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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION
of 27 April 1989
on high-definition television
(89/337/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

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

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

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

Whereas high-definition television (HDTV) is of strategic importance for the European consumer electronics industry and for the European television and film industries;

Whereas a single world standard for the origination and exchange of HDTV programmes and films is urgently required;

Whereas European industry has developed, within the Eureka framework, a suitable proposal for such a single world production standard;

Whereas prototype equipment built to this standard was successfully demonstrated at the International Broadcasting Convention in September 1988 at Brighton;

Whereas 1992 may be set as a target date for the launch of commercial equipment on the market and the beginning of operational HDTV services;

Whereas the success of the launch of commercial HDTV will depend not only on the availability of appropriate hardware but also on the European film and television production industry achieving the necessary capability and experience;

Whereas a substantial promotion campaign needs to be launched immediately to prepare professional users and the general television viewing public for such a launch;

Whereas relevant decision-makers and other concerned parties should also be kept fully aware of developments relating to European HDTV;

Whereas there is an urgent requirement to prepare a strategy and action plan for the launch of Europe-wide HDTV services;

Whereas it is of great importance that all Member States participate in these activities;

Whereas these initiatives should lead to closer cooperation at Community level between industry (the consumer and professional electronics industry and the film and television production industry) and service providers (terrestrial broadcasters, satellite television stations, cable operators and cinema distributors);

Whereas the Treaty does not provide, for the action concerned, powers other than those of Article 235,

HAS DECIDED AS FOLLOWS:

Article 1

The following objectives are hereby adopted as the basis of a comprehensive strategy for the introduction of high-definition television (HDTV) services in Europe:

⁽¹⁾ OJ No C 37, 14. 2. 1989, p. 5.

⁽²⁾ OJ No C 120, 16. 4. 1989.

⁽³⁾ Opinion delivered on 26 April 1989 (not yet published in the Official Journal).

Objective 1

To make every effort to ensure that the European industry develops in time all the technology, components and equipment required for the launching of HDTV services.

Objective 2

To promote the adoption of the European proposal based on the 1 250 lines, 50 complete frames per second progressive scanning parameters, as the single world standard for the origination and exchange of HDTV programme material.

Objective 3

To promote the widest use of the European HDTV system throughout the world.

Objective 4

To promote the introduction, as soon as possible — and in accordance with a suitable timetable from 1992 — of HDTV services in Europe.

Objective 5

To make every effort to ensure that the European film and television production industry achieves the capability, experience and dimension required to occupy a competitive position on the HDTV world market and to allow the Member States to make their own cultural contribution.

Article 2

In order to attain the objectives referred to in Article 1, an action plan for the introduction of HDTV shall be prepared in close coordination at Community level between the Commission and the Member States, where appropriate

through national mechanisms, in consultation, in particular, with:

- terrestrial broadcasters,
- satellite television broadcasters and distributors,
- cable operators,
- professional and consumer electronics equipment manufacturers,
- the television and film production industry,
- audiovisual and higher education technological institutes,
- consumer organizations,

throughout the Community, and throughout Europe as a whole, in close coordination on a complementary basis with the Eureka HDTV project participants and coordinators.

Article 3

On the basis of the results of the consultations referred to in Article 2 and on a proposal from the Commission, the Council shall examine an action plan for the introduction of HDTV services. This action plan should also include mechanisms allowing European third countries to participate.

Done at Luxembourg, 27 April 1989.

For the Council

The President

J. BARRIONUEVO PEÑA

COUNCIL DIRECTIVE

of 27 April 1989

amending Directive 85/3/EEC on the weights, dimensions and certain other technical characteristics of certain road vehicles

(89/338/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

Having regard to the Treaty establishing the European Economic Community, and in particular Article 75 thereof,

Article 1

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

Directive 85/3/EEC is hereby amended as follows:

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

1. Article 1 (1) (a) is replaced by the following:

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

'(a) the dimensions of vehicles with at least four wheels and a maximum speed in excess of 25 kilometres per hour, intended to be used on the road for:

Whereas Directive 85/3/EEC ⁽⁴⁾, as last amended by Directive 88/218/EEC ⁽⁵⁾, lays down certain weights and dimensions and other technical characteristics for certain road vehicles intended for the carriage of goods;

— either the carriage of goods where their maximum laden weight is greater than 3,5 tonnes,

— or passenger transport where they have more than nine seats, including the driver's seat;'

Whereas certain weights and dimensions should also be fixed for other vehicles, including vehicles used for passenger transport, namely motor vehicles with two, three and four axles, including articulated buses, and combined vehicles with four axles;

2. Article 2 is replaced by the following:

Article 2

For the purposes of this Directive:

Whereas account must be taken of the equipment of the vehicle (twin tyres and air suspension or suspension recognized as being equivalent within the Community) in order to establish the maximum authorized weights for motor vehicles with three and four axles and for the tandem axles of motor vehicles;

— "motor vehicle" shall mean any power-driven vehicle which travels on the road by its own means,

— "trailer" shall mean any vehicle intended to be coupled to a motor vehicle excluding semi-trailers, and constructed and equipped for the carriage of goods,

— "semi-trailer" shall mean any vehicle intended to be coupled to a motor vehicle in such a way that part of it rests on the motor vehicle with a substantial part of its weight and of the weight of its load being borne by the motor vehicle, and constructed and equipped for the carriage of goods,

— "combined vehicle" shall mean either:

— a road train consisting of a motor vehicle coupled to a trailer, or

— an articulated vehicle consisting of a motor vehicle coupled to a semi-trailer,

— "thick-walled refrigerated vehicle" shall mean any vehicle whose fixed or movable superstructures are specially equipped for the carriage of goods at controlled temperatures in accordance with classes B,

⁽¹⁾ OJ No C 90, 11. 9. 1971, p. 25; OJ No C 16, 18. 1. 1979, p. 3; OJ No C 173, 2. 7. 1988, p. 12.

⁽²⁾ OJ No C 124, 17. 12. 1971, p. 63; OJ No C 144, 15. 6. 1981, p. 80; OJ No C 187, 18. 7. 1988, p. 209.

⁽³⁾ OJ No C 61, 10. 6. 1972, p. 5; OJ No C 113, 7. 5. 1980, p. 14; OJ No C 208, 8. 8. 1988, p. 56.

⁽⁴⁾ OJ No L 2, 3. 1. 1985, p. 14.

⁽⁵⁾ OJ No L 98, 15. 4. 1988, p. 48.

C, E and F of the Agreement of 1 September 1970 on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be used for such Carriage (ATP) and whose side walls, inclusive of insulation, are each at least 45 millimetres thick,

- "bus" shall mean a vehicle with more than nine seats including the driver's seat, and constructed and equipped to carry passengers and their luggage. It may have one or two decks and may also draw a luggage trailer,
- "articulated bus" shall mean a bus consisting of two rigid sections connected to each other by an articulated section. On this type of vehicle the passenger compartments in each of the two rigid sections shall be intercommunicating. The articulated section shall permit the free movement of travellers between the rigid sections. Connection and disconnection of the two sections shall be possible only in a workshop,
- "maximum authorized dimensions" shall mean the maximum dimensions at which a vehicle is authorized for use in international traffic under this Directive by the competent authority of the State in which the vehicle is registered or put into circulation,
- "maximum authorized weight" shall mean the maximum weight at which a laden vehicle is authorized for use in international traffic under this Directive by the competent authority of the State in which the vehicle is registered or put into circulation,
- "maximum authorized axle weight" shall mean the maximum weight at which a laden axle or group of axles is authorized for use in international traffic under this Directive by the competent authority of the State in which the vehicle is registered or put into circulation.'

3. Article 7 is replaced by the following:

Article 7

After consulting the Commission, Member States shall take the measures necessary to comply with this Directive:

- as from 1 July 1986 as regards application of provisions of the Directive other than those referred to in the following indents.
- no later than 1 January 1989 as regards the application of section 1.2 (b) of Annex I,
- as from 1 January 1990 as regards the application of Article 4 and Annex II,
- as from 1 July 1991 as regards the application of section 1 of Annex I concerning vehicles intended for passenger transport,

- as from 1 January 1992 as regards the application of section 3.4.1 of Annex I,
- as from 1 January 1993 as regards the application of sections 2.2.3, 2.2.4, 2.3, 2.4, 3.4.2, 3.5 and 4.3 of Annex I.

Member States shall inform the Commission of the measures which they take for the purposes of implementing this Directive.'

4. Article 8 is amended as follows:

- in paragraph 1, the first subparagraph shall be replaced by the following:

'1. The provisions of Article 3 as regards the standards referred to in sections 2.2.1, 2.2.2 and 3.3.2 of Annex I shall temporarily not apply to Ireland and the United Kingdom.'

- paragraph 3 is replaced by the following:

'3. The provisions of Article 3 as regards the standard referred to in section 3.4.1 of Annex I shall temporarily not apply to Ireland and the United Kingdom.

However, these two Member States shall apply Article 3 to the combined vehicles referred to in sections 2.2.1 and 2.2.2 of Annex I where the weight per driving axle does not exceed 10,5 tonnes.'

- the following paragraphs are added:

'5. The provisions of Article 3 as regards the standards referred to in sections 2.2.3, 2.2.4, 2.3.1, 2.3.3, 2.4 and 3.4.2 of Annex I shall temporarily not apply to Ireland and the United Kingdom.

However, these two Member States shall apply Article 3 to the vehicles referred to in sections 2.2.3, 2.2.4, 2.3 and 2.4 of Annex I where:

- (a) the weight per driving axle does not exceed 10,5 tonnes and
- (b) the total laden weight does not exceed:
 - 35 tonnes for the vehicles referred to in sections 2.2.3 and 2.2.4,
 - 17 tonnes for the vehicles referred to in section 2.3.1,
 - 30 tonnes for the vehicles referred to in section 2.3.3, under the conditions specified in that section and in section 4.3,
 - 27 tonnes for the vehicles referred to in section 2.4.

6. The Commission shall submit to the Council, within one month of the adoption of this Directive, a proposal based on it concerning the date on which the derogation referred to in paragraph 5 shall expire.

The Council shall act by a qualified majority on that proposal before 1 July 1989.'

5. Annex I is amended as follows:

(a) the following indent is added to section 1.1:

— articulated bus 18,00 m';

(b) the following subsections are added to section 2.2:

2.2.3. Road trains with four axles consisting of a two-axle motor vehicle and a two-axle trailer 36 tonnes

2.2.4. Articulated vehicles with four axles consisting of a two-axle motor vehicle and a two-axle semi-trailer, if the distance between the axles of the semi-trailer:

2.2.4.1. is 1,3 m or greater but not more than 1,8 m 36 tonnes

2.2.4.2. is greater than 1,8 m 36 tonnes
+ 2 tonnes of

margin when the MAW of the motor vehicle (18 tonnes) and the MAW of the tandem axle of the semi-trailer (20 tonnes) are respected and the driving axle is fitted with twin tyres and air suspension or suspension recognized as being equivalent within the Community.';

(c) the following sections are added:

2.3. *Motor vehicles*

2.3.1. Two-axle motor vehicles 18 tonnes

2.3.2. Three-axle motor vehicles — 25 tonnes
— 26 tonnes where the driving axle is fitted with twin tyres and air suspension or suspension recognized as being equivalent within the Community

2.3.3. Four-axle motor vehicles with two steering axles 32 tonnes where the driving axle is fitted with twin tyres and air suspension or suspension recognized as being equivalent within the Community

2.4. Three-axle articulated buses 28 tonnes.';

(d) Section 3 is amended as follows:

— Section 3.4 is subdivided thus:

3.4. *Driving axle*

i6:

3.4.1. Driving axle of the vehicles referred to in sections 2.2.1 and 2.2.2 11,5 tonnes

3.4.2. Driving axle of the vehicles referred to in sections 2.2.3, 2.2.4, 2.3 and 2.4 11,5 tonnes',

— the following section is added:

3.5. *Tandem axles of motor vehicles.*

The sum of the axle weights per tandem axle must not exceed, if the distance (d) between the axles is:

3.5.1. less than 1 m ($d < 1,0$ m) 11,5 tonnes

- 3.5.2. 1,0 m or greater but less than 1,3 m
(1,0 m $\leq$ d < 1,3 m) 16 tonnes
- 3.5.3. 1,3 m or greater but less than 1,8 m
(1,3 m $\leq$ d < 1,8 m)
- 18 tonnes
 - 19 tonnes where the driving axle is fitted with twin tyres and air suspension or suspension recognized as being equivalent within the Community';
- (e) The following is added to section 4:
- 4.3. *Maximum authorized weight depending on the wheelbase.*
- The maximum authorized weight in tonnes of a four-axle motor vehicle may not exceed five times the distance in metres between the axes of the foremost and rearmost axles of the vehicle.'

Article 2

This Directive is addressed to the Member States.

Done at Luxembourg, 27 April 1989.

For the Council
The President
J. BARRIONUEVO PEÑA

COUNCIL DECISION

of 3 May 1989

accepting on behalf of the Community the recommendation of 5 June 1962 of the Customs Cooperation Council concerning the customs treatment of registered baggage carried by rail as amended on 21 June 1988

(89/339/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS DECIDED AS FOLLOWS:

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

Having regard to the proposal from the Commission,

Whereas on 21 June 1988 the Customs Cooperation Council adopted amendments to the recommendation of 5 June 1962, introducing a new specimen customs declaration form for registered baggage and permitting customs or economic unions to accept the recommendation;

Whereas the new specimen customs declaration form for registered baggage was approved by the Customs Cooperation Council on a proposal from the Community; whereas that specimen form corresponds to the draft submitted by the Community and is designed to update the content of the customs declaration for registered baggage and to facilitate the introduction of that document by countries which hitherto were unable to use it;

Whereas the amendment is of fundamental interest to the Community which should therefore adopt the recommendation of 5 June 1962, as amended,

Article 1

The recommendation of 5 June 1962 of the Customs Cooperation Council concerning the customs treatment of registered baggage carried by rail, as amended on 21 June 1988, is hereby accepted on behalf of the Community with immediate effect.

The text of the recommendation is attached to this Decision.

Article 2

The President of the Council is hereby authorized to designate the person empowered to notify the Secretary-General of the Customs Cooperation Council of the acceptance by the Community of the recommendation referred to in Article 1.

Done at Brussels, 3 May 1989.

*For the Council**The President*

P. SOLBES

RECOMMENDATION OF THE CUSTOMS COOPERATION COUNCIL

of 5 June 1962

concerning the customs treatment of registered baggage carried by rail

(amended on 21 June 1988)

THE CUSTOMS COOPERATION COUNCIL,

CONSIDERING that the efforts made by the railway authorities to ensure efficiency in the international transport of registered baggage deserve to be supported,

DESIRING, to that end, to facilitate the expeditious handling of such baggage by simplifying customs formalities,

CONSIDERING that, in so far as possible, passengers should not be required to report in person to the customs authorities of the countries of departure and destination for the clearance of their registered baggage, and should be able to claim their baggage immediately on arrival at their destination,

RECOMMENDS that Members of the Council and customs or economic unions, apply the following provisions with regard to registered baggage:

1. When having their baggage registered by the railway authorities, passengers shall have the possibility of making a declaration on the appended form in order to expedite customs formalities;
2. The form shall be printed either on the back of the consignment note made out by the railway authorities or on a separate sheet to be glued to the consignment note; it shall be printed in the language (or one of the official languages) of the country of departure, but the passenger

shall be given the opportunity to obtain a translation in another language;

3. The declaration shall be presented by the railway authorities to the customs authorities of the countries of departure and destination where so required;
4. The written declaration shall be regarded as being in substitution for, and shall have the same effect as, the declaration normally required from passengers;
5. The customs authorities shall, so far as they deem it possible, waive the examination of the contents of baggage covered by a written declaration;
6. Where the customs authorities waive examination of the contents of baggage, it shall be released immediately to the railway authorities for forwarding to destination;
7. The customs authorities remain free to adopt any control measures they deem necessary in order to prevent abuses,

NOTWITHSTANDING the provisions of paragraph 1 above, the declaration form may be adapted where appropriate by agreement between customs administrations,

THE COUNCIL invites Members and customs or economic unions which accept the present recommendation to notify the Secretary-General of the Council and specify the date and the terms of its implementation. The Secretary-General will communicate this information to Members' customs administrations, to customs or economic unions and to the International Union of Railways.

Annex

CUSTOMS DECLARATION FOR REGISTERED BAGGAGE

1. I HEREBY DECLARE

- (a) that the baggage referred to below contains only articles of personal use normally used when travelling, such as clothing, household linen, toiletries, books and sports equipment, and that these articles are not being imported for commercial purposes;
- (b) that the baggage does not contain:
- foodstuffs, tobacco, alcoholic beverages, anethol, firearms, sidearms, ammunition, explosives, drugs, live animals, plants, radio transmitters or transmitter-receivers, currency, species and products obtained from species protected under the Washington Convention of 3 March 1973 on International Trade in Endangered Species of Wild Flora and Fauna; articles forbidden by the laws of the country of destination on the protection of public decency and morality,
 - goods intended for distribution free of charge or otherwise or for professional or commercial purposes,
 - goods bought or received by myself outside the customs territory of my country and not yet declared to the customs authorities of my country of normal residence (this restriction applies only when returning to the country of normal residence).

2. I HEREBY AUTHORIZE the railway authorities to carry out all customs formalities.

3. I KNOW that making a false statement renders me liable to prosecution and seizure of my goods.

Country of destination: Place of destination:

Number of items

Number of persons accompanying the passenger

IN BLOCK LETTERS

SURNAME:

OTHER NAMES:

.....

Normal residence: Street: No:

Town: Country:

Signature of passenger:

Date-stamp of
departure station

Consignment Note No

COUNCIL DECISION

of 3 May 1989

concerning work for third parties performed by the Joint Research Centre relevant to the European Economic Community

(89/340/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

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

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

Whereas in the fulfilment of the overall objectives of the Community relating to research and technological development it is desirable to enable the Joint Research Centre (JRC) to perform work for third parties, both public and private;

Whereas, in its resolution 88/C 197/03 ⁽³⁾, the Council considered that the JRC should, in addition to its predominant task for the period 1988 to 1991 of executing specific programmes, including preparatory research, nevertheless utilize the facilities and manpower at its disposal to strengthen and develop its work for third parties in those areas in which it is competent to do so;

Whereas, in the context of the conclusion of contracts with third parties, the JRC may be led to subscribe to clauses limiting the dissemination of the results of the research involved, under the conditions laid down by the Director-General in cooperation with the board of governors and ensuring in particular that the Community's scientific and financial interests are protected;

Whereas the Treaty does not provide, for the action concerned, powers other than those of Article 235,

HAS DECIDED AS FOLLOWS:

Article 1

For the purpose of fulfilling the overall objectives of the Community relating to research and technological development, the Commission may place the installations, equipment or expert assistance of the Joint Research Centre at the disposal of third parties whether public or private, as appropriate, against payment.

Article 2

This Decision shall be published in the *Official Journal of the European Communities*. It shall enter into effect on the day following its publication.

Done at Brussels, 3 May 1989.

For the Council
The President
P. SOLBES

⁽¹⁾ OJ No C 13, 17. 1. 1989, p. 6.

⁽²⁾ OJ No C 120, 16. 5. 1989.

⁽³⁾ OJ No C 197, 27. 7. 1988, p. 4.

COUNCIL DIRECTIVE

of 3 May 1989

amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

(89/341/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

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

In cooperation with the European Parliament ⁽²⁾,

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

Whereas the essential aim of any rules governing the production, distribution or use of medicinal products must be to safeguard public health;

Whereas the Directives on the approximation of the laws relating to proprietary medicinal products must be adapted to scientific progress and take account of the experience obtained since their adoption so as to ensure improved quality and greater safety and efficacy;

Whereas, in its conclusions of 15 May 1987 on improvement in the use of proprietary medicinal products by consumers ⁽⁴⁾, the Council considered that the system for leaflets accompanying proprietary medicinal products, for human consumption, on the market in the Community should be improved;

Whereas the guarantees of the quality of medicinal products manufactured within the Community should be maintained by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the products;

Whereas the Commission should be empowered to define in detail the principles of good manufacturing practice for medicinal products in close cooperation with the Committee for Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers in the Proprietary Medicinal Products Sector;

Whereas, having regard to the resolution of the European Parliament of 13 June 1986 on the export of pharmaceutical

products to the Third World, measures should be taken to improve the provision of information for third countries on the conditions of use of medicinal products within the Member States;

Whereas the scope of Directive 65/65/EEC ⁽⁵⁾, as last amended by Directive 87/21/EEC ⁽⁶⁾, of Directive 75/318/EEC ⁽⁷⁾, as last amended by Directive 87/19/EEC ⁽⁸⁾, and of Second Directive 75/319/EEC ⁽⁹⁾, as last amended by Directive 83/570/EEC ⁽¹⁰⁾, should be extended to cover other industrially produced medicinal products hitherto excluded,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 65/65/EEC is hereby amended as follows:

1. In the title, preamble and Chapters II to V, all references to 'proprietary medicinal product' are replaced by 'medicinal product'.

2. In Article 1, the following points are inserted:

4. *Magistral formula:*

Any medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient.

5. *Official formula:*

Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question.'

3. Article 2 is replaced by the following:

'Article 2

1. Chapters II to V shall apply to proprietary medicinal products for human use intended to be placed on the market in Member States.

⁽¹⁾ OJ No C 36, 8. 2. 1988, p. 22.

⁽²⁾ OJ No C 290, 14. 11. 1988, p. 128; OJ No C 120, 16. 5. 1989.

⁽³⁾ OJ No C 208, 8. 8. 1988, p. 64.

⁽⁴⁾ OJ No C 178, 7. 7. 1987, p. 2.

⁽⁵⁾ OJ No 22, 9. 2. 1965, p. 369/65.

⁽⁶⁾ OJ No L 15, 17. 1. 1987, p. 36.

⁽⁷⁾ OJ No L 147, 9. 6. 1975, p. 1.

⁽⁸⁾ OJ No L 15, 17. 1. 1987, p. 31.

⁽⁹⁾ OJ No L 147, 9. 6. 1975, p. 13.

⁽¹⁰⁾ OJ No L 332, 28. 11. 1983, p. 1.

2. Where a Member State authorizes the placing on the market of industrially produced medicinal products which do not comply with the definition of a proprietary medicinal product, it shall also apply Chapters II to V to them.
3. Chapters II to V shall not apply to:
 - medicinal products prepared on the basis of a magistral or official formula,
 - medicinal products intended for research and development trials,
 - intermediate products intended for further processing by an authorized manufacturer.
4. A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from Chapters II to V medicinal products supplied in response to a *bona fide* unsolicited order, formulated in accordance with the specifications of an authorized health care professional and for use by his individual patients on his direct personal responsibility.
4. In Article 4a, the following point is added:

'6.6. special precautions for disposal of unused products or waste materials derived from such products, if appropriate.'
5. In Article 13, the following point is added:

'9. special precautions for disposal of unused products or waste materials derived from such products, if appropriate.'
6. In Article 14, the following fifth indent is added:

— manufacturer's batch number.'

Article 2

In Directive 75/318/EEC all references to 'proprietary medicinal product' or to 'proprietary product' are replaced by 'medicinal product'.

Article 3

Directive 75/319/EEC is hereby amended as follows:

1. In Article 4, (b) is replaced by the following:

'(b) may submit the medicinal product, its starting materials and, if need be, its intermediate products or other constituent materials for testing by a State laboratory or by a laboratory designated for that purpose in order to ensure that the control methods employed by the

manufacturer and described in the particulars accompanying the application in accordance with the second subparagraph of point 7 of Article 4 of Directive 65/65/EEC are satisfactory.'

2. In Article 6, the last subparagraph is replaced by the following:

'The inclusion of a package leaflet in the packaging of medicinal products shall be obligatory unless all the information required by this Article is directly conveyed on the container itself and the outer packaging.'

3. Article 16, (1) is replaced by the following:

'1. Member States shall take all appropriate measures to ensure that the manufacture of medicinal products is subject to the holding of an authorization. This manufacturing authorization shall be required notwithstanding that the medicinal products manufactured are intended for export.'

4. In Article 19, the following point is added:

'(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products as laid down by Community law.'

5. The following Article is inserted:

'Article 19a

The principles and guidelines of good manufacturing practices for medicinal products referred to in Article 19 (f) shall be adopted in the form of a directive addressed to the Member States, in accordance with the procedure laid down in Article 2c of Directive 75/318/EEC. Detailed guidelines in line with those principles will be published by the Commission and revised as necessary to take account of technical and scientific progress.'

6. In Article 26:

- the first subparagraph is replaced by the following:

'The competent authority of the Member State concerned shall ensure, by means of repeated inspections, that the legal requirements governing medicinal products are complied with.'

- the following subparagraph is inserted:

'After every inspection as referred to in the first subparagraph, the officials representing the competent authority shall report on whether the manufacturer complies with the principles and guidelines of good manufacturing practice laid down by Community law. The content of such reports shall be communicated to the manufacturer who has to undergo the inspection.'

7. The following Article is inserted:

'Article 28a

At the request of the manufacturer, the exporter or the authorities of an importing third country, Member

States shall certify that a manufacturer of medicinal products is in possession of the authorization referred to in Article 16 (1). When issuing such certificates they shall comply with the following conditions:

1. Member States shall have regard to the prevailing administrative arrangements of the World Health Organization.
2. For medicinal products intended for export which are already authorized on their territory, they shall supply the summary of the product characteristics as approved in accordance with Article 4 (b) of Directive 65/65/EEC.
3. When the manufacturer is not in possession of a marketing authorization he shall provide the authorities responsible for establishing the certificate referred to above with a declaration explaining why no marketing authorization is available.'

8. In Article 30, the following subparagraph is added:

'Upon reasoned request, Member States shall forthwith communicate the reports referred to in the third subparagraph of Article 26 to the competent authorities of another Member State. If, after considering the reports, the Member State receiving the reports considers that it cannot accept the conclusions reached by the competent authorities of the Member State in which the report was established, it shall inform the competent authorities concerned of its reasons and may request further information. The Member States concerned shall use their best endeavours to reach agreement. If necessary, in the case of serious differences of opinion, the Commission shall be informed by one of the Member States concerned.'

9. The following paragraphs are added to Article 33:

'2. The person responsible for the marketing of a medicinal product shall be obliged to notify the Member States concerned forthwith of any action taken by him to suspend the marketing of a product or to withdraw a product from the market, together with the reasons for such action if the latter concerns the efficacy of the medicinal product or the protection of public health. Member States shall ensure that this

information is brought to the attention of the committee.

3. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 which may affect the protection of public health in third countries is forthwith brought to the attention of the World Health Organization, with a copy to the committee.

4. The Commission shall publish annually a list of the medicinal products which are prohibited in the Community.'

10. The first paragraph of Article 34 is hereby amended as follows:

'This Directive shall apply to medicinal products for human use within the limits referred to in Article 2 of Directive 65/65/EEC.'

Article 4

1. Member States shall take the measures necessary to comply with this Directive before 1 January 1992. They shall forthwith inform the Commission thereof.

2. Requests for marketing authorizations lodged after the time limit referred to in paragraph 1 must comply with this Directive.

3. Articles 1, 2 and 3, where relevant, shall be progressively extended to existing medicinal products before 31 December 1992.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council
The President
P. SOLBES

COUNCIL DIRECTIVE

of 3 May 1989

extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens

(89/342/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

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

In cooperation with the European Parliament ⁽²⁾,

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

Whereas disparities in the provisions laid down by law, regulation or administrative action by Member States may hinder trade in immunological products within the Community;

Whereas the essential aim of any rules governing the production, distribution or use of medicinal products must be to safeguard public health;

Whereas Directive 65/65/EEC ⁽⁴⁾, as last amended by Directive 87/21/EEC ⁽⁵⁾, and Second Directive 75/319/EEC ⁽⁶⁾, as last amended by Directive 83/570/EEC ⁽⁷⁾, on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, although appropriate, are inadequate for immunological medicinal products consisting of vaccines, toxins or serums and allergens;

Whereas, in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology ⁽⁸⁾, the Commission is required to submit proposals to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of immunological medicinal products before 22 December 1987;

Whereas, before an authorization to market an immunological product can be granted, the manufacturer must demonstrate his ability to attain batch-to-batch consistency;

Whereas the Commission should be empowered to adopt any necessary changes in the requirements for the testing of proprietary medicinal products set out in the Annex to Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products ⁽⁹⁾, as last amended by Directive 87/19/EEC ⁽¹⁰⁾, to take account of the special nature of immunological medicinal products in close cooperation with the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector, thus ensuring greater quality, safety and efficacy,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. In derogation from Article 34 of Directive 75/319/EEC, and subject to the provisions of this Directive, Directives 65/65/EEC and 75/319/EEC shall apply to immunological medicinal products for human use consisting of vaccines, toxins or serums and allergen products.

2. For the purposes of this Directive, the following definitions shall apply:

- 'allergen product' shall mean any product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent,
- vaccines, toxins and serums shall have the meaning assigned to them in the Annex to Directive 75/319/EEC.

Article 2

1. The quantitative particulars of an immunological medicinal product shall be expressed by mass or by international units or by units of biological activity or by specific protein content, where possible, as appropriate to the product concerned.

⁽¹⁾ OJ No C 36, 8. 2. 1988, p. 25.

⁽²⁾ OJ No C 290, 14. 11. 1988, p. 131; OJ No C 120, 16. 5. 1989.

⁽³⁾ OJ No C 208, 8. 8. 1988, p. 64.

⁽⁴⁾ OJ No 22, 9. 2. 1965, p. 369/65.

⁽⁵⁾ OJ No L 15, 17. 1. 1987, p. 36.

⁽⁶⁾ OJ No L 147, 9. 6. 1975, p. 13.

⁽⁷⁾ OJ No L 332, 28. 11. 1983, p. 1.

⁽⁸⁾ OJ No L 15, 17. 1. 1987, p. 38.

⁽⁹⁾ OJ No L 147, 9. 6. 1975, p. 1.

⁽¹⁰⁾ OJ No L 15, 17. 1. 1987, p. 31.

2. In respect of immunological products in Directives 65/65/EEC and 75/319/EEC the expressions 'qualitative and quantitative particulars of the constituents' shall also include particulars relating to biological activity or to protein content and 'qualitative and quantitative composition' shall include the composition of the product expressed in terms of biological activity or of protein content.

3. Whenever the name of an immunological medicinal product is expressed, the common or scientific name of the active constituents shall also be included.

Article 3

In addition to the information referred to in Article 4a of Directive 65/65/EEC the summary of product characteristics referred to in point 9 of the second subparagraph of Article 4 of Directive 65/65/EEC shall contain the following information in respect of immunological products:

- under point 5.4, information regarding any special precautions to be taken by persons handling the immunological medicinal product and persons administering it to patients, together with any precautions to be taken by the patient.

Article 4

1. Member States shall take all appropriate steps to ensure that the manufacturing processes used in the manufacture of immunological products are properly validated and attain batch-to-batch consistency.

2. For the purpose of implementing Article 8 of Directive 65/65/EEC and Article 27 of Directive 75/319/EEC, Member States may require manufacturers of immunological products to submit to a competent authority copies of all the control reports signed by the qualified person in accordance with Article 22 of Directive 75/319/EEC.

3. Where it considers it necessary in the interests of public health, a Member State may require persons responsible for marketing:

- live vaccines,
- immunological medicinal products used in the primary immunization of infants or of other groups at risk,
- immunological medicinal products used in public health immunization programmes,
- new immunological medicinal products or immunological medicinal products manufactured using

new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorization,

to submit samples from each batch of the bulk and/or finished product for examination by a State laboratory or a laboratory designated for that purpose before release on to the market unless, in the case of a batch manufactured in another Member State, the competent authority of another Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.

Article 5

Any amendments which are necessary in the testing requirements for medicinal products set out in the Annex to Directive 75/318/EEC to take account of the extension of the scope of Directives 65/65/EEC and 75/319/EEC to cover immunological medicinal products shall be adopted in accordance with the procedure laid down in Article 2c of Directive 75/318/EEC.

Article 6

1. Except as provided in paragraph 2, Member States shall take the necessary measures to comply with this Directive not later than 1 January 1992. They shall forthwith inform the Commission thereof.

2. If the amendments to Directive 75/318/EEC referred to in Article 5 have not been adopted by the date referred to in paragraph 1, this Directive shall come into force on the same date as those amendments.

3. Requests for marketing authorizations for products covered by this Directive lodged after the date on which it comes into force must comply with the provisions of this Directive.

4. This Directive shall be progressively extended to existing immunological medicinal products before 31 December 1992.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council
The President
P. SOLBES

COUNCIL DIRECTIVE

of 3 May 1989

extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for radiopharmaceuticals

(89/343/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

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

In cooperation with the European Parliament ⁽²⁾,

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

Whereas disparities in the provisions currently laid down by law, regulation or administrative action by Member States may hinder trade in radiopharmaceuticals within the Community;

Whereas the essential aim of any rules governing the production, distribution or use of medicinal products must be to safeguard public health;

Whereas the provisions laid down by Directive 65/65/EEC ⁽⁴⁾, as last amended by Directive 87/21/EEC ⁽⁵⁾, and by Second Directive 75/319/EEC ⁽⁶⁾, as last amended by Directive 83/570/EEC ⁽⁷⁾, on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, although appropriate, are inadequate for radiopharmaceuticals;

Whereas, in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national provisions relating to the placing on the market of high technology medicinal products, particularly those derived from biotechnology ⁽⁸⁾, the Commission is required to submit proposals to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of radiopharmaceuticals before 22 December 1987;

Whereas, in the case of radiopharmaceuticals, generators, kits and precursors, authorization should be required;

whereas, however, a specific authorization should not be required for radiopharmaceuticals in their finished form which are made up exclusively from authorized kits, generators or precursor radiopharmaceuticals in health care establishments;

Whereas the Commission should be empowered to adopt any necessary changes in the requirements for the testing of proprietary medicinal products set out in the Annex to Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products ⁽⁹⁾, as last amended by Directive 87/19/EEC ⁽¹⁰⁾, to take account of the special nature of radiopharmaceuticals in close cooperation with the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector, thus ensuring the greater quality, safety and efficacy of the medicinal products;

Whereas any rules governing radiopharmaceuticals must take into account the provisions of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment ⁽¹¹⁾; whereas account should also be taken of Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation ⁽¹²⁾, as last amended by Directive 84/467/Euratom ⁽¹³⁾, the objective of which is to prevent the exposure of workers or patients to excessive or unnecessarily high levels of ionizing radiation, and in particular of Article 5c thereof, which requires prior authorization for the addition of radioactive substances to medicinal products as well as for the importation of such medicinal products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. In derogation from Article 34 of Directive 75/319/EEC, and subject to the provisions of this Directive,

⁽¹⁾ OJ No C 36, 8. 2. 1988, p. 30.

⁽²⁾ OJ No C 290, 14. 11. 1988, p. 136; OJ No C 120, 16. 5. 1989.

⁽³⁾ OJ No C 208, 8. 8. 1988, p. 64.

⁽⁴⁾ OJ No 22, 9. 2. 1965, p. 369/65.

⁽⁵⁾ OJ No L 15, 17. 1. 1987, p. 36.

⁽⁶⁾ OJ No L 147, 9. 6. 1975, p. 13.

⁽⁷⁾ OJ No L 332, 28. 11. 1983, p. 1.

⁽⁸⁾ OJ No L 15, 17. 1. 1987, p. 38.

⁽⁹⁾ OJ No L 147, 9. 6. 1975, p. 1.

⁽¹⁰⁾ OJ No L 15, 17. 1. 1987, p. 31.

⁽¹¹⁾ OJ No L 265, 5. 10. 1984, p. 1.

⁽¹²⁾ OJ No L 246, 17. 9. 1980, p. 1.

⁽¹³⁾ OJ No L 265, 5. 10. 1984, p. 4.

the provisions of Directives 65/65/EEC and 75/319/EEC shall apply to radiopharmaceuticals for human use, excluding radionuclides in the form of sealed sources.

2. For the purposes of this Directive, the following definitions apply:

- 'radiopharmaceutical' shall mean any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose,
- 'generator' shall mean any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and used in a radiopharmaceutical,
- 'kit' shall mean any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration,
- 'precursor' shall mean any other radionuclide produced for the radio-labelling of another substance prior to administration.

3. Nothing in this Directive shall in any way derogate from the Community rules for the radiation protection of persons undergoing medical examination or treatment or from the Community rules laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation.

Article 2

The authorization referred to in Article 3 of Directive 65/65/EEC shall be required for generators, kits, precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals. However, authorization shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorized, according to national legislation, to use such medicinal products in an approved health care establishment exclusively from authorized generators, kits or precursor radiopharmaceuticals in accordance with the manufacturer's instructions.

Article 3

In addition to the requirements set out in Article 4 of Directive 65/65/EEC, an application for authorization to market a generator shall also contain the following information and particulars:

- a general description of the system together with a detailed description of the components of the system which may effect the composition or quality of the daughter nucleid preparation,

- qualitative and quantitative particulars of the eluate or the sublimate.

Article 4

For radiopharmaceuticals, in addition to the information referred to in Article 4a of Directive 65/65/EEC, the summary of product characteristics referred to in point 9 of the second paragraph of Article 4 of Directive 65/65/EEC shall contain the following additional points 7 and 8:

7. Full details of internal radiation dosimetry.
8. Additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready to use pharmaceutical will conform with its specifications.

Article 5

The outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the following provisions:

- (a) The label on the shielding shall include the particulars mentioned in Article 13 of Directive 65/65/EEC. In addition, the labelling on the shielding shall explain in full the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container;
- (b) The vial shall be labelled with the following information:
 - the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;
 - the batch identification and expiry date,
 - the international symbol for radioactivity,
 - the name of the manufacturer,
 - the amount of radioactivity as specified under (a).

Article 6

1. Member States shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, generators, kits or precursor radiopharmaceuticals. The text of this leaflet shall be established in accordance with the provisions of Article 6 of Directive 75/319/EEC and shall contain all the information referred to therein. In addition, the leaflet shall include any precautions to be taken by the user and the patient during the

preparation and administration of the product and special precautions for the disposal of the container and its unused contents.

2. Without prejudice to Article 8 of Directive 65/65/EEC and Article 6 of Directive 75/319/EEC, Member States shall permit the use of user information leaflets which have been established in more than one of the languages of the Community provided that the information contained in all the language versions of the leaflet is identical.

Article 7

Any amendments which are necessary in the testing requirements for medicinal products set out in the Annex to Directive 75/318/EEC to take account of the extension of the scope of Directives 65/65/EEC and 75/319/EEC to cover radiopharmaceuticals shall be adopted in accordance with the procedure laid down in Article 2c of Directive 75/318/EEC.

Article 8

1. Save in the case provided for in paragraph 2, Member States shall take the necessary measures to comply with this

Directive not later than 1 January 1992. They shall forthwith inform the Commission thereof.

2. If the amendments to Directive 75/318/EEC referred to in Article 7 have not been adopted by the date referred to in paragraph 1, this Directive shall come into force on the same date as those amendments.

3. Requests for marketing authorization for products covered by this Directive lodged after the date of entry into force must comply with the provisions of this Directive.

4. This Directive shall be progressively extended to existing radiopharmaceutical medicinal products covered by this Directive before 31 December 1992.

Article 9

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council

The President

P. SOLBES

COUNCIL DIRECTIVE

of 3 May 1989

amending, for the ninth time, Directive 73/241/EEC on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption

(89/344/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament ⁽¹⁾,

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

Whereas the Act of Accession of Spain and Portugal authorized the Kingdom of Spain to continue to place on its internal market, until 31 December 1987, products of the type 'familiar a la taza' and 'a la taza' under the name of chocolate;

Whereas Directive 73/241/EEC ⁽³⁾, as last amended by the Act of Accession, did not define in Annex I chocolate of this type containing flours and/or starches and intended for consumption after cooking;

Whereas the situation could lead to the prohibition of the sale of this product, which would be undesirable; whereas Directive 73/241/EEC should therefore be amended,

Article 1

The following is added to Article 14 (2) of Directive 73/241/EEC:

'(g) authorizing the marketing under the name of "chocolate familiar a la taza" and "chocolate a la taza" of chocolate containing flours and/or starches and intended for consumption with milk after cooking, not defined in Annex I;'

Article 2

With effect from 1 January 1988, Member States shall, where necessary, amend their national legislation in order to comply with this Directive. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council

The President

P. SOLBES

⁽¹⁾ OJ No C 290, 14. 11. 1988, p. 137; OJ No C 96, 17. 4. 1989.

⁽²⁾ OJ No C 80, 28. 3. 1988, p. 4.

⁽³⁾ OJ No L 228, 16. 8. 1973, p. 23.

COUNCIL DECISION

of 3 May 1989

authorizing the Member States to accept an amendment to the Customs Convention on the ATA Carnet for the Temporary Admission of Goods (ATA Convention)

(89/345/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 13 thereof,

Having regard to the proposal from the Commission,

Whereas the Member States are contracting parties to the Customs Convention on the ATA Carnet for the Temporary Admission of Goods (ATA Convention) done at Brussels on 6 December 1961; whereas the Community is not a contracting party to that Convention, in the absence of a provision allowing it to accede thereto;

Whereas a recommendation for an amendment to the said Convention was adopted on the initiative of certain Member States at the first meeting of the contracting parties held on 26 November 1987 and whereas the amendment concerned the Annex thereto containing the model of the ATA carnet; whereas the Secretary-General of the Customs Cooperation Council notified the contracting parties of this recommendation on 4 November 1988;

Whereas Community rules allow the use of ATA carnets for the temporary importation of goods, in Articles 12 and 14 of Commission Regulation (EEC) No 1751/84 of 13 June 1984 laying down certain provisions for the application of Council Regulation (EEC) No 3599/82 on temporary importation arrangements ⁽¹⁾; whereas the use of ATA carnets facilitates the completion of formalities for the temporary importation of goods and provides benefits for international commercial

activities; whereas the recommended amendment therefore falls within the Community's sphere of competence under the common commercial policy; whereas, in order to enable the amendment to enter into force the Member States should be authorized to accept it,

HAS DECIDED AS FOLLOWS:

Article 1

The Member States are hereby authorized to accept the amendment to the Customs Convention on the ATA Carnet for the Temporary Admission of Goods (ATA Convention), done at Brussels on 6 December 1961, concerning in particular the Annex containing the model of the ATA carnet.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council
The President
P. SOLBES

⁽¹⁾ OJ L 171, 29. 6. 1984, p. 1.