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### Contents

#### I Acts whose publication is obligatory

- ★ Council Directive 96/47/EC of 23 July 1996 amending Directive 91/439/EEC on driving licences ..... 1
- ★ Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system ..... 6
- ★ Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail ..... 25
- ★ Council Directive 96/50/EC of 23 July 1996 on the harmonization of the conditions for obtaining national boatmasters' certificates for the carriage of goods and passengers by inland waterway in the Community ..... 31
- ★ Council Directive 96/51/EC of 23 July 1996 amending Directive 70/524/EEC concerning additives in feedingstuffs ..... 39
- ★ Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorized dimensions in national and international traffic and the maximum authorized weights in international traffic ..... 59

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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

## I

*(Acts whose publication is obligatory)*

## COUNCIL DIRECTIVE 96/47/EC

of 23 July 1996

amending Directive 91/439/EEC on driving licences

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Acting in accordance with the procedure referred to in Article 189c of the Treaty<sup>(3)</sup>,

Whereas Council Directive 91/439/EEC of 29 July 1991 on driving licences<sup>(4)</sup> provides that national driving licences shall be introduced in accordance with the Community model described in Annex I thereto;

Whereas an alternative model should be introduced to take account of existing practices and to meet the wishes of certain Member States;

Whereas, in the context of mutual recognition of licences, there is a need to ensure compatibility and interoperability of such licences throughout the Community; whereas, to that end, the introduction on an individual basis of computer technology into the Community model licence should be avoided, while nevertheless leaving space on it for the possible later introduction of a microchip or similar computer device;

Whereas the Member States should be left the possibility of entering, in a particular place, information not related

to the administration of the driving licence or to road safety on the understanding that such entries are subject to the specific written agreement of the holder;

Whereas, with regard to the technical specifications of the Community model driving licence, this Directive applies the 'new approach' to technical harmonization by establishing a general framework for the specifications leaving detailed requirements to industrial standardization procedures,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 91/439/EEC is hereby amended as follows:

1. Article 1 (1) and Article 2 (3) shall be amended by adding 'or a' after 'Annex I';
2. The following paragraph shall be added to Article 2:  
  
    '4. Without prejudice to provisions to be adopted by the Council in this regard, the model driving licences specified in Annexes I and Ia may not contain any computerized electronic devices.';
3. Annex Ia, as defined in the Annex to this Directive, shall be added.

*Article 2*

1. After consulting the Commission, Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive by 1 July 1996. 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 a reference shall be laid down by the Member States.

<sup>(1)</sup> OJ No C 21, 25. 1. 1996, p. 4, and OJ No C 54, 23. 2. 1996, p. 5.

<sup>(2)</sup> OJ No C 301, 13. 11. 1996, p. 22, and OJ No C 204, 15. 7. 1996, p. 20.

<sup>(3)</sup> Opinion of the European Parliament of 16 November 1995 (OJ No C 323, 4. 12. 1995, p. 109), Council Common Position of 26 February 1996 (OJ No C 120, 24. 4. 1996, p. 1) and Decision of the European Parliament of 6 June 1996 (OJ No C 181, 24. 6. 1996, p. 16).

<sup>(4)</sup> OJ No L 237, 24. 8. 1991, p. 1. Directive as last amended by Directive 94/72/EC (OJ No L 337, 24. 12. 1994, p. 86).

2. Member States shall communicate to the Commission the text of the main provisions of domestic law which they adopt in the field governed by this Directive.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 23 July 1996.

*Article 3*

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

*For the Council*

*The President*

I. YATES

## ANNEX

## ANNEX Ia

## PROVISIONS CONCERNING THE COMMUNITY MODEL DRIVING LICENCE

*(Alternative to the model in Annex I)*

1. The physical characteristics of the card of the Community model driving licence shall be in accordance with ISO 7810 and ISO 7816-1.

Methods for testing the characteristics of driving licences for the purpose of confirming their compliance with the international standards shall be in accordance with ISO 10373.

2. The licence shall have two sides.

Page 1 shall contain:

- (a) the words "Driving Licence" printed in large type in the language or languages of the Member State issuing the licence;
- (b) the name of the Member State issuing the licence (optional);
- (c) the distinguishing sign of the Member State issuing the licence, printed in negative in a blue rectangle and encircled by twelve yellow stars; the distinguishing signs shall be as follows:

B: Belgium	L: Luxembourg
DK: Denmark	NL: The Netherlands
D: Germany	A: Austria
GR: Greece	P: Portugal
E: Spain	FIN: Finland
F: France	S: Sweden
IRL: Ireland	UK: The United Kingdom;
I: Italy	

- (d) information specific to the licence issued, numbered as follows:

1. surname of the holder;
2. other name(s) of the holder;
3. date and place of birth;
4. (a) date of issue of the licence;
- (b) date of expiry of the licence, or a dash if the licence is valid indefinitely;
- (c) the name of the issuing authority (may be printed on page 2);
- (d) a different number from the one under heading 5, for administrative purposes (optional);
5. number of the licence;
6. photograph of the holder;
7. signature of the holder;
8. permanent place of residence, or postal address (optional);
9. (sub)category(ies) of vehicle(s) the holder is entitled to drive (national categories shall be printed in a different type from harmonized categories);

- (e) the words "European Communities model" in the language(s) of the Member State issuing the licence and the words "Driving Licence" in the other languages of the Community, printed in pink to form the background of the licence:

Permiso de Conducción

Kørekort

Führerschein

Άδεια Οδήγησης

Driving Licence

Ajokortti

Permis de conduire

Ceadúnas Tiomána

Patente di guida

Rijbewijs

Carta de Condução

Körkort;

(f) Colour references:

— blue: pantone reflex blue,

— yellow: pantone yellow.

Page 2 shall contain:

- (a) 9. (sub)category(ies) of vehicle(s) the holder is entitled to drive (national categories shall be printed in a different type from harmonized categories);
10. date of first issue of each (sub)category (this date must be repeated on the new licence in the event of subsequent replacement or exchange);
11. date of expiry of each (sub)category;
12. additional information/restriction(s), in code form, facing the (sub)category affected.

The codes shall be as follows:

- codes 1-99: harmonized Community codes,
- codes 100 and above: national codes valid only for driving in the territory of the Member State which issued the licence.

Where a code applies to all (sub)categories for which the licence is issued, it may be printed under columns 9, 10 and 11;

13. in implementation of paragraph 3 (a) of this Annex, a space reserved for the possible entry by the host Member State of information essential for administering the licence;
14. a space reserved for the possible entry by the Member State which issues the licence of information essential for administering the licence or related to road safety (optional). If the information relates to one of the headings defined in this Annex, it should be preceded by the number of the heading in question.

With the specific written agreement of the holder, information which is not related to the administration of the driving licence or road safety may also be added in this space; such addition shall not alter in any way the use of the model as a driving licence.

- (b) an explanation of the numbered items which appear on pages 1 and 2 of the licence (at least items 1, 2, 3, 4 (a), 4 (b), 4 (c), 5, 10, 11 and 12).

If a Member State wishes to make the entries in a national language other than one of the following languages: Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish or Swedish, it shall draw up a bilingual version of the licence using one of the aforementioned languages, without prejudice to the other provisions of this Annex.

- (c) a space shall be reserved on the Community model licence to allow for the possible introduction of a microchip or similar computer device.


### 3. Special provisions

- (a) Where the holder of a driving licence issued by a Member State in accordance with this Annex has his normal place of residence in another Member State, that Member State may enter in the licence such information as is essential for administering it, provided that it also enters this type of information in the licences which it issues and provided that there remains enough space for the purpose.
- (b) After consulting the Commission, Member States may add colours or markings, such as bar codes, national symbols and security features, without prejudice to the other provisions of this Annex.

In the context of mutual recognition of licences, the bar code may not contain information other than what can already be read on the driving licence or which is essential to the process of issuing the licence.

COMMUNITY MODEL DRIVING LICENCE

Page 1



DRIVING LICENCE

MEMBER STATE

1.

2.

3.

4a.

4c.

4b.

4d.

5.

6.

7.

(8.)

6. PHOTO














9.

Page 2

13.


(14.)

1. Surname 2. Name 3. Date and place of birth 4a. Licence issuing date 4b. Administrative expiry date 4c. Issuing authority 5. Licence number 8. Address 9. Category 10. Category expiry 11. Category expiry 12. Restrictions

	9.	10.	11.	12.
A1				
A				
B1				
B				
C1				
C				
D1				
D				
BE				
C1E				
CE				
D1E				
DE				

SPECIMEN COMMUNITY MODEL DRIVING LICENCE

Belgian licence (for information)



RIJBEWIJS

KONINKRIJK BELGIE

1. Steven

2. Anne-Marie M.E.


3. 01.04.73 D-53170 Bonn

4a. 01.07.96 4c. B-9000 Gent

4b. 30.06.06

5. DA 003 360

6.


7. 

9. 

A

B

6. FOTO



PERMIS DE CONDUIRE ROYAUME DE BELGIQUE

1. Quentin

2. Maria N.E.

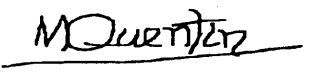
3. 01.04.73 B-7000 Mons

4a. 01.07.96 4c. B-1180 Uccle

4b. 30.06.06

5. DA 003 361

6.

7. 

9. 

A

B

6. PHOTO

## COUNCIL DIRECTIVE 96/48/EC

of 23 July 1996

## on the interoperability of the trans-European high-speed rail system

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the third paragraph of Article 129d thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions<sup>(3)</sup>,

Acting in accordance with the procedure laid down in Article 189c<sup>(4)</sup>,

Whereas in order to enable citizens of the Union, economic operators and regional and local authorities to benefit to the full from the advantages deriving from establishing an area without internal frontiers, it is advisable, in particular, to improve the interlinking and interoperability of national high-speed train networks, as well as access thereto;

Whereas a high-level working party consisting of representatives of the governments of the Member States, of the European railways and of the European railway industry convened by the Commission in order to meet the request expressed by the Council in its resolution of 4 and 5 December 1989 drew up the master plan for a European high-speed train network;

Whereas in December 1990 the Commission sent to the Council a communication on the high-speed train network, and whereas the Council gave a favourable reception to that communication in its resolution of 17 December 1990<sup>(5)</sup>;

Whereas Article 129c of the Treaty provides that the Community shall implement any measures that may

prove necessary to ensure network interoperability, in particular in the field of technical standardization;

Whereas the commercial operation of high-speed trains requires excellent compatibility between the characteristics of the infrastructure and those of the rolling stock; whereas performance levels, safety, quality of service and cost depend upon such compatibility as does, in particular, the interoperability of the European high-speed rail system;

Whereas pursuant to Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways<sup>(6)</sup> railway companies must have increased access to the rail networks of the Member States, which in turn requires infrastructure, equipment and rolling stock interoperability;

Whereas the Member States are responsible for ensuring compliance with the safety, health and consumer protection rules applying to the railway networks in general during the design, construction, placing in service and operation of those railways; whereas, together with the local authorities, they also have responsibilities in respect of rights in land, regional planning and environmental protection; whereas that is also especially pertinent with regard to high-speed train networks;

Whereas Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment<sup>(7)</sup> requires an assessment of the impact on the environment of the construction of lines for long-distance rail traffic;

Whereas national regulations and the railways' internal rules and the technical specifications which the railways apply contain major differences; whereas those national regulations and internal rules incorporate techniques that are specific to the national industries; whereas they prescribe specific dimensions and devices and special characteristics; whereas this situation runs counter to high-speed trains being able to run normally throughout Community territory;

Whereas, over the years, this situation has created very close links between the national railway industries and the national railways, to the detriment of the genuine opening-up of contracts; whereas, in order to enhance

<sup>(1)</sup> OJ No C 134, 17. 5. 1994, p. 6.

<sup>(2)</sup> OJ No C 397, 31. 12. 1994, p. 8.

<sup>(3)</sup> OJ No C 210, 14. 8. 1995, p. 38.

<sup>(4)</sup> Opinion of the European Parliament of 19 January 1995 (OJ No C 43, 20. 2. 1995, p. 60), Council common position of 8 December 1995 (OJ No 356, 30. 12. 1995, p. 43) and Decision of the European Parliament of 16 April 1996 (OJ No C 141, 13. 5. 1996, p. 48).

<sup>(5)</sup> OJ No C 33, 8. 2. 1991, p. 1.

<sup>(6)</sup> OJ No L 237, 24. 8. 1991, p. 25.

<sup>(7)</sup> OJ No L 175, 5. 7. 1985, p. 40.

their competitiveness at world level those industries require an open, competitive European market;

Whereas it is therefore appropriate to define essential requirements for the whole of the Community which will apply to the trans-European high-speed train system;

Whereas, in view of the extent and complexity of the trans-European high-speed rail system, it has proved necessary for practical reasons to break it down into subsystems; whereas for each of those subsystems the essential requirements must be specified, the basic parameters laid down and the technical specifications determined for the whole of the Community, particularly in respect of constituents and interfaces, in order to meet those essential requirements; whereas, however, certain subsystems (environment, users and operation) will be subject to technical specifications for interoperability (TSIs) only in so far as is necessary to ensure interoperability in the fields of infrastructure, energy, control-and-command and signalling and rolling-stock;

Whereas the introduction of provisions on the interoperability of the trans-European high-speed rail system must not create unjustified cost-benefit barriers to the preservation of the existing rail network of each Member State, but must endeavour to maintain the objective of the circulation of high-speed trains throughout the Community;

Whereas individual Member States should be allowed not to apply certain technical specifications for interoperability in specific cases, provided that there are procedures to ensure that such possibilities for derogation are justified; whereas Article 129c of the Treaty requires the Community's activities in the area of interoperability to take into account the potential economic viability of projects;

Whereas in order to comply with the appropriate provisions on government procurement procedures in the rail sector and in particular Directive 93/38/EEC<sup>(1)</sup>, contracting entities must include technical specifications in the general documents or the contract documents relating to each contract; whereas it is necessary to build up a body of European specifications to serve as references for those technical specifications;

Whereas, within the meaning of Directive 93/38/EEC, a European specification is a common technical specification, a European technical approval or a national standard implementing a European standard; whereas harmonized European standards are to be drawn up by a European standardization body such as the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization

(CENELEC) or the European Telecommunications Standards Institute (ETSI), to the order of the Commission, and their references published in the *Official Journal of the European Communities*;

Whereas it would be in the Community's interests for there to be an international system of standardization capable of generating standards which are actually used by those involved in international trade and which meet the requirements of Community policy; whereas the European standardization bodies must therefore continue their cooperation with the international standardization bodies;

Whereas contracting entities define such further requirements as are necessary to complete European specifications or other standards; whereas those specifications must not prevent the essential requirements that have been harmonized at Community level and which the trans-European high-speed train system must satisfy, from being met;

Whereas the procedures governing the assessment of conformity or of suitability of use of constituents must be based on the use of the modules covered by Decision 93/465/EEC<sup>(2)</sup>; whereas, as far as possible and in order to promote the development of the industries concerned, it is appropriate to expand the procedures involving a system of quality assurance; whereas the notion of constituent covers both tangible objects and intangible objects such as software;

Whereas the suitability for use of the most critical constituents as regards safety, availability or system economy should be assessed;

Whereas in their contract documents, contracting entities, lay down, in particular for constituents, by reference to the European specifications, the characteristics which must be met, in contractual terms, by the manufacturers; whereas, this being the case, constituent conformity is mainly linked to their area of use in order to ensure and guarantee the interoperability of the system, and not only to their free movement on the Community market;

Whereas it is therefore not necessary for a manufacturer to affix the CE mark to constituents that are subject to the provisions of this Directive as, on the basis of the assessment of conformity and/or suitability for use conducted in accordance with the procedures provided for that purpose in the Directive, the manufacturer's declaration of conformity is sufficient; whereas that does not affect the obligation on manufacturers to affix the

<sup>(1)</sup> Council Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors (OJ No L 199, 9. 8. 1993, p. 84), as amended by the 1994 Act of Accession.

<sup>(2)</sup> Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives (OJ No L 220, 30. 8. 1993, p. 23).



CE mark to certain components in order to certify their compliance with other Community provisions relating to them;

Whereas the subsystems constituting the trans-European high-speed rail system must be subjected to a verification procedure; whereas that verification must enable the authorities responsible for authorizing their placing in service to be assured that at the stages of design, construction and placing in service the result is in line with the regulations and technical operational provisions in force; whereas that must also enable manufacturers to be able to count upon equality of treatment whatever the country; whereas it is therefore necessary to lay down a module defining the principles and conditions applying to EC verification of subsystems;

Whereas the EC verification procedure is based on TSIs; whereas those TSIs are drawn up to the order of the Commission by the joint body representing the infrastructure managers, the railway companies and the industry; whereas the reference to TSIs is required in order to ensure interoperability of the trans-European high-speed rail system and whereas those TSIs are subject to the provisions of Article 18 of Directive 93/38/EEC;

Whereas the notified bodies responsible for examining the conformity assessment procedures or that applying to the use of constituents, together with the procedure for the assessment of subsystems must, particularly in the absence of any European specification, coordinate their decisions as closely as possible;

Whereas Council Directive 91/440/EEC requires a separation of activities, in accounting terms, between transport service operation and those concerning railway infrastructure management; whereas, this being the case, the specialized services provided by the railway infrastructure managers designated as notified bodies should be structured in such a way as to meet the criteria which must apply to this type of body; whereas other specialized bodies may be notified where these meet the same criteria;

Whereas interoperability within the trans-European high-speed train system is Community wide in scale; whereas the Member States are unable, on an individual basis, to take the action needed in order to achieve that interoperability; whereas it is therefore necessary, pursuant to the principle of subsidiarity, for this action to be taken at Community level,

HAS ADOPTED THIS DIRECTIVE:

## CHAPTER I

### General provisions

#### Article 1

1. In accordance with Articles 129b and 129c of the Treaty, the aim of this Directive is to establish the

conditions to be met in order to achieve interoperability within Community territory of the trans-European high-speed rail system as described in Annex I.

2. These conditions concern projects for and the construction, upgrading and operation of the infrastructures and rolling stock which will contribute to the functioning of the system to be put into service after the date of entry into force of this Directive.

#### Article 2

For the purposes of this Directive:

- (a) *trans-European high-speed rail system* means the structure described in Annex I, composed of the railway infrastructures comprising lines and fixed installations, of the trans-European transport network, constructed or upgraded to be travelled on at high speeds, and rolling stock designed for travelling on those infrastructures;
- (b) *interoperability* means the ability of the trans-European high-speed rail system to allow the safe and uninterrupted movement of high-speed trains which accomplish the specified levels of performance. This ability rests on all the regulatory, technical and operational conditions which must be met in order to satisfy essential requirements;
- (c) *subsystems* means that the trans-European high-speed rail system is subdivided, as described in Annex II, into structural or functional subsystems for which essential requirements must be laid down;
- (d) *interoperability constituents* means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the trans-European high-speed rail system depends either directly or indirectly;
- (e) *essential requirements* means all the conditions set out in Annex III which must be met by the trans-European high-speed rail system, subsystems and their interoperability constituents;
- (f) *European specification* means a common technical specification, a European technical approval or a national standard implementing a European standard, as defined in points 8 to 12 of Article 1 of Directive 93/38/EEC;
- (g) *technical specifications for interoperability* (hereinafter *TSIs*) means the specifications by which each subsystem is covered in order to meet the essential requirements by establishing the necessary

reciprocal functional relations between the subsystems of the trans-European high-speed rail system and by ensuring the latter's compatibility;

- (h) *joint representative body* means the body bringing together representatives of the infrastructure managers, railway companies and industry which is responsible for drawing up TSIs. 'Infrastructure managers' means those referred to in Articles 3 and 7 of Directive 91/440/EEC;
- (i) *notified bodies* means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the EC procedure for verification of the subsystems.

### Article 3

1. This Directive applies to the provisions concerning, for each subsystem, the parameters, interoperability constituents, interfaces and procedures as well as the conditions for the overall compatibility of the trans-European high-speed rail system required to achieve its interoperability.

2. The provisions of this Directive shall apply without prejudice to other Community provisions. However, in the case of interoperability constituents, compliance with the essential requirements of this Directive may require the use of the individual European specifications drawn up for that purpose.

### Article 4

1. The trans-European high-speed rail system, subsystems and their interoperability constituents must meet the relevant essential requirements.

2. The further technical specification referred to in Article 18 (4) of Directive 93/38/EEC, which are necessary to supplement European specifications or other standards in use within the Community, must not conflict with the essential requirements.

## CHAPTER II

### Technical specifications for interoperability

#### Article 5

1. Each of the subsystems shall be covered by a TSI. In the case of subsystems concerning the environment, operation or users, TSIs will be drawn up only to the extent necessary to ensure interoperability of the trans-European high-speed rail system in the fields of infrastructure, energy, control and command, signalling and rolling stock.

2. The subsystems must conform to the TSIs; this conformity must be permanently maintained while each subsystem is in use.

3. To the extent necessary in order to achieve interoperability of the trans-European high-speed rail system, the TSIs shall:

- (a) specify the essential requirements for the subsystems and their interfaces;
- (b) establish the basic parameters described in Annex II (3) necessary to meet the essential requirements;
- (c) establish the conditions to be complied with to achieve the specified performances for each of the following categories of line:
  - lines specially built for high speed;
  - lines specially upgraded for high speed;
  - lines specially upgraded for high speed which have special features as a result of topographical, relief or town-planning constraints;
- (d) establish possible implementing provisions in certain specific cases;
- (e) determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are needed in order to achieve interoperability within the trans-European high-speed rail system while meeting the essential requirements;
- (f) state, in each case under consideration, which of the modules defined in Decision 93/465/EEC or, where appropriate, which specific procedures are to be used in order to assess either the conformity or the suitability for use of the interoperability constituents, as well as EC verification of the subsystems.

4. The TSIs shall not be an impediment to decisions by the Member States concerning the use of new or upgraded infrastructures for running other trains.

5. Compliance with all the TSIs shall enable a compatible trans-European high-speed rail system to be set up that will preserve, as appropriate, the compatibility of each Member State's existing rail network.

#### Article 6

1. Draft TSIs shall be drawn up to the order of the Commission, to be established in accordance with the

procedure laid down in Article 21 (2) by the joint representative body. TSIs shall be adopted and reviewed by the same procedure. They shall be published by the Commission in the *Official Journal of the European Communities*.

2. The joint representative body shall be responsible for preparing the review and updating of TSIs and making recommendations to the Committee referred to in Article 21 in order to take account of developments in technology or social requirements.

3. The preparation, adoption and review of TSIs shall take account of the estimated cost of technical solutions by which they may be met, with a view to defining and implementing the most viable solutions. To that end, the joint representative body shall attach to each draft TSI an assessment of the estimated costs and benefits of those technical solutions for all the economic operators and agents concerned.

4. The Committee shall be kept regularly informed of the preparatory work on the TSIs by the joint representative body. The Committee may give the joint body any useful recommendation or brief regarding the design of the TSIs, on the basis of the essential requirements or regarding cost assessment.

5. When each TSI is adopted, the date of its entry into force shall be laid down in accordance with the procedure referred to in Article 21 (2).

6. The joint representative body must work in an open and transparent manner in accordance with general Community standardization procedures.

#### Article 7

A Member State need not apply certain TSIs, including those relating to rolling stock, in the following cases and circumstances:

- (a) in the case of a project for a new line or upgrading an existing line for high speed which is at an advanced stage of development when the TSIs in question are published.

The Member State concerned shall notify its intended derogation to the Commission in advance, shall inform the Commission of the stage the project has reached and shall forward to it a file setting out the TSIs or parts thereof which it wishes not to apply, the provisions it intends to apply in carrying out the project in order to promote its eventual interoperability, and the technical, administrative or economic reasons which justify the derogation;

- (b) in the case of a project for upgrading an existing line for high speed, where the loading gauge, track gauge or space between the tracks of the line are different from those on the majority of the European rail network, and where the line does not form a direct connection with the high-speed network of another Member State which is a part of the trans-European high-speed network.

The Member State concerned shall notify its intended derogation to the Commission in advance and shall forward to it a file setting out the TSIs or parts thereof concerning the physical parameter(s) referred to in the first subparagraph which it wishes not to apply, the provisions it intends to apply in carrying out the project in order to promote its eventual interoperability, the transitional measures it intends to take to guarantee compatibility of operation, and the technical, administrative or economic reasons which justify the derogation;

- (c) in the case of projects for new lines or upgrading existing lines for high speed carried out in the territory of the Member State concerned where its rail network is not linked to or is isolated by sea from the high-speed rail network of the rest of the Community.

The Member State concerned shall notify its intended derogation to the Commission in advance and shall forward to it a file containing the documents specified in the second subparagraph of paragraph (b);

- (d) in the case of a project for upgrading an existing line for high speed, where application of these TSIs compromises the economic viability of the project.

The Member State concerned shall notify its intended derogation to the Commission in advance and shall forward to it a file setting out the technical specifications or parts of specifications for interoperability which it wishes not to apply. The Commission shall examine whether the measures envisaged by the Member State are justified and shall take a decision in accordance with the procedure in Article 21 (2).

### CHAPTER III

#### Interoperability constituents

#### Article 8

Member States shall take all necessary steps to ensure that interoperability constituents:

- are placed on the market only if they enable interoperability to be achieved within the trans-European high-speed rail system while at the same time meeting the essential requirements;
- are used in their area of use as intended and are suitably installed and maintained.

These provisions do not exclude the placing on the market of these constituents for other purposes, nor their use for conventional railway lines.

#### Article 9

Member States may not, in their territory and on grounds of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use on the trans-European high-speed rail system if they comply with the Directive.

#### Article 10

1. Member States shall consider as complying with the essential requirements of this Directive applying to them those interoperability constituents which bear the EC declaration of conformity or suitability for use, the components of which are set out in Annex IV.
2. Compliance of an interoperability constituent with the essential requirements applying to it shall be established in relation to any relevant European specifications that may exist.
3. The references to European specifications shall be published in the *Official Journal of the European Communities*.
4. Member States shall publish the references to the national standards transposing the European standards.
5. In the absence of any European specifications and without prejudice to Article 20 (5), Member States shall inform the other Member States and the Commission of the standards and technical specifications in use in order to implement the essential requirements.

#### Article 11

Where it appears to a Member State or the Commission that European specifications do not meet the essential requirements, partial or total withdrawal of the

specifications concerned from the publications containing them, or their amendments, may be decided upon in accordance with the procedure laid down in Article 21 (2) after consultation of the Committee set up under Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>(1)</sup> where European standards are concerned.

#### Article 12

1. Where a Member State confirms that an interoperability constituent covered by the EC declaration of conformity or suitability for use, and placed on the market is likely, when used as intended, not to meet the essential requirements, it shall take all necessary steps to restrict its area of application, prohibit its use or withdraw it from the market. That Member State shall forthwith inform the Commission of the measures taken and shall give the reasons for its decision, stating in particular whether the failure to conform is due to:

- failure to meet the essential requirements;
- incorrect application of the European specifications where application of the specifications is invoked;
- inadequacy of the European specifications.

2. The Commission shall consult the parties concerned as quickly as possible. Where, following that consultation, the Commission establishes that the measure is justified, it shall forthwith so inform the Member State that has taken the initiative and the other Member States. Where, following that consultation, the Commission establishes that the measure is unjustified, it shall forthwith so inform the Member State that has taken the initiative and the manufacturer or his authorized representative established within the Community. Where the decision referred to in paragraph 1 is justified by the existence of a gap in the European specifications, the procedure defined in Article 11 shall apply.

3. Where an interoperability constituent bearing the EC declaration of conformity fails to comply, the competent Member State shall take the appropriate measures against whomsoever has drawn up the declaration and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and the results of that procedure.

<sup>(1)</sup> OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by the 1994 Act of Accession.

*Article 13*

1. In order to draw up the EC declaration of conformity or suitability for use of an interoperability constituent, its manufacturer or his authorized representative established within the Community must apply the provisions laid down in the TSIs referring to it.

2. Where so required by the TSIs, the assessment of conformity or suitability for use of an interoperability constituent shall be appraised by the notified body with which the manufacturer or his authorized representative established within the Community has lodged the application.

3. Where the interoperability constituents are the subject of other Community Directives covering other aspects, the EC declaration of conformity or suitability for use shall, in such instances, state that the interoperability constituents also meet the requirements of those other Directives.

4. Where neither the manufacturer nor his authorized representative established within the Community has met the obligations of the paragraphs 1, 2 and 3, those obligations shall be incumbent on any person who places that interoperability constituent on the market. The same obligations shall apply to any person who assembles interoperability constituents or parts of interoperability constituents having diverse origins or who manufactures the interoperability constituents for his own use, for the purposes of this Directive.

5. Without prejudice to the provisions of Article 12:

- (a) in each instance where a Member State finds that the EC declaration of conformity has been drawn up improperly, the manufacturer or his authorized representative established within the Community shall be required to ensure that the conformity of the interoperability constituent is re-established and that the infringement ceases under the conditions laid down by that Member State;
- (b) where non-conformity persists, the Member State shall take all appropriate steps to restrict or prohibit the placing on the market of the interoperability constituent in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 12.

## CHAPTER IV

**Subsystems***Article 14*

Each Member State shall authorize the placing in service of those structural subsystems constituting the

trans-European high-speed rail system which are located in its territory or operated by railway undertakings established there.

For this purpose Member States shall take all necessary steps to ensure that these subsystems may be placed in service only if they are designed, constructed and installed and/or operated in such a way as not to hinder satisfaction of the essential requirements concerning them when integrated into the trans-European high-speed rail system.

*Article 15*

Without prejudice to Article 19, Member States may not, in their territory and on grounds of this Directive, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the trans-European high-speed rail system which satisfy the essential requirements.

*Article 16*

1. Member States shall consider as being interoperable and meeting the essential requirements concerning them those structural subsystems constituting the trans-European high-speed rail system which are covered by the EC declaration of verification.

2. Verification of the interoperability, in accordance with the essential requirements, of a structural subsystem constituting the trans-European high-speed rail system shall be established by reference to TSIs where these exist.

3. In the absence of TSIs, Member States shall send the other Member States and the Commission a list of the technical rules in use for implementing the essential requirements.

*Article 17*

If it emerges that the TSIs do not fully meet the essential requirements, the Committee referred to in Article 21 may be consulted at the request of a Member State or on the initiative of the Commission.

*Article 18*

1. In order to draw up the EC declaration of verification, the awarding authority or its official representative shall cause the EC checking procedure to be appraised by the notified body chosen by it for that purpose.

2. The activities of the notified body responsible for the EC verification of a subsystem shall begin at the design stage and shall cover all of the manufacturing period up to the type-approval stage before a subsystem is placed in service.

3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification. The technical file must contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the constituents of interoperability. It must also contain all of the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.

#### Article 19

1. Where a Member State finds that a structural subsystem covered by the EC declaration of verification accompanied by the technical file does not fully comply with this Directive and in particular does not meet the essential requirements, it may request that additional checks be carried out.

2. The Member State making the request shall forthwith inform the Commission of any additional checks requested and set out the reasons which justify them. The Commission shall without delay initiate the procedure provided for in Article 21 (2).

### CHAPTER V

#### Notified bodies

##### Article 20

1. Member States shall notify the Commission and the other Member States of the bodies responsible for carrying out the procedure for the assessment of conformity or suitability for use referred to in Article 13 and the checking procedure referred to in Article 18, indicating each body's area of responsibility.

The Commission shall assign identification numbers to them. It shall publish in the *Official Journal of the European Communities* the list of bodies, their identification numbers and the tasks entrusted to them, and shall ensure that the list is kept updated.

2. Member States shall apply the criteria provided for in Annex VII for the assessment of the bodies to be notified. Bodies meeting the assessment criteria provided for in the relevant European standards shall be deemed to meet the said criteria.

3. A Member State shall withdraw approval from a body which no longer meets the criteria referred to in Annex VII. It shall forthwith inform the Commission and the other Member States thereof.

4. Should a Member State or the Commission consider that a body notified by another Member State no longer meets the relevant criteria, the matter shall be referred to the Committee provided for in Article 21, which shall deliver its opinion within three months; in the light of the Committee's opinion, the Commission shall inform the Member State concerned of all the changes needed if the notified body is to maintain the status awarded to it.

5. Where appropriate, coordination of the notified bodies shall be implemented in accordance with Article 21 (4).

### CHAPTER VI

#### Committee

##### Article 21

1. The Commission shall be assisted by a Committee, composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

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

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

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

3. The Committee may discuss any matter concerning the interoperability of the trans-European high-speed rail system.

4. Should it prove necessary, the Committee may set up working parties to aid it in carrying out its tasks, in particular with a view to coordinating the notified bodies.

5. The Committee shall be set up as soon as this Directive enters into force.

#### CHAPTER VII

#### Final provisions

##### *Article 22*

Any decision taken pursuant to this Directive concerning the assessment of conformity or suitability for use of interoperability constituents, the checking of subsystems constituting the trans-European high-speed rail system and any decision taken pursuant to Articles 11, 12, 17 and 19 shall set out in detail the reasons on which it is based. It shall be notified as soon as possible to the party concerned, together with an indication of the remedies available under the laws in force in the Member States concerned and of the time limits allowed for the exercise of such remedies.

##### *Article 23*

1. Member States shall amend and adopt their laws, regulations and administrative provisions so as to authorize the use of interoperability constituents and the putting into service and operation of subsystems which comply with this Directive no later than 30 months after entry into force of this Directive. They shall forthwith inform the Commission thereof.

2. When Member States adopt the provisions referred to in paragraph 1, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

##### *Article 24*

Every two years the Commission shall report to the European Parliament and the Council on the progress made towards achieving interoperability of the trans-European high-speed rail system.

##### *Article 25*

This Directive shall enter into force on the 21st day following that of its publication in the *Official Journal of the European Communities*

Done at Brussels, 23 July 1996.

*For the Council*

*The President*

I. YATES

## ANNEX I

## THE TRANS-EUROPEAN HIGH-SPEED RAIL SYSTEM

## 1. Infrastructure

- (a) The infrastructure of the trans-European high-speed rail system shall be that on the lines of the trans-European transport network identified in the framework of the guidelines referred to in Article 129c of the Treaty:

- those specially built for high-speed travel,
- those specially upgraded for high-speed travel.

They may include connecting lines, in particular junctions of new lines or lines upgraded for high speed with town centre stations located on them, on which speeds must take account of local conditions.

- (b) High-speed lines shall comprise:

- specially built high-speed lines equipped for speeds generally equal to or greater than 250 km/h,
- specially upgraded high-speed lines equipped for speeds of the order of 200 km/h,
- specially upgraded high-speed lines which have special features as a result of topographical, relief or town-planning constraints, on which the speed must be adapted to each case.

## 2. Rolling stock

The high-speed advanced-technology trains shall be designed in such a way as to guarantee safe, uninterrupted travel:

- at a speed of at least 250 km/h on the lines specially built for high speed, while enabling speeds of over 300 km/h to be reached in appropriate circumstances;
- at a speed of the order of 200 km/h on existing lines which have been or are to be specially upgraded;
- at the highest possible speed on other lines.

## 3. Compatibility of infrastructure and rolling stock

High-speed train services presuppose excellent compatibility between the characteristics of the infrastructure and those of the rolling stock. Performance levels, safety, quality of service and cost depend upon that compatibility.

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## ANNEX II

## SUBSYSTEMS

1. For the purposes of this Directive, the system constituting the trans-European high-speed rail system may be broken down into subsystems, as follows:

- 1.1. basically structural areas:

- infrastructures
- energy
- control and command and signalling
- rolling stock;

- 1.2. basically operational areas:

- maintenance
- environment
- operation
- users.

2. For each subsystem, the list of aspects relating to interoperability is indicated in the order given to the representative joint body for drawing up draft TSIs.

Under the provisions of Article 6 (1), this order shall be established in accordance with the procedure laid down in Article 21 (2).

Where necessary, the list of aspects relating to interoperability indicated in the order is specified by the representative joint body in accordance with the provisions of Article 5 (3) (e).

3. Within the meaning of Article 5 (3) (b), the following are regarded as basic parameters for achieving interoperability:

## BASIC PARAMETERS

- Minimum infrastructure gauges
- Minimum radius of curvature
- Track gauge
- Maximum track stressing
- Minimum platform length
- Platform height
- Power-supply voltage
- Catenary geometry
- ERTMS characteristics(\*)
- Axle loading
- Maximum train length
- Gauge of rolling stock
- Minimum braking characteristics
- Boundary electrical characteristics of rolling stock
- Boundary mechanical characteristics of rolling stock
- Operating characteristics linked to train safety
- Boundary characteristics linked to outside noise
- Boundary characteristics linked to outside vibrations
- Boundary characteristics linked to outside electromagnetic interference
- Boundary characteristics linked to inside noise
- Boundary characteristics linked to air conditioning
- Characteristics linked to the carriage of disabled persons.

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(\*) European Rail Traffic Management System.

## ANNEX III

## ESSENTIAL REQUIREMENTS

## 1. General requirements

1.1. *Safety*

- 1.1.1. The design, construction or assembly, maintenance and monitoring of safety-critical components, and more particularly of the components involved in train movements must be such as to guarantee safety at the level corresponding to the aims laid down for the network, including those for specific degraded situations.
- 1.1.2. The parameters involved in the wheel/rail contact must meet the stability requirements needed in order to guarantee safe movement at the maximum authorized speed.
- 1.1.3. The components used must withstand any normal or exceptional stresses that have been specified during their period in service. The safety repercussions of any accidental failures must be limited by appropriate means.
- 1.1.4. The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting the generation, propagation and effects of fire and smoke in the event of a fire.
- 1.1.5. Any devices intended to be handled by users must be so designed as not to impair their safety if used foreseeably in a manner not in accordance with the posted instructions.

1.2. *Reliability and availability*

The monitoring and maintenance of fixed or movable components that are involved in train movements must be organized, carried out and quantified in such a manner as to maintain their operation under the intended conditions.

1.3. *Health*

- 1.3.1. Materials likely, by virtue of the way they are used, to constitute a health hazard to those having access to them must not be used in trains and railway infrastructures.
- 1.3.2. Those materials must be selected, deployed and used in such a way as to restrict the emission of harmful and dangerous fumes or gases, particularly in the event of fire.

1.4. *Environmental protection*

- 1.4.1. The repercussions on the environment of the establishment and operation of the trans-European high-speed rail system must be assessed and taken into account at the design stage of the system in accordance with the Community provisions in force.
- 1.4.2. The materials used in the trains and infrastructures must prevent the emission of fumes or gases which are harmful and dangerous to the environment, particularly in the event of fire.
- 1.4.3. The rolling stock and energy-supply systems must be designed and manufactured in such a way as to be electromagnetically compatible with the installations, equipment and public or private networks with which they might interfere.

1.5. *Technical compatibility*

The technical characteristics of the infrastructures and fixed installations must be compatible with each other and with those of the trains to be used on the trans-European high-speed rail system.

If adherence to these characteristics proves difficult on certain sections of the network, temporary solutions, which ensure compatibility in the future, may be implemented.

## 2. Requirements specific to each subsystem

### 2.1. *Infrastructures*

#### 2.1.1. Safety

Appropriate steps must be taken to prevent access to or undesirable intrusions into installations on lines travelled at high speed.

Steps must be taken to limit the dangers to which persons are exposed, particularly in stations through which trains pass at high speed.

Infrastructures to which the public has access must be designed and made in such a way as to limit any human health hazards (stability, fire, access, evacuation, platforms, etc.).

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels.

### 2.2. *Energy*

#### 2.2.1. Safety

Operation of the energy-supply systems must not impair the safety either of high-speed trains or of persons (users, operating staff, trackside dwellers and third parties).

#### 2.2.2. Environmental protection

The functioning of the energy-supply systems must not interfere with the environment beyond the specified limits.

#### 2.2.3. Technical compatibility

The electricity supply systems used throughout the trans-European high-speed rail system must:

- enable trains to achieve the specified performance levels;
- be compatible with the collection devices fitted to the trains.

### 2.3. *Control and command and signalling*

#### 2.3.1. Safety

The control and command and signalling installation and procedures used on the trans-European high-speed rail system must enable trains to travel with a level of safety which corresponds to the objectives set for the network.

#### 2.3.2. Technical compatibility

All new high-speed infrastructures and all new high-speed rolling stock manufactured or developed after adoption of compatible control and command and signalling must be tailored to the use of those systems.

The control and command and signalling equipment installed within the train drivers' cabs must permit normal operation, under the specified conditions, throughout the trans-European high-speed rail system.

### 2.4. *Rolling stock*

#### 2.4.1. Safety

The rolling-stock structures and those of the links between vehicles must be designed in such a way as to protect the passenger and driving compartments in the event of collision or derailment.

The electrical equipment must not impair the safety and functioning of the control and command and signalling installations.

The braking techniques and the stresses exerted must be compatible with the design of the tracks, engineering structures and signalling systems.

Steps must be taken to prevent access to electrically-live constituents in order not to endanger the safety of persons.

In the event of danger devices must enable passengers to inform the driver and accompanying staff to contact him.

The access doors must incorporate an opening and closing system which guarantees passenger safety.

Emergency exits must be provided and indicated.

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels.

An emergency lighting system having a sufficient intensity and duration is an absolute requirement on board trains.

Trains must be equipped with a public address system which provides a means of communication to the public from on-board staff and ground control.

#### 2.4.2. Reliability and availability

The design of the vital equipment and the running, traction and braking equipment and also the control and command system must, in a specific degraded situation, be such as to enable the train to continue without adverse consequences for the equipment remaining in service.

#### 2.4.3. Technical compatibility

The electrical equipment must be compatible with the operation of the control and command and signalling installations.

The characteristics of the current-collection devices must be such as to enable trains to travel under the energy-supply systems for the trans-European high-speed rail system.

The characteristics of the rolling stock must be such as to allow it to travel on any line on which it is expected to operate.

### 2.5. *Maintenance*

#### 2.5.1. Health

The technical installations and the procedures used in the maintenance centres must not constitute a danger to human health.

#### 2.5.2. Environmental protection

The technical installations and the procedures used in the maintenance centres must not exceed the permissible levels of nuisance with regard to the surrounding environment.

#### 2.5.3. Technical compatibility

The maintenance installations on high-speed trains must be such as to enable safety, health and comfort operations to be carried out on all trains for which they have been designed.

### 2.6. *Environment*

#### 2.6.1. Health

Operation of the trans-European high-speed rail system must remain within the statutory noise-nuisance limits.

#### 2.6.2. Environmental protection

Operation of the trans-European high-speed rail system must not cause a level of ground vibrations which is unacceptable for activities and the immediate environment in the vicinity of the infrastructure and in a normal state of maintenance.

### 2.7. *Operation*

#### 2.7.1. Safety

Alignment of the network operating rules and the qualifications of drivers and on-board staff must be such as to ensure safe international operation.

The operations and maintenance intervals, the training and qualifications of maintenance staff and the quality assurance system set up in the maintenance centres of the operators concerned must be such as to ensure a high level of safety.

#### 2.7.2. Reliability and availability

The operation and maintenance periods, the training and qualifications of the maintenance staff and the quality assurance system set up by the operators concerned in the maintenance centres must be such as to ensure a high level of system reliability and availability.

#### 2.7.3. Technical compatibility

The alignment of the operating rules of the networks and the qualifications of drivers, on-board staff and managers in charge of traffic must be such as to ensure operating efficiency on the trans-European high-speed rail system.

## ANNEX IV

## INTEROPERABILITY CONSTITUENTS

## EC declaration

- of conformity
- of suitability for use

1. *Interoperability constituents*

The EC declaration applies to the interoperability constituents involved in the interoperability of the trans-European high-speed rail systems, as referred to in Article 3. These interoperability constituents may be:

## 1.1. multiple-use constituents

These are constituents that are not specific to the railway system and which may be used as such in other areas;

## 1.2. multiple-use constituents having specific characteristics

These are multiple-use constituents which are not, as such, specific to a railway system, but which must display specific performance levels when used for railway purposes;

## 1.3. specific constituents

These are constituents that are specific to railway applications.

2. *Scope*

The EC declaration covers:

- either the assessment by a notified body or bodies of the intrinsic conformity of an interoperability constituent, considered in isolation, to the technical specifications to be met;
- or the assessment/judgment by a notified body or bodies of the suitability for use of an interoperability constituent, considered within its railway environment and in particular in cases where the interfaces are involved, in relation to the technical specifications, particularly those of a functional nature, which are to be checked.

The assessment procedures implemented by the notified bodies at the design and production stages will draw upon the modules defined in Decision 93/465/EEC, in accordance with the conditions referred to in the TSIs.

3. *Contents of the EC declaration*

The EC declaration of conformity or of suitability for use, and the accompanying documents must be dated and signed.

That declaration must be written in the same language as the instructions and must contain the following:

- the Directive references;
- the name and address of the manufacturer or his authorized representative established within the Community (give trade name and full address and in the case of the authorized representative also give the trade name of the manufacturer or constructor);
- description of interoperability constituent (make, type, etc.);
- description of the procedure followed in order to declare conformity, suitability for use (Article 13);
- all of the relevant descriptions met by the interoperability constituent and in particular its conditions of use;
- name and address of notified body (bodies) involved in the procedure followed in respect of conformity or suitability for use and date of examination certificate together, where appropriate, with the duration and conditions of validity of the certificate;
- where appropriate, reference to the European specification;
- identification of signatory having received powers to engage the manufacturer or his authorized representative established within the Community.

## ANNEX V

## SUBSYSTEMS

## EC DECLARATION OF VERIFICATION

The EC declaration of verification and the accompanying documents must be dated and signed.

That declaration must be written in the same language as the technical file and must contain the following:

- the Directive references;
  - name and address of the contracting entity or its authorized representative established within the Community. (Give trade name and full address, and in the case of the authorized representative also give the trade name of the contracting entity);
  - a brief description of the subsystem;
  - name and address of the notified body which has conducted the EC inspection referred to in Article 18;
  - the references of the documents contained in the technical file;
  - all of the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions;
  - if temporary: duration of validity of the EC declaration;
  - identity of signatory.
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## ANNEX VI

## SUBSYSTEMS

## EC VERIFICATION

1. EC verification is the procedure whereby a notified body checks and certifies, at the request of a contracting entity or its authorized representative established within the Community, that a subsystem:
  - complies with the Directive;
  - complies with the other regulations deriving from the Treaty and may be put into operation.
2. The subsystem is checked at each of the following stages:
  - overall design;
  - structure of subsystem, including, in particular, civil-engineering activities, constituent assembly, overall adjustment;
  - final testing of the subsystem.
3. The notified body responsible for EC verification draws up the certificate of conformity intended for the contracting entity or its authorized representative established within the Community, which in turn draws up the EC verification declaration intended for the supervisory authority in the Member State within which the subsystem is located and/or operates.
4. The technical record accompanying the verification statement must be made up as follows:
  - for infrastructures: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete;
  - for the other subsystems: general and detailed drawings in line with execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems, operating and maintenance manuals, etc.;
  - list of interoperability constituents, as referred to in Article 3, incorporated into the subsystem;
  - copies of the EC declarations of conformity or suitability for use with which said constituents must be provided in accordance with Article 13 of the Directive, accompanied where appropriate by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications;
  - certificate from the notified body responsible for EC verification, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with this Directive and mentioning, where appropriate, reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up in connection with the verification, as specified in points 5.3 and 5.4.
5. **Monitoring**
  - 5.1. The aim of EC monitoring is to ensure that the obligations deriving from the technical record have been met during production of the subsystem.
  - 5.2. The notified body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The contracting entity or its authorized representative within the Community must send it or have sent to it all the documents needed for that purpose and in particular the implementation plans and technical records concerning the subsystem.
  - 5.3. The body notified responsible for checking implementation must periodically carry out audits in order to confirm compliance with the Directive. It must provide those responsible for implementation with an audit report. It may require to be present at certain stages of the building operations.

- 5.4. In addition, the notified body may pay unexpected visits to the worksite or to the production workshops. At the time of such visits the notified body may conduct complete or partial 'audits'. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.
6. The complete record referred to in paragraph 4 must be lodged with the contracting entity or its authorized agent established within the Community in support of the certificate of conformity issued by the notified body responsible for checking the subsystem in working order. The record must be attached to the EC declaration of verification which the contracting entity sends to the supervisory authority in the Member State concerned.

A copy of the record must be kept by the contracting entity throughout the service life of the subsystem. It must be sent to any other Member States who so request.

7. Each body must periodically pass on relevant information concerning the following:
- requests for EC verification received;
  - certificates of conformity issued;
  - certificates of conformity refused.
8. The records and correspondence relating to the EC verification procedures must be written in an official language of the Member State in which the contracting entity or its authorized representative is established within the Community, or in a language accepted by the Community.
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## ANNEX VII

**MINIMUM CRITERIA WHICH MUST BE TAKEN INTO ACCOUNT BY THE MEMBER STATES  
WHEN NOTIFYING BODIES**

1. The body, its Director and the staff responsible for carrying out the checking operations may not become involved either directly or as authorized representatives in the design, manufacture, construction, marketing or maintenance of the interoperability constituents or subsystems or in their use. This does not exclude the possibility of an exchange of technical information between the manufacturer or constructor and that body.
  2. The body and the staff responsible for inspection must carry out the checking operations with the greatest possible professional integrity and the greatest possible technical competence and must be free of any pressure and incentive, in particular of a financial type, which may affect their judgment or the results of their inspection, and in particular those generated by persons or groups of persons affected by the results of the checks.
  3. That body must employ staff and possess the means required to perform adequately the technical and administrative tasks linked with the conducting of checks. It should also have access to the equipment needed for exceptional checks.
  4. The staff responsible for the checks must possess:
    - proper technical and vocational training;
    - a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks;
    - the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.
  5. The independence of the staff responsible for inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.
  6. The body must take out civil liability insurance unless that liability is covered by the State under national law or unless the inspections are carried out directly by that Member State.
  7. The staff of that body are bound by professional secrecy with regard to everything they learn in the performance of their duties (with the exception of the competent administrative authorities in the State where they perform those activities) in pursuance of this Directive or any provision of national law implementing the Directive.
-

## COUNCIL DIRECTIVE 96/49/EC

of 23 July 1996

on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Acting in accordance with the procedure referred to in Article 189c of the Treaty<sup>(3)</sup>,

and international transport operations, to guarantee the elimination of distortions of competition by facilitating the free movement of goods and services throughout the Community and to ensure consistency with the other Community provisions;

- (1) Whereas in recent years the transport of dangerous goods by rail has considerably expanded, thus increasing the risks of accidents occurring; whereas measures must therefore be taken to ensure that such transport is carried out under the best possible conditions of safety;
- (2) Whereas all Member States are Contracting Parties to the Convention concerning international carriage by rail (COTIF), which, in Appendix B thereto, defines uniform rules concerning the contract for international carriage of goods by rail (CIM), Annex 1 to which constitutes the regulations concerning the international carriage of dangerous goods by rail (RID); whereas the geographical scope of the Convention extends beyond the Community;
- (3) Whereas the Convention does not cover the national carriage of dangerous goods by rail; whereas it is therefore important to ensure the uniform application of harmonized safety rules throughout the Community; whereas the most appropriate way of achieving this is to align the laws applied by the Member States on the RID;
- (4) Whereas, in compliance with the principle of subsidiarity, these laws must be approximated in order to ensure a high level of safety for national
- (5) Whereas the provisions of this Directive are without prejudice to the commitment entered into by the Community and its Member States, in accordance with the goals set under Agenda 21, Chapter 19, at the UNCED Conference in June 1992 in Rio de Janeiro, to strive for the future harmonization of systems for the classification of dangerous substances;
- (6) Whereas no specific Community legislation yet governs the safety conditions under which biological agents and genetically modified micro-organisms, regulated under Directives 90/219/EEC<sup>(4)</sup>, 90/220/EEC<sup>(5)</sup> and 90/676/EEDC<sup>(6)</sup> should be transported;
- (7) Whereas the provisions of this Directive are without prejudice to the application of other Community provisions in the field of worker safety and environmental protection;
- (8) Whereas the Member States must be able to apply specific traffic regulations to the transport on their territory of dangerous goods by rail;
- (9) Whereas, the Member States should retain the right, with regard to the transport of dangerous goods by rail, provisionally to implement rules in conformity with the United Nations recommendations on the multimodal transport of dangerous goods, in so far as the RID is not yet harmonized with those regulations, which should facilitate the inter-modal transport of dangerous goods;
- (10) Whereas each Member State must retain the right to regulate or prohibit, strictly for reasons other

<sup>(1)</sup> OJ No C 389, 31. 12. 1994, p. 15, and amended proposal forwarded on 3 October 1995 (not yet published in the Official Journal).

<sup>(2)</sup> OJ No C 236, 11. 9. 1995, p. 36.

<sup>(3)</sup> Opinion of the European Parliament of 13 July 1995 (OJ No C 249, 25. 9. 1995, p. 138), Council common position of 8 December 1995 (OJ No C 356, 30. 12. 1995, p. 34) and Decision of the European Parliament of 16 April 1996 (OJ No C 141, 13. 5. 1996, p. 51).

<sup>(4)</sup> OJ No L 117, 8. 5. 1990, p. 1. Directive amended by Commission Directive 94/51/EC (OJ No L 297, 18. 11. 1994, p. 29).

<sup>(5)</sup> OJ No L 117, 8. 5. 1990, p. 15. Directive amended by Commission Directive 94/15/EC (OJ No L 103, 23. 4. 1994, p. 20).

<sup>(6)</sup> OJ No L 374, 31. 12. 1990, p. 1. Directive as last amended by Commission Directive 95/30/EC (OJ No L 155, 6. 7. 1995, p. 41).

than safety, the internal transport of certain dangerous goods by rail;

- (11) Whereas account should be taken of the more stringent safety measures applied in the Channel Tunnel because of its specific characteristics, in particular its route and length; whereas provision should also be made for Member States to be able to introduce the same kind of measures where similar situations arise; whereas it must be possible for some Member States to apply more stringent standards for material intended for transport because of the ambient temperature in their countries;
- (12) Whereas, in view of the volume of investment required in this sector, a transitional period should be laid down to enable Member States to retain temporarily certain specific national provisions concerning construction requirements or the use of tanks, receptacles, packaging or an emergency action code;
- (13) Whereas the introduction of new developments in technology and industry must not be hindered; whereas temporary derogations should be provided for that purpose;
- (14) Whereas the provisions of the RID authorize the conclusion of agreements derogating therefrom; whereas the large number of agreements concluded bilaterally between Member States impedes the free provision of dangerous-goods transport services; whereas including the necessary provisions in the Annex to this Directive should overcome the need for such derogations; whereas provision should be made for a transitional period during which the Member States may continue to apply existing agreements amongst themselves;
- (15) Whereas the transport of dangerous goods by rail to or from a third country is authorized, provided it is carried out in accordance with the requirements of the RID; whereas, however, in the case of transport operations from and to the Republics of the former Soviet Union which are not contracting parties to the COTIF, the Member States are entitled to adopt appropriate measures with regard to such operations; whereas they guarantee a level of safety equivalent to that provided for in the RID;
- (16) Whereas it must be possible to adapt this Directive rapidly to technical progress, notably by adoption of the new provisions laid down within the framework of the RID; whereas, for that purpose, a Committee should be set up and a procedure established for close cooperation between Member States and the Commission within that Committee,

HAS ADOPTED THIS DIRECTIVE:

## CHAPTER I

### Scope

#### Article 1

1. This Directive shall apply to the transport of dangerous goods by rail within Member States or between Member States. Member States may, however, exempt from the scope of this Directive the transport of dangerous goods conducted by means of transport equipment belonging to or under the responsibility of the armed forces.

2. This Directive shall not, however, affect the Member State's right, having due regard to Community law, to lay down specific safety requirements for the national or international transport of dangerous goods by rail, in so far as the Annex thereto does not cover that area, in particular as regards, *inter alia*:

- the running of trains;
- the marshalling of freight wagons in trains in national traffic;
- operating rules for operations ancillary to transport such as marshalling and stabling;
- the training of staff and the management of information concerning the dangerous goods transported;
- special rules for the transport of dangerous goods in passenger trains.

#### Article 2

For the purposes of this Directive:

- 'RID' shall mean the regulations concerning the international carriage of dangerous goods by rail, appearing as Annex I to Appendix B to the Convention concerning international carriage by rail (COTIF), together with its amendments;
- 'CIM' shall mean the uniform rules concerning the contract for international carriage of goods by rail, appearing as Appendix B to the Convention concerning international carriage by rail (COTIF), together with its amendments;
- 'dangerous goods' shall mean those substances and articles the transport by rail of which is prohibited or authorized only on certain conditions by the Annex to this Directive;
- 'transport' shall mean any operation for the transport of dangerous goods by rail, conducted wholly or partially within the territory of a Member State, including the activities of loading, unloading and transfer to or from another mode of transport and the

stops necessitated by the circumstances of the transport, covered by the Annex to this Directive, without prejudice to the arrangements laid down by the laws of the Member States concerning liability in respect of such operations; it shall not include transport wholly performed within the perimeter of an undertaking.

#### *Article 3*

1. Without prejudice to Article 6, dangerous goods the transport of which is prohibited by the provisions of the Annex may not be transported by rail.

2. Save as otherwise provided in this Directive and without prejudice to the rules on market access for railway undertakings or to the rules generally applicable to the transport of goods by rail, the transport of dangerous goods by rail shall be authorized, subject to compliance with the rules laid down in the Annex.

### CHAPTER II

#### **Derogations, restrictions and exemptions**

#### *Article 4*

Each Member State may, for the purposes of national rail transport operations within its territory, retain provisions of its national law on the transport of dangerous goods by rail which are consistent with the United Nations recommendations on the transport of dangerous goods, until such time as the Annex to this Directive is revised to reflect those recommendations. In such cases, the Member State concerned shall inform the Commission thereof.

#### *Article 5*

1. Without prejudice to other Community provisions, each Member State shall retain the right to regulate or prohibit, strictly for reasons other than safety during transport connected in particular with national security or environmental protection, the transport of certain dangerous goods within its territory.

2. (a) For transport via the Channel Tunnel, France and the United Kingdom may impose more stringent provisions than those provided for in the Annex. The Commission shall be informed of such provisions and it shall inform the other Member States.

(b) Where a Member State considers that stricter provisions should be applied to transport through tunnels with characteristics similar to the Channel Tunnel within its territory, it shall inform the Commission. The Commission, acting in accordance with the procedure laid down in

Article 9, shall decide whether the tunnel in question has similar characteristics. Provisions adopted by a Member State shall be notified to the Commission, which shall inform the other Member States.

(c) A Member State in which the ambient temperature is regularly lower than  $-20^{\circ}\text{C}$  may impose more stringent standards as regards the operating temperature of material intended for use in the national transport of dangerous goods by rail within its territory until provisions on the appropriate reference temperatures for given climatic zones are incorporated in the Annex.

3. If, on the occasion of an accident or an incident, a Member State considers that the safety provisions applicable have been found to be insufficient to limit the hazards involved in the transport operation and if there is an urgent need to take action, that Member State shall notify the Commission at the planning stage of the measures which it proposes to take. Acting in accordance with the procedure laid down in Article 9, the Commission shall decide whether the implementation of the measures in question should be authorized and shall determine the duration thereof.

4. Member States may maintain all national provisions applicable on 31 December 1996 to the transport and packaging of substances containing dioxins or furans.

#### *Article 6*

1. Each Member State may authorize the transport by rail within its territory of dangerous goods classified, packed and labelled in accordance with international requirements for maritime or air transport whenever the transport involves a sea or air voyage.

Where a national or international journey involves carriage by sea, a Member State may apply provisions additional to those of the Annex to take account of international rules governing maritime transport, including international rules governing ferry transport.

2. The provisions of the Annex concerning the format of transport documentation and the use of languages in marking or in the documentation required shall not apply to transport operations confined to the territory of a single Member State. A Member State may authorize the use of documentation and languages other than those provided for in the Annex for transport operations confined to its territory.

3. Within its territory a Member State may allow the use of rail wagons constructed before 1 January 1997 which do not conform with the provisions of this Directive, but were constructed according to national provisions in force on 31 December 1996, provided that those wagons are maintained to the required safety levels.

4. A Member State may retain national provisions in force on 31 December 1996 relating to the construction, use and conditions of carriage of new tanks, and new receptacles as defined in Class 2 of the Annex, which differ from the provisions of that Annex, until references to standards for the construction and use of tanks and receptacles are added to the Annex, with the same binding force as the provisions therein, but in any event no later than 31 December 1998. Receptacles and tanks constructed before 1 January 1999 and maintained to the required safety levels may continue to be used under the original conditions.

5. A Member State may retain national provisions other than those in the Annex with regard to the reference temperature for the transport in its territory of liquefied gases or mixtures of liquefied gases, until provisions relating to appropriate reference temperatures for designated climatic areas are incorporated into European standards and referred to in the Annex.

6. A Member State may allow the use, in transport within its territory, of packaging constructed but not certified in accordance with the RID before 1 January 1997, provided that such packaging bears the date of its manufacture, is capable of passing the tests laid down in national provisions in force on 31 December 1996 and provided that they are maintained to the relevant safety levels (including testing and inspection where required), according to the following scheme: metal intermediate bulk containers and metal drums exceeding 50 litres in capacity may be used for up to 15 years after the date of their manufacture; other metal packagings and all plastic packagings may be used for up to five years after the date of their manufacture, but not after 31 December 1998.

7. A Member State may authorize the transport within its territory of certain dangerous goods packed before 1 January 1997 until 31 December 1998, provided that the goods are classified, packed and labelled in accordance with the requirements laid down in national provisions in force before 1 January 1997.

8. A Member State may retain the provisions of its national legislation which are in force on 31 December 1996 and relate to the display of an emergency action code in place of the hazard identification number, laid down in the Annex, for national rail transport operations conducted within its territory.

9. Any Member State may, after consulting the Commission, maintain provisions less stringent than those in the Annex for the transport by rail within its territory of small quantities of certain dangerous goods, with the exception of substances having a medium or high level of radioactivity.

10. A Member State may authorize within its territory *ad hoc* transport operations involving dangerous goods

or transport operations which are prohibited by the Annex or transport operations performed under conditions different from those laid down in the Annex.

11. With due regard to Community law, this Directive shall not prejudice the right of a Member State, after consultation with the Commission, to authorize regular transport operations on particular designated routes within its territory, of dangerous goods, forming part of a defined industrial process, which are either prohibited by the Annex or are performed under conditions different from those laid down in the Annex where those operations are of a local nature and are tightly controlled under clearly specified conditions.

12. Provided that there is no loss of safety, a Member State may grant temporary derogations from the Annex for the purpose of carrying out within its territory the trials necessary before the amendment of that Annex in order to adapt them to technological and industrial developments. The Commission shall be informed accordingly and shall in turn inform the other Member States.

Those temporary derogations, agreed among the Member States' competent authorities on the basis of the Annex, shall take the form of a multilateral agreement proposed to all the Member States' competent authorities by the authority that takes the initiative on any agreement. The Commission shall be informed.

The derogations referred to in the first and second subparagraphs shall be applied without discrimination on grounds of the nationality or place of establishment of the consignor, operator or consignee; they may last for up to five years and shall be non-renewable.

13. A Member State may, until 31 December 1998 at the latest, apply existing agreements with other Member States, without discrimination on grounds of the nationality or place of establishment of the consignor, operator or consignee. Any future derogations shall comply with paragraph 12.

14. In accordance with Community law, this Directive shall not affect a Member State's right, after consulting the Commission, to authorize the transport of dangerous goods under conditions less stringent than those laid down in the Annex to this Directive in the case of local transport over short distances within the perimeters of ports, airports or industrial sites.

#### Article 7

1. Subject to national or Community provisions on market access, the transport of dangerous goods by rail between Community territory and third countries shall be

authorized in so far as it complies with the requirements of the RID.

2. This Directive shall not affect a Member State's right, after informing the Commission, to adopt regulations for its territory on the transport of dangerous goods by rail from and to those Republics of the former Soviet Union that are not contracting parties to the COTIF. Such regulations shall apply only to the transport of dangerous goods by rail (in packaging, in bulk or in tanks) by means of railway wagons authorized in a State which is not a contracting party to the COTIF. By means of appropriate measures and obligations the Member States concerned shall guarantee the maintenance of a level of safety equivalent to that provided for in the RID. In the case of certain Member States the provisions referred to in this paragraph shall apply only to tank wagons.

### CHAPTER III

#### Final provisions

##### Article 8

The amendments necessary to adapt the Annex to scientific and technical progress in the fields covered by this Directive, in particular to take account of amendments to the RID, shall be adopted in accordance with the procedure laid down in Article 9.

##### Article 9

1. The Commission shall be assisted by the committee on the transport of dangerous goods set up by Article 9 of Directive 94/55/EC<sup>(1)</sup>, hereinafter referred to as 'the Committee', which shall be composed of representatives of the Member States and chaired by a representative of the Commission.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

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

If, on the expiry of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

##### Article 10

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1997. 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 Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

##### Article 11

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

##### Article 12

This Directive is addressed to the Member States.

Done at Brussels, 23 July 1996.

For the Council  
The President  
I. YATES

<sup>(1)</sup> OJ No L 319, 12. 12. 1994, p. 7.

## ANNEX

**Regulations concerning the International Carriage of Dangerous Goods by Rail (RID), as applicable with effect from 1 January 1995, on the understanding that 'contracting party' and 'the States or the railways' will be replaced by 'Member State'**

*NB:* Versions in all the official languages of the Community will be published as soon as a consolidated text is ready in all languages.

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\*       \*

For the purposes of this Annex, 'consignment' note means a CIM consignment note used for international transport, but shall not prejudice the right of a Member State to use, for transport not covered by CIM, any other equivalent documentation. In addition, the use of the expression 'ADR' in marginal 15 of this Annex shall not affect a Member State's right, in national traffic, to authorize the rail transport of road vehicles in accordance with national provisions laid down in implementation of Directive 94/55/EC.

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## COUNCIL DIRECTIVE 96/50/EC

of 23 July 1996

on the harmonization of the conditions for obtaining national boatmasters' certificates for the carriage of goods and passengers by inland waterway in the Community

THE COUNCIL OF THE EUROPEAN UNION

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

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Acting in accordance with the procedure referred to in Article 189c of the Treaty<sup>(3)</sup>,

Whereas common provisions on the sailing of inland waterway vessels on the Community's inland waterways should be introduced; whereas a first step towards this goal was accomplished with the adoption of Council Directive 91/672/EEC of 19 December 1991 on the reciprocal recognition of national boatmasters' certificates for the carriage of goods and passengers by inland waterway<sup>(4)</sup>;

Whereas, because of differences in national legislation relating to the conditions for obtaining boatmasters' certificates for inland navigation and the need to make safety requirements in the inland navigation industry gradually stricter, Community rules for the issue of such certificates should be adopted in order to prevent any distortions of competition;

Whereas, in order to guarantee the necessary uniformity and transparency, the Community should define a model for a single national boatmasters' certificate, mutually recognized by the Member States with no exchange obligation, responsibility for the granting of which would, in accordance with the subsidiarity principle, lie with the Member States;

Whereas national navigable waterways not linked to the navigable network of another Member State are not subject to international competition and it is therefore

not necessary to make compulsory on those waterways the common provisions for the granting of boatmasters' certificates laid down in this Directive;

Whereas the main objective of these common provisions must be to improve the safety of navigation and the protection of human life; whereas it appears therefore essential that these provisions establish the minimum requirements which the applicant must meet in order to obtain the boatmasters' certificate for inland navigation;

Whereas the requirements in question must concern at least the age required to sail a vessel, the physical and mental fitness of applicants, their professional experience and knowledge of certain subjects relating to the sailing of a vessel; whereas, in the interests of the safety of the vessel and of the persons on board, Member States may impose additional requirements regarding in particular the knowledge of certain local situations; whereas additional professional knowledge is required to navigate with the aid of radar or to sail a vessel carrying passengers;

Whereas it is necessary to make provision for appropriate procedures to adapt the Annexes of this Directive; whereas it is thus appropriate that the Committee set up by Article 7 of Directive 91/672/EEC should assist the Commission in adapting the Annexes,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. Member States issuing a boatmasters' certificate for the carriage of goods and passengers by inland waterway, hereinafter referred to as the 'certificate', shall do so in accordance with the Community model described in Annex I, which complies with this Directive.

2. Member States shall take all appropriate measures to preclude the risk of certificates being forged.

3. The certificate shall be issued by the competent authority of the Member States in accordance with this Directive. It shall take account of the special characteristics of the waterways and of the certificates referred to in Article 1 of Directive 91/672/EEC, namely:

<sup>(1)</sup> OJ No C 280, 6. 10. 1994, p. 5.

<sup>(2)</sup> Opinion delivered on 25 January 1995 (OJ No C 102, 24. 4. 1995, p. 5).

<sup>(3)</sup> Opinion of the European Parliament of 2 March 1995 (OJ No C 68, 20. 3. 1995, p. 41), common position of the Council of 8 December 1995 (OJ No C 356, 30. 12. 1995, p. 66) and Decision of the European Parliament of 9 May 1996 (OJ No C 152, 27. 5. 1996, p. 46).

<sup>(4)</sup> OJ No L 373, 31. 12. 1991, p. 29.



- the boatmasters' certificate valid for all waterways in the Member States, with the exception of waterways to which the Regulation on the issue of Rhine navigation licences applies (Group A),
  - the boatmasters' certificate valid for all waterways in the Member States, with the exception of the waterways of a maritime character referred to in Annex II to Directive 91/672/EEC, and with the exception of waterways to which the Regulation on the issue of Rhine navigation licences applies (Group B).
4. The Group A or Group B certificate issued by Member States in conformity with this Directive shall be valid for all Group A or Group B waterways in the Community.
5. Subject to Article 8 (2), the Rhine navigation licence, issued in accordance with the revised Convention for the Navigation of the Rhine, shall be valid for all waterways in the Community.
6. The national boatmasters' certificates mutually recognized by Directive 91/672/EEC, appearing in Annex I to this Directive, which are issued not later than 18 months after the date of entry into force of this Directive shall remain valid with no exchange obligation.

#### Article 2

For the purposes of this Directive:

- (a) 'competent authority' shall mean the authority designated by a Member State to issue certificates after verifying that applicants satisfy the requirements;
- (b) 'boatmaster' shall mean the person who has the necessary aptitude and qualifications to sail a vessel on the Member States' waterways and who has nautical responsibility on board;
- (c) 'member of the deck crew' shall mean a person who has regularly participated in sailing a vessel in inland navigation, including manning the tiller.

#### Article 3

1. This Directive shall apply to all boatmasters of inland-waterway vessels: self-propelled barges, tugs, pusher craft, barges, pushed convoys or side-by-side formations, intended for the transport of goods or passengers, except for:

- boatmasters of vessels intended for goods transport which are under 20 metres in length,
- boatmasters of vessels intended for passenger transport, which carry no more than 12 people in addition to the crew.

2. A Member State may, after consulting the Commission, exempt from the application of this

Directive boatmasters operating exclusively on national waterways not linked to the navigable network of another Member State and issue them with national boatmasters' certificates, the conditions for obtaining which may differ from those defined in this Directive. The validity of those national certificates shall in that case be limited to those waterways.

#### Article 4

1. In order to obtain a certificate, an applicant must satisfy the minimum requirements set out in Articles 5 to 8. The certificate shall mention whether the boatmaster has Group A or Group B authorization.
2. The certificates issued by the Member States which meet the minimum requirements mentioned in paragraph 1 shall be mutually recognized.

#### Article 5

An applicant must be at least 21 years old to obtain a certificate. However, Member States may still issue certificates to persons 18 years old or older. Recognition by a Member State of a Group A or B certificate issued by another Member State may be subject to the same minimum age conditions as are required in that Member State for the issue of a certificate for the same Group.

#### Article 6

1. The applicant shall provide proof of physical and mental fitness by passing a medical examination carried out by a doctor recognized by the competent authority. That examination shall cover in particular visual and auditory acuity, colour vision, motricity of the upper and lower limbs and the neuro-psychiatric state and cardiovascular condition of the applicant.
2. On reaching the age of 65 years, the holder of a certificate must, in the following three months and subsequently every year, undergo the examination referred to in paragraph 1; the competent authority shall attest on the certificate that the boatmaster has satisfied this obligation.

#### Article 7

1. An applicant must provide proof of at least four years' professional experience as a member of the deck crew on an inland waterway vessel.
2. To be taken into account, professional experience must be validated by the competent authority of the Member State by being entered in a personal service record. It may have been acquired on any of the Member States' waterways. In the case of waterways part of whose courses are within Community territory, such as the Danube, Elbe and Oder, the professional experience acquired on all sections of those watercourses will be taken into consideration.

3. The minimum duration of the professional experience referred to in paragraph 1 may be reduced by a maximum of three years:

- (a) where the applicant has a diploma recognized by the competent authority which confirms specialized training in inland navigation comprising practical navigation work; the reduction may not be greater than the duration of the specialized training; or
- (b) where the applicant can provide proof of professional experience acquired on a seagoing vessel as a member of the deck crew; in order to obtain the maximum reduction of three years, the applicant must provide proof of at least four years' experience in maritime navigation.

4. The minimum duration of professional experience provided for in paragraph 1 may be reduced by a maximum of three years where the applicant has passed a practical examination in sailing a vessel; the certificate shall in that case cover only vessels with nautical characteristics similar to those of the vessel which underwent the practical examination.

#### Article 8

1. An applicant must have passed an examination of professional knowledge; that examination must include at least the general subjects listed in Chapter A of Annex II.

2. Subject to consultation of the Commission, a Member State may require a boatmaster to satisfy additional requirements concerning knowledge of the local situation for navigation of certain waterways, with the exception of the waterways of a maritime character referred to in Annex II to Directive 91/672/EEC.

Subject to the same reservation, a Member State may require the boatmaster of a passenger vessel, in certain limited transport areas, to have more detailed professional knowledge of special provisions relating to passenger safety, particularly in the event of accidents, fire or shipwreck.

#### Article 9

1. In order to be authorized to navigate with the aid of radar, the boatmaster must hold a special attestation delivered by the competent authority as proof that he has passed the examination covering professional knowledge of the subjects referred to in Chapter B of Annex II.

The Member States shall recognize the qualification issued under the regulation of the issuing of qualifications to sail a vessel with the aid of radar on the Rhine.

2. An applicant satisfying the conditions set out in paragraph 1 shall have his or her fitness to navigate by

radar attested by the competent authority in the form of an endorsement on the certificate.

#### Article 10

In order to be allowed to sail a boat transporting passengers on the waterways of the Member States, either the boatmaster or another member of the crew must be in possession of a special certificate issued by the competent authority as proof of his/her having passed an examination of professional knowledge in the subjects referred to in Chapter C of Annex II.

#### Article 11

The Commission, acting in accordance with the procedure laid down in Article 12, may take the necessary steps with a view to adapting the form of boatmasters' certificate in Annex I and in the light of the development of the necessary professional knowledge required for the issue of the certificate and specified in Annex II.

#### Article 12

1. The Commission shall be assisted in application of Article 11 by the Committee set up by Article 7 of Directive 91/672/EEC.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

(3) a) The Commission shall adopt measures which apply immediately;

(b) However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event the Commission may defer application of the measures which it has decided for a period of not more than one month from the date of such communication. The Council, acting by a qualified majority, may take a different decision within the same time limit.

#### Article 13

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to

comply with this Directive not later than 18 months after the date of entry into force of this Directive. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, 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 Member States.

2. Member States shall immediately communicate to the Commission the text of the provisions they adopt in the field governed by this Directive.

3. Where necessary, Member States shall assist one another in the implementation of this Directive.

#### *Article 14*

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

#### *Article 15*

This Directive is addressed to the Member States.

Done at Brussels, 23 July 1996.

*For the Council*

*The President*

I. YATES

## ANNEX I

## MODEL BOATMASTERS' CERTIFICATE FOR INLAND NAVIGATION

(85 mm × 54 mm — light blue background)

The physical characteristics of the paper must comply with ISO standards 78.10.

BOATMASTERS' CERTIFICATE FOR INLAND NAVIGATION: A/B		UNITED KINGDOM
1. xxx		
2. xxx		
3. 1. 1. 1996 — UK-London		
4. 2. 1. 1996		
	6.	
7. #####		
8. A B		
9. R tonnes, kW, xx		
10. 1. 1. 2061		
11.	5. xxx	

BOATMASTERS' CERTIFICATE FOR THE CARRIAGE OF GOODS AND PASSENGERS BY INLAND WATERWAY	
1. Holder's name	9. — R – Radar
2. First name(s)	— Sole category and capacity of vessel (tonnes, kW, passengers)
3. Date and place of birth	10. Expiry date
4. Date of issue of the certificate	11. Endorsement(s)
5. Issue number	Restriction(s)
6. Photograph of the holder	
7. Holder's signature	
8. A. All waterways except the Rhine	
B. All waterways except those of a maritime character and the Rhine	
	European Union model

## ANNEX II

PROFESSIONAL KNOWLEDGE REQUIRED TO OBTAIN THE BOATMASTERS' CERTIFICATE FOR  
INLAND NAVIGATION

## CHAPTER A

## General subjects relating to the transport of goods and passengers

## PART 1: GROUP A CERTIFICATE

1. *Navigation*

- (a) Exact knowledge of the traffic regulations of inland and maritime waterways, particularly of ECIW (European code for inland waterways) and of the International Regulations for Preventing Collisions at Sea, including nautical signing (designation and buoying of waterways);
- (b) Knowledge of the general geographical, hydrological, meteorological and morphological characteristics of the main inland and maritime waterways;
- (c) Terrestrial navigation with:  
Determination of the course, position lines and ship's position, nautical printed matters and publications, work in the sea chart, nautical marks and buoyage systems, checking of the compass and bases of tidology.

2. *Vessel manoeuvring and handling*

- (a) Handling of the vessel taking account of the effect of wind, current, thrust deduction and draught for the evaluation of sufficient buoyancy and stability;
- (b) Role and functioning of the rudder and propeller;
- (c) Anchoring and berthing in all conditions;
- (d) Manoeuvres in locks and ports, manoeuvres when meeting and passing other vessels.

3. *Vessel construction and stability*

- (a) Knowledge of the basic principles of vessel construction with regard in particular to the safety of persons, the crew and the vessel;
- (b) Basic knowledge of Council Directive 82/714/EEC of 4 October 1982 on the technical provisions for inland waterway vessels<sup>(1)</sup>;
- (c) Basic knowledge of the main component parts of the vessel;
- (d) Theoretical knowledge of the buoyancy and stability rules and their practical application, especially seaworthiness;
- (e) Additional requirements and in particular additional equipment, on maritime waterways.

4. *Engines*

- (a) Basic knowledge of the design and working of the engines in order to ensure their proper functioning;
- (b) Operation and inspection of the main and auxiliary engines and action to be taken in case of disorder.

5. *Loading and unloading*

- (a) Use of draught indicators;
- (b) Determination of the loading weight using the certificate of measurement;
- (c) Loading and unloading, stowage of cargo (stowage plan).

<sup>(1)</sup> OJ No L 301, 28. 10. 1982, p. 1.

#### 6. *Action in special circumstances*

- (a) Principles of accident prevention;
- (b) Measures to be taken in the event of damage, collision and running aground including the sealing of leaks;
- (c) Use of rescue apparatus and equipment;
- (d) First aid in the event of accidents;
- (e) Prevention of fires and use of fire-fighting equipment;
- (f) Prevention of pollution of waterways;
- (g) Specific measures relating to the rescue of persons, vessels and cargo on maritime shipping routes, survival in distress.

### PART 2: GROUP B CERTIFICATE

#### 1. *Navigation*

- (a) Exact knowledge of the traffic regulations of inland waterways, particularly of ECIW (European code for inland waterways), including nautical signing (designation and buoying of waterways);
- (b) Knowledge of the general geographical, hydrological, meteorological and morphological characteristics of the main inland waterways;
- (c) Determination of the course, nautical printed matters and publications, buoyage systems.

#### 2. *Vessel manoeuvring and handling*

- (a) Handling of the vessel taking account of the effect of wind, current, thrust deduction and draught for the evaluation of sufficient buoyancy and stability;
- (b) Role and functioning of the rudder and propeller;
- (c) Anchoring and berthing in all conditions;
- (d) Manoeuvres in locks and ports; manoeuvres when meeting and passing other vessels.

#### 3. *Vessel construction and stability*

- (a) Knowledge of the basic principles of vessel construction with regard in particular to the safety of persons, the crew and the vessel;
- (b) Basic knowledge of Council Directive 82/714/EEC of 4 October 1982 on the technical provisions for inland waterway vessels;
- (c) Basic knowledge of the main component parts of the vessel;
- (d) Theoretical knowledge of the buoyancy and stability rules and their practical application.

#### 4. *Engines*

- (a) Basic knowledge of the design and working of the engines in order to ensure their proper functioning;
- (b) Operation and inspection of the main and auxiliary engines and action to be taken in case of disorder.

#### 5. *Loading and unloading*

- (a) Use of draught indicators;
- (b) Determination of the loading weight using the certificate of measurement;
- (c) Loading and unloading, stowage of cargo (stowage plan).

6. *Action in special circumstances*

- (a) Principles of accident prevention;
- (b) Measures to be taken in the event of damage, collision and running aground, including the sealing of leaks;
- (c) Use of rescue apparatus and equipment;
- (d) First aid in the event of accidents;
- (e) Prevention of fires and use of fire-fighting equipment;
- (f) Prevention of pollution of waterways.

CHAPTER B

**Obligatory additional subjects for radar navigation**

- (a) Knowledge of radar theory: general knowledge of radioelectric waves and principles of radar operation;
- (b) Ability to use radar equipment, interpretation of the radar display, analysis of the information supplied by the equipment and knowledge of the limits of the information supplied by radar;
- (c) Use of the turn indicator;
- (d) Knowledge of the ECIW rules on radar navigation.

CHAPTER C

**Obligatory additional knowledge for passenger transport**

- 1. Basic knowledge of technical regulations on: the stability of passenger vessels in case of damage, division into watertight compartments, plane of maximum draught.
  - 2. First aid in case of accidents.
  - 3. Fire prevention and fire-fighting equipment.
  - 4. Life-saving methods and equipment.
  - 5. How to protect passengers in general, especially in the case of evacuation, damage, collision, running aground, fire, explosion and other situations which may give rise to panic.
  - 6. Knowledge of safety instructions (emergency exits, gangplank, use of emergency helm).
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## COUNCIL DIRECTIVE 96/51/EC

of 23 July 1996

amending Directive 70/524/EEC concerning additives in feedingstuffs

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the European Parliament<sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

(1) Whereas application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>(4)</sup> has shown that certain basic concepts must be revised to take account of the need to ensure a greater degree of protection of animal and human health and of the environment;

(2) Whereas experience has shown that the current rules on the use of additives in feedingstuffs do not provide all the necessary assurances as to safety, particularly because of the circulation in the Community of poor copies of zootechnical additives; whereas it is therefore essential to link the authorization of such additives to the person responsible for putting the additive authorized by the Community into circulation;

(3) Whereas a distinction should be made between additives which are widely used and present no particular dangers for the manufacture of feedingstuffs and high technology additives with a very specific composition for which the person responsible for putting them into circulation must receive authorization, in order to avoid copies which might not be in conformity and might therefore be unsafe;

(4) Whereas there should be drawn up in the form of an Annex to this Directive, first a list of additives for which authorization to put them into circulation is granted to persons responsible who

alone are entitled to put the additives in question into circulation, second, a list of other additives which may be put into circulation by any person provided that they are additives which meet the specifications in the dossiers on the basis of which they have been authorized;

(5) Whereas, to facilitate application of Directive 70/524/EEC, the list of definitions should be supplemented and certain definitions should be amended; whereas, in particular, the concept of additives should be defined so as also to take account of their possible effects on feed materials, animal products, animal welfare or the environment; whereas processing aids should be excluded from the scope of this Directive insofar as these substances are used in the processing of feed materials or of feedingstuffs and no longer have any effect in the finished product;

(6) Whereas micro-organisms authorized as such in group 0 for improving animal production and in particular influencing gastro-intestinal flora must form colonies;

(7) Whereas, where in particular vitamins, trace elements or colouring matter are present in certain raw materials in their natural state, they must not be considered as additives unless products specially enriched with such a substance corresponding to an additive are concerned which cannot therefore be considered as raw materials naturally containing the substances concerned;

(8) Whereas the premixtures referred to in this Directive may under no circumstances be regarded as preparations covered by the definition of additive;

(9) Whereas experience has shown that the authorization of additives by means of directives causes considerable delays; whereas such delays in the transposition of directives have sometimes resulted in distortions of competition and even created barriers to trade; whereas, to remedy this situation, additives should be authorized by means of regulations;

(10) Whereas fees may be charged for the examination of dossiers by the Member State acting as rapporteur; whereas the levels of such fees should be harmonized in order to obviate distortion of

<sup>(1)</sup> OJ No C 218, 12. 8. 1993, p. 1.

<sup>(2)</sup> OJ No C 128, 9. 5. 1994, p. 97.

<sup>(3)</sup> OJ No C 52, 19. 2. 1994, p. 18.

<sup>(4)</sup> OJ No L 270, 14. 2. 1970, p. 1. Directive as last amended by Directive 92/25/EC (OJ No L 125, 23. 5. 1996, p. 35).



competition; whereas such harmonization will fall within the general framework of future Community rules on fees or charges to be levied in the animal feed sector; whereas it will then be necessary to examine whether the levels of fees to be charged should not vary depending on the type of authorization sought or the additive group concerned; whereas it would be fair to charge higher fees, for example for examining dossiers concerning growth promoters than for examining dossiers concerning vitamins; whereas it would be fair not to charge a fee for additives or examining the dossier concerning very simple technological additives; whereas the fee should be paid to the Member State acting as rapporteur at the time of submission of the dossier;

- (11) Whereas, until the Council has adopted legal provisions regarding fees, a Member State acting as rapporteur should be able to adopt provisions or retain the legal provisions which it has adopted in this area;
- (12) Whereas the introduction of fees must be accompanied by the assurance that a decision will be reached by a given deadline on the application for authorization to put an additive into circulation;
- (13) Whereas certain feed additives may reach the human food chain; whereas it is necessary for the Scientific Committee for Animal Nutrition to be able to collaborate with the Scientific Committee for Food on such matters which may influence consumer health;
- (14) Whereas the search for new additives belonging to the group of substances for which authorization is linked to those persons responsible for putting them into circulation requires costly investment; whereas protection for a period fixed at ten years should therefore be afforded to scientific data or information included in the dossier on the basis of which the first authorization is granted; whereas protection should also be afforded to new data supplied with a view to renewal or alteration of the conditions of the original authorization for a shorter period which is fixed at five years; whereas, during those periods of protection, any new applicant for authorization will be obliged to submit a dossier drawn up in accordance with Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition<sup>(1)</sup> unless the parties reach agreement on shared use of the data; whereas where two or more persons benefit from the authorization granted to a single additive, they must respond individually or collectively to any

request from the Commission for scientific information on pain of losing the benefit of the authorization;

- (15) Whereas, in order to put an end to the differences between Member States regarding the arrangements for admitting the additives in Annex II onto their territory, the provisional authorization of additives meeting a minimum number of conditions should be extended throughout the Community; whereas such authorizations become definitive for certain additives or are valid for a period of 10 years for other additives when all the conditions for authorization are fulfilled, although that may occur no later than the date of expiry of the period of provisional authorization;
- (16) Whereas for applications for authorization concerning additives referred to in Article 2 (aaa) and (aaaa) lodged before 1 April 1998 and in respect of which provisional authorization has been given before 1 October 1999, Member States may allow the putting into circulation and use of the additive on their national territory for a period not exceeding five years from the date of adoption of the authorizing regulation;
- (17) Whereas for applications for authorization concerning additives referred to in Article 2 (aaa) and (aaaa) submitted with effect from 1 April 1998 and in respect of which provisional authorization has been given before 1 October 1999, Member States may allow the putting into circulation and use of the additive for a period not exceeding five years from the date of adoption of the authorizing regulation;
- (18) Whereas it is necessary to have transitional arrangements for the changeover from the old to the new authorization system; whereas the date of entry into force of the relevant provisions must therefore be brought forward;
- (19) Whereas account should be taken of developments in techniques for using additives; whereas provision should therefore be made, in certain cases, for the possibility of administering additives, under certain conditions, by means other than incorporation in feedingstuffs;
- (20) Whereas, in the present state of scientific and technical knowledge and taking account of the methods of inspection, the use of antibiotics, coccidiostats and other medicinal substances and growth promoters should not be authorized by any mode of administration other than incorporation in feedingstuffs;
- (21) Whereas monographs of zootechnical additives should no longer be published; whereas an

<sup>(1)</sup> OJ No L 64, 7. 3. 1987, p. 19. Directive as last amended by Commission Directive 95/11/EC (OJ No L 106, 11. 5. 1995, p. 23).

information note on the additives in question should be published instead in order to facilitate their identification during controls;

(22) Whereas the national authorities should be provided with a standard sample to enable them to carry out checks;

(23) Whereas the mixing of additives belonging respectively to the groups of antibiotics, coccidiostats, other medicinal substances and growth promoters with micro-organisms must be prohibited, unless the specific authorization of the micro-organism allows such mixing;

(24) Whereas, in view of the deletion of Annexes I and II, in the interests of clarity and transparency, there should be published annually the list of persons responsible for putting the additives referred to in Article 2 (aaa) into circulation and a list of producers who have received from an authorized person the right to manufacture additives as well as a list of all authorized additives,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

Directive 70/524/EEC is hereby amended as follows:

1) Article 1 shall be replaced by the following:

‘SCOPE

#### *Article 1*

1. This Directive shall apply to additives in feedingstuffs.

2. This Directive shall not apply to processing aids used deliberately as substances in the processing of feed materials or of feedingstuffs in order to achieve a certain technological objective during treatment or processing which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

3. Provided they are not products specially enriched with substances corresponding to additives, substances present in their natural state in feed materials which are part of the normal composition of feedingstuffs and which correspond to a substance authorized under this Directive shall not be regarded as additives.’;

2) the following title shall be inserted between Articles 1 and 2:

‘DEFINITIONS’;

3) Article 2 shall be amended as follows:

(i) point (a) shall be replaced by the following:

‘(a) additives: substances or preparations used in animal nutrition in order to:

— affect favourably the characteristics of feed materials or of compound feedingstuffs or of animal products; or

— satisfy the nutritional needs of animals or improve animal production, in particular by affecting the gastro-intestinal flora or the digestibility of feedingstuffs; or

— introduce into nutrition elements conducive to attaining particular nutritional objectives or to meeting the specific nutritional needs of animals at a particular time; or

— prevent or reduce the harmful effects caused by animal excretions or improve the animal environment;

(aa) “micro-organisms”: micro-organisms forming colonies;

(aaa) additives subject to authorization linked to the person responsible for putting them into circulation: the additives listed in Part I of Annex C;

(aaaa) other additives: additives not subject to authorization linked to the person responsible for putting them into circulation and referred to in Part II of Annex C;’

(ii) point (f) shall be replaced by the following:

‘(f) feed materials: various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures, hereinafter referred to as “feed materials”;

(iii) the following points shall be added:

'(k) "putting into circulation" or "circulation": the holding of products for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves;

(l) person responsible for putting into circulation: the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorization and for putting it into circulation.';

4) Articles 3 to 9 shall be replaced by the following:

#### PROCEDURE FOR THE AUTHORIZATION OF ADDITIVES

##### Article 3

Member States shall require that no additive may be put into circulation unless a Community authorization has been granted. This authorization shall be granted under a Commission regulation in accordance with the procedure laid down in Article 4.

##### Article 3a

Community authorization of an additive shall be given only if:

- (a) when used in animal nutrition it has one of the effects referred to in Article 2 (a);
- (b) taking account of the conditions of use, it does not adversely affect human or animal health or the environment, nor harm the consumer by impairing the characteristics of animal products;
- (c) its presence can be monitored:
  - as an additive per se,
  - in premixtures,
  - in feedingstuffs or, where appropriate, in feed materials;
- (d) at the level permitted, treatment or prevention of animal disease is excluded; this condition shall not apply to additives belonging to the group of coccidiostats and other medicinal substances;
- (e) for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.

##### Article 4

1. In order to obtain the Community authorization for a substance or a preparation as an additive or for a new use in the case of an already authorized additive, the applicant for authorization shall select a Member State to act as rapporteur during the scrutiny procedure on the dossier he has compiled in accordance with the provisions of Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition(\*). Where the applicant is established in a third country, he must have a representative in the Community.

2. The Member State acting as rapporteur shall check that:

- (a) the dossier has been compiled in accordance with Directive 87/153/EEC;
- (b) the substance or preparation, according to the information given, appears to meet the conditions laid down in Article 3a.

3. The applicant for Community authorization shall dispatch to the Commission, via the Member State acting as rapporteur, an application accompanied by the dossier, sending copies to the other Member States, which shall acknowledge receipt at the earliest opportunity. That dispatch shall be affected no later than one year after the date of submission of the applicant's dossier in the Member State acting as rapporteur, unless the latter is rejected or postponed. The Member State acting as rapporteur shall inform the applicant, the other Member States and the Commission of the reasons for rejection or postponement of the dossier.

4. Member States shall have a period of sixty days from the date on which the dossier was dispatched to them in which to check whether the dossier has been compiled in accordance with Directive 87/153/EEC and, where appropriate, to submit their comments in writing to the Commission and the other Member States.

If, on expiry of the period referred to in the first paragraph, no objection has been made, the representative of the Commission shall have a period of thirty days in which to include the authorization application on the agenda for the Standing Committee for Feedingstuffs.

5. If, after consultation of the Standing Committee for Feedingstuffs, it is deemed that the rules on presentation of dossiers have not been complied with, a representative of the Commission shall so notify the applicant for authorization to put into circulation and the Member State acting as rapporteur; where necessary, a new application must be submitted in accordance with the above provisions.

6. The Commission shall ensure that a decision is taken, in accordance with the procedure laid down

in Article 23, on the application for Community authorization within 320 days following its inclusion on the agenda for the Standing Committee for Feedingstuffs in accordance with the second subparagraph of paragraph 4. However, this time limit shall be interrupted where a request is made for additional information by a Member State in the Standing Committee for Feedingstuffs, or at the request of the Scientific Committee for Animal Nutrition.

Where an application for Community authorization to put an additive into circulation is rejected or the decision on it is postponed, a representative of the Commission shall inform the applicant for authorization and the Member State acting as rapporteur of the reasons for the rejection or postponement of the decision.

(\*) OJ No L 64, 7. 3. 1987, p. 19. Directive as last amended by Directive 95/11/EC (OJ No L 106, 11. 5. 1995, p. 23).

#### Article 5

Amendments to Directive 87/153/EEC:

- which arise from developments in scientific and technical knowledge and
- take account of the provisions of Article 9b (1), Article 9c (3), Article 9o and Article 9q (5)

shall be adopted in accordance with the procedure laid down in Article 23.

#### Article 6

1. A fee may be charged, according to the additive groups and the nature of the Community authorization requested, by the Member State acting as rapporteur for the examination of dossiers arising from the obligations laid down in Articles 4 (2), 9b (1), 9c (3) and 9g (4). This fee shall be paid at the time of submission of the dossier.

2. Before 1 October 1999, the Council, acting by a qualified majority on a proposal from the Commission, shall fix the level of the fee referred to in paragraph 1.

#### Article 7

1. Member States and the Commission shall ensure that any information which, if disseminated, could affect industrial and commercial property rights is kept confidential.

2. Confidentiality shall not apply to:

- the name and composition of the additive,
- the physico-chemical and biological characteristics of the additive,
- the interpretation of the pharmacological, toxicological and ecotoxicological data relating to the additive,

- the analytical methods for monitoring the additive itself and the additive in premixtures, in the feedingstuffs and, where appropriate, in feed materials,
- the methods for testing for residues of the additive or metabolites thereof in animal products.

#### Article 7a

If an additive contains or consists of genetically modified organisms within the meaning of Article 2 (1) and (2) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms(\*), a specific environmental risk assessment similar to that laid down in the abovementioned Directive shall be carried out; for this purpose, the following documents shall be included in the dossier submitted pursuant to Article 4 of this Directive in order to ensure compliance with the principles set out in Article 3a:

- a copy of any written consent or consents of the competent authorities to the deliberate release into the environment of genetically modified organisms for research and development purposes pursuant to Article 6 (4) of Directive 90/220/EEC and the result of the release(s) with respect to the risk in each case to human health and the environment,
- the complete technical dossier supplying the information requested in Annexes II and III to Directive 90/220/EEC and the environmental risk assessment resulting from this information; the results of any investigations performed for the purposes of research or development.

Articles 11 to 18 of Directive 90/220/EEC shall not apply to additives consisting of or containing genetically modified organisms.

(\*) OJ No L 117, 8. 5. 1990, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).

#### Article 8

1. The Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC(\*) shall be responsible for assisting the Commission, at the latter's request, on all scientific questions relating to the use of additives in animal nutrition.

2. At the request of the Commission, the Member State acting as rapporteur shall ensure that all or part of the dossier referred to in Article 4 is officially forwarded to the members of the Committee referred to in paragraph 1.

(\*) OJ No L 279, 9. 10. 1976, p. 35. Decision as amended by Decision 86/105/EEC (OJ No L 93, 8. 4. 1986, p. 14).

ARRANGEMENTS APPLICABLE TO  
AUTHORIZATIONS FOR ADDITIVES LINKED TO  
THE PERSON RESPONSIBLE FOR PUTTING THEM  
INTO CIRCULATION

**Authorization given for 10 years**

*Article 9*

Additives as referred to in Article 2 (aaa) which meet the conditions laid down in Article 3a shall be authorized and included in Chapter I of the list referred to in Article 9t (b).

**Provisional authorization for a maximum of four years**

*Article 9a*

1. In the case of the additives referred to in Article 2 (aaa), provisional authorization may be given at Community level for the use of a new additive or a new use of an additive already authorized, provided that the conditions laid down in Article 3a (b), (c), (d) and (e) are met and it is reasonable to assume, in view of the available results, that the other condition laid down in Article 3a (a) is also met. These additives shall be included in Chapter II of the list referred to in Article 9t (b).

2. Provisional authorization as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.

**Renewal of authorization after 10 years**

*Article 9b*

1. Community authorization of additives referred to in Article 2 (aaa) shall be valid for 10 years from the date on which final authorization takes effect and shall be renewable for 10-year periods. In the event of renewal, the authorization holder shall send to the Commission, via the Member State acting as rapporteur, an application accompanied by a dossier complying with the provisions to be laid down for the renewal of authorizations for additives in Directive 87/153/EEC. The application and the dossier shall be sent, at least one year before the date of expiry of the authorization, to the Commission, which shall acknowledge receipt thereof at the earliest opportunity. A copy of the renewal application, together with the dossier, shall be officially forwarded by the authorization holder via the Member State acting as rapporteur to the other Member States, which shall acknowledge receipt thereof at the earliest opportunity.

2. Articles 3, 3a, 4, 7, and 7a shall apply *mutatis mutandis* to applications for renewal.

3. Where, for reasons beyond the control of the authorization holder, no decision may be taken on the renewal application before the expiry date of the authorization, the period of authorization of the additive shall be automatically extended until the Commission takes a decision.

**DATA PROTECTION**

*Article 9c*

1. In the case of the additives referred to in Article 2 (aaa), the scientific data and other information in the initial dossier submitted for the purpose of the first authorization may not be used for the benefit of other applicants for a period of 10 years:

- (a) from the date on which the first authorization by means of regulation takes effect for the additives referred to in Article 9g (1), Article 9h (1) and Article 9i (1), or
- (b) for other additives from the date on which the first authorization by means of regulation takes effect or counting from 1 October 1999 if the latter date of taking effect is earlier,

unless the applicant has agreed with the authorization holder that such data and information may be used.

During this period, however, authorizations for putting into circulation may be granted to persons other than the person responsible for first putting the additive into circulation provided that the conditions in Articles 3a and 4 are met.

2. Where additional information is supplied on an additive which has been provisionally authorized under Article 9a, for the purpose of obtaining authorization of the additive under Article 3a, that information shall be considered as an integral part of the initial dossier and shall consequently cease to be protected at the same time as the information in the initial dossier.

3. On expiry of the 10-year period referred to in paragraph 1, the findings of all or part of the evaluation conducted on the basis of the scientific data and information in the dossier which led to authorization of the additive may be used by the Commission or by a Member State for the benefit of another applicant for authorization to put an additive which has already been authorized into circulation.

In such a case, an application accompanied by a dossier in accordance with the provisions to be laid down for this purpose in Directive 87/153/EEC shall be addressed by the new applicant, via a Member State acting as rapporteur, to the Commission,

which shall acknowledge receipt thereof as quickly as possible. A copy of the application, together with the dossier, shall be officially forwarded by the new applicant, via a Member State acting as rapporteur, to the other Member States, which shall acknowledge receipt thereof at the earliest opportunity.

The provisions of Articles 3, 3a, 4, 7 and 7a shall apply *mutatis mutandis*.

4. The provisions of paragraph 3 shall also apply to the use of data from a dossier concerning an additive which has been the subject of withdrawal of authorization at the request of the holder of that authorization.

5. The additional scientific data and information required for modification of the conditions for listing an additive or for renewal of the authorization in accordance with Article 9b (1) or any new scientific data or information provided during the period of authorization of the additive may not be used by the Commission or by a Member State for the benefit of another applicant for a period of five years from the date on which the authorization of a new use, the renewal or the submission of new scientific data or information takes effect.

Where the data-protection period granted for modification of the conditions for listing an additive expires before the end of the period provided for in paragraph 1, the five-year period shall be extended so that both periods expire simultaneously.

6. Without prejudice to paragraph 1, an applicant for an authorization for an additive referred to in Article 2 (3) (aaa) shall, before beginning toxicological tests on vertebrates, check whether his product or its active substance has not already been authorized. If necessary, he shall find out from a Member State's competent authorities whether the product or active substance concerned is the same as that already authorized.

If the product or active substance concerned has already been authorized, the applicant and the holder(s) of earlier authorizations shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat the toxicological tests on vertebrates.

If, however, the applicant and the holder(s) of previous authorizations for the same product do not reach agreement on sharing the information, the Member States may take national measures to oblige the applicant and the holder(s) of previous authorizations established within their territories to share the information, in order to avoid repeating toxicological tests on vertebrates undertaken on their territory and may lay down conditions for the use of the information while ensuring a reasonable balance between the interests of the parties concerned.

## ARRANGEMENTS APPLICABLE TO AUTHORIZATION OF OTHER ADDITIVES

### Authorization without a time limit

#### Article 9d

1. Additives as referred to in Article 2 (aaaa) which meet the conditions laid down in Article 3a shall be authorized and included in Chapter III of the list referred to in Article 9t (b).

2. Additives as referred to in Article 2 (aaaa) included in Annex I before 1 April 1998 shall be authorized and included in Chapter III of the list referred to in Article 9t (b).

### Provisional authorization for a maximum of four or five years

#### Article 9e

1. In the case of the additives referred to in Article 2 (aaaa), provisional authorization may be given at Community level for the use of a new additive or a new use of an additive already authorized, provided that the conditions laid down in Article 3a (b), (c), (d) and (e) are met and it is reasonable to assume that the condition laid down in Article 3a (a) is also met. These additives shall be included in Chapter IV of the list referred to in Article 9t (b).

2. Provisional authorization as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.

3. Additives as referred to in Article 2 (aaa), included in Annex II before 1 April 1998, may continue to be the subject of national provisional authorizations; they shall be included in Chapter IV of the list referred to in Article 9t (b). The period of provisional authorization of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.

## TRANSITIONAL ARRANGEMENTS APPLICABLE TO AUTHORIZATIONS FOR ADDITIVES LINKED TO THE PERSON RESPONSIBLE FOR PUTTING THEM INTO CIRCULATION

#### Article 9f

Notwithstanding Article 3, Member States shall permit the additives listed in Annex B to be put into circulation.

### Additives included in Annex I before 1 January 1988

#### Article 9g

1. Additives as referred to in Article 2 (aaaa) included in Annex I before 1 January 1988 shall be provisionally authorized as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation.

2. With a view to their re-evaluation, the additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was granted or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.

3. In accordance with the procedure laid down in Article 23, provisional authorization of the additives shall be withdrawn through the adoption of a Regulation and they shall be deleted from the list in Chapter I of Annex B before 1 October 1999:

- (a) if the documents prescribed in paragraph 2 are not submitted within the time allowed or
- (b) if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the date in the dossier on the basis of which the original authorization was given.

4. Member States shall ensure that the person responsible for putting an additive as referred to in paragraph 1 into circulation submits, as provided for in Article 4 and not later than 30 September 2000, the dossier referred to in Article 4 with a view to re-evaluation. Where he fails to do so, the authorization of the additive in question shall be withdrawn through the adoption of a regulation in accordance with the procedure laid down in Article 23 and it shall be deleted from the list in Chapter I of Annex B.

5. The Commission shall take all necessary measures to ensure that re-evaluation of the dossiers referred to in paragraph 4 is completed no later than three years after the dossier is submitted.

In accordance with the procedure laid down in Article 23, authorizations of the additives referred to in Article 1:

- (a) shall be withdrawn and they shall be deleted from the list in Chapter I of Annex B through the adoption of a regulation, or
- (b) shall be replaced by authorizations linked to the person responsible for putting them into circulation for a period of 10 years through the adoption of a regulation taking effect no later than 1 October 2003 and included in Chapter I of the list referred to in Article 9t (b).

6. The provisions of Article 9b (3) shall apply *mutatis mutandis*.

#### **Additives included in Annex I after 31 December 1987**

##### *Article 9h*

1. Additives as referred to in Article 2 (aaa) included in Annex I after 31 December 1987 shall

be authorized provisionally as from 1 April 1998 and transferred to Chapter II of Annex B with a view to their authorization for a period of 10 years as additives linked to a person responsible for putting them into circulation in accordance with paragraphs 2 and 3.

2. The additives referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was given or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.

3. In accordance with the procedure laid down in Article 23, provisional authorizations of the additives referred to in paragraph 1:

- (a) shall be withdrawn and they shall be deleted from the list in Chapter II of Annex B, through the adoption of a regulation, if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs or the identification notes are not in accordance with the data in the dossier on the basis of which the original authorization was given, or
- (b) shall be replaced by authorizations linked to the person responsible for putting them into circulation, which shall be given for a period of ten years through the adoption of a regulation taking effect no later than 1 October 1999 and included in Chapter I of the list referred to in Article 9t (b).

4. The provisions of Article 9b (3) shall apply *mutatis mutandis*.

#### **Additives included in Annex II before 1 April 1998**

##### *Article 9i*

1. Additives as referred to in Article 2 (aaa) included in Annex II before 1 April 1998 may continue to be the subject of national provisional authorizations; they shall be authorized and transferred to Chapter III of Annex B with a view to their authorization as additives linked to a person responsible for putting them into circulation; the period of provisional authorization of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.

2. The additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person

responsible for the dossier on the basis of which the former authorization was given or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.

3. In accordance with the procedure laid down in Article 23, provisional authorizations of the additives referred to in paragraph 1:

- (a) shall be withdrawn and they shall be deleted from the list in Chapter III of Annex B through the adoption of a regulation if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the data in the dossier on the basis of which the original authorization was given, or
- (b) shall be replaced by provisional authorizations as referred to in paragraph 1 linked to the person responsible for putting them into circulation through the adoption of a regulation taking effect no later than 1 October 1999 and the additives shall be included in Chapter II of the list referred to in Article 9t (b).

4. The provisions provided for in Article 9b (3) shall apply *mutatis mutandis*.

#### Article 9j

Applications for authorization to put into circulation submitted between 1 April 1998 and 30 September 1999 in respect of which the Commission has not yet given a ruling at that date shall be examined in accordance with Articles 3, 3a, 7, 7a, 9, 9a, 9b, 9c, 9d, 9e, 9n and 9o, as appropriate.

### DISTRIBUTION AND USE OF ADDITIVES

#### Article 9k

1. Member States shall ensure that in the field of animal nutrition only additives authorized in accordance with this Directive may be put into circulation and that they may be used only if incorporated in feedingstuffs under the conditions set out in the authorization regulation.

2. Notwithstanding paragraph 1, additives belonging to groups other than "antibiotics", "coccidiostats and other medicinal substances", and growth promoters may be used if administered by a method other than incorporation in feedingstuffs, on condition that that method is provided for in the authorization regulation.

3. Member States shall, in particular, ensure that additives are added to feed materials and to straight feedingstuffs only where their use is expressly provided for in the authorization regulation.

### REGISTRATION

#### Article 9l

1. Where additives as referred to in Article 2 (aaa) are authorized, the person(s) responsible for putting them into circulation shall be given a registration number and the additive shall be given a Community registration number.

2. Authorized additives as referred to in Article 2 (aaaa) shall be given a Community registration number.

### WITHDRAWAL OF ADDITIVES

#### Article 9m

A regulation shall be adopted to withdraw the authorization of an additive:

- at the request of the person responsible for putting the additive into circulation, if the additive is one of those referred to in Article 2 (aaa),
- if any of the conditions for the authorization of the additive referred to in Article 3a are no longer met,
- if a standard sample of the additive is not supplied to the official authorities which have requested it or if an additive put into circulation does not correspond to the standard sample of the authorized additive,
- if a reference sample of the active substance is not supplied to the official authorities which have requested it,
- if the person responsible for putting the additive into circulation does not provide, within a given period of time, the information requested by a person responsible at the Commission.

However, such additives may continue to be authorized in order to use up stocks for a period of no longer than one year if at least the conditions laid down in Article 3a (b) and (e) continue to be met.

### MONOGRAPHS AND IDENTIFICATION NOTES

#### Article 9n

1. In accordance with Directive 87/153/EEC, Member States shall ensure that applicants present a monograph for additives as referred to in Article 2 (aaa).

2. During the authorization procedure for additives as referred to in Article 2 (aaa), the Standing Committee for Feedingstuffs shall give an opinion, if appropriate after having made the necessary amendments, on the monograph of the additive presented in the dossier provided for in Article 4.



The Commission shall approve the opinion given by the Standing Committee for Feedingstuffs on the monograph and its amendments in accordance with the procedure laid down in Article 23.

3. Monographs may also be approved for additives other than those referred to in paragraph 1 in accordance with the procedure laid down in paragraph 2.

4. The competent authorities of the Member States shall have recourse to the monograph:

- (a) to determine whether an additive for which authorization to put into circulation has been requested constitutes an innovation or should be considered as a copy;
- (b) to ascertain whether the additive put into circulation actually corresponds to the additive described in the dossier on the basis of which the Community authorization was granted.

5. Subsequent amendments to be made to monographs on account of developments in scientific and technical knowledge shall be submitted to the Standing Committee for Feedingstuffs for its opinion in accordance with the procedure laid down in Article 23.

#### Article 9o

1. In accordance with Directive 87/153/EEC, Member States shall ensure that the applicant presents an identification note summarizing the characteristics and properties of the additive. In the case of the additives referred to in Article 2 (aaa), or should Article 9n (3) be applied, the identification note shall contain a summary of the most important characteristics and properties given in the monograph referred to in Article 9n.

2. The following shall be adopted in accordance with the procedure laid down in Article 23:

- the identification note,
- subsequent amendments to the identification note as a result of developments in scientific and technical knowledge.

3. In order to facilitate identification of the additives referred to in paragraph 1 during official checks, the identification note provided for in that paragraph shall be published in the *Official Journal of the European Communities*.

#### STANDARD SAMPLE

##### Article 9p

1. For the additives referred to in Article 2 (aaa) a standard sample having the characteristics and properties described in the monograph referred to in Article 9n together with a reference sample of the active substance shall be made available, upon request, to the national inspection authorities of the

Member States by the person responsible for putting them into circulation.

2. If the characteristics or properties of the additive are modified, a new standard sample corresponding to the new monograph shall be provided.

3. Detailed rules concerning the provision and maintenance of standard samples shall be adopted in accordance with the procedure laid down in Article 23.

#### MIXTURES AND ADDITIVE LEVELS

##### Article 9q

1. The maximum and minimum levels set for certain additives shall refer to complete feedingstuffs with a moisture content of 12 % insofar as no special provisions are laid down in the authorization regulation.

If the substance permitted as an additive also exists in the natural state in certain feed materials, the amount of additive to be incorporated shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorization regulation.

2. The mixing of additives shall be permitted in premixtures and feedingstuffs only where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

3. Unless the mixture concerned is the subject of a specific authorization as an additive, Member States shall require that:

- (a) antibiotics and growth promoters may not be mixed together, either with substances from their own group or with substances from the other group;
- (b) coccidiostats and other medicinal substances may not be mixed with antibiotics and growth promoters where coccidiostats also act, for the same category of animal, as an antibiotic or as a growth promoter;
- (c) coccidiostats and other medicinal substances may not be mixed together if their effects are similar.

4. Mixing antibiotics, growth promoters, coccidiostats and other medicinal substances with micro-organisms shall be prohibited unless such a mixture is authorized by the regulation authorizing the micro-organisms.

5. By way of derogation from Article 3 and paragraphs 2 and 3 of this Article, Member States may authorize, but only for practical tests conducted for scientific purposes and for non-commercial ends,

the use as additives of products which are not authorized at Community level or the use of additives under conditions other than those laid down in the authorization regulation, provided that:

- the tests are carried out in accordance with the principles and conditions to be laid down in Directive 87/153/EEC, and
- an adequate official inspection has been performed.

#### AMENDMENTS TO THE ANNEXES

##### Article 9r

Amendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 23.

#### INFORMATION ON PRODUCERS OF ADDITIVES

##### Article 9s

Member State shall ensure that the persons responsible for putting the additives referred to in Article 2 (aaa) into circulation forward to the Commission as quickly as possible the name or corporate name and the address or registered office of the producers to whom they have granted the right to manufacture the additive and, if the producers are established in a third country, also the name or corporate name and the address or registered office of their representatives in the Community.

#### PUBLICATION IN THE OFFICIAL JOURNAL

##### Article 9t

The Commission shall publish in the *Official Journal of the European Communities*, "C" Series, not later than 30 November each year:

- (a) the list of persons responsible for putting additives into circulation as referred to in Article 9s, the names of the producers to whom they have granted the right to manufacture the additives and their representatives in the Community if such producers are established in a third country;
- (b) the list of authorized additives subdivided as follows:
  - Chapter I: list of additives linked to a person responsible for putting them into circulation and authorized for a period of 10 years,
  - Chapter II: list of additives linked to a person responsible for putting them into circulation and authorized on a provisional basis for no longer than four years or five years in the case of additives which have been the subject of provisional authorization before 1 April 1998,

— Chapter III: list of other additives authorized for an unlimited period,

— Chapter IV: list of other additives authorized on a provisional basis for no longer than four years or five years in the case of additives which have been the subject of provisional authorization before 1 April 1998.'

- 5) The following title shall be inserted between Articles 9t and 10:

'PACKAGING'.

- 6) The following title shall be inserted between Articles 10 and 11:

'SAFEGUARD AND MEASURES'.

- 7) In Article 11 (1), 'listed in Annex I' shall be replaced by 'authorized'.

- 8) The following title shall be inserted between Articles 11 and 12:

'ADDITIVE LEVELS IN COMPLEMENTARY FEEDINGSTUFFS'.

- 9) The following title shall be inserted between Articles 12 and 13:

'RULES FOR THE DISTRIBUTION AND INCORPORATION IN FEEDINGSTUFFS OF ADDITIVES AND PREMIXTURES'.

- 10) Article 13 shall be replaced by the following:

##### 'Article 13

1. Member States shall require that certain additives covered by this Directive, premixtures prepared from those additives with a view to their being incorporated in compound feedingstuffs and compound feedingstuffs containing those premixtures may be put into circulation or used only by the establishments or intermediaries which meet the conditions laid down, as appropriate, in Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector(\*).

2. Member States shall require that:

- (a) additives referred to in Part A of Annex A may be supplied only by approved establishments:
  - (i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (b) respectively of Directive 95/69/EC, and

- (ii) in the form of premixtures, only to intermediaries or establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (c) or (e) respectively of the above Directive;
- (b) additives listed in Part B of Annex A may be supplied only by approved establishments:
  - (i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (b) respectively of the above Directive, and
  - (ii) in the form of premixtures, only to:
    - intermediaries which have been approved in accordance with the provisions laid down in Article 3 of the above Directive, or
    - establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been registered in accordance with the provisions laid down in Article 7 (2) (c) or (d) respectively of the said Directive or, as appropriate, approved in accordance with the provisions laid down in Article 2 (2) (c) or (e) of this Directive.

3. Member States shall require that additives referred to in Annex A (a) and (B) may be incorporated in compound feedingstuffs only if they have been prepared beforehand in the form of premixtures containing a carrier substance by establishments which meet the conditions laid down in Article 2 (2) (b) of Directive 95/69/EC. Such premixtures may be incorporated in compound feedingstuffs only in a proportion of at least 0,2 % by weight.

By way of derogation from the first subparagraph, Member States may allow premixtures to be incorporated in compound feedingstuffs in a proportion as low as 0,05 % by weight, provided that the quantitative and qualitative composition of the premixture so permits and that they have first established that the establishments satisfy the conditions set out in Chapter I.2 (b) of the Annex, with a view to achieving homogeneous distribution of premixtures and observing the additive levels set for the whole feedingstuff.

These manufacturers as referred to in the second paragraph shall be entered on the national list under a special heading as follows: "Manufacturers of compound feedingstuffs authorized to use a

minimum proportion of 0,05 % by weight of premixtures".

4. By way of derogation from paragraph 2, Member States shall require that:

- (a) additives referred to in Annex A (B) may be supplied to approved intermediaries or registered establishments which manufacture compound feedingstuffs for pets and fulfil the conditions laid down, as appropriate, in Article 3 (1) or Article 3 (2) (c) or (d) of Directive 95/69/EC;
- (b) additives referred to in Annex A (A) or (B) may be delivered at the last stage of circulation to establishments which manufacture compound feedingstuffs, provided that:
  - the Community regulation authorizing the additive provides, in the case of a specific preparation of the additive, for direct addition to feedingstuffs, and
  - the manufacturer of compound feedingstuffs is approved in accordance with Article 2 (2) (c) of the above Directive for the additives referred to in Annex A (A) or is registered in accordance with Article 7 (2) (c) of the above Directive for the additives referred to in Annex A (B), and
  - it has been checked on the spot that the manufacturer is in possession of the appropriate technology defined in Chapter I (3) (b) or Chapter II (c) of the Annex to the above Directive in order to add the preparation in question directly to the compound feedingstuff.

Such manufacturers shall appear on the national list under a special heading as follows: "Manufacturers of compound feedingstuffs referred to in point (b) authorized to add antibiotics, coccidiostats and other medicinal substances, and growth promoters directly to compound feedingstuffs" or "Manufacturers of compound feedingstuffs authorized to add copper, selenium and vitamins A and D directly to compound feedingstuffs".

5. By way of derogation from Article 7 of Directive 95/69/EC and paragraphs 1 and 2 of this Article, Finland and, as regards that part of its territory situated to the north of latitude 60°, Sweden shall be authorized, in view of the special feeding conditions on their farms, to allow premixtures of vitamins, provitamins and chemically well-defined substances having similar effect to be supplied to stock farmers for direct addition to feed materials of vegetable origin, provided that:

- the directions for use state precisely the dosage to be complied with according to the species or category of animals and the type of fodder used, and

- special measures are taken by Finland and Sweden to monitor use of such premixtures.

(\*) OJ No L 332, 30. 12. 1995, p. 15.'

- 11) The following title shall be inserted between Articles 13 and 14:

'LABELLING OF ADDITIVES'

- 12) Articles 14 to 16 shall be replaced by the following:

'Article 14

1. Member States shall require that authorized additives may be put into circulation for use in feedingstuffs only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:

- A. for all additives, with the exception of enzymes and micro-organisms:

- (a) the specific name given to the additive upon authorization, the EC registration number of the additive and, in the case of an additive within the meaning of Article 2 (aaa), the trade name and the registration number given to the person responsible for putting it into circulation;
- (b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
- (c) the net weight and, in the case of liquid additives, either the net volume or the net weight;
- (d) as applicable, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the above Directive.

- B. In addition, with regard to:

- (a) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars in the label, the active-substance level, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where appropriate, a safety recommendation regarding use in the case of additives which are the subject of special provisions upon authorization;

- (b) vitamin E: the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

- (c) vitamins, other than vitamin E, provitamins and substances having a similar effect: the active-substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

- (d) trace elements, colourants including pigments, preserving agents and other additives, with the exception of those belonging to the enzyme and micro-organism groups: the active-substance level.

- C. For additives belonging to the groups:

- (a) of enzymes: the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorization given, the International Union of Biochemistry identification number, units of activity(\*) (units of activity per gram or units of activity per millilitre), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive and, where applicable, safety recommendations as provided for in the authorization for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization for the additive;
- (b) of micro-organisms: identification of the strain(s) in accordance with the authorization granted, the file number of the strain(s), the number of colony-forming units (CFU per gram), the EC registration number of the additive, the name or

business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where applicable, safety recommendations as provided for in the authorization for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate an indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.

2. Member States shall require that the specific name of the additive may be accompanied, in cases where the indications are not required by virtue of paragraph 1:

- (a) by the trade name;
- (b) by the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the directions for use and, where appropriate, a safety recommendation regarding use.

3. Member States shall require that information other than that required or authorized pursuant to paragraphs 1 and 2 may appear on packages, containers or labels, provided that they are clearly separated from the abovementioned marking particulars.

(\*) Units of activity expressed in micromoles of product released per minute, per gram of enzyme preparation.

#### Article 15

1. Member States shall require that premixtures may be marketed only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:

A. For all premixtures:

- (a) the description "premixture";

- (b) directions for use, and any safety recommendations regarding the use of the premixtures;
- (c) the animal species or category of animals for which the premixture is intended;
- (d) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
- (e) the net weight and, in the case of liquids, either the volume or net weight;
- (f) as applicable, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the above Directive.

B. In addition, for the premixtures incorporating the additives listed below:

- (a) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the details on the label, specific name given to the additive upon authorization, active substance level and expiry date of the guarantee of that level, or storage life from the date of manufacture;
- (b) substances having antioxidant effects: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs on authorization of the additive;
- (c) colourants, including pigments: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
- (d) vitamin E: specific name given to the additive upon authorization, alpha-tocopherol level and expiry date of the guarantee of that level or storage life from the date of manufacture;
- (e) vitamins other than vitamin E, provitamins and substances having a similar effect: specific name given to the additive upon authorization, active substance level and expiry date of the guarantee of that level or storage life from the date of manufacture;

- (f) trace elements: specific name given to the additive upon authorization, and level of the various elements insofar as a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
- (g) preserving agents: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
- (h) enzymes: the specific name of the active component(s) according to its (their) enzymatic activity(ies) in accordance with the authorization given, the identification number according to the International Union of Biochemistry, the activity units (activity units per g or activity units per ml), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
- (i) micro-organisms: the identification of the strain(s) in accordance with the authorization given, the file number of the strain(s) in accordance with the authorization given, the file number of the strain(s), the number of colony-forming units (CFU/g), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee of the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
- (j) other additives belonging to the groups referred to in (b) or (i) for which no maximum level is laid down and additives belonging to other groups authorized: specific name given to the additive upon authorization and active substance level, provided that these additives fulfil a function in the feedingstuff as such and the

amounts present can be determined by official methods of analysis or, failing this, by valid scientific methods.

## 2. Member States shall require that:

- (a) the specific name of additives may be accompanied by the tradename;
- (b) the name of the producer of the additives referred to in paragraph 1 (B) (a) may be indicated in the labelling of premixtures. However, they may stipulate that this indication shall be compulsory;
- (c) the specific name of the additives authorized may be accompanied by the additive's EC registration number.

3. Where, pursuant to paragraph 1, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, Member States shall require that a single date of guarantee or a single reference to the storage life may be indicated for all the additives, namely the deadline which will be reached first.

4. Member States shall require that information other than that required or authorized pursuant to paragraphs 1 to 3 may appear on packages, containers or labels, provided that they are clearly separated from the abovementioned marking particulars.

## Article 16

1. Member States shall require that feedingstuffs incorporating the additives belonging to the groups listed below may be put into circulation only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:

- (a) for antibiotics, coccidiostats and other medicinal substances and growth promoters: the specific name given to the additive upon authorization, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture, the approval number assigned to the establishment in accordance with Article 5 of Directive 95/69/EC;
- (b) for substances having antioxidant effects:
  - in the case of pet foods: use of the words "with antioxidant" followed by the specific name given to the additive upon authorization,
  - in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;

- (c) for colourants, including pigments provided that these are used for the colouration of feedingstuffs or animal products:
- in the case of pet foods: use of the words “colourant” or “coloured with” followed by the specific name given to the additive upon authorization,
  - in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
- (d) for vitamin E: the specific name given to the additive upon authorization, the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
- (e) for vitamins A and D: the specific name given to the additive upon authorization, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
- (f) for copper: the specific name given to the additive upon authorization and the level expressed in Cu;
- (g) for preserving agents:
- in the case of pet foods: use of the words “preservative” or “preserved with” followed by the specific name given to the additive upon authorization,
  - in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
- (h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with the authorization given, the identification number according to the International Union of Biochemistry, the activity units (activity units per kilogram or activity unit per litre), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
- (i) for micro-organisms: the identification of the strain(s) in accordance with the authorization given, the file number of the strain(s), the number of colony-forming units (CFU/kg), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.
2. In addition to the particulars provided for by paragraph 1, particulars concerning the proper use of the feedingstuffs may be laid down in the authorization of the additive in accordance with the procedure provided for in Article 23.
- Member States shall require that these particulars must appear on the package or the container or on a label affixed thereto.
3. The presence of trace elements other than copper and of vitamins other than vitamins A, D and E, provitamins and additives having a similar effect may be indicated if the amounts of these substances can be determined by official methods of analysis or, failing this, by valid scientific methods of analysis. In such cases the following details shall be given:
- (a) for trace elements other than copper: the specific name of the additive in accordance with the authorization given and level of the various elements;
- (b) for vitamins other than vitamins A, D and E, provitamins and substances having a similar chemical effect: the specific name of the additive in accordance with the authorization given, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
4. Member States shall require that:
- (a) the details provided for in paragraphs 1 to 3 shall be printed close to the particulars which have to appear on the package, container or the label affixed thereto in accordance with Community rules on feedingstuffs;
- (b) where a level or a quantity is stated pursuant to paragraphs 1 to 3, such statement shall refer to the amount of additive incorporated in the feedingstuff;
- (c) the details of additives may be accompanied by the EC registration number of the additive or the trade name where those particulars are not required by virtue of paragraph 1.
5. Where, pursuant to paragraph 1, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, Member States shall require that a single date of guarantee or a single reference to the storage life from the date of manufacture may be indicated for all the additives, namely the deadline which will be reached first.

6. In the case of feedingstuffs distributed by road tankers or similar vehicles or in bulk, the details provided for in paragraphs 1 to 3 shall be given in the accompanying document.

Where small quantities intended for the end-user are involved, it shall be sufficient for such details to be conveyed to the purchaser by a suitable notice.

7. Member States shall require that, in the case of pet foods containing colourants, preservatives or substances having antioxidant effects and put up in packages having a net weight of not more than 10 kilograms, it shall be sufficient for the package to bear the words "coloured with", or "preserved with", or the words "with antioxidant" as appropriate, followed by the words "EC additives", provided that:

- (a) the package, container or label bears a reference number by means of which the feedingstuff may be identified, and
- (b) the manufacturer gives, on request, the specific name, or names, of the additive or additives used.

8. Any reference to additives other than in the form provided for in this Directive shall be prohibited.

- 13) In Article 17 (1), the second subparagraph shall be replaced by the following:

'This information must be in accordance with the conditions of use prescribed upon authorization of the additive.'

- 14) The following title shall be inserted between Articles 20 and 21:

'INSPECTION MEASURES'.

- 15) The following shall be added after Article 21:

'MONITORING OF UNDESIRABLE INTERACTIONS

#### *Article 21a*

Where there is found to be unforeseen undesirable interaction between additives referred to in Article 2 (aaa) and other additives or veterinary medicines, Member States shall require that the person responsible for putting the additive into circulation, or his representative within the Community where additives originate in third countries, gathers all the relevant information and forwards it to the competent authorities.'

- 16) The following title shall be inserted between Articles 21a and 22:

'EXPORTS TO THIRD COUNTRIES'.

- 17) The following title shall be inserted between Articles 22 and 23:

'IMPLEMENTATION POWERS OF THE COMMISSION'.

- 18) The following title shall be inserted between Articles 24 and 25:

'FINAL PROVISIONS'.

- 19) Annexes I, II and III shall be deleted.

- 20) The Annexes A, B and C set out in the Annex to this Directive shall be added.

#### *Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with:

- (a) the following provisions provided for in Article 1:

— point (4): Article 6 (1), Article 9d (2), Article 9e (3), Article 9f, Article 9g, Article 9h, Article 9i, Article 9j, Article 9n, Article 9o,

— points 10, 12, 19 and 20,

on 1 April 1998;

- (b) the other provisions of this Directive by 1 October 1999.

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 Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

#### *Article 3*

This Directive is addressed to the Member States.

Done at Brussels, 23 July 1996.

*For the Council*  
*The President*  
I. YATES



## ANNEX

*'Annex A*

referred to in Article 13

## PART A

- Antibiotics: all additives belonging to this group
- Coccidiostats and other medicinal substances: all additives belonging to this group
- Growth promoters: all additives belonging to this group

## PART B

- Trace elements: copper and selenium
  - Vitamins, provitamins and chemically well-defined substances with similar effects: vitamins A and D.'
-

## ANNEX B

## CHAPTER I

Additives linked to a person responsible for putting them into circulation, inserted in Annex I before 1 January 1988

Registration number	Name and registration number of person responsible for marketing(*)	Additive	Chemical name, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions
						mg/kg, complete feedingstuff		
		A. Antibiotics						
		B. Coccidiostats and other medicinal substances						
		C. Growth promoters						

(\*) Authorization to be linked to the person responsible with effect from 1 October 1999.

## CHAPTER II

Additives linked to a person responsible for putting them into circulation, inserted in Annex I after 31 December 1987

Registration number	Name and registration number of person responsible for marketing(*)	Additive	Chemical name, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions
						mg/kg complete feedingstuff		
		A. Antibiotics						
		B. Coccidiostats and other medicinal substances						
		C. Growth promoters						

(\*) Authorization to be linked to the person responsible with effect from 1 October 1999.

## CHAPTER III

Additives linked to a person responsible for marketing, inserted in Annex II before 1 April 1998

Registration number	Name and registration number of person responsible for marketing(*)	Additive	Chemical name, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorization
						mg/kg, complete feedingstuff			
		A. Antibiotics							
		B. Coccidiostats and other medicinal substances							
		C. Growth promoters							

(\*) Authorization linked to the person responsible with effect from 1 October 1999.

## ANNEX C

## PART I

Additives subject to authorization linked to the person responsible for putting them into circulation referred to in Article 2 (aaa) of the Directive:

- antibiotics: all additives belonging to this group,
- coccidiostats and other medicinal substances: all additives belonging to this group,
- growth promoters: all additives belonging to this group.

## PART II

Other additives referred to in Article 2 (aaaa) of the Directive:

- antioxidant substances: all additives belonging to this group,
  - flavouring and appetizing substances,
  - emulsifying and stabilizing agents, thickeners and gelling agents: all additives belonging to this group,
  - colourants, including pigments: all additives belonging to this group,
  - preservatives,
  - vitamins, provitamins and chemically well-defined substances having similar effect: all additives belonging to this group,
  - trace elements: all additives belonging to this group,
  - binders, anti-caking agents and coagulants: all additives belonging to this group,
  - acidity regulators: all additives belonging to this group,
  - enzymes: all additives belonging to this group,
  - micro-organisms: all additives belonging to this group.
-

## COUNCIL DIRECTIVE 96/53/EC

of 25 July 1996

laying down for certain road vehicles circulating within the Community the maximum authorized dimensions in national and international traffic and the maximum authorized weights in international traffic

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 189c of the Treaty<sup>(3)</sup>,

(1) Whereas Council Directive 85/3/EEC of 19 December 1984 on the weights, dimensions and certain other technical characteristics of certain road vehicles<sup>(4)</sup> established, in the framework of the common transport policy, common standards permitting improved use of road vehicles in traffic between Member States;

(2) Whereas Directive 85/3/EEC has been significantly amended on many occasions; whereas on the occasion of its further amendment it should for reasons of clarity and rationality be recast in a single text together with Council Directive 86/364/EEC of 24 July 1986 relating to proof of compliance of vehicles with Directive 85/3/EEC<sup>(5)</sup>;

(3) Whereas differences between standards in force in the Member States with regard to the weights and dimensions of commercial road vehicles could have an adverse effect on the conditions of competition and constitute an obstacle to traffic between Member States;

(4) Whereas, under the principle of subsidiarity, action should be taken at Community level in order to remove this obstacle;

(5) Whereas the abovementioned standards reflect a balance between the rational and economical use of commercial road vehicles and the requirements of infrastructure maintenance, road safety and the protection of the environment and the fabric of life;

(6) Whereas common standards on the dimensions of vehicles intended for the carriage of goods should remain stable in the long term;

(7) Whereas additional technical requirements related to the weights and dimensions of vehicles may apply to commercial vehicles registered or put into circulation in a Member State; whereas these requirements must not constitute an obstacle to the circulation of commercial vehicles between Member States;

(8) Whereas the definition of 'thick-walled refrigerated vehicle' in Article 2 of Directive 85/3/EEC, as amended by Directive 89/388/EEC<sup>(6)</sup>, should be broadened in order to permit Member States to allow refrigerated vehicles no longer meeting the insulation requirements defined in that Article to circulate in their territory;

(9) Whereas it is necessary to clarify the concept of 'indivisible load' in order to ensure uniform application of this Directive in respect of permits for vehicles or vehicle combinations carrying such loads;

(10) Whereas the tonne is universally used and understood as the unit of measurement for vehicle weight and is, therefore, applied in this Directive whilst recognizing that the formal unit of weight is the newton;

(11) Whereas, in implementation of the internal market, the scope of this Directive should be extended to national transport insofar as it concerns characteristics that significantly affect the conditions of competition in the transport sector and in particular the values relating to the

<sup>(1)</sup> OJ No C 38, 8. 2. 1994, p. 3 and OJ NO C 247, 23. 9. 1995, p. 1.

<sup>(2)</sup> OJ No C 295, 22. 10. 1994, p. 72.

<sup>(3)</sup> Opinion of the European Parliament delivered on 15 November 1994 (OJ No C 341, 5. 12. 1994, p. 39), Council common position of 8 December 1995 (OJ No C 356, 30. 12. 1995, p. 13), and Decision of the European Parliament of 14 March 1996 (OJ No C 96, 4. 4. 1996, p. 233).

<sup>(4)</sup> OJ No L 2, 3. 1. 1985, p. 14. Directive as last amended by Directive 92/7/EEC (OJ No L 57, 2. 3. 1992, p. 29).

<sup>(5)</sup> OJ No L 221, 7. 8. 1986, p. 48).

<sup>(6)</sup> OJ No L 142, 25. 5. 1989, p. 3.

maximum authorized length and width of vehicles and vehicle combinations intended for the carriage of goods;

- (12) Whereas, for the other vehicle characteristics, Member States are authorized to apply in their territory different values from those laid down in this Directive only to vehicles used in national traffic;
- (13) Whereas road trains using extensible coupling systems in practice attain a maximum length of 18,75 m when fully extended; whereas the same maximum length should be authorized for road trains using fixed coupling systems;
- (14) Whereas the maximum authorized width of 2,50 m for vehicles intended for the carriage of goods can leave insufficient internal space for the efficient loading of pallets, which has given rise to the application of different tolerances beyond that level in the legislation of the Member States concerning domestic traffic; whereas a general adaptation to the current situation is therefore necessary in order to provide for clarity in technical requirements, bearing in mind the road safety aspects of these characteristics;
- (15) Whereas if the maximum width of vehicles intended for the carriage of goods is increased to 2,55 m, that standard should also be applied to buses; whereas, in respect of buses, it is however necessary to provide for a transitional period to allow the manufacturers concerned to adapt industrial plant;
- (16) Whereas, to prevent excessive road damage and to ensure manoeuvrability, when authorizing and using vehicles preference should be given to pneumatic or equivalent suspension rather than mechanical suspension; whereas certain maximum axle loads should not be exceeded, and the vehicle must be capable of turning through 360° within certain limit values for the path followed;
- (17) Whereas Member States should be permitted, in national goods transport, to allow vehicles or vehicle combinations with dimensions deviating from those laid down in this Directive to circulate in their territory if the transport operations carried out by such vehicles are defined by this Directive as not significantly affecting international competition in the transport sector, i.e. operations carried out by specialized vehicles and operations carried out according to a modular concept;
- (18) Whereas, in the case of modular concept operations, there should be provision for a transitional period to enable a Member State to adapt its road infrastructure;
- (19) Whereas vehicles or vehicle combinations constructed applying new technologies or new concepts, according to standards which deviate from those laid down by this Directive, should be allowed to carry out local transport operations for a trial period to enable profit to be drawn from technical progress;
- (20) Whereas vehicles which entered into service before the date of implementation of this Directive and which do not comply with the dimension characteristics laid down in this Directive, owing to previously differing national provisions or methods of measurement, should be allowed for a transitional period to continue to provide transport services within the Member State in which the vehicle is registered or put into circulation;
- (21) Whereas progress has been made towards adopting Type-Approval Directives for vehicle combinations with five or six axles; whereas, the requirements regarding conformity with characteristics other than weights and dimensions as laid down in Annex II of Directive 85/3/EEC should therefore be deleted;
- (22) Whereas such a modification is also necessary in order to avoid rules conflicting with international conventions on road traffic and circulation;
- (23) Whereas in order to facilitate the monitoring of compliance with this Directive, it is necessary to ensure that vehicles carry proof of such compliance;
- (24) Whereas this Directive does not affect the obligations of the Member States concerning the deadlines for transposition into national law and for application of the Directives which this Directive replaces,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

1. This Directive applies to:

- (a) the dimensions of motor vehicles in categories M2, M3 and N2 and N3 and their trailers in categories 03 and 04, as defined in Annex II to Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers<sup>(1)</sup>;

<sup>(1)</sup> OJ No L 42, 23. 2. 1970, p. 1. Directive as last amended by the 1994 Act of Accession.

- (b) the weights and certain other characteristics of the vehicles defined in (a) and specified in Annex I (2) to this Directive.

2. All the values of weights indicated in Annex I are valid as circulation standards and thus refer to loading conditions, not production standards, which will be defined in a later Directive.

### Article 2

For the purposes of this Directive:

- '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,
- 'vehicle combination' 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,
- 'conditioned vehicle' shall mean any vehicle whose fixed or movable superstructures are specially equipped for the carriage of goods at controlled temperatures and whose side walls, inclusive of insulation, are each at least 45 mm thick,
- 'bus' shall mean a vehicle with more than nine seats including the driver's seat, 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 for use of a vehicle, as laid down in Annex I to this Directive,

— 'maximum authorized weight' shall mean the maximum weight for use of a laden vehicle in international traffic,

— 'maximum authorized axle weight' shall mean the maximum weight for use in international traffic of a laden axle or group of axles,

— 'indivisible load' shall mean a load that cannot, for the purpose of carriage by road, be divided into two or more loads without undue expense or risk of damage and which owing to its dimensions or mass cannot be carried by a motor vehicle, trailer, road train or articulated vehicle complying with this Directive in all respects,

— 'tonne' shall mean the weight executed by the mass of a tonne and shall correspond to 9,8 kilonewtons (kN),

All maximum authorized dimensions specified in Annex I shall be measured in accordance with Annex I to Directive 70/156/EEC, with no positive tolerances.

### Article 3

1. A Member State may not reject or prohibit the use in its territory:

- in international traffic, of vehicles registered or put into circulation in any other Member State for reasons relating to their weights and dimensions,
- in national traffic, of goods vehicles registered or put into circulation in any other Member State for reasons relating to their dimensions,

provided that such vehicles comply with the limit values specified in Annex I.

This provision shall apply notwithstanding the fact that:

- (a) the said vehicles are not in conformity with the requirements of that Member State with regard to certain weight and dimension characteristics not covered by Annex I;
- (b) the competent authority of the Member State in which the vehicles are registered or put into circulation has authorized limits not referred to in Article 4 (1) exceeding those laid down in Annex I.

2. However, paragraph 1 (a) shall not affect the right of Member States, with due regard to Community law, to require vehicles registered or put into circulation in their own territory to be in conformity with their national requirements on weight and dimension characteristics not covered by Annex I.

3. Member States may require conditioned vehicles to carry an ATP certificate or ATP certification plate provided for in the Agreement of 1 September 1970 on the international carriage of perishable foodstuffs and on the special equipment to be used for such carriage.

#### *Article 4*

1. Member States shall not allow the normal circulation of vehicles or vehicle combinations for the national transport of goods in their territory which are not in conformity with the characteristics set out in points 1.1, 1.2, 1.4 to 1.8, 4.2 and 4.4 of Annex I.

2. Member States may nonetheless allow circulation in their territory of vehicles or vehicle combinations for the national transport of goods freight which are not in conformity with the characteristics set out in 1.3, 2, 3, 4.1 and 4.3 of Annex I.

3. Vehicles or vehicle combinations which exceed the maximum dimensions may only be allowed to circulate on the basis of special permits issued without discrimination by the competent authorities, or on the basis of similar non-discriminatory arrangements agreed on a case-by-case basis with those authorities, where these vehicles or vehicle combinations carry or are intended to carry indivisible loads.

4. Member States may allow vehicles or vehicle combinations used for goods transport which carry out certain national transport operations that do not significantly affect international competition in the transport sector to circulate in their territory with dimensions deviating from those laid down in points 1.1, 1.2, 1.4 to 1.8, 4.2 and 4.4 of Annex I.

Transport operations shall be considered not significantly to affect international competition in the transport sector if one of the conditions under (a) and (b) is fulfilled:

- (a) the transport operations are carried out in a Member State's territory by specialized vehicles or specialized vehicle combinations in circumstances in which they are not normally carried out by vehicles from other Member States, e.g. operations linked to logging and the forestry industry;
- (b) the Member State which permits transport operations to be carried out in its territory by vehicles or vehicle combinations with dimensions deviating from those laid down in Annex I also permits motor vehicles, trailers and semi-trailers which comply with the dimensions laid down in Annex I to be used in such combinations as to achieve at least the loading length authorized in that Member State, so that every operator may benefit

from equal conditions of competition (modular concept).

The Member State concerned which has to adapt its road infrastructure in order to be able to fulfil the condition under (b) may nevertheless prohibit, until 31 December 2003 at the latest, the circulation in its territory, in national goods transport operations, of vehicles or vehicle combinations which exceed current national standards on dimensions, provided that national legislation continues to apply to all Community carriers in a non-discriminatory manner.

The Member States shall inform the Commission of the measures taken pursuant to this paragraph.

5. Member States may allow vehicles or vehicle combinations incorporating new technologies or new concepts which cannot comply with one or more requirements of this Directive to carry out certain local transport operations for a trial period. Member States shall inform the Commission thereof.

6. Member States may allow vehicles or vehicle combinations used for goods transport and registered or put into circulation before the implementation of this Directive to circulate in their territory until 31 December 2006 with dimensions exceeding those laid down in points 1.1, 1.2, 1.4 to 1.8, 4.2 and 4.4 of Annex I by virtue of differing national provisions or methods of measurement.

#### *Article 5*

Without prejudice to Article 4 (6):

- (a) articulated vehicles put into circulation before 1 January 1991 which do not comply with the specifications contained in points 1.6 and 4.4 of Annex I shall be deemed to comply with such specifications for the purposes of Article 3 if they do not exceed a total length of 15,50 m;
- (b) road trains, the motor vehicle of which was put into circulation before 31 December 1991 and which do not comply with the specifications contained in points 1.7 and 1.8 of Annex I, shall until 31 December 1998 be deemed to comply with such specifications for the purposes of Article 3 if they do not exceed a total length of 18,00 m.

#### *Article 6*

1. Member States shall take the necessary measures to ensure that Article 1 vehicles referred to in Article 1 and

complying with this Directive carry one of the proofs referred to in (a), (b) and (c):

(a) a combination of the following two plates:

- the 'manufacturer's plate' established and attached in accordance with Directive 76/114/EEC<sup>(1)</sup>,
- the plate relating to dimensions, in accordance with Annex III, established and attached in accordance with Directive 76/114/EEC;

(b) a single plate established and attached in accordance with Directive 76/114/EEC and containing the information on the two plates referred to in (a);

(c) a single document issued by the competent authorities of the Member State in which the vehicle is registered or put into circulation. Such document shall bear the same headings and information as the plates referred to in (a). It shall be kept in a place easily accessible to inspection and shall be adequately protected.

2. If the characteristics of the vehicle no longer correspond to those indicated on the proof of compliance, the Member State in which the vehicle is registered shall take the necessary steps to ensure that the proof of compliance is altered.

3. The plates and documents referred to in paragraph 1 shall be recognized by the Member States as the proof of vehicle compliance provided for in this Directive.

4. Vehicles carrying proof of compliance may be subject:

- as regards common standards on weights, to random checks,
- as regards common standards on dimensions, only to checks where there is a suspicion of non-compliance with this Directive.

5. The middle column of the proof of compliance relating to weights shall contain, where appropriate, the Community weight standards applicable to the vehicle in question. As regards vehicles referred to in point 2.2.2 (c) of Annex I, the entry '44 tonnes' shall be included in brackets under the maximum authorized weight of the vehicle combination.

6. Each Member State may decide, in respect of any vehicle registered or put into circulation in its territory, that the maximum weights authorized by its national

legislation shall be indicated in the proof of compliance in the left-hand column and the technically permissible weights in the right-hand column.

#### Article 7

This Directive shall not preclude the application of road traffic provisions in force in each Member State which permit the weight and/or dimensions of vehicles on certain roads or civil engineering structures to be limited, irrespective of the State of registration of such vehicles.

#### Article 8

Article 3 shall not apply in Ireland and the United Kingdom until 31 December 1998:

(a) as regards the standards referred to in points 2.2, 2.3.1, 2.3.3, 2.4 and 3.3.2 of Annex I:

- with the exception of the articulated vehicles referred to in point 2.2.2 where:

- (i) the total laden weight does not exceed 38 tonnes;
- (ii) the weight on any tri-axle at the spacing specified in point 3.3.2 does not exceed 22,5 tonnes,

- with the exception of the vehicles referred to in points 2.2.3, 2.2.4, 2.3 and 2.4, where the total laden weight does not exceed:

- (i) 35 tonnes for the vehicles referred to in points 2.2.3 and 2.2.4;
- (ii) 17 tonnes for the vehicles referred to in point 2.3.1;
- (iii) 30 tonnes for the vehicles referred to in point 2.3.3, subject to compliance with the conditions specified in that point and in point 4.3;
- (iv) 27 tonnes for the vehicles referred to in point 2.4,

(b) as regards the standard referred to in point 3.4 of Annex I, with the exception of the vehicles referred to in points 2.2, 2.3 and 2.4, where the weight per driving axle does not exceed 10,5 tonnes.

#### Article 9

As regards the standard referred to in point 1.2 (a) of Annex I, a Member State may reject or prohibit the use in its territory, until 31 December 1999, of buses with a width exceeding 2,5 m.

Member States shall inform the Commission of the measures taken pursuant to this Article. The Commission shall inform the other Member States thereof.

<sup>(1)</sup> OJ No L 24, 30. 1. 1976, p. 1. Directive as amended by Commission Directive 78/507/EEC (OJ No L 155, 13. 6. 1978, p. 31).



*Article 10*

The Directive listed in Annex IV, Part A, shall be repealed with effect from the date in Article 11, without prejudice to the obligations of the Member States concerning the deadlines for transposition set out in Annex IV, Part B.

References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex V.

*Article 11*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 September 1997. 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 Member States.

2. Member States shall communicate to the Commission the text of the main provisions of domestic law which they adopt in the field covered by this Directive.

*Article 12*

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

*Article 13*

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1996.

*For the Council*

*The President*

H. COVENEY

## ANNEX I

## MAXIMUM WEIGHTS AND DIMENSIONS AND RELATED CHARACTERISTICS OF VEHICLES

1. **Maximum authorized dimensions for the vehicles referred to in Article 1 (1) (a)**
  - 1.1 *Maximum length:*

— motor vehicle	12,00 m
— trailer	12,00 m
— articulated vehicle	16,50 m
— road train	18,75 m
— articulated bus	18,00 m
  - 1.2 *Maximum width:*

(a) all vehicles	2,55 m
(b) superstructures of conditioned vehicles	2,60 m
  - 1.3 *Maximum height (any vehicle)*

	4,00 m
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  - 1.4 Removable superstructures and standardized freight items such as containers are included in the dimensions specified in points 1.1, 1.2, 1.3, 1.6, 1.7, 1.8 and 4.4
  - 1.5 Any motor vehicle or vehicle combination which is in motion must be able to turn within a swept circle having an outer radius of 12,50 m and an inner radius of 5,30 m
  - 1.6 Maximum distance between the axis of the fifth-wheel king pin and the rear of a semi-trailer

	12,00 m
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  - 1.7 Maximum distance measured parallel to the longitudinal axis of the road train from the foremost external point of the loading area behind the cabin to the rearmost external point of the trailer of the combination, minus the distance between the rear of the drawing vehicle and the front of the trailer

	15,65 m
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  - 1.8 Maximum distance measured parallel to the longitudinal axis of the road train from the foremost external point of the loading area behind the cabin to the rearmost external point of the trailer of the combination

	16,40 m
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2. **Maximum authorized vehicle weight (in tonnes)**
  - 2.1 *Vehicles forming part of a vehicle combination*
    - 2.1.1 Two-axle trailer

	18 tonnes
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2.1.2	Three-axle trailer	24 tonnes
2.2	<i>Vehicle combinations</i>	
2.2.1	Road trains with five or six axles	
	(a) two-axle motor vehicle with three-axle trailer	40 tonnes
	(b) three-axle motor vehicle with two or three-axle trailer	40 tonnes
2.2.2	Articulated vehicles with five or six axles	
	(a) two-axle motor vehicle with three-axle semi-trailer	40 tonnes
	(b) three-axle motor vehicle with two or three-axle semi-trailer	40 tonnes
	(c) three-axle motor vehicle with two or three-axle semi-trailer carrying a 40-foot ISO container as a combined transport operation	44 tonnes
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 margin when the maximum authorized weight (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 as defined in Annex II
2.3	<i>Motor vehicles</i>	
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 as defined in Annex II, or where each driving axle is fitted with twin tyres and the maximum weight of each axle does not exceed 9,5 tonnes
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 as defined in Annex II, or where each driving axle is fitted with twin tyres and the maximum weight of each axle does not exceed 9,5 tonnes
2.4	<i>Three-axle articulated buses</i>	28 tonnes

3. **Maximum authorized axle weight of the vehicles referred to in Article 1 (1) (b) (in tonnes)**
- 3.1 *Single axles*  
Single non-driving axle 10 tonnes
- 3.2 *Tandem axles of trailers and semi-trailers*  
The sum of the axle weights per tandem axle must not exceed, if the distance (d) between the axles is:
- 3.2.1 less than 1 m ( $d < 1,0$ ) 11 tonnes
- 3.2.2 between 1,0 m and less than 1,3 m ( $1,0 \leq d < 1,3$ ) 16 tonnes
- 3.2.3 between 1,3 m and less than 1,8 m ( $1,3 \leq d < 1,8$ ) 18 tonnes
- 3.2.4 1,8 m or more ( $1,8 \leq d$ ) 20 tonnes
- 3.3 *Tri-axles of trailers and semi-trailers*  
The sum of the axle weights per tri-axle must not exceed, if the distance (d) between the axles is:
- 3.3.1 1,3 m or less ( $d \leq 1,3$ ) 21 tonnes
- 3.3.2 over 1,3 m and up to 1,4 m ( $1,3 < d \leq 1,4$ ) 24 tonnes
- 3.4 *Driving axle*
- 3.4.1 Driving axle of the vehicles referred to in 2.2.1 and 2.2.2 11,5 tonnes
- 3.4.2 Driving axle of the vehicles referred to in points 2.2.3, 2.2.4, 2.3 and 2.4 11,5 tonnes
- 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 ( $d < 1,0$ ) 11,5 tonnes
- 3.5.2 1,0 m or greater but less than 1,3 m ( $1,0 \leq d < 1,3$ ) 16 tonnes
- 3.5.3 1,3 m or greater but less than 1,8 m ( $1,3 \leq d < 1,8$ ) — 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 as defined in Annex II, or where each driving axle is fitted with twin tyres and where the maximum weight for each axle does not exceed 9,5 tonnes

4. **Related characteristics of the vehicles referred to in Article 1 (1) (b)**

4.1 *All vehicles*

The weight borne by the driving axle or driving axles of a vehicle or vehicle combination must not be less than 25% of the total laden weight of the vehicle or vehicle combination, when used in international traffic

4.2 *Road trains*

The distance between the rear axle of a motor vehicle and the front axle of a trailer must not be less than 3,00 m.

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

4.4 *Semi-trailers*

The distance measured horizontally between the axis of the fifth-wheel king pin and any point at the front of the semi-trailer must not exceed 2,04 m

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## ANNEX II

**CONDITIONS RELATING TO EQUIVALENCE BETWEEN CERTAIN NON-AIR SUSPENSION  
SYSTEMS AND AIR SUSPENSION FOR VEHICLE DRIVING AXLE(S)**

**1. DEFINITION OF AIR SUSPENSION**

A suspension system is considered to be air suspended if at least 75 % of the spring effect is caused by the air spring.

**2. EQUIVALENCE TO AIR SUSPENSION**

A suspension recognized as being equivalent to air suspension must conform to the following:

- 2.1. during free transient low frequency vertical oscillation of the sprung mass above a driving axle or bogie, the measured frequency and damping with the suspension carrying its maximum load must fall within the limits defined in points 2.2 to 2.5;
- 2.2. each axle must be fitted with hydraulic dampers. On tandem axle bogies, the dampers must be positioned to minimize the oscillation of the bogies;
- 2.3. the mean damping ratio  $D$  must be more than 20 % of critical damping for the suspension in its normal conditions with hydraulic dampers in place and operating;
- 2.4. the damping ratio  $D$  of the suspension with all hydraulic dampers removed or incapacitated must be not more than 50 % of  $D$ ;
- 2.5. the frequency of the sprung mass above the driving axle or bogie in a free transient vertical oscillation must not be higher than 2,0 Hz;
- 2.6. the frequency and damping of the suspension are given in paragraph 3. The test procedures for measuring the frequency and damping are laid down in paragraph 4.

**3. DEFINITION OF FREQUENCY AND DAMPING**

In this definition a sprung mass  $M$  (kg) above a driving axle or bogie is considered. The axle or bogie has a total vertical stiffness between the road surface and the sprung mass of  $K$  Newtons/metre (N/m) and a total damping coefficient of  $C$  Newtons per metre per second (N.s/m). The vertical displacement of the sprung mass is  $Z$ . The equation of motion for free oscillation of the sprung mass is:

$$M \frac{d^2 Z}{dt^2} + C \frac{dZ}{dt} + kZ = 0$$

The frequency of oscillation of the sprung mass  $F$  (rad/sec) is:

$$F = \sqrt{\frac{K}{M} - \frac{C^2}{4M^2}}$$

The damping is critical when  $C = C_0$ ,

where

$$C_0 = 2\sqrt{KM}$$

The damping ratio as a fraction of critical damping is  $C/C_0$ .

During free transient oscillation of the sprung mass the vertical motion of the mass will follow a damped sinusoidal path (Figure 2). The frequency can be estimated by measuring the time for as many cycles of oscillation as can be observed. The damping can be estimated by measuring the

heights of successive peaks of the oscillation in the same direction. If the peak amplitudes of the first and second cycles of the oscillation are  $A_1$  and  $A_2$ , then the damping ratio  $D$  is;

$$D = \frac{C}{C_0} = \frac{1}{2\pi} \ln \frac{A_1}{A_2}$$

'ln' being the natural logarithm of the amplitude ratio.

#### 4. TEST PROCEDURE

To establish by test the damping ratio  $D$ , the damping ratio with hydraulic dampers removed, and the frequency  $F$  of the suspension, the loaded vehicle should either:

- (a) be driven at low speed ( $5 \text{ km/hr} \pm 1 \text{ km/hr}$ ) over an 80 mm step with the profile shown in Figure 1. The transient oscillation to be analyzed for frequency and damping occurs after the wheels on the driving axle have left the step;
- or
- (b) be pulled down by its chassis so that the driving axle load is 1,5 times its maximum static value. The vehicle held down is suddenly released and the subsequent oscillation analyzed;
- or
- (c) be pulled up by its chassis so that the sprung mass is lifted by 80 mm above the driving axle. The vehicle held up is suddenly dropped and the subsequent oscillation analyzed;
- or
- (d) be subjected to other procedures insofar as it has been proved by the manufacturer, to the satisfaction of the technical department, that they are equivalent.

The vehicle should be instrumented with a vertical displacement transducer between driving axle and chassis, directly above the driving axle. From the trace, the time interval between the first and second compression peaks can be measured to obtain the frequency  $F$  and the amplitude ratio to obtain the damping. For twin-drive bogies, vertical displacement transducers should be fitted between each driving axle and the chassis directly above it.

Figure 1

Step for suspension tests

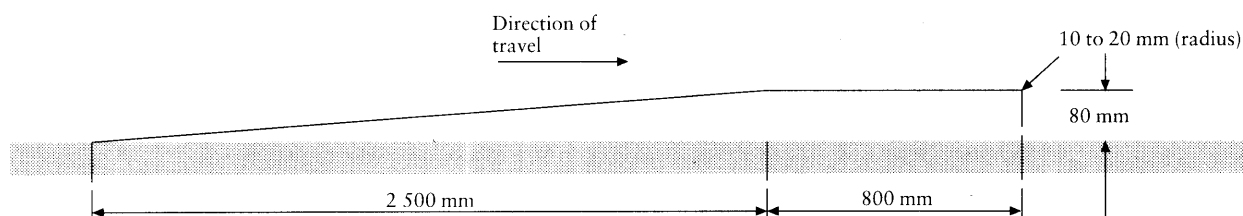
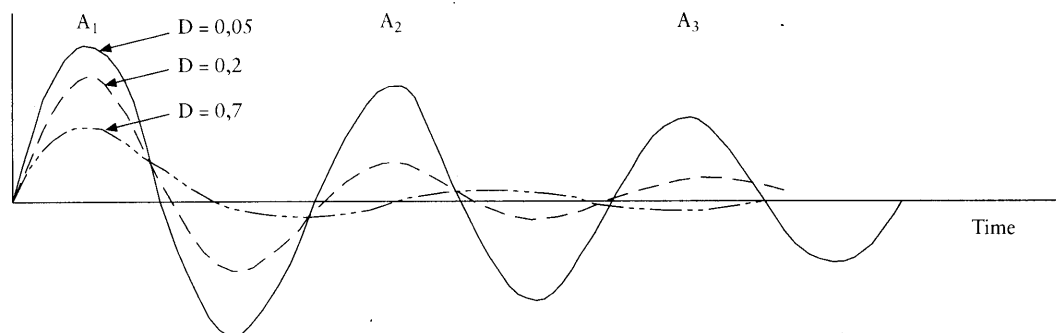


Figure 2

A damped transient response



## ANNEX III

## PLATE RELATING TO DIMENSIONS REFERRED TO IN ARTICLE 6 (1) (a)

I. The plate relating to dimensions, as far as possible affixed next to the plate referred to in Directive 76/114/EEC, must contain the following data:

1. name of the manufacturer<sup>(1)</sup>;
2. vehicle identification number<sup>(1)</sup>;
3. length of the motor vehicle, trailer or semi-trailer (L);
4. width of the motor vehicle, trailer or semi-trailer (W);
5. data for the measurement of the length of vehicle combinations:
  - the distance (a) between the front of the motor vehicle and the centre of the coupling device (coupling hook or fifth wheel); in the case of a fifth wheel with several coupling points, the minimum and maximum values must be given ( $a_{\min}$  and  $a_{\max}$ ),
  - the distance (b) between the centre of the coupling device of the trailer (fifth wheel ring) or of the semi-trailer (kingpin) and the rear of the trailer or of the semi-trailer; in the case of a device with several coupling points, the minimum and maximum values must be given ( $b_{\min}$  and  $b_{\max}$ ).

The length of vehicle combinations is the length of the motor vehicle and trailer or semi-trailer placed in a straight line behind each other.

II. The values given on the proof of compliance shall reproduce exactly the measurements carried out directly on the vehicle.

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<sup>(1)</sup> This information need not be repeated where the vehicle carries a single plate containing data on both weights and dimensions.



## ANNEX IV

## PART A

## REPEALED DIRECTIVES

(referred to in Article 10)

- Directive 83/3/EEC on the weights, dimensions and certain other technical characteristics of certain road vehicles and its successive amendments:
  - Directive 86/360/EEC
  - Directive 88/218/EEC
  - Directive 89/338/EEC
  - Directive 89/460/EEC
  - Directive 89/461/EEC
  - Directive 91/60/EEC
  - Directive 92/7/EEC
- Directive 86/364/EEC relating to proof of compliance of vehicles with Directive 85/3/EEC on the weights, dimensions and certain other technical characteristics of certain road vehicles.

## PART B

<i>Directive</i>	<i>Deadline for transposition</i>
85/3/EEC (OJ No L 2, 3. 1. 1985, p. 14)	1 July 1986 1 January 1990
86/360/EEC (OJ No L 217, 5. 8. 1986, p. 19)	1 January 1992
86/364/EEC (OJ No L 221, 7. 8. 1986, p. 48)	29 July 1987
88/218/EEC (OJ No L 98, 15. 4. 1988, p. 48)	1 January 1989
89/338/EEC (OJ No L 142, 25. 5. 1989, p. 3)	1 July 1991
89/460/EEC (OJ No L 226, 3. 8. 1989, p. 5)	1 January 1993
89/461/EEC (OJ No L 226, 3. 8. 1989, p. 7)	1 January 1991
91/60/EEC (OJ No L 37, 9. 2. 1991, p. 37)	30 September 1991
92/7/EEC (OJ No L 57, 2. 3. 1992, p. 29)	31 December 1992

ANNEX V  
CORRELATION TABLE

This Directive	85/3/EEC	86/360/EEC	86/364/EEC	88/218/EEC	89/338/EEC	89/460/EEC	89/461/EEC	91/60/EEC	92/7/EEC
Article 1 (1)	Article 1 (1)								
Article 1 (1) (a)	—								
Article 1 (1) (b)	Article 1 (1) (b)								
Article 1 (2)	Article 1 (2)								
Article 2 1st to 4th and 6th to 10th indents					Article 1 (2)				
Article 2 5th, 11th and 12th indents	—								
Article 2 last paragraph	—								
Article 3 (1)	—								
Article 3 (1) (a) (b)	Article 3 (1) (a) (b)								
Article 3 (2)	Article 3 (2)								
Article 3 (3)	—								
Article 4	—								
Article 5 (a)							Article 1 (1)		
Article 5 (b)								Article 1 (1)	
Article 6 (1 to 4)			Article 1 (1 to 4)						

[illegible]

This Directive	85/3/EEC	86/360/EEC	86/364/EEC	88/218/EEC	89/338/EEC	89/460/EEC	89/461/EEC	91/60/EEC	92/7/EEC
Point 2.3 to 2.3.1					Article 1 (5) (c)				
Point 2.3.2 to 2.3.3									Article 1 (1) (b to c)
Point 2.4					Article 1 (5) (c)				
Point 3 to 3.3.2	Point 3 to 3.3.2								
Point 3.4 to 3.4.1		Article 1 (3)							
Point 3.4.2 to 3.5.2					Article 1 (5) (d)				
Point 3.5.3									Article 1 (1) (d)
Point 4 to 4.2	Point 4 to 4.2								
Point 4.3					Article 1 (5) (e)				
Point 4.4							Article 1 (4)		
Annex II									Annex III
Annex III			Annex						