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⁽¹⁾ Text with EEA relevance

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⁽¹⁾ Text with EEA relevance

I

(Acts whose publication is obligatory)

**REGULATION (EC) No 638/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 31 March 2004
on Community statistics relating to the trading of goods between Member States and repealing
Council Regulation (EEC) No 3330/91**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 285(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) Council Regulation (EEC) No 3330/91 of 7 November 1991 on the statistics relating to the trading of goods between Member States ⁽³⁾ introduced a completely new system of data collection, which has been simplified on two occasions. In order to improve the transparency of this system and to make it easier to understand, Regulation (EEC) No 3330/91 should be replaced by this Regulation.

(2) This system should be retained, as a sufficiently detailed level of statistical information is still required for the Community policies involved in the development of the internal market and for Community enterprises to analyse their specific markets. Aggregated data also need to be available quickly in order to analyse the development of the Economic and Monetary Union. Member States should have the possibility of collecting information which meets their specific needs.

(3) There is, however, a need to improve the wording of the rules on compiling statistics relating to the trading of goods between Member States so that they can be more easily understood by the companies responsible for providing the data, the national services collecting the data and users.

(4) A system of thresholds should be retained, but in a simplified form, in order to provide a satisfactory response to users' needs whilst reducing the burden of response on the parties responsible for providing statistical information, particularly small and medium-sized enterprises.

(5) A close link should be maintained between the system for collecting statistical information and the fiscal formalities which exist in the context of trade of goods between Member States. This link makes it possible, in particular, to check the quality of the information collected.

(6) The quality of the statistical information produced, its evaluation by means of common indicators and transparency in this field are important objectives, which call for regulation at Community level.

(7) Since the objective of the planned action, namely the creation of a common legal framework for the systematic production of Community statistics relating to the trading of goods between Member States, cannot be sufficiently achieved at national level and can be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is required to achieve this objective.

(8) Council Regulation (EC) No 322/97 of 17 February 1997 on Community statistics ⁽⁴⁾ provides a reference framework for this Regulation. However, the very detailed level of information in the field of statistics relating to the trading of goods requires specific rules with regard to confidentiality.

⁽¹⁾ OJ C 32, 5.2.2004, p. 92.

⁽²⁾ Opinion of the European Parliament of 16 December 2003 (not yet published in the Official Journal) and Council Decision of 22 March 2004.

⁽³⁾ OJ L 316, 16.11.1991, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽⁴⁾ OJ L 52, 22.2.1997, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

- (9) It is important to ensure the uniform application of this Regulation and, in order to do so, to make provision for a Community procedure to help determine the implementing arrangements within an appropriate timescale and to make the necessary technical adaptations.
- (10) The measures necessary for implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾,
- (iii) goods obtained in the customs territory of the Community either from the goods referred to exclusively in point (ii) or from the goods referred to in points (i) and (ii);
- (e) 'Member State of dispatch': the Member State as defined by its statistical territory from which goods are dispatched to a destination in another Member State;
- (f) 'Member State of arrival': the Member State as defined by its statistical territory in which goods arrive from another Member State;
- (g) 'goods in simple circulation between Member States': Community goods dispatched from one Member State to another, which, on the way to the Member State of destination, travel directly through another Member State or stop for reasons related only to the transport of the goods.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes a common framework for the systematic production of Community statistics relating to the trading of goods between Member States.

Article 2

Definitions

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

- (a) 'goods': all movable property, including electric current;
- (b) 'specific goods or movements': goods or movements which, by their very nature, call for specific provisions, and in particular industrial plants, vessels and aircraft, sea products, goods delivered to vessels and aircraft, staggered consignments, military goods, goods to or from offshore installations, spacecraft, motor vehicle and aircraft parts and waste products;
- (c) 'national authorities': national statistical institutes and other bodies responsible in each Member State for producing Community statistics relating to the trading of goods between Member States;
- (d) 'Community goods':
- (i) goods entirely obtained in the customs territory of the Community, without addition of goods from third countries or territories which are not part of the customs territory of the Community;
 - (ii) goods from third countries or territories which are not part of the customs territory of the Community, which have been released for free circulation in a Member State;

Article 3

Scope

1. Statistics relating to the trading of goods between Member States shall cover dispatches and arrivals of goods.
2. Dispatches shall cover the following goods leaving the Member State of dispatch for a destination in another Member State:
 - (a) Community goods, except goods which are in simple circulation between Member States;
 - (b) goods placed in the Member State of dispatch under the inward processing customs procedure or the processing under customs control procedure.
3. Arrivals shall cover the following goods entering the Member State of arrival, which were initially dispatched from another Member State:
 - (a) Community goods, except goods which are in simple circulation between Member States;
 - (b) goods formerly placed in the Member State of dispatch according to the inward processing customs procedure or the processing according to customs control procedure, which are maintained according to the inward processing customs procedure or the processing according to customs control procedure or released for free circulation in the Member State of arrival.
4. Different or specific rules, to be determined in accordance with the procedure referred to in Article 14(2), may apply to specific goods or movements.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

5. Some goods, a list of which shall be drawn up in accordance with the procedure referred to in Article 14(2), shall be excluded from the statistics for methodological reasons.

Article 4

Statistical territory

1. The statistical territory of the Member States shall correspond to their customs territory as defined in Article 3 of Council Regulation (EEC) No 2913/92⁽¹⁾ of 12 October 1992 establishing the Community Customs Code.

2. By way of derogation from paragraph 1, the statistical territory of Germany shall include Heligoland.

Article 5

Data sources

1. A specific data collection system, hereinafter referred to as the 'Intrastat' system, shall apply for the provision of the statistical information on dispatches and arrivals of Community goods which are not the subject of a single administrative document for customs or fiscal purposes.

2. The statistical information on dispatches and arrivals of other goods shall be provided directly by customs to the national authorities, at least once a month.

3. For specific goods or movements, sources of information other than the Intrastat system or customs declarations may be used.

4. Each Member State shall organise the way Intrastat data is supplied by the parties responsible for providing information. To facilitate the task of these parties, the conditions for increased use of automatic data processing and electronic data transmission shall be promoted by the Commission (Eurostat) and the Member States.

Article 6

Reference period

1. The reference period for the information to be provided in accordance with Article 5 shall be the calendar month of dispatch or arrival of the goods.

2. The reference period may be adapted to take into account the linkage with value added tax (VAT) and customs obligations, pursuant to provisions adopted in accordance with the procedure referred to in Article 14(2).

⁽¹⁾ OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council (OJ L 311, 12.12.2000, p. 17).

Article 7

Parties responsible for providing information

1. The parties responsible for providing the information for the Intrastat system shall be:

- (a) the natural or legal person registered for VAT in the Member State of dispatch who:
 - (i) has concluded the contract, with the exception of transport contracts, giving rise to the dispatch of goods or, failing that,
 - (ii) dispatches or provides for the dispatch of the goods or, failing that,
 - (iii) is in possession of the goods which are the subject of the dispatch;
- (b) the natural or legal person registered for VAT in the Member State of arrival who:
 - (i) has concluded the contract, with the exception of transport contracts, giving rise to the delivery of goods or, failing that,
 - (ii) takes delivery or provides for delivery of the goods or, failing that,
 - (iii) is in possession of the goods which are the subject of the delivery.

2. The parties responsible for providing information may transfer the task to a third party, but such transfer shall in no way reduce the responsibility of the said party.

3. Failure by any party responsible for providing information to fulfil his/her obligations under this Regulation shall render him/her liable to the penalties which the Member States shall lay down.

Article 8

Registers

1. National authorities shall set up and manage a register of intra-Community operators containing at least the consignors, upon dispatch, and the consignees, upon arrival.

2. In order to identify the parties responsible for providing information referred to in Article 7 and to check the information which is provided, the tax administration responsible in each Member State shall furnish the national authority:

- (a) at least once a month, with the lists of natural or legal persons who have declared that, during the period in question, they have supplied goods to other Member States or acquired goods from other Member States. The lists shall show the total values of the goods declared by each natural or legal person for fiscal purposes;

(b) on its own initiative or at the request of the national authority, with any information provided for fiscal purposes which could improve the quality of statistics.

The arrangements for the communication of the information shall be determined in accordance with the procedure referred to in Article 14(2).

This information shall be treated by the national authority in accordance with the rules applied to it by the tax administration.

3. The tax administration shall bring to the attention of VAT-registered traders the obligations which they may incur as parties responsible for providing the information required by Intrastat.

Article 9

Intrastat information to be collected

1. The following information shall be collected by the national authorities:

- (a) the identification number allocated to the party responsible for providing information in accordance with Article 22(1)(c) of the Sixth Council Directive 77/388/EEC of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes — common system of value added tax: uniform basis of assessment ⁽¹⁾, in the version given in Article 28h thereof;
- (b) the reference period;
- (c) the flow (arrival, dispatch);
- (d) the commodity, identified by the eight-digit code of the Combined Nomenclature as defined in Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽²⁾;
- (e) the partner Member State;
- (f) the value of the goods;
- (g) the quantity of the goods;
- (h) the nature of the transaction.

Definitions of the statistical data referred to in points (e) to (h) are given in the Annex. Where necessary, the arrangements for the collection of this information, particularly the codes to be employed, shall be determined in accordance with the procedure referred to in Article 14(2).

⁽¹⁾ OJ L 145, 13.6.1977, p. 1. Directive as last amended by Directive 2004/15/EC (OJ L 52, 21.2.2004, p. 61).

⁽²⁾ OJ L 256, 7.9.1987, p. 1. Regulation as last amended by Commission Regulation (EC) No 2344/2003 (OJ L 346, 31.12.2003, p. 38).

2. Member States may also collect additional information, for example:

- (a) the identification of the goods, at a more detailed level than the Combined Nomenclature;
- (b) the country of origin, on arrival;
- (c) the region of origin, on dispatch, and the region of destination, on arrival;
- (d) the delivery terms;
- (e) the mode of transport;
- (f) the statistical procedure.

Definitions of the statistical data referred to in points (b) to (f) are given in the Annex. Where necessary, the arrangements for the collection of this information, particularly the codes to be employed, shall be determined in accordance with the procedure referred to in Article 14(2).

Article 10

Simplification within the Intrastat system

1. In order to satisfy users' needs for statistical information without imposing excessive burdens on economic operators, Member States shall define each year thresholds expressed in annual values of intra-Community trade, below which parties are exempted from providing any Intrastat information or may provide simplified information.

2. The thresholds shall be defined by each Member State, separately for arrivals and dispatches.

3. For defining thresholds below which parties are exempted from providing any Intrastat information, Member States shall ensure that information referred to in Article 9(1), first subparagraph, points (a) to (f), made available by the parties responsible for providing information, is such that at least 97 % of the relevant Member State's total trade expressed in value is covered.

4. Member States may define other thresholds below which parties may benefit from the following simplification:

- (a) exemption from providing information about the quantity of the goods;

- (b) exemption from providing information about the nature of the transaction;
- (c) possibility of reporting a maximum of 10 of the detailed relevant subheadings of the Combined Nomenclature, that are the most used in terms of value, and regrouping the other products in accordance with rules determined in accordance with the procedure referred to in Article 14(2).

Every Member State applying these thresholds shall ensure that the trade of these parties shall amount to a maximum of 6 % of its total trade.

5. Member States may, under certain conditions, which meet quality requirements and which shall be defined in accordance with the procedure referred to in Article 14(2), simplify the information to be provided for small individual transactions.

6. The information on the thresholds applied by the Member States shall be sent to the Commission (Eurostat) no later than 31 October of the year preceding the year to which they apply.

Article 11

Statistical confidentiality

Where the parties who have provided information so request, the national authorities shall decide whether statistical results which make it possible indirectly to identify the said provider(s) are to be disseminated or are to be amended in such a way that their dissemination does not prejudice statistical confidentiality.

Article 12

Transmission of data to the Commission

1. Member States shall transmit to the Commission (Eurostat) the monthly results of their statistics relating to the trading of goods between Member States no later than:

- (a) 40 calendar days after the end of the reference month for the aggregated data to be defined in accordance with the procedure referred to in Article 14(2);
- (b) 70 calendar days after the end of the reference month in the case of detailed results including the information referred to in Article 9(1), first subparagraph, points (b) to (h).

As regards the value of the goods, the results shall include the statistical value only, as defined in the Annex.

Member States shall transmit to the Commission (Eurostat) the data which are confidential.

2. Member States shall provide the Commission (Eurostat) with monthly results which cover their total trade in goods by using estimates, where necessary.

3. Member States shall transmit the data to the Commission (Eurostat) in electronic form, in accordance with an interchange standard. The practical arrangements for the transmission of data shall be determined in accordance with the procedure referred to in Article 14(2).

Article 13

Quality

1. Member States shall take all measures necessary to ensure the quality of the data transmitted according to the quality indicators and standards in force.

2. Member States shall present to the Commission (Eurostat) a yearly report on the quality of the data transmitted.

3. The indicators and standards enabling the quality of the data to be assessed, the structure of the quality reports to be presented by the Member States and any measures necessary for assessing or improving the quality of the data shall be determined in accordance with the procedure referred to in Article 14(2).

Article 14

Committee procedure

1. The Commission shall be assisted by a Committee for the statistics on the trading of goods between Member States.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 15

Repeal

1. Regulation (EEC) No 3330/91 is hereby repealed.

2. References to the repealed regulation shall be construed as being made to this Regulation.

Article 16

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2005.

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

Done at Strasbourg, 31 March 2004.

For the European Parliament

The President

P. COX

For the Council

The President

D. ROCHE

ANNEX

DEFINITIONS OF STATISTICAL DATA

1. Partner Member State

- (a) The partner Member State is the Member State of consignment, on arrival. This means the presumed Member State of dispatch in cases where goods enter directly from another Member State. Where, before reaching the Member State of arrival, goods have entered one or more Member States in transit and have been subject in those States to halts or legal operations not inherent in their transport (e.g. change of ownership), the Member State of consignment shall be taken as the last Member State where such halts or operations occurred.
- (b) The partner Member State is the Member State of destination, on dispatch. This means the last Member State to which it is known, at the time of dispatch, that the goods are to be dispatched.

2. Quantity of the goods

The quantity of the goods can be expressed in two ways:

- (a) the net mass, which means the actual mass of the goods excluding all packaging;
- (b) the supplementary units, which mean the possible units measuring quantity other than net mass, as detailed in the annual Commission regulation updating the Combined Nomenclature.

3. Value of the goods

The value of the goods can be expressed in two ways:

- (a) the taxable amount, which is the value to be determined for taxation purposes in accordance with Directive 77/388/EEC;
- (b) the statistical value, which is the value calculated at the national borders of the Member States. It includes only incidental expenses (freight, insurance) incurred, in the case of dispatches, in the part of the journey located on the territory of the Member State of dispatch and, in the case of arrivals, in the part of the journey located outside the territory of the Member State of arrival. It is said to be a fob value (free on board) for dispatches, and a cif value (cost, insurance, freight) for arrivals.

4. Nature of the transaction

The nature of transaction means the different characteristics (purchase/sale, work under contract, etc.) which are deemed to be useful in distinguishing one transaction from another.

5. Country of origin

- (a) The country of origin, on arrivals only, means the country where the goods originate.
- (b) Goods which are wholly obtained or produced in a country originate in that country.
- (c) Goods whose production involved more than one country shall be deemed to originate in the country where they underwent their last, substantial, economically justified processing or working in a company equipped for that purpose, resulting in the manufacture of a new product or representing an important stage of manufacture.

6. Region of origin or destination

- (a) The region of origin, on dispatch, means the region of the Member State of dispatch where the goods were produced or were erected, assembled, processed, repaired or maintained; failing that, the region of origin is the region where the goods were dispatched, or, failing that, the region where the commercial process took place.
- (b) The region of destination, on arrival, means the region of the Member State of arrival where the goods are to be consumed or erected, assembled, processed, repaired or maintained; failing that, the region of destination is the region to which the goods are to be dispatched, or, failing that, the region where the commercial process is to take place.

7. Delivery terms

The delivery terms mean those provisions of the sales contract which lay down the obligations of the seller and the buyer respectively, in accordance with the Incoterms of the International Chamber of Commerce (cif, fob, etc.).

8. Mode of transport

The mode of transport is determined by the active means of transport by which the goods are presumed to be going to leave the statistical territory of the Member State of dispatch, on dispatch, and by the active means of transport by which the goods are presumed to have entered the statistical territory of the Member State of arrival, on arrival.

9. Statistical procedure

The statistical procedure means the different characteristics which are deemed to be useful in distinguishing different types of arrivals/dispatches for statistical purposes.

**COUNCIL REGULATION (EC) No 639/2004
of 30 March 2004**

on the management of fishing fleets registered in the Community outermost regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 and Article 299(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Whereas:

(1) Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy ⁽²⁾, and in particular Chapter III thereof, establishes a Community scheme to adjust the fishing capacities of the Member States' fleets, to a level globally compatible with fishing opportunities.

(2) Council Regulation (EC) No 2792/1999 of 17 December 1999 laying down the detailed rules and arrangements regarding Community structural assistance in the fisheries sector ⁽³⁾ covers modernisation of fishing vessels with public aid and public aid for the renewal of fishing vessels.

(3) Given the relative importance of the fisheries sector in those regions, it is justifiable to take account of the particular structural, social and economic situation of the Community outermost regions (outermost regions) in respect of management of fishing fleets. To that end, the provisions on management of entry/exit schemes and compulsory withdrawal of capacity, in Regulation (EC) No 2371/2002, and the rules on access to public aid for the modernisation and for the renewal of fishing vessels should be adapted to the needs of those regions.

(4) Any capacity increase for fleets registered in ports of outermost regions should also be limited to that justified by local fishing opportunities and the size of fleets kept in balance with those opportunities. To that end the objectives fixed by the multiannual guidance programmes IV (MAGP IV) for each fleet segment, as established in the Annex to Commission Decision

2002/652/EC of 29 July 2002 amending Decisions 98/119/EC to 98/131/EC in order to prolong the multi-annual guidance programmes for the fishing fleets of the Member States until 31 December 2002 ⁽⁴⁾, should be considered as reference levels for, or the upper limit to, the expansion of fleets registered in the French overseas departments, the Azores and Madeira.

(5) Specific reference levels should be determined for vessel segments registered in the Canary Islands, for which no specific objectives were fixed in the MAGP IV framework. These reference levels should take account of the capacity of the local fleet in relation to fishing possibilities.

(6) It is necessary to prevent vessels registered in the outermost regions from being transferred and used in the mainland after benefiting from more favourable treatment as regards the granting of public aid and/or conditions for entry into the fleet.

(7) It is justifiable to apply to the fleets registered in the outermost regions the same rules on fleet capacity management and public aid as are applied to vessels registered in the rest of the Community as soon as the reference levels defined in this Regulation are met, and in any case as from 1 January 2007, except for vessels having received public aid for renewal, where the entry into the fleet might take place until 31 December 2007.

(8) To facilitate the implementation of this Regulation, Member States should collect information on vessels registered in the outermost regions. The Commission should be provided with this information and report on it to ensure full transparency of measures implemented.

(9) As new general rules for fleet capacity management and public aid have been introduced in Regulations (EC) No 2371/2002 and (EC) No 2792/1999 with effect from 1 January 2003, the specific arrangements for the outermost regions should also apply from that date.

(10) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽⁵⁾,

⁽¹⁾ Opinion delivered on 4 December 2003 (not yet published in the Official Journal).

⁽²⁾ OJ L 358, 31.12.2002, p. 59.

⁽³⁾ OJ L 337, 30.12.1999, p. 10. Regulation as last amended by Regulation (EC) No 2369/2002 (OJ L 358, 31.12.2002, p. 49).

⁽⁴⁾ OJ L 215, 10.8.2002, p. 23.

⁽⁵⁾ OJ L 184, 17.7.1999, p. 23.

HAS ADOPTED THIS REGULATION:

Article 1

Specific reference levels

1. For the fleet segments registered in the outermost regions as indicated in Article 299(2) of the Treaty the following specific reference levels for fishing capacity shall apply:

- (a) for the French overseas departments, the Azores and Madeira: the respective MAGP IV objectives for each fleet segment, expressed in kW and GT, for each outermost region at the end of 2002;
- (b) for the Canary Islands: reference levels that take as their starting point the capacities in kW and GT of the relevant fleet segments for vessels registered in Canary Island ports on 1 January 2003 and may be increased on the basis of fishing opportunities for these segments. Increases may be justified up to the objectives that would have been adopted if MAGP IV procedures had applied to these particular segments and shall be in accordance with the most recent scientific advice validated by the Scientific Technical and Economic Committee for Fisheries established pursuant to Article 33 of Regulation (EC) No 2371/2002.

2. Implementing rules for this Article shall be adopted in accordance with the procedure referred to in Article 5(2).

Article 2

Fleet renewal and modernisation

For the fleet segments covered by Article 1(1):

1. by way of derogation from Article 13 of Regulation (EC) No 2371/2002:
 - (a) new capacity may enter the fleet, with or without public aid, within the limits of the specific reference levels indicated in Article 1,
 - (b) the obligation to achieve a reduction in overall fleet capacity of 3 % of the reference levels is not applicable;
2. by way of derogation from Article 9(1)(c)(i) of Regulation No 2792/1999, public aid to modernise the fleet in terms of tonnage and/or power may be granted;
3. the derogations laid down in paragraphs 1 and 2 above shall cease to apply as soon as the reference levels are reached, and in any case not later than 31 December 2006;
4. by way of derogation from Article 9(1)(a) of Regulation No 2792/1999, public aid for the renewal of fishing vessels may be granted until 31 December 2005;

5. notwithstanding paragraph 3 above, for fishing vessels having received public aid for renewal, the derogation in paragraph 1(a) above, will cease to apply two years after the public aid for renewal has been granted and in any case not later than 31 December 2007.

Article 3

Transfer of vessels to the continent

Any transfer of a vessel from an outermost region to the continent shall be treated as an entry in the continental fleet within the meaning of Article 13 of Regulation (EC) No 2371/2002. Public aid for fleet renewal and for the equipment or modernisation of fishing vessels shall be reimbursed pro rata temporis in the case of transfer of a vessel to the continent before the end of a period of:

- (a) 10 years in the case of public aid for fleet renewal; and
- (b) five years in the case of public aid for the equipment or modernisation of fishing vessels

to be dated from the time when the administrative decision to grant aid was taken.

Article 4

Management of capacity

1. Member States shall manage fleets registered in outermost regions in such a way as to comply with this Regulation.
2. Member States shall make available to the Commission information on vessels registered in their outermost regions in accordance with Article 15 of Regulation (EC) No 2371/2002.
3. Rules for the application of this Article shall be adopted in accordance with the procedure referred to in Article 5(2).

Article 5

Committee procedure

1. The Commission shall be assisted by the Committee for Fisheries and Aquaculture.
2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at 20 working days.

3. The Committee shall adopt its Rules of Procedure.

*Article 6***Reporting**

The Commission shall submit to the European Parliament and the Council a report on the implementation of this Regulation no later than 31 December 2006.

*Article 7***Entry into force**

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

It shall apply from 1 January 2003.

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

Done at Brussels, 30 March 2004.

For the Council
The President
M. McDOWELL

COMMISSION REGULATION (EC) No 640/2004
of 6 April 2004
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,

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 7 April 2004.

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

Done at Brussels, 6 April 2004.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

⁽¹⁾ OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 1947/2002 (OJ L 299, 1.11.2002, p. 17).

ANNEX

to the Commission Regulation of 6 April 2004 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	052	97,0
	204	48,2
	212	120,5
	624	124,3
	999	97,5
0707 00 05	052	148,8
	204	132,9
	999	140,9
0709 10 00	220	131,3
	999	131,3
0709 90 70	052	131,7
	204	80,8
	999	106,3
0805 10 10, 0805 10 30, 0805 10 50	052	39,9
	204	42,5
	212	60,8
	220	44,5
	388	44,2
	400	47,2
	600	48,2
	624	57,2
	999	48,1
	0805 50 10	052
999		40,0
0808 10 20, 0808 10 50, 0808 10 90	060	50,7
	388	79,0
	400	94,2
	404	100,9
	508	76,2
	512	73,2
	524	76,9
	528	71,0
	720	71,1
	804	135,0
	999	82,8
	0808 20 50	388
512		68,5
524		80,3
528		76,6
999		73,9

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2081/2003 (OJ L 313, 28.11.2003, p. 11). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 641/2004
of 6 April 2004

on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Articles 5(7), 8(8), 17(7), 20(8) and 47(4) thereof,

After consulting the European Food Safety Authority in accordance with Articles 5(7) and 17(7) of Regulation (EC) No 1829/2003,

Whereas:

- (1) Regulation (EC) No 1829/2003 lays down Community procedures for the authorisation and supervision of genetically modified food and feed and for the labelling of such food and feed.
- (2) It is necessary to provide detailed rules concerning applications for authorisations submitted in accordance with Regulation (EC) No 1829/2003.
- (3) In addition, Regulation (EC) No 1829/2003 provides that the European Food Safety Authority (the Authority) is to publish detailed guidance to assist the applicant in the preparation and the presentation of the application, concerning notably the information and data to be provided in order to demonstrate that the product complies with the criteria referred to in Articles 4(1) and 16(1) of that Regulation.
- (4) In order to ensure a smooth transition to the regime provided by Regulation (EC) No 1829/2003 transitional measures laid down in that Regulation as regards requests and notifications of products falling within the scope of other Community legislation, should be subject to implementing rules.

(5) It is also necessary to provide detailed rules on the preparation and presentation of notifications of existing products submitted to the Commission under Regulation (EC) No 1829/2003 as regards products placed on the market in the Community before 18 April 2004.

(6) Such rules should facilitate the task of operators, in preparing applications for authorisations and in the preparation of notifications of existing products, and the Authority in evaluating such applications and verifying such notifications.

(7) The scope of Regulation (EC) No 1829/2003 includes food which consists of, contains or is produced from genetically modified organisms (GMOs) such as genetically modified plants and micro-organisms. Therefore, in the interests of consistency of Community legislation, the scope of the present Regulation should also cover existing food consisting of, containing or produced from genetically modified plants and micro-organisms.

(8) The scope of Regulation (EC) No 1829/2003 covers feed, including feed additives as defined in Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs ⁽²⁾ consisting of, containing or produced from GMOs such as genetically modified plants and micro-organisms. Therefore, the scope of the present Regulation should also cover existing feed, including feed additives consisting of, containing or produced from genetically modified plants and micro-organisms.

(9) The scope of Regulation (EC) No 1829/2003 does not cover processing aids, including enzymes used as processing aids. Therefore, the scope of the present Regulation similarly should not cover existing processing aids.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

- (10) Regulation (EC) No 1829/2003 provides that detailed rules are to be adopted for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. In the interests of consistency of Community legislation those rules should in particular clarify which genetically modified material is covered by such transitional measures and how the 0,5 % threshold is to be applied.
- (11) It is necessary for this Regulation to apply as a matter of urgency as Regulation (EC) No 1829/2003 applies from 18 April 2004.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Applications for authorisation

Article 1

This chapter provides detailed rules concerning applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation.

SECTION 1

Requirements for applications for authorisation of genetically modified food and feed

Article 2

1. Without prejudice to Article 5(3) and (5) and Article 17(3) and (5) of Regulation (EC) No 1829/2003, and taking into account the guidance of the European Food Safety Authority (the Authority) provided for in Articles 5(8) and 17(8) of that Regulation, applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (the applications) shall comply with the requirements of paragraphs 1 to 4 of this Article and with Articles 3 and 4 of this Regulation.

2. In supplying the information required under Article 5(3)(b) and Article 17(3)(b) of Regulation (EC) No 1829/2003, the application shall clearly identify the products covered by it in accordance with Articles 3(1) and 15(1) of that Regulation. Where the application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation should not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003.

3. The application shall clearly state which parts of the application are considered to be confidential, together with a verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts shall be submitted in separate documents.

4. The application shall specify, in supplying the information required under Article 5(3)(c) and Article 17(3)(c) of Regulation (EC) No 1829/2003, whether the information included in the application may be notified as such to the biosafety clearing house under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol) approved by Council Decision 2002/628/EC ⁽¹⁾.

If the application may not be notified as such, it shall include the information which complies with Annex II to the Cartagena Protocol and which may be notified to the biosafety clearing house by the Commission as provided in Article 44 of Regulation (EC) No 1829/2003 in a separate and clearly identified document.

5. Paragraph 4 shall not apply to applications concerning only food and feed produced from genetically modified organisms (GMOs) or containing ingredients produced from GMOs.

Article 3

1. The application shall include the following:
- (a) the monitoring plan referred to in Article 5(5)(b) and Article 17(5)(b) of Regulation (EC) No 1829/2003, taking into account Council Decision 2002/811/EC ⁽²⁾;
- (b) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for labelling complying with the requirements of Annex IV to Directive 2001/18/EC of the European Parliament and of the Council ⁽³⁾;

⁽¹⁾ OJ L 201, 31.7.2002, p. 48.

⁽²⁾ OJ L 280, 18.10.2002, p. 27.

⁽³⁾ OJ L 106, 17.4.2001, p. 1.

(c) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for a unique identifier for the GMO in question, developed in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾;

(d) a proposal for labelling in all official Community languages, where a proposal for specific labelling is needed in accordance with Article 5(3)(f) and Article (g) and 17(3)(f) and (g) of Regulation (EC) No 1829/2003;

(e) a description of a method(s) of detection, sampling and event specific identification of the transformation event, as provided for in Article 5(3)(i) and Article 17(3)(i) of Regulation (EC) No 1829/2003, in accordance with Annex I to this Regulation;

(f) a proposal for post-market monitoring regarding the use of the food for human consumption or the feed for animal consumption, as provided for in Article 5(3)(k) and Article 17(3)(k) of Regulation (EC) No 1829/2003, and according to the characteristics of the products concerned, or a verifiable justification to the effect that a post-market monitoring is not necessary.

2. Points (a), (b) and (c) of paragraph 1 shall not apply to applications concerning only food and feed produced from GMOs or containing ingredients produced from GMOs.

Article 4

1. Samples of the food and feed and their control samples which are to be submitted in accordance with Article 5(3)(j) and Article 17(3)(j) of Regulation (EC) No 1829/2003 shall be in accordance with the requirements set out in Annexes I and II to this Regulation.

The application shall be accompanied by information concerning the place where the reference material developed in accordance with Annex II may be found.

2. The summary to be provided in accordance with Article 5(3)(l) and Article 17(3)(l) of Regulation (EC) No 1829/2003 shall:

(a) be presented in an easily comprehensible and legible form;

(b) not contain parts which are considered to be confidential.

SECTION 2

Transformation of requests and notifications into applications in accordance with Regulation (EC) No 1829/2003

Article 5

1. Where a request submitted under Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽²⁾ is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(1) of that Regulation, the national competent authority of the Member State in which the request was submitted shall, without delay, ask the applicant to submit a complete dossier in accordance with Article 5 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

(a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt. The acknowledgement shall state the date of receipt: of the information;

(b) inform the Authority without delay;

(c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the initial assessment report provided for in Article 6(3) of Regulation (EC) No 258/97, as well as any comments or objections which may have been made by Member States or the Commission under Article 6(4) of that Regulation.

3. The Authority shall:

(a) inform the other Member States and the Commission without delay that the request under Article 4 of Regulation (EC) No 258/97 has been transformed into an application under Regulation (EC) No 1829/2003 and make the application and any supplementary information supplied by the applicant available to them;

(b) make the summary of the dossier referred to in Article 5(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 6(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 5 of Regulation (EC) No 1829/2003.

⁽¹⁾ OJ L 10, 16.1.2004, p. 5.

⁽²⁾ OJ L 43, 14.2.1997, p. 1.

Article 6

1. Where a notification concerning a product including its use as feed submitted under Article 13 of Directive 2001/18/EC is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(3) of that Regulation, the national competent authority, within the meaning of Directive 2001/18/EC, of the Member State in which the notification was submitted shall ask without delay the notifier to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

- (a) acknowledge receipt of the information supplied by the notifier in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;
- (b) inform the Authority without delay;
- (c) make the notification and the information supplied by the notifier in accordance with paragraph 1 available to the Authority;
- (d) where applicable, make available to the Authority the assessment report provided for in Article 14(2) of Directive 2001/18/EC.

3. The Authority shall:

- (a) inform the other Member States and the Commission without delay that the notification under Article 13 of Directive 2001/18/EC has been transformed into an application under Regulation (EC) No 1829/2003 and shall make the application and any supplementary information supplied by the notifier available to them;
- (b) make the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

Article 7

1. Where a request submitted under Article 7 of Council Directive 82/471/EEC⁽¹⁾, concerning products produced from GMOs, is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(4) of that

⁽¹⁾ OJ L 213, 21.7.1982, p. 8.

Regulation, the Commission shall ask the applicant without delay to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

The applicant shall send the complete dossier to the Member States and to the Commission.

2. The Commission shall:

- (a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;
- (b) inform the Authority without delay;
- (c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;
- (d) where applicable, make available to the Authority the dossier provided for in Article 7(1) of Directive 82/471/EEC.

3. The Authority shall make:

- (a) any supplementary information supplied by the applicant available to the Member States and the Commission;
- (b) the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

SECTION 3

Supplementation of requests under Directive 70/524/EEC by an application under Regulation (EC) No 1829/2003

Article 8

1. Where a request submitted under Article 4 of Directive 70/524/EEC, concerning products referred to in Article 15(1) of Regulation (EC) No 1829/2003, is supplemented by an application under Regulation (EC) No 1829/2003, in accordance with Article 46(5) of that Regulation, the Member State acting as rapporteur shall ask the applicant without delay to submit a separate application for authorisation in accordance with Article 17 of Regulation (EC) No 1829/2003.

2. The application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

(ii) information as to the place where the reference material, which shall be developed in accordance with Annex II to this Regulation, may be found.

CHAPTER II

Notification of existing products

Article 9

This chapter provides the requirements concerning the preparation and presentation of notifications of existing products submitted to the Commission in accordance with Articles 8 and 20 of Regulation (EC) No 1829/2003 and applies to existing products covered by the scope of that Regulation and placed on the market in the Community prior to 18 April 2004.

SECTION 1

General requirements for notifications of certain products placed on the market before 18 April 2004

Article 10

1. Notifications submitted in accordance with Articles 8(1) and 20(1) of Regulation (EC) No 1829/2003 shall:
 - (a) clearly identify the products covered by the notification, taking account of Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003;
 - (b) include relevant information and studies, including, where available, independent and peer-reviewed studies, which demonstrate that the product complies with the requirements provided for in Articles 4(1) or 16(1) of Regulation (EC) No 1829/2003;
 - (c) clearly indicate which parts of the notification are considered to be confidential, together with a verifiable justification, and those parts shall be submitted in separate documents;
 - (d) include a method(s) of detection, sampling and identification of the transformation event in accordance with Annex I to this Regulation;
 - (e) in accordance with Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 provide:
 - (i) samples of the food and feed and their control samples in accordance with Annex I to this Regulation;

2. The notifications referred to in paragraph 1 shall be submitted to the Commission before 18 October 2004.

SECTION 2

Additional requirements for notifications of certain products placed on the market before 18 April 2004

Article 11

1. In addition to the requirements of Article 10, notifications of GMOs which have been placed on the market in accordance with part C of Council Directive 90/220/EEC⁽¹⁾ or part C of Directive 2001/18/EC shall include a copy of the relevant consent granted under those directives.

2. The date of publication in the *Official Journal of the European Union* of the Decision to grant consent under Directive 90/220/EEC or Directive 2001/18/EC shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date

Article 12

1. In addition to the requirements of Article 10, notifications of food produced from GMOs which have been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97 shall include a copy of the original notification letter to the Commission.

2. The date of the letter from the Commission forwarding the original notification to the Member States shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date.

Article 13

1. In addition to the requirements of Article 10, notifications of genetically modified food which have been placed on the market in accordance with Articles 6 and 7 of Regulation (EC) No 258/97 shall include a copy of the authorisation of that food.

⁽¹⁾ OJ L 117, 8.5.1990, p. 15.

2. The date the authorisation of the product took effect under Regulation No (EC) 258/97 shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 14

1. In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been placed on the market in accordance with Articles 3 and 4 of Directive 82/471/EEC shall include a copy of the authorisation at Community level or, where applicable, the authorisation granted by a Member State.

2. The date the authorisation of the product took effect in accordance with Directive 82/471/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 15

1. In addition to the requirements of Article 10, notifications of feed containing, consisting of or produced from GMOs which have been authorised in accordance with Directive 70/524/EEC shall include:

- (a) the identification of the feed additive(s) to be covered by the number or the EC number, where applicable, as laid down in Article 9(l) of Directive 70/524/EEC;
- (b) a copy of the authorisation.

2. The date the authorisation of the product took effect under Directive 70/524/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 16

In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been lawfully placed on the market in the Community, which are not covered by Articles 11, 14 and 15, and for which the GMO(s) has been notified for authorisation for use as animal feed under part C of Directive 2001/18/EC shall:

- (a) contain a reference to the notification under evaluation submitted according to Article 13 of Directive 2001/18/EC;

- (b) include a declaration that the product was placed on the market before 18 April 2004.

Article 17

In addition to the requirements of Article 10, notifications of food and feed produced from GMOs which have been lawfully placed on the market in the Community and which are not covered by Articles 11 to 16 shall include a declaration that the product was placed on the market before 18 April 2004.

CHAPTER III

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

Article 18

1. For the purpose of implementing Article 47 of Regulation (EC) No 1829/2003, the Commission shall, on 18 April 2004, publish a list of the genetically modified material that has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before that date and for which an application for authorisation has not been rejected in accordance with the relevant Community legislation.

2. This list shall distinguish between:

- (a) material in respect of which the Commission has been informed, by any interested party, that a detection method is publicly available; an indication of where the detection method has been made available shall be included;
- (b) material in respect of which the Commission has not yet been informed that a detection method is publicly available.

Any interested party may, at any time, inform the Commission that a detection method for material referred to in point (b) of the first subparagraph is publicly available, with an indication of where the detection method is available.

3. The list referred to in paragraph 1 shall be maintained by the Commission. Amendments to the list may result, in particular, from:

- (a) the granting of an authorisation or the rejection of an application for authorisation for material included in the list, in accordance with the relevant Community legislation;

- (b) notifications to the Commission, in accordance with Articles 8 or 20 of Regulation (EC) No 1829/2003, that material included in the list has been lawfully placed on the market in the Community before 18 April 2004, or adoption by the Commission of a measure in accordance with Article 8(6) or 20(6) of Regulation (EC) No 1829/2003;
- (c) information received by the Commission that a detection method in respect of material included in the list is publicly available.

Information about amendments brought to the list shall be compiled in an Annex to the list.

Article 19

1. The 0,5 % threshold provided for in Article 47(1) of Regulation (EC) No 1829/2003 shall apply to genetically modified material included in part (a) of the list referred to in Article

18(2) of the present Regulation. Where a lower threshold has been established in accordance with Article 47(3) of Regulation (EC) No 1829/2003, it shall be specified in that list.

2. The thresholds provided for in Article 47 of Regulation (EC) No 1829/2003 shall apply to food ingredients considered individually or food consisting of a single ingredient and to feed and each feed of which it is composed.

CHAPTER IV

Final provision

Article 20

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

It shall apply from 18 April 2004.

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

Done at Brussels, 6 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

METHOD VALIDATION

1. INTRODUCTION

- A. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, this Annex provides technical provisions on the type of information on detection methods that shall be provided by the applicant and that is needed to verify the preconditions for the fitness of the method. This includes information about the method as such and about the method testing carried out by the applicant. All guidance documents referred to in this Annex or produced by the Community Reference Laboratory (CRL) shall be made available by the CRL.
- B. The method acceptance criteria and method performance requirements have been compiled by the European Network of GMO Laboratories (ENGL) in a document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing', which shall be made available by the CRL. 'Method acceptance criteria' are criteria, which should be fulfilled prior to the initiation of any method validation by the CRL. The 'method performance requirements' define the minimum performance criteria that the method should demonstrate upon completion of a validation study carried out by the CRL according to internationally accepted technical provisions and this in order to certify that the method validated is fit for the purpose of enforcement of Regulation (EC) No 1829/2003.
- C. The CRL, established under Regulation (EC) No 1829/2003 and assisted by ENGL, will evaluate the provided information for its completeness and fitness for the purpose. Here, the method acceptance criteria recommended by ENGL, which are described under 1(B), will be taken into account.
- D. If the information provided about the method is considered adequate and fulfils the method acceptance criteria, the CRL will initiate the validation process for the method.
- E. The validation process will be carried out by the CRL according to internationally accepted technical provisions.
- F. The CRL, together with ENGL, shall provide further information about the operational procedures of the validation process and shall make the documents available.
- G. The CRL, assisted by ENGL, shall evaluate the results obtained in the validation study for the fitness for the purpose. Here, the method performance requirements as described under 1(B) shall be taken into account.

2. INFORMATION ABOUT THE METHOD

- A. The method shall refer to all the methodological steps needed to analyse the relevant material in accordance with Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003.

For a particular material this must include the methods for DNA extraction and the subsequent quantification in a polymerase chain reaction (PCR) system. In such a case, the whole process from extraction up to the PCR-technique (or equivalent) constitutes a method. The applicant shall provide information about the whole method.

- B. As described in the document referred to under 1(B), ENGL recognises the modularity of a method. According to this principle, the applicant is allowed to refer to existing methods for a certain module(s), if available and appropriate. This could be, for instance, a DNA extraction method from a certain matrix. In such a case, the applicant shall provide experimental data from an in-house validation in which the method module has been successfully applied in the context of the application for authorisation.
- C. The applicant shall demonstrate that the method fulfils the following requirements.
 1. The method shall be event-specific and thus must only be functional with the GMO or GM based product considered and shall not be functional if applied to other events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised events and conventional counterparts, in the case of GM plants. This testing shall include closely related events, where relevant, and cases where the limits of the detection are truly tested. The same specificity principle must be applied for products that consist of or contain GMOs other than plants.
 2. The method shall be applicable to samples of the food or feed, to the control samples and to the reference material, which is referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003.

3. The method shall be developed taking the following documents in consideration as appropriate:
 - General requirements and definitions: draft European standard prEN ISO 24276:2002,
 - Nucleic acid extraction prEN ISO 21571:2002,
 - Quantitative nucleic acid based methods: draft European standard prEN ISO 21570:2002,
 - Protein based methods: adopted European standard EN ISO 21572:2002,
 - Qualitative nucleic acid based methods: draft European standard prEN ISO 21569:2002.
 - D. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, the applicant shall provide:
 - (a) in the case of an application for authorisation covering a GMO, products consisting of or containing a GMO or products produced from a GMO, the event-specific quantitative detection method of the GM material;
 - (b) in addition, in the case of an application for authorisation covering products produced from a GMO where the genetically modified material is detectable, the event-specific quantitative detection method in the foods or feeds produced from the GMO.
 - E. The applicant shall provide a complete and detailed description of the method. The following points shall be clearly addressed.
 1. Scientific basis: An overview of the principles of how the method works, such as DNA molecular biology based (e.g. for real-time PCR) information must be provided. It is recommended to provide references to relevant scientific publications.
 2. Scope of the method: Indication of the matrix (e.g. processed food, raw materials), the type of samples and the percentage range to which the method can be applied.
 3. Operational characteristics of the method: The required equipment for the application of the method shall be clearly mentioned, with regard to the analysis *per se* and the sample preparation. Further information of any specific aspects crucial for the application of the method shall also be mentioned here.
 4. Protocol: The applicant shall provide a complete optimised protocol of the method. The protocol shall present all the details as required to transfer and apply the method independently in other laboratories. It is recommended to use a protocol template, which can be obtained from the CRL. The protocol shall include details of:
 - analyte to be tested,
 - working conditions, instructions and rules,
 - all the materials needed, including an estimation of their amounts and storage and handling instructions,
 - all the equipment needed, including not only the main equipment such as a PCR system or centrifuge but also small items such as micropipettes and reaction tubes with an indication of their appropriate sizes, etc.,
 - all the steps of the operative protocol, clearly described,
 - instructions for the data recording (e.g. the programme settings or parameters to be included).
 5. The prediction model (or alike) needed to interpret results and to make inferences must be described in full details. Instructions for the correct application of the model should be provided.
3. INFORMATION ABOUT THE METHOD TESTING CARRIED OUT BY THE APPLICANT
- A. The applicant shall provide all the available and relevant data of the method optimisation and testing carried out. These data and results shall be presented, where possible and appropriate, by using the performance parameters recommended by the ENGL as referred to under 1(B). A summary of the testing carried out and the main results as well as all the data including the outliers shall be provided. The CRL, together with ENGL, shall continue to provide further technical provisions about the appropriate formats for these data.
 - B. The information provided shall demonstrate the robustness of the method for inter-laboratory transferability. This means that the method should have been tested by at least one laboratory that is independent from the laboratory which has developed the method. This is an important pre-condition for the success of the validation of the method.
 - C. Information required about the method development and the method optimisation:
 1. primer pairs tested (in the case of a PCR-based test): justification shall be given of how and why the proposed primer pair has been selected;
 2. stability testing: experimental results from testing the method with different varieties shall be provided;
 3. specificity: the applicant shall submit the full sequence of the insert(s), together with the base pairs of the host flanking sequences needed to establish an event-specific detection method. The CRL shall enter these data in a molecular database. By running homology searches, the CRL will thus be in a position to assess the specificity of the proposed method.

- D. Testing report. Besides the values obtained for the performance indices, the following information regarding the testing shall be provided, as appropriate:
- participating laboratories, time of the analysis and outline of the experimental design, including the details about the number of runs, samples, replicates etc.,
 - description of the laboratory samples (e.g. size, quality, date of sampling), positive and negative controls as well as reference material, plasmids and alike used,
 - description of the approaches that have been used to analyse the test results and outliers,
 - any particular points observed during the testing,
 - references to relevant literature or technical provisions used in the testing.

4. SAMPLES OF THE FOOD AND FEED AND THEIR CONTROL SAMPLES

In view of implementing Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003, the applicant shall, together with the information specified under sections 1, 2 and 3 of this Annex, also provide samples of the food and feed and their control samples of a type and amount to be specified by the CRL for the specific application for authorisation.

ANNEX II

REFERENCE MATERIAL

The reference material as referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 shall be produced in accordance with internationally accepted technical provisions such as ISO Guides 30 to 34 (and more particularly ISO Guide 34, specifying the general requirements for the competence of reference material producers). The reference material shall be preferably certified and, if such is the case, certification shall be done in accordance with ISO Guide 35.

For verification and value assignment, a method that has been properly validated (see ISO/IEC 17025:5.4.5) shall be used. Uncertainties have to be estimated according to GUM (ISO Guide to the Expression of Uncertainty in Measurement: GUM). Major characteristics of these internationally accepted technical provisions are given below.

A. Terminology:

reference material (RM): material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials;

Certified reference material (CRM): reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

B. GM RM containers:

- GM RM container (bottles, vials, ampoules, etc.) must be tight and contain not less than the stated amount of material,
- samples must have appropriate homogeneity and stability,
- the commutability of the GM RM has to be assured,
- packaging must be appropriate to the purpose,
- labelling must be of good aspect and quality.

C. Homogeneity testing:

between-bottle homogeneity must be examined;

any possible between-bottle heterogeneity must be accounted for in the overall estimated RM uncertainty. This requirement applies even when no statistically significant between-bottle variation is present. In this case, the method variation or the actual calculated between-bottle variation (whichever is larger) must be included in the overall uncertainty;

D. Stability testing:

stability must be positively demonstrated by appropriate statistical extrapolation for the GM RM shelf-life to be within the stated uncertainty; the uncertainty related to this demonstration is normally part of the estimated RM uncertainty;

assigned values are valid only for a limited time and must be subject to a stability monitoring.

E. Batch characterisation:

the methods used for verification and for certification must:

- be applied under metrologically valid conditions,
- have been properly technically validated before use,
- have precision and accuracy compatible with the target uncertainty;

each set of measurements must:

- be traceable to the stated references, and
- be accompanied by an uncertainty statement whenever possible;

participating laboratories must:

- have the required competence for the execution of the task,
- be able to achieve traceability to the required stated references,
- be able to estimate its measurement uncertainty,
- have in place a sufficient and appropriate quality assurance system.

F. Final storage:

- to avoid a posterior degradation, all samples are best stored under conditions designated for the final storage of the GM RM before measurements are started,
- otherwise, they must be transported from door to door keeping them at all times under such storage conditions for which it has been demonstrated that there is no influence on the assigned values.

G. Establishment of a certificate for CRMs:

- a certificate complemented by a certification report has to be established, containing all information relevant to and needed by the user. The certificate and report must be made available when the GM CRM is distributed,
 - certified values must be traceable to stated references and be accompanied by an expanded uncertainty statement valid for the entire shelf-life of the GM CRM.
-

COMMISSION REGULATION (EC) No 642/2004**of 6 April 2004****on precision requirements for data collected in accordance with Council Regulation (EC) No 1172/98 on statistical returns in respect of the carriage of goods by road****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Article 2

Having regard to the Treaty establishing the European Community,

Percentage standard error

Having regard to Council Regulation (EC) No 1172/98 of 25 May 1998 on statistical returns in respect of the carriage of goods by road ⁽¹⁾, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ⁽²⁾, and in particular Article 4 thereof,

1. Where the methods used by Member States in compiling the data involve sample methodology, the percentage standard error (95 % confidence) of the annual estimates for tonnes transported, tonne-kilometres performed and total kilometres travelled loaded for total goods road transport and for national goods road transport shall not be greater than $\pm 5\%$.

Whereas:

- (1) In accordance with Article 4 of Regulation (EC) 1172/98, the Commission shall ensure that the statistical results transmitted by the Member States meet minimum standards of precision, taking account of the structural characteristics of road transport in the Member States.
- (2) In accordance with Article 7(2) of Regulation (EC) 1172/98, Member States shall provide Eurostat with information each year on sample sizes, non-response rates and, in the form of standard error or confidence intervals, the reliability of the main results.
- (3) It is necessary to specify the structure and content of the minimum standards of precision of the statistical results transmitted by the Member States.
- (4) The measures provided for in this Regulation are in accordance with the opinion delivered by the Statistical Programme Committee, set up by Council Decision 89/382/EEC, Euratom ⁽³⁾,

2. Where the total stock of goods road motor vehicles relevant to the survey in a Member State is less than 25 000 vehicles, or the total stock of vehicles engaged in international transport is less than 3 000 vehicles, the percentage standard error (95 % confidence) of the annual estimates for tonnes transported, tonne-kilometres performed and total kilometres travelled loaded for total goods road transport and for national goods road transport shall not be greater than $\pm 7\%$.

*Article 3***Information to be provided to Eurostat**

HAS ADOPTED THIS REGULATION:

*Article 1***Time periods to be covered in a survey**

1. Where the methods used by Member States in compiling the data involve sample methodology, all time periods shall be covered by the survey.
2. Where the total stock of goods road motor vehicles in a Member State that can be included in the survey is less than 25 000 vehicles, or the total stock of vehicles engaged in international transport is less than 3 000 vehicles, the minimum number of weeks covered by the survey in a quarter shall be seven.

1. Member States shall provide Eurostat with information each quarter to permit the calculation of sample size, response rates and register quality rates. Where the primary sample unit is the goods road motor vehicle, the information shall be provided in the format of Table B1 in the Annex to this Regulation. Where the primary sample unit is not the goods road motor vehicle, the information shall be provided in the format of Table B2 in the Annex to this Regulation. The table shall be provided within the same timescale as for the transmission of the data set out in Article 5(3) of Regulation (EC) No 1172/98.

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

- (a) 'response rate' means a value, of which the denominator is the number of sample units to which questionnaires were despatched to the selected operators, and of which the numerator is the number of sample units to which questionnaires were despatched, minus the aggregate of the number of units refusing to participate and the number of units for which no information of any kind was received;

⁽¹⁾ OJ L 163, 6.6.1998, p. 1.

⁽²⁾ OJ L 284, 31.10.2003, p. 1.

⁽³⁾ OJ L 181, 28.6.1989, p. 47.

(b) 'register quality rate' means a value, of which the denominator is the number of sample units to which questionnaires were despatched, minus the aggregate of the number of units refusing to participate and the number of units for which no information of any kind was received, and of which the numerator is the number of sample units where vehicles were working actively during the survey period, plus the number of units where vehicles were not working during the survey period but could be considered to be part of the active stock of vehicles.

2. If the percentage standard errors of the data provided by a Member State pursuant to Regulation (EC) No 1172/98 have been calculated for a number of years and Eurostat has noted that these standard errors are within the limits laid down in Article 2 of this Regulation, Eurostat may release that Member State from the obligation to provide Table B1 or Table B2 on a quarterly basis.

3. Where paragraph 2 applies, the Member State may provide Eurostat with information for each year to permit the calculation of response rate and register quality rate. The information may be provided in the format of Tables B3 or B4 (as appropriate) in the Annex to this Regulation. The table shall be submitted within five months of the end of the last quarterly

period of observation of the relevant year. In addition within the same timescale, the Member State shall provide Eurostat with the calculated figures of percentage standard error (95 % confidence) of the estimates for tonnes transported, tonne-kilometres performed and total kilometres travelled loaded for total goods road transport, for national goods road transport and for total international goods road transport.

Article 4

Where the total stock of goods road motor vehicles in a Member State that are engaged in international transport and can be included in the survey is less than 1 000 vehicles, the Member State concerned shall be exempted from the application of the present Regulation.

Article 5

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 1 shall apply from 1 January 2006.

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

Done at Brussels, 6 April 2004.

For the Commission
Pedro SOLBES MIRA
Member of the Commission

ANNEX

TABLES B1, B2, B3, B4

TABLE B1: For surveys where the goods motor vehicle is the statistical unit: information on sample

	Reporting country: Quarter ____/ Year _____	Stratum					Total
		1	2	3	4	etc.	
1	Number of vehicles in the country in each stratum.						
2	Number of vehicles selected for initial sample and questionnaires despatched to vehicle owners (Note: row 2 = rows 3 + 4 + 5 + 6).						
3	Number of cases classified as non-respondents. Non-response includes refusals, cases where no reply or communication of any kind has been received about the sampled unit and where a response has been received but the questionnaire has been so badly completed that it cannot be used in the analysis.						
4	Number of cases where sample register information was wrong and response could not be used. Wrong vehicle register information includes cases where selected vehicle has been scrapped, sold, leased, is outside the scope of the survey (e.g. does not carry goods, load capacity is too low, contact never owned vehicle, vehicle is unlicensed at time of survey, address is incorrect or undeliverable).						
5	Number of questionnaires used in analysis (that is, vehicle records (in A1 data set), that are sent to Eurostat recording vehicle activity)						
6	Number of cases where no vehicle activity was recorded during the sampled period but the vehicle could be considered as part of the active stock (vehicles not used in the sampled period due to illness, holidays, no driver, no work, temporary repair, etc.)						
7	Grossing factor used						

TABLE B2: For surveys where the goods motor vehicle is not the statistical unit: information on sample

	Reporting country: Quarter ____/Year ____	Stratum					Total
		1	2	3	4	etc.	
1	Number of primary statistical units in the country in each stratum.						
2	Number of primary statistical units selected for initial sample and questionnaires despatched to vehicle owners (Note: row 2 = rows 3 + 4 + 5 + 6)						
3	Number of primary statistical units classified as non-respondents. Non-response includes refusals and cases where no reply or communication of any kind has been received about the sampled unit.						
4	Number of cases where sample register information was wrong and response could not be used. (Wrong register information includes cases where selected unit has been sold, is outside the scope of the survey, no longer in business, unlicensed at time of survey, address incorrect or undeliverable.)						
5	Number of primary statistical units providing information about vehicles						
6	Of the statistical units in row 5, total number of vehicles for which information was supplied on journeys made in survey period						
7	Of the statistical units in row 5, total number of vehicles where no vehicle activity was recorded during the sampled period but the vehicle could be considered as part of the active stock (vehicle not used in the sampled period due to illness, holidays, no driver, no work, temporary repair, etc.)						
8	Estimated number of vehicles in the country in each stratum (if available)						
9	Grossing factor used						

TABLE B3: For surveys where the goods motor vehicle is the statistical unit: information on sample

Reporting country:		
Year _____		
1	Number of vehicles in the country at mid-point of year.	
2	Number of vehicles selected for initial sample and questionnaires despatched to vehicle owners (Note : row 2 = rows 3 + 4 + 5 + 6).	
3	Number of cases classified as non-respondents. Non-response includes refusals, cases where no reply or communication of any kind has been received about the sampled unit and where a response has been received but the questionnaire has been so badly completed that it cannot be used in the analysis.	
4	Number of cases where sample register information was wrong and response could not be used. Wrong vehicle register information includes cases where selected vehicle has been scrapped, sold, leased, is outside the scope of the survey (e.g. does not carry goods, load capacity is too low), contact never owned vehicle, address incorrect or undeliverable.	
5	Number of questionnaires used in analysis (that is, vehicle records (in A1 data set) that are sent to Eurostat recording vehicle activity)	
6	Number of cases where no vehicle activity was recorded during the sampled period but the vehicle could be considered as part of the active stock (vehicle not used in the sampled period due to illness, holidays, no driver, no work, temporary repair, etc.)	

TABLE B4: For surveys where the goods motor vehicle is not the statistical unit: information on sample

Reporting country:		
Year _____		
1	Number of primary statistical units in the country at mid-point of the year	
2	Number of primary statistical units selected for initial sample and questionnaires despatched to vehicle owners (Note: row 2 = rows 3 + 4 + 5)	
3	Number of primary statistical units classified as non-respondents. Non-response includes refusals and cases where no reply or communication of any kind has been received about the sampled unit.	
4	Number of cases where sample register information was wrong and response could not be used. Wrong register information includes cases where selected unit has been sold, is outside the scope of the survey, no longer in business, addresses incorrect or undeliverable.	
5	Number of primary statistical units providing information about vehicles	
6	Of the statistical units in row 5, total number of vehicles for which information was supplied of journeys made in survey period	
7	Of the statistical units in row 5, total number of vehicles where no vehicle activity was recorded during the sampled period but the vehicle could be considered as part of the active stock (vehicle not used in the sampled period due to illness, holidays, no driver, no work, temporary repair, etc.)	
8	Estimated number of vehicles in the country at mid-point of the year (if available)	

COMMISSION REGULATION (EC) No 643/2004

of 6 April 2004

fixing the rates of the refunds applicable to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs ⁽¹⁾, and in particular Article 8(3) thereof,

Whereas:

- (1) Article 8(1) of Regulation (EEC) No 2771/75 provides that the difference between prices in international trade for the products listed in Article 1(1) of that Regulation and prices within the Community may be covered by an export refund where these goods are exported in the form of goods listed in the Annex to that Regulation. Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common detailed rules for the application of the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds ⁽²⁾, specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex I to Regulation (EEC) No 2771/75.
- (2) In accordance Article 4(1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for a period of the same duration as that for which refunds are fixed for the same products exported unprocessed.
- (3) Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lays down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.
- (4) By Regulations (EC) No 1039/2003 ⁽³⁾, (EC) No 1086/2003 ⁽⁴⁾, (EC) No 1087/2003 ⁽⁵⁾, (EC) No 1088/2003 ⁽⁶⁾, (EC) No 1089/2003 ⁽⁷⁾ and (EC) No 1090/2003 ⁽⁸⁾ the Council adopted autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Estonia, Slovenia, Latvia, Lithuania, Slovakia and the Czech Republic and the exportation of certain processed agricultural products to those countries.. Those Regulations provide that with effect from 1 July 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Estonia, Slovenia, Latvia, Lithuania, Slovakia or the Czech Republic, shall not be eligible for export refunds.
- (5) In accordance with Council Regulation (EC) No 999/2003 of 2 June 2003 adopting autonomous and transitional measures concerning the import of certain processed agricultural products originating in Hungary and the export of certain processed agricultural products to Hungary ⁽⁹⁾, with effect from 1 July 2003, the goods referred to in its Article 1(2) which are exported to Hungary shall not be eligible for export refunds.
- (6) In accordance with Council Regulation (EC) No 1890/2003 of 27 October 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Malta and the exportation of certain processed agricultural products to Malta ⁽¹⁰⁾, with effect from 1 November 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Malta are not eligible for export refunds.
- (7) With a view to enlargement of the European Union on 1 May 2004, and in order to encourage the gradual alignment of prices in the acceding states on the Community level and to prevent any abuse through the reimport or reintroduction into the Community of products in receipt of export refunds, the setting of all remaining export refunds has been discontinued in the milk and milk products, sugar, cereals and rice sectors in relation to the products concerned when exported unprocessed to the acceding states. Agricultural products from these sectors account for more than 95% of the amounts of export refunds granted on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty.

⁽¹⁾ OJ L 282, 1.11.1975, p. 49. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 177, 15.7.2000, p. 1. Regulation as last amended by Regulation (EC) No 740/2003 (OJ L 106, 29.4.2003, p. 16).

⁽³⁾ OJ L 151, 19.6.2003, p. 1.

⁽⁴⁾ OJ L 163, 1.7.2003, p. 1.

⁽⁵⁾ OJ L 163, 1.7.2003, p. 19.

⁽⁶⁾ OJ L 163, 1.7.2003, p. 38.

⁽⁷⁾ OJ L 163, 1.7.2003, p. 56.

⁽⁸⁾ OJ L 163, 1.7.2003, p. 73.

⁽⁹⁾ OJ L 146, 13.6.2003, p. 10.

⁽¹⁰⁾ OJ L 278, 29.10.2003, p. 1.

- (8) Therefore, account being taken of the minor economic incidence of the eggs and eggs yolk sector to the amounts of export refunds granted on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, it is appropriate that with effect from 7 April 2004 no refund should be set for eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and for the goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.
- (9) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.
- (10) The Management Committee for Poultrymeat and Eggs has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products listed in Annex A to Regulation (EC) No 1520/2000 and in Article 1(1) of Regulation (EEC) No 2771/75, exported in the form of goods listed in Annex I to Regulation (EEC) No 2771/75, are fixed as set out in the Annex to this Regulation.

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

Done at Brussels, 6 April 2004.

Article 2

1. Without prejudice to Article 1 and with effect from 1 July 2003 the rates set out in the Annex are not applicable to goods not covered by Annex I to the Treaty when exported to the Czech Republic, Estonia, Latvia, Lithuania, Slovakia or Slovenia and to the goods referred to in Article 1(2) of Council Regulation (EC) No 999/2003 when exported to Hungary.

With effect from 1 November 2003 these rates are not applicable to goods not covered by Annex I to the Treaty when exported to Malta.

2. Without prejudice to Article 1 and with effect from 7 April 2004 no rates of refund shall be set in respect of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and in respect of goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.

Article 3

This Regulation shall enter into force on 7 April 2004.

For the Commission

Erkki LIIKANEN

Member of the Commission

ANNEX

Rates of the refunds applicable from 7 April 2004 to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)			
CN code	Description	Destination ⁽¹⁾	Rate of refund
0407 00	Birds' eggs, in shell, fresh, preserved or cooked:		
	– Of poultry:		
0407 00 30	– – Other:		
	(a) On exportation of ovalbumin of CN codes 3502 11 90 and 3502 19 90	02	6,00
		03	25,00
		04	3,00
	(b) On exportation of other goods	01	3,00
0408	Birds' eggs, not in shell and egg yolks, fresh, dried, cooked by steaming or by boiling in water, moulded, frozen or otherwise preserved, whether or not containing added sugar or other sweetening matter:		
	– Egg yolks:		
0408 11	– – Dried:		
ex 0408 11 80	– – – Suitable for human consumption: not sweetened	01	40,00
0408 19	– – Other:		
	– – – Suitable for human consumption:		
ex 0408 19 81	– – – – Liquid: not sweetened	01	20,00
ex 0408 19 89	– – – – Frozen: not sweetened	01	20,00
	– Other:		
0408 91	– – Dried:		
ex 0408 91 80	– – – Suitable for human consumption: not sweetened	01	75,00
0408 99	– – Other:		
ex 0408 99 80	– – – Suitable for human consumption: not sweetened	01	19,00

⁽¹⁾ The destinations are as follows:

01 Third countries,

02 Kuwait, Bahrain, Oman, Qatar, United Arab Emirates, Yemen, Turkey, Hong Kong SAR and Russia,

03 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines,

04 All destinations except Switzerland and those of 02 and 03.

COMMISSION REGULATION (EC) No 644/2004

of 6 April 2004

fixing the rates of refunds applicable to certain products from the sugar sector exported in the form of goods not covered by Annex I to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the market in sugar ⁽¹⁾, and in particular Article 27(5)(a) and (15),

Whereas:

(1) Article 27(1) and (2) of Regulation (EEC) No 1260/2001 provides that the differences between the prices in international trade for the products listed in Article 1(1)(a), (c), (d), (f), (g) and (h) of that Regulation and prices within the Community may be covered by an export refund where these products are exported in the form of goods listed in Annex V to that Regulation. Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty and the criteria for fixing the amount of such refunds ⁽²⁾ specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex I to Regulation (EC) No 1260/2001.

(2) In accordance with Article 4(1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month.

(3) Article 27(3) of Regulation (EC) No 1260/2001 and Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lay down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.

(4) The refunds fixed under this Regulation may be fixed in advance as the market situation over the next few months cannot be established at the moment.

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

(6) Pursuant to Regulations (EC) No 1039/2003 ⁽³⁾, (EC) No 1086/2003 ⁽⁴⁾, (EC) No 1087/2003 ⁽⁵⁾, (EC) No 1088/2003 ⁽⁶⁾, (EC) No 1089/2003 ⁽⁷⁾ and (EC) No 1090/2003 ⁽⁸⁾ the Council adopted autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Estonia, Slovenia, Latvia, Lithuania, Slovakia and the Czech Republic and the exportation of certain processed agricultural products to those countries. Those regulations provide that, from 1 July 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Estonia, Slovenia, Latvia, Lithuania, Slovakia or the Czech Republic, shall not be eligible for export refunds.

(7) In accordance with Council Regulation (EC) No 999/2003 of 2 June 2003 adopting autonomous and transitional measures concerning the import of certain processed agricultural products originating in Hungary and the export of certain processed agricultural products to Hungary ⁽⁹⁾, from 1 July 2003, the goods referred to in its Article 1(2) which are exported to Hungary shall not be eligible for export refunds.

(8) In accordance with Council Regulation (EC) No 1890/2003 of 27 October 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Malta and the exportation of certain processed agricultural products to Malta ⁽¹⁰⁾, from 1 November 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Malta are not eligible for export refunds.

⁽³⁾ OJ L 151, 19.6.2003, p. 1.

⁽⁴⁾ OJ L 163, 1.7.2003, p. 1.

⁽⁵⁾ OJ L 163, 1.7.2003, p. 19.

⁽⁶⁾ OJ L 163, 1.7.2003, p. 38.

⁽⁷⁾ OJ L 163, 1.7.2003, p. 56.

⁽⁸⁾ OJ L 163, 1.7.2003, p. 73.

⁽⁹⁾ OJ L 146, 13.6.2003, p. 10.

⁽¹⁰⁾ OJ L 278, 29.10.2003, p. 1.

⁽¹⁾ OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 2196/2003 (OJ L 328, 17.12.2003, p. 17).

⁽²⁾ OJ L 177, 15.7.2000, p. 1. Regulation as last amended by Regulation (EC) No 740/2003 (OJ L 106, 29.4.2003, p. 12).

- (9) With a view to enlargement of the European Union on 1 May 2004, and in order to prevent any abuse through the re-import or re-introduction into the Community of products in receipt of export refunds, the setting of all remaining export refunds has been discontinued in the sugar sector, in relation to the products concerned when exported unprocessed to the acceding States.
- (10) Therefore, with effect from 7 April 2004 no refund should be set for certain products from the sugar sector exported in the form of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and for the goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.
- (11) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.
- (12) The Management Committee for Sugar has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products listed in Annex A to Regulation (EC) No 1520/2000 and in Article 1(1) and (2) of Regulation (EC) No 1260/2001, exported in the form of goods listed in Annex V to Regulation (EC) No 1260/2001, are fixed as set out in the Annex to this Regulation.

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

Done at Brussels, 6 April 2004.

Article 2

1. Without prejudice to Article 1 and with effect from 1 July 2003 the rates set out in the Annex are not applicable to goods not covered by Annex I to the Treaty when exported to the Czech Republic, Estonia, Latvia, Lithuania, Slovakia or Slovenia nor to the goods referred to in Article 1(2) of Council Regulation (EC) No 999/2003 when exported to Hungary.

With effect from 1 November 2003 these rates are not applicable to goods not covered by Annex I to the Treaty when exported to Malta.

2. Without prejudice to Article 1 and with effect from 7 April 2004 no rates of refund shall be set in respect of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland nor in respect of goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.

Article 3

This Regulation shall enter into force on 7 April 2004.

For the Commission

Erkki LIIKANEN

Member of the Commission

ANNEX

Rates of refunds applicable from 7 April 2004 to certain products from the sugar sector exported in the form of goods not covered by Annex I to the Treaty

CN code	Description	Rate of refund in EUR/100 kg	
		In case of advance fixing of refunds	Other
1701 99 10	White sugar	47,42	47,42

**COMMISSION REGULATION (EC) No 645/2004
of 6 April 2004**

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ⁽¹⁾, and in particular Article 13(3) thereof,

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

Whereas:

- (1) Article 13(1) of Regulation (EEC) No 1766/92 and Article 13(1) of Regulation (EC) No 3072/95 provide that the difference between quotations of prices on the world market for the products listed in Article 1 of each of those Regulations and the prices within the Community may be covered by an export refund.
- (2) Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds ⁽³⁾, specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex B to Regulation (EEC) No 1766/92 or in Annex B to Regulation (EC) No 3072/95 as appropriate.
- (3) In accordance with the first subparagraph of Article 4(1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month.
- (4) The commitments entered into with regard to refunds which may be granted for the export of agricultural products contained in goods not covered by Annex I to the Treaty may be jeopardised by the fixing in advance of high refund rates. It is therefore necessary to take precautionary measures in such situations without, however, preventing the conclusion of long-term

contracts. The fixing of a specific refund rate for the advance fixing of refunds is a measure which enables these various objectives to be met.

- (5) Taking into account the settlement between the European Community and the United States of America on Community exports of pasta products to the United States, approved by Council Decision 87/482/EEC ⁽⁴⁾, it is necessary to differentiate the refund on goods falling within CN codes 1902 11 00 and 1902 19 according to their destination.
- (6) Pursuant to Article 4(3) and (5) of Regulation (EC) No 1520/2000, a reduced rate of export refund has to be fixed, taking account of the amount of the production refund applicable, pursuant to Council Regulation (EEC) No 1722/93 ⁽⁵⁾, for the basic product in question, used during the assumed period of manufacture of the goods.
- (7) Spirituous beverages are considered less sensitive to the price of the cereals used in their manufacture. However, Protocol 19 to the Act of Accession of the United Kingdom, Ireland and Denmark provides that the necessary measures must be decided to facilitate the use of Community cereals in the manufacture of spirituous beverages obtained from cereals. Accordingly, it is necessary to adapt the refund rate applying to cereals exported in the form of spirituous beverages.
- (8) In accordance with Council Regulations (EC) No 1039/2003 ⁽⁶⁾, (EC) No 1086/2003 ⁽⁷⁾, (EC) No 1087/2003 ⁽⁸⁾, (EC) No 1088/2003 ⁽⁹⁾, (EC) No 1089/2003 ⁽¹⁰⁾ and (EC) No 1090/2003 ⁽¹¹⁾ the Council adopted autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Estonia, Slovenia, Latvia, Lithuania, Slovakia and the Czech Republic and the exportation of certain processed agricultural products to those countries. Those regulations provide that with effect from 1 July 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Estonia, Slovenia, Latvia, Lithuania, Slovakia or the Czech Republic shall not be eligible for export refunds.

⁽⁴⁾ OJ L 275, 29.9.1987, p. 36.

⁽⁵⁾ OJ L 159, 1.7.1993, p. 112. Regulation as last amended by Regulation (EC) No 216/2004 (OJ L 36, 7.2.2004, p. 13).

⁽⁶⁾ OJ L 151, 19.6.2003, p. 1.

⁽⁷⁾ OJ L 163, 1.7.2003, p. 1.

⁽⁸⁾ OJ L 163, 1.7.2003, p. 19.

⁽⁹⁾ OJ L 163, 1.7.2003, p. 38.

⁽¹⁰⁾ OJ L 163, 1.7.2003, p. 56.

⁽¹¹⁾ OJ L 163, 1.7.2003, p. 73.

⁽¹⁾ OJ L 181, 1.7.1992, p. 21. Regulation as last amended by Regulation (EC) No 1784/2003 (OJ L 270, 21.10.2003, p. 78).

⁽²⁾ OJ L 329, 30.12.1995, p. 18. Regulation as last amended by Commission Regulation (EC) No 411/2002 (OJ L 62, 5.3.2002, p. 27).

⁽³⁾ OJ L 177, 15.7.2000, p. 1. Regulation as last amended by Regulation (EC) No 543/2004 (OJ L 87, 25.3.2004, p. 8).

- (9) Council Regulation (EC) No 999/2003 of 2 June 2003 adopting autonomous and transitional measures concerning the import of certain processed agricultural products originating in Hungary and the export of certain processed agricultural products to Hungary⁽¹⁾, provides that with effect from 1 July 2003, the goods referred to in Article 1(2) thereof which are exported to Hungary shall not be eligible for export refunds.
- (10) Council Regulation (EC) No 1890/2003 of 27 October 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Malta and the exportation of certain processed agricultural products to Malta⁽²⁾, provides that with effect from 1 November 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Malta shall not be eligible for export refunds.
- (11) With a view to enlargement of the European Union on 1 May 2004, the setting of all remaining export refunds has been discontinued in the cereals and rice sector, in relation to the Annex I processed products concerned when exported to the acceding States.
- (12) Therefore, with effect from 7 April 2004 no refund should be set for certain cereal and rice products exported in the form of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and for the goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.
- (13) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.
- (14) The Management Committee for Cereals has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products listed in Annex A to Regulation (EC) No 1520/2000 and listed either in Article 1 of Regulation (EEC) No 1766/92 or in Article 1(1) of Regulation (EC) No 3072/95, exported in the form of goods listed in Annex B to Regulation (EEC) No 1766/92 or in Annex B to Regulation (EC) No 3072/95 respectively, are fixed as shown in the Annex to this Regulation.

Article 2

1. Without prejudice to Article 1 and with effect from 1 July 2003, the rates set out in the Annex are not applicable to goods not covered by Annex I to the Treaty when exported to the Czech Republic, Estonia, Latvia, Lithuania, Slovakia or Slovenia nor to the goods referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.

With effect from 1 November 2003 these rates are not applicable to goods not covered by Annex I to the Treaty when exported to Malta.

2. Without prejudice to Article 1 and with effect from 7 April 2004 no rates of refund shall be set in respect of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and in respect of goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.

Article 3

This Regulation shall enter into force on 7 April 2004.

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

Done at Brussels, 6 April 2004.

For the Commission

Erkki LIIKANEN

Member of the Commission

⁽¹⁾ OJ L 146, 13.6.2003, p. 10.

⁽²⁾ OJ L 278, 29.10.2003, p. 1.

ANNEX

Rates of the refunds applicable from 7 April 2004 to certain cereals and rice products exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)

CN code	Description of products ⁽¹⁾	Rate of refund per 100 kg of basic product	
		In case of advance fixing of refunds	Other
1001 10 00	Durum wheat:		
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America	—	—
	– in other cases	—	—
1001 90 99	Common wheat and meslin:		
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America	—	—
	– in other cases:		
	– – where Article 4(5) of Regulation (EC) No 1520/2000 applies ⁽²⁾	—	—
	– – where goods falling within subheading 2208 ⁽³⁾ are exported	—	—
	– – in other cases	—	—
1002 00 00	Rye	—	—
1003 00 90	Barley		
	– where goods falling within subheading 2208 ⁽⁴⁾ are exported	—	—
	– in other cases	—	—
1004 00 00	Oats	—	—
1005 90 00	Maize (corn) used in the form of:		
	– starch:		
	– – where Article 4(5) of Regulation (EC) No 1520/2000 applies ⁽²⁾	1,870	1,870
	– – where goods falling within subheading 2208 ⁽³⁾ are exported	—	—
	– – in other cases	1,870	1,870
	– glucose, glucose syrup, maltodextrine, maltodextrine syrup of CN codes 1702 30 51, 1702 30 59, 1702 30 91, 1702 30 99, 1702 40 90, 1702 90 50, 1702 90 75, 1702 90 79, 2106 90 55 ⁽⁴⁾ :		
	– – where Article 4(5) of Regulation (EC) No 1520/2000 applies ⁽²⁾	1,403	1,403
	– – where goods falling within subheading 2208 ⁽²⁾ are exported	—	—
	– – in other cases	1,403	1,403
	– where goods falling within subheading 2208 ⁽²⁾ are exported	—	—
	– other (including unprocessed)	1,870	1,870
	Potato starch of CN code 1108 13 00 similar to a product obtained from processed maize:		
	– where Article 4(5) of Regulation (EC) No 1520/2000 applies ⁽³⁾	1,870	1,870
	– – where goods falling within subheading 2208 ⁽³⁾ are exported	—	—
	– in other cases	1,870	1,870

(EUR/100 kg)

CN code	Description of products ⁽¹⁾	Rate of refund per 100 kg of basic product	
		In case of advance fixing of refunds	Other
ex 1006 30	Wholly milled rice:		
	– round grain	6,200	6,200
	– medium grain	6,200	6,200
	– long grain	6,200	6,200
1006 40 00	Broken rice	—	1,800
1007 00 90	Grain sorghum, other than hybrid for sowing	—	—

⁽¹⁾ As far as agricultural products obtained from the processing of a basic product or/and assimilated products are concerned, the coefficients shown in Annex E to Commission Regulation (EC) No 1520/2000 shall be applied (OJ L 177, 15.7.2000, p. 1).

⁽²⁾ The goods concerned fall under CN code 3505 10 50.

⁽³⁾ Goods listed in Annex B to Regulation (EEC) No 1766/92 or referred to in Article 2 of Regulation (EEC) No 2825/93.

⁽⁴⁾ For syrups of CN codes NC 1702 30 99, 1702 40 90 and 1702 60 90, obtained from mixing glucose and fructose syrup, the export refund may be granted only for the glucose syrup.

COMMISSION REGULATION (EC) No 646/2004

of 6 April 2004

fixing the rates of the refunds applicable to certain milk products exported in the form of goods not covered by Annex I to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 15 May 1999 on the common organisation of the market in milk and milk products ⁽¹⁾, and in particular Article 31(3) thereof,

Whereas:

- (1) Article 31(1) of Regulation (EC) No 1255/1999 provides that the difference between prices in international trade for the products listed in Article 1(a), (b), (c), (d), (e), and (g) of that Regulation and prices within the Community may be covered by an export refund. Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and criteria for fixing the amount of such refunds ⁽²⁾, specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex II to Regulation (EC) No 1255/1999.
- (2) In accordance with the first subparagraph of Article 4(1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month.
- (3) However in the case of certain milk products exported in the form of goods not covered by Annex I to the Treaty, there is a danger that, if high refund rates are fixed in advance, the commitments entered into in relation to those refunds may be jeopardised. In order to avert that danger, it is therefore necessary to take appropriate precautionary measures, but without precluding the conclusion of long-term contracts. The fixing of specific refund rates for the advance fixing of refunds in respect of those products should enable those two objectives to be met.

- (4) Article 4(3) of Regulation (EC) No 1520/2000 provides that, when the rate of the refund is being fixed, account should be taken, where necessary, of production refunds, aids or other measures having equivalent effect applicable in all Member States in accordance with the Regulation on the common organisation of the market in the product in question to the basic products listed in Annex A to Regulation (EC) No 1520/2000 or to assimilated products.
- (5) Article 12(1) of Regulation (EC) No 1255/1999 provides for the payment of aid for Community-produced skimmed milk processed into casein if such milk and the casein manufactured from it fulfil certain conditions.
- (6) Commission Regulation (EC) No 2571/97 of 15 December 1997 on the sale of butter at reduced prices and the granting of aid for cream, butter and concentrated butter for use in the manufacture of pastry products, ice cream and other foodstuffs ⁽³⁾, as last amended by Regulation (EC) No 635/2000, lays down that butter and cream at reduced prices should be made available to industries which manufacture certain goods.
- (7) By Regulations (EC) No 1039/2003 ⁽⁴⁾, (EC) No 1086/2003 ⁽⁵⁾, (EC) No 1087/2003 ⁽⁶⁾, (EC) No 1088/2003 ⁽⁷⁾, (EC) No 1089/2003 ⁽⁸⁾ and (EC) No 1090/2003 ⁽⁹⁾ the Council adopted autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Estonia, Slovenia, Latvia, Lithuania, Slovakia and the Czech Republic and the exportation of certain processed agricultural products to those countries. Those Regulations provide that with effect from 1 July 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Estonia, Slovenia, Latvia, Lithuania, Slovakia or the Czech Republic, shall not be eligible for export refunds.
- (8) Council Regulation (EC) No 999/2003 of 2 June 2003 adopting autonomous and transitional measures concerning the import of certain processed agricultural products originating in Hungary and the export of certain processed agricultural products to Hungary ⁽¹⁰⁾, provides that with effect from 1 July 2003, the goods referred to in Article 1(2) thereof, which are exported to Hungary shall not be eligible for export refunds.

⁽¹⁾ OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).

⁽²⁾ OJ L 177, 15.7.2000, p. 1. Regulation as last amended by Commission Regulation (EC) No 543/2004 (OJ L 87, 25.3.2004, p. 8).

⁽³⁾ OJ L 350, 20.12.1997, p. 3. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).

⁽⁴⁾ OJ L 151, 19.6.2003, p. 1.

⁽⁵⁾ OJ L 163, 1.7.2003, p. 1.

⁽⁶⁾ OJ L 163, 1.7.2003, p. 19.

⁽⁷⁾ OJ L 163, 1.7.2003, p. 38.

⁽⁸⁾ OJ L 163, 1.7.2003, p. 56.

⁽⁹⁾ OJ L 163, 1.7.2003, p. 73.

⁽¹⁰⁾ OJ L 146, 13.6.2003, p. 10.

- (9) Council Regulation (EC) No 1890/2003 of 27 October 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Malta and the exportation of certain processed agricultural products to Malta ⁽¹⁾, provides that with effect from 1 November 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Malta, shall not be eligible for export refunds.
- (10) With a view to enlargement of the European Union on 1 May 2004, and in order to encourage the gradual alignment of prices in the acceding states on the Community level and to prevent any abuse through the re-import or re-introduction into the Community of products in receipt of export refunds, the setting of all remaining export refunds has been discontinued in the milk and milk products sector, in relation to the products concerned when exported unprocessed to the acceding states.
- (11) Therefore, with effect from 7 April 2004 no refund should be set for certain milk products exported in the form of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and for the goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.
- (12) The Management Committee for Milk and Milk Products has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products appearing in Annex A to Regulation (EC) No 1520/2000 and listed in Article 1 of Regulation (EC) No 1255/1999, and exported in the form of goods listed in Annex II to Regulation (EC) No 1255/1999 shall, in respect of the products listed in the Annex to this Regulation, be fixed in accordance with that Annex.

Article 2

1. Without prejudice to Article 1 and with effect from 1 July 2003 the rates set out in the Annex are not applicable to goods not covered by Annex I to the Treaty when exported to the Czech Republic, Estonia, Latvia, Lithuania, Slovakia or Slovenia and to the goods referred to in Article 1(2) of Council Regulation (EC) No 999/2003 when exported to Hungary.

With effect from 1 November 2003 these rates are not applicable to goods not covered by Annex I to the Treaty when exported to Malta.

2. Without prejudice to Article 1 and with effect from 7 April 2004 no rates of refund shall be set in respect of goods not covered by Annex I to the Treaty when exported to Cyprus and Poland and in respect of goods which are not referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary.

Article 3

This Regulation shall enter into force on 7 April 2004.

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

Done at Brussels, 6 April 2004.

For the Commission

Erkki LIIKANEN

Member of the Commission

⁽¹⁾ OJ L 278, 29.10.2003, p. 1.

ANNEX

Rates of the refunds applicable from 7 April 2004 to certain milk products exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)

CN code	Description	Rate of refund	
		In case of advance fixing of refunds	Other
ex 0402 10 19	Powdered milk, in granules or other solid forms, not containing added sugar or other sweetening matter, with a fat content not exceeding 1,5 % by weight (PG 2):		
	(a) on exportation of goods of CN code 3501	—	—
	(b) on exportation of other goods	38,15	54,50
ex 0402 21 19	Powdered milk, in granules or other solid forms, not containing added sugar or other sweetening matter, with a fat content of 26 % by weight (PG 3):		
	(a) where goods incorporating, in the form of products assimilated to PG 3, reduced-price butter or cream obtained pursuant to Regulation (EC) No 2571/97 are exported	46,66	66,65
	(b) on exportation of other goods	65,10	93,00
ex 0405 10	Butter, with a fat content by weight of 82 % (PG 6):		
	(a) where goods containing reduced-price butter or cream which have been manufactured in accordance with the conditions provided for in Regulation (EC) No 2571/97 are exported	58,10	83,00
	(b) on exportation of goods of CN code 2106 90 98 containing 40 % or more by weight of milk fat	122,68	175,25
	(c) on exportation of other goods	117,60	168,00

COMMISSION REGULATION (EC) No 647/2004**of 6 April 2004****on granting of import licences for cane sugar for the purposes of certain tariff quotas and preferential agreements**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector ⁽¹⁾

Having regard to Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations ⁽²⁾,

Having regard to Commission Regulation (EC) No 1159/2003 of 30 June 2003 laying down detailed rules of application for the 2003/04, 2004/05 and 2005/06 marketing years for the import of cane sugar under certain tariff quotas and preferential agreements and amending Regulations (EC) No 1464/95 and (EC) No 779/96 ⁽³⁾, and in particular Article 5(3) thereof,

Whereas:

- (1) Article 9 of Regulation (EC) No 1159/2003 stipulates how the delivery obligations at zero duty of products of CN code 1701, expressed in white sugar equivalent, are to be determined for imports originating in signatory countries to the ACP Protocol and the Agreement with India.
- (2) Article 16 of Regulation (EC) No 1159/2003 stipulates how the zero duty tariff quotas for products of CN code 1701 11 10, expressed in white sugar equivalent, are to be determined for imports originating in signatory countries to the ACP Protocol and the Agreement with India.

(3) Article 22 of Regulation (EC) No 1159/2003 opens tariff quotas at a duty of EUR 98 per tonne for products of CN code 1701 11 10 for imports originating in Brazil, Cuba and other third countries.

(4) In the week of 29 March to 2 April 2004 applications were presented to the competent authorities in line with Article 5(1) of Regulation (EC) No 1159/2003 for import licences for a total quantity exceeding a country's delivery obligation quantity of ACP-India preferential sugar determined under Article 9 of that Regulation.

(5) In these circumstances the Commission must set reduction coefficients to be used so that licences are issued for quantities scaled down in proportion to the total available and must indicate that the limit in question has been reached,

HAS ADOPTED THIS REGULATION:

Article 1

In the case of import licence applications presented from 29 March to 2 April 2004 in line with Article 5(1) of Regulation (EC) No 1159/2003 licences shall be issued for the quantities indicated in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 7 April 2004.

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

Done at Brussels, 6 April 2004.

For the Commission

J. M. SILVA RODRÍGUEZ

Agriculture Director-General

⁽¹⁾ OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 39/2004 (OJ L 6, 10.1.2004, p. 2).

⁽²⁾ OJ L 146, 20.6.1996, p. 1.

⁽³⁾ OJ L 162, 1.7.2003, p. 25. Regulation as amended by Regulation (EC) No 96/2004 (OJ L 15, 22.1.2004, p. 3).

ANNEX

ACP-India Preferential Sugar**Title II of Regulation (EC) No 1159/2003****2003/04 marketing year**

Country	Week of 29 March to 2 April 2004: percentage of requested quantity to be granted	Limit
Barbados	100	
Belize	0	reached
Congo	0	reached
Fiji	100	
Guyana	100	
India	0	reached
Côte d'Ivoire	100	
Jamaica	100	
Kenya	100	
Madagascar	100	
Malawi	100	
Mauritius	71,8081	
Saint Kitts and Nevis	100	
Swaziland	100	
Tanzania	100	
Trinidad and Tobago	100	
Zambia	100	
Zimbabwe	0	reached

Special Preferential Sugar**Title III of Regulation (EC) No 1159/2003****2003/04 marketing year****Quota opened for the Member States referred to in Article 39 of Regulation (EC) No 1260/2001, except Slovenia**

Country	Week of 29 March to 2 April 2004: percentage of requested quantity to be granted	Limit
India	100	
Other countries	100	

Special Preferential Sugar**Title III of Regulation (EC) No 1159/2003****2003/04 marketing year****Quota opened for Slovenia**

Country	Week of 29 March to 2 April 2004: percentage of requested quantity to be granted	Limit
ACP	100	

CXL concessions sugar**Title IV of Regulation (EC) No 1159/2003****2003/04 marketing year**

Country	Week of 29 March to 2 April 2004: percentage of requested quantity to be granted	Limit
Brazil	0	reached
Cuba	100	
Other third countries	100	

**DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 31 March 2004**

**on setting standards of quality and safety for the donation, procurement, testing, processing,
preservation, storage and distribution of human tissues and cells**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

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

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

Following consultation of the Committee of the Regions,

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

Whereas:

- (1) The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases.
- (2) The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use.
- (3) It is necessary to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme 'we are all potential donors'. The aim of these campaigns should be to help European citizens decide to become donors during their lifetime and let their families or legal representatives know their wishes. As there is a need to ensure the availability of tissues and cells for medical treatments, Member States should promote the donation of tissues and cells, including haematopoietic progenitors, of high quality and safety, thereby also increasing self-sufficiency in the Community.

- (4) There is an urgent need for a unified framework in order to ensure high standards of quality and safety with respect to the procurement, testing, processing, storage and distribution of tissues and cells across the Community and to facilitate exchanges thereof for patients receiving this type of therapy each year. It is essential, therefore, that Community provisions ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety. The establishment of such standards, therefore, will help to reassure the public that human tissues and cells that are procured in another Member State, nonetheless carry the same guarantees as those in their own country.

- (5) As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards. The Community should therefore endeavour to promote the highest possible level of protection to safeguard public health regarding quality and safety of tissues and cells. The Commission should include in its report to the European Parliament and to the Council information on the progress made in this respect.

- (6) Tissues and cells intended to be used for industrially manufactured products, including medical devices, should be covered by this Directive only as far as donation, procurement and testing are concerned, where the processing, preservation, storage and distribution are regulated by other Community legislation. The further manufacturing steps are covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽⁴⁾.

- (7) This Directive should apply to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells.

- (8) This Directive excludes blood and blood products (other than haematopoietic progenitor cells) and human organs, as well as organs, tissues, or cells of animal origin. Blood and blood products are currently regulated by

⁽¹⁾ OJ C 227 E, 24.9.2002, p. 505.

⁽²⁾ OJ C 85, 8.4.2003, p. 44.

⁽³⁾ Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal), Council common position of 22 July 2003 (OJ C 240 E, 7.10.2003, p. 3), position of the European Parliament of 16 December 2003 (not yet published in the Official Journal) and decision of the Council of 2 March 2004.

⁽⁴⁾ OJ L 311, 28.11.2001, p. 67. Directive as last amended by Commission Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).

- Directives 2001/83/EC and 2000/70/EC ⁽¹⁾, Recommendation 98/463/EC ⁽²⁾ and Directive 2002/98/EC ⁽³⁾. Tissues and cells used as an autologous graft (tissues removed and transplanted back to the same individual), within the same surgical procedure and without being subjected to any banking process, are also excluded from this Directive. The quality and safety considerations associated with this process are completely different.
- (9) The use of organs to some extent raises the same issues as the use of tissues and cells, though there are serious differences, and the two subjects should therefore not be covered by one directive.
- (10) This Directive covers tissues and cells intended for human applications, including human tissues and cells used for the preparation of cosmetic products. However, in view of the risk of transmission of communicable diseases, the use of human cells, tissues and products in cosmetic products is prohibited by Commission Directive 95/34/EC of 10 July 1995 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products ⁽⁴⁾.
- (11) This Directive does not cover research using human tissues and cells, such as when used for purposes other than application to the human body, e.g. *in vitro* research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.
- (12) This Directive should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. Moreover, this Directive should not interfere with provisions of Member States defining the legal term 'person' or 'individual'.
- (13) The donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications should comply with high standards of quality and safety in order to ensure a high level of health protection in the Community. This Directive should establish standards for each one of the steps in the human tissues and cells application process.
- (14) The clinical use of tissues and cells of human origin for human application may be constrained by limited availability. Therefore it would be desirable that the criteria for access to such tissues and cells are defined in a transparent manner, on the basis of an objective evaluation of medical needs.
- (15) It is necessary to increase confidence among the Member States in the quality and safety of donated tissues and cells, in the health protection of living donors and respect for deceased donors and in the safety of the application process.
- (16) Tissues and cells used for allogeneic therapeutic purposes can be procured from both living and deceased donors. In order to ensure that the health status of a living donor is not affected by the donation, a prior medical examination should be required. The dignity of the deceased donor should be respected, notably through the reconstruction of the donor's body, so that it is as similar as possible to its original anatomical shape.
- (17) The use of tissues and cells for application in the human body can cause diseases and unwanted effects. Most of these can be prevented by careful donor evaluation and the testing of each donation in accordance with rules established and updated according to the best available scientific advice.
- (18) As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development.
- (19) Voluntary and unpaid tissue and cell donations are a factor which may contribute to high safety standards for tissues and cells and therefore to the protection of human health.
- (20) Any establishment may also be accredited as a tissue and cell establishment, provided it complies with the standards.
- ⁽¹⁾ Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma (OJ L 313, 13.12.2000, p. 22).
- ⁽²⁾ Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community (OJ L 203, 21.7.1998, p. 14).
- ⁽³⁾ Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (OJ L 33, 8.2.2003, p. 30).
- ⁽⁴⁾ OJ L 167, 18.7.1995, p. 19.

- (21) With due regard to the principle of transparency, all tissue establishments accredited, designated, authorised or licensed under the provisions of this Directive, including those manufacturing products from human tissues and cells, whether subject or not to other Community legislation, should have access to relevant tissues and cells procured in accordance with the provisions of this Directive, without prejudice to the provisions in force in Member States on the use of tissues and cells.
- (22) This Directive respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union ⁽¹⁾ and takes into account as appropriate the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Neither the Charter nor the Convention makes express provision for harmonisation or prevents Member States from introducing more stringent requirements in their legislation.
- (23) All necessary measures need to be taken in order to provide prospective donors of tissues and cells with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of tests on their donations, as well as any future traceability of their donation.
- (24) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data ⁽²⁾ applies to personal data processed in application of this Directive. Article 8 of that directive prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC also provides for the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.
- (25) An accreditation system for tissue establishments and a system for notification of adverse events and reactions linked to the procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be established in the Member States.
- (26) Member States should organise inspections and control measures, to be carried out by officials representing the competent authority, to ensure that tissue establishments
- comply with the provisions of this Directive. Member States should ensure that the officials involved in inspections and control measures are appropriately qualified and receive adequate training.
- (27) Personnel directly involved in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be appropriately qualified and provided with timely and relevant training. The provisions laid down in this Directive as regards training should be applicable without prejudice to existing Community legislation on the recognition of professional qualifications.
- (28) An adequate system to ensure the traceability of human tissues and cells should be established. This would also make it possible to verify compliance with quality and safety standards. Traceability should be enforced through accurate substance, donor, recipient, tissue establishment and laboratory identification procedures as well as record maintenance and an appropriate labelling system.
- (29) As a general principle, the identity of the recipient(s) should not be disclosed to the donor or his/her family and vice versa, without prejudice to legislation in force in Member States on the conditions of disclosure, which could authorise in exceptional cases, notably in the case of gametes donation, the lifting of donor anonymity.
- (30) In order to increase the effective implementation of the provisions adopted in accordance with this Directive, it is appropriate to provide for penalties to be applied by Member States.
- (31) Since the objective of this Directive, namely to set high standards of quality and safety for human tissues and cells throughout the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of scale and effects, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (32) It is necessary that the best possible scientific advice is available to the Community in relation to the safety of tissues and cells; in particular in order to assist the Commission in adapting the provisions of this Directive to scientific and technical progress in the light of the rapid advance in biotechnology knowledge and practice in the field of human tissues and cells.

⁽¹⁾ OJ C 364, 18.12.2000, p. 1.

⁽²⁾ OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(33) The opinions of the Scientific Committee for Medicinal Products and Medical Devices and that of the European Group on Ethics in Science and New Technologies have been taken into account, as well as international experience in this field, and will be sought in the future whenever necessary.

(34) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Objective

This Directive lays down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health.

Article 2

Scope

1. This Directive shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications.

Where such manufactured products are covered by other directives, this Directive shall apply only to donation, procurement and testing.

2. This Directive shall not apply to:

- (a) tissues and cells used as an autologous graft within the same surgical procedure;
- (b) blood and blood components as defined by Directive 2002/98/EC;
- (c) organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

Article 3

Definitions

For the purposes of this Directive:

- (a) 'cells' means individual human cells or a collection of human cells when not bound by any form of connective tissue;
- (b) 'tissue' means all constituent parts of the human body formed by cells;
- (c) 'donor' means every human source, whether living or deceased, of human cells or tissues;
- (d) 'donation' means donating human tissues or cells intended for human applications;
- (e) 'organ' means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;
- (f) 'procurement' means a process by which tissue or cells are made available;
- (g) 'processing' means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;
- (h) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;
- (i) 'quarantine' means the status of retrieved tissue or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;
- (j) 'storage' means maintaining the product under appropriate controlled conditions until distribution;
- (k) 'distribution' means transportation and delivery of tissues or cells intended for human applications;
- (l) 'human application' means the use of tissues or cells on or in a human recipient and extracorporeal applications;
- (m) 'serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;
- (n) 'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

- (o) 'tissue establishment' means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;
- (p) 'allogeneic use' means cells or tissues removed from one person and applied to another;
- (q) 'autologous use' means cells or tissues removed from and applied in the same person.

Article 4

Implementation

1. Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.
2. This Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary unpaid donation, which include the prohibition or restriction of imports of human tissues and cells, to ensure a high level of health protection, provided that the conditions of the Treaty are met.
3. This Directive does not affect the decisions of the Member States prohibiting the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells or cells from any specified source, including where those decisions also concern imports of the same type of human tissues or cells.
4. In carrying out the activities covered by this Directive, the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure.

CHAPTER II

OBLIGATIONS ON MEMBER STATES' AUTHORITIES

Article 5

Supervision of human tissue and cell procurement

1. Member States shall ensure that tissue and cell procurement and testing are carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorised or licensed for that purpose by the competent authority or authorities.

2. The competent authority or authorities shall take all necessary measures to ensure that tissue and cell procurement complies with the requirements referred to in Article 28(b), (e) and (f). The tests required for donors shall be carried out by a qualified laboratory accredited, designated, authorised or licensed by the competent authority or authorities.

Article 6

Accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes

1. Member States shall ensure that all tissue establishments where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.
2. The competent authority or authorities, having verified that the tissue establishment complies with the requirements referred to in Article 28(a), shall accredit, designate, authorise or license the tissue establishment and indicate which activities it may undertake and which conditions apply. It or they shall authorise the tissue and cell preparation processes which the tissue establishment may carry out in accordance with the requirements referred to in Article 28(g). Agreements between tissue establishments and third parties, as referred to in Article 24, shall be examined within the framework of this procedure.
3. The tissue establishment shall not undertake any substantial changes to its activities without the prior written approval of the competent authority or authorities.
4. The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation or licensing of a tissue establishment or of a tissue or cell preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Directive.
5. Some specified tissues and cells, which will be determined in accordance with the requirements referred to in Article 28(i), may, with the agreement of the competent authority or authorities, be distributed directly for immediate transplantation to the recipient as long as the supplier is provided with an accreditation, designation, authorisation or licence for this activity.

Article 7

Inspections and control measures

1. Member States shall ensure that the competent authority or authorities organise inspections and that tissue establishments carry out appropriate control measures in order to ensure compliance with the requirements of this Directive.

2. Member States shall also ensure that appropriate control measures are in place for the procurement of human tissues and cells.

3. Inspections shall be organised and control measures shall be carried out by the competent authority or authorities on a regular basis. The interval between two inspections shall not exceed two years.

4. Such inspections and control measures shall be carried out by officials representing the competent authority, who shall be empowered to:

- (a) inspect tissue establishments and the facilities of any third parties as specified in Article 24;
- (b) evaluate and verify the procedures and the activities carried out in tissue establishments and the facilities of third parties that are relevant to the requirements of this Directive;
- (c) examine any documents or other records relating to the requirements of this Directive.

5. Guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance, shall be established in accordance with the procedure referred to in Article 29(2).

6. The competent authority or authorities shall organise inspections and carry out control measures as appropriate whenever there is any serious adverse reaction or serious adverse event. In addition, such an inspection shall be organised and control measures shall be carried out at the duly justified request of the competent authority or authorities in another Member State in any such case.

7. Member States shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out in relation to the requirements of this Directive.

Article 8

Traceability

1. Member States shall ensure that all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.

2. Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

3. All tissues and cells must be identified with a label that contains the information or references allowing a link to the information referred to in Article 28(f) and (h).

4. Tissue establishments shall keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form.

5. The traceability requirements for tissues and cells, as well as for products and materials coming into contact with these tissues and cells and having an effect on their quality and safety, shall be established by the Commission in accordance with the procedure referred to in Article 29(2).

6. The procedures for ensuring traceability at Community level shall be established by the Commission in accordance with the procedure referred to in Article 29(2).

Article 9

Import/export of human tissues and cells

1. Member States shall take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities, and that imported tissues and cells can be traced from the donor to the recipient and vice versa in accordance with the procedures referred to in Article 8. Member States and tissue establishments that receive such imports from third countries shall ensure that they meet standards of quality and safety equivalent to the ones laid down in this Directive.

2. Member States shall take all necessary measures to ensure that all exports of tissues and cells to third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities. Those Member States that send such exports to third countries shall ensure that the exports comply with the requirements of this Directive.

3. (a) The import or export of tissues and cells referred to in Article 6(5) may be authorised directly by the competent authority or authorities.
 - (b) In case of emergency, the import or export of certain tissues and cells may be authorised directly by the competent authority or authorities.
 - (c) The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive.

4. The procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 shall be established by the Commission, in accordance with the procedure referred to in Article 29(2).

Article 10

Register of tissue establishments and reporting obligations

1. Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in Article 28(f). They shall submit to the competent authority or authorities an annual report on these activities. This report shall be publicly accessible.

2. The competent authority or authorities shall establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been accredited, designated, authorised or licensed.
3. Member States and the Commission shall establish a network linking the national tissue establishment registers.

Article 11

Notification of serious adverse events and reactions

1. Member States shall ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells.
2. All persons or establishments using human tissues and cells regulated by this Directive shall report any relevant information to establishments engaged in the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to facilitate traceability and ensure quality and safety control.
3. The responsible person referred to in Article 17 shall ensure that the competent authority or authorities is or are notified of any serious adverse events and reactions referred to in paragraph 1 and is or are provided with a report analysing the cause and the ensuing outcome.
4. The procedure for notifying serious adverse events and reactions shall be established by the Commission, in accordance with the procedure referred to in Article 29(2).
5. Each tissue establishment shall ensure that an accurate, rapid and verifiable procedure is in place which will enable it to recall from distribution any product which may be related to an adverse event or reaction.

CHAPTER III

DONOR SELECTION AND EVALUATION

Article 12

Principles governing tissue and cell donation

1. Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells.

Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.

Member States shall report to the Commission on these measures before 7 April 2006 and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take at Community level.

2. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage.

Member States shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis.

Article 13

Consent

1. The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met.
2. Member States shall, in keeping with their national legislation, take all necessary measures to ensure that donors, their relatives or any persons granting authorisation on behalf of the donors are provided with all appropriate information as referred to in the Annex.

Article 14

Data protection and confidentiality

1. Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive and to which third parties have access, have been rendered anonymous so that neither donors nor recipients remain identifiable.
2. For that purpose, they shall ensure that:
 - (a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;
 - (b) procedures are in place to resolve data discrepancies; and
 - (c) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations.
3. Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Member States on the conditions for disclosure, notably in the case of gametes donation.

*Article 15***Selection, evaluation and procurement**

1. The activities related to tissue procurement shall be carried out in such a way as to ensure that donor evaluation and selection is carried out in accordance with the requirements referred to in Article 28(d) and (e) and that the tissues and cells are procured, packaged and transported in accordance with the requirements referred to in Article 28(f).
2. In the case of an autologous donation, the suitability criteria shall be established in accordance with the requirements referred to in Article 28(d).
3. The results of the donor evaluation and testing procedures shall be documented and any major anomalies shall be reported in accordance with the requirements referred to in the Annex.
4. The competent authority or authorities shall ensure that all activities related to tissue procurement are carried out in accordance with the requirements referred to in Article 28(f).

CHAPTER IV

PROVISIONS ON THE QUALITY AND SAFETY OF TISSUES AND CELLS*Article 16***Quality management**

1. Member States shall take all necessary measures to ensure that each tissue establishment puts in place and updates a quality system based on the principles of good practice.
2. The Commission shall establish the Community standards and specifications referred to in Article 28(c) for activities relating to a quality system.
3. Tissue establishments shall take all necessary measures to ensure that the quality system includes at least the following documentation:
 - standard operating procedures,
 - guidelines,
 - training and reference manuals,
 - reporting forms,
 - donor records,
 - information on the final destination of tissues or cells.
4. Tissue establishments shall take all necessary measures to ensure that this documentation is available for inspection by the competent authority or authorities.
5. Tissue establishments shall keep the data necessary to ensure traceability in accordance with Article 8.

*Article 17***Responsible person**

1. Every tissue establishment shall designate a responsible person who shall at least fulfil the following conditions and have the following qualifications:
 - (a) possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;
 - (b) at least two years' practical experience in the relevant fields.
2. The person designated in paragraph 1 shall be responsible for:
 - (a) ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with this Directive and with the laws in force in the Member State;
 - (b) providing information to the competent authority or authorities as required in Article 6;
 - (c) implementing the requirements of Articles 7, 10, 11, 15, 16 and 18 to 24 within the tissue establishment.
3. Tissue establishments shall inform the competent authority or authorities of the name of the responsible person referred to in paragraph 1. Where the responsible person is permanently or temporarily replaced, the tissue establishment shall immediately inform the competent authority of the name of the new responsible person and the date on which the duties of that person commence.

*Article 18***Personnel**

Personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells in a tissue establishment shall be qualified to perform such tasks and shall be provided with the training referred to in Article 28(c).

*Article 19***Tissue and cell reception**

1. Tissue establishments shall ensure that all donations of human tissues and cells are subjected to tests in accordance with the requirements referred to in Article 28(e) and that the selection and acceptance of tissues and cells comply with the requirements referred to in Article 28(f).
2. Tissue establishments shall ensure that human tissue and cells and associated documentation comply with the requirements referred to in Article 28(f).

3. Tissue establishments shall verify and record the fact that the packaging of human tissue and cells received complies with the requirements referred to in Article 28(f). All tissues and cells that do not comply with those provisions shall be discarded.

4. The acceptance or rejection of received tissues/cells shall be documented.

5. Tissue establishments shall ensure that human tissues and cells are correctly identified at all times. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with Article 8.

6. Tissue and cells shall be held in quarantine until such time as the requirements relating to donor testing and information have been met in accordance with Article 15.

Article 20

Tissue and cell processing

1. Tissue establishments shall include in their standard operating procedures all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions. Tissue establishments shall ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements referred to in Article 28(h).

2. Any modifications to the processes used in the preparation of tissues and cells shall also meet the criteria laid down in paragraph 1.

3. Tissue establishments shall include in their standard operating procedures special provisions for the handling of tissues and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel.

Article 21

Tissue and cell storage conditions

1. Tissue establishments shall ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in Article 28(h).

2. Tissue establishments shall ensure that all storage processes are carried out under controlled conditions.

3. Tissue establishments shall establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells.

4. Processed tissues or cells shall not be distributed until all the requirements laid down in this Directive have been met.

5. Member States shall ensure that tissue establishments have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishment or establishments accredited, designated, authorised or licensed in accordance with Article 6, without prejudice to Member States' legislation concerning the disposal of donated tissues or cells, according to the consent pertaining to them.

Article 22

Labelling, documentation and packaging

Tissue establishments shall ensure that labelling, documentation and packaging conform to the requirements referred to in Article 28(f).

Article 23

Distribution

Tissue establishments shall ensure the quality of tissues and cells during distribution. Distribution conditions shall comply with the requirements referred to in Article 28(h).

Article 24

Relations between tissue establishments and third parties

1. Tissue establishments shall establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party, and in particular in the following circumstances:

- (a) where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party;
- (b) where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution;
- (c) where a tissue establishment provides services to a tissue establishment which is not accredited;
- (d) where a tissue establishment distributes tissue or cells processed by third parties.

2. Tissue establishments shall evaluate and select third parties on the basis of their ability to meet the standards laid down in this Directive.

3. Tissue establishments shall keep a complete list of the agreements referred to in paragraph 1 that they have established with third parties.

4. Agreements between tissue establishments and third parties shall specify the responsibilities of the third parties and detailed procedures.

5. Tissue establishments shall provide copies of agreements with third parties at the request of the competent authority or authorities.

CHAPTER V

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES*Article 25***Coding of information**

1. Member States shall establish a system for the identification of human tissues and cells, in order to ensure the traceability of all human tissues and cells pursuant to Article 8.
2. The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells.

*Article 26***Reports**

1. Member States shall send the Commission, before 7 April 2009 and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.
2. The Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions the reports submitted by the Member States on experience gained in implementing this Directive.
3. Before 7 April 2008 and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of the requirements of this Directive, in particular as regards inspection and monitoring.

*Article 27***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 7 April 2006 and shall notify it without delay of any subsequent amendments affecting them.

CHAPTER VI

CONSULTATION OF COMMITTEES*Article 28***Technical requirements and their adaptation to scientific and technical progress**

The following technical requirements and their adaptation to scientific and technical progress shall be decided in accordance with the procedure referred to in Article 29(2):

- (a) requirements for the accreditation, designation, authorisation or licensing of tissue establishments;

- (b) requirements for the procurement of human tissues and cells;
- (c) quality system, including training;
- (d) selection criteria for the donor of tissues and/or cells;
- (e) laboratory tests required for donors;
- (f) cell and/or tissue procurement procedures and reception at the tissue establishment;
- (g) requirements for the tissue and cell preparation process;
- (h) tissue and cell processing, storage and distribution;
- (i) requirements for the direct distribution to the recipient of specific tissues and cells.

*Article 29***Committee**

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

*Article 30***Consultation of one or more scientific committees**

The Commission may consult the relevant scientific committee(s) when defining or adapting the technical requirements referred to in Article 28 to scientific and technical progress.

CHAPTER VII

FINAL PROVISIONS*Article 31***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 7 April 2006. They shall forthwith inform the Commission thereof.

When Member States adopt these measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States may decide for one year after the date laid down in the first subparagraph of paragraph 1 not to apply the requirements of this Directive to tissue establishments bound by national provisions before the entry into force of this Directive.

3. Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.

Article 33

Addressees

This Directive is addressed to the Member States.

Article 32

Done at Strasbourg, 31 March 2004.

Entry into force

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

For the European Parliament

For the Council

The President

The President

P. COX

D. ROCHE

ANNEX

INFORMATION TO BE PROVIDED ON THE DONATION OF CELLS AND/OR TISSUES

A. Living donors

1. The person in charge of the donation process shall ensure that the donor has been properly informed of at least those aspects relating to the donation and procurement process outlined in paragraph 3. Information must be given prior to the procurement.
2. The information must be given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the donor.
3. The information must cover: the purpose and nature of the procurement, its consequences and risks; analytical tests, if they are performed; recording and protection of donor data, medical confidentiality; therapeutic purpose and potential benefits and information on the applicable safeguards intended to protect the donor.
4. The donor must be informed that he/she has the right to receive the confirmed results of the analytical tests, clearly explained.
5. Information must be given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the tissue and/or cell procurement can be carried out.

B. Deceased donors

1. All information must be given and all necessary consents and authorisations must be obtained in accordance with the legislation in force in Member States.
 2. The confirmed results of the donor's evaluation must be communicated and clearly explained to the relevant persons in accordance with the legislation in Member States.
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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 11 November 2003

on the State aid which the United Kingdom is planning to provide under the WRAP environmental grant funding and WRAP lease guarantee fund

(notified under document number C(2003) 4087)

(Only the English text is authentic)

(Text with EEA relevance)

(2004/317/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the first subparagraph of Article 88(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to those provisions⁽¹⁾ and having regard to their comments,

Whereas:

1. PROCEDURE

(1) By letter dated 9 July 2002, registered on 16 July 2002, the United Kingdom notified the Commission, pursuant to Article 88(3) of the Treaty, of the Waste and resources action programme (WRAP). By letter dated 2 August 2002, the Commission asked for further information, which was provided by the United Kingdom authorities by letter dated 28 August 2002. Following a meeting between the Commission and the United Kingdom authorities that was held on 29 August 2002, the United Kingdom authorities provided further information by letter dated 13 September 2002, registered on 18 September 2002. The Commission sent another request for information by letter dated 23 October 2002, to which the United Kingdom authorities replied by letter dated 3 December 2002, registered on 6 December 2002. By letter dated 15 January 2003, regis-

tered on 23 January 2003, the United Kingdom authorities requested a new meeting with the Commission, which was held on 21 January 2003. Following that meeting, the United Kingdom authorities provided supplementary information by a series of letters dated between 24 January 2003 and 7 February 2003.

(2) On 19 March 2003, the Commission decided partly to approve the WRAP programme and to initiate the procedure laid down in Article 88(2) of the Treaty with respect to the WRAP environmental grant funding and part of the WRAP lease guarantee fund that had been notified on the basis of the Community guidelines on State aid for environmental protection⁽²⁾ (the environmental aid guidelines). By letter dated 21 March 2003, the Commission informed the United Kingdom of this decision. The case was registered under number C 21/2003.

(3) By e-mail dated 8 April 2003, registered on the same day under number A/32568, the United Kingdom authorities requested the removal of certain elements of confidential information from the Commission decision. The Commission replied by letter dated 22 April 2003. The United Kingdom authorities responded by e-mail dated 2 May 2003, registered under number A/33144. The Commission sent further comments on the question of confidentiality by letter dated 7 May 2003. The United Kingdom authorities agreed to these comments by letter dated 12 May 2003, registered on 19 May 2003 under number A/33512.

⁽¹⁾ OJ C 129, 3.6.2003, p. 6.

⁽²⁾ OJ C 37, 3.2.2001, p. 3.

- (4) By letter dated 25 April 2003, and registered on the same day under number A/32958, the United Kingdom responded to the opening of the procedure.
- (5) The Commission decision to initiate the procedure was published in the *Official Journal of the European Union* ⁽³⁾. The Commission invited interested parties to submit their comments on the aid.
- (6) The Commission received 29 comments from interested parties. It forwarded them to the United Kingdom by letter dated 17 July 2003. The United Kingdom's comments were received by e-mail dated 26 August 2003, and registered the same day, under number A/35866.
- (7) In its decision of 23 July 2003 in case C 61/2002, the Commission decided partially to approve the aid granted to Shotton Newsprint. That case was an individual application of the WRAP Environmental Grant Funding.
- (8) By letter dated 1 August 2003, the Commission requested further information, which was provided by the United Kingdom authorities by letter dated 3 September 2003, registered on 4 September 2003, under number A/36039.
- (9) A meeting was held on 12 September 2003 between the Commission and representatives of the United Kingdom government and of the WRAP programme. In the course of this meeting, the Commission asked further questions of the United Kingdom authorities, to which they replied by e-mail dated 26 September 2003 and registered on 29 September 2003 under number A/36643, and e-mail dated 30 October 2003 and registered on 31 October 2003 under number A/37458.
- (11) The legal basis for the programme is Section 153 of the Environmental Protection Act 1990 and the Financial Assistance for Environmental Purposes (No 2) Order 2000.
- (12) The objective of WRAP is to promote sustainable waste management and efficient markets for waste management and recycling. In particular, the aim of the United Kingdom authorities is to fulfil the Community targets for waste recycling set by Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste ⁽⁴⁾, (the landfill Directive) which requires Member States to reduce the disposal of municipal waste to landfill and by Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste ⁽⁵⁾ (the packaging Directive) which requires significant increases in packaging waste recycling by at least 2006.
- (13) In order to increase waste recycling in the United Kingdom, WRAP has put into place different schemes, notified on 16 July 2003. The Commission gave a positive decision on the following ones: the WRAP grant funding regional scheme, notified on the basis of the guidelines on national regional aid, the WRAP SME grant funding scheme, notified on the basis of the Commission Regulation (EC) No 70/2001 of 12 January 2001 on the application of Articles 87 and 88 of the EC Treaty to State aid to small and medium-sized enterprises ⁽⁶⁾, the WRAP pilot fund, and the part of the WRAP lease guarantee fund that had been notified on the basis of the Guidelines on national regional aid ⁽⁷⁾ and Regulation (EC) No 70/2001. On two remaining schemes, the WRAP environmental grant funding and the part of the WRAP lease guarantee fund that had been notified on the basis of the Community guidelines on State aid for environmental protection, the Commission decided to open the formal investigation procedure laid down in Article 88(2) of the EC Treaty.

2. DESCRIPTION OF THE MEASURE

2.1. Presentation of WRAP and its objectives

- (10) The aid is given within the framework of the Waste and resources action programme. According to the information submitted by the United Kingdom, WRAP is an entity established to promote efficient markets for recycled materials and products, by stimulating demand for recycled materials and products. WRAP's members comprise the charity Wastewatch, the Environmental Services Association and the Secretary of State for Environment, Food and Rural Affairs. It is responsible for administering the aid, and is funded by the government for the period 2001 to 2004. WRAP functions as an adjunct to the government, and implements government policies, although it has a private corporate form.

⁽³⁾ See footnote 1.

2.2. The WRAP environmental grant funding

2.2.1. Aim and mechanisms of the scheme

- (14) The purpose of this grant funding programme is to subsidise investments by private companies in recycling facilities in order to increase the recycling of waste in the United Kingdom. According to the United Kingdom authorities, the necessity of such investment aid stems from the uncertainty of returns on this type of investments, due to the risks and costs associated with obtaining and using appropriate waste materials and the difficulty in motivating the purchase of products made from recycled materials. The selected firms will commit

⁽⁴⁾ OJ L 182, 16.7.1999, p. 1.

⁽⁵⁾ OJ L 365, 31.12.1994, p. 10.

⁽⁶⁾ OJ L 10, 13.1.2001, p. 33.

⁽⁷⁾ OJ C 74, 10.3.1998, p. 9.

themselves to recycle a certain amount of waste per year. These firms will then conclude supply contracts with local authorities. As a result, local authorities will have the incentives to set up systems of selective collection of waste since they will have the guarantee of selling their selected waste. Through the creation of these reprocessing units, it is therefore expected that markets for waste products will be created.

- (15) The waste products concerned by this scheme are wood, glass, plastics, aggregates and compost. In order to select the recipients of support, and to determine the proportional level of aid funding, WRAP uses open and competitive tenders for each type of products. These tenders are advertised in the specialised press throughout the Community. Projects are selected on the basis of a certain number of criteria: most economically advantageous offer, magnitude and relevance of deliverables in relation to the environmental objectives of the competition and organisational feasibility.

2.2.2. *Types of projects to be subsidised*

- (16) Under the WRAP environmental grant funding, WRAP intends to fund projects in various sectors.
- (17) In the wood sector, WRAP will finance three or more projects, involving the creation of new reprocessing capacity that will produce different types of end products: animal bedding, horticultural and landscaping mulches, or activated carbon (a specific type of filter to be used in industrial chemical engineering applications). According to the United Kingdom authorities, waste wood is not normally used for the manufacture of end products. Animal bedding, for example, has traditionally been manufactured from virgin wood. In 2001, only about 5 % of all bedding in the United Kingdom was manufactured from waste wood. According to the United Kingdom authorities, this is due to the fact that the cost of waste wood processed for recycling is normally higher than the cost of virgin wood processed for equivalent application. This is why support to stimulate investment in new recycling infrastructure (for example, advanced decontamination equipment) is necessary.
- (18) In the glass sector, WRAP wants to subsidise one new facility that would process up to 80 000 tonnes of waste glass per annum (from domestic and commercial waste stream) by grinding it to very small particle size, below 90 microns. This will allow for and facilitate new end uses, in particular for waste green glass, which currently has very limited end uses. One possible use of this fine glass powder is as a fluxing agent in bricks and sanitary ware products. This is a relatively innovative technology. According to the United Kingdom authorities, the only comparable facility in the Community that they are aware of is in Sweden, where the ground glass is used as a cement additive. A potential recipient has already been selected. It is a joint venture project between Cleanaway Ltd and Glass Group Ltd. The United Kingdom authori-

ties also stress that this project has further environmental benefits, other than the diversion of 80 000 tonnes of glass from landfills. For instance, the use of glass in sanitary ware will reduce the need for primary mineral extraction.

- (19) In the plastic sector, WRAP's proposed intervention involves the creation of a new automated plastic bottle sorting and reprocessing capacity, which would divide the materials by polymer type and by colour. The sorted material would then be converted into plastic feedstock, which could be used for the production of new plastic bottles. Currently, waste plastic sorting is normally done by hand in the United Kingdom, and the state of the art manufacture of plastic bottles uses virgin polymer. In 2001, 460 000 tonnes of plastic bottles were consumed in the United Kingdom, of which less than 500 tonnes (0,1 %) contained any recycled material.
- (20) With respect to aggregates, the United Kingdom authorities have already implemented a levy on aggregates extraction from the ground to provide an incentive for the reuse of waste aggregates (for example, from construction and excavation activity). Due to the already low costs of virgin aggregates and high costs of aggregates recycling equipment, the levy in itself is insufficient incentive for the market to invest in such capacity. As a result, WRAP intends to subsidise up to 20 projects across the United Kingdom that would involve the creation of sorting and reprocessing capacity for waste aggregate. These projects would focus on waste aggregates that are currently hardly recycled at all, in particular waste aggregates with a high level of contamination from soil, clays and other contaminants. It is expected that this intervention will increase recycling of waste aggregates by two million tonnes by 2004.
- (21) With respect to the compost sector, WRAP considers that this is an immature sector, with a lack of comprehensive infrastructure for collection, processing and composting of organic waste (mainly garden and public park waste). This is due to the relatively high capital cost of establishing infrastructure and the low value of compost products. WRAP intends to support up to 20 projects that will involve the processing of organic waste into basic compost products, and the manufacturing of more sophisticated horticultural products by blending these basic compost products with other inputs to create more sophisticated horticultural products. These end products will mostly be used in horticulture, landscaping and organic horticulture. It is expected that this intervention will increase the recycling of organic waste by 500 000 tonnes, and the share of composted products in these sectors. For instance, in 2002, in the United Kingdom, composted products represented less than 3 % of the three million cubic metres of raw materials used in horticulture. The product normally used for this end application is peat. Its replacement by composted products will also have the environmental benefit of conserving peat bogs.

2.2.3. Eligible costs

(22) The United Kingdom authorities have included in the calculation of the eligible costs the entirety of the investments linked to the recycling activity.

(23) For example, for the wood projects, the eligible investments include the segregation, chipping and shredding equipment capable of producing different grades of reprocessed wood, the equipment for contaminant removal, and the equipment for end product processing (for example, dyeing equipment and baling and bagging equipment). For the glass project, the eligible investments include the grinding equipment capable of processing glass to produce finely ground glass. For the plastics project, the eligible investment costs include the equipment to sort and reprocess waste plastics. In the case of compost, they include the equipment to shred, aerate, turn and mix the organic waste material. Finally, in the case of aggregates, they include the equipment to sort, screen, wash, crush and grind aggregate materials so that they meet specific requirements required for end applications.

(24) From these eligible investment costs, the United Kingdom authorities will deduct the costs of investments necessary to comply with any mandatory compliance standards. They will also deduct the net benefit to the recipient over five years, taking account of the savings over five years of life of the investment, any increase in production during that five year period, and any increased revenue or other benefits to the recipient during that period. For example, in the aggregate project involving Huntsmans Quarries Ltd, the calculation of the benefits includes an estimate of the profit after tax including the operational costs, cost of capital and aggregate levy contribution, using costing presented by the company. To those profits, valued at GBP 110 000 the United Kingdom authorities have also added an estimate of Huntsmans's saved reserve,⁽⁸⁾ valued at GBP 26 532. From those benefits, they have deducted various additional extra costs, such as management overhead, which result in a valuation of the net benefits over the first five years of GBP 109 632. In some cases, like the glass project, no net benefit is expected. However, WRAP will require that the relevant portion of the aid be repaid, should a net benefit occur.

2.2.4. Aid intensity

(25) The aid intensity of the grants will not exceed 30 %, plus the extra percentage points allowed under point 34 of the environmental aid guidelines for projects involving small and medium-sized enterprises and/or located in assisted areas.

(26) The United Kingdom authorities will ensure that no project receives aid for the same eligible costs from other sources if the cumulated aid exceeds the aid intensities applicable under the environmental aid guidelines. In order to ensure compliance with this principle, recipients will be asked to provide a declaration concerning any other aid applied for.

2.2.5. Budget

(27) The total budget for the WRAP environmental grant fund is EUR 20,3 million. The total budget for the three wood projects is EUR 0,75 million. The budget is EUR 1 million for the glass project, and EUR 3,3 million for the plastics project. The budget for the 20 aggregates projects is EUR 8,55 million, and EUR 5,7 million for the 20 compost projects.

2.2.6. Reporting

The United Kingdom authorities will report annually to the Commission on the activity of the scheme.

2.3. The WRAP lease guarantee fund

(28) Like the WRAP environmental grant funding, the WRAP lease guarantee fund supports investments in reprocessing activities and aims, in this way, to contribute to an increase in the waste recycling capacity in the United Kingdom.

(29) The fund will provide guarantees that will cover leases of machinery and equipment for the purpose of reprocessing waste material and manufacturing products from those materials. Only leases that have a duration of at least five years will be eligible. The maximum value for an individual asset to be supported under this measure will be GBP 5 million. As regards the part of the WRAP lease guarantee fund notified on the basis of the environmental aid guidelines, which the object of this Decision, the United Kingdom authorities made the commitment that projects involving 'state of the art' processes will not be eligible for lease guarantee support. By 'state of the art', is meant a process in which the use of a waste product to manufacture an end product is economically profitable and normal practice (for example, the use of waste paper for the production of newsprint).

⁽⁸⁾ Thanks to the production of recycled aggregate, Huntsmans Quarries Ltd will be able to spare its quarry of virgin aggregate, the life of which will therefore be extended.

- (30) According to the United Kingdom authorities, leasing companies are very reluctant to provide leases for waste recycling equipment. This is due to the perceived low resale value of the specialist equipment used in the recycling sector. As a result, leasing contracts for such equipment are regarded by leasing companies as very high-risk and are therefore disproportionately expensive.
- (31) In order to remedy this situation, the guarantees provided by the fund will cover the residual value of the equipment, which, under an operating lease, will remain the lessor's asset, and which the lessor will sell at the end of the lease-period or earlier, in the case of bankruptcy of the lessee. Before the lease contract is signed, the management agent will set a residual value for the asset concerned in negotiation with a panel of lessors. The Fund will be obliged to acquire this asset for the agreed residual value in two circumstances: either if the lessee becomes bankrupt, or if the residual value of the assets falls short of the guaranteed value at the end of the lease period.
- (32) In order to calculate the net grant equivalent of these guarantees, the United Kingdom authorities have used the method laid down in the Commission Notice on the application of Articles 87 and 88 of the EC Treaty to State aid in the form of guarantees⁽⁹⁾, which states that the grant equivalent is equal to (guaranteed sum x risk) — premium. In the case of a GBP 100 000 investment, the guaranteed residual value would typically be GBP 20 000. According to the United Kingdom, a normal commercial asset finance portfolio has a risk basis of 10 to 20 % default rate. Given the higher risk profile of the waste recycling activities covered by the fund, the United Kingdom authorities estimate that it would be appropriate to apply a higher default rate, namely 30 %. The grant equivalent for a GBP 100 000 investment would therefore be GBP 20 000 x 30 % = GBP 6 000. There are unlikely to be premiums paid to WRAP. This means that the aid intensity for this aid will be 6 000/100 000 = 6 %. The calculation of this aid intensity is based on the assumption that the guaranteed residual value is set at 20 % of the value of the investment. In some cases, this guaranteed residual value could exceed 20 %. In such cases, the calculation of the aid element will vary accordingly. In any case, the United Kingdom authorities confirmed that the aid intensity should normally not be higher than 15 %.
- (33) The section of the WRAP lease guarantee fund to which this decision relates concerns the application of the fund to investments carried out by large firms in non-assisted areas, and is notified under the environmental aid guidelines⁽¹⁰⁾. As in the WRAP environmental grant funding scheme, the United Kingdom authorities have included in the calculation of the eligible costs all of the investments linked to the recycling activity, that is to say, in that case, the investments that are the object of the guaranteed lease. From these eligible costs, the United Kingdom authorities will deduct the benefits from the investment over a five-year period.
- (34) The size of the lease guarantee fund is approximately EUR 3,6 million, which will enable it to guarantee a maximum of EUR 12 million in residual values over a five-year period (the fund will operate until 31 December 2006). Since this fund is mainly directed at small and medium-sized enterprises, it is likely that few large firms located in non-assisted areas will, in any case, benefit from the application of this fund.
- (35) The United Kingdom authorities will report annually to the Commission on the activity of the scheme.

3. REASONS TO INITIATE THE FORMAL INVESTIGATION PROCEDURE

- (36) The Commission doubted that the WRAP environmental grant funding and the WRAP lease guarantee fund would qualify for an assessment under the environmental aid guidelines.
- (37) In particular, under point 29 of the environmental aid guidelines, investment aid may be authorised on the basis of the guidelines when firms undertake investment in the absence of mandatory Community standards or where they have to undertake investment in order to comply with national standards that are more stringent than Community ones. The Commission considered that investment aid granted under the WRAP environmental grant funding and the WRAP lease guarantee fund does not fulfil such an aim and is actually meant to enable the United Kingdom to fulfil the targets set by the landfill Directive. The Commission noted that investment aid approved under the environmental aid guidelines aims at reducing the emissions and pollution caused by the beneficiary in the course of its production process. The aim of these schemes is different: it is the whole activity of the beneficiaries (the recycling of waste) that is supposed to have environmental benefits. The Commission doubted that the aim of the environmental aid guidelines was to apply to such situations.

⁽⁹⁾ OJ C 71, 11.3.2000, p. 14.

⁽¹⁰⁾ As for the guarantees given to investments carried out by large firms in assisted areas or by SMEs, the Commission, in its decision of 19 March 2003, found that they were compatible with the guidelines on national regional aid and with Regulation (EC) No 70/2001 respectively.

- (38) Furthermore, supposing the environmental aid guidelines were applicable to these schemes, the Commission doubted whether the calculation of the eligible costs was in conformity with the guidelines. This is because the United Kingdom authorities included the entirety of the investments linked to the recycling activity, and because they did not provide sufficient information on how they intended to calculate the benefits accruing to the recipients of the aid over a five-year period.
- (39) Finally, the Commission expressed doubts as to whether these two schemes could be exempted directly on the basis of Article 87(3) of the Treaty, since the United Kingdom authorities had not sufficiently shown why State aid was necessary in this area, and why it did not adversely affect trading conditions to an extent contrary to the common interest.
- (42) Comments from the other interested parties are very similar to one another in content and form. They underline the existence of a market failure in the recycling of various waste products, and the unsatisfactory level of selected waste collection in the United Kingdom. Some comments acknowledged that raising tax on landfills is part of the solution, but this cannot be done until cheap alternatives to landfills have been developed. In their views, WRAP's intervention will help to create these alternatives and to establish markets for recyclable products.
- (43) Most comments underline the relative smallness of the support provided by WRAP, and the lack of significant impact on competition of the measures involved. At the same time, they underline the positive effects of the measures on the environment, with a reduction of waste going to landfills. Some third parties mention more specific benefits. For instance, the Royal Society for the Protection of Birds underlines the problems raised by the use of peat bog and its impact on birds' habitat. The replacement of the use of peat by compost will help to protect this natural habitat.

4. COMMENTS FROM INTERESTED PARTIES

- (40) The Commission received comments from 29 third parties. These comments were introduced by the German and the Irish governments, by the Community Recycling Network, the Local Authority Recycling Advisory Committee, Friends of the Earth, the Consumers' Association, the Soft Drinks Association, Coca Cola Enterprises Ltd, the Composting Association, the Soil Association Producer Services, the Royal Society for the Protection of Birds, Recycling of Used Plastics Ltd, Nampak Plastics, Dryden Aqua, the Glass Recycling Group Ltd, Knauf Insulation, Dr Andrew Smith and Dr Philip Jackson from CERAM Research Ltd, the Aggregate Industries United Kingdom Ltd, Hanson Aggregates Ltd, the British Aggregates Association, the Wood Recyclers Association, the Wood Panel Industries Federation, Kronospan Ltd, the Environmental, Food and Rural Affairs Committee, Mr. Colin Pickthall MP, Mr. David Kidney MP, Mrs Helen Clarke MP and Mrs Julia Drown MP. All these comments, apart from those of the British Aggregates Association, were in favour of the WRAP schemes.
- (41) The British Aggregates Association claims that the proposed aid to the aggregate sector would discriminate between different types of waste aggregates. According to the Association, aid will be granted to recyclers of industrial mineral processing waste and to recyclers of slate and shale quarry processing waste. Therefore, the scheme cannot deliver any environmental benefits since the subsidised recycled material would simply replace other material that is currently recycled without subsidy.
- (44) Therefore, all third parties, with the exception of the British Aggregates Association, consider that this is a clear case of environmental aid, which should be exempted on the basis of the environmental aid guidelines.

5. COMMENTS FROM THE UNITED KINGDOM

- (45) On the question of the applicability of the environmental aid guidelines, the United Kingdom authorities state that there is no reason to limit the application of these guidelines to the pollution caused by the beneficiary, as stated in the Commission decision to open the formal investigation procedure. They note that under point 42 of the environmental aid guidelines, aid can be approved for the management of waste. They also recall that the guidelines refer to the Community strategy for waste management, which makes waste management a 'priority objective for the Community in order to reduce the risks to the environment' ⁽¹⁾. Therefore, it is, in their view, wrong that schemes designed to increase waste recycling should be excluded from the environmental aid guidelines on an a priori basis.

⁽¹⁾ COM(96) 399 final of 30.7.1996.

(46) Concerning point 29 of the environmental aid guidelines, the United Kingdom authorities interpret this point as simply meaning that a firm cannot receive aid if the aid is merely designed to help it comply with a legal obligation imposed on that firm as the result of Community law. If there is no relevant law with which the firm must comply, as is the case here, then the aid may have the desired incentive effect and a company is in no way precluded from receiving State aid under the environmental aid guidelines. The United Kingdom authorities further add that there is no per se prohibition on a Member State supporting companies which assist that Member State in complying with its obligations deriving from Community law. For these reasons, the United Kingdom authorities consider that these two aid measures can fall within the scope of the environmental aid guidelines.

(47) On the question of the eligible costs, the United Kingdom authorities quote point 37 of the guidelines which states that 'eligible costs must be confined strictly to the extra investment costs necessary to meet the environmental objectives'. Since the environmental objective of the schemes is to increase waste recycling, the United Kingdom authorities claim that all the extra investment costs necessary to increase waste recycling, that is to say, all the investments linked to the recycling activity, are to be included in the eligible costs. As to the calculation of the benefits accruing to the recipient of the aid over the first five years, the United Kingdom authorities have provided a detailed description of how they are calculated in a number of concrete examples.

(48) If the Commission concludes that the environmental aid guidelines are not applicable to the case in question, the United Kingdom authorities submit that the two aid measures can be exempted directly on the basis of Article 87(3)(c) of the Treaty. On the question of the necessity of the aid, the United Kingdom authorities first underline that measures taken to increase waste recycling and based on the principle of the internalisation of costs have been taken. They include an increase of the tax on landfill. However, given that the pre-tax cost of landfill is so low in the United Kingdom, the post-tax cost of landfill in the United Kingdom remains well below European averages and will not be sufficient in itself to deter excessive landfill. Furthermore, the fact that landfill does not happen does not necessarily ensure that recycling does happen. That is why the United Kingdom authorities have concluded that it is necessary to target recycling directly under the WRAP programme. Under the terms of Article 87(3)(c) of the Treaty, aid

may be considered to be compatible with the common market when it facilitates the development of certain economic activities and certain economic areas and where it does not adversely affect trading conditions to an extent contrary to the common interest. In the present case, the United Kingdom authorities put forward that the two aid schemes at stake aim at supporting waste recycling, which is fully in line with Community environmental policy. Furthermore, the aid is proportional and does not adversely distort competition. The aid amounts are relatively small, the aid is targeted at sectors where there is a market failure and the use of competitive tenders ensures that only the minimum support necessary to stimulate market forces is provided.

(49) On the specific objection of the British Aggregate Association, the United Kingdom authorities replied that the waste aggregates that are allegedly discriminated against are in fact the by-products of virgin aggregate extraction. The United Kingdom authorities do not consider that these products are real waste, whose recycling needs to be supported, since such support would also encourage increased extraction of virgin aggregate and would defeat the objective of encouraging the use and recycling of aggregates. Under the WRAP environmental grant funding, the United Kingdom authorities will limit their support to the recycling of waste aggregate, that is to say, aggregate that has been used once, and aggregates that are by-products of industrial processes other than extraction of virgin aggregates, such as mineral wastes arising from the production of china, clay, coal and slate.

6. ASSESSMENT OF THE AID

6.1. The WRAP environmental grant funding

6.1.1. Existence of the aid within the meaning of Article 87(1) of the Treaty.

(50) Under Article 87(1) of the Treaty, 'any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, insofar as it affects trade between Member States, be incompatible with the common market.'

(51) In this case, the measure is funded by resources granted by the State under the WRAP programme. It gives a selective economic advantage to certain firms, operating in specific sectors, in the form of a grant. The use of a public tender procedure can ensure that the amount of

the subsidy is limited to the minimum necessary but does not remove the aid character of the measure. Furthermore, the waste products that are recycled can be internationally traded. For instance, it is estimated that up to 25 % of United Kingdom waste plastics was exported in 2001, while 10 000 tonnes of waste glass was imported, mainly from Ireland. Similarly, the end products that are made from the recycled waste (for example, animal bedding or activated carbon made from waste wood or sanitary ware incorporating waste glass) can also be internationally traded. For these reasons, the WRAP environmental grant funding constitutes aid within the meaning of Article 87(1) of the Treaty.

6.1.2. *Assessment of the compatibility with Article 87 of the Treaty*

- (52) The Commission has assessed whether the exemptions set out in Article 87(2) and (3) of the Treaty apply. The exemptions in paragraph 2 of Article 87 of the Treaty could serve as a basis to consider aid compatible with the common market. However, the aid does not have a social character and is not granted to individual consumers, it does not make good the damages caused by natural disasters or exceptional occurrences and it is not required in order to compensate for the economic disadvantages caused by the division of Germany. The exemptions in Article 87(3)(a), (b) and (d) of the Treaty, which refer to promotion of the economic development of areas where the standard of living is abnormally low or where there is serious underemployment, to projects of common European interest and to the promotion of culture and conservation cannot apply either. In any case, the United Kingdom did not attempt to justify the aid on those grounds.
- (53) As far as the first part of the exemption in Article 87(3)(c) of the Treaty is concerned, namely aid to facilitate the development of certain economic activities, the Commission notes that the aid did not have purposes such as research and development. Nor can it be found to be compatible with the guidelines on national regional aid or Regulation (EC) No 70/2000. All the projects of the WRAP environmental grant funding that were compatible with those two texts, were the object of a positive decision of the Commission on 19 March 2003. Therefore, by definition, the WRAP environmental grant funding exclusively comprises projects that are not compatible with Community rules on regional aid or aid to small and medium-sized enterprises.
- (54) It should therefore be examined whether this scheme qualifies for an exemption under Article 87(3)(c) of the Treaty on other grounds than those referred to in recitals
- 52 and 53. The Commission will assess in the following recitals whether the WRAP environmental grant funding scheme is compatible with the environmental aid guidelines, and whether it is directly compatible with Article 87(3)(c) of the Treaty.
- #### 6.1.2.1. *Assessment under the environmental aid guidelines*
- (55) In its decision of 19 March 2003, the Commission acknowledged that the WRAP environmental grant funding scheme has environmental benefits. The recycling of waste is more environmentally friendly than putting it into landfill. However, in its decision of 17 July 2003, in case C 61/2002 Shotton paper — newspaper reprocessing case, which concerned investment aid for waste paper recycling, the Commission concluded that the environmental aid guidelines were not applicable to this type of aid. Since that case is an individual application of the WRAP environmental grant funding to the specific sector of waste paper, the same conclusion must be drawn with respect to the scheme itself.
- (56) The reasons why the environmental aid guidelines are not applicable are the following. According to point 29 of the environmental aid guidelines, investment aid may be granted 'to enable firms to improve on Community standards applicable, or when the firms undertake investment in the absence of Community standards applicable (...)'.
(57) The first possibility expressed in point 29 of the environmental aid guidelines, which allows aid to be granted in order to enable firms to improve on Community standards applicable, does not apply in this case. The aid is granted in order to improve the United Kingdom's environment in general, and to help the United Kingdom to achieve its obligations under the landfill and packaging Directives. It is not granted to enable the beneficiaries to improve on the standards applicable to them directly.
(58) As regards the second possibility in point 29 of the environmental aid guidelines, which concerns aid for firms to undertake investments in the absence of Community standards applicable, the United Kingdom argued that the relevant standards applied to the Member State itself, rather than to the firm, and that investment aid under the environmental aid guidelines could therefore be allowed. In its decision in case C 61/2002, the Commission has already rejected that argument. This exception should be interpreted in the light of point 18 (b) of the environmental aid guidelines, which states that

aid 'may act as an incentive to firms to improve on standards or to undertake further investment designed to reduce pollution from their plants'. On this basis, the Commission considers that point 29 of the environmental aid guidelines concerns cases of investment aid where an undertaking invests to improve its own environmental record, and to reduce its own pollution. This is not the case under the present scheme.

(59) The Commission also considers that no other provisions of the environmental aid guidelines apply to the case at stake. The Commission recalls, in this context, that operating aid to promote waste management may be authorised, under the conditions set out in points 42 to 46 of the Guidelines, for waste management. However, the measures in question, which constitute investment aid, do not fulfil these conditions.

(60) The United Kingdom authorities tried to draw a distinction between case C 61/2002 Shotton Paper and the present case, and argued that there were sufficient differences between the two cases to reach different conclusions concerning the applicability of the environmental aid guidelines in this case. In particular, they noted that the Shotton paper case involved a much higher amount of aid than the individual amounts provided under the WRAP environmental grant funding, that it concerned a mature market while the scheme is targeted at immature markets with a clear market failure, and that the aid measure subsidised a 'state of the art' process while the technologies which the WRAP environmental grant funding seeks to develop are untested in the market place. The Commission considers that these arguments are of a factual nature, which are relevant in the context of the discussion of the direct applicability of Article 87(3)(c) of the Treaty. They are not, however, such as to alter the Commission's legal interpretation of point 29 of the environmental aid guidelines which leads it to conclude that the guidelines are not applicable in the present case.

(61) It must therefore be concluded that the environmental aid guidelines are not applicable to the WRAP environmental grant funding.

6.1.2.2. Direct Application of Article 87(3)(c) of the Treaty

(62) The granting of investment aid in favour of waste recycling is not foreseen in the environmental aid guidelines, despite its environmental benefits. It is therefore appropriate to consider whether this type of aid fulfills the criteria to be directly compatible with Article 87(3)(c) of the Treaty.

(63) Article 87(3)(c) of the Treaty states that 'aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest' may be considered to be compatible with the common market.

(64) The Commission first notes that the objective of this aid measure is to encourage waste recycling. Waste recycling is an essential element of waste management, which the Commission considers to be 'a priority objective for the Community in order to reduce the risks to the environment' ⁽¹²⁾. The importance of this objective was underlined by the landfill Directive, which requires Member States to reduce the disposal of municipal waste to landfill and by the packaging Directive, which requires significant increases in packaging waste recycling. Waste recycling is therefore an economic activity, the development of which should be encouraged, because of its environmental benefits, both at national and Community levels.

(65) In order to be compatible with Article 87(3)(c) of the Treaty, the aid measure must also be proportionate to the objective, and must not distort competition to an extent contrary to the common interest. Some elements of appreciation of the proportionality of this type of aid measure were set out by the Commission in its decision in case C 61/2002. In that case, the Commission concluded that the aid given to increase waste paper recycling capacity of Shotton was not proportionate, nor necessary, and led to an undue distortion of competition. The Commission first noted that producing newsprint paper on the basis of waste paper is the normal state of the art technique, which is economically profitable and widely spread. Therefore, providing aid for the development of such equipment appeared to be disproportionate and not necessary. Furthermore, given the high amount of aid involved (EUR 35 million), granted to one single undertaking, which is a major player in the market of newsprint, the Commission concluded that the aid would cause an undue distortion of competition.

(66) The Commission considers that a different conclusion can be reached as regards this aid measure. The United Kingdom authorities have convincingly argued that the projects to be subsidised under the WRAP environmental grant funding do not involve 'state of the art' processes, which can be defined as processes in which the use of a waste product to manufacture an end product is economically profitable and therefore normal practice. Some of the WRAP projects involve techniques that are little tested in the market place. This appears to

⁽¹²⁾ Community strategy for waste management, COM(96) 399 final of 30.7.1996.

- be the case of the glass project, which involved the fine grinding of glass for its subsequent incorporation into sanitary ware or bricks, or the plastics project, which involves automated plastic bottle sorting equipment (a process normally done by hand in the United Kingdom). Other projects, like the wood, compost or aggregates projects, involve activities in which the use of waste product as raw material is not the normal practice. In the case of wood, for instance, the cost of waste wood processed for recycling is normally higher than the cost of virgin wood processed for equivalent application, which normally makes its use unprofitable. Since this aid scheme does not subsidise 'state of the art' processes, the aid can be considered to be necessary.
- (67) As to the impact of the measure on competition and on trade between Member States, the Commission first notes that the amounts of aid are significantly lower than that granted in the Shotton paper case. The largest amount of individual aid to be granted under this scheme is EUR 3,3 million, compared to EUR 35 million in the Shotton case. Furthermore, for most waste products, the aid is spread over several projects (up to 20 in the case of compost and aggregates). All but one of the comments from third parties were in favour of the project. Only one comment, from the British Aggregates Association underlined the potential negative impact on competition of the measure, in the specific sector of aggregates, since it would discriminate between different types of recycled materials. However, it appears that the waste aggregates that are allegedly discriminated against are by-products of virgin aggregate extraction. The United Kingdom authorities have argued that these products cannot be considered as real waste. However, according to the definition of waste contained in Council Directive 75/442/EEC of 15 July 1975 on waste⁽¹³⁾, such by-products are to be generally considered as waste. Additionally, the Court of Justice of the European Communities has recently defined criteria for case-by-case determination of whether by-products may be considered as waste⁽¹⁴⁾. This jurisprudence does not alter the general conclusion that by-products of virgin aggregate extraction are to be considered as waste. Nevertheless, the Commission considers that it is legitimate not to support the reprocessing of by-products of virgin aggregate extraction. Supporting the latter would have the unwanted effect of encouraging extraction of virgin aggregate and would defeat the objective of encouraging the recycling of materials that have already been used. In addition, the relevant projects would focus on waste aggregates which are currently hardly recycled at all, in particular waste aggregates with a high level of contamination from soil, clays and other contaminants. The situation of such aggregates clearly differs from that of by-products of virgin aggregate extraction. The Commission therefore considers that there is no undue discrimination in the area of aggregates.
- (68) Furthermore, in order to determine whether the aid does cause an undue distortion of competition, regard must be paid to the aid intensities granted to the various projects. The United Kingdom authorities have based their calculation of the eligible costs and the relevant aid intensities on the principles laid down in the environmental aid guidelines. The Commission has already concluded that the guidelines are not applicable to the aid measure in question. However, given the environmental objective of the WRAP environmental grant funding, it is appropriate to find guidance in the environmental aid guidelines on the way the eligible costs should be calculated and aid intensities determined in this case.
- (69) On the question of the eligible costs, point 37 of the environmental aid guidelines states that 'eligible costs must be confined strictly to the extra investments costs necessary to meet the environmental objectives', which is normally done by deducting, from the eligible investment costs, 'the cost of a technically comparable investment that does not provide the same degree of environmental protection'. Under the WRAP environmental grant funding scheme, the United Kingdom authorities have not deducted the cost of any such comparable investment from the eligible investment costs. This approach appears to be justifiable given the specificity of the measure. As explained in point 6.1.2.1, the environmental aid guidelines are applicable to aid measures intended to make a certain production process more environmentally friendly, by reducing its polluting emissions. This is why point 37 recommends the deduction from the eligible investment costs of a comparable, less environmentally friendly investment. In the present case, however, the situation is different. It is the whole economic activity of the aid beneficiary (waste recycling) that is environmentally friendly. It is therefore appropriate to consider that the whole cost of investment is eligible. Furthermore, as recommended by point 37 of the guidelines, the United Kingdom authorities have deducted from the costs of these investments the benefits over a five-year period. They have provided the Commission with descriptions showing how these benefits had been calculated. These calculations appear to be correct. The aid intensities calculated on the basis of these eligible costs will not exceed the thresholds laid down in points 34 and 35 of the environmental aid guidelines.
- (70) Finally, the Commission notes that an open tender procedure is used to select the beneficiaries and determine the amount of the aid. This system helps to guarantee that the aid is limited to the minimum and is proportionate.

⁽¹³⁾ OJ L 194, 25.7.1975, p. 39. Directive as last amended by Directive 96/350/EC (OJ L 135, 6.6.1996, p. 32.)

⁽¹⁴⁾ See judgment of 11 September 2003, in Case C-114/2001 *Avesta-Polarit Chrome Oy*, not yet reported.

- (71) Given that the aid amounts granted are relatively small, that they are calculated in accordance with the principle laid down in the environmental aid guidelines and set at the end of a open tender procedure, and that no comment convincingly demonstrated that the measure in question was creating an undue distortion of competition, it may be concluded that the WRAP Environmental Grant Funding does not adversely affect trading conditions to an extent contrary to the common interest.
- (72) In the light of the above, it is concluded that the WRAP environmental grant funding is compatible with Article 87(3)(c) of the Treaty.
- (73) The Commission intends to amend the environmental aid guidelines in order to expressly provide for the possibility to approve State aid which has environmental benefits at the global level of the Member State or the Community, and not at the individual level of the beneficiary. Given the lack of experience in this field of environmental aid, such cases will be assessed on their own merits. Pending the amendment of the guidelines, the Commission will apply the same criteria as in the present decision to any similar case

6.2. The WRAP lease guarantee fund

6.2.1. Existence of the aid within the meaning of Article 87(1) of the Treaty.

- (74) The WRAP lease guarantee fund is funded by resources granted by the State under the WRAP programme. The Commission notes that the fund provides guarantees that cover leases of machinery used to recycle waste. It enables firms that want to acquire this equipment to obtain a lease on conditions that are more favourable than normally available on the market. Since the lessees do not pay any premium for the guarantee, they clearly get an economic advantage from this measure. This economic advantage is specific, since only firms operating in the sectors of waste recycling can benefit from the application of this fund. Furthermore, the products manufactured by those companies may be internationally traded, so this aid measure may have an effect on competition and trade between Member States. For these reasons, it may be concluded that the WRAP lease guarantee fund constitutes aid to the lessees within the meaning of Article 87(1).

6.2.2. Assessment of the compatibility with Article 87 of the Treaty

- (75) In its decision of 19 March 2003, the Commission made a detailed analysis of the WRAP guarantee fund, in the

light of the Commission Notice on State aid in the form of guarantees. It concluded that the guarantee fund was in line with the Notice, and in particular that the calculation of the grant equivalent was correct and the aid intensity was estimated to be around 6 % on average⁽¹³⁾. Since the mechanisms of this fund have not changed and will apply in exactly the same way to large firms in non-assisted areas, the same conclusions are applicable to the present analysis.

- (76) Secondly, this aid measure is very similar to the WRAP environmental grant funding. The only significant difference between the two measures is the form of the aid: grant in the case of the WRAP environmental grant funding, and guarantee in the case of the WRAP lease guarantee fund. Like the WRAP environmental grant funding, this scheme aims at supporting investment aid in the field of waste recycling. Consequently, the conclusions concerning the compatibility of the WRAP environmental grant funding with Article 87(2) and Article 87(3) of the Treaty can be applied to the WRAP lease guarantee fund. For the same reasons, it can be concluded that Article 87(2), the guidelines on national regional aid, Regulation (EC) No 70/2001⁽¹⁴⁾ and the environmental aid guidelines do not apply.

- (77) On the question of whether the WRAP lease guarantee fund is directly compatible with Article 87(3)(c) of the Treaty, the United Kingdom authorities have committed themselves not to grant guarantees to leases of equipment involved in 'state of the art' processes.

- (78) Secondly, the calculation of the eligible costs is comparable to the situation under the WRAP environmental grant funding, and the principles laid down in point 37 of the environmental aid guidelines. It notes in particular that the United Kingdom authorities will deduct from the eligible investment costs, the benefits from the investment over a five year period.

- (79) The Commission also notes that the maximum value of an individual asset to be supported under this fund is GBP 5 million, that the aid intensity will not exceed 15 %, and that, therefore, the maximum possible grant equivalent of a guarantee is GBP 750 000. In the large majority of cases, this amount is likely to be significantly smaller, because the value of the asset will be lower, and the aid intensity will generally be around 6 %.

⁽¹³⁾ See point 83 and 84 of the decision.

⁽¹⁴⁾ The part of the Lease Guarantee Fund that was compatible with the regional aid guidelines and Commission regulation (EC) No 70/2001 was the object of a positive decision of the Commission on 19 March 2003.

(80) Therefore, given that no 'state of the art' process will be eligible for guarantees, given that the grant equivalent of the guarantees will not be, on average, of a high level, and that the aid intensities will be significantly lower than the thresholds imposed in the environmental aid guidelines, it can be concluded that guarantees granted by the WRAP lease guarantee fund will 'not affect trading conditions to an extent contrary to the common interest.' Since its aim is to encourage the recycling of waste, which is a priority objective of the Community, the WRAP lease guarantee fund fulfills the criteria to be considered compatible with Article 87(3)(c) of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The WRAP environmental grant funding and the WRAP lease guarantee fund are compatible with the common market within the meaning of Article 87(3)(c) of the EC Treaty.

Implementation of the aid is accordingly authorised.

Article 2

This Decision is addressed to the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 11 November 2003.

For the Commission

Mario MONTI

Member of the Commission

COMMISSION DECISION**of 30 March 2004****adapting Decision 2001/672/EC as regards summer grazing in certain areas of Slovenia by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia***(notified under document number C(2004) 1022)***(Text with EEA relevance)**

(2004/318/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty of Accession to the European Union of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic, and in particular Article 2(3) thereof,

Having regard to the Act of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 57(2) thereof,

Whereas:

- (1) For certain acts adopted by the Commission, which remain valid beyond 1 May 2004, and require adaptation by reason of accession, the necessary adaptations were not provided for in the Act of Accession, in particular in its Annex II. Those adaptations need to be adopted before accession so as to be applicable as from accession.
- (2) Slovenia has requested to apply from the date of accession the special rules applicable to movements of bovine animals when put out to summer grazing in mountain areas as laid down in Commission Decision 2001/672/EC ⁽¹⁾.
- (3) It is justified to take account of Slovenia's request and to amend Decision 2001/672/EC accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In the Annex to Decision 2001/672/EC, the text in the Annex to this Decision is added.

Article 2

This Decision shall apply, subject to, and as from the date of, the entry into force of the Treaty of Accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 30 March 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 235, 4.9.2001, p. 23.

ANNEX

'SLOVENIJA

POMURSKA REGIJA	Ljutomer, Ormož
PODRAVSKA REGIJA	Lenart, Ptuj, Slovenska Bistrica, Maribor, Pesnica, Ruše
KOROŠKA REGIJA	Dravograd, Radlje ob Dravi, Ravne na Koroškem, Slovenj Gradec
SAVINJSKA REGIJA	Celje, Laško, Mozirje, Šentjur pri Celju, Slovenske Konjice, Šmarje pri Jelšah, Velenje, Žalec
ZASAVSKA REGIJA	Hrastnik, Trbovlje, Zagorje ob Savi
SPODNJE POSAVSKA REGIJA	Brežice, Sevnica
JUGOVZHODNA SLOVENIJA	Črnomelj, Kočevje, Metlika, Novo Mesto, Ribnica, Trebnje
OSREDJESLOVENSKA REGIJA	Domžale, Grosuplje, Kamnik, Litija, Ljubljana, Logatec
GORENJSKA REGIJA	Jesenice, Kranj, Radovljica, Škofja Loka, Tržič
NOTRANJSKO-KRAŠKA REGIJA	Cerknica, Ilirska Bistrica, Postojna
GORIŠKA REGIJA	Ajdovščina, Idrija, Nova Gorica, Tolmin
OBALNO KRAŠKA REGIJA	Izola/Isola, Koper, Piran, Sežana'

COMMISSION DECISION

of 30 March 2004

amending Annex I to Decision 2003/804/EC laying down the animal health conditions and certification requirements for imports of molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption*(notified under document number C(2004) 1076)***(Text with EEA relevance)**

(2004/319/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products ⁽¹⁾, and in particular Article 19(1) thereof,

Whereas:

(1) A list of third countries from which Member States are authorised to import live molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption in the Community, as well as model certificates that must accompany such consignments were drawn up by Decision 2003/804/EC ⁽²⁾.

(2) At the time of adoption of Decision 2003/804/EC, no third countries could be listed in Annex I to the Decision.

(3) Since the entering into force of Directive 91/67/EEC, the animal health requirements for import of aquaculture animals into the Community from third countries have been unchanged. Pending the establishment of harmonised certification requirements, the Member States have been responsible for ensuring that imports of aquaculture animals and products thereof from third countries be subjected to conditions at least equivalent to those applying to placing on the market of Community products according to Article 20(3) of Directive 91/67/EEC.

(4) There is therefore an ongoing trade in live bivalve molluscs for the purpose of human consumption between certain third countries and certain Member States. This trade would be blocked from 1 May 2004, when Decision 2003/804/EC will be implemented.

(5) In order not to interrupt, unnecessarily, ongoing trade from third countries that Member States have found to comply with conditions at least equivalent to those applicable for placing on the market within the Community, certain third countries should be included in Annex I to this Decision for a interim period of time, pending the completion of the on-the-spot inspections provided for by Community rules.

(6) Such temporary listing should be limited to imports of live bivalve molluscs for the purpose of human consumption only, from areas authorised according to Council Directive 91/492/EEC ⁽³⁾.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 2003/804/EC is replaced by the Annex to this Decision.

Article 2

This Decision shall apply from 1 May 2004.

⁽¹⁾ OJ L 46, 19.2.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 302, 21.11.2003, p. 22.

⁽³⁾ OJ L 268, 24.9.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 30 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

'ANNEX I

Territories from which importation of certain species of live molluscs, their eggs and gametes intended for further growth, fattening, or relaying in European Community waters are authorised

Country		Territory		Specific requirements ⁽¹⁾		Comments ⁽²⁾
ISO code	Name	Code	Description	<i>Bonamia ostreae</i>	<i>Marteilia refringens</i>	
CA	Canada ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾
HR	Croatia ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾
MA	Morocco ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾
NZ	New Zealand ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾
TN	Tunisia ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾
TR	Turkey ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾
US	United States of America ⁽³⁾			NO	NO	Live bivalve molluscs for human consumption only ⁽³⁾

⁽¹⁾ "Yes" or "No" as relevant if designated farm, coastal or continental zone is approved by the central competent authority of the exporting country as a territory that also fulfils the specific animal health requirements for introduction into Community zones and farms having a Community approved programme or status as regards *Bonamia ostreae* and/or *Marteilia refringens*.

⁽²⁾ No limitations if left empty. If country or territory is allowed to export only certain species and/or eggs or gametes, the species should be specified and/or a comment with for example "eggs only" shall be inserted in this column.

⁽³⁾ Temporary listing for the purpose of import for human consumption only. Shall be reconsidered before 1 January 2005.'

COMMISSION DECISION

of 31 March 2004

amending Decisions 93/52/EEC, 2001/618/EC and 2003/467/EC as regards the status of acceding countries with regard to brucellosis (*B. melitensis*), Aujeszky's disease, enzootic bovine leukosis, bovine brucellosis and tuberculosis and of France with regard to Aujeszky's disease

(notified under document number C(2004) 1094)

(Text with EEA relevance)

(2004/320/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 2(3) thereof,

Having regard to the Act of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 21 and 57 thereof,

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⁾, and in particular Article 9(2), Article 10(2), Annex A(I)(4), Annex A(II)(7) and Annex D(I)(E) thereof,

Having regard to Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals⁽²⁾ and in particular Annex A, Chapter 1(II) thereof,

Whereas:

- (1) With a view to their accession, the status of the acceding countries with regard to brucellosis (*B. melitensis*), Aujeszky's disease and enzootic bovine leukosis, brucellosis and tuberculosis should be laid down.
- (2) Commission Decision 93/52/EEC⁽³⁾ records compliance by certain Member States or regions with the requirements relating to brucellosis (*B. melitensis*) and accords them the status of a Member State or region officially free of the disease.

- (3) Commission Decision 2001/618/EC⁽⁴⁾ lays down the additional guarantees relating to the implementation of eradication programmes for Aujeszky's disease applicable to intra-Community trade of swine, and the lists of territories in the Member States where approved disease control programmes are in place.

- (4) Commission Decision 2003/467/EC⁽⁵⁾ establishes the official tuberculosis, brucellosis, and enzootic bovine leukosis-free status of certain Member States and regions of Member States as regards bovine herds.

- (5) The Czech Republic, Hungary and Slovakia as regards their respective territories submitted to the Commission documentation demonstrating compliance with all requirements laid down in Annex A(1)(II)(1)(b) of Directive 91/68/EEC in order that the territories of the Czech Republic, Hungary and Slovakia may be declared officially free of brucellosis (*B. melitensis*) as regards ovine flocks and caprine herds.

- (6) France has submitted supporting documentation to the Commission as regards the Aujeszky's disease free status of the department of Pas-de-Calais demonstrating the eradication of the disease from that department.

- (7) The Czech Republic and Cyprus as regards their respective territories submitted to the Commission documentation demonstrating freedom from Aujeszky's disease and that vaccination against that disease is prohibited in order that the whole territories of the Czech Republic and Cyprus may be declared free of Aujeszky's disease as regards swine herds.

- (8) The Czech Republic as regards its territory submitted to the Commission documentation demonstrating compliance with all requirements laid down in Annex A(II)(4) to Directive 64/432/EEC in order that the whole territory of the Czech Republic may be declared officially free of tuberculosis as regards bovine herds.

⁽¹⁾ OJ L 121, 29.7.1964, p. 1977/64. Directive as last amended by Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

⁽²⁾ OJ L 46, 19.2.1991, p. 19. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽³⁾ OJ L 13, 21.1.1993, p. 14. Decision as last amended by Decision 2004/199/EC (OJ L 64, 2.3.2004, p. 41).

⁽⁴⁾ OJ L 215, 9.8.2001, p. 48. Decision as last amended by Decision 2003/575/EC (OJ L 196, 2.8.2003, p. 41).

⁽⁵⁾ OJ L 156, 25.6.2003, p. 74. Decision as amended by Decision 2004/230/EC (OJ L 70, 9.3.2004, p. 41).

- (9) The Czech Republic as regards its territory submitted to the Commission documentation demonstrating compliance with all requirements laid down in Annex A(II)(7) to Directive 64/432/EEC in order that the whole territory of the Czech Republic may be declared officially free of brucellosis as regards bovine herds.
- (10) The Czech Republic and Cyprus as regards their respective territories submitted to the Commission documentation demonstrating compliance with all requirements laid down in Annex D, Chapter I, sections E, F and G to Directive 64/432/EEC in order that the whole territories of the Czech Republic and Cyprus may be declared officially free of enzootic bovine leucosis as regards bovine herds.
- (11) Following evaluation of the documentation submitted by the Czech Republic, Hungary and Slovakia, the whole territories of these countries should be declared officially free of brucellosis (*B. melitensis*) as regards ovine flocks and caprine herds.
- (12) Following evaluation of the documentation submitted by France, the Czech Republic and Cyprus, the department of Pas-de-Calais in France and the whole territories of the Czech Republic and Cyprus should be declared free of Aujeszky's disease as regards swine herds.
- (13) Following evaluation of the documentation submitted by the Czech Republic the whole territory of that country should be declared officially free of tuberculosis, brucellosis and enzootic bovine leucosis as regards bovine herds.
- (14) Following evaluation of the documentation submitted by Cyprus the whole territory of that country should be declared officially free of enzootic bovine leucosis as regards bovine herds.
- (15) Decisions 93/52/EEC, 2001/618/EC and 2003/467/EC should therefore be amended accordingly.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 93/52/EEC is replaced by Annex I to this Decision.

Article 2

Annexes I and II to Decision 2001/618/EC are replaced by Annex II to this Decision.

Article 3

Decision 2003/467/EC is amended as follows:

- (a) in Annex I, Chapter 1 is replaced by Annex III to this Decision;
- (b) in Annex II, Chapter 1 is replaced by Annex IV to this Decision;
- (c) in Annex III, Chapter 1 is replaced by Annex V to this Decision.

Article 4

This Decision shall apply subject to and from the date of the entry into force of the Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 31 March 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

(as referred to in Article 1)

ANNEX I

MEMBER STATE

ISO code	Member State
AT	Austria
BE	Belgium
CZ	Czech Republic
DE	Germany
DK	Denmark
FI	Finland
HU	Hungary
IE	Ireland
LU	Luxembourg
NL	Netherlands
SE	Sweden
SK	Slovakia
UK	United Kingdom'

ANNEX II

(as referred to in Article 2)

ANNEX I

Member States or regions thereof free of Aujeszky's disease and where vaccination is prohibited

ISO code	Member State	Regions
AT	Austria	Whole territory.
CY	Cyprus	Whole territory.
CZ	Czech Republic	All regions.
DE	Germany	All regions.
DK	Denmark	All regions.
FI	Finland	All regions.
FR	France	The Departments of Aisne, Allier, Alpes-de-Haute-Provence, Alpes-Maritimes, Ardèche, Ardennes, Ariège, Aube, Aude, Aveyron, Bas-Rhin, Bouches-du-Rhône, Calvados, Cantal, Charente, Charente-Maritime, Cher, Corrèze, Côte-d'Or, Creuse, Deux-Sèvres, Dordogne, Doubs, Drôme, Essonne, Eure, Eure-et-Loir, Gard, Gers, Gironde, Hautes-Alpes, Hauts-de-Seine, Haute Garonne, Haute-Loire, Haute-Marne, Hautes-Pyrénées, Haut-Rhin, Haute-Saône, Haute-Savoie, Haute-Vienne, Hérault, Indre, Indre-et-Loire, Isère, Jura, Landes, Loire, Loire-Atlantique, Loir-et-Cher, Loiret, Lot, Lot-et-Garonne, Lozère, Maine-et-Loire, Manche, Marne, Mayenne, Meurthe-et-Moselle, Meuse, Moselle, Nièvre, Oise, Orne, Paris, Pas-de-Calais, Pyrénées-Atlantiques, Pyrénées-Orientales, Puy-de-Dôme, Réunion, Rhône, Sarthe, Saône-et-Loire, Savoie, Seine-et-Marne, Seine-Maritime, Seine-Saint-Denis, Somme, Tarn, Tarn-et-Garonne, Territoire de Belfort, Val-de-Marne, Val-d'Oise, Var, Vaucluse, Vendée, Vienne, Vosges, Yonne, Yvelines.
LU	Luxembourg	All regions.
SE	Sweden	All regions.
UK	United Kingdom	All regions in England, Scotland and Wales.

ANNEX II

Member States or regions thereof where approved Aujeszky's disease control programmes are in place

ISO code	Member State	Regions
BE	Belgium	Whole territory.
FR	France	The departments of Ain, Côtes-d'Armor, Finistère, Ille-et-Vilaine, Morbihan and Nord.
IT	Italy	The Province of Bolzano.
NL	Netherlands	Whole territory.'

ANNEX III

(as referred to in Article 3(a))

'CHAPTER 1

Officially tuberculosis-free Member States

ISO code	Member State
AT	Austria
BE	Belgium
CZ	Czech Republic
DE	Germany
DK	Denmark
FI	Finland
FR	France
LU	Luxembourg
NL	Netherlands
SE	Sweden'

ANNEX IV

(as referred to in Article 3(b))

'CHAPTER 1

Officially brucellosis-free Member States

ISO code	Member State
AT	Austria
BE	Belgium
CZ	Czech Republic
DE	Germany
DK	Denmark
FI	Finland
LU	Luxembourg
NL	Netherlands
SE	Sweden'

ANNEX V

(as referred to in Article 3(c))

'CHAPTER 1

Officially enzootic-bovine-leukosis-free Member States

ISO code	Member State
AT	Austria
BE	Belgium
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
ES	Spain
FI	Finland
FR	France
IE	Ireland
LU	Luxembourg
NL	Netherlands
SE	Sweden
UK	United Kingdom'

DECISION OF THE ADMINISTRATIVE BOARD OF THE EUROPEAN FOUNDATION FOR THE IMPROVEMENT OF LIVING AND WORKING CONDITIONS**of 26 March 2004****on the adoption of rules for implementing Regulation (EC) No 1049/2001 on public access to documents**

(2004/321/EC)

THE ADMINISTRATIVE BOARD,

Having regard to Council Regulation (EC) No 1649/2003 amending Regulation (EEC) No 1365/75 on the creation of a European Foundation for the Improvement of Living and Working Conditions and repealing Regulation (EEC) No 1417/76 ⁽¹⁾,

Whereas:

- (1) The general principles and limits governing right of access to documents As provided for in Article 255 of the Treaty have been laid down by Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ⁽²⁾.
- (2) When Regulation (EC) No 1049/2001 was adopted, the three institutions agreed in a joint declaration that the Agencies and similar bodies should implement rules conforming to those of that Regulation.
- (3) Regulation (EC) No 1649/2003 of 18 June 2003 amending Regulation (EEC) No 1365/75 on the creation of a European Foundation for the Improvement of Living and Working Conditions and repealing Regulation (EEC) No 1417/76 states that Regulation EC 1049/2001 shall apply to documents held by the Foundation.
- (4) Regulation (EC) No 1649/2003 states also that the Administrative Board shall adopt practical arrangements for implementing Regulation (EC) No 1049/2001 within six months of 29 September 2003, or entry into force of Council Regulation (EC) No 1649/2003.
- (5) Clear rules will assist smooth administration by helping those responsible to deal accurately and rapidly with applications made by the public,

HAS ADOPTED THIS DECISION:

*Article 1***Applicability and scope**

1. The right of access concerns documents held by the Foundation, that is to say, documents drawn up or received by it and in its possession.

⁽¹⁾ OJ L 245, 29.9.2003, p. 25.

⁽²⁾ OJ L 145, 31.5.2001, p. 43.

2. Citizens of the European Union and natural or legal persons residing or having their registered office in a Member State shall exercise right of access to Foundation documents pursuant to Article 2(1) of Regulation (EC) No 1049/2001.

3. Pursuant to Article 2(2) of Regulation (EC) No 1049/2001, citizens of third countries not residing in a Member State and legal persons not having their registered office in one of the Member States shall enjoy the right of access to Foundation documents on the same terms as the beneficiaries referred to in Article 2(1) of Regulation (EC) No 1049/2001.

*Article 2***Applications for access**

1. Applications for access to Foundation documents which are not publicly available shall be made in written form, including electronic form and in a sufficiently precise manner to enable the Foundation to identify the documents.

2. The Foundation shall answer initial and confirmatory access applications within 15 working days from the date of registration of the application.

3. In the case of complex or bulky applications, the deadline may be extended by 15 working days. Reasons must be given for any extension of the deadline and it must be notified to the applicant beforehand.

4. If an application is imprecise, as referred to in Article 6(2) of Regulation (EC) No 1049/2001, the Foundation shall ask the applicant to provide additional information making it possible to identify the documents requested; the deadline for reply shall run only from the time when the Foundation has this information.

5. Any decision which is partly negative shall state the reason for the refusal based on one of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001.

*Article 3***Treatment of initial applications**

1. As soon as the application is registered, an acknowledgement of receipt shall be sent to the applicant, unless the answer can be sent by return post. The acknowledgement of receipt and the answer shall be sent in writing, where appropriate, by electronic means.

2. The applicant shall be informed of the response to his application by the Head of Administration.

3. In the event of a total or partial refusal, the applicant may within 15 working days of receiving the Foundation's reply, make a confirmatory application asking the Foundation to reconsider its position

4. Failure by the Foundation to reply within the prescribed time limit shall entitle the applicant to make a confirmatory application.

Article 4

Treatment of confirmatory applications

1. The Director shall take the decisions refusing access relating to confirmatory applications. He shall inform the Administrative Board of the Foundation of such actions.

2. The decision shall be notified to the applicant in writing, or where appropriate by electronic means, and shall specify which of the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001 it is based on and the reasons for it. It shall also inform him of his right to bring an action before the Court of First Instance or to lodge a complaint with the European Ombudsman.

Article 5

Consultations

1. Where the Foundation receives an application for access to a document which it holds but which originates from a third party, the Foundation shall check whether one of the exceptions provided for under Article 4 of the Regulation applies.

2. If, after that examination, the Foundation considers that access to it must be refused under one of the exceptions provided for by Article 4 of Regulation (EC) No 1049/2001, the negative answer shall be sent to the applicant without consultation of the third-party author.

3. The Foundation shall grant the application without consulting the third-party author where:

- (a) the document requested has already been disclosed either by its author or under the Regulation or similar provisions;
- (b) the disclosure, or partial disclosure, of its contents will not affect one of the interests referred to in Article 4 of the Regulation.

Article 6

Exercise of the right of access

1. Documents shall be sent by mail, fax or, if available, by e-mail. If documents are voluminous or difficult to handle, the applicant may be invited to consult the documents on the spot. This consultation shall be free of charge.

2. If the document has been published, the answer shall consist of the publication references and/or the place where the document is available and where appropriate, of its web address on the Foundation's website.

3. If the volume of the documents requested exceeds twenty pages, the applicant may be charged a fee of EUR 0,40 per page plus carriage costs. The charges for other media shall be decided case by case but shall not exceed a reasonable amount.

Article 7

Register of documents

1. In order to make citizen's rights deriving from Regulation (EC) No 1049/2001 effective, the Foundation shall provide access to a register of documents available through the Foundation's internet site.

2. The register shall contain the title of the document, a unique reference, the subject matter and/or a short description of the document and the date on which it was received or drawn up and recorded in the register.

Article 8

Documents directly accessible to the public

1. This Article applies only to documents drawn up or received after the date from which Regulation (EC) No 1049/2001 applies.

2. The following documents shall be automatically provided on request and as far as possible made directly accessible:

- (a) agendas and final minutes of meetings of the Administrative Board and Bureau;
- (b) decisions adopted by the Administrative Board and Bureau;
- (c) documents originating from third parties which have already been disclosed by their author or with his consent;
- (d) documents already disclosed following a previous application.

Article 9

Report

The Foundation shall publish annually as part of the Annual Report, information concerning the implementation of this decision, in particular statistics on the number of requests for access to documents of the Foundation, the number of refusals and the reasons for such refusals.

*Article 10***Entry into force**

This decision shall be published in the *Official Journal of the European Union* and shall enter into force on the day of its publication.

Done at Dublin, 26 March 2004.

For the Administrative Board

Marjaana VALKONEN

COMMITTEE OF THE REGIONS

DECISION No 26/2004 OF THE COMMITTEE OF THE REGIONS

of 10 February 2004

relating to the conditions and procedures for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests

THE BUREAU OF THE COMMITTEE OF THE REGIONS,

Having regard to Commission Decision 1999/352/EC, ECSC, Euratom, of 28 April 1999, establishing a European Anti-Fraud Office ⁽¹⁾,

Having regard to Regulation (EC) No. 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office ⁽²⁾,

Having regard to the inter-institutional agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning investigations conducted by the European Anti-Fraud Office ⁽³⁾,

Whereas Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (hereinafter the Office) provides that the Office is to initiate and conduct administrative investigations within the institutions, bodies, offices and agencies established by or on the basis of the Treaties;

Whereas the responsibility of the European Anti-Fraud Office as established by the Commission extends beyond the protection of financial interests to include all activities by the Office relating to the need to safeguard Community interests against irregular conduct liable to give rise to administrative or criminal proceedings;

Whereas the scope of the fight against fraud should be broadened by exploiting existing expertise in the area of administrative investigations;

Whereas therefore, on the basis of their administrative autonomy, all the institutions, bodies and offices and agencies should entrust to the Office the task of conducting internal administrative investigations with a view to bringing to light serious situations relating to the discharge of professional duties which may constitute a failure to comply with the obligations of officials and servants of the Communities, as referred to in Articles 11, 12, second and third paragraphs, 13, 14, 16

and 17, first paragraph, of the Staff Regulations of the European Communities (hereinafter the Staff Regulations), detrimental to the interests of those Communities and liable to result in disciplinary or, where appropriate, criminal proceedings, or serious misconduct, as referred to in Article 22 of the Staff Regulations, or a failure to comply with the analogous obligations of the members, managers or members of staff of the institutions, bodies, offices and agencies of the Communities not subject to the Staff Regulations;

Whereas such investigations should be carried out under appropriate conditions in all the Community institutions, bodies, offices and agencies; whereas assignment of this task to the Office should not affect the responsibilities of the institutions, bodies, offices or agencies themselves and should in no way reduce the legal protection of the persons concerned;

Whereas, pending the amendment of the Staff Regulations, practical arrangements should be laid down stipulating how the members of the institutions and bodies, the managers of the offices and agencies and the officials and servants of the institutions, bodies and offices and agencies are to cooperate in the smooth operation of the internal investigations;

Whereas Regulation (EC) No 1073/1999 provides in Article 4(6), that each institution, body, office and agency is to adopt a decision, which shall in particular include rules concerning a duty on the part of members, managers, officials and other servants of the institutions, bodies, offices and agencies to cooperate with and supply information to the Office's employees, the procedures to be observed by the Office's employees when conducting internal investigations and guarantees of the rights of persons concerned by an internal investigation;

Whereas, however, account should be taken of the fact that unlike the members of the other institutions, the members of the Committee exercise essentially national functions and that, in the exercise thereof they remain subject to national law; whereas, therefore, the application of this Decision should be limited to the professional activities of such persons undertaken in their capacity as members of the Committee;

⁽¹⁾ OJ L 136, 31.5.1999, p. 20.

⁽²⁾ OJ L 136, 31.5.1999, p. 1.

⁽³⁾ OJ L 136, 31.5.1999, p. 15.

Whereas the Office has no judicial powers and conducts only administrative investigations; whereas such investigations should be conducted in full compliance with the relevant provisions of the Treaties establishing the European Communities, in particular the Protocol on privileges and immunities, the texts implementing them and the Staff Regulations;

Whereas, in the long term, the prevention of fraud, corruption and any other illegal activity should be the responsibility of a body that is not an integral part of the administrative structure of the European Commission, but which enjoys the independence necessary for it to carry out its tasks as effectively as possible;

Considering Decision No 294/99 of the Bureau of the Committee of the Regions of 17 November 1999, relating to the conditions and procedures for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests,

HAS DECIDED AS FOLLOWS:

Article 1

Duty to cooperate with the Office

Without prejudice to the relevant provisions of the Treaties establishing the European Communities, in particular the Protocol on privileges and immunities, the texts implementing them and the provisions of the Staff Regulations, the Secretary-General, the services and any manager, official or servant of the Committee of the Regions (hereinafter the Committee) and the members, shall be required to cooperate with the European Anti-Fraud Office (hereinafter the Office).

Article 2

Duty to supply information

Any official or servant of the General Secretariat who becomes aware of evidence which gives rise to a presumption of the existence of possible cases of fraud, corruption or any other illegal activity detrimental to the interests of the Communities, or of serious situations relating to the discharge of professional duties which may constitute a failure to comply with the obligations of officials or servants of the Communities liable to result in disciplinary or, in appropriate cases, criminal proceedings, or a failure to comply with the obligations imposed by Community law on Members of the Committee in the context of the duties they perform in that capacity, where that failure is detrimental to the interests of the Communities, shall without delay inform his head of service, his director or the Secretary-General, or, if he considers it useful, the Office direct.

The Secretary-General, the directors and the heads of service shall transmit without delay to the Office any evidence of which they are aware from which the existence of irregularities as referred to in the first paragraph may be presumed.

Officials or servants of the General Secretariat must in no way suffer inequitable or discriminatory treatment as a result of having communicated the information referred to in the first and second paragraphs.

Members of the Committee who acquire knowledge of facts as referred to in the first paragraph shall inform the President of the Committee or, if they consider it useful, the Office direct.

Article 3

Assistance from the Security Office

At the request of the Director of the Office, the Security Office of the Committee shall assist the Office in the practical conduct of investigations.

Article 4

Informing the interested party

Where the possible personal implication of a member, manager, official or servant emerges, the interested party shall be informed rapidly provided that this does not jeopardise the investigation. In any event, conclusions referring by name to a member, manager, official or servant of the Committee may not be drawn once the investigation has been completed without the interested party having been enabled to express his views on all the facts which concern him.

In cases necessitating the maintenance of absolute secrecy for the purposes of the investigation and requiring the use of investigative procedures falling within the remit of a national judicial authority, compliance with the obligation to invite the member, manager, official or servant of the Committee to give his views may be deferred in agreement with either the president or the Secretary-General.

Article 5

Information on the closing of the investigation with no further action taken

If, following an internal investigation, no case can be made out against the person against whom allegations have been made, the internal investigation concerning him shall be closed, with no further action taken, by decision of the Director of the Office, who shall inform the interested party in writing.

Article 6

Waiver of immunity

Any request from a national police or judicial authority regarding the waiver of immunity from judicial proceedings of an official or servant of the Committee, concerning possible cases of fraud, corruption or any other illegal activity shall be transmitted to the Director of the Office for his opinion. If a request for a waiver of immunity concerns a member of the Committee, the Office shall be informed.

*Article 7***Final provision**

This Decision cancels Decision No 294/99 of the Bureau of the Committee of the Regions of 17 November 1999, relating to the conditions and procedures for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests.

This Decision shall take effect on 1 March 2004.

Done at Brussels, 10 February 2004.

For the Bureau of the Committee of the Regions

The President

Albert BORE
