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⁽¹⁾ Text with EEA relevance

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EN

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

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I

(Acts whose publication is obligatory)

REGULATION (EC) No 816/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 May 2006

on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission,

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

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

Whereas:

(1) On 14 November 2001 the Fourth Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health. The Declaration recognises that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also recognises that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing.

(2) On 30 August 2003 the WTO General Council, in the light of the statement read out by its Chairman, adopted the Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Decision). Subject to certain conditions, the Decision waives certain obligations concerning the issue of compulsory licences set out in the TRIPS Agreement in order to address the needs of WTO Members with insufficient manufacturing capacity.

(3) Given the Community's active role in the adoption of the Decision, its commitment made to the WTO to fully contribute to the implementation of the Decision and its appeal to all WTO Members to ensure that the conditions are put in place which will allow the system set up by the Decision to operate efficiently, it is important for the Community to implement the Decision in its legal order.

(4) Uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for the manufacture and sale of pharmaceutical products, when such products are intended for export, are the same in all Member States and to avoid distortion of competition for operators in the single market. Uniform rules should also be applied to prevent re-importation into the territory of the Community of pharmaceutical products manufactured pursuant to the Decision.

(5) This Regulation is intended to be part of wider European and international action to address public health problems faced by least developed countries and other developing countries, and in particular to improve access to affordable medicines which are safe and effective, including fixed-dose combinations, and whose quality is guaranteed. In that connection, the procedures laid down in Community pharmaceutical legislation guaranteeing the scientific quality of such products will be available, in particular that provided for in Article 58 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ⁽³⁾.

(6) As the compulsory licensing system set up by this Regulation is intended to address public health problems, it should be used in good faith. This system should not be used by countries to pursue industrial or commercial policy objectives. This Regulation is designed to create a secure legal framework and to discourage litigation.

⁽¹⁾ OJ C 286, 17.11.2005, p. 4.

⁽²⁾ Opinion of the European Parliament of 1.12.2005 (not yet published in the Official Journal), and Council Decision of 28 April 2006.

⁽³⁾ OJ L 136, 30.4.2004, p. 1.

- (7) As this Regulation is part of wider action to address the issue of access to affordable medicines for developing countries, complementary actions are set out in the Commission Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction and in the Commission Communication on a Coherent European Policy Framework for External Action to Confront HIV/AIDS, malaria and tuberculosis. Continued urgent progress is necessary, including actions to support research to combat these diseases and to enhance capacity in developing countries.
- (8) It is imperative that products manufactured pursuant to this Regulation reach only those who need them and are not diverted from those for whom they were intended. The issuing of compulsory licences under this Regulation must therefore impose clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which the products will be exported.
- (9) Provision should be made for customs action at external borders to deal with products manufactured and sold for export under a compulsory licence which a person attempts to reimport into the territory of the Community.
- (10) Where pharmaceutical products produced under a compulsory licence have been seized under this Regulation, the competent authority may, in accordance with national legislation and with a view to ensuring that the intended use is made of the seized pharmaceutical products, decide to send the products to the relevant importing country according to the compulsory licence which has been granted.
- (11) To avoid facilitating overproduction and possible diversion of products, the competent authorities should take into account existing compulsory licences for the same products and countries, as well as parallel applications indicated by the applicant.
- (12) Since the objectives of this Regulation, in particular the establishment of harmonised procedures for the granting of compulsory licences which contribute to the effective implementation of the system set up by the Decision, cannot be sufficiently achieved by the Member States because of the options available to exporting countries under the Decision and can therefore, by reason of the potential effects on operators in the internal market, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (13) The Community recognises the utmost desirability of promoting the transfer of technology and capacity-building to countries with insufficient or no manufacturing capacity in the pharmaceutical sector, in order to facilitate and increase the production of pharmaceutical products by those countries.
- (14) In order to ensure the efficient processing of applications for compulsory licences under this Regulation, Member States should have the ability to prescribe purely formal or administrative requirements, such as rules on the language of the application, the form to be used, the identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought, and rules on applications made in electronic form.
- (15) The simple formula for setting remuneration is intended to accelerate the process of granting a compulsory licence in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement. The figure of 4 % could be used as a reference point for deliberations on adequate remuneration in circumstances other than those listed above,

HAVE ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems.

Member States shall grant a compulsory licence to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10.

Article 2

Definitions

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

- (1) 'pharmaceutical product' means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽¹⁾, active ingredients and diagnostic kits *ex vivo*;
- (2) 'rights-holder' means the holder of any patent or supplementary protection certificate in relation to which a compulsory licence has been applied for under this Regulation;
- (3) 'importing country' means the country to which the pharmaceutical product is to be exported;
- (4) 'competent authority' for the purposes of Articles 1 to 11, 16 and 17 means any national authority having competence to grant compulsory licences under this Regulation in a given Member State.

Article 3

Competent authority

The competent authority as defined in Article 2(4) shall be that which has competence for the granting of compulsory licences under national patent law, unless the Member State determines otherwise.

Member States shall notify the Commission of the designated competent authority as defined in Article 2(4).

Notifications shall be published in the *Official Journal of the European Union*.

Article 4

Eligible importing countries

The following are eligible importing countries:

- (a) any least-developed country appearing as such in the United Nations list;
- (b) any member of the WTO, other than the least-developed country members referred to in point (a), that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way;

⁽¹⁾ OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

- (c) any country that is not a member of the WTO, but is listed in the OECD Development Assistance Committee's list of low-income countries with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

However, any WTO member that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing country.

Article 5

Extension to least-developed and developing countries which are not members of the WTO

The following provisions shall apply to importing countries eligible under Article 4 which are not WTO members:

- (a) the importing country shall make the notification referred to in Article 8(1) directly to the Commission;
- (b) the importing country shall, in the notification referred to in Article 8(1), state that it will use the system to address public health problems and not as an instrument to pursue industrial or commercial policy objectives and that it will adopt the measures referred to in paragraph 4 of the Decision;
- (c) the competent authority may, at the request of the rights-holder, or on its own initiative if national law allows the competent authority to act on its own initiative, terminate a compulsory licence granted pursuant to this Article if the importing country has failed to honour its obligations referred to in point (b). Before terminating a compulsory licence, the competent authority shall take into account any views expressed by the bodies referred to in Article 6(3)(f).

Article 6

Application for a compulsory licence

1. Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.

2. If the person applying for a compulsory licence is submitting applications to authorities in more than one country for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.

3. The application pursuant to paragraph 1 shall set out the following:

- (a) the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;
- (b) the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;
- (c) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;
- (d) the importing country or countries;
- (e) where applicable, evidence of prior negotiation with the rights-holder pursuant to Article 9;
- (f) evidence of a specific request from:
 - (i) authorised representatives of the importing country or countries; or
 - (ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or
 - (iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries,

indicating the quantity of product required.

4. Purely formal or administrative requirements necessary for the efficient processing of the application may be prescribed under national law. Such requirements shall not add unnecessarily to the costs or burdens placed upon the applicant and, in any event, shall not render the procedure for granting compulsory licences under this Regulation more burdensome than the procedure for the granting of other compulsory licences under national law.

Article 7

Rights of the rights-holder

The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority shall give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

Article 8

Verification

1. The competent authority shall verify that:

- (a) each importing country cited in the application which is a WTO member has made a notification to the WTO pursuant to the Decision,
- or
- (b) each importing country cited in the application which is not a WTO member has made a notification to the Commission pursuant to this Regulation in respect of each of the products covered by the application that:
 - (i) specifies the names and expected quantities of the product(s) needed;
 - (ii) unless the importing country is a least-developed country, confirms that the country has established that it had insufficient or no manufacturing capacity in the pharmaceutical sector in relation to a particular product or products in one of the ways set out in the Annex to the Decision;
 - (iii) confirms that where a pharmaceutical product is patented in the territory of the importing country, that importing country has granted or intends to grant a compulsory licence for import of the product concerned in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.

This paragraph is without prejudice to the flexibility that least-developed countries have under the Decision of the Council for TRIPS of 27 June 2002.

2. The competent authority shall verify that the quantity of product cited in the application does not exceed that notified to the WTO by an importing country which is a WTO member, or to the Commission by an importing country which is not a WTO member, and that, taking into account other compulsory licences granted elsewhere, the total amount of product authorised to be produced for any importing country does not significantly exceed the amount notified by that country to the WTO, in the case of importing countries which are WTO members, or to the Commission, in the case of importing countries which are not WTO members.

Article 9

Prior negotiation

1. The applicant shall provide evidence to satisfy the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.

2. The requirement in paragraph 1 shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement.

*Article 10***Compulsory licence conditions**

1. The licence granted shall be non-assignable, except with that part of the enterprise or goodwill which enjoys the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.

2. The amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere.

3. The duration of the licence shall be indicated.

4. The licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question.

5. Products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the rights-holder through special packaging and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the Member States.

6. Before shipment to the importing country or countries cited in the application, the licensee shall post on a website the following information:

- (a) the quantities being supplied under the licence and the importing countries to which they are supplied;
- (b) the distinguishing features of the product or products concerned.

The website address shall be communicated to the competent authority.

7. If the product(s) covered by the compulsory licence are patented in the importing countries cited in the application, the

product(s) shall only be exported if those countries have issued a compulsory licence for the import, sale and/or distribution of the products.

8. The competent authority may at the request of the rights-holder or on its own initiative, if national law allows the competent authority to act on its own initiative, request access to books and records kept by the licensee, for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the products, have been met. The books and records shall include proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f).

9. The licensee shall be responsible for the payment of adequate remuneration to the rights-holder as determined by the competent authority as follows:

- (a) in the cases referred to in Article 9(2), the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country or on its behalf;
- (b) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence.

10. The licence conditions are without prejudice to the method of distribution in the importing country.

Distribution may be carried out for example by any of the bodies listed in Article 6(3)(f) and on commercial or non-commercial terms including completely without charge.

*Article 11***Refusal of the application**

The competent authority shall refuse an application if any of the conditions set out in Articles 6 to 9 are not met, or if the application does not contain the elements necessary to allow the competent authority to grant the licence in accordance with Article 10. Before refusing an application, the competent authority shall give the applicant an opportunity to rectify the situation and to be heard.

*Article 12***Notification**

When a compulsory licence has been granted, the Member State shall notify the Council for TRIPS through the intermediary of the Commission of the grant of the licence, and of the specific conditions attached to it.

The information provided shall include the following details of the licence:

- (a) the name and address of the licensee;
- (b) the product or products concerned;
- (c) the quantity to be supplied;
- (d) the country or countries to which the product or products are to be exported;
- (e) the duration of the licence;
- (f) the address of the website referred to in Article 10(6).

Article 13

Prohibition of importation

1. The import into the Community of products manufactured under a compulsory licence granted pursuant to the Decision and/or this Regulation for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse shall be prohibited.

2. Paragraph 1 shall not apply in the case of re-export to the importing country cited in the application and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing country.

Article 14

Action by customs authorities

1. If there are sufficient grounds for suspecting that products manufactured under a compulsory licence granted pursuant to the Decision and/or this Regulation are being imported into the Community contrary to Article 13(1), customs authorities shall suspend the release of, or detain, the products concerned for the time necessary to obtain a decision of the competent authority on the character of the merchandise. Member States shall ensure that a body has the authority to review whether such importation is taking place. The period of suspension or detention shall not exceed 10 working days unless special circumstances apply, in which case the period may be extended by a maximum of 10 working days. Upon expiry of that period, the products shall be released, provided that all customs formalities have been complied with.

2. The competent authority, the rights-holder and the manufacturer or exporter of the products concerned shall be informed without delay of the suspended release or detention of the products and shall be given all information available with respect to the products concerned. Due account shall be taken of national provisions on the protection of personal data and commercial and industrial secrecy and professional and administrative confidentiality.

The importer, and where appropriate, the exporter shall be given ample opportunity to supply the competent authority with the information which it deems appropriate regarding the products.

3. If it is confirmed that products suspended for release or detained by customs authorities were intended for import into the Community contrary to the prohibition in Article 13(1), the competent authority shall ensure that the products are seized and disposed of in accordance with national legislation.

4. The procedure of suspension or detention or seizure of the goods shall be carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

5. If the products suspended for release or detained by customs authorities are subsequently found not to violate the prohibition in Article 13(1), the customs authorities shall release the products to the consignee, provided that all customs formalities have been complied with.

6. The competent authority shall inform the Commission of any decisions on seizure or destruction adopted pursuant to this Regulation.

Article 15

Personal luggage exception

Articles 13 and 14 shall not apply to goods of a non-commercial nature contained in travellers' personal luggage for personal use within the limits laid down in respect of relief from customs duty.

Article 16

Termination or review of the licence

1. Subject to adequate protection of the legitimate interests of the licensee, a compulsory licence granted pursuant to this Regulation may be terminated by a decision of the competent authority or by one of the bodies referred to in Article 17 if the licence conditions are not respected by the licensee.

The competent authority shall have the authority to review, upon reasoned request by the rights-holder or the licensee, whether the licence conditions have been respected. This review shall be based on the assessment made in the importing country where appropriate.

2. Termination of a licence granted under this Regulation shall be notified to the Council for TRIPS through the intermediary of the Commission.

3. Following termination of the licence, the competent authority, or any other body appointed by the Member State, shall be entitled to establish a reasonable period of time within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need as referred to in Article 4 or otherwise disposed of as prescribed by the competent authority, or by another body appointed by the Member State, in consultation with the rights-holder.

4. When notified by the importing country that the amount of pharmaceutical product has become insufficient to meet its needs, the competent authority may, following an application by the licensee, modify the conditions of the licence permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned. In such cases the licensee's application shall be processed in accordance with a simplified and accelerated procedure, whereby the information set out in Article 6(3), points (a) and (b), shall not be required provided that the original compulsory licence is identified by the licensee. In situations where Article 9(1) applies but the derogation set out in Article 9(2) does not apply, no further evidence of negotiation with the rights-holder will be required, provided that the additional amount requested does not exceed 25 % of the amount granted under the original licence.

In situations where Article 9(2) applies, no evidence of negotiation with the rights-holder will be required.

Article 17

Appeals

1. Appeals against any decision of the competent authority, and disputes concerning compliance with the conditions of the licence, shall be heard by the appropriate body responsible under national law.

2. Member States shall ensure that the competent authority and/or the body referred to in paragraph 1 have the power to rule that an appeal against a decision granting a compulsory licence shall have suspensory effect.

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

Done at Strasbourg, 17 May 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

Article 18

Safety and efficacy of medicinal products

1. Where the application for a compulsory licence concerns a medicinal product, the applicant may avail himself of:

- (a) the scientific opinion procedure as provided for under Article 58 of Regulation (EC) No 726/2004, or
- (b) any similar procedures under national law, such as scientific opinions or export certificates intended exclusively for markets outside the Community.

2. If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC shall not apply.

Article 19

Review

Three years after the entry into force of this Regulation, and every three years thereafter, the Commission shall present a report to the European Parliament, the Council, and the European Economic and Social Committee on the operation of this Regulation including any appropriate plans for amendments. The report shall cover, in particular:

- (a) the application of Article 10(9) on determining the remuneration of the rights-holder;
- (b) the application of the simplified and accelerated procedure referred to in Article 16(4);
- (c) the sufficiency of the requirements under Article 10(5) to prevent trade diversion, and
- (d) the contribution this Regulation has made to the implementation of the system established by the Decision.

Article 20

Entry into force

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

For the Council

The President

H. WINKLER

DIRECTIVE 2006/38/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 May 2006

amending Directive 1999/62/EC on the charging of heavy goods vehicles for the use of certain infrastructures

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71(1) thereof,

Having regard to Directive 1999/62/EC⁽¹⁾, and in particular Article 7 thereof,

Having regard to the proposal from the Commission,

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

Having regard to the opinion of the Committee of the Regions⁽³⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽⁴⁾,

Whereas:

- (1) Eliminating distortions of competition between transport undertakings in the Member States, the proper functioning of the internal market and improved competitiveness all depend on fair mechanisms being established to charge hauliers for the cost of infrastructure use. A degree of harmonisation has already been achieved through Directive 1999/62/EC.
- (2) A fairer system of charging for the use of road infrastructure, based on the 'user pays' principle and the ability to apply the 'polluter pays' principle, for instance through the variation of tolls to take account of the environmental performance of vehicles, is crucial in order to encourage sustainable transport in the Community. The objective of making optimum use of the existing road network and achieving a significant reduction in its negative impact should be achieved in such a way as to avoid double taxation and without imposing additional burdens on operators, in the interests of sound economic growth and the proper functioning of the internal market, including outlying regions.
- (3) The Commission announced its intention of proposing a directive on charging for the use of road infrastructure in the White Paper 'European transport policy for 2010: time to decide'. The European Parliament confirmed the need for infrastructure charging when it adopted its

resolution⁽⁵⁾ on the conclusions of the White Paper on 12 February 2003. Following the Göteborg European Council of 15 and 16 June 2001, which drew particular attention to the issue of sustainable transport, the Copenhagen European Council of 12 and 13 December 2002 and the Brussels European Council of 20 and 21 March 2003 also welcomed the Commission's intention of presenting a new 'Eurovignette' Directive.

- (4) In paragraph 29 of the Presidency conclusions of its meeting in Göteborg, the European Council stated that a sustainable transport policy should tackle rising volumes of traffic and levels of congestion, noise and pollution and encourage the use of environment-friendly modes of transport as well as the full internalisation of social and environmental costs.
- (5) For the purposes of setting tolls, Directive 1999/62/EC takes account of infrastructure construction, operating, maintenance and development costs. A specific provision is needed to ensure clarity regarding the construction costs that may be taken into account.
- (6) International road transport operations are concentrated on the trans-European road transport network. Furthermore, the proper functioning of the internal market is vital to commercial transport. Consequently, the Community framework should apply to commercial transport on the trans-European road network as defined in Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the trans-European transport network⁽⁶⁾. Member States should, in accordance with the principle of subsidiarity, be free to apply tolls and/or user charges on roads other than those on the trans-European road network, in compliance with the Treaty. Where Member States choose to maintain or introduce tolls and/or user charges only on parts of the trans-European road network in their territory and not on others, for reasons such as their isolation or low levels of congestion or pollution or where essential for the introduction of a new tolling arrangement, the choice of the parts of the network subject to tolls or charges should not discriminate against international traffic and should not result in distortions of competition

⁽¹⁾ OJ L 187, 20.7.1999, p. 42. Directive as amended by the 2003 Act of Accession.

⁽²⁾ OJ C 241, 28.9.2004, p. 58.

⁽³⁾ OJ C 109, 30.4.2004, p. 14.

⁽⁴⁾ Opinion of the European Parliament of 20 April 2004 (OJ C 104 E, 30.4.2004, p. 371), Council Common Position of 6 September 2005 (OJ C 275 E, 8.11.2005, p. 1) and Position of the European Parliament of 15 December 2005 (not yet published in the Official Journal). Council Decision of 27 March 2006.

⁽⁵⁾ OJ C 43 E 19.2.2004, p. 250.

⁽⁶⁾ OJ L 228, 9.9.1996, p. 1. Decision as last amended by Decision No 884/2004/EC (OJ L 167, 30.4.2004, p. 1).

between operators. The same requirements should apply to cases where a Member State maintains or introduces tolls and/or user charges on roads not forming part of the trans-European road network, for example on parallel roads, with a view to managing traffic flows.

- (7) Where a Member State chooses to extend tolls and/or user charges beyond the trans-European road network, for example to include parallel roads to which traffic may be diverted from the trans-European road network and/or which are in direct competition with certain parts of that network, it should ensure coordination with the authorities responsible for these roads.
- (8) For reasons of cost efficiency in the implementation of tolling systems, the entire infrastructure to which a toll relates may not necessarily be subject to access restrictions controlling tolls charged. Member States may choose to implement this Directive through the use of tolls at only a particular point on the infrastructure to which the toll relates. This should not discriminate against non-local traffic.
- (9) Toll should be based on the principle of recovery of infrastructure costs. In cases where such infrastructures have been co-financed through the general budget of the European Union, the contribution made from Community funds should not be recovered through tolls, unless there are specific provisions in the relevant Community instruments which take into account future toll receipts in establishing the amount of Community co-financing.
- (10) The fact that the user is able to take decisions which will influence the burden of tolls by choosing the least polluting vehicles and less congested periods or itineraries is an important component of a charging system. Member States should therefore be able to differentiate tolls according to a vehicle's emission category ('EURO' classification) and the level of damage it causes to roads, the place, the time and the amount of congestion. Such differentiation in the level of tolls should be proportionate to the objective pursued.
- (11) Aspects of commercial pricing for road infrastructure use not covered by this Directive should respect the rules of the Treaty.
- (12) This Directive does not affect the freedom of Member States which introduce a system of tolls and/or user charges for infrastructure to provide, without prejudice to Articles 87 and 88 of the Treaty, appropriate compensation for these charges. Such compensation should not lead to distortions of competition within the internal market and should be subject to the relevant provisions of Community law, in particular the minimum rates of vehicle taxes set out in Annex I to Directive 1999/62/EC and the provisions of Council Directive 2003/96/EC of 27 October 2003 restructuring the Community framework for the taxation of energy products and electricity⁽¹⁾.
- (13) Where Member States levy tolls or user charges for use of roads in the trans-European road network, the roads subject to charging should be given appropriate priority in the maintenance schedules of Member States. Revenues from tolls or user charges should be used for the maintenance of the infrastructure concerned and for the transport sector as a whole, in the interest of the balanced and sustainable development of transport networks.
- (14) Particular attention should be devoted to mountain regions such as the Alps or the Pyrenees. The launch of major new infrastructure projects has often failed because the substantial financial resources they would require were not available. In such regions, users may therefore be required to pay a mark-up to finance essential projects of very high European value, including those involving another mode of transport in the same corridor. This amount should be linked to the financial needs of the project. It should also be linked to the basic level of the tolls in order to avoid artificially high charges in any one corridor, which could lead to traffic being diverted to other corridors, thereby causing local congestion problems and inefficient use of networks.
- (15) Fees should be non-discriminatory and their collection should not involve excessive formalities or create barriers at internal borders. Appropriate measures should therefore be taken to facilitate payment by occasional users, in particular where tolls and/or user charges are collected exclusively by means of a system that requires use of an electronic payment tool (on-board unit).
- (16) In order to prevent traffic being diverted because of different regimes between Member States and third countries, the Commission should try to ensure that, when negotiating international agreements, no measures are taken by third countries, such as a transit right trading system, that might have a discriminatory effect on transit traffic.

⁽¹⁾ OJ L 283, 31.10.2003, p. 51. Directive as last amended by Directive 2004/75/EC (OJ L 157, 30.4.2004, p. 100).

- (17) In order to ensure consistent, harmonised application of the infrastructure charging system, new tolling arrangements should calculate costs in accordance with the set of core principles set out in Annex II or be set at a level which does not go beyond that which would result from the application of these principles. These requirements should not apply to existing arrangements unless they are substantially modified in the future. Such substantial modifications would include any significant change to the original terms and conditions of the tolling scheme through modification of a contract with the tolling system operator but would exclude changes provided for in the original scheme. In the case of concession contracts, substantial modification could be implemented pursuant to a public procurement process. In order to achieve transparency without creating obstacles to the functioning of the market economy and public private partnerships, Member States must also communicate to the Commission, so that the Commission is in a position to give an opinion, the unit values and other parameters they intend to apply to calculate the various cost elements of the charges or, in the case of concession contracts, the relevant contract and base case. Opinions adopted by the Commission before the introduction of new tolling arrangements in Member States are entirely without prejudice to the Commission's obligation under the Treaty to ensure that Community law is applied.
- (18) So as to enable an informed and objective decision to be taken in the future regarding the possible application of the 'polluters pays' principle for all modes of transport, by means of the internalisation of external costs, uniform calculation principles should be developed, based on scientifically recognised data. Any future decision on this question should take full account of the tax burden already borne by road haulage companies, including vehicle taxes and fuel excise duties.
- (19) The Commission should begin work on developing a generally applicable, transparent and comprehensible model for the assessment of external costs for all modes of transport to serve as the basis for future calculations of infrastructure charges. In carrying out this work, the Commission should examine all possible options regarding the composition of the external costs to be taken into account, having regard to the elements listed in its 2001 White Paper 'European Transport Policy for 2010', carefully assessing the impact that internalisation of the various cost options would have. The European Parliament and the Council will examine diligently any such proposal of the Commission for further revision of Directive 1999/62/EC.
- (20) Further technical progress is still needed to develop the system of charging for the use of road infrastructure. There should be a procedure allowing the Commission to adapt the requirements of Directive 1999/62/EC to technical progress following consultation with Member States for this purpose.
- (21) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾.
- (22) Since the objective of this Directive, namely to harmonise the conditions applicable to tolls and user charges for the use of road infrastructure, cannot be satisfactorily achieved by the Member States acting alone and can therefore, by reason of its European dimension and with a view to safeguarding the internal market for transport, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity enshrined in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.
- (23) Directive 1999/62/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. Article 2 of Directive 1999/62/EC shall be amended as follows:

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

(a) "trans-European road network" means the road network defined in Section 2 of Annex I to Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the trans-European transport network (*) as illustrated by maps. The maps refer to the corresponding sections mentioned in the operative part of and/or in Annex II to that Decision;

(*) OJ L 228, 9.9.1996, p. 1. Decision as last amended by Decision No 884/2004/EC (OJ L 167, 30.4.2004, p. 1).

(b) the following points shall be inserted:

(aa) "construction costs" means the costs related to construction, including, where appropriate, the financing costs, of:

— new infrastructure or new infrastructure improvements (including significant structural repairs), or

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

— infrastructure or infrastructure improvements (including significant structural repairs) completed no more than 30 years before 10 June 2008, where tolling arrangements are already in place on 10 June 2008, or completed no more than 30 years before the establishment of any new tolling arrangements introduced after 10 June 2008; costs regarding infrastructure or infrastructure improvements completed before these time limits may also be considered as construction costs where:

- (i) a Member State has established a tolling system which provides for the recovery of these costs by means of a contract with a tolling system operator, or other legal acts having equivalent effect, which enter into force before 10 June 2008, or
- (ii) a Member State can demonstrate that the case for building the infrastructure in question depended on its having a design lifetime in excess of 30 years.

In any event, the proportion of the construction costs to be taken into account shall not exceed the proportion of the current design lifetime period of infrastructure components still to run on 10 June 2008 or on the date when the new tolling arrangements are introduced, where this is a later date.

Costs of infrastructure or infrastructure improvements may include any specific expenditure on infrastructure designed to reduce nuisance related to noise or to improve road safety and actual payments made by the infrastructure operator corresponding to objective environmental elements such as protection against soil contamination;

- (ab) “financing costs” means interest on borrowings and/or return on any equity funding contributed by shareholders;
- (ac) “significant structural repairs” means structural repairs excluding those repairs no longer of any current benefit to road users, e.g. where the repair work has been replaced by further road resurfacing or other construction work;’;

(c) point (b) shall be replaced by the following:

(b) ‘toll’ means a specified amount payable for a vehicle travelling a given distance on the infrastructures referred to in Article 7(1); the amount shall be based on the distance travelled and the type of vehicle,

(d) the following point shall be inserted:

(ba) “weighted average toll” means the total revenue raised through tolls over a given period divided by the number of vehicle kilometres travelled on a given network subject to tolling during that period, both the revenue and the vehicle kilometres being calculated for the vehicles to which tolls apply;’;

(e) points (c), (d), (e) and (f) shall be replaced by the following:

(c) “user charge” means a specified amount payment of which confers the right for a vehicle to use for a given period the infrastructures referred to in Article 7(1);

(d) “vehicle” means a motor vehicle or articulated vehicle combination intended or used exclusively for the carriage by road of goods and having a maximum permissible laden weight of over 3,5 tonnes;

(e) vehicle of the “EURO 0”, “EURO I”, “EURO II”, “EURO III”, “EURO IV”, “EURO V”, “EEV” category means a vehicle that complies with the emission limits set out in Annex 0;

(f) “type of vehicle” means a category into which a vehicle falls according to the number of its axles, its dimensions or weight, or other vehicle classification factors reflecting road damage, e.g. the road damage classification system set out in Annex IV, provided that the classification system used is based on vehicle characteristics which either appear in the vehicle documentation used in all Member States or are visually apparent;’;

(f) the following points shall be added:

(g) “concession contract” means a “public works concession” or a “service concession” as defined in Article 1 of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (*);

(h) "concession toll" means a toll levied by a concessionaire under a concession contract.'

(*) OJ L 134, 30.4.2004, p. 114. Directive as last amended by Commission Regulation (EC) No 2083/2005 (OJ L 333, 20.12.2005, p. 28).

2. Article 7 is hereby amended as follows:

(a) paragraphs 1, 2, 3 and 4 shall be replaced by the following:

1. 'Member States may maintain or introduce tolls and/or user charges on the trans-European road network, or on parts of that network, only under the conditions set out in paragraphs 2 to 12. This shall be without prejudice to the right of Member States, in compliance with the Treaty, to apply tolls and/or user charges on roads not included in the trans-European road network, *inter alia* on parallel roads to which traffic may be diverted from the trans-European road network and/or which are in direct competition with certain parts of that network, or to other types of motor vehicle not covered by the definition of "vehicle" on the trans-European road network, provided that the imposition of tolls and/or user charges on such roads does not discriminate against international traffic and does not result in distortions of competition between operators.

1a. Where a Member State decides to maintain or introduce tolls and/or user charges on only parts of the trans-European road network, the resulting exemptions for the other parts (for reasons such as their isolation or low levels of congestion or pollution or where essential for the introduction of a new tolling arrangement) shall not result in any discrimination against international traffic.

2. (a) A Member State may choose to maintain or introduce tolls and/or user charges applicable only to vehicles having a maximum permissible laden weight of not less than 12 tonnes. Where a Member State chooses to apply tolls and/or user charges to vehicles below this weight limit, the provisions of this Directive shall apply.

(b) Toll and/or user charges shall be applied to all vehicles from 2012.

(c) A Member State may derogate from the requirement set out in point (b) where it considers that the extension of tolling to vehicles of less than 12 tonnes would:

— create significant adverse effects on the free flow of traffic, the environment, noise levels, congestion or health, or

— involve administrative costs which would be more than 30 % of additional revenue generated.

3. Tolls and user charges may not both be imposed at the same time on any given category of vehicle for the use of a single road section. However, Member States may also impose tolls on networks where user charges are levied for the use of bridges, tunnels and mountain passes.

4. Tolls and user charges may not discriminate, directly or indirectly, on the grounds of nationality of the haulier, the country or place of establishment of the haulier or of registration of the vehicle, or the origin or destination of the transport operation.;

(b) the following paragraphs shall be inserted:

'4a. Member States may provide for reduced toll rates or user charges or exemptions from the obligation to pay tolls or user charges for vehicles exempted from the requirement to install and use recording equipment under Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport (*), and in the cases covered by, and subject to the conditions contained in, Article 6(2)(a) and (b) of this Directive.

4b. As charging structures involving discounts or reductions in tolls for frequent users may lead to actual savings in administrative costs for the infrastructure operator, Member States may provide for such discounts or reductions on condition that:

— they fulfil the conditions set out in paragraph 10(a),

— they comply with the Treaty, in particular Articles 12, 49, 86 and 87 thereof,

— they do not distort competition in the internal market,

— the resulting charging structure is linear, proportionate, available to all users on equal terms and does not lead to additional costs being passed on to other users in the form of higher tolls.

Such discounts or reductions shall in no case exceed 13 % of the toll paid by equivalent vehicles not eligible for the discount or reduction.

4c. All discount and reduction schemes shall be communicated to the Commission, which shall verify compliance with the conditions set out in paragraphs 4a and 4b and shall approve them in accordance with the procedure referred to in Article 9c(2).'

(*) OJ L 370, 31.12.1985, p. 8. Regulation as last amended by Commission Regulation (EC) No 432/2004 (OJ L 71, 10.3.2004, p. 3).

(c) paragraph 6 shall be replaced by the following:

6. 'The arrangements for the collection of tolls and/or user charges shall not, financially or otherwise, place non-regular users of the road network at an unjustified disadvantage. In particular, where a Member State collects tolls and/or user charges exclusively by means of a system that requires the use of a vehicle on-board unit, it shall make available the appropriate on-board units under reasonable administrative and economic arrangements.'

(d) the second and third subparagraphs of paragraph 7 shall be deleted;

(e) paragraphs 9 and 10 shall be replaced by the following:

9. 'Tolls shall be based on the principle of the recovery of infrastructure costs only. Specifically the weighted average tolls shall be related to the construction costs and the costs of operating, maintaining and developing the infrastructure network concerned. The weighted average tolls may also include a return on capital or profit margin based on market conditions.'

10. (a) Without prejudice to the weighted average tolls referred to in paragraph 9, Member States may vary the toll rates for purposes such as combating environmental damage, tackling congestion, minimising infrastructure damage, optimising the use of the infrastructure network concerned or promoting road safety, provided that such variation:

- is proportionate to the objective pursued;
- is transparent and non-discriminatory particularly regarding the nationality of the haulier, the country or place of establishment of the haulier or of registration of the vehicle, and the origin or destination of the transport operation;
- is not designed to generate additional tolling revenue, any unintended increase in revenue (leading to weighted average tolls which are not in accordance with paragraph 9) being counterbalanced through changes to the structure of the variation which must be implemented within two years of the end of the accounting year in which the additional revenue is generated;
- respects the maximum flexibility thresholds set out in point (b).

(b) Subject to the conditions of point (a), toll rates may be varied according to:

- EURO emission class as set out in Annex 0, including the level of PM and NOx,

provided that no toll is more than 100 % above the toll charged for equivalent vehicles meeting the strictest emission standards; and/or

— the time of day, type of day or season, provided that:

- (i) no toll is more than 100 % above the toll charged during the cheapest period of the day, type of day or season; or
- (ii) where the cheapest period is zero-rated, the penalty for the most expensive time of day, type of day or season is no more than 50 % of the level of toll that would otherwise be applicable to the vehicle in question.

Member States shall be required to vary the rates at which tolls are charged in conformity with the first indent no later than 2010, or in the case of concession contracts, when that concession contract is renewed.

A Member State may nevertheless derogate from this requirement if:

- (i) this would seriously undermine the coherence of the tolling systems in its territory;
- (ii) for the tolling system concerned, it would not be technically practicable to introduce such differentiation; or
- (iii) this would lead to diversion of the most polluting vehicles away from the trans-European road network with consequential impacts on road safety and public health.

Any such derogations shall be notified to the Commission.

(c) Subject to the conditions of point (a), toll rates may in exceptional cases for specific projects of high European interest be subject to other forms of variation in order to secure the commercial viability of such projects, when they are exposed to direct competition with other modes of transport for vehicles. The resulting charging structure shall be linear, proportionate, openly published, available to all users on equal terms and shall not lead to additional costs being passed on to other users in the form of higher tolls. The Commission shall verify compliance with the conditions of this point prior to the implementation of the charging structure in question.'

(f) the following paragraphs shall be added:

11. Without prejudice to Article 9(1) and (1a), in exceptional cases concerning infrastructure in mountainous regions and after informing the Commission, a mark-up may be added to the tolls of specific road sections:

- (a) which are the subject of acute congestion affecting the free movement of vehicles; or
- (b) the use of which by vehicles is the cause of significant environmental damage,

on condition that:

- the revenue generated from the mark-up is invested in priority projects of European interest identified in Annex III to Decision No 884/2004/EC, which contribute directly to the alleviation of the congestion or environmental damage in question and which are located in the same corridor as the road section on which the mark-up is applied,
- the mark-up, which may be applied to tolls varied in accordance with paragraph 10, does not exceed 15 % of the weighted average toll calculated in accordance with paragraph 9 except where the revenue generated is invested in cross-border sections of priority projects of European interest involving infrastructure in mountainous regions, in which case the mark-up may not exceed 25 %,
- the application of the mark-up does not result in unfair treatment of commercial traffic compared to other road users,
- financial plans for the infrastructure on which the mark-up is applied and a cost/benefit analysis for the new infrastructure project are submitted to the Commission in advance of the mark-up's application,
- the period for which the mark-up is to apply is defined and limited in advance and is consistent in terms of the expected revenue to be raised with the financial plans and cost/benefit analysis submitted.

Application of this provision to new cross-border projects shall be subject to the agreement of the Member States concerned.

When the Commission receives the financial plans from a Member State intending to apply a mark-up, it shall make this information available to the members of the Committee referred to in Article 9c(1). Should the Commission consider that the planned mark-up

does not meet the conditions set out in this paragraph, or if it considers that the planned mark-up will have significant adverse effects on the economic development of peripheral regions, it may reject or request modification of the plans for charges submitted by the Member State concerned, in accordance with the procedure referred to in Article 9c(2).

12. Where a driver is unable to produce the vehicle documents necessary to ascertain the information referred to in the first indent of paragraph 10(b), and the type of vehicle in the event of a check, Member States may apply tolls up to the highest level chargeable.;

3. the following Article shall be inserted:

'Article 7a

1. In determining the levels of weighted average tolls to be charged on the infrastructure network concerned or a clearly defined part of such a network, Member States shall take into account the various costs set out in Article 7(9). The costs taken into account shall relate to the network or part of the network on which tolls are levied and to the vehicles that are subject to the tolling. Member States may choose not to recover these costs through toll revenue or to recover only a percentage of the costs.

2. Toll levels shall be determined in accordance with Article 7 and paragraph 1 of this Article.

3. For new tolling arrangements other than those involving concession tolls put in place by Member States after 10 June 2008, Member States shall calculate costs using a methodology based on the core calculation principles set out in Annex III.

For new concession tolls put in place after 10 June 2008, the maximum level of tolls shall be equivalent to, or less than, the level that would have resulted from the use of a methodology based on the core calculation principles set out in Annex III. The assessment of such equivalence shall be made on the basis of a reasonably long reference period appropriate to the nature of a concession contract.

Tolling arrangements already in place on 10 June 2008 or for which tenders or responses to invitations to negotiate under the negotiated procedure have been received pursuant to a public procurement process before 10 June 2008 shall not be subject to the obligations set out in this paragraph, for as long as these arrangements remain in force and provided that they are not substantially modified.

4. Member States shall communicate to the Commission at least four months before the implementation of a new tolling arrangement:

(a) for tolling arrangements other than those involving concession tolls:

- the unit values and other parameters they use in calculating the various cost elements, and
- clear information on the vehicles covered by their tolling regime and the geographic extent of the network, or part of the network, used for each cost calculation and the percentage of costs that they are seeking to recover;

(b) for tolling arrangements involving concession tolls:

- the concession contracts or significant changes to such contracts,
- the base case on which the grantor has founded the notice of concession, as referred to in Annex VII B to Directive 2004/18/EC; this base case shall include the estimated costs as defined in Article 7(9) envisaged under the concession, the forecasted traffic divided into types of vehicle, the levels of tolls envisaged and the geographic extent of the network covered by the concession contract.

5. Member States shall also inform the Commission at least four months before their implementation of new tolling arrangements applicable to parallel roads to which traffic may be diverted from the trans-European road network and/or which are in direct competition with certain parts of that network on which tolls are levied. This information shall include at least an explanation of the geographic extent of the network covered by the toll, the vehicles covered and the levels of toll envisaged, together with an explanation of how the level of toll was determined.

6. For the cases subject to the obligations in paragraph 3 the Commission shall, within four months of receiving the information in accordance with paragraph 4, give an opinion as to whether these obligations appear to have been fulfilled.

For the tolling arrangements referred to in paragraph 5, the Commission may also give an opinion, in particular regarding the proportionality and the transparency of the proposed arrangements and their likely impact on competition in the context of the internal market and the free movement of goods.

The opinions of the Commission shall be made available to the Committee referred to in Article 9c(1).

7. Where a Member State wishes to apply the provisions contained in Article 7(11) in respect of tolling arrangements already in place on 10 June 2008, it shall provide information that demonstrates that the weighted average toll being applied to the infrastructure concerned complies with Articles 2(aa), 7(9) and 7(10).;

4. the following Article shall be inserted:

'Article 7b

This Directive does not affect the freedom of Member States which introduce a system of tolls and/or user charges for infrastructure to provide, without prejudice to Articles 87 and 88 of the Treaty, appropriate compensation for these charges.;

5. Article 8(2)(b) shall be replaced by the following:

(b) 'payment of the common user charge shall give access to the network as defined by the participating Member States in accordance with Article 7(1).;

6. the following Article shall be inserted:

'Article 8a

Each Member State shall monitor the system of tolls and/or user charges to ensure that it functions in a transparent and non-discriminatory manner.;

7. Article 9 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

1. This Directive shall not prevent the non-discriminatory application by Member States of:

(a) specific taxes or charges:

— levied upon registration of the vehicle, or

— imposed on vehicles or loads of abnormal weights or dimensions;

(b) parking fees and specific urban traffic charges.

1a. This Directive shall not prevent the non-discriminatory application by Member States of:

(a) regulatory charges specifically designed to combat time and place-related traffic congestion;

(b) regulatory charges designed to combat environmental impacts, including poor air quality

on any road, notably in urban areas, including trans-European road network roads crossing an urban area.;

(b) paragraph 2 shall be replaced by the following:

2. 'Member States shall determine the use to be made of revenue from charges for the use of road infrastructure. To enable the transport network to be developed as a whole, revenue from charges should be used to benefit the transport sector and optimise the entire transport system.';

8. the following Articles shall be inserted:

'Article 9a

Member States shall establish appropriate controls and determine the system of penalties applicable to infringements of the national provisions adopted under this Directive. They shall take all necessary measures to ensure that they are implemented. The penalties established shall be effective, proportionate and dissuasive.

Article 9b

The Commission shall facilitate dialogue and the exchange of technical know-how between Member States in relation to the implementation of this Directive and in particular Annex III. The Commission shall update and clarify Annexes 0, III and IV in the light of technical progress and Annexes I and II in the light of inflation, in accordance with the procedure referred to in Article 9c(3).

Article 9c

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Article 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

4. The Committee shall adopt its rules of procedure.';
9. Article 11 shall be replaced by the following:

'Article 11

No later than 10 June 2011, the Commission shall present a report to the European Parliament and the Council on the implementation and effects of this Directive, taking account of developments in technology and the trend in traffic density, including the use of vehicles of more than

3,5 and less than 12 tonnes, and evaluating its impact on the internal market, including on island, landlocked and peripheral regions of the Community, levels of investment in the sector and its contribution to the objectives of a sustainable transport policy.

Member States shall forward the necessary information for the report to the Commission no later than 10 December 2010.

No later than 10 June 2008, the Commission shall present, after examining all options including environment, noise, congestion and health-related costs, a generally applicable, transparent and comprehensible model for the assessment of all external costs to serve as the basis for future calculations of infrastructure charges. This model shall be accompanied by an impact analysis of the internalisation of external costs for all modes of transport and a strategy for a stepwise implementation of the model for all modes of transport.

The report and the model shall be accompanied, if appropriate, by proposals to the European Parliament and the Council for further revision of this Directive.';

10. the table in Annex II indicating the amount of annual charges shall be replaced by the following:

	maximum three axles	minimum four axles
EURO 0	1 332	2 233
EURO I	1 158	1 933
EURO II	1 008	1 681
EURO III	876	1 461
EURO IV and less polluting	797	1 329

11. the last sentence of Annex II shall be replaced by the following:

'The daily user charge is equal for all vehicle categories and amounts to EUR 11.';

12. Annex 0, the text of which appears in Annex I to this Directive, shall be inserted;
13. Annex III, the text of which appears in Annex II to this Directive, shall be added;
14. Annex IV, the text of which appears in Annex III 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 this Directive not later than 10 June 2008. They shall forthwith inform the Commission thereof.

When Member States adopt such 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 provisions of domestic law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Strasbourg, 17 May 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

H. WINKLER

ANNEX I

ANNEX 0

EMISSION LIMITS

1. "EURO 0" vehicle

Mass of carbon monoxide (CO) g/kWh	Mass of hydrocarbons (HC) g/kWh	Mass of nitrogen oxides (NOx) g/kWh
12,3	2,6	15,8

2. "EURO I"/"EURO II" vehicles

	Mass of carbon monoxide (CO) g/kWh	Mass of hydrocarbons (HC) g/kWh	Mass of nitrogen oxides (NOx) g/kWh	Mass of particulates (PT) g/kWh
"EURO I" vehicle	4,9	1,23	9,0	0,4 ⁽¹⁾
"EURO II" vehicle	4,0	1,1	7,0	0,15

⁽¹⁾ A coefficient of 1,7 is applied to the particulate emission limit value in the case of engines with a power rating of 85 kW or less.

3. "EURO III"/"EURO IV"/"EURO V"/"EEV" vehicles

The specific masses of carbon monoxide, total hydrocarbons, nitrogen oxides and particulates, determined by the ESC test and the exhaust gas opacity, determined by the ELR test, must not exceed the following values ⁽¹⁾:

	Mass of carbon monoxides (CO) g/kWh	Mass of hydrocarbons (HC) g/kWh	Mass of nitrogen oxides (NOx) g/kWh	Mass of particulates (PT) g/kWh	Exhaust gas m ⁻¹
"EURO III" vehicle	2,1	0,66	5,0	0,10 ⁽²⁾	0,8
"EURO IV" vehicle	1,5	0,46	3,5	0,02	0,5
"EURO V" vehicle	1,5	0,46	2,0	0,02	0,5
"EEV" vehicle	1,5	0,25	2,0	0,02	0,15

⁽¹⁾ A test cycle consists of a sequence of test points, each point being defined by a speed and a torque which the engine must respect in steady state (ESC test) or transient operating conditions (ETC and ELR tests).

⁽²⁾ 0,13 for engines whose unit cylinder capacity is less than 0,7 dm³ and the nominal speed is in excess of 3 000 min⁻¹.

4. Future emission classes of vehicles as defined in Directive 88/77/EEC and subsequent amendments may be considered.

ANNEX II

ANNEX III

CORE PRINCIPLES FOR THE ALLOCATION OF COSTS AND CALCULATION OF TOLLS

This Annex stipulates the core principles for the calculation of weighted average tolls to reflect Article 7(9). The obligation to relate tolls to costs shall be without prejudice to the freedom of Member States to choose, in accordance with Article 7a(1), not to recover the costs in full through toll revenue, or to the freedom, in accordance with Article 7(10), to vary the amounts of specific tolls away from the average ⁽¹⁾.

The application of these principles shall be fully consistent with other existing obligations under Community law, in particular the requirement for concession contracts to be awarded in accordance with Directive 2004/18/EC and other Community instruments in the field of public procurement.

Where a Member State engages in negotiations with one or more third parties with a view to establishing a concession contract regarding the construction or operation of a part of its infrastructure, or in view of this purpose engages in a similar arrangement based on national legislation or an agreement entered into by the government of a Member State, compliance with these principles shall be judged on the basis of the outcome of these negotiations.

1. Definition of the network and of vehicles covered

- Where a single tolling regime is not to be applied to the whole TEN road network, a Member State shall specify precisely the part or parts of the network which are to be subject to a tolling regime as well as the system it uses to classify vehicles for the purposes of toll variation. Member States shall also specify whether they are extending the scope of their tolling regime to cover vehicles below the 12-tonne threshold.
- Where a Member State chooses to adopt different policies regarding cost recovery for different parts of its network (as permitted under Article 7a(1)), each clearly defined part of the network shall be subject to a separate calculation of costs. A Member State may choose to split its network up into a number of clearly defined parts so as to establish separate concession arrangements or similar for each part.

2. Infrastructure costs**2.1. Investment costs**

- Investment costs shall include the costs of construction (including financing costs) and the costs of developing the infrastructure plus, where appropriate, a return on the capital investment or profit margin. Costs of land acquisition, planning, design, supervision of construction contracts and project management, and of archaeological and ground investigations, as well as other relevant incidental costs, shall also be included.
- The recovery of construction costs shall be based on either the design lifetime of the infrastructure or such other amortisation period (not being less than 20 years) as may be considered appropriate for reasons of financing through a concession contract or otherwise. The length of the amortisation period may be a key variable in negotiations regarding the establishment of concession contracts, particularly if the Member State concerned wishes, as part of the contract, to set a ceiling regarding the weighted average toll applicable.
- Without prejudice to the calculation of investment costs, the recovery of costs may:
 - be apportioned evenly over the amortisation period or weighted to the early, middle or later years, provided that such weighting is carried out in a transparent manner,
 - provide for indexation of tolls over the amortisation period.
- All historic costs shall be based on the amounts paid. Costs which are still to be incurred will be based on reasonable cost forecasts.

⁽¹⁾ These provisions, together with the flexibility offered in the way costs are recovered over time (see the third indent of point 2.1), give considerable margin to fix tolls at levels which are acceptable to users and adapted to the specific transport policy objectives of the Member State.

- Government investment may be assumed to be financed borrowings. The rate of interest to be applied to historical costs shall be the rates that applied to government borrowings over that period.
- Costs shall be apportioned to heavy goods vehicles (HGVs) on an objective and transparent basis taking account of the proportion of HGV traffic to be carried on the network and the associated costs. The vehicle kilometres travelled by HGVs may for this purpose be adjusted by objectively justified “equivalence factors” such as those set out in point 4 ⁽¹⁾.
- Provision for estimated return on capital or profit margin shall be reasonable in the light of market conditions and may be varied for the purpose of providing performance incentives for a contracted third party with regard to quality of service requirements. Return on capital may be evaluated using economic indicators such as IRR (internal rate of return on investment) or WACC (weighted average cost of capital).

2.2. Annual maintenance costs and structural repair costs

- These costs shall include both the annual costs of maintaining the network and the periodic costs relating to repair, reinforcement and resurfacing, with a view to ensuring that the level of operational functionality of the network is maintained over time.
- Such costs shall be apportioned between HGV and other traffic on the basis of actual and forecast shares of vehicle kilometres and may be adjusted by objectively justified equivalence factors such as those set out in point 4.

3. Operating, management and tolling costs

These costs shall include all costs incurred by the infrastructure operator which are not covered under Section 2 and which relate to the implementation, operation and management of the infrastructure and of the tolling system. They shall include in particular:

- the costs of constructing, establishing and maintaining toll booths and other payment systems,
- the day to day costs of operating, administering and enforcing the toll collection system,
- administrative fees and charges relating to concession contracts,
- management, administrative and service costs relating to the operation of the infrastructure.

The costs may include a return on capital or profit margin reflecting the degree of risk transferred.

Such costs shall be apportioned on a fair and transparent basis between all vehicle classes that are subject to the tolling system.

4. Share of goods traffic, equivalence factors and correction mechanism

- The calculation of tolls shall be based on actual or forecast HGV shares of vehicle kilometres adjusted, if desired, by equivalence factors, to make due allowance for the increased costs of constructing and repairing infrastructure for use by goods vehicles.
- The following table gives a set of indicative equivalence factors. Where a Member State uses equivalence factors with ratios differing from those in the table, they shall be based on objectively justifiable criteria and shall be made public.

⁽¹⁾ The application of equivalence factors by Member States may take account of road construction developed on a phased basis or using a long life cycle approach.

Vehicle class ⁽¹⁾	Equivalence factors		
	Structural repair ⁽²⁾	Investments	Annual maintenance
Between 3,5 t and 7,5 t, Class 0	1	1	1
> 7,5 t, Class I	1,96	1	1
> 7,5 t, Class II	3,47	1	1
> 7,5 t, Class III	5,72	1	1

⁽¹⁾ See Annex IV for the determination of the vehicle class.

⁽²⁾ The vehicle classes correspond to axle weights of 5,5, 6,5, 7,5 and 8,5 tonnes respectively.

- Tolling regimes which are based on forecast traffic levels shall provide for a correction mechanism whereby tolls are adjusted periodically to correct any under or over-recovery of costs due to forecasting errors.'
-

ANNEX III

ANNEX IV

INDICATIVE VEHICLE CLASS DETERMINATION

The vehicle classes are defined by the table below.

Vehicles are classed in subcategories 0, I, II and III according to the damage they cause to the road surface, in ascending order (Class III is thus the category causing most damage to road infrastructure). The damage increases exponentially with the increase in axle weight.

All motor vehicles and vehicle combinations of a maximum permissible laden weight below 7,5 tonnes belong to damage class 0.

Motor vehicles

Driving axles with air suspension or recognised equivalent ⁽¹⁾		Other driving axle suspension systems		Damage class	
Number of axles and maximum permissible gross laden weight (in tonnes)		Number of axles and maximum permissible gross laden weight (in tonnes)			
Not less than	Less than	Not less than	Less than		
<i>Two axles</i>					
7,5	12	7,5	12	I	
12	13	12	13		
13	14	13	14		
14	15	14	15		
15	18	15	18		
<i>Three axles</i>					
15	17	15	17	II	
17	19	17	19		
19	21	19	21		
21	23	21	23		
23	25				
25	26				
		23	25		
		25	26		
<i>Four axles</i>					
23	25	23	25		I
25	27	25	27		
27	29			II	
		27	29		
		29	31		
		31	32		
29	31				
31	32				

⁽¹⁾ Suspension recognised as equivalent according to the definition in Annex II to Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (OJ L 235, 17.9.1996, p. 59). Directive as last amended by Directive 2002/7/EC of the European Parliament and of the Council (OJ L 67, 9.3.2002, p. 47).

Vehicle combinations (articulated vehicles and road trains)

Driving axles with air suspension or recognised as equivalent		Other driving axle suspension systems		Damage class
Number of axles and maximum permissible gross laden weight (in tonnes)		Number of axles and maximum permissible gross laden weight (in tonnes)		
Not less than	Less than	Not less than	Less than	
<i>2 + 1 axles</i>				
7,5	12	7,5	12	I
12	14	12	14	
14	16	14	16	
16	18	16	18	
18	20	18	20	
20	22	20	22	
22	23	22	23	
23	25	23	25	
25	28	25	28	
<i>2 + 2 axles</i>				
23	25	23	25	
25	26	25	26	
26	28	26	28	
28	29	28	29	
29	31	29	31	II
31	33	31	33	
33	36	33	36	III
36	38			
<i>2 + 3 axles</i>				
36	38	36	38	II
38	40			
		38	40	III
<i>3 + 2 axles</i>				
36	38	36	38	II
38	40			
		38	40	III
		40	44	
40	44			
<i>3 + 3 axles</i>				
36	38	36	38	I
38	40			
		38	40	II
		40	44	
40	44	40	44	

DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 17 May 2006
on machinery, and amending Directive 95/16/EC (recast)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

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

Whereas:

- (1) Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery ⁽⁴⁾ codified Directive 89/392/EEC ⁽⁵⁾. Now that new substantial amendments are being made to Directive 98/37/EC, it is desirable, in order to clarify matters, that that Directive should be recast.
- (2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.
- (3) Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.
- (4) OJ C 154 E, 29.5.2001, p. 164.
- (5) OJ C 311, 7.11.2001, p. 1.
- (6) Opinion of the European Parliament of 4 July 2002 (OJ C 271 E, 12.11.2003, p. 491), Council Common Position of 18 July 2005 (OJ C 251 E, 11.10.2005, p. 1) and Position of the European Parliament of 15 December 2005 (not yet published in the Official Journal). Council Decision of 25 April 2006.
- (7) OJ L 207, 23.7.1998, p. 1. Directive as amended by Directive 98/79/EC (OJ L 331, 7.12.1998, p. 1).
- (8) Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery (OJ L 183, 29.6.1989, p. 9).
- (4) In order to ensure legal certainty for users, the scope of this Directive and the concepts relating to its application should be defined as precisely as possible.
- (5) The Member States' mandatory provisions governing construction site hoists intended for lifting persons or persons and goods, which are often supplemented by de facto compulsory technical specifications and/or by voluntary standards, do not necessarily lead to different levels of health and safety but, because of their disparities, do nevertheless constitute barriers to trade within the Community. Moreover, the national systems for the conformity assessment and certification of these machines diverge considerably. It is therefore desirable not to exclude from the scope of this Directive construction site hoists intended for lifting persons or persons and goods.
- (6) It is appropriate to exclude from the scope of this Directive weapons, including firearms, that are subject to Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons ⁽⁶⁾; the exclusion of firearms should not apply to portable cartridge-operated fixing and other impact machinery designed for industrial or technical purposes only. It is necessary to provide for transitional arrangements enabling Member States to authorise the placing on the market and putting into service of such machinery manufactured in accordance with national provisions in force upon adoption of this Directive, including those implementing the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms. Such transitional arrangements will also enable the European standardisation organisations to draft standards ensuring the safety level based on the state of the art.
- (7) This Directive does not apply to the lifting of persons by means of machines not designed for the lifting of persons. However, this does not affect the right of Member States to take national measures, in accordance with the Treaty, with respect to such machines, with a view to implementing Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ⁽⁷⁾.
- (8) OJ L 256, 13.9.1991, p. 51.
- (9) OJ L 393, 30.12.1989, p. 13. Directive as last amended by Directive 2001/45/EC of the European Parliament and of the Council (OJ L 195, 19.7.2001, p. 46).

- (8) In relation to agricultural and forestry tractors, the provisions of this Directive concerning the risks currently not covered by Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units⁽¹⁾ should no longer apply when such risks are covered by Directive 2003/37/EC.
- (9) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Directives. It is therefore appropriate to put in place the legal framework within which market surveillance can proceed harmoniously.
- (10) Member States are responsible for ensuring that this Directive is effectively enforced on their territory and that the safety of the machinery concerned is, as far as possible, improved in accordance with its provisions. Member States should ensure their capacity to carry out effective market surveillance, taking account of guidelines developed by the Commission, in order to achieve the proper and uniform application of this Directive.
- (11) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery and the safeguard clause relating to machinery.
- (12) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. This does not preclude the laying down of conditions of use external to the machinery, provided that it is not thereby modified in a way not specified in this Directive.
- (13) It is also necessary to provide for an adequate mechanism allowing for the adoption of specific measures at Community level requiring Member States to prohibit or restrict the placing on the market of certain types of machinery presenting the same risks to the health and safety of persons either due to shortcomings in the relevant harmonised standard(s) or by virtue of their technical characteristics, or to make such machinery subject to special conditions. In order to ensure the appropriate assessment of the need for such measures, they should be taken by the Commission, assisted by a committee, in the light of consultations with the Member States and other interested parties. Since such measures are not directly applicable to economic operators, Member States should take all necessary measures for their implementation.
- (14) The essential health and safety requirements should be satisfied in order to ensure that machinery is safe; these requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.
- (15) Where the machinery may be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of this in the design and construction. The same applies where a machine is normally used to provide a service to a consumer.
- (16) Although the requirements of this Directive do not apply to partly completed machinery in their entirety, it is nevertheless important that the free movement of such machinery be guaranteed by means of a specific procedure.
- (17) For trade fairs, exhibitions and such like, it should be possible to exhibit machinery which does not satisfy the requirements of this Directive. However, interested parties should be properly informed that the machinery does not conform and cannot be purchased in that condition.
- (18) This Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery. In order to help manufacturers to prove conformity to these essential requirements, and to allow inspection of conformity to the essential requirements, it is desirable to have standards that are harmonised at Community level for the prevention of risks arising out of the design and construction of machinery. These standards are drawn up by private-law bodies and should retain their non-binding status.
- (19) In view of the nature of the risks involved in the use of machinery covered by this Directive, procedures for assessing conformity to the essential health and safety requirements should be established. These procedures should be devised in the light of the extent of the danger inherent in such machinery. Consequently, each category of machinery should have its appropriate procedure in conformity with 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 harmonisation directives⁽²⁾, taking account of the nature of the verification required for such machinery.

⁽¹⁾ OJ L 171, 9.7.2003, p. 1. Directive as last amended by Commission Directive 2005/67/EC (OJ L 273, 19.10.2005, p. 17).

⁽²⁾ OJ L 220, 30.8.1993, p. 23.

- (20) Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of this Directive. Nevertheless, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable.
- (21) The CE marking should be fully recognised as being the only marking which guarantees that machinery conforms to the requirements of this Directive. All other markings which are likely to mislead third parties as to the meaning or the form of the CE marking, or both, should be prohibited.
- (22) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.
- (23) The manufacturer or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures.
- (24) It is essential that, before drawing up the EC declaration of conformity, the manufacturer or his authorised representative established in the Community should prepare a technical construction file. However, it is not essential that all documentation should be permanently available in material form, but it must be possible to make it available on request. It need not include detailed plans of subassemblies used for the manufacture of machinery, unless knowledge of such plans is essential in order to ascertain conformity with the essential health and safety requirements.
- (25) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.
- (26) Member States should provide for penalties applicable to infringements of the provisions of this Directive. Those penalties should be effective, proportionate and dissuasive.
- (27) The application of this Directive to a number of machines intended for lifting persons requires a better delimitation of the products covered by this Directive
- with respect to those covered by Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts ⁽¹⁾. A redefinition of the scope of the latter Directive is thus deemed necessary. Directive 95/16/EC should therefore be amended accordingly.
- (28) Since the objective of this Directive, namely, to lay down the essential health and safety requirements in relation to design and manufacture in order to improve the safety of machinery placed on the market, cannot be sufficiently achieved by the Member States and can be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (29) In accordance with point 34 of the Interinstitutional Agreement on better law-making ⁽²⁾, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.
- (30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽³⁾,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope

1. This Directive applies to the following products:

- (a) machinery;
- (b) interchangeable equipment;
- (c) safety components;
- (d) lifting accessories;
- (e) chains, ropes and webbing;
- (f) removable mechanical transmission devices;
- (g) partly completed machinery.

⁽¹⁾ OJ L 213, 7.9.1995, p. 1. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ C 321, 31.12.2003, p. 1.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

2. The following are excluded from the scope of this Directive:

- (a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;
- (b) specific equipment for use in fairgrounds and/or amusement parks;
- (c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
- (d) weapons, including firearms;
- (e) the following means of transport:
 - agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles,
 - motor vehicles and their trailers covered by 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 ⁽¹⁾, with the exclusion of machinery mounted on these vehicles,
 - vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles ⁽²⁾, with the exclusion of machinery mounted on these vehicles,
 - motor vehicles exclusively intended for competition, and
 - means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;
- (f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;
- (g) machinery specially designed and constructed for military or police purposes;
- (h) machinery specially designed and constructed for research purposes for temporary use in laboratories;
- (i) mine winding gear;
- (j) machinery intended to move performers during artistic performances;
- (k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits ⁽³⁾:
 - household appliances intended for domestic use,
 - audio and video equipment,
 - information technology equipment,
 - ordinary office machinery,
 - low-voltage switchgear and control gear,
 - electric motors;
- (l) the following types of high-voltage electrical equipment:
 - switch gear and control gear,
 - transformers.

Article 2

Definitions

For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).

The following definitions shall apply:

- (a) 'machinery' means:
 - an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
 - an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
 - an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
 - assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,
 - an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

⁽¹⁾ OJ L 42, 23.2.1970, p. 1. Directive as last amended by Commission Directive 2006/28/EC (OJ L 65, 7.3.2006, p. 27).

⁽²⁾ OJ L 124, 9.5.2002, p. 1. Directive as last amended by Commission Directive 2005/30/EC (OJ L 106, 27.4.2005, p. 17).

⁽³⁾ OJ L 77, 26.3.1973, p. 29. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

- (b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;
- (c) 'safety component' means a component:
- which serves to fulfil a safety function,
 - which is independently placed on the market,
 - the failure and/or malfunction of which endangers the safety of persons, and
 - which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a);

- (d) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;
- (e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;
- (f) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;
- (g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;
- (h) 'placing on the market' means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;
- (i) 'manufacturer' means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the

partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;

- (j) 'authorised representative' means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive;
- (k) 'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;
- (l) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services⁽¹⁾.

Article 3

Specific Directives

Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.

Article 4

Market surveillance

1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.

⁽¹⁾ OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.

2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.

3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.

4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.

Article 5

Placing on the market and putting into service

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

- (a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;
- (b) ensure that the technical file referred to in Annex VII, part A is available;
- (c) provide, in particular, the necessary information, such as instructions;
- (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;
- (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;
- (f) affix the CE marking in accordance with Article 16.

2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.

3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I.

4. Where machinery is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives.

However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during

a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the *Official Journal of the European Union*, shall be given on the EC declaration of conformity.

Article 6

Freedom of movement

1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive.

2. Member States shall not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part 1, Section B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form machinery.

3. At trade fairs, exhibitions, demonstrations, and such like, Member States shall not prevent the showing of machinery or partly completed machinery which does not conform to this Directive, provided that a visible sign clearly indicates that it does not conform and that it will not be made available until it has been brought into conformity. Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety measures shall be taken to ensure the protection of persons.

Article 7

Presumption of conformity and harmonised standards

1. Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity, the content of which is set out in Annex II, part 1, Section A, as complying with the provisions of this Directive.

2. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard.

3. The Commission shall publish in the *Official Journal of the European Union* the references of the harmonised standards.

4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.

Article 8

Specific measures

1. The Commission, acting in accordance with the procedure referred to in Article 22(3), may take any appropriate measure to implement the provisions relating to the following points:

- (a) updating of the indicative list of safety components in Annex V referred to in point (c) in Article 2;
- (b) restriction of the placing on the market of machinery referred to in Article 9.

2. The Commission, acting in accordance with the procedure referred to in Article 22(2), may take any appropriate measure connected with the implementation and practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).

Article 9

Specific measures to deal with potentially hazardous machinery

1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.

When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.

2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1.

3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons.

Taking due account of the results of this consultation, it shall adopt the necessary measures in accordance with the procedure referred to in Article 22(3).

Article 10

Procedure for disputing a harmonised standard

Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the *Official Journal of the European Union*.

Article 11

Safeguard clause

1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to compromise the health and safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict free movement thereof.

2. The Member State shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to:

- (a) failure to satisfy the essential requirements referred to in Article 5(1)(a);
- (b) incorrect application of the harmonised standards referred to in Article 7(2);
- (c) shortcomings in the harmonised standards themselves referred to in Article 7(2).

3. The Commission shall enter into consultation with the parties concerned without delay.

The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.

4. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.

5. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.

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

Article 12

Procedures for assessing the conformity of machinery

1. The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive, apply one of the procedures for assessment of conformity described in paragraphs 2, 3 and 4.

2. Where the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall apply the procedure for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VIII.

3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:

- (a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;
- (b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;
- (c) the full quality assurance procedure provided for in Annex X.

4. Where the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exist for the machinery in

question, the manufacturer or his authorised representative shall apply one of the following procedures:

- (a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;
- (b) the full quality assurance procedure provided for in Annex X.

Article 13

Procedure for partly completed machinery

1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:

- (a) the relevant technical documentation described in Annex VII, part B is prepared;
- (b) assembly instructions described in Annex VI are prepared;
- (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.

2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.

Article 14

Notified bodies

1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(3) and (4), together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.

2. The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.

3. Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.

4. The Commission shall publish in the *Official Journal of the European Union*, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

5. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the *Official Journal of the European Union*, shall be presumed to fulfil the relevant criteria.

6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.

7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.

8. A Member State which has notified a body shall immediately withdraw its notification if it finds:

- (a) that the body no longer meets the criteria set out in Annex XI; or
- (b) that the body seriously fails to fulfil its responsibilities.

The Member State shall immediately inform the Commission and the other Member States accordingly.

Article 15

Installation and use of machinery

This Directive shall not affect Member States' entitlement to lay down, in due observance of Community law, such require-

ments as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive.

Article 16

CE marking

1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.

2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.

3. The affixing on machinery of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

Article 17

Non-conformity of marking

1. Member States shall consider the following marking not to conform:

- (a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive;
- (b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;
- (c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).

2. Where a Member State ascertains that marking does not conform to the relevant provisions of this Directive, the manufacturer or his authorised representative shall be obliged to make the product conform and to put an end to the infringement under conditions fixed by that Member State.

3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11.

*Article 18***Confidentiality**

1. Without prejudice to existing national provisions and practices in the area of confidentiality, Member States shall ensure that all parties and persons concerned by the application of this Directive are required to treat as confidential information obtained in the execution of their tasks. More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons.

2. The provisions of paragraph 1 shall not affect the obligations of the Member States and the notified bodies with regard to mutual exchange of information and the issuing of warnings.

3. Any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11 shall be published.

*Article 19***Cooperation between Member States**

1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

*Article 20***Legal remedies**

Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

*Article 21***Dissemination of information**

The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.

*Article 22***Committee**

1. The Commission shall be assisted by a committee, hereinafter referred to as the 'Committee'.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

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

4. The Committee shall adopt its rules of procedure.

*Article 23***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.

*Article 24***Amendment of Directive 95/16/EC**

Directive 95/16/EC is hereby amended as follows:

1. in Article 1, paragraphs 2 and 3 shall be replaced by the following:

2. 'For the purposes of this Directive, "lift" shall mean a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, intended for the transport of:

- persons,
- persons and goods,
- goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.

Lifting appliances moving along a fixed course even where they do not move along guides which are rigid shall be considered as lifts falling within the scope of this Directive.

A "carrier" means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered.

3. This Directive shall not apply to:

- lifting appliances whose speed is not greater than 0,15 m/s,
- construction site hoists,
- cableways, including funicular railways,
- lifts specially designed and constructed for military or police purposes,
- lifting appliances from which work can be carried out,
- mine winding gear,
- lifting appliances intended for lifting performers during artistic performances,
- lifting appliances fitted in means of transport,
- lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery,
- rack and pinion trains,
- escalators and mechanical walkways.;

2. in Annex I, point 1.2 shall be replaced by the following:

1.2. 'Carrier

The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.'

Article 25

Repeal

Directive 98/37/EC is hereby repealed.

References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XII.

Article 26

Transposition

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 29 June 2008 at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from 29 December 2009.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

Article 27

Derogation

Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge-operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive.

Article 28

Entry into force

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

Article 29

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 17 May 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

H. WINKLER

ANNEX I

Essential health and safety requirements relating to the the design and construction of machinery**GENERAL PRINCIPLES**

1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:
 - determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,
 - identify the hazards that can be generated by the machinery and the associated hazardous situations,
 - estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
 - evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,
 - eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).
2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 apply.
3. The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.
4. This Annex is organised in several parts. The first one has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles.

1. *ESSENTIAL HEALTH AND SAFETY REQUIREMENTS*1.1. *GENERAL REMARKS*1.1.1. **Definitions**

For the purpose of this Annex:

- (a) 'hazard' means a potential source of injury or damage to health;
- (b) 'danger zone' means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;
- (c) 'exposed person' means any person wholly or partially in a danger zone;
- (d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;
- (e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;
- (f) 'guard' means a part of the machinery used specifically to provide protection by means of a physical barrier;
- (g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;
- (h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use;
- (i) 'reasonably foreseeable misuse' means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.

1.1.2. **Principles of safety integration**

- (a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

- (b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:

- eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
- take the necessary protective measures in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

- (c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.

- (d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.

- (e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

1.1.3. **Materials and products**

The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. **Lighting**

Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting.

1.1.5. **Design of machinery to facilitate its handling**

Machinery, or each component part thereof, must:

- be capable of being handled and transported safely,
- be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.

Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:

- either be fitted with attachments for lifting gear, or
- be designed so that it can be fitted with such attachments, or
- be shaped in such a way that standard lifting gear can easily be attached.

Where machinery or one of its component parts is to be moved by hand, it must:

- either be easily moveable, or
- be equipped for picking up and moving safely.

Special arrangements must be made for the handling of tools and/or machinery parts which, even if light-weight, could be hazardous.

1.1.6. **Ergonomics**

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

- allowing for the variability of the operator's physical dimensions, strength and stamina,
- providing enough space for movements of the parts of the operator's body,
- avoiding a machine-determined work rate,
- avoiding monitoring that requires lengthy concentration,
- adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7. **Operating positions**

The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. **Seating**

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery.

The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.

1.2. CONTROL SYSTEMS

1.2.1. **Safety and reliability of control systems**

Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:

- they can withstand the intended operating stresses and external influences,
- a fault in the hardware or the software of the control system does not lead to hazardous situations,
- errors in the control system logic do not lead to hazardous situations,
- reasonably foreseeable human error during operation does not lead to hazardous situations.

Particular attention must be given to the following points:

- the machinery must not start unexpectedly,
- the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations,
- the machinery must not be prevented from stopping if the stop command has already been given,
- no moving part of the machinery or piece held by the machinery must fall or be ejected,
- automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
- the protective devices must remain fully effective or give a stop command,
- the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery.

For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.

1.2.2. **Control devices**

Control devices must be:

- clearly visible and identifiable, using pictograms where appropriate,
- positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity,
- designed in such a way that the movement of the control device is consistent with its effect,
- located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant,
- positioned in such a way that their operation cannot cause additional risk,
- designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action,
- made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary.

Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position.

From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.

If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations.

Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.

1.2.3. **Starting**

It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.

The same requirement applies:

- when restarting the machinery after a stoppage, whatever the cause,
- when effecting a significant change in the operating conditions.

However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.

1.2.4. **Stopping**

1.2.4.1. **Normal stop**

Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe.

The machinery's stop control must have priority over the start controls.

Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.

1.2.4.2. **Operational stop**

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.

1.2.4.3. **Emergency stop**

Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

- machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,
- portable hand-held and/or hand-guided machinery.

The device must:

- have clearly identifiable, clearly visible and quickly accessible control devices,
- stop the hazardous process as quickly as possible, without creating additional risks,
- where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

The emergency stop function must be available and operational at all times, regardless of the operating mode.

Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.

1.2.4.4. **Assembly of machinery**

In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.

1.2.5. **Selection of control or operating modes**

The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.

If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator.

If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:

- disable all other control or operating modes,
- permit operation of hazardous functions only by control devices requiring sustained action,
- permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences,
- prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.

1.2.6. **Failure of the power supply**

The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations.

Particular attention must be given to the following points:

- the machinery must not start unexpectedly,
- the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations,
- the machinery must not be prevented from stopping if the command has already been given,

- no moving part of the machinery or piece held by the machinery must fall or be ejected,
- automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
- the protective devices must remain fully effective or give a stop command.

1.3. PROTECTION AGAINST MECHANICAL HAZARDS

1.3.1. **Risk of loss of stability**

Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery.

If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.

1.3.2. **Risk of break-up during operation**

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used.

The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons:

- when the workpiece comes into contact with the tool, the latter must have attained its normal working condition,
- when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.

1.3.3. **Risks due to falling or ejected objects**

Precautions must be taken to prevent risks from falling or ejected objects.

1.3.4. **Risks due to surfaces, edges or angles**

Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5. **Risks related to combined machinery**

Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.

For this purpose, it must be possible to start and stop separately any elements that are not protected.

1.3.6. **Risks related to variations in operating conditions**

Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. **Risks related to moving parts**

The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided to enable the equipment to be safely unblocked.

The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.

1.3.8. **Choice of protection against risks arising from moving parts**

Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help to make the choice.

1.3.8.1. **Moving transmission parts**

Guards designed to protect persons against the hazards generated by moving transmission parts must be:

- either fixed guards as referred to in section 1.4.2.1, or
- interlocking movable guards as referred to in section 1.4.2.2.

Interlocking movable guards should be used where frequent access is envisaged.

1.3.8.2. **Moving parts involved in the process**

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:

- either fixed guards as referred to in section 1.4.2.1, or
- interlocking movable guards as referred to in section 1.4.2.2, or
- protective devices as referred to in section 1.4.3, or
- a combination of the above.

However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with:

- fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and
- adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.

1.3.9. **Risks of uncontrolled movements**

When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES

1.4.1. **General requirements**

Guards and protective devices must:

- be of robust construction,
- be securely held in place,
- not give rise to any additional hazard,

- not be easy to by-pass or render non-operational,
- be located at an adequate distance from the danger zone,
- cause minimum obstruction to the view of the production process, and
- enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.

In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.

1.4.2. *Special requirements for guards*

1.4.2.1. **Fixed guards**

Fixed guards must be fixed by systems that can be opened or removed only with tools.

Their fixing systems must remain attached to the guards or to the machinery when the guards are removed.

Where possible, guards must be incapable of remaining in place without their fixings.

1.4.2.2. **Interlocking movable guards**

Interlocking movable guards must:

- as far as possible remain attached to the machinery when open,
- be designed and constructed in such a way that they can be adjusted only by means of an intentional action.

Interlocking movable guards must be associated with an interlocking device that:

- prevents the start of hazardous machinery functions until they are closed and
- gives a stop command whenever they are no longer closed.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:

- prevents the start of hazardous machinery functions until the guard is closed and locked, and
- keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.

Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.

1.4.2.3. **Adjustable guards restricting access**

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be:

- adjustable manually or automatically, depending on the type of work involved, and
- readily adjustable without the use of tools.

1.4.3. *Special requirements for protective devices*

Protective devices must be designed and incorporated into the control system in such a way that:

- moving parts cannot start up while they are within the operator's reach,

- persons cannot reach moving parts while the parts are moving, and
- the absence or failure of one of their components prevents starting or stops the moving parts.

Protective devices must be adjustable only by means of an intentional action.

1.5. RISKS DUE TO OTHER HAZARDS

1.5.1. *Electricity supply*

Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive.

1.5.2. *Static electricity*

Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. *Energy supply other than electricity*

Where machinery is powered by source of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4. *Errors of fitting*

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

1.5.5. *Extreme temperatures*

Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures.

The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.

1.5.6. *Fire*

Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

1.5.7. *Explosion*

Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.

1.5.8. Noise

Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

1.5.9. Vibrations

Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.

1.5.10. Radiation

Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.

1.5.11. External radiation

Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.

1.5.12. Laser radiation

Where laser equipment is used, the following should be taken into account:

- laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation,
- laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,
- optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.

1.5.13. Emissions of hazardous materials and substances

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.

1.5.14. Risk of being trapped in a machine

Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.

1.5.15. **Risk of slipping, tripping or falling**

Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.

Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

1.5.16. **Lightning**

Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.

1.6. MAINTENANCE

1.6.1. **Machinery maintenance**

Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5).

In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided.

Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

1.6.2. **Access to operating positions and servicing points**

Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.

1.6.3. **Isolation of energy sources**

Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to persons.

As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.

1.6.4. **Operator intervention**

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.

1.6.5. **Cleaning of internal parts**

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside. If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.

1.7. INFORMATION

1.7.1. **Information and warnings on the machinery**

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

1.7.1.1. **Information and information devices**

The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

1.7.1.2. **Warning devices**

Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.

The requirements of the specific Community Directives concerning colours and safety signals must be complied with.

1.7.2. **Warning of residual risks**

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.

1.7.3. **Marking of machinery**

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

- the business name and full address of the manufacturer and, where applicable, his authorised representative,
- designation of the machinery,
- the CE Marking (see Annex III),
- designation of series or type,
- serial number, if any,
- the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

1.7.4. **Instructions**

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand.

The instructions must be drafted in accordance with the principles set out below.

1.7.4.1. General principles for the drafting of instructions

- (a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.
- (b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.
- (c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.
- (d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and of his authorised representative;
- (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);
- (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;
- (d) a general description of the machinery;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
- (f) a description of the workstation(s) likely to be occupied by operators;
- (g) a description of the intended use of the machinery;
- (h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;
- (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;
- (j) instructions relating to installation and assembly for reducing noise or vibration;
- (k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;
- (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
- (m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
- (n) the essential characteristics of tools which may be fitted to the machinery;
- (o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
- (p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;
- (q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;

- (r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;
- (s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- (t) the specifications of the spare parts to be used, when these affect the health and safety of operators;
- (u) the following information on airborne noise emissions:
 - the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
 - the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa),
 - the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;

- (v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.

1.7.4.3. Sales literature

Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements must be observed:

- (a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;
- (b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:
 - be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,
 - be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
 - be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;
- (c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a 'cleaning' position);
- (d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;
- (e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.

2.1.2. **Instructions**

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY

2.2.1. **General**

Portable hand-held and/or hand-guided machinery must:

- depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,
- except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,
- present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,
- permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed.

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

2.2.1.1. **Instructions**

The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:

- the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned,
- the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.

2.2.2. **Portable fixing and other impact machinery**

2.2.2.1. **General**

Portable fixing and other impact machinery must be designed and constructed in such a way that:

- energy is transmitted to the impacted element by the intermediary component that does not leave the device,
- an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material,
- involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact,
- accidental triggering is prevented during handling or in case of shock,
- loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.

2.2.2.2. **Instructions**

The instructions must give the necessary information regarding:

- the accessories and interchangeable equipment that can be used with the machinery,
- the suitable fixing or other impacted elements to be used with the machinery,
- where appropriate, the suitable cartridges to be used.

2.3. **MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS**

Machinery for working wood and materials with similar physical characteristics must comply with the following requirements:

- (a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece;
- (b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;
- (c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;
- (d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

3. **SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY**

Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

3.1. GENERAL

3.1.1. **Definitions**

(a) 'Machinery presenting hazards due to its mobility' means

- machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or
- machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

(b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.

3.2. WORK POSITIONS

3.2.1. **Driving position**

Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.

3.2.2. **Seating**

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.

3.2.3. **Positions for other persons**

If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk.

The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other than the driver.

3.3. CONTROL SYSTEMS

If necessary, steps must be taken to prevent unauthorised use of controls.

In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

The remote control system must be designed and constructed in such a way as to affect only:

- the machinery in question,
- the functions in question.

Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.

3.3.1. **Control devices**

The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.

Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.

3.3.2. **Starting/moving**

All travel movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls.

Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the aforementioned parts.

It must not be possible for unintentional movement of the machinery to occur while the engine is being started.

3.3.3. **Travelling function**

Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.

The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.

Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

- if the driver loses control,
- if it receives a stop signal,
- if a fault is detected in a safety-related part of the system,
- if no validation signal is detected within a specified time.

Section 1.2.4 does not apply to the travelling function.

3.3.4. **Movement of pedestrian-controlled machinery**

Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started.

The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:

- crushing,
- injury from rotating tools.

The speed of travel of the machinery must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.

3.3.5. **Control circuit failure**

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.

3.4. PROTECTION AGAINST MECHANICAL HAZARDS

3.4.1. **Uncontrolled movements**

Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. **Moving transmission parts**

By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.

3.4.3. **Roll-over and tip-over**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.4. **Falling objects**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

This structure must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5. **Means of access**

Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.

3.4.6. **Towing devices**

All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.

Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.

3.4.7. **Transmission of power between self-propelled machinery (or tractor) and recipient machinery**

Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.

If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.

3.5. PROTECTION AGAINST OTHER HAZARDS

3.5.1. **Batteries**

The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators.

Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

3.5.2. **Fire**

Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:

- either allow easily accessible fire extinguishers to be fitted, or
- be provided with built-in extinguisher systems.

3.5.3. **Emissions of hazardous substances**

The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.

3.6. INFORMATION AND INDICATIONS

3.6.1. *Signs, signals and warnings*

All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:

- an acoustic warning device to alert persons,
- a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power,
- where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.

Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.

Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2. *Marking*

The following must be shown legibly and indelibly on all machinery:

- nominal power expressed in kilowatts (kW),
- mass of the most usual configuration, in kilograms (kg);

and, where appropriate:

- maximum drawbar pull provided for at the coupling hook, in Newtons (N),
- maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. *Instructions*

3.6.3.1. *Vibrations*

The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

- the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned,
- the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s². Where this value does not exceed 0,5 m/s², this must be mentioned,
- the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned.

The operating conditions during measurement and the measurement codes used must be described.

3.6.3.2. **Multiple uses**

The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.

4. *SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS*

Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

4.1. GENERAL

4.1.1. **Definitions**

- (a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level.
- (b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.
- (c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component.
- (d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory.
- (e) 'Static test' means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred.
- (f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly.
- (g) 'Carrier' means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.

4.1.2. **Protection against mechanical hazards**

4.1.2.1. **Risks due to lack of stability**

Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.

4.1.2.2. **Machinery running on guide rails and rail tracks**

Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.

If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.

4.1.2.3. **Mechanical strength**

Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling.

Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use.

The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.

Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:

- (a) manually-operated machinery and lifting accessories: 1,5;
- (b) other machinery: 1,25.

Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.

4.1.2.4. **Pulleys, drums, wheels, ropes and chains**

Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains with which they can be fitted.

Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.

Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.

In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.

4.1.2.5. **Lifting accessories and their components**

Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.

Moreover:

- (a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;
- (b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

- (c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;
- (d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;
- (e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;
- (f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.

4.1.2.6. Control of movements

Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe.

- (a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.
- (b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.
- (c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.
- (d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way.
- (e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.

4.1.2.7. Movements of loads during handling

The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.

4.1.2.8. Machinery serving fixed landings

4.1.2.8.1. *Movements of the carrier*

The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

4.1.2.8.2. *Access to the carrier*

Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

4.1.2.8.3. *Risks due to contact with the moving carrier*

Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.

4.1.2.8.4. *Risk due to the load falling off the carrier*

Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

4.1.2.8.5. *Landings*

Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:

- hazardous movements of the carrier until the guards are closed and locked,
- hazardous opening of a guard until the carrier has stopped at the corresponding landing.

4.1.3. ***Fitness for purpose***

When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.

The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.

Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.

4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1. ***Control of movements***

Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.

4.2.2. ***Loading control***

Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event:

- of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or
- of the overturning moment being exceeded.

4.2.3. ***Installations guided by ropes***

Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.

4.3. INFORMATION AND MARKINGS

4.3.1. **Chains, ropes and webbing**

Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate.

The certificate mentioned above must show at least the following information:

- (a) the name and address of the manufacturer and, if appropriate, his authorised representative;
- (b) a description of the chain or rope which includes:
 - its nominal size,
 - its construction,
 - the material from which it is made, and
 - any special metallurgical treatment applied to the material;
- (c) the test method used;
- (d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

4.3.2. **Lifting accessories**

Lifting accessories must show the following particulars:

- identification of the material where this information is needed for safe use,
- the maximum working load.

In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory.

The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.

4.3.3. **Lifting machinery**

The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

4.4. INSTRUCTIONS

4.4.1. **Lifting accessories**

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:

- (a) the intended use;
- (b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e));
- (c) instructions for assembly, use and maintenance;
- (d) the static test coefficient used.

4.4.2. **Lifting machinery**

Lifting machinery must be accompanied by instructions containing information on:

- (a) the technical characteristics of the machinery, and in particular:
 - the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,
 - the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,
 - where appropriate, the definition and the means of installation of the ballast;
- (b) the contents of the logbook, if the latter is not supplied with the machinery;
- (c) advice for use, particularly to offset the lack of direct vision of the load by the operator;
- (d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative;
- (e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.

5. *SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK*

Machinery intended for underground work must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

5.1. RISKS DUE TO LACK OF STABILITY

Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.

5.2. MOVEMENT

Powered roof supports must allow for unhindered movement of persons.

5.3. CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated.

The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.

5.5. FIRE

The second indent of section 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts.

The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.

Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.

5.6. EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines must not be discharged upwards.

6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS

Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

6.1. GENERAL

6.1.1. **Mechanical strength**

The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

6.1.2. **Loading control for machinery moved by power other than human strength**

The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices.

The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. **Risks due to movements of the carrier**

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

6.3.2. **Risk of persons falling from the carrier**

The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.

Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.

If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height.

Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.

6.3.3. ***Risk due to objects falling on the carrier***

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

6.4. MACHINERY SERVING FIXED LANDINGS

6.4.1. ***Risks to persons in or on the carrier***

The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.

The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

6.4.2. ***Controls at landings***

Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:

- the control devices in the carrier are being operated,
- the carrier is not at a landing.

6.4.3. ***Access to the carrier***

The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

6.5. MARKINGS

The carrier must bear the information necessary to ensure safety including:

- the number of persons permitted on the carrier,
 - the maximum working load.
-

ANNEX II

Declarations**1. CONTENT****A. EC DECLARATION OF CONFORMITY OF THE MACHINERY**

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the technical file, who must be established in the Community;
3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the *Official Journal of the European Union*;
5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate;
6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;
7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);
8. where appropriate, the reference to other technical standards and specifications used;
9. the place and date of the declaration;
10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;
3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;
4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the *Official Journal of the European Union*;
5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;
7. the place and date of the declaration;
8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

2. CUSTODY

The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.

The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.

ANNEX III

CE marking

The CE conformity marking shall consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.

Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.

ANNEX IV

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
 - 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the work-piece or with a demountable power feed;
 - 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
 - 1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;
 - 1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
 2. Hand-fed surface planing machinery for woodworking.
 3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
 4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
 - 4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
 - 4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
 5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.
 6. Hand-fed tenoning machinery with several tool holders for woodworking.
 7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
 8. Portable chainsaws for woodworking.
 9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
 10. Injection or compression plastics-moulding machinery with manual loading or unloading.
 11. Injection or compression rubber-moulding machinery with manual loading or unloading.
 12. Machinery for underground working of the following types:
 - 12.1. locomotives and brake-vans;
 - 12.2. hydraulic-powered roof supports.
 13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
 14. Removable mechanical transmission devices including their guards.
 15. Guards for removable mechanical transmission devices.
 16. Vehicle servicing lifts.
 17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.
 18. Portable cartridge-operated fixing and other impact machinery.
 19. Protective devices designed to detect the presence of persons.
 20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.
 21. Logic units to ensure safety functions.
 22. Roll-over protective structures (ROPS).
 23. Falling-object protective structures (FOPS).
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ANNEX V

Indicative list of the safety components referred to in Article 2(c)

1. Guards for removable mechanical transmission devices.
 2. Protective devices designed to detect the presence of persons.
 3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.
 4. Logic units to ensure safety functions.
 5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.
 6. Extraction systems for machinery emissions.
 7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.
 8. Monitoring devices for loading and movement control in lifting machinery.
 9. Restraint systems to keep persons on their seats.
 10. Emergency stop devices.
 11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
 12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.
 13. Systems and devices to reduce the emission of noise and vibrations.
 14. Roll-over protective structures (ROPS).
 15. Falling-object protective structures (FOPS).
 16. Two-hand control devices.
 17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:
 - (a) devices for locking landing doors;
 - (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
 - (c) overspeed limitation devices;
 - (d) energy-accumulating shock absorbers,
 - non-linear, or
 - with damping of the return movement;
 - (e) energy-dissipating shock absorbers;
 - (f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
 - (g) electric safety devices in the form of safety switches containing electronic components.
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ANNEX VI

Assembly instructions for partly completed machinery

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

ANNEX VII

A. Technical file for machinery

This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.

1. The technical file shall comprise the following:

(a) a construction file including:

- a general description of the machinery,
- the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,
- the documentation on risk assessment demonstrating the procedure followed, including:
 - (i) a list of the essential health and safety requirements which apply to the machinery,
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
- the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
- any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
- a copy of the instructions for the machinery,
- where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
- a copy of the EC declaration of conformity;

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.

The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.

2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.

The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.

3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

B. Relevant technical documentation for partly completed machinery

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

It shall comprise the following:

- (a) a construction file including:
 - the overall drawing of the partly completed machinery and drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,
 - the risk assessment documentation showing the procedure followed, including:
 - (i) a list of the essential health and safety requirements applied and fulfilled,
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
 - (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
 - (v) a copy of the assembly instructions for the partly completed machinery;
- (b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.

ANNEX VIII

Assessment of conformity with internal checks on the manufacture of machinery

1. This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.
 2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.
 3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.
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ANNEX IX

EC type-examination

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.
2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, where appropriate, his authorised representative,
- a written declaration that the application has not been submitted to another notified body,
- the technical file.

Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.

3. The notified body shall:
 - 3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;
 - 3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;
 - 3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;
 - 3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.
4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.

5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.
6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.
7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.
8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.

9. Validity of the EC type-examination certificate

- 9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.
- 9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.
- 9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.

If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.

The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.

- 9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.
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ANNEX X

Full quality assurance

This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.

2. Quality system

- 2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.

The application shall contain:

- the name and address of the manufacturer and, where appropriate, his authorised representative,
- the places of design, manufacture, inspection, testing and storage of the machinery,
- the technical file described in Annex VII, Part A, for one model of each category of machinery referred to in Annex IV which he intends to manufacture,
- the documentation on the quality system,
- a written declaration that the application has not been submitted to another notified body.

- 2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

- the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,
- the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,
- the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Directive,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,
- the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

- 2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.

The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

- 2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.
- The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.
- The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.
- It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
3. Surveillance under the responsibility of the notified body
- 3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:
- the documentation concerning the quality system,
 - the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,
 - the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.
- 3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.
- 3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:
- the results of previous surveillance visits,
 - the need to monitor remedial measures,
 - where appropriate, special conditions attaching to approval of the system,
 - significant modifications in the organisation of the manufacturing process, measures or techniques.
- On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.
4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:
- the documentation referred to in point 2.1,
 - the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.
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ANNEX XI

Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
 2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
 3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.
 4. The staff responsible for inspection shall have:
 - sound technical and vocational training,
 - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
 5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
 6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
 7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.
 8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.
 9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.
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ANNEX XII

Correlation table ⁽¹⁾

Directive 98/37/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)(a)	Article 2(a) and (b)
Article 1(2)(b)	Article 2(c)
Article 1(3)	Article 1(2)
Article 1(4)	Article 3
Article 1(5)	—
Article 2(1)	Article 4(1)
Article 2(2)	Article 15
Article 2(3)	Article 6(3)
Article 3	Article 5(1)(a)
Article 4(1)	Article 6(1)
Article 4(2), first subparagraph	Article 6(2)
Article 4(2), second subparagraph	—
Article 4(3)	—
Article 5(1), first subparagraph	Article 7(1)
Article 5(1), second subparagraph	—
Article 5(2), first subparagraph	Article 7(2) and (3)
Article 5(2), last subparagraph	—
Article 5(3)	Article 7(4)
Article 6(1)	Article 10
Article 6(2)	Article 22
Article 7(1)	Article 11(1) and (2)
Article 7(2)	Article 11(3) and (4)
Article 7(3)	Article 11(4)
Article 7(4)	Article 11(5)
Article 8(1), first subparagraph	Article 5(1)(e) and Article 12(1)
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Article 8(2)(a)	Article 12(2)
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⁽¹⁾ This table indicates the relation between parts of Directive 98/37/EC and the parts of this Directive that deal with the same subject. However, the content of the correlated parts is not necessarily identical.

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DIRECTIVE 2006/43/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 May 2006

on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 44(2)(g) thereof,

Having regard to the proposal from the Commission,

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

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

Whereas:

(1) Currently, the Fourth Council Directive 78/660/EEC of 25 July 1978 on the annual accounts of certain types of companies ⁽³⁾, the Seventh Council Directive 83/349/EEC of 13 June 1983 on consolidated accounts ⁽⁴⁾, Council Directive 86/635/EEC of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions ⁽⁵⁾ and Council Directive 91/674/EEC of 19 December 1991 on the annual accounts and consolidated accounts of insurance undertakings ⁽⁶⁾ require that the annual accounts or consolidated accounts be audited by one or more persons entitled to carry out such audits.

(2) The conditions for the approval of persons responsible for carrying out the statutory audit were laid down in the Eighth Council Directive 84/253/EEC of 10 April 1984 on the approval of persons responsible for carrying out the statutory audits of accounting documents ⁽⁷⁾.

(3) The lack of a harmonised approach to statutory auditing in the Community was the reason why the Commission proposed, in its 1998 Communication on the statutory audit in the European Union: the way forward ⁽⁸⁾, the creation of a Committee on Auditing which could develop further action in close cooperation with the accounting profession and Member States.

(4) On the basis of the work of that Committee, on 15 November 2000 the Commission issued a Recommendation on quality assurance for the statutory audit in the European Union: minimum requirements ⁽⁹⁾ and on 16 May 2002 a Recommendation on Statutory Auditors' Independence in the EU: A Set of Fundamental Principles ⁽¹⁰⁾.

(5) This Directive aims at high-level — though not full — harmonisation of statutory audit requirements. A Member State requiring statutory audit may impose more stringent requirements, unless otherwise provided for by this Directive.

(6) Audit qualifications obtained by statutory auditors on the basis of this Directive should be considered equivalent. It should therefore no longer be possible for Member States to insist that a majority of the voting rights in an audit firm must be held by locally approved auditors or that a majority of the members of the administrative or management body of an audit firm must be locally approved.

(7) The statutory audit requires adequate knowledge of matters such as company law, fiscal law and social law. Such knowledge should be tested before a statutory auditor from another Member State can be approved.

(8) In order to protect third parties, all approved auditors and audit firms should be entered in a register which is accessible to the public and which contains basic information concerning statutory auditors and audit firms.

⁽¹⁾ OJ C 157, 28.6.2005, p. 115.

⁽²⁾ Opinion of the European Parliament of 28 September 2005 (not yet published in the Official Journal) and Council Decision of 25 April 2006.

⁽³⁾ OJ L 222, 14.8.1978, p. 11. Directive as last amended by Directive 2003/51/EC of the European Parliament and of the Council (OJ L 178, 17.7.2003, p. 16).

⁽⁴⁾ OJ L 193, 18.7.1983, p. 1. Directive as last amended by Directive 2003/51/EC.

⁽⁵⁾ OJ L 372, 31.12.1986, p. 1. Directive as last amended by Directive 2003/51/EC.

⁽⁶⁾ OJ L 374, 31.12.1991, p. 7. Directive as amended by Directive 2003/51/EC.

⁽⁷⁾ OJ L 126, 12.5.1984, p. 20.

⁽⁸⁾ OJ C 143, 8.5.1998, p. 12.

⁽⁹⁾ OJ L 91, 31.3.2001, p. 91.

⁽¹⁰⁾ OJ L 191, 19.7.2002, p. 22.

- (9) Statutory auditors should adhere to the highest ethical standards. They should therefore be subject to professional ethics, covering at least their public-interest function, their integrity and objectivity and their professional competence and due care. The public-interest function of statutory auditors means that a broader community of people and institutions rely on the quality of a statutory auditor's work. Good audit quality contributes to the orderly functioning of markets by enhancing the integrity and efficiency of financial statements. The Commission may adopt implementing measures on professional ethics as minimum standards. When doing so, it might consider the principles contained in the International Federation of Accountants (IFAC) Code of Ethics.
- (10) It is important that statutory auditors and audit firms respect the privacy of their clients. They should therefore be bound by strict rules on confidentiality and professional secrecy which, however, should not impede proper enforcement of this Directive. Those confidentiality rules should also apply to any statutory auditor or audit firm which has ceased to be involved in a specific audit task.
- (11) Statutory auditors and audit firms should be independent when carrying out statutory audits. They may inform the audited entity of matters arising from the audit, but should abstain from the internal decision processes of the audited entity. If they find themselves in a situation where the significance of the threats to their independence, even after application of safeguards to mitigate those threats, is too high, they should resign or abstain from the audit engagement. The conclusion that there is a relationship which compromises the auditor's independence may be different as regards the relationship between the auditor and the audited entity from that in respect of the relationship between the network and the audited entity. Where a cooperative within the meaning of Article 2(14), or a similar entity as referred to in Article 45 of Directive 86/635/EEC, is required or permitted under national provisions to be a member of a non-profit-making auditing entity, an objective, reasonable and informed party would not conclude that the membership-based relationship compromises the statutory auditor's independence, provided that when such an auditing entity is conducting a statutory audit of one of its members, the principles of independence are applied to the auditors carrying out the audit and those persons who may be in a position to exert influence on the statutory audit. Examples of threats to the independence of a statutory auditor or audit firm are a direct or indirect financial interest in the audited entity and the provision of additional non-audit services. Also, the level of fees received from one audited entity and/or the structure of the fees can threaten the independence of a statutory auditor or audit firm. Types of safeguards to be applied to mitigate or eliminate those threats include prohibitions, restrictions, other policies and procedures, and disclosure. Statutory auditors and audit firms should refuse to undertake any additional non-audit service that compromises their independence. The Commission may adopt implementing measures on independence as minimum standards. In doing so, the Commission might take into consideration the principles contained in the abovementioned Recommendation of 16 May 2002. In order to determine the independence of auditors, the concept of a 'network' in which auditors operate needs to be clear. In this regard, various circumstances have to be taken into account, such as instances where a structure could be defined as a network because it is aimed at profit- or cost-sharing. The criteria for demonstrating that there is a network should be judged and weighed on the basis of all factual circumstances available, such as whether there are common usual clients.
- (12) In cases of self-review or self-interest, where appropriate to safeguard the statutory auditor's or audit firm's independence, it should be for the Member State rather than the statutory auditor or the audit firm to decide whether the statutory auditor or audit firm should resign or abstain from an audit engagement with regard to its audit clients. However, this should not lead to a situation where Member States have a general duty to prevent statutory auditors or audit firms from providing non-audit services to their audit clients. For the purposes of determining whether it is appropriate, in cases of self-interest or self-review, that a statutory auditor or audit firm should not carry out statutory audits, so as to safeguard the statutory auditor's or audit firm's independence, the factors to be taken into account should include the question whether or not the audited public-interest entity has issued transferable securities admitted to trading on a regulated market within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments ⁽¹⁾.
- (13) It is important to ensure consistently high quality in all statutory audits required by Community law. All statutory audits should therefore be carried out on the basis of international auditing standards. Measures implementing those standards in the Community should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽²⁾. A technical committee or group on auditing should assist the Commission in the assessment of the technical soundness of all the international auditing standards, and should also involve the system of

⁽¹⁾ OJ L 145, 30.4.2004, p. 1.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

public oversight bodies of the Member States. In order to achieve a maximum degree of harmonisation, Member States should be allowed to impose additional national audit procedures or requirements only if these stem from specific national legal requirements relating to the scope of the statutory audit of annual or consolidated accounts, meaning that those requirements have not been covered by the adopted international auditing standards. Member States could maintain those additional audit procedures until the audit procedures or requirements have been covered by subsequently adopted international auditing standards. If, however, the adopted international auditing standards contain audit procedures the performance of which would create a specific legal conflict with national law stemming from specific national requirements related to the scope of the statutory audit, Member States may carve out the conflicting part of the international auditing standard as long as those conflicts exist, provided the measures referred to in Article 26(3) are applied. Any addition or carving out by Member States should add a high level of credibility to the annual accounts of companies and be conducive to the public good. The above implies that Member States may, for example, require an additional auditor's report to the supervisory board or prescribe other reporting and audit requirements based on national corporate governance rules.

(14) For the Commission to adopt an international auditing standard for application in the Community, it must be generally accepted internationally and have been developed with full participation of all interested parties following an open and transparent procedure, add to the credibility and quality of annual accounts and consolidated accounts and be conducive to the European public good. The need for the adoption of an International Auditing Practice Statement as part of a standard should be assessed in accordance with Decision 1999/468/EC on a case-by-case basis. The Commission should ensure that before the start of the adoption process a review is conducted in order to verify whether those requirements have been met and report to members of the Committee set up under this Directive on the outcome of the review.

(15) In the case of consolidated accounts, it is important that there be a clear definition of responsibilities as between the statutory auditors who audit components of the group. For this purpose, the group auditor should bear full responsibility for the audit report.

(16) In order to increase comparability between companies applying the same accounting standards, and to enhance public confidence in the audit function, the Commission may adopt a common audit report for the audit of annual accounts or consolidated accounts prepared on the basis of approved international accounting standards,

unless an appropriate standard for such a report has been adopted at Community level.

(17) Regular inspections are a good means of achieving a consistently high quality in statutory audits. Statutory auditors and audit firms should therefore be subject to a system of quality assurance that is organised in a manner which is independent from the reviewed statutory auditors and audit firms. For the application of Article 29 on quality assurance systems, Member States may decide that if individual auditors have a common quality assurance policy, only the requirements for audit firms need to be considered. Member States may organise the system of quality assurance in such a manner that each individual auditor is to be subject to a quality assurance review at least every six years. In this respect, the funding for the quality assurance system should be free from undue influence. The Commission should have the competence to adopt implementing measures in matters relevant to the organisation of quality assurance systems, and in respect of its funding, in cases where public confidence in the quality assurance system is seriously compromised. The public oversight systems of Member States should be encouraged to find a coordinated approach to the carrying-out of quality assurance reviews with a view to avoiding the imposition of unnecessary burdens on the parties concerned.

(18) Investigations and appropriate penalties help to prevent and correct inadequate execution of a statutory audit.

(19) Statutory auditors and audit firms are responsible for carrying out their work with due care and thus should be liable for the financial damage caused by a lack of the care owed. However, the auditors' and audit firms' ability to obtain professional indemnity insurance cover may be affected by whether they are subject to unlimited financial liability. For its part, the Commission intends examining these issues, taking into account the fact that liability regimes of the Member States may vary considerably.

(20) Member States should organise an effective system of public oversight for statutory auditors and audit firms on the basis of home country control. The regulatory arrangements for public oversight should make possible effective cooperation at Community level in respect of the Member States' oversight activities. The public oversight system should be governed by non-practitioners who are knowledgeable in the areas relevant to statutory audit. These non-practitioners may be specialists who have never been linked with the audit profession or former practitioners who have left the profession. Member States may, however, allow a minority of practitioners to be involved in the governance of the public oversight system. Competent authorities of Member

States should cooperate with each other whenever necessary for the purpose of carrying out their oversight duties on statutory auditors or audit firms approved by them. Such cooperation can make an important contribution to ensuring consistently high quality in the statutory audit in the Community. Since it is necessary to ensure effective cooperation and coordination at European level among competent authorities designated by Member States, the designation of one entity, responsible for ensuring cooperation, should be without prejudice to the ability of each single authority to cooperate directly with the other competent authorities of the Member States.

- (21) In order to ensure compliance with Article 32(3) on principles of public oversight, a non-practitioner is deemed to be knowledgeable in the areas relevant to the statutory audit either because of his or her past professional skill or, alternatively, because he or she has knowledge of at least one of the subjects listed in Article 8.
- (22) The statutory auditor or audit firm should be appointed by the general meeting of shareholders or members of the audited entity. In order to protect the independence of the auditor it is important that dismissal should be possible only where there are proper grounds and if those grounds are communicated to the authority or authorities responsible for public oversight.
- (23) Since public-interest entities have a higher visibility and are economically more important, stricter requirements should apply in the case of a statutory audit of their annual or consolidated accounts.
- (24) Audit committees and an effective internal control system help to minimise financial, operational and compliance risks, and enhance the quality of financial reporting. Member States might have regard to the Commission Recommendation of 15 February 2005 on the role of non-executive or supervisory directors of listed companies and on the committees of the (supervisory) board ⁽¹⁾, which sets out how audit committees should be established and function. Member States may determine that the functions assigned to the audit committee or a body performing equivalent functions may be performed by the administrative or supervisory body as a whole. With regard to the duties of the audit committee under Article 41, the statutory auditor or

audit firm should in no way be subordinated to the committee.

- (25) Member States may also decide to exempt public-interest entities which are collective investment undertakings whose transferable securities are admitted to trading on a regulated market from the requirement to have an audit committee. This option takes into account the fact that where a collective investment undertaking functions merely for the purpose of pooling assets, the employment of an audit committee will not always be appropriate. The financial reporting and related risks are not comparable to those of other public-interest entities. In addition, undertakings for collective investment in transferable securities (UCITS) and their management companies operate in a strictly defined regulatory environment and are subject to specific governance mechanisms such as controls exercised by their depository. For those collective investment undertakings which are not harmonised by Directive 85/611/EEC ⁽²⁾ but are subject to equivalent safeguards as provided for by that Directive, Member States should, in this particular case, be allowed to provide for equal treatment with Community-harmonised collective investment undertakings.
- (26) In order to reinforce the independence of auditors of public-interest entities, the key audit partner(s) auditing such entities should rotate. To organise such rotation, Member States should require a change of key audit partner(s) dealing with an audited entity, while allowing the audit firm with which the key audit partner(s) is/are associated to continue being the statutory auditor of such entity. Where a Member State considers it appropriate in order to attain the objectives pursued, that Member State might, alternatively, require a change of audit firm, without prejudice to Article 42(2).
- (27) The interrelation of capital markets underlines the need also to ensure high-quality work performed by auditors from third countries in relation to the Community capital market. The auditors concerned should therefore be registered so as to make them subject to quality assurance reviews and to the system of investigations and penalties. Derogations on the basis of reciprocity should be possible subject to an equivalence testing to be performed by the Commission in cooperation with Member States. In any case, an entity which has issued transferable securities on a regulated market within the

⁽¹⁾ OJ L 52, 25.2.2005, p. 51.

⁽²⁾ Council Directive 85/611/EEC of 20 December 1985 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (OJ L 375, 31.12.1985, p. 3). Directive as last amended by Directive 2005/1/EC of the European Parliament and of the Council (OJ L 79, 24.3.2005, p. 9).

meaning of point 14 of Article 4(1) of Directive 2004/39/EC should always be audited by an auditor either registered in a Member State or overseen by competent authorities of the third country from which the auditor comes from, provided that the said third country is acknowledged by the Commission or a Member State as meeting the requirements equivalent to Community requirements in the field of principles of oversight, quality assurance systems and systems of investigations and penalties, and that the basis of this arrangement is reciprocity. While one Member State may consider a third country's quality assurance system equivalent, other Member States should not be bound to accept that assessment, nor should the Commission's decision be pre-empted thereby.

- (28) The complexity of international group audits requires good cooperation between the competent authorities of Member States and those of third countries. Member States should therefore ensure that competent authorities of third countries can have access to audit working papers and other documents through the national competent authorities. In order to protect the rights of the parties concerned and at the same time facilitate access to those papers and documents, Member States should be allowed to grant direct access to the competent authorities of third countries, subject to the agreement of the national competent authority. One of the relevant criteria for the granting of access is whether the competent authorities in third countries meet requirements which the Commission has declared adequate. Pending such a decision by the Commission, and without prejudice thereto, Member States may assess whether the requirements are adequate.
- (29) Disclosure of information as referred to in Articles 36 and 47 should be in accordance with the rules on the transfer of personal data to third countries as laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽¹⁾.
- (30) The measures necessary for the implementation of this Directive should be adopted in accordance with Decision 1999/468/EC and with due regard to the declaration made by the Commission in the European Parliament on 5 February 2002 concerning the implementation of financial services legislation.
- (31) The European Parliament should be given a period of three months from the first transmission of draft amendments and implementing measures to allow it to examine them and to give its opinion. However, in urgent and duly justified cases, it should be possible to shorten that period. If, within that period, a resolution is

adopted by the European Parliament, the Commission should re-examine the draft amendments or measures.

- (32) Since the objectives of this Directive — namely requiring the application of a single set of international auditing standards, the updating of the educational requirements, the definition of professional ethics and the technical implementation of the cooperation between competent authorities of Member States and between those authorities and the authorities of third countries, in order further to enhance and harmonise the quality of statutory audit in the Community and to facilitate cooperation between Member States and with third countries so as to strengthen confidence in the statutory audit — cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of this Directive, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (33) With a view to rendering the relationship between the statutory auditor or audit firm and the audited entity more transparent, Directives 78/660/EEC and 83/349/EEC should be amended so as to require disclosure of the audit fee and the fee paid for non-audit services in the notes to the annual accounts and the consolidated accounts.
- (34) Directive 84/253/EEC should be repealed because it lacks a comprehensive set of rules to ensure an appropriate audit infrastructure, such as public oversight, disciplinary systems and systems of quality assurance, and because it does not provide specifically for regulatory cooperation between Member States and third countries. In order to ensure legal certainty, there is a clear need to indicate that statutory auditors and audit firms that have been approved under Directive 84/253/EEC are considered as approved under this Directive,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Directive establishes rules concerning the statutory audit of annual and consolidated accounts.

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

Article 2

Definitions

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

1. 'statutory audit' means an audit of annual accounts or consolidated accounts insofar as required by Community law;
2. 'statutory auditor' means a natural person who is approved in accordance with this Directive by the competent authorities of a Member State to carry out statutory audits;
3. 'audit firm' means a legal person or any other entity, regardless of its legal form, that is approved in accordance with this Directive by the competent authorities of a Member State to carry out statutory audits;
4. 'third-country audit entity' means an entity, regardless of its legal form, which carries out audits of the annual or consolidated accounts of a company incorporated in a third country;
5. 'third-country auditor' means a natural person who carries out audits of the annual or consolidated accounts of a company incorporated in a third country;
6. 'group auditor' means the statutory auditor(s) or audit firm(s) carrying out the statutory audit of consolidated accounts;
7. 'network' means the larger structure:
 - which is aimed at cooperation and to which a statutory auditor or an audit firm belongs, and
 - which is clearly aimed at profit- or cost-sharing or shares common ownership, control or management, common quality-control policies and procedures, a common business strategy, the use of a common brand-name or a significant part of professional resources;
8. 'affiliate of an audit firm' means any undertaking, regardless of its legal form, which is connected to an audit firm by means of common ownership, control or management;
9. 'audit report' means the report referred to in Article 51a of Directive 78/660/EEC and Article 37 of Directive 83/349/EEC issued by the statutory auditor or audit firm;
10. 'competent authorities' means the authorities or bodies designated by law that are in charge of the regulation and/or oversight of statutory auditors and audit firms or of specific aspects thereof; the reference to 'competent authority' in a specific article means a reference to the authority or body(ies) responsible for the functions referred to in that Article;
11. 'international auditing standards' means International Standards on Auditing (ISA) and related Statements and Standards, insofar as relevant to the statutory audit;
12. 'international accounting standards' means International Accounting Standards (IAS), International Financial Reporting Standards (IFRS) and related Interpretations (SIC-IFRIC interpretations), subsequent amendments to those standards and related interpretations, and future standards and related interpretations issued or adopted by the International Accounting Standards Board (IASB);
13. 'public-interest entities' means entities governed by the law of a Member State whose transferable securities are admitted to trading on a regulated market of any Member State within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC, credit institutions as defined in point 1 of Article 1 of Directive 2000/12/EC of the European Parliament and of the Council of 20 March 2000 relating to the taking up and pursuit of the business of credit institutions⁽¹⁾ and insurance undertakings within the meaning of Article 2(1) of Directive 91/674/EEC. Member States may also designate other entities as public-interest entities, for instance entities that are of significant public relevance because of the nature of their business, their size or the number of their employees;
14. 'cooperative' means a European Cooperative Society as defined in Article 1 of Council Regulation (EC) No 1435/2003 of 22 July 2003 on the Statute for a European Cooperative Society (SCE)⁽²⁾, or any other cooperative for which a statutory audit is required under Community law, such as credit institutions as defined in point 1 of Article 1 of Directive 2000/12/EC and insurance undertakings within the meaning of Article 2(1) of Directive 91/674/EEC;
15. 'non-practitioner' means any natural person who, for at least three years before his or her involvement in the governance of the public oversight system, has not carried out statutory audits, has not held voting rights in an audit firm, has not been a member of the administrative or management body of an audit firm and has not been employed by, or otherwise associated with, an audit firm;

⁽¹⁾ OJ L 126, 26.5.2000, p. 1. Directive as last amended by Commission Directive 2006/29/EC (OJ L 70, 9.3.2006, p. 50).

⁽²⁾ OJ L 207, 18.8.2003, p. 1.

16. 'key audit partner(s)' mean(s):

- (a) the statutory auditor(s) designated by an audit firm for a particular audit engagement as being primarily responsible for carrying out the statutory audit on behalf of the audit firm; or
- (b) in the case of a group audit, at least the statutory auditor(s) designated by an audit firm as being primarily responsible for carrying out the statutory audit at the level of the group and the statutory auditor(s) designated as being primarily responsible at the level of material subsidiaries; or
- (c) the statutory auditor(s) who sign(s) the audit report.

audit of cooperatives and similar entities as referred to in Article 45 of Directive 86/635/EEC, Member States may establish other specific provisions in relation to voting rights;

- (c) a majority — up to a maximum of 75 % — of the members of the administrative or management body of the entity must be audit firms which are approved in any Member State or natural persons who satisfy at least the conditions imposed by Articles 4 and 6 to 12. Member States may provide that such natural persons must also have been approved in another Member State. Where such a body has no more than two members, one of those members must satisfy at least the conditions in this point;
- (d) the firm must satisfy the condition imposed by Article 4.

CHAPTER II

APPROVAL, CONTINUING EDUCATION AND MUTUAL RECOGNITION

Article 3

Approval of statutory auditors and audit firms

1. A statutory audit shall be carried out only by statutory auditors or audit firms which are approved by the Member State requiring the statutory audit.
2. Each Member State shall designate competent authorities which shall be responsible for approving statutory auditors and audit firms.

The competent authorities may be professional associations, provided that they are subject to a system of public oversight as provided for in Chapter VIII.

3. Without prejudice to Article 11, the competent authorities of the Member States may approve as statutory auditors only natural persons who satisfy at least the conditions laid down in Articles 4 and 6 to 10.
4. The competent authorities of the Member States may approve as audit firms only those entities which satisfy the following conditions:
 - (a) the natural persons who carry out statutory audits on behalf of an audit firm must satisfy at least the conditions imposed by Articles 4 and 6 to 12 and must be approved as statutory auditors in the Member State concerned;
 - (b) a majority of the voting rights in an entity must be held by audit firms which are approved in any Member State or by natural persons who satisfy at least the conditions imposed by Articles 4 and 6 to 12. Member States may provide that such natural persons must also have been approved in another Member State. For the purpose of the statutory

Article 4

Good repute

The competent authorities of a Member State may grant approval only to natural persons or firms of good repute.

Article 5

Withdrawal of approval

1. Approval of a statutory auditor or an audit firm shall be withdrawn if the good repute of that person or firm has been seriously compromised. Member States may, however, provide for a reasonable period of time for the purpose of meeting the requirements of good repute.
2. Approval of an audit firm shall be withdrawn if any of the conditions imposed in Article 3(4), points (b) and (c) is no longer fulfilled. Member States may, however, provide for a reasonable period of time for the purpose of fulfilling those conditions.
3. Where the approval of a statutory auditor or of an audit firm is withdrawn for any reason, the competent authority of the Member State where the approval is withdrawn shall communicate that fact and the reasons for the withdrawal to the relevant competent authorities of Member States where the statutory auditor or audit firm is also approved which are entered in the first-named Member State's register in accordance with Article 16(1), point (c).

Article 6

Educational qualifications

Without prejudice to Article 11, a natural person may be approved to carry out a statutory audit only after having attained university entrance or equivalent level, then completed a course of theoretical instruction, undergone practical training and passed an examination of professional competence of university final or equivalent examination level, organised or recognised by the Member State concerned.

Article 7

Examination of professional competence

The examination of professional competence referred to in Article 6 shall guarantee the necessary level of theoretical knowledge of subjects relevant to statutory audit and the ability to apply such knowledge in practice. Part at least of that examination shall be written.

Article 8

Test of theoretical knowledge

1. The test of theoretical knowledge included in the examination shall cover the following subjects in particular:

- (a) general accounting theory and principles;
- (b) legal requirements and standards relating to the preparation of annual and consolidated accounts;
- (c) international accounting standards;
- (d) financial analysis;
- (e) cost and management accounting;
- (f) risk management and internal control;
- (g) auditing and professional skills;
- (h) legal requirements and professional standards relating to statutory audit and statutory auditors;
- (i) international auditing standards;
- (j) professional ethics and independence.

2. It shall also cover at least the following subjects insofar as they are relevant to auditing:

- (a) company law and corporate governance;
- (b) the law of insolvency and similar procedures;
- (c) tax law;

(d) civil and commercial law;

(e) social security law and employment law;

(f) information technology and computer systems;

(g) business, general and financial economics;

(h) mathematics and statistics;

(i) basic principles of the financial management of undertakings.

3. The Commission may, in accordance with the procedure referred to in Article 48(2), adapt the list of subjects to be included in the test of theoretical knowledge referred to in paragraph 1. When adopting those implementing measures the Commission shall take into account developments in auditing and the audit profession.

Article 9

Exemptions

1. By way of derogation from Articles 7 and 8, a Member State may provide that a person who has passed a university or equivalent examination or holds a university degree or equivalent qualification in one or more of the subjects referred to in Article 8 may be exempted from the test of theoretical knowledge in the subjects covered by that examination or degree.

2. By way of derogation from Article 7, a Member State may provide that a holder of a university degree or equivalent qualification in one or more of the subjects referred to in Article 8 may be exempted from the test of the ability to apply in practice his or her theoretical knowledge of such subjects if he or she has received practical training in those subjects attested by an examination or diploma recognised by the State.

Article 10

Practical training

1. In order to ensure the ability to apply theoretical knowledge in practice, a test of which is included in the examination, a trainee shall complete a minimum of three years' practical training in, *inter alia*, the auditing of annual accounts, consolidated accounts or similar financial statements. At least two thirds of such practical training shall be completed with a statutory auditor or audit firm approved in any Member State.

2. Member States shall ensure that all training is carried out with persons providing adequate guarantees regarding their ability to provide practical training.

Article 11

Qualification through long-term practical experience

A Member State may approve a person who does not satisfy the conditions laid down in Article 6 as a statutory auditor, if he or she can show either:

- (a) that he or she has, for 15 years, engaged in professional activities which have enabled him or her to acquire sufficient experience in the fields of finance, law and accountancy, and has passed the examination of professional competence referred to in Article 7, or
- (b) that he or she has, for seven years, engaged in professional activities in those fields and has, in addition, undergone the practical training referred to in Article 10 and passed the examination of professional competence referred to in Article 7.

Article 12

Combination of practical training and theoretical instruction

1. Member States may provide that periods of theoretical instruction in the fields referred to in Article 8 shall count towards the periods of professional activity referred to in Article 11, provided that such instruction is attested by an examination recognised by the State. Such instruction shall not last less than one year, nor may it reduce the period of professional activity by more than four years.

2. The period of professional activity and practical training shall not be shorter than the course of theoretical instruction together with the practical training required in Article 10.

Article 13

Continuing education

Member States shall ensure that statutory auditors are required to take part in appropriate programmes of continuing education in order to maintain their theoretical knowledge, professional skills and values at a sufficiently high level, and that failure to respect the continuing education requirements is subject to appropriate penalties as referred to in Article 30.

Article 14

Approval of statutory auditors from other Member States

The competent authorities of the Member States shall establish procedures for the approval of statutory auditors who have been approved in other Member States. Those procedures shall not go beyond a requirement to pass an aptitude test in accordance with Article 4 of Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three years' duration⁽¹⁾. The aptitude test, which shall be conducted in one of the languages permitted by the language rules applicable in the Member State concerned, shall cover only the statutory auditor's adequate knowledge of the laws and regulations of that Member State in so far as relevant to statutory audits.

CHAPTER III

REGISTRATION

Article 15

Public register

1. Each Member State shall ensure that statutory auditors and audit firms are entered in a public register in accordance with Articles 16 and 17. In exceptional circumstances, Member States may disapply the requirements laid down in this Article and Article 16 regarding disclosure only to the extent necessary to mitigate an imminent and significant threat to the personal security of any person.

2. Member States shall ensure that each statutory auditor and audit firm is identified in the public register by an individual number. Registration information shall be stored in the register in electronic form and shall be electronically accessible to the public.

3. The public register shall also contain the name and address of the competent authorities responsible for approval as referred to in Article 3, for quality assurance as referred to in Article 29, for investigations and penalties on statutory auditors and audit firms as referred to in Article 30, and for public oversight as referred to in Article 32.

4. Member States shall ensure that the public register is fully operational by 29 June 2009.

⁽¹⁾ OJ L 19, 24.1.1989, p. 16. Directive as amended by Directive 2001/19/EC of the European Parliament and of the Council (OJ L 206, 31.7.2001, p. 1).

*Article 16***Registration of statutory auditors**

1. As regards statutory auditors, the public register shall contain at least the following information:

- (a) name, address and registration number;
- (b) if applicable, the name, address, website address and registration number of the audit firm(s) by which the statutory auditor is employed, or with whom he or she is associated as a partner or otherwise;
- (c) all other registration(s) as statutory auditor with the competent authorities of other Member States and as auditor with third countries, including the name(s) of the registration authority(ies), and, if applicable, the registration number(s).

2. Third-country auditors registered in accordance with Article 45 shall be clearly indicated in the register as such and not as statutory auditors.

*Article 17***Registration of audit firms**

1. As regards audit firms, the public register shall contain at least the following information:

- (a) name, address and registration number;
- (b) legal form;
- (c) contact information, the primary contact person and, where applicable, the website address;
- (d) address of each office in the Member State;
- (e) name and registration number of all statutory auditors employed by or associated as partners or otherwise with the audit firm;
- (f) names and business addresses of all owners and shareholders;
- (g) names and business addresses of all members of the administrative or management body;
- (h) if applicable, the membership of a network and a list of the names and addresses of member firms and affiliates or an indication of the place where such information is publicly available;
- (i) all other registration(s) as audit firm with the competent authorities of other Member States and as audit entity with third countries, including the name(s) of the registration authority(ies), and, if applicable, the registration number(s).

2. Third-country audit entities registered in accordance with Article 45 shall be clearly indicated in the register as such and not as audit firms.

*Article 18***Updating of registration information**

Member States shall ensure that statutory auditors and audit firms notify the competent authorities in charge of the public register without undue delay of any change of information contained in the public register. The register shall be updated without undue delay after notification.

*Article 19***Responsibility for registration information**

The information provided to the relevant competent authorities in accordance with Articles 16, 17 and 18 shall be signed by the statutory auditor or audit firm. Where the competent authority provides for the information to be made available electronically, that can, for example, be done by means of an electronic signature as defined in point 1 of Article 2 of Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures ⁽¹⁾.

*Article 20***Language**

1. The information entered in the public register shall be drawn up in one of the languages permitted by the language rules applicable in the Member State concerned.

2. Member States may additionally allow the information to be entered in the public register in any other official language(s) of the Community. Member States may require the translation of the information to be certified.

In all cases, the Member State concerned shall ensure that the register indicates whether or not the translation is certified.

CHAPTER IV

PROFESSIONAL ETHICS, INDEPENDENCE, OBJECTIVITY, CONFIDENTIALITY AND PROFESSIONAL SECRECY*Article 21***Professional ethics**

1. Member States shall ensure that all statutory auditors and audit firms are subject to principles of professional ethics, covering at least their public-interest function, their integrity and objectivity and their professional competence and due care.

⁽¹⁾ OJ L 13, 19.1.2000, p. 12.

2. In order to ensure confidence in the audit function and to ensure uniform application of paragraph 1 of this Article, the Commission may, in accordance with the procedure referred to in Article 48(2), adopt principle-based implementing measures governing professional ethics.

(c) the cases of self-review and self-interest referred to in the second subparagraph of paragraph 2, in which statutory audits may or may not be carried out.

Article 22

Independence and objectivity

1. Member States shall ensure that when carrying out a statutory audit, the statutory auditor and/or the audit firm is independent of the audited entity and is not involved in the decision-taking of the audited entity.

2. Member States shall ensure that a statutory auditor or an audit firm shall not carry out a statutory audit if there is any direct or indirect financial, business, employment or other relationship — including the provision of additional non-audit services — between the statutory auditor, audit firm or network and the audited entity from which an objective, reasonable and informed third party would conclude that the statutory auditor's or audit firm's independence is compromised. If the statutory auditor's or audit firm's independence is affected by threats, such as self-review, self-interest, advocacy, familiarity or trust or intimidation, the statutory auditor or audit firm must apply safeguards in order to mitigate those threats. If the significance of the threats compared to the safeguards applied is such that his, her or its independence is compromised, the statutory auditor or audit firm shall not carry out the statutory audit.

Member States shall in addition ensure that, where statutory audits of public-interest entities are concerned and where appropriate to safeguard the statutory auditor's or audit firm's independence, a statutory auditor or an audit firm shall not carry out a statutory audit in cases of self-review or self-interest.

3. Member States shall ensure that a statutory auditor or audit firm documents in the audit working papers all significant threats to his, her or its independence as well as the safeguards applied to mitigate those threats.

4. In order to ensure confidence in the audit function and to ensure uniform application of paragraphs 1 and 2 of this Article, the Commission may, in accordance with the procedure referred to in Article 48(2), adopt principle-based implementing measures concerning:

- (a) the threats and safeguards referred to in paragraph 2;
- (b) the situations in which the significance of the threats, as referred to in paragraph 2, is such that the independence of the statutory auditor or audit firm is compromised;

Article 23

Confidentiality and professional secrecy

1. Member States shall ensure that all information and documents to which a statutory auditor or audit firm has access when carrying out a statutory audit are protected by adequate rules on confidentiality and professional secrecy.

2. Confidentiality and professional secrecy rules relating to statutory auditors or audit firms shall not impede enforcement of the provisions of this Directive.

3. Where a statutory auditor or audit firm is replaced by another statutory auditor or audit firm, the former statutory auditor or audit firm shall provide the incoming statutory auditor or audit firm with access to all relevant information concerning the audited entity.

4. A statutory auditor or audit firm who has ceased to be engaged in a particular audit assignment and a former statutory auditor or audit firm shall remain subject to the provisions of paragraphs 1 and 2 with respect to that audit assignment.

Article 24

Independence and objectivity of the statutory auditors carrying out the statutory audit on behalf of audit firms

Member States shall ensure that the owners or shareholders of an audit firm as well as the members of the administrative, management and supervisory bodies of such a firm, or of an affiliated firm, do not intervene in the execution of a statutory audit in any way which jeopardises the independence and objectivity of the statutory auditor who carries out the statutory audit on behalf of the audit firm.

Article 25

Audit fees

Member States shall ensure that adequate rules are in place which provide that fees for statutory audits:

- (a) are not influenced or determined by the provision of additional services to the audited entity;
- (b) cannot be based on any form of contingency.

CHAPTER V

Article 27

AUDITING STANDARDS AND AUDIT REPORTING**Statutory audits of consolidated accounts**

Article 26

Auditing standards

1. Member States shall require statutory auditors and audit firms to carry out statutory audits in compliance with international auditing standards adopted by the Commission in accordance with the procedure referred to in Article 48(2). Member States may apply a national auditing standard as long as the Commission has not adopted an international auditing standard covering the same subject-matter. Adopted international auditing standards shall be published in full in each of the official languages of the Community in the *Official Journal of the European Union*.

2. The Commission may decide, in accordance with the procedure referred to in Article 48(2), on the applicability of international auditing standards within the Community. The Commission shall adopt international auditing standards for application in the Community only if they:

- (a) have been developed with proper due process, public oversight and transparency, and are generally accepted internationally;
- (b) contribute a high level of credibility and quality to the annual or consolidated accounts in conformity with the principles set out in Article 2(3) of Directive 78/660/EEC and in Article 16(3) of Directive 83/349/EEC; and
- (c) are conducive to the European public good.

3. Member States may impose audit procedures or requirements in addition to — or, in exceptional cases, by carving out parts of — the international auditing standards only if these stem from specific national legal requirements relating to the scope of statutory audits. Member States shall ensure that these audit procedures or requirements comply with the provisions laid down in points (b) and (c) of paragraph 2 and shall communicate them to the Commission and Member States before their adoption. In the exceptional case of the carving out of parts of an international auditing standard, Member States shall communicate their specific national legal requirements, as well as the grounds for maintaining them, to the Commission and the other Member States at least six months before their national adoption or, in the case of requirements already existing at the time of adoption of an international auditing standard, at the latest within three months of the adoption of the relevant international auditing standard.

4. Member States may impose additional requirements relating to the statutory audits of annual and consolidated accounts for a period expiring on 29 June 2010.

Member States shall ensure that in the case of a statutory audit of the consolidated accounts of a group of undertakings:

- (a) the group auditor bears the full responsibility for the audit report in relation with the consolidated accounts;
- (b) the group auditor carries out a review and maintains documentation of his or her review of the audit work performed by third-country auditor(s), statutory auditor(s), third-country audit entity(ies) or audit firm(s) for the purpose of the group audit. The documentation retained by the group auditor shall be such as enables the relevant competent authority to review the work of the group auditor properly;
- (c) when a component of a group of undertakings is audited by auditor(s) or audit entity(ies) from a third country that has no working arrangement as referred to in Article 47, the group auditor is responsible for ensuring proper delivery, when requested, to the public oversight authorities of the documentation of the audit work performed by the third-country auditor(s) or audit entity(ies), including the working papers relevant to the group audit. To ensure such delivery, the group auditor shall retain a copy of such documentation, or alternatively agree with the third-country auditor(s) or audit entity(ies) his proper and unrestricted access upon request, or take any other appropriate action. If legal or other impediments prevent audit working papers from being passed from a third country to the group auditor, the documentation retained by the group auditor shall include evidence that he or she has undertaken the appropriate procedures in order to gain access to the audit documentation, and in the case of impediments other than legal ones arising from country legislation, evidence supporting such an impediment.

Article 28

Audit reporting

1. Where an audit firm carries out the statutory audit, the audit report shall be signed by at least the statutory auditor(s) carrying out the statutory audit on behalf of the audit firm. In exceptional circumstances Member States may provide that this signature need not be disclosed to the public if such disclosure could lead to an imminent and significant threat to the personal security of any person. In any case the name(s) of the person(s) involved shall be known to the relevant competent authorities.

2. Notwithstanding Article 51a(1) of Directive 78/660/EEC, if the Commission has not adopted a common standard for audit reports in accordance with Article 26(1) of this Directive, it may, in accordance with the procedure referred to in Article 48(2) of this Directive, adopt a common standard for audit reports for annual or consolidated accounts which have been prepared in accordance with approved international accounting standards, in order to enhance public confidence in the audit function.

- (i) the overall results of the quality assurance system shall be published annually;
- (j) recommendations of quality reviews shall be followed up by the statutory auditor or audit firm within a reasonable period.

If the recommendations referred to in point (j) are not followed up, the statutory auditor or audit firm shall, if applicable, be subject to the system of disciplinary actions or penalties referred to in Article 30.

2. The Commission may, in accordance with the procedure referred to in Article 48(2), adopt implementing measures in order to enhance public confidence in the audit function and to ensure uniform application of points (a), (b) and (e) to (j) of paragraph 1.

CHAPTER VI

QUALITY ASSURANCE

Article 29

Quality assurance systems

1. Each Member State shall ensure that all statutory auditors and audit firms are subject to a system of quality assurance which meets at least the following criteria:

- (a) the quality assurance system shall be organised in such a manner that it is independent of the reviewed statutory auditors and audit firms and subject to public oversight as provided for in Chapter VIII;
- (b) the funding for the quality assurance system shall be secure and free from any possible undue influence by statutory auditors or audit firms;
- (c) the quality assurance system shall have adequate resources;
- (d) the persons who carry out quality assurance reviews shall have appropriate professional education and relevant experience in statutory audit and financial reporting combined with specific training on quality assurance reviews;
- (e) the selection of reviewers for specific quality assurance review assignments shall be effected in accordance with an objective procedure designed to ensure that there are no conflicts of interest between the reviewers and the statutory auditor or audit firm under review;
- (f) the scope of the quality assurance review, supported by adequate testing of selected audit files, shall include an assessment of compliance with applicable auditing standards and independence requirements, of the quantity and quality of resources spent, of the audit fees charged and of the internal quality control system of the audit firm;
- (g) the quality assurance review shall be the subject of a report which shall contain the main conclusions of the quality assurance review;
- (h) quality assurance reviews shall take place at least every six years;

CHAPTER VII

INVESTIGATIONS AND PENALTIES

Article 30

Systems of investigations and penalties

1. Member States shall ensure that there are effective systems of investigations and penalties to detect, correct and prevent inadequate execution of the statutory audit.

2. Without prejudice to Member States' civil liability regimes, Member States shall provide for effective, proportionate and dissuasive penalties in respect of statutory auditors and audit firms, where statutory audits are not carried out in conformity with the provisions adopted in the implementation of this Directive.

3. Member States shall provide that measures taken and penalties imposed on statutory auditors and audit firms are appropriately disclosed to the public. Penalties shall include the possibility of the withdrawal of approval.

Article 31

Auditors' liability

Before 1 January 2007 the Commission shall present a report on the impact of the current national liability rules for the carrying out of statutory audits on European capital markets and on the insurance conditions for statutory auditors and audit firms, including an objective analysis of the limitations of financial liability. The Commission shall, where appropriate, carry out a public consultation. In the light of that report, the Commission shall, if it considers it appropriate, submit recommendations to the Member States.

CHAPTER VIII

Article 33

**PUBLIC OVERSIGHT AND REGULATORY ARRANGEMENTS
BETWEEN MEMBER STATES***Article 32***Principles of public oversight**

1. Member States shall organise an effective system of public oversight for statutory auditors and audit firms based on the principles set out in paragraphs 2 to 7.

2. All statutory auditors and audit firms shall be subject to public oversight.

3. The system of public oversight shall be governed by non-practitioners who are knowledgeable in the areas relevant to statutory audit. Member States may, however, allow a minority of practitioners to be involved in the governance of the public oversight system. Persons involved in the governance of the public oversight system shall be selected in accordance with an independent and transparent nomination procedure.

4. The system of public oversight shall have the ultimate responsibility for the oversight of:

- (a) the approval and registration of statutory auditors and audit firms;
- (b) the adoption of standards on professional ethics, internal quality control of audit firms and auditing, and
- (c) continuing education, quality assurance and investigative and disciplinary systems.

5. The system of public oversight shall have the right, where necessary, to conduct investigations in relation to statutory auditors and audit firms and the right to take appropriate action.

6. The system of public oversight shall be transparent. This shall include the publication of annual work programmes and activity reports.

7. The system of public oversight shall be adequately funded. The funding for the public oversight system shall be secure and free from any undue influence by statutory auditors or audit firms.

Cooperation between public oversight systems at Community level

Member States shall ensure that regulatory arrangements for public oversight systems permit effective cooperation at Community level in respect of Member States' oversight activities. To that end, each Member State shall make one entity specifically responsible for ensuring that cooperation.

*Article 34***Mutual recognition of regulatory arrangements between Member States**

1. Regulatory arrangements of Member States shall respect the principle of home-country regulation and oversight by the Member State in which the statutory auditor or audit firm is approved and the audited entity has its registered office.

2. In the case of a statutory audit of consolidated accounts, the Member State requiring the statutory audit of the consolidated accounts may not impose additional requirements in relation to the statutory audit concerning registration, quality assurance review, auditing standards, professional ethics and independence on a statutory auditor or audit firm carrying out a statutory audit of a subsidiary established in another Member State.

3. In the case of a company whose securities are traded on a regulated market in a Member State other than that in which that company has its registered office, the Member State in which the securities are traded may not impose any additional requirements in relation to the statutory audit concerning registration, quality assurance review, auditing standards, professional ethics and independence on a statutory auditor or audit firm carrying out the statutory audit of the annual or consolidated accounts of that company.

*Article 35***Designation of competent authorities**

1. Member States shall designate one or more competent authorities for the purposes of the tasks provided for in this Directive. Member States shall inform the Commission of their designation.

2. The competent authorities shall be organised in such a manner that conflicts of interests are avoided.

Article 36

Professional secrecy and regulatory cooperation between Member States

1. The competent authorities of Member States responsible for approval, registration, quality assurance, inspection and discipline shall cooperate with each other whenever necessary for the purpose of carrying out their respective responsibilities under this Directive. The competent authorities in a Member State responsible for approval, registration, quality assurance, inspection and discipline shall render assistance to competent authorities in other Member States. In particular, competent authorities shall exchange information and cooperate in investigations related to the carrying-out of statutory audits.

2. The obligation of professional secrecy shall apply to all persons who are employed or who have been employed by competent authorities. Information covered by professional secrecy may not be disclosed to any other person or authority except by virtue of the laws, regulations or administrative procedures of a Member State.

3. Paragraph 2 shall not prevent competent authorities from exchanging confidential information. Information thus exchanged shall be covered by the obligation of professional secrecy, to which persons employed or formerly employed by competent authorities are subject.

4. Competent authorities shall, on request, and without undue delay, supply any information required for the purpose referred to in paragraph 1. Where necessary, the competent authorities receiving any such request shall, without undue delay, take the necessary measures to gather the required information. Information thus supplied shall be covered by the obligation of professional secrecy to which the persons employed or formerly employed by the competent authorities that received the information are subject.

If the requested competent authority is not able to supply the required information without undue delay, it shall notify the requesting competent authority of the reasons therefor.

The competent authorities may refuse to act on a request for information where:

(a) supplying information might adversely affect the sovereignty, security or public order of the requested Member State or breach national security rules; or

(b) judicial proceedings have already been initiated in respect of the same actions and against the same statutory auditors or audit firms before the authorities of the requested Member State; or

(c) final judgment has already been passed in respect of the same actions and on the same statutory auditors or audit firms by the competent authorities of the requested Member State.

Without prejudice to the obligations to which they are subject in judicial proceedings, competent authorities which receive information pursuant to paragraph 1 may use it only for the exercise of their functions within the scope of this Directive and in the context of administrative or judicial proceedings specifically related to the exercise of those functions.

5. Where a competent authority concludes that activities contrary to the provisions of this Directive are being or have been carried out on the territory of another Member State, it shall notify the competent authority of the other Member State of that conclusion in as specific a manner as possible. The competent authority of the other Member State shall take appropriate action. It shall inform the notifying competent authority of the outcome and, to the extent possible, of significant interim developments.

6. A competent authority of one Member State may also request that an investigation be carried out by the competent authority of another Member State on the latter's territory.

It may further request that some of its own personnel be allowed to accompany the personnel of the competent authority of that other Member State in the course of the investigation.

The investigation shall be subject throughout to the overall control of the Member State on whose territory it is conducted.

The competent authorities may refuse to act on a request for an investigation to be carried out as provided for in the first subparagraph, or on a request for its personnel to be accompanied by personnel of a competent authority of another Member State as provided for in the second subparagraph, where:

(a) such an investigation might adversely affect the sovereignty, security or public order of the requested Member State; or

- (b) judicial proceedings have already been initiated in respect of the same actions and against the same persons before the authorities of the requested Member State; or
- (c) final judgment has already been passed in respect of the same actions on such persons by the competent authorities of the requested Member State.

7. In accordance with the procedure referred to in Article 48(2) the Commission may adopt implementing measures in order to facilitate cooperation between competent authorities on the procedures for the exchange of information and modalities for cross-border investigations provided for in paragraphs 2 to 4 of this Article.

CHAPTER IX

APPOINTMENT AND DISMISSAL

Article 37

Appointment of statutory auditors or audit firms

1. The statutory auditor or audit firm shall be appointed by the general meeting of shareholders or members of the audited entity.
2. Member States may allow alternative systems or modalities for the appointment of the statutory auditor or audit firm, provided that those systems or modalities are designed to ensure the independence of the statutory auditor or audit firm from the executive members of the administrative body or from the managerial body of the audited entity.

Article 38

Dismissal and resignation of statutory auditors or audit firms

1. Member States shall ensure that statutory auditors or audit firms may be dismissed only where there are proper grounds. Divergence of opinions on accounting treatments or audit procedures shall not be proper grounds for dismissal.
2. Member States shall ensure that the audited entity and the statutory auditor or audit firm inform the authority or authorities responsible for public oversight concerning the dismissal or resignation of the statutory auditor or audit firm during the term of appointment and give an adequate explanation of the reasons therefor.

CHAPTER X

SPECIAL PROVISIONS FOR THE STATUTORY AUDITS OF PUBLIC-INTEREST ENTITIES

Article 39

Application to non-listed public-interest entities

Member States may exempt public-interest entities which have not issued transferable securities admitted to trading on a regulated market within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC and their statutory auditor(s) or audit firm(s) from one or more of the requirements in this Chapter.

Article 40

Transparency report

1. Member States shall ensure that statutory auditors and audit firms that carry out statutory audit(s) of public-interest entities publish on their websites, within three months of the end of each financial year, annual transparency reports that include at least the following:
 - (a) a description of the legal structure and ownership;
 - (b) where the audit firm belongs to a network, a description of the network and the legal and structural arrangements in the network;
 - (c) a description of the governance structure of the audit firm;
 - (d) a description of the internal quality control system of the audit firm and a statement by the administrative or management body on the effectiveness of its functioning;
 - (e) an indication of when the last quality assurance review referred to in Article 29 took place;
 - (f) a list of public-interest entities for which the audit firm has carried out statutory audits during the preceding financial year;
 - (g) a statement concerning the audit firm's independence practices which also confirms that an internal review of independence compliance has been conducted;
 - (h) a statement on the policy followed by the audit firm concerning the continuing education of statutory auditors referred to in Article 13;

- (i) financial information showing the importance of the audit firm, such as the total turnover divided into fees from the statutory audit of annual and consolidated accounts, and fees charged for other assurance services, tax advisory services and other non-audit services;
- (j) information concerning the basis for the partners' remuneration.

Member States may in exceptional circumstances disapply the requirement in point (f) to the extent necessary to mitigate an imminent and significant threat to the personal security of any person.

2. The transparency report shall be signed by the statutory auditor or audit firm, as the case may be. This can be done, for example, by means of an electronic signature as defined in Article 2(1) of Directive 1999/93/EC.

Article 41

Audit committee

1. Each public-interest entity shall have an audit committee. The Member State shall determine whether audit committees are to be composed of non-executive members of the administrative body and/or members of the supervisory body of the audited entity and/or members appointed by the general meeting of shareholders of the audited entity. At least one member of the audit committee shall be independent and shall have competence in accounting and/or auditing.

In public-interest entities which meet the criteria of Article 2(1), point (f) of Directive 2003/71/EC⁽¹⁾, Member States may permit the functions assigned to the audit committee to be performed by the administrative or supervisory body as a whole, provided at least that when the chairman of such a body is an executive member, he or she is not the chairman of the audit committee.

2. Without prejudice to the responsibility of the members of the administrative, management or supervisory bodies, or of other members who are appointed by the general meeting of shareholders of the audited entity, the audit committee shall, *inter alia*:

- (a) monitor the financial reporting process;
- (b) monitor the effectiveness of the company's internal control, internal audit where applicable, and risk management systems;
- (c) monitor the statutory audit of the annual and consolidated accounts;

⁽¹⁾ Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003 on the prospectus to be published when securities are offered to the public or admitted to trading (OJ L 345, 31.12.2003, p. 64).

- (d) review and monitor the independence of the statutory auditor or audit firm, and in particular the provision of additional services to the audited entity.

3. In a public-interest entity, the proposal of the administrative or supervisory body for the appointment of a statutory auditor or audit firm shall be based on a recommendation made by the audit committee.

4. The statutory auditor or audit firm shall report to the audit committee on key matters arising from the statutory audit, and in particular on material weaknesses in internal control in relation to the financial reporting process.

5. Member States may allow or decide that the provisions laid down in paragraphs 1 to 4 shall not apply to any public-interest entity that has a body performing equivalent functions to an audit committee, established and functioning according to provisions in place in the Member State in which the entity to be audited is registered. In such a case the entity shall disclose which body carries out these functions and how it is composed.

6. Member States may exempt from the obligation to have an audit committee:

- (a) any public-interest entity which is a subsidiary undertaking within the meaning of Article 1 of Directive 83/349/EEC if the entity complies with the requirements in paragraphs 1 to 4 of this Article at group level;
- (b) any public-interest entity which is a collective investment undertaking as defined in Article 1(2) of Directive 85/611/EEC. Member States may also exempt public-interest entities the sole object of which is the collective investment of capital provided by the public, which operate on the principle of risk spreading and which do not seek to take legal or management control over any of the issuers of its underlying investments, provided that those collective investment undertakings are authorised and subject to supervision by competent authorities and that they have a depositary exercising functions equivalent to those under Directive 85/611/EEC;
- (c) any public-interest entity the sole business of which is to act as issuer of asset-backed securities as defined in Article 2(5) of Commission Regulation (EC) No 809/2004⁽²⁾. In such instances, the Member State shall require the entity to explain to the public the reasons for which it considers it not appropriate to have either an audit committee or an administrative or supervisory body entrusted to carry out the functions of an audit committee;

⁽²⁾ OJ L 149, 30.4.2004, p. 1.

- (d) any credit institution within the meaning of Article 1(1) of Directive 2000/12/EC whose shares are not admitted to trading on a regulated market of any Member State within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC and which has, in a continuous or repeated manner, issued only debt securities, provided that the total nominal amount of all such debt securities remains below EUR 100 000 000 and that it has not published a prospectus under Directive 2003/71/EC.

Article 42

Independence

1. In addition to the provisions laid down in Articles 22 and 24, Member States shall ensure that statutory auditors or audit firms that carry out the statutory audit of a public-interest entity:
- (a) confirm annually in writing to the audit committee their independence from the audited public-interest entity;
 - (b) disclose annually to the audit committee any additional services provided to the audited entity; and
 - (c) discuss with the audit committee the threats to their independence and the safeguards applied to mitigate those threats as documented by them pursuant to Article 22(3).
2. Member States shall ensure that the key audit partner(s) responsible for carrying out a statutory audit rotate(s) from the audit engagement within a maximum period of seven years from the date of appointment and is/are allowed to participate in the audit of the audited entity again after a period of at least two years.
3. The statutory auditor or the key audit partner who carries out a statutory audit on behalf of an audit firm shall not be allowed to take up a key management position in the audited entity before a period of at least two years has elapsed since he or she resigned as a statutory auditor or key audit partner from the audit engagement.

Article 43

Quality assurance

The quality assurance review referred to in Article 29 shall be carried out at least every three years for statutory auditors or audit firms that carry out statutory audits of public-interest entities.

CHAPTER XI

INTERNATIONAL ASPECTS

Article 44

Approval of auditors from third countries

1. Subject to reciprocity, the competent authorities of a Member State may approve a third-country auditor as statutory auditor if that person has furnished proof that he or she complies with requirements equivalent to those laid down in Articles 4 and 6 to 13.
2. The competent authorities of a Member State shall, before granting approval to a third-country auditor who meets the requirements of paragraph 1, apply the requirements laid down in Article 14.

Article 45

Registration and oversight of third-country auditors and audit entities

1. The competent authorities of a Member State shall, in accordance with Articles 15 to 17, register every third-country auditor and audit entity that provides an audit report concerning the annual or consolidated accounts of a company incorporated outwith the Community whose transferable securities are admitted to trading on a regulated market of that Member State within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC, except when the company is an issuer exclusively of debt securities admitted to trading on a regulated market in a Member State within the meaning of Article 2(1)(b) of Directive 2004/109/EC ⁽¹⁾, the denomination per unit of which is at least EUR 50 000 or, in case of debt securities denominated in another currency, equivalent, at the date of issue, to at least EUR 50 000.
2. Articles 18 and 19 shall apply.

3. Member States shall subject registered third-country auditors and audit entities to their systems of oversight, their quality assurance systems and their systems of investigation and penalties. A Member State may exempt a registered third-country auditor or audit entity from being subject to its quality assurance system if another Member State's or third country's system of quality assurance that has been assessed as equivalent in accordance with Article 46 has carried out a quality review of the third-country auditor or audit entity concerned during the previous three years.

⁽¹⁾ Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market (OJ L 390, 31.12.2004, p. 38).

4. Without prejudice to Article 46, audit reports concerning annual accounts or consolidated accounts referred to in paragraph 1 of this Article issued by third-country auditors or audit entities that are not registered in the Member State shall have no legal effect in that Member State.

5. A Member State may register a third-country audit entity only if:

- (a) it meets requirements which are equivalent to those laid down in Article 3(3);
- (b) the majority of the members of the administrative or management body of the third-country audit entity meet requirements which are equivalent to those laid down in Articles 4 to 10;
- (c) the third-country auditor carrying out the audit on behalf of the third-country audit entity meets requirements which are equivalent to those laid down in Articles 4 to 10;
- (d) the audits of the annual or consolidated accounts referred to in paragraph 1 are carried out in accordance with international auditing standards as referred to in Article 26, as well as the requirements laid down in Articles 22, 24 and 25, or with equivalent standards and requirements;
- (e) it publishes on its website an annual transparency report which includes the information referred to in Article 40 or it complies with equivalent disclosure requirements.

6. In order to ensure uniform application of paragraph 5(d) the equivalence referred to therein shall be assessed by the Commission in cooperation with Member States and shall be decided upon by the Commission in accordance with the procedure referred to in Article 48(2). Pending such a decision by the Commission, Member States may assess the equivalence referred to in paragraph 5(d) as long as the Commission has not taken any decision.

Article 46

Derogation in the case of equivalence

1. Member States may disapply or modify the requirements in Article 45(1) and (3) on the basis of reciprocity only if the third-country auditors or audit entities are subject to systems of public oversight, quality assurance and investigations and penalties in the third country that meet requirements equivalent to those of Articles 29, 30 and 32.

2. In order to ensure uniform application of paragraph 1 of this Article, the equivalence referred to therein shall be assessed by the Commission in cooperation with Member States and shall be decided upon by the Commission in accordance with the procedure referred to in Article 48(2). Member States may assess the equivalence referred to in paragraph 1 of this Article

or rely on the assessments carried out by other Member States as long as the Commission has not taken any decision. If the Commission decides that the requirement of equivalence referred to in paragraph 1 of this Article is not complied with, it may allow the auditors and audit entities concerned to continue their audit activities in accordance with the relevant Member State's requirements during an appropriate transitional period.

3. Member States shall communicate to the Commission:

- (a) their assessments of the equivalence referred to in paragraph 2; and
- (b) the main elements of their cooperative arrangements with third-country systems of public oversight, quality assurance and investigations and penalties, on the basis of paragraph 1.

Article 47

Cooperation with competent authorities from third countries

1. Member States may allow the transfer to the competent authorities of a third country of audit working papers or other documents held by statutory auditors or audit firms approved by them, provided that:

- (a) those audit working papers or other documents relate to audits of companies which have issued securities in that third country or which form part of a group issuing statutory consolidated accounts in that third country;
- (b) the transfer takes place via the home competent authorities to the competent authorities of that third country and at their request;
- (c) the competent authorities of the third country concerned meet requirements which have been declared adequate in accordance with paragraph 3;
- (d) there are working arrangements on the basis of reciprocity agreed between the competent authorities concerned;
- (e) the transfer of personal data to the third country is in accordance with Chapter IV of Directive 95/46/EC.

2. The working arrangements referred to in paragraph 1(d) shall ensure that:

- (a) justification as to the purpose of the request for audit working papers and other documents is provided by the competent authorities;
- (b) the persons employed or formerly employed by the competent authorities of the third country that receive the information are subject to obligations of professional secrecy;

(c) the competent authorities of the third country may use audit working papers and other documents only for the exercise of their functions of public oversight, quality assurance and investigations that meet requirements equivalent to those of Articles 29, 30 and 32;

(d) the request from a competent authority of a third country for audit working papers or other documents held by a statutory auditor or audit firm can be refused:

— where the provision of those working papers or documents would adversely affect the sovereignty, security or public order of the Community or of the requested Member State, or

— where judicial proceedings have already been initiated in respect of the same actions and against the same persons before the authorities of the requested Member State.

3. The adequacy referred to in paragraph 1(c) shall be decided upon by the Commission in accordance with the procedure referred to in Article 48(2) in order to facilitate cooperation between competent authorities. The assessment of adequacy shall be carried out in cooperation with Member States and be based on the requirements of Article 36 or essentially equivalent functional results. Member States shall take the measures necessary to comply with the Commission's decision.

4. In exceptional cases and by way of derogation from paragraph 1, Member States may allow statutory auditors and audit firms approved by them to transfer audit working papers and other documents directly to the competent authorities of a third country, provided that:

(a) investigations have been initiated by the competent authorities in that third country;

(b) the transfer does not conflict with the obligations with which statutory auditors and audit firms are required to comply in relation to the transfer of audit working papers and other documents to their home competent authority;

(c) there are working arrangements with the competent authorities of that third country that allow the competent authorities in the Member State reciprocal direct access to audit working papers and other documents of that third-country's audit entities;

(d) the requesting competent authority of the third country informs in advance the home competent authority of the statutory auditor or audit firm of each direct request for information, indicating the reasons therefor;

(e) the conditions referred to in paragraph 2 are respected.

5. The Commission may, in accordance with the procedure referred to in Article 48(2), specify the exceptional cases

referred to in paragraph 4 of this Article in order to facilitate cooperation between competent authorities and to ensure the uniform application of paragraph 4 of this Article.

6. Member States shall communicate to the Commission the working arrangements referred to in paragraphs 1 and 4.

CHAPTER XII

TRANSITIONAL AND FINAL PROVISIONS

Article 48

Committee procedure

1. The Commission shall be assisted by a committee (hereinafter referred to as the Committee).

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

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

3. The Committee shall adopt its Rules of Procedure.

4. Without prejudice to the implementing measures already adopted, and except for the provisions laid down in Article 26, upon expiry of a two-year period following the adoption of this Directive and on 1 April 2008 at the latest, the application of its provisions requiring the adoption of technical rules, amendments and decisions in accordance with paragraph 2 shall be suspended. Acting on a proposal from the Commission, the European Parliament and the Council may renew the provisions concerned in accordance with the procedure laid down in Article 251 of the Treaty and to that end they shall review them prior to the expiry of the period or date referred to above.

Article 49

Amendment of Directive 78/660/EEC and Directive 83/349/EEC

1. Directive 78/660/EEC is hereby amended as follows:

(a) in Article 43(1) the following point shall be added:

(15) 'separately, the total fees for the financial year charged by the statutory auditor or audit firm for the statutory audit of annual accounts, the total fees charged for other assurance services, the total fees charged for tax advisory services and the total fees charged for other non-audit services.'

Member States may provide that this requirement shall not apply where the company is included within the consolidated accounts required to be drawn up under Article 1 of Directive 83/349/EEC, provided that such information is given in the notes to the consolidated accounts.;

(b) paragraph 1 of Article 44 shall be replaced by the following:

1. 'Member States may permit the companies referred to in Article 11 to draw up abridged notes on their accounts without the information required in Article 43(1)(5) to (12), (14)(a) and (15). However, the notes must disclose the information specified in Article 43(1)(6) in total for all the items concerned.;

(c) paragraph 2 of Article 45 shall be replaced by the following:

2. 'Paragraph 1(b) shall also apply to the information specified in Article 43(1)(8).

The Member States may permit the companies referred to in Article 27 to omit disclosure of the information specified in Article 43(1)(8). The Member States may also permit the companies referred to in Article 27 to omit disclosure of the information specified in Article 43(1)(15), provided that such information is delivered to the public oversight system referred to in Article 32 of Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audit of annual accounts and consolidated accounts (*) when requested by such a public oversight system.'

(*) OJ L 157, 9.6.2006, p. 87.

2. In Article 34 of Directive 83/349/EEC the following point shall be added:

(16) 'Separately, the total fees for the financial year charged by the statutory auditor or audit firm for the statutory audit of the consolidated accounts, the total fees charged for other assurance services, the total fees charged for tax advisory services and the total fees charged for other non-audit services.'

Article 50

Repeal of Directive 84/253/EEC

Directive 84/253/EEC shall be repealed with effect from 29 June 2006. References to the repealed Directive shall be construed as references to this Directive.

Article 51

Transitional provision

Statutory auditors or audit firms that are approved by the competent authorities of the Member States in accordance with Directive 84/253/EEC before the entry into force of the provisions referred to in Article 53(1) shall be considered as having been approved in accordance with this Directive.

Article 52

Minimum harmonisation

Member States requiring statutory audit may impose more stringent requirements, unless otherwise provided for by this Directive.

Article 53

Transposition

1. Before 29 June 2008 Member States shall adopt and publish the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

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

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

Article 54

Entry into force

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

Article 55

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 17 May 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

H. WINKLER