January
   to 31 March 2000 submitted under Regulation (EC) No 1899/97
   shall be met as referred to in Annex I.

2. During the first 10 days of the period of 1 April to 30
   June 2000 application may be lodged pursuant to Regulation
   (EC) No 1899/97 for import licences for a total quantity as
   referred to in Annex II.

Article 2

This Regulation shall enter into force on 22 January 2000.

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

Done at Brussels, 21 January 2000.

For the Commission

Franz FISCHLER

Member of the Commission

---

**ANNEX I**

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<th>Group No</th>
<th>Percentage of acceptance of import licences submitted for the period 1 January to 31 March 2000</th>
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### ANNEX II

<table>
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<tr>
<th>Group No</th>
<th>Total quantity available for the period 1 April to 30 June 2000</th>
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II

(Acts whose publication is not obligatory)

COMMITTEE OF THE REGIONS

RULES OF PROCEDURE

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INTRODUCTION

The Committee of the Regions has adopted the following Rules of Procedure on the basis of Article 264(2) of the Treaty establishing the European Community (EC Treaty) (Decision of 18 November 1999).

Preliminary comment

The terms used in these Rules of Procedure for the various offices are not gender-specific.

TITLE I
MEMBERS AND CONSTITUENT BODIES OF THE COMMITTEE

CHAPTER 1
CONSTITUENT BODIES

Rule 1

Constituent bodies of the Committee

The constituent bodies of the Committee shall be the plenary assembly, the President, the Bureau and the commissions.

CHAPTER 2
MEMBERS OF THE COMMITTEE

Rule 2

Status of members and alternates

The members and alternates shall be representatives of regional and local bodies pursuant to Article 263 of the EC Treaty. They may not be bound by any mandatory instructions and shall be completely independent in the performance of their duties, in the general interest of the Community.

Rule 3

Term of office

1. The four-year term of office of a member or alternate shall commence on the date on which his formal appointment by the Council takes effect.

2. The term of office of a member or alternate shall be terminated by resignation or death. A successor shall be appointed by the Council for the remainder of the term.

3. Any resignation must be in writing, signed by the resigning member or alternate and sent to the President of the Committee. The President shall inform the Council, which shall confirm the vacancy and implement the replacement procedure.

Rule 4

Privileges and immunities

Members and their duly mandated alternates shall enjoy privileges and immunities in accordance with the Protocol on the privileges and immunities of the European Communities, annexed to the Treaty of 8 April 1965 establishing a single Council and a single Commission of the European Communities.

Rule 5

Attendance of alternates

1. Any member prevented from attending a plenary session may be represented by an alternate from his national delegation.

2. Any member prevented from attending a commission meeting, a working party meeting or any other meeting which has been approved by the Bureau may be represented by another member or an alternate from his national delegation.

3. An alternate or a member acting as an alternate can stand in for one member only. They shall exercise the same powers as a member at the relevant meeting. The Secretary-General must be notified in writing of the delegation of vote before the relevant meeting.

4. The appointment of alternates for a plenary session shall be limited to individual days. At a plenary session the expenses of only the member or the alternate shall be reimbursed. The detailed provisions shall be laid down by the Bureau in the implementing arrangements regarding travel and subsistence expenses.

5. An alternate who has been appointed rapporteur may present the draft opinion for which he is responsible at the plenary session at which the draft opinion is on the agenda. This shall apply even if the member whom he has been designated to replace is also at the meeting. The member may delegate his vote to his alternate while the draft opinion in question is being discussed. The Secretary-General must be notified in writing of the delegation of vote before the relevant meeting.

Rule 6

Delegation of vote

Except as provided for in Rules 5 and 29, the right to vote may not be delegated.

Rule 7

National delegations and political groups

National delegations and political groups shall help in a balanced way with the organisation of the Committee’s work.
Rule 8

National delegations

1. The members and alternates from each Member State shall form a national delegation. Each national delegation shall adopt its own internal rules and shall elect a chairman. The Committee President shall be officially informed of the name of the person elected.

2. The Secretary-General shall make arrangements, within the Committee's administration, for national delegations to receive assistance. These arrangements shall also permit each individual member to receive information and assistance in his official language. The arrangements shall form part of a specific service consisting of Committee of the Regions officials or other servants and shall ensure that national delegations can make appropriate use of the Committee's facilities. Specifically, the Secretary-General shall provide the national delegations with suitable means for holding meetings immediately before or during plenary sessions.

Rule 9

Political groups and non-attached members

1. Members and alternates may form groups which reflect their political affinities. The criteria for membership shall be laid down in the internal rules of each political group.

2. At least 20 members/alternates from no fewer than two Member States, 18 members/alternates from no fewer than three Member States or 16 members/alternates from no fewer than four Member States — half of whom at least, in all cases, must be members — shall be needed to form a political group. A member/alternate may belong to only one political group. A political group shall be dissolved if its membership falls below the required number.

3. The Committee President shall be notified in a statement when a political group is set up, dissolved or otherwise changed. The statement notifying the formation of a political group shall specify the name of the political group, its members and its bureau. Notification of the formation (including name, bureau and number of members) and dissolution of a political group shall be published by the President in the Official Journal of the European Communities.

4. Each political group shall be assisted by a secretariat staffed by Secretariat-General personnel. The political groups may submit proposals to the appointing authority for the selection, appointment and promotion of such staff and for extending their contracts. The appointing authority shall make its decision after consulting the chairmen of the political groups.

5. The Secretary-General shall provide the political groups and their constituent bodies with adequate resources for meetings, activities and publications and for the work of their secretariats. The resources for each political group shall be earmarked in the budget. The political groups and their secretariats may make appropriate use of the Committee's facilities.

6. The political groups and their bureaux may meet immediately before or during plenary sessions. They may hold extraordinary meetings twice a year. An alternate attending these meetings is only entitled to travel and subsistence expenses if he is representing a member from his political group.

7. Non-attached members shall be provided with administrative support. The detailed arrangements shall be laid down by the Bureau on a proposal from the Secretary-General.

Rule 10

Interregional groups

Members and alternates may form interregional groups. They shall inform the Committee President thereof.

TITLE II

ORGANISATION AND PROCEDURE OF THE COMMITTEE

CHAPTER 1

INITIAL CONVENING AND INSTALLATION IN OFFICE OF THE COMMITTEE

Rule 11

Convening the first meeting

The Committee shall be convened, after each four-yearly renewal, by the oldest member and shall meet not later than one month after the appointment of its members by the Council. The first meeting shall be chaired by the oldest member present (interim president) assisted by the four youngest members present and the Secretary-General of the Committee, who together shall constitute the interim bureau.

Rule 12

Installation in office of the Committee and verification of credentials

1. At the first meeting, the interim president shall inform the Committee of the communication from the Council concerning the appointment of its members. If requested, the interim president may decide to verify the appointment and credentials of members, after which he shall declare the Committee installed in office for the new term.

2. The interim bureau shall remain in office until the results of the elections of the President, the first Vice-President and the remaining members of the Bureau have been declared.
CHAPTER 2
PLENARY ASSEMBLY

Rule 13
Tasks of the plenary assembly
The Committee shall meet as a plenary assembly. Its main tasks shall be:

a) to adopt opinions, reports and resolutions;
b) to adopt the draft estimates of expenditure and revenue of the Committee;
c) to elect the President, the first Vice-President and the remaining members of the Bureau;
d) to set up commissions;
e) to adopt and revise the Rules of Procedure of the Committee.

Rule 14
Convening the plenary assembly

1. The President of the Committee shall convene the plenary assembly at least once every three months. The dates of the plenary sessions are to be fixed by the Bureau during the third quarter of the previous year. A plenary session can meet on one or more days.

2. At the written request of at least one quarter of the members, the President shall be obliged to convene an extraordinary plenary session, which shall take place not sooner than one week and not later than one month after the date of the request. The written request shall state the subject matter which is to be discussed at the extraordinary plenary session. No other matter may be dealt with.

Rule 15
Agenda for the plenary session

1. The preliminary draft agenda containing a provisional list of the draft opinions and resolutions to be discussed at the next but one plenary session together with all the other documents requiring a decision shall be prepared by the Bureau.

2. The draft agenda accompanied by all the documents requiring a decision listed therein shall be sent by the President to the members and alternates in their official language at least four weeks before the opening of the plenary session.

3. The draft opinions and resolutions shall in principle be put on the agenda in the order in which they were adopted by the commissions or submitted in accordance with the Rules of Procedure. Account shall also be taken of agenda items which deal with related subject matter.

4. In exceptional and duly motivated cases where the deadline referred to in paragraph 2 cannot be met, the President may decide to include a document requiring a decision on the draft agenda provided the relevant document has been received by the members and alternates in their official language not later than one week before the opening of the plenary session.

5. Written amendments to the draft agenda must be submitted to the Secretary-General not later than three working days before the opening of the plenary session.

6. The Bureau shall finalise the draft agenda at its meeting immediately prior to the opening of the plenary session. At this meeting the Bureau may decide, by a two-thirds majority of the votes cast, to include on the agenda matters of an urgent or topical nature whose discussion cannot be deferred until the next plenary session.

Rule 16
Opening of the plenary session
The President shall open the plenary session and call for the adoption of the final draft agenda.

Rule 17
Admission of the public, guests and guest speakers

1. Plenary sessions shall be open to the public, unless the plenary assembly decides otherwise in respect of the whole meeting or a specific item on the agenda.

2. Representatives of the European Parliament, Council and Commission may attend plenary sessions. They may be asked to take the floor.

3. The President may also invite other distinguished guests to address the plenary assembly. A general debate may follow, during which the general rules on speaking time shall apply.

Rule 18
Speaking time

1. The plenary assembly shall, at the beginning of its meeting and acting on a proposal from the Bureau, allocate speaking time for every item on the agenda. During a plenary session the President, acting on his own initiative or at the request of a member, shall arrange for a decision to be taken to limit speaking time.

2. The President, acting on a proposal from the Bureau, may propose to the plenary Assembly that when debates are held on general or specific issues, speaking time should be divided among the political groups and national delegations.

3. As a general rule, speaking time shall be limited to two minutes for comments on minutes, for points of order and for comments on amendments to the final draft agenda or the agenda.

4. If a speaker exceeds his allotted speaking time, the President may, after an initial call to order, forbid him to speak.

5. Any request by a member that the debate be brought to a close shall be put to the vote by the President.
Rule 19

List of speakers

1. The names of members who ask to speak shall be entered in a list in the order in which their requests are received. The President shall call upon members to speak on the basis of this list, ensuring as far as possible that speakers of different political views and from different national delegations are heard in turn.

2. Priority, may be given, however, to the rapporteur of the commission concerned, to the chairmen of political groups and national delegations wishing to speak on behalf of their group or delegation, or to speakers deputising for them.

3. No one may take the floor more than twice on the same subject, except by leave of the President. The chairman and the rapporteur of the commission concerned shall, however, be allowed to speak at their request for a period to be decided by the President.

Rule 20

Points of order

1. A member shall be allowed to speak to raise a point of order or to draw the attention of the President to any failure to respect the Rules of Procedure. The point of order must concern the agenda or the subject under discussion.

2. A request to raise a point of order shall take precedence over all other requests to speak.

3. The President shall take an immediate decision on points of order in accordance with the Rules of Procedure and shall announce his ruling immediately after the point of order has been raised. No vote shall be taken on the President's ruling.

Rule 21

Quorum

1. A quorum shall exist at a plenary session if a majority of the members is present. The quorum shall be verified only during the meeting and only if at least 10 members so request. If the verification of a quorum is not requested, all votes shall be valid regardless of the number of voters. The President may interrupt the plenary session for up to 10 minutes before proceeding with a verification of the quorum. Members who have requested verification of the quorum but are no longer present in the plenary session chamber shall be considered to be present for the purposes of the count. If fewer than ten members are present, the President may rule that there is no quorum.

2. If it is established that there is no quorum, all items on the agenda which require voting shall be postponed until the following meeting day, when the plenary Assembly may hold a valid vote on these items whatever the number of members present.

3. All members and alternates taking part in the meeting and other persons present shall sign an attendance list.

Rule 22

Voting

1. The plenary assembly shall decide by a majority of the votes cast, save where otherwise provided in these rules.

2. The valid forms of vote shall be ‘for’, ‘against’ and ‘abstention’. In calculating the majority, only the votes cast for and against shall be taken into account. In the event of a tied vote, the text or proposal shall be deemed rejected.

3. A fresh vote may be called for by the President or requested by at least 10 members if the result of the count is queried.

4. Votes relating to persons shall be by secret ballot.

Rule 23

Tabling of amendments

1. Only members and duly mandated alternates may table amendments to documents requiring a decision. These amendments must be in writing.

2. Except as provided for in the first sentence of Rule 26(1), amendments to documents requiring a decision must be submitted by at least six members and must bear their names.

3. They must reach the Secretary-General not later than the seventh working day before the opening of the plenary session and shall be electronically retrievable as soon as they have been translated, but not later than two working days prior to the plenary session. The deadline for the submission of amendments can be reduced to three working days by the President in cases where Rule 15(4) is applied. The deadline shall also not apply in the case of amendments to urgent matters pursuant to the second sentence of Rule 15(6).

4. All amendments shall be distributed to members before the beginning of the plenary session.

Rule 24

Procedure for dealing with amendments

1. If more than twenty amendments are submitted to a document requiring a decision, the Bureau or the plenary assembly may refer the document back to the commission for further consideration. This shall not apply in the case of documents requiring a decision whose adoption cannot be deferred.

2. An amendment tabled in due and proper form which is not supported at the meeting by its authors or by another member shall not be considered.

3. If one or more amendments have been tabled to a part of a text, the President, the rapporteur or the authors of these amendments may propose compromise amendments during the debate. A compromise amendment can only be proposed with the consent of the movers of the original amendment. A compromise amendment shall be given priority when voting takes place and, if adopted, shall invalidate any amendment on which the compromise is based.
4. Voting on amendments shall follow the order of the points in the text. The President may order a joint vote on amendments with a similar content and objective.

5. Amendments shall have priority over the text to which they relate and shall be put to the vote before that text.

6. If two or more mutually exclusive amendments have been tabled to the same part of a text, the amendment that departs furthest from the original text shall have priority and shall be put to the vote first.

7. The final vote shall be on the text as a whole, whether amended or not.

**Rule 25**

**Urgent opinions**

In urgent cases where a deadline set by the Council, Commission or European Parliament cannot be met under the normal procedure, and the relevant commission has adopted its draft opinion unanimously, the President shall transmit this draft opinion to the Council, Commission and European Parliament for information. The draft opinion shall be submitted to the following plenary session for adoption without amendment. All documents relating to the said opinion must testify to the urgent nature of the opinion.

**Rule 26**

**Simplified procedures**

1. Draft opinions adopted unanimously by a (lead) commission in the presence of a majority of its members shall be adopted by the plenary Assembly without debate unless at least 32 members table an amendment in accordance with the first sentence of Rule 23(3). In this case, the draft opinion shall be dealt with by the plenary Assembly. The commission’s draft opinion shall be forwarded to members, with a reference to this procedure, together with the draft agenda.

2. If the (lead) commission is of the view that the Committee has no reason to comment on or propose changes to a document referred to it by the Bureau, it may propose that no objections be raised to the document. The proposal shall be submitted to the plenary Assembly for adoption without debate.

**Rule 27**

**Closing of the plenary session**

Before the closing of the plenary session, the President shall announce the time and place of the following plenary session together with any items already on the agenda.

**CHAPTER 3**

**THE BUREAU AND THE PRESIDENT**

**Rule 28**

**Composition of the Bureau**

The Bureau shall consist of:

- a) the President;
- b) the first Vice-President;
- c) other Vice-Presidents;
- d) other members;
- e) the chairmen of the political groups.

One member per country shall have the rank of Vice-President.

Seats on the Bureau (excluding the seats of the President and the chairmen of the political groups) shall be divided among the national delegations as follows:

- three seats: Germany, Spain, France, Italy, United Kingdom,
- two seats: Belgium, Denmark, Greece, Ireland, Luxembourg, the Netherlands, Austria, Portugal, Finland, Sweden.

**Rule 29**

**Replacements at Bureau meetings**

1. For each member of the Bureau, apart from the President, a member or alternate from the same national delegation shall be named at the same time as an ad personam replacement. This replacement shall not be entitled to participate, speak and vote unless he is replacing the Bureau member in question. The delegation of vote must be notified in writing to the Secretary-General prior to the relevant meeting.

2. For each political group chairman, the political group in question shall name a replacement from among its members to whom the second and third sentences of paragraph 1 shall apply mutatis mutandis.

**Rule 30**

**Election rules**

1. The Bureau shall be elected by the plenary assembly for two years.

2. The elections of the President, the first Vice-President, the 14 Vice-Presidents, the other members of the Bureau and the chairmen of the political groups as members of the Bureau shall be held under the chairmanship of the interim president in accordance with Rules 11 and 12. All candidatures must be submitted in writing to the Secretary-General at least one hour before the beginning of the plenary session. The elections shall take place only if at least two-thirds of the members are present.

**Rule 31**

**Election of the President and the first Vice-President**

1. Before the elections, candidates for the posts of President and first Vice-President may make a short statement before the plenary assembly. The speaking time for candidates shall be of equal length and shall be laid down by the interim president.
2. The election of the President and the first Vice-President shall take place separately. They shall be elected by a majority of more than 50% of the votes cast.

3. The valid forms of vote shall be a vote for and an abstention. In calculating the majority required, only the votes cast for shall be taken into account.

4. If no candidate obtains the required majority in the first ballot, a second ballot shall be held in which the candidate receiving the highest number of votes shall be deemed to be elected. In the event of a tied vote, a decision shall be taken by drawing lots.

**Rule 32**

**Election of the 14 Vice-Presidents, the other Bureau members and the chairmen of the political groups as members of the Bureau**

1. For the election of the 14 Vice-Presidents and the other 20 Bureau members, a joint list may be drawn up for the candidates from those national delegations which nominate only one candidate for each of the seats allocated to them on the Bureau. This list may be adopted in a single ballot if it obtains a majority of more than 50% of the votes cast.

2. In cases where a joint list of candidates is not adopted, or where the number of candidates exceeds the number of seats allocated to a national delegation on the Bureau, each of these seats shall be decided upon in separate ballots; in this case the provisions on the election of the President and the first Vice-President shall be applicable in accordance with Rules 30 and 31(2) to (4).

3. For the election of the chairmen of the political groups as members of the Bureau, the interim president shall present the plenary assembly with a list of their names for adoption, which is to be voted on as a whole.

**Rule 33**

**Election of replacements**

When a candidate for a seat on the Bureau is elected, his replacement shall also be elected automatically.

**Rule 34**

**Vacant Bureau seats**

In the event of termination of Committee membership or of resignation from the Bureau, a member of the Bureau and/or his replacement shall be replaced for the remainder of his term of office in accordance with the procedures laid down in Rules 28 to 33.

**Rule 35**

**Tasks of the Bureau**

The Bureau shall have the following tasks:

- establishment of the policy programme at the beginning of each term, monitoring of its implementation and presentation of the annual and end-of term assessments;
- preparation, organisation and coordination of the work of the plenary assembly and the commissions.

To this end the Bureau may:

- set up working groups of Bureau members or of Committee members to advise it in specific areas,
- invite other members of the Committee, by virtue of their expertise or mandate, and persons not belonging to the Committee, to attend its meetings;

- overall responsibility for financial, organisational and administrative matters concerning members and alternates; internal organisation of the Committee, its Secretariat-General, including the establishment plan, and its constituent bodies;

- engagement of the Secretary-General and the officials and other servants listed in Rule 62(1) and (2);

- submission of the draft estimates of expenditure and revenue to the plenary assembly in accordance with Rule 63;

- authorisation of meetings away from the usual place of work;

- laying down of the implementing arrangements regarding travel and subsistence expenses for members, duly mandated alternates and experts, in compliance with the provisions laid down under the budget procedure.

**Rule 36**

**Convening of the Bureau/Quorum**

1. The Bureau shall be convened by the President, who shall set the date of the meeting and the agenda in agreement with the first Vice-President. The Bureau shall meet at least once every three months, or within 14 days following receipt of a written request by at least ten of its members.

2. A quorum shall exist at a Bureau meeting if at least one half of its members are present. The Bureau shall decide by a majority of the votes cast, save where otherwise provided for in these rules. Rule 22(2) shall also apply mutatis mutandis.

3. In preparation for the Bureau decisions, the Secretary-General shall draw up discussion documents and recommendations for a decision on each item to be discussed; these documents and recommendations shall be enclosed with the draft agenda. After an exploratory debate the Bureau shall, where necessary, issue the Secretary-General or a working group with further instructions, clearly specifying the subject to be covered and the time-frame. The working group or Secretary-General shall subsequently submit documents for discussion together with a recommendation for a decision. Amendments to recommendations for decisions must be submitted in writing to the Secretary-General not later than the third working day before the opening of the Bureau meeting and shall be electronically retrievable as soon as they have been translated.
Rule 37

The President

1. The President shall direct the work of the Committee.

2. The President shall be the Committee’s representative. He may delegate these powers.

3. If the President is absent or unable to attend, he shall be represented by the first Vice-President; if the first Vice-President is absent or unable to attend, the President shall be represented by one of the other Vice-Presidents.

OPINIONS AND RESOLUTIONS — PROCEDURE IN BUREAU

Rule 38

Opinions — Legal bases

The Committee shall adopt its opinions pursuant to Article 265 of the EC Treaty:

a) on the basis of a referral from the Commission or the Council in the cases provided for in the EC Treaty or on the basis of a referral from these institutions or the European Parliament in all other cases;

b) on its own initiative;

c) when, in the event of the Economic and Social Committee being consulted under Article 262 of the EC Treaty, it considers that specific regional interests are involved.

Rule 39

Opinions — Designation of commission

1. The Bureau shall establish the annual work programme of the commissions after consulting them. This programme shall indicate to which commissions the anticipated referrals are to be allocated. After the documents listed in the annual work programme have been received, the Bureau shall give the responsible commission a deadline for submission of its draft opinion.

2. When it receives documents from the Council, Commission or European Parliament which are not contained in the work programme, the Bureau shall designate the responsible commission and give it a deadline for the submission of its draft opinion. In urgent cases the President may designate the responsible commission; when this is the case, the Bureau shall be informed at its next meeting.

3. If the subject of an opinion concerns more than one commission, the Bureau shall designate a lead commission and, where necessary, one or more supplementary commissions. In such a case, the Bureau may either:

a) decide to set up a working party comprising representatives of the commissions concerned; or

b) in exceptional cases, designate one or more commissions, other than the lead commission, to issue a draft supplementary opinion. The lead commission shall vote on the recommendations made in the draft opinions of the other commissions and integrate the adopted recommendations into its own draft opinion. However, only the lead commission shall report to the plenary assembly.

Rule 40

Appointment of a rapporteur-general

1. If the commission concerned cannot draw up a draft opinion by the deadline set by the Council, Commission or European Parliament, the Bureau may propose that the plenary assembly appoint a rapporteur-general, who shall submit his draft opinion straight to the plenary assembly.

2. When a deadline set by the Council, Commission or European Parliament does not give the plenary assembly time to appoint a rapporteur-general, the rapporteur-general may be appointed by the President; when this is the case, the plenary assembly shall be informed at its next meeting.

3. In both cases, the commission concerned shall meet, where possible, to hold a general exploratory debate on the subject.

Rule 41

Own-initiative opinions

1. Applications for own-initiative opinions may be submitted to the Bureau by three of its members, by a commission via its chairman or by 32 members of the Committee. These applications must be submitted, with reasons, not later than three working days before the opening of the Bureau meeting and, wherever possible, before the annual work programme is adopted.

2. The Bureau shall decide on applications for own-initiative opinions by a majority of its members and shall refer the opinions to the relevant commissions in accordance with Rule 39. The President shall inform the plenary assembly of all Bureau decisions approving and allocating own-initiative opinions.

3. This rule shall apply mutatis mutandis in the case of opinions which come under Rule 38(c).

Rule 42

Tabling of resolutions

1. Resolutions are to be put on the agenda only if they refer to the activities of the European Union, deal with important concerns of regional and local authorities and are of topical interest.

2. Draft resolutions or applications for the drafting of a resolution may be submitted to the Committee by at least 32 members or a political group. All drafts or applications, indicating the names of the members or political group supporting them, shall be submitted to the Bureau in writing. They must reach the Secretary-General not later than three working days before the opening of the Bureau meeting.

3. If the Bureau decides that the Committee is to discuss a draft resolution or an application for the drafting of a resolution, it may:
a) put the draft resolution on the plenary session preliminary draft agenda in accordance with Rule 15(1); or

b) appoint a commission to draw up a draft resolution by a specific deadline under the procedure used for drawing up draft opinions. Rule 51 shall not apply in such cases.

4. In urgent cases the Bureau may, in accordance with the second sentence of Rule 15(6), place a draft resolution on the agenda for the next plenary session. Such draft resolutions shall be dealt with on the second day of the session.

Rule 43
Promotion of opinions and resolutions

The Bureau shall be responsible for promoting the Committee’s opinions and resolutions. An impact assessment shall be presented to the plenary assembly by the President annually and at the end of each four-year term.

CHAPTER 4
COMMISSIONS

Rule 44
Composition and powers

1. At the beginning of each four-year term, the plenary assembly shall set up commissions to prepare its work. It shall decide on their composition and powers on a proposal from the Bureau.

2. The composition of the commissions shall reflect the national composition of the Committee.

3. Members of the Committee must belong to at least one commission but may not belong to more than two. Exceptions may be made by the Bureau for members belonging to the smaller national delegations.

Rule 45
Chairman and vice-chairmen

1. At its first meeting each commission shall appoint from among its members a chairman, a first vice-chairman and no more than two vice-chairmen, who together shall form the commission bureau.

2. Where the number of candidates corresponds to the number of seats to be filled, the election may take place by acclamation. Where this is not the case, or one sixth of the members of the commission so request, the election shall be in accordance with the provisions laid down in Rule 31(2) to (4) for the election of the Committee President and first Vice-President.

3. If a commission bureau member terminates his Committee membership or resigns as a commission bureau member, the vacancy shall be filled in accordance with the provisions of this rule.

Rule 46
Tasks of commissions

The commissions shall in particular draw up the draft versions of opinions and resolutions. These drafts shall be submitted to the plenary Assembly for adoption.

Rule 47
Convening of commissions and their agendas

1. The dates of meetings and their agendas shall be set by the chairman of each commission acting in agreement with the first vice-chairman.

2. A commission shall be convened by its chairman. The convening notice for an ordinary meeting together with the agenda must reach members not later than four weeks before the date of the meeting.

3. At the written request of at least one quarter of its members, the chairman shall be obliged to convene an extraordinary commission meeting, which must be held not later than four weeks after the submission of the request. The agenda for an extraordinary meeting shall be set by the members submitting the request for such a meeting. It shall be forwarded to members together with the convening notice.

4. All draft opinions and other discussion documents to be translated and distributed before a meeting shall be sent to the secretariat of the commission in question not later than five weeks before the date set for the meeting. They shall then be forwarded to members not later than two weeks before the date of the meeting. In exceptional cases the above time limits may be amended by the chairman.

Rule 48
Admission of the public

1. The proceedings of the commissions shall be open to the public, unless a commission decides otherwise in respect of the whole meeting or of a specific item on the agenda.

2. Representatives of the European Parliament, Council and Commission may attend the deliberations of the commissions and reply to questions from members.

Rule 49
Public hearings

In specific cases and with the agreement of the Bureau, a commission may hold a public hearing or invite outside speakers by virtue of their expertise with regard to one or more items on the agenda.

Rule 50
Time limits for drawing up opinions

1. The commissions shall present their draft opinions within the time limit set by the Bureau. The production of a draft opinion shall require no more than two meetings, not including the first meeting at which the work shall be organised.
2. In exceptional cases the Bureau may authorise further meetings to discuss a draft opinion, or may extend the time limit for the presentation of the draft.

Rule 51

Layout of opinions

1. A Committee opinion shall consist of:
   — a preamble setting out the legal basis of the opinion and the procedure followed in its preparation, and, if necessary, containing introductory comments, and
   — a main part giving the views and recommendations of the Committee on the question under consideration.
2. A separate explanatory statement shall be drawn up for each opinion explaining the views of the Committee as a whole and individual points. The explanatory statement shall be the responsibility of the rapporteur and shall not be put to the vote. It must, however, accord with the text of the opinion that was put to the vote. If it fails to do so, the chairman of the commission may delete the explanatory statement.

Rule 52

Rapporteurs

1. Each commission, acting on a proposal from its chairman, shall appoint a rapporteur or, in duly motivated cases, two rapporteurs to draw up a draft opinion. In urgent cases the chairman may, after informing the Secretary-General, apply a written procedure to appoint a rapporteur.
2. Under this procedure the chairman shall write to the members of the commission, asking them to submit any objections to the appointment of the proposed rapporteur in writing within three working days. In such cases the chairman and first vice-chairman shall decide by mutual agreement.

Rule 53

Working parties

1. In duly motivated cases the commissions may set up working parties, with the approval of the Bureau. Working party members may also come from other commissions.
2. Each working party can appoint a chairman and a vice-chairman from among its members.

Rule 54

Experts

1. The members of the commissions may call on the services of an expert.
2. A commission may appoint experts to assist it in its work and to assist any working parties which it has set up. At the invitation of the chairman, these experts may take part in meetings of the commission or of one of its working parties. The floor may also be given to these experts and to the experts working for and accompanying rapporteurs.
3. Only rapporteurs’ experts and experts invited by the commission shall be entitled to travel and subsistence expenses.

Rule 55

Quorum

1. A quorum shall exist at a commission meeting if more than one half of its members are present.
2. The quorum shall be verified only during the meeting and only if at least six members so request. If the verification of a quorum is not requested, all votes shall be valid regardless of the number of voters. If it is established that there is no quorum, the commission may continue its discussions but voting shall take place at the next meeting.
3. All members and alternates taking part in the meeting and other persons present shall sign an attendance list.

Rule 56

Voting

Decisions shall be taken by a majority of the votes cast. Rule 22(2) shall also apply mutatis mutandis.

Rule 57

Amendments

1. Amendments must be sent to commission secretariats not later than the fifth working day before the date of the meeting. In exceptional cases the above time limit may be amended by the chairman.
2. Voting on amendments shall follow the order of the points in the draft opinion under discussion. Thereafter the whole text shall be voted on. If two or more mutually exclusive amendments have been tabled to the same part of a text, the amendment that departs furthest from the original text shall have priority and shall be put to the vote first.
3. Once a draft opinion has been adopted by a commission, it shall be forwarded by the commission chairman to the President of the Committee.

Rule 58

Decision not to draw up an opinion

Where the (lead) commission considers that a document referred to it by the Bureau has no regional or local interest, or is not of political importance, it may decide not to draw up an opinion.
CHAPTER 5

ADMINISTRATION OF THE COMMITTEE

Rule 59

Secretariat-General

1. The Committee shall be assisted by a Secretariat-General.

2. The Secretariat-General shall be headed by a Secretary-General.

3. The Bureau, acting on a proposal from the Secretary-General, shall organise the Secretariat-General in such a way that it can ensure the efficient functioning of the Committee and its constituent bodies and help the members of the Committee in the performance of their duties. The services to be provided by the Secretariat-General for members, national delegations, political groups and non-attached members shall be determined in the process.

4. The Secretariat-General shall draw up the minutes of the meetings of the Committee's constituent bodies.

Rule 60

Secretary-General

1. The Secretary-General shall be responsible for giving effect to the decisions taken by the Bureau or the President pursuant to these Rules of Procedure and the applicable legal provisions. The Secretary-General shall attend the meetings of the Bureau in an advisory capacity and shall keep the minutes of those meetings.

2. The Secretary-General shall discharge his duties under the direction of the President, representing the Bureau.

Rule 61

Engagement of Secretary-General

1. The Bureau shall engage the Secretary-General on the basis of a decision adopted by a two-thirds majority of its members, pursuant to the provisions of Articles 2 and 8 of the Conditions of employment of other servants of the European Communities.

2. The Secretary-General shall be engaged for five years. The detailed provisions of his contract of employment shall be laid down by the Bureau.

3. The powers which the Conditions of employment of other servants of the European Communities confer on the authority responsible for concluding contracts shall be exercised, in the case of the Secretary-General, by the Bureau.

Rule 62

Staff Regulations of officials and Conditions of employment of other servants

1. The powers which the Staff Regulations of officials of the European Communities confer on the appointing authority shall be exercised as follows:

— for officials in grades 6 to 8 of category A and of the language service and for officials in categories B, C and D, by the Secretary-General,

— for other officials, by the Bureau, acting on a proposal from the Secretary-General.

2. The powers which the Conditions of employment of other servants of the European Communities confer on the authority competent to conclude contracts of employment shall be exercised as follows:

— for temporary staff in grades 6 to 8 of category A and of the language service and for temporary staff in categories B, C and D, by the Secretary-General,

— for other temporary staff, by the Bureau, acting on a proposal from the Secretary-General,

— for temporary staff in the private office of the President:

— temporary staff in grades 6 to 8 of category A and for temporary staff in grades B, C and D, by the Secretary-General, acting on a proposal from the President,

— for other temporary staff, by the Bureau, acting on a proposal from the President.

Temporary staff employed in the private office of the President shall be engaged until the end of the President's term of office,

— for auxiliary and local staff, by the Secretary-General,

— for special advisers, by the Secretary-General in accordance with the conditions set out in Article 82 of the Conditions of employment of other servants of the European Communities.

Rule 63

Budget

1. The Secretary-General shall submit the preliminary draft estimates of the Committee's expenditure and revenue for the following financial year to the Bureau. The Bureau shall submit the draft to the plenary assembly for adoption.

2. The plenary assembly shall adopt the draft estimates of the Committee's expenditure and revenue and forward them to the Commission, Council and European Parliament in good time to ensure that the deadlines laid down in the financial provisions are met.

3. The Committee's budget shall be implemented in accordance with the Financial Regulation applicable to the general budget of the European Communities. The President shall be the highest authority empowered to implement the budget in accordance with Articles 28, 29, 39, 48 and 52 of the Financial Regulation of the European Communities. He shall act on a proposal from the Secretary-General.
TITLE III
GENERAL PROVISIONS

CHAPTER 1
COOPERATION WITH OTHER EU BODIES

Rule 64
Cooperation agreements with other EU bodies
The Bureau, acting on a proposal from the Secretary-General, may conclude cooperation agreements with institutions and other bodies of the European Union within the framework of interinstitutional cooperation.

Rule 65
Forwarding and publication of opinions and resolutions
1. The Committee’s opinions, as well as any communication relating to the use of a simplified procedure under Rule 26 or a decision not to draw up an opinion under Rule 58, shall be addressed to the Council, Commission and European Parliament. As in the case of resolutions, they shall be forwarded by the President.

2. The opinions and resolutions of the Committee shall be published in the Official Journal of the European Communities.

Done at Brussels, 18 November 1999.

CHAPTER 2
RULES OF PROCEDURE

Rule 66
Revision of Rules of Procedure
1. The plenary assembly shall decide by a majority of its members if there is a need to amend these Rules of Procedure, either in part or in full.

2. It shall appoint an ad hoc commission to draw up a report and a draft text as a basis for the adoption of new rules by a majority of its members. The new rules shall enter into force the day after their publication in the Official Journal of the European Communities.

Rule 67
Bureau instructions
The Bureau may give instructions determining the procedure for implementing the provisions of these Rules of Procedure, in compliance with the latter.

Rule 68
Entry into force of Rules of Procedure
These Rules of Procedure shall enter into force the day after their publication in the Official Journal of the European Communities.

By the Committee of the Regions
The President
Manfred DAMMEYER