

Official Journal

of the European Communities

ISSN 0378-6978

L 138

Volume 42

1 June 1999

English edition

Legislation

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Price: EUR 19,50

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)

COUNCIL DIRECTIVE 1999/35/EC

of 29 April 1999

on a system of mandatory surveys for the safe operation of regular ro-ro ferry and high-speed passenger craft services

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 84(2),

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

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

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

- (1) Whereas within the framework of the common transport policy further measures must be taken to improve safety in the maritime transport of passengers;
- (2) Whereas the Community is seriously concerned by shipping accidents involving ro-ro ferries which have resulted in a massive loss of life; whereas persons using ro-ro ferries and high-speed passenger craft throughout the Community have the right to expect and to be able to rely on an appropriate level of safety;
- (3) Whereas the Council invited the Commission, in its resolution of 22 December 1994 on the safety of roll-on/roll-off passenger ferries⁽⁴⁾, to

submit proposals for a mandatory survey and control regime for the safety of all ro-ro passenger ferries operating to or from ports of the Community, including the right of investigation of marine casualties;

- (4) Whereas in view, in particular, of the internal market dimension of maritime passenger transport, action at Community level is the most effective way of establishing a common minimum level of safety for ships throughout the Community;
- (5) Whereas action at Community level is the best way to ensure the harmonised enforcement of some principles agreed on within the International Maritime Organisation (IMO), thus avoiding distortions of competition between different Community ports and ro-ro ferries and high-speed passenger craft;
- (6) Whereas, in view of the proportionality principle, a Council Directive is the appropriate legal instrument as it provides a framework for the Member States' uniform and compulsory application of the common safety standards, while leaving each Member State the right to decide which implementation tools best fit its internal system;
- (7) Whereas the safety of ships is primarily the responsibility of flag States; whereas each Member State should ensure compliance with the safety requirements applicable to the ro-ro ferries and high speed passenger craft flying the flag of that Member State and to the companies that operate them;

⁽¹⁾ OJ C 108, 7.4.1998, p. 122.

⁽²⁾ OJ C 407, 28.12.1998, p. 106.

⁽³⁾ Opinion of the European Parliament of 7 October 1998 (OJ C 328, 26.10.1998, p. 82), Council Common Position of 21 December 1998 (OJ C 49, 22.2.1999, p. 15) and Decision of the European Parliament of 10 February 1999 (not yet published in the Official Journal).

⁽⁴⁾ OJ C 379, 31.12.1994, p. 8.

- (8) Whereas port State control does not provide for regular in-depth preventive surveys and verifications for ro-ro ferries and high speed passenger craft; whereas it therefore should be verified that companies and their ferries and craft comply with the safety standards agreed within the IMO and, where appropriate, at regional level, through a system of regular mandatory inspections by host States; whereas companies should be prevented from operating such ferries and craft if these inspections reveal dangerous non-conformity with these safety standards;
- (9) Whereas this Directive addresses the Member States in their capacity as host States; whereas the responsibilities exercised in that capacity are based on specific port State responsibilities that are fully in line with the 1982 United Nations Convention on the Law of the Sea (Unclos);
- (10) Whereas in the interest of improving safety and avoiding distortion of competition, the common safety standards should apply to all ro-ro ferries and high-speed passenger craft, regardless of the flag they fly, providing regular services to or from a port in the Member States both on international voyages and on domestic voyages in sea areas beyond 20 miles from a coast line where shipwrecked persons can land, while leaving the possibility to the Member States to extend the scope of application of the Directive to ro-ro ferries and high-speed passenger craft operating on domestic voyages in sea areas within 20 miles from a coast line;
- (11) Whereas it is necessary that host States check whether the ro-ro ferries and high-speed passenger craft operating to and from Community ports conform to certain harmonised requirements for certification and survey by the flag State;
- (12) Whereas those ro-ro ferries and high-speed passenger craft should also conform, at the building stage and during their entire lifetime, with the applicable classification standards as regards the construction and maintenance of their hull, main and auxiliary machinery, electrical installation and control installation and should be fitted with a voyage data recorder complying with the relevant international requirements;
- (13) Whereas host States should check that the companies providing those services operate their ro-ro ferries and high-speed passenger craft so as to guarantee maximum safety; whereas interested Member States, other than the flag State, should be allowed to participate fully in any investigation of a marine casualty;
- (14) Whereas it is fundamental to check that third flag State administrations concur with the companies' commitments to cooperate with any investigation of a marine casualty or incident and to comply with the rules of recognised organisations for classification and, where applicable, for certification; whereas such administrations should accept the use of harmonised survey and certification procedures;
- (15) Whereas, in order to ensure continuous compliance of ro-ro ferries and high-speed passenger craft with the requirements of this Directive, host States should carry out surveys prior to the start of a service and thereafter at regular intervals and whenever a significant change occurs in the operating circumstances;
- (16) Whereas in order to reduce the burden placed on companies, due account should be taken of previous verifications and surveys; ro-ro ferries and high-speed passenger craft should be exempted from surveys where it has been confirmed that they comply with this Directive for operation on similar routes and replacement ferries and craft should benefit from special arrangements; whereas ro-ro ferries and high-speed passenger craft which have been surveyed to the satisfaction of the host State should not be subjected to expanded inspections under Council Directive 95/21/EC of 19 June 1995 concerning the enforcement, in respect of shipping using Community ports and sailing in the waters under the jurisdiction of the Member States, of international standards for ship safety, pollution prevention and shipboard living and working conditions (port State control)⁽¹⁾;
- (17) Whereas Member States should cooperate to exercise their responsibilities as host States;
- ⁽¹⁾ OJ L 157, 7.7.1995, p. 1. Directive as last amended by Commission Directive 98/42/EC (OJ L 184, 27.6.1998, p. 40).

(18) Whereas Member States might find it useful to be assisted in the performance of their tasks by recognised organisations which meet the requirements of Council Directive 94/57/EC of 22 November 1994 on common rules and standards for ship inspection and survey organisations and for the relevant activities of marine administrations⁽¹⁾;

to improve its regime to take into account future amendments to the 1974 International Convention for the Safety of Life at Sea (SOLAS) which have entered into force and to ensure a harmonised implementation of amendments to some IMO resolutions without broadening its scope,

(19) Whereas due account should be taken, in planning the surveys, of the operational and maintenance schedules of the ro-ro ferries and high-speed passenger craft;

HAS ADOPTED THIS DIRECTIVE:

Article 1

(20) Whereas Member States should ensure that their internal legal systems enable them and any other substantially interested Member States to participate or cooperate in, or conduct, accident investigations on the basis of the provisions of the IMO Code for the investigation of marine casualties; whereas the outcome of such investigations should be made publicly available;

Purpose

The purpose of this Directive is to lay down a system of mandatory surveys which will provide a greater assurance of safe operation of regular ro-ro ferries and high-speed passenger craft services to or from ports in the Member States of the Community and to provide for the right of Member States to conduct, participate in or cooperate with any investigation of maritime casualties or incidents on these services.

(21) Whereas a set of accompanying measures in the areas of navigational guidance systems, contingency planning and local operational restrictions will further improve safety;

Article 2

(22) Whereas, in order to enable the monitoring of the application of this Directive, a database should be established based on the information derived from the surveys;

Definitions

For the purpose of this Directive and its Annexes,

(23) Whereas it is necessary for a committee consisting of representatives of the Member States to assist the Commission in the effective application of this Directive; whereas the Committee set up in Article 12 of Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods⁽²⁾, can undertake that function;

(a) 'ro-ro ferry' shall mean a seagoing passenger vessel with facilities to enable road or rail vehicles to roll on and roll off the vessel, and carrying more than 12 passengers;

(b) 'high-speed passenger craft' shall mean a high-speed craft as defined in Regulation 1 of Chapter X of the 1974 SOLAS Convention, as amended on the date of the adoption of this Directive, which carries more than 12 passengers;

(24) Whereas certain provisions of the Directive may be adapted by that Committee to bring them into line with Community or IMO measures and

(c) 'a passenger' is every person other than:

(i) the master and the members of the crew or other persons employed or engaged in any capacity on board a ship on the business of that ship, and

(ii) a child under one year of age;

⁽¹⁾ OJ L 319, 12.12.1994, p. 20. Directive as amended by Commission Directive 97/58/EC (OJ L 274, 7.10.1997, p. 8).

⁽²⁾ OJ L 247, 5.10.1993, p. 19. Directive as last amended by Commission Directive 98/74/EC (OJ L 276, 13.10.1998, p. 7).

- (d) '1974 SOLAS Convention' shall mean the International Convention for the Safety Of Life At Sea, together with Protocols and amendments thereto, in force on the date of adoption of this Directive;
- (e) 'High-speed Craft Code' shall mean the 'International Code for Safety of High-speed Craft' contained in IMO Maritime Safety Committee Resolution MSC 36 (63) of 20 May 1994, as amended on the date of the adoption of this Directive;
- (f) 'regular service' shall mean a series of ro-ro ferry or high-speed passenger craft crossings operated so as to serve traffic between the same two or more ports, or a series of voyages from and to the same port without intermediate calls, either:
- (i) according to a published timetable; or
 - (ii) with crossings so regular or frequent that they constitute a recognisable systematic series;
- (g) 'sea area' shall mean any sea area included in a list established in accordance with Article 4 of Council Directive 98/18/EC of 17 March 1998 on safety rules and standards for passenger ships⁽¹⁾;
- (h) 'certificates' shall mean:
- (i) for ro-ro ferries and high-speed passenger craft engaged on international voyages, the safety certificates issued under the 1974 SOLAS Convention as amended, together with the relevant records of equipment and where appropriate exemption certificates and permits to operate;
 - (ii) for ro-ro ferries and high-speed passenger craft engaged on domestic voyages, the safety certificates issued in accordance with Directive 98/18/EC together with the relevant records of equipment and where appropriate exemption certificates and permits to operate;
- (i) 'exemption certificate' shall mean any certificate issued under the provisions of Regulation I B/12(a)(vi) of the 1974 SOLAS Convention;
- (j) 'administration of the flag State' shall mean the competent authorities of the State whose flag the ro-ro ferry or the high-speed passenger craft is entitled to fly;
- (k) 'host State' shall mean a Member State to or from whose port(s) a ro-ro ferry or a high-speed passenger craft is engaged on a regular service;
- (l) 'international voyage' shall mean a voyage by sea from a port of a Member State to a port outside that Member State, or conversely;
- (m) 'domestic voyage' shall mean a voyage in sea areas from a port of a Member State to the same or another port within that Member State;
- (n) 'recognised organisation' shall mean an organisation recognised in accordance with Article 4 of Directive 94/57/EC;
- (o) 'company' shall mean a company operating one or more ro-ro ferries to which a document of compliance has been issued in compliance with Article 5(2) of Council Regulation (EC) No 3051/95 of 8 December 1995 on the safety management of roll on/roll off passenger ferries (ro-ro ferries) ⁽²⁾ or a company operating high-speed passenger craft, to which a document of compliance has been issued in accordance with Regulation IX/4 of the 1974 SOLAS Convention, as amended on the date of adoption of this Directive;
- (p) 'Code for the investigation of marine casualties' shall mean the Code for the investigation of marine casualties and incidents adopted by the IMO by means of Assembly Resolution A.849(20) of 27 November 1997;
- (q) 'specific survey' shall mean a survey by the host State as specified in Articles 6 and 8;
- (r) 'qualified inspector' shall mean a public-sector employee or other person, duly authorised by the competent authority of a Member State to carry out surveys and inspections related to the certificates and fulfilling the criteria of qualification and independence specified in Annex V;
- (s) 'deficiency' shall mean a condition found not to be in compliance with the requirements of this Directive.

⁽¹⁾ OJ L 144, 15.5.1998, p. 1.

⁽²⁾ OJ L 320, 30.12.1995, p. 14. Regulation as amended by Commission Regulation (EC) No 179/98 (OJ L 19, 24.1.1998, p. 35).

*Article 3***Scope**

1. This Directive shall apply to all ro-ro ferries and high-speed passenger craft operating to or from a port of a Member State on a regular service, regardless of their flag, when engaged on international voyages or on domestic voyages in sea areas covered by Class A as referred to in Article 4 of Directive 98/18/EC.

2. Member States may apply this Directive to ro-ro ferries and high-speed passenger craft engaged on domestic voyages in sea areas other than those referred to in paragraph 1. In those circumstances the relevant rules shall be applied to all ro-ro ferries or high-speed passenger craft operating under the same conditions, without discrimination in respect of flag, nationality or place of establishment of the company.

*Article 4***Initial verifications required in relation to ro-ro ferries and high-speed passenger craft**

1. Prior to the start of operation by a ro-ro ferry or high-speed passenger craft on a regular service, or within 12 months of the date referred to in Article 19(1) for a ro-ro ferry or high-speed passenger craft already operating a regular service on that date, host States shall check that ro-ro ferries and high-speed passenger craft:

- (a) carry valid certificates, issued by the administration of the flag State or by a recognised organisation acting on its behalf;
- (b) have been surveyed for the issue of certificates in accordance with the relevant procedures and guidelines annexed to IMO Assembly Resolution A.746(18) on survey guidelines under the harmonised system of survey and certification, as they stand at the time of adoption of this Directive or with procedures designed to achieve the same goal;
- (c) comply with the standards specified for classification by the rules of a recognised organisation, or rules accepted as equivalent by the administration of the flag State for construction and maintenance of their hull, machinery and electrical and control installation;

(d) are fitted with a voyage data recorder (VDR) for the purpose of providing information for the benefit of a possible casualty investigation. The VDR shall meet the performance standards of IMO Assembly Resolution A.861(20) of 27 November 1997 and comply with the testing standards laid down in International Electrotechnical Commission (IEC) standard No 61996. However, for VDRs to be placed on board ro-ro ferries and high-speed passenger craft built before the entry into force of this Directive, exemptions for compliance with some of the requirements may be granted. These exemptions and the conditions under which they can be granted shall be adopted in accordance with the procedure laid down in Article 16;

(e) comply with specific stability requirements adopted at regional level, and transposed into their national legislation in accordance with the notification procedure 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⁾, when operating in that region a service covered by that national legislation, provided those requirements do not exceed those specified in the Annex on Resolution 14 (Stability Requirements Pertaining to the Agreement) of the 1995 SOLAS Conference and have been notified to the Secretary-General of the IMO, in accordance with the procedures specified in point 3 of that resolution.

2. Paragraph 1(e) shall apply to high speed passenger craft only where appropriate.

*Article 5***Initial verifications required in relation to companies and flag States**

Prior to the start of operation by a ro-ro ferry or high-speed passenger craft on a regular service, or within 12 months of the date referred to in Article 19(1) for a ro-ro ferry or high-speed passenger craft already operating on a regular service on that date, host States shall:

⁽¹⁾ OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

1. check that companies which operate or intend to operate such a ferry or craft on regular service:
 - (a) take the necessary measures to ensure that the specific requirements laid down in Annex I are applied and provide the evidence of compliance with this paragraph and with Article 4 to the host States involved in the regular service;
 - (b) will agree in advance that host States and any substantially interested Member State may conduct, participate fully in or cooperate with any investigation of a marine casualty or incident in accordance with Article 12, and will give them access to the information retrieved from the VDR of their ferry or craft involved in such a casualty or incident.
2. Check for such a ferry or craft flying a flag other than that of a Member State, the concurrence of that flag State that it has accepted the company's commitment to meet the requirements of this Directive.

Article 6

Initial specific surveys

1. Prior to the start of operation by a ro-ro ferry or high-speed passenger craft on a regular service, or within 12 months of the date referred to in Article 19(1) for a ro-ro ferry and high-speed passenger craft already operating a regular service on that date, host States shall carry out an initial specific survey, in accordance with Annexes I and III, to satisfy themselves that the ro-ro ferry or high-speed passenger craft fulfils the necessary requirements for safe operation of a regular service.
2. Where this Article is applied prior to the start of operation, host States shall set a date for the initial specific survey which is no more than one month after receipt of the evidence necessary to complete the verification under Articles 4 and 5.

Article 7

Special provisions

1. When a ro-ro ferry or high-speed passenger craft is to be engaged on another regular service, a new

host State shall take the utmost account of verifications and surveys previously carried out for that ferry or craft for operation on a previous regular service covered by this Directive. Provided that the new host State is satisfied with these previous verifications and surveys and that they are relevant to the new operational conditions, Articles 4, 5 and 6 need not be applied prior to the ro-ro ferry or high-speed passenger craft starting operation on the new regular service.

2. Articles 4, 5 and 6 need not apply when a ro-ro ferry or high-speed passenger craft which complies with this Directive already operating a regular service covered by this Directive transfers to another regular service where the route characteristics are agreed by the relevant host States to be similar, and the host States all agree that the ro-ro ferry or high-speed passenger craft fulfils all the requirements for safe operation on that service.

At the request of a company, the host States concerned may confirm in advance their agreement as to where route characteristics are similar.

3. In cases where, following unforeseen circumstances, a replacement ro-ro ferry or high-speed passenger craft must be introduced rapidly to ensure continuity of service, and paragraphs 1 and 2 are not applicable, the host State may allow the ferry or craft to start operating provided that:

- (a) a visual inspection and document check raise no concerns that the ro-ro ferry or high-speed passenger craft does not fulfil the necessary requirements for safe operation, and
- (b) the host State completes the verifications and surveys under Articles 4, 5 and 6 within one month.

Article 8

Regular specific surveys and other surveys

1. Host States shall, once in every 12-month period, carry out:

- a specific survey, in accordance with Annex III, and
- a survey during a regular service, which shall aim to cover enough items listed in Annexes I, III and IV in order to satisfy the host State that the ferry or craft continues to fulfil all the necessary requirements for safe operation.

An initial specific survey in accordance with Article 6 counts as a specific survey for the purposes of this Article.

2. A host State shall carry out a specific survey in accordance with Annex III each time the ro-ro ferry or high-speed passenger craft undergoes repairs, alterations and modifications of a major character, or when there is a change in management or flag, or a transfer of class. However, in case of change in management or flag, or transfer of class, the host State may, after taking account of verifications and surveys previously issued for the ferry or craft, and provided that the safe operation of the ferry or craft is not affected by this change or transfer, dispense the ferry or craft from the specific survey required by this paragraph.

3. Should the surveys referred to in paragraph 1 confirm or reveal deficiencies in relation to the requirements of this Directive warranting a prevention of operation, all costs relating to the surveys in any normal accounting period shall be covered by the company.

Article 9

Notification

Host States shall inform companies promptly, in writing, of the outcome of verifications and surveys under Articles 4, 5, 6 and 8.

Article 10

Prevention of operation

1. A host State shall prevent the operation of a ro-ro ferry or high-speed passenger craft on a regular service:

- (a) when it has been unable to confirm compliance with the requirements in Articles 4 and 5;
- (b) whenever deficiencies are found during the surveys referred to in Articles 6 and 8 which pose an immediate danger to life, the ferry or craft, its crew and passengers;

(c) when there is an established failure to comply with the Community instruments listed in Annex II which poses an immediate danger of life, the ferry or craft, its crew and passengers;

(d) whenever it has not been consulted by the flag State on the matters referred to in Article 13(1) or (5),

until the host State has established that the danger has been removed and the requirements of the Directive are met.

The host State shall inform the company in writing of the decision to prevent that ro-ro ferry or high-speed passenger craft operating, giving full reasoning.

2. However, where the ro-ro ferry or high-speed passenger craft is already operating a regular service and deficiencies are established, host States shall require the company to take the necessary measures for their prompt rectification or within a well-defined and reasonable period of time, provided they do not pose an immediate danger to the safety of the ferry or craft, its crew and passengers. After rectification of the deficiencies, the host States concerned shall verify that the rectification has been carried out to their full satisfaction. If this is not the case, they shall prevent the ferry or craft from operating.

3. Member States shall, in accordance with national legislation, establish and maintain appropriate procedures covering the right of appeal by a company against a decision to prevent operation. Appeals should be dealt with expeditiously. An appeal shall not cause the decision to be automatically suspended.

The competent authority shall duly inform the company of its right of appeal.

4. In cases where Articles 4, 5 and 6 are applied prior to the start of operation by a ro-ro ferry or high-speed passenger craft on a regular service, a decision to prevent a ship operating must be taken within one month of the initial specific survey and communicated to the company immediately.

*Article 11***Procedures related to initial and regular specific surveys**

1. Ro-ro ferries and high-speed passenger craft that have been subject to the specific surveys to the satisfaction of the involved host State(s) shall be exempted by these host State(s) from expanded inspections referred to in Article 7(4) of Directive 95/21/EC and from expanded inspections based on the clear grounds that they belong to the category of passenger ships referred to in Article 7(1) and Annex V.A.3 of that Directive.

2. Administrations of two or more host States involved in a specific survey of the same ship or craft shall cooperate with each other. The specific surveys shall be carried out by a team composed of qualified inspectors of the involved host State(s). Wherever there is a need for qualitative assessment of the fulfilment of class-related provisions, host States shall ensure the necessary expertise is included in the team, where appropriate by including a surveyor of a recognised organisation. The inspectors shall report deficiencies to the administrations of the host States. The host State shall communicate this information to the flag State, if that State is not a host State involved in the survey.

3. An involved host State may agree to carry out a survey at the request of another involved host State.

4. Host States, when requested by companies, shall invite the administration of the flag State which is not a host State to be represented in any specific survey under the provisions of this Directive.

5. Host States, in planning a survey in accordance with Articles 6 and 8, shall take due account of the operational and maintenance schedule of the ferry or craft.

6. The findings of the specific surveys shall be recorded in a report of which the format shall be established in accordance with the procedure laid down in Article 16.

7. In case of persistent disagreement between host States on the fulfilment of the requirements of Articles

4 and 5(1), the administration of any host State involved in a specific survey shall immediately notify to the Commission the reasons of the disagreement.

8. The Commission shall immediately start proceedings in order to take a decision in accordance with the procedure laid down in Article 16.

*Article 12***Accident investigation**

1. Member States shall define, in the framework of their respective internal legal systems, a legal status that will enable them and any other substantially interested Member State to participate, to cooperate in, or where provided for under the Code for the investigation of marine casualties, to conduct any marine casualty or incident investigation involving a ro-ro ferry or high-speed passenger craft.

2. 'Substantially interested State', 'lead investigating State' and 'marine casualty' shall have the same meaning as in the Code for the investigation of marine casualties.

3. When a ro-ro ferry or high-speed passenger craft is involved in a marine casualty, the investigation procedure shall be launched by the State in whose waters the accident or incident occurs or, if in other waters, by the last Member State visited by the ferry or craft. This State shall remain responsible for the investigation and coordination with other substantially interested States until such time as it is mutually agreed which is to be the lead investigating State.

4. Member States conducting, participating in or cooperating with such investigations shall ensure that the investigation is concluded in the most efficient way and within the shortest possible time taking into account the Code for the investigation of marine casualties.

5. Member States shall ensure that reports resulting from such an investigation are made public in accordance with point 12.3 of the Code for the investigation of marine casualties and notified to the Commission.

*Article 13***Accompanying measures**

1. Member States issuing or recognising an exemption certificate shall work together with the involved host State or administration of the flag State to resolve any disagreement concerning the suitability of the exemptions prior to the initial specific survey.

2. Member States should operate shore-based navigational guidance systems and other information schemes in accordance with IMO Resolution A.795(19) to assist ro-ro ferries and high-speed passenger craft in the safe conduct of the regular service, or part of it, for the safety of which they bear responsibility.

3. Each Member State shall provide to the Commission copies of the survey reports referred to in Article 11(6), with the IMO identification number where applicable. The Commission may, in accordance with the procedure laid down in Article 16, decide on appropriate means for allocating an identification number to other vessels. If two or more host States are involved in the regular service, the data may be provided by one of these host States. The Commission shall set up and maintain a database containing the information provided. Conditions of access to the database shall be decided in accordance with the procedure laid down in Article 16.

4. Member States shall ensure that companies operating ro-ro ferries or high-speed passenger craft on regular services to or from their ports are able to maintain and implement an integrated system of contingency planning for shipboard emergencies. To this end they shall make use of the framework provided by IMO Assembly Resolution A.852(20) on guidelines for a structure of an integrated system of contingency. If two or more Member States are involved as host States in the regular service they shall jointly establish a plan for the different routes.

5. Member States shall ensure that they have been fully involved in their capacity as host State by the administration of the flag State, before the issuance of the permit to operate high speed craft, in accordance with the provisions of paragraph 1.9.3 of the High-speed Craft Code. They shall ensure that operational restrictions required by local situations, necessary to protect life, natural resources and coastal activities are established or maintained and they shall

take measures to ensure the enforcement of these restrictions.

*Article 14***Cooperation between host States**

Host States involved in the same regular service shall liaise with each other when applying this Directive.

*Article 15***Supporting measures**

The Member States shall inform third States which have either flag State responsibilities or responsibilities similar to those of a host State for ro-ro ferries and high-speed passenger craft falling under the scope of this Directive and operating between a port of a Member State and a port of a third State of the requirements imposed by this Directive on any company providing a regular service to or from a port of the Community.

*Article 16***Regulatory committee**

1. The Commission shall be assisted by the committee set up under Article 12(1) of Directive 93/75/EEC.

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

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken.

The Council shall act by a qualified majority. If, on the expiry of eight weeks from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 17

Amendment procedure

In accordance with the procedure laid down in Article 16:

- (a) the Annexes,
- (b) the definitions,
- (c) references to Community instruments,
- (d) references to IMO resolutions,

may be amended to the extent necessary to bring them into line with Community or IMO measures which have entered into force, but without broadening the scope of this Directive.

The Annexes may also be amended in accordance with the procedure laid down in Article 16 when it is necessary to improve the arrangements established by this Directive, but without broadening its scope.

Article 18

Penalties

Member States shall lay down the system of penalties for breaching the national provisions adopted pursuant to this Directive and shall take all the measures necessary to ensure that those penalties are applied. The penalties thus provided for shall be effective, proportionate and dissuasive.

Article 19

Application

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 December 2000 and forthwith inform the Commission thereof.

2. The provisions of Article 4(1)(d) shall be applied no later than 30 months after the publication date of IEC standard No 61996 or by 1 January 2001, whichever of these dates comes later.

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

4. The Member States shall immediately notify to the Commission all provisions of domestic law which they adopt in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 20

Assessment of application

Three years after the date referred to in Article 19(1), the Commission shall assess, on the basis of information to be provided by the Member States in accordance with Article 13, the application of this Directive.

Article 21

Entry into force

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

Article 22

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1999.

For the Council

The President

W. MÜLLER

ANNEX I

SPECIFIC REQUIREMENTS TO BE FULFILLED BY COMPANIES

as referred to in Article 5(1), and Articles 6 and 8

Companies are to ensure that on board their ro-ro ferries and high-speed passenger craft:

1. the master is provided with appropriate information on the availability of shore-based navigational guidance systems and other information schemes to assist him in the safe conduct of the voyages, before the ferry or craft begins to sail, and that he makes use of the navigational guidance and information schemes set up by Member States;
 2. the relevant provisions of paragraphs 2 to 6 of MSC/Circular 699, on revised guidelines for passenger safety instructions, are applied;
 3. a table with the shipboard working arrangements is posted in an easily accessible place, and contains:
 - (a) the schedule of service at sea and service in port, and
 - (b) the maximum hours of work or the minimum hours of rest required for watchkeepers;
 4. the master is not constrained from taking any decision, which in his professional judgment is necessary for safe navigation and operation, in particular in severe weather and in heavy seas;
 5. the master keeps a record of navigational activities and incidents which are of importance to safety of navigation;
 6. any damage to, or permanent deflection of shell doors and associated hull plating that may affect the integrity of the ferry or craft, and any deficiencies in the securing arrangements of such doors, are promptly reported to both the flag State administration and the host State and are promptly repaired to their satisfaction;
 7. an up-to-date voyage plan is available before the departure of the ro-ro ferry or high-speed passenger craft on its voyage. In preparing the voyage plan the guidelines set out in MSC Resolution ... (70), on guidelines on voyage planning, are to be taken fully into account;
 8. general information about the services and assistance available to elderly and disabled persons on board is made known to the passengers and is made available in formats suitable for people with impaired sight.
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*ANNEX II***LIST OF COMMUNITY INSTRUMENTS**

referred to in Article 10(1c)

- Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods (OJ L 247, 5.10.1993, p. 19). Directive as last amended by Commission Directive 98/74/EC (OJ L 276, 13.10.1998, p. 7),
 - Council Directive 94/58/EC of 22 November 1994 on the minimum level of training of seafarers (OJ L 319, 12.12.1994, p. 28). Directive as last amended by Directive 98/35/EC (OJ L 172, 17.6.1998, p. 1), where applicable,
 - Council Regulation (EC) No 3051/95 of 8 December 1995 on the safety management of roll on/roll off passenger ferries (ro-ro ferries) (OJ L 320, 30.12.1995, p. 14). Regulation as amended by Commission Regulation (EC) No 179/98 (OJ L 19, 24.1.1998, p. 35).
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ANNEX III

PROCEDURES FOR SPECIFIC SURVEYS

(as referred to in Articles 6 and 8)

1. The specific surveys are to ensure that statutory requirements, in particular those for construction, subdivision and stability, machinery and electrical installations, loading, stability, fire protection, maximum number of passengers, life saving appliances and the carriage of dangerous goods, radiocommunications and navigation are fulfilled and are for that purpose, and where applicable at least to include:
 - the starting of the emergency generator,
 - an inspection of emergency lighting,
 - an inspection of the emergency source of power for radio-installations,
 - a test of the public address system,
 - a fire drill, including a demonstration of the ability to use firemen's outfits,
 - the operation of the emergency fire-pump with two firehoses connected to the fire main line in operation,
 - the testing of the remote emergency stop controls for fuel supply to boilers, main and auxiliary engines, and for ventilation fans,
 - the testing of remote and local controls for the closing of fire dampers,
 - the testing of fire detection and alarm systems,
 - the testing of proper closing of fire doors,
 - the operation of bilge pumps,
 - the closing of watertight bulkhead doors; both from the local and remote control positions,
 - a demonstration that shows that key crew members are acquainted with the damage control plan,
 - the lowering of at least one rescue boat and one lifeboat to the water, starting and testing their propulsion and steering system, and recovering them from the water into their stowed position on board,
 - the checking that all lifeboats and rescue boats correspond to the inventory,
 - the testing of the ship's or craft's steering gear and auxiliary steering gear.
2. Specific surveys shall include the verification of the planned maintenance system on board.
3. Specific surveys shall focus on the familiarisation of crew members with, and their effectiveness in, safety procedures, emergency procedures, maintenance, working practices, passenger safety, bridge procedures and cargo and vehicle-related operations. Seafarers' ability to understand and, where appropriate, give orders and instructions and report back in the common working language, as recorded in the ship's logbook shall be checked. The documented evidence that crew members have successfully followed a special training shall be checked, in particular with regard to:
 - crowd-management training,
 - familiarisation training,

- safety training for personnel providing direct safety assistance to passengers in passenger spaces, and in particular to elderly and disabled persons in an emergency, and
- crisis management and human behaviour training.

The specific survey shall include an assessment as to whether rostering patterns are causing unreasonable fatigue particularly for watch-keeping personnel.

4. Certificates of competence of the crew members issued by third States shall only be recognised when they comply with Regulation I/10 of the revised International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978 (STCW Convention).

ANNEX IV

INDICATIVE GUIDELINES FOR QUALIFIED INSPECTORS WHEN CARRYING OUT
UNSCHEDULED SURVEYS DURING A REGULAR CROSSING

(as referred to in Article 8(1))

1. *Passenger information*

The means used to ensure that the passenger number for which the ro-ro ferry or high-speed passenger craft (hereafter referred to as 'ship') is certified is not exceeded. That the system for registration of passenger information complies with the regulations and is effective. How the information on the total number of passengers is passed to the master and, if appropriate, how passengers undertaking a double crossing without going ashore are included in the total for the return voyage.

2. *Loading and stability information*

That, when applicable, reliable draught gauges are fitted and are in use. That measures are taken to ensure that the ship is not overloaded and the appropriate sub-division load line is not submerged. That the loading and stability assessment is carried out as required. That goods vehicles and other cargo are weighed where required and the figures passed to the ship for use in the loading and stability assessment. That damage control plans are permanently exhibited and that booklets containing damage control information are provided for the ship's officers.

3. *Security for sea*

The procedure to ensure that the ship is secured for sea before leaving the berth, which should include a positive reporting procedure that all the shell watertight and weather-tight doors are closed. That all the vehicle deck doors are closed before the ship leaves the berth or remain open long enough only to enable the bow visor to be closed, the closing arrangements for the bow, stern and side doors, and the provision of indicator lights and TV surveillance to show their status on the navigating bridge. Any difficulties with the operation of the indicator lights, particularly the switches at the doors, should be ascertained and reported.

4. *Safety announcements*

The form of routine safety announcements and the posting of instructions and guidance on emergency procedures in the appropriate language(s). That the routine safety announcement takes place at the commencement of the voyage and can be heard in all public spaces, including open decks, to which passengers have access.

5. *Log book entries*

An examination of the log book to ensure that the entries are being made regarding the closing of the bow, stern and other watertight and weather-tight doors, drills for sub-division watertight doors, testing of steering gears, etc. Also that draughts, freeboard and stability are being recorded as well as the common working language for the crew.

6. *Dangerous goods*

That any cargo of dangerous or polluting goods is carried in accordance with the relevant regulations and, in particular, that a declaration concerning dangerous and polluting goods is provided together with a manifest or stowage plan to show their location on board, that the carriage of the particular cargo is permitted on passenger ships, and that the dangerous and polluting goods are properly marked, labelled, stowed, secured and segregated.

That vehicles carrying dangerous and polluting goods are properly placarded and secured. That, when dangerous and polluting goods are carried, a copy of the relevant manifest or stowage plan is available ashore. That the master is aware of the notification requirements under Directive 93/75/EEC and of the instructions on the emergency procedures to be followed and the rendering of first aid should there be an incident involving the dangerous goods or marine pollutants. That the means of ventilating the vehicle decks is in use at all times, is increased when the engines of the vehicles are running and that there is some form of indication on the bridge to show that the vehicle deck ventilation is in operation.

7. *Securing freight vehicles*

How freight vehicles are secured, for example, whether block stow or individual lashings. Whether sufficient strong points are available. The arrangements for securing freight vehicles when adverse weather is experienced or expected. The method of securing coaches and motor cycles, if any. That the ship has a cargo securing manual.

8. *Vehicle decks*

Whether special category and ro-ro cargo spaces are being continuously patrolled or monitored by a TV surveillance system so that the movement of vehicles in adverse weather and the unauthorised entry of passengers may be observed. That fire doors and entrances are kept shut and that notices are posted to keep passengers off the vehicle decks whilst the ship is at sea.

9. *Closure of watertight doors*

That the policy laid down in the ship's operational instructions for the sub-division watertight doors is being followed. That the required drills are being carried out. That the bridge control for the watertight doors is kept, when possible, on 'local' control. That the doors are being kept closed in restricted visibility and any hazardous situation. That crews are instructed in the correct way to operate the doors and are aware of the dangers of their misuse.

10. *Fire patrols*

It should be confirmed that an efficient patrol is being maintained so that any outbreak of fire may be readily detected. This should include special category spaces where a fixed fire detection and alarm system is not fitted noting that these spaces may be patrolled as indicated in paragraph 8.

11. *Communications in an emergency*

That there are sufficient crew members in accordance with the muster list to assist passengers in an emergency and that they are readily identifiable and able to communicate with the passengers in an emergency, taking into account an appropriate and adequate combination of any of the following factors:

- (a) the language or languages appropriate to the principal nationalities of passengers carried on a particular route;
- (b) the likelihood that an ability to use elementary English vocabulary for basic instructions can provide a means of communicating with a passenger in need of assistance whether or not the passenger and crew member share a common language;
- (c) the possible need to communicate during an emergency by some other means (e.g. by demonstration, hand signals, or calling attention to the location of instructions, muster stations, life-saving devices or evacuation routes when verbal communication is impractical);
- (d) the extent to which complete safety instructions have been provided to passengers in their native language or languages;
- (e) the languages in which emergency announcements may be broadcast during an emergency or drill to convey critical guidance to passengers and to facilitate crew members in assisting passengers.

12. *Common working language between crew members*

Verify that a working language is established to ensure effective crew performance in safety matters and that this working language is recorded in the ship's logbook.

13. *Safety equipment*

That the live-saving and fire appliances, including the fire doors and other items of the structural fire protection that may be readily inspected, are being maintained. That fire control plans are permanently exhibited or booklets containing the equivalent information are provided for the information of the ship's officers. That the stowage of the lifejackets is appropriate and that the stowage of children's lifejackets may be readily identified. That the loading of vehicles does not prevent the operation of the fire controls, emergency shut-offs, controls for the storm valves, etc. that may be located on the vehicle decks.

14. *Navigational and radio equipment*

That the navigational and radio communications equipment, including emergency position-indicating radio beacons (EPIRBs), are operational.

15. *Supplementary emergency lighting*

That supplementary emergency lighting is fitted, when required by the regulations, and that a record of deficiencies is being kept.

16. *Means of escape*

Marking, in accordance with the applicable requirements, and the lighting, from both the main and emergency sources of power, of the means of escape. The measures taken to keep vehicles clear of escape routes where the means of escape cross or pass through vehicle decks. That exits, particularly exits from duty free shops, which have been found to be blocked by an excess of goods, are kept clear.

17. *Operations book*

That copies of the operations book are provided for the master and each senior officer and that other copies are available for all members of the crew. Also that there are check lists to cover the preparation for sea and other operations.

18. *Engine room cleanliness*

That the engine room is maintained in a clean condition with regard to maintenance procedures.

19. *Garbage disposal*

That the arrangements for the handling and disposal of garbage are satisfactory.

20. *Planned maintenance*

All companies should have specific standing orders, with a planned maintenance system, for all safety related areas including bow and stern doors and side openings, together with their closing arrangements, but also covering engine room maintenance and safety equipment. Plans should be in place for periodically checking all items so as to maintain safety standards at the highest level. Procedures should be in place for recording deficiencies and confirming they have been properly rectified so that the master and the designated person ashore within the company management

structure are aware of the deficiencies and are notified when they have been rectified within a time specified. Periodic checking of the operation of the inner and outer bow door closing arrangements should include the indicators, surveillance equipment and any scuppers in the spaces between the bow visor and the inner door and especially the closing mechanisms and their associated hydraulic systems.

21. *Making a voyage*

When making a voyage the opportunity should be taken to check overcrowding, including the availability of seats and the blocking of passageways, stairs and emergency exits by baggage and by passengers unable to find seats. That the vehicle deck is vacated by passengers before the ship sails and that they do not again have access until immediately prior to docking should also be checked.

ANNEX V

CRITERIA OF QUALIFICATION AND INDEPENDENCE FOR QUALIFIED INSPECTORS

(as referred to in Article 2(r))

1. The qualified inspector must be authorised to carry out the specific surveys referred to in Article 6 by the competent authority of the Member State.
 2. Either:
 - the qualified inspector must have completed a minimum of one year's service with the competent authority of a Member State as a flag State inspector dealing with surveys and certification in accordance with the 1974 SOLAS Convention,
 - and be in possession of:
 - (a) a certificate of competency as master, enabling that person to take command of a ship of 1 600 GT or more (see STCW, Regulation II/2), or
 - (b) a certificate of competency as chief engineer enabling him to take up that task on board a ship whose main power plant has a power equal or superior to 3 000 kW (see STCW, Regulation III/2), or
 - (c) have passed in a Member State an examination as a naval architect, mechanical engineer or an engineer related to the maritime fields and worked in that capacity for at least five years,
 - the qualified inspectors mentioned under (a) and (b) must have served for a period of not less than five years at sea as officer in the deck or engine department respectively;or:
 - the qualified inspector must hold a relevant university degree or equivalent in a Member State, and
 - have been trained and qualified at a school for ship safety inspectors in a Member State, and
 - have served at least two years with the competent authority of a Member State as a flag State inspector dealing with surveys and certification in accordance with the 1974 SOLAS Convention.
 3. Qualified inspectors shall have the ability to communicate orally and in writing with seafarers in the language most commonly spoken at sea.
 4. Qualified inspectors shall have an appropriate knowledge of the provisions of the 1974 SOLAS Convention and of the relevant procedures of this Directive.
 5. The qualified inspectors carrying out specific surveys shall have no commercial interest either in the company concerned or any other company operating on a regular service to and from the involved host State or in the ro-ro ferries or high-speed passenger craft inspected, nor shall the qualified inspectors be employed by or undertake work on behalf of non-governmental organisations which carry out statutory or classification surveys or issue certificates for that ro-ro ferry or high-speed passenger craft.
 6. Inspectors not fulfilling the above criteria are also accepted if they were employed by the competent authority for statutory surveys or port State control inspections at the date of adoption of Directive 95/21/EC.
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COUNCIL DIRECTIVE 1999/36/EC

of 29 April 1999

on transportable pressure equipment

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 75(1)(c) thereof,

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

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

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

- (1) Whereas within the framework of the common transport policy further measures must be adopted to ensure transport safety;
- (2) Whereas each Member State currently requires all transportable equipment to be used on its territory to undergo certification and inspection, including periodic inspections, by its designated bodies; whereas this practice, requiring multiple approvals if equipment is to be used in more than one State in the course of a transport operation, constitutes an obstacle to the provision of transport services within the Community; whereas action by the Community to harmonise approval procedures is justified in order to facilitate the use of transportable pressure equipment on the territory of another Member State in the context of a transport operation;
- (3) Whereas measures should be adopted for the progressive establishment of a single market in transport and, in particular, for free movement of transportable pressure equipment;

(4) Whereas action at Community level is the only possible way of achieving such harmonisation, since Member States acting independently or through international agreements cannot establish the same degree of harmonisation in the approvals for such equipment; whereas, currently, recognition of approvals given in different Member States is not satisfactory because of the element of discretion;

(5) Whereas a Council Directive is the appropriate legal instrument to enhance the safety of this equipment, as it provides a framework for uniform and compulsory application of the approval procedures by Member States;

(6) Whereas Council Directives 94/55/EC⁽⁴⁾ and 96/49/EC⁽⁵⁾ have extended the application of the provisions of the ADR⁽⁶⁾ and RID⁽⁷⁾ to cover national traffic in order to harmonise across the Community the conditions under which dangerous goods are transported by road and by rail;

(7) Whereas Directives 94/55/EC and 96/49/EC provide for the option of applying conformity assessment procedures based on modules in accordance with Decision 93/465/EEC⁽⁸⁾ to certain new transportable pressure equipment; whereas this option should be replaced by an obligation extended to cover all new transportable pressure equipment used for the

⁽¹⁾ OJ C 95, 24.3.1997, p. 2, and OJ C 186, 16.6.1998, p. 11.

⁽²⁾ OJ C 296, 29.9.1997, p. 6.

⁽³⁾ Opinion of the European Parliament of 19 February 1998 (OJ C 80, 16.3.1998, p. 217), Council Common Position of 30 November 1998 (OJ C 18, 22.1.1999, p. 1) and Decision of the European Parliament of 10 March 1999 (not yet published in the Official Journal).

⁽⁴⁾ Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (OJ L 319, 12.12.1994, p. 7).

⁽⁵⁾ Council Directive 94/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail (OJ L 235, 17.9.1996, p. 25).

⁽⁶⁾ ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

⁽⁷⁾ RID: Regulations concerning the International Carriage of Dangerous Goods by Rail as set out in Annex I to Appendix B of the amended version of the Convention concerning the international carriage of goods by rail (COTIF).

⁽⁸⁾ 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 directive (OJ L 220, 30.8.1993, p. 23).

- transport of dangerous goods and falling within the scope of Directives 94/55/EC and 96/49/EC;
- (8) Whereas Directive 97/23/EC⁽¹⁾ lays down the general requirements for the free movement and safety of pressure equipment;
- (9) Whereas aerosol dispensers and gas cylinders for breathing appliances should be excluded from the scope of this Directive as their free movement and safety are already covered by Directive 75/324/EEC⁽²⁾ and Directive 97/23/EC;
- (10) Whereas recognition of the approval certificates issued by the inspection bodies designated by the Member States' competent authorities, of the conformity assessment or reassessment procedures and of the periodic inspection procedures contributes towards removing obstacles to freedom to provide transport services; whereas such an objective cannot be achieved satisfactorily at another level by the Member States; whereas, to eliminate the element of discretion, it is necessary to establish clearly which procedures should be followed;
- (11) Whereas it is necessary to lay down common rules for establishing recognition of designation inspection bodies which ensure compliance with Directives 94/55/EC and 96/49/EC; whereas these common rules will have the effect of eliminating unnecessary costs and administrative procedures related to the approval of the equipment and of eliminating technical barriers to trade;
- (12) Whereas, in order not to hinder transport operations between a Member State and a third country, this Directive should not be applied to transportable pressure equipment exclusively used for transport operations of dangerous goods between the territory of the Community and that of third countries;
- (13) Whereas Member States have to designate inspection bodies entitled to perform the conformity assessment or reassessment procedures and periodic inspections; whereas they must also ensure that such bodies are sufficiently independent, efficient and professionally able to carry out their appointed tasks;
- (14) Whereas specific procedures should be introduced for evaluating the conformity of new valves and other accessories used for transport;
- (15) Whereas provisions should be introduced regarding the reassessment of existing equipment, as defined in Annex IV, Part II; so as to enable this Directive to be applied to such equipment;
- (16) Whereas compliance with the technical provisions of the Annexes to Directives 94/55/EC and 96/49/EC for new equipment must be shown by means of the conformity assessment procedures set out in Annex IV, Part I; whereas periodic inspections of existing equipment will be carried out according to the procedures set out in Annex IV, Part III;
- (17) Whereas equipment referred to in this Directive should bear a mark to indicate its compliance with the requirements of Directive 94/55/EC or 96/49/EC and this Directive in order to be placed on the market, filled, used and refilled in accordance with its intended purpose;
- (18) Whereas Member States must allow transportable pressure equipment bearing the mark referred to in Annex VII to move freely on their territory, to be placed on the market, to be used in the course of any transport operation or to be used in accordance with its intended purpose, without undergoing further assessment or having to comply with further technical requirements;
- (19) Whereas it is appropriate that a Member State, provided it informs the Commission, should be able to take measures to limit or prohibit the placing on the market and use of equipment in cases where it presents a particular risk to safety;
- (20) Whereas a committee procedure should be followed for amendment of the Annexes to this Directive and for postponing the date the Directive is brought into effect for certain transportable pressure equipment;
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- ⁽¹⁾ Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1).
- ⁽²⁾ Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40). Directive as amended by Directive 94/1/EC (OJ L 23, 28.1.1994, p. 28).

- (21) Whereas provision should be made for transitional arrangements to enable pressure equipment, manufactured in accordance with the national rules in force before this Directive is brought into effect, to be placed on the market and put into service;
- (22) Whereas Directives 84/525/EEC⁽¹⁾ 84/526/EEC⁽²⁾ and 84/527/EEC⁽³⁾ on gas cylinders provide for a conformity procedure different from that provided for by this Directive; whereas a single procedure should be established for all transportable pressure equipment;
- (23) Whereas a periodic inspection procedure should be established for existing gas cylinders which are in accordance with Directives 84/525/EEC, 84/526/EEC and 84/527/EEC,
- (c) for repeated use and periodic inspections:
- to the transportable pressure equipment referred to in (a) and (b),
 - to existing gas cylinders bearing the conformity marking laid down in Directives 84/525/EEC, 84/526/EEC and 84/527/EEC.
3. Transportable pressure equipment which was placed on the market before 1 July 2001 or, in the case of Article 18, within two years of that date and which has not been reassessed as to its conformity with the requirements of Directives 94/55/EC and 96/49/EC, shall be outside the scope of this Directive.
4. Transportable pressure equipment used exclusively for the transport of dangerous goods between Community territory and third-country territory, carried out in accordance with Article 6(1) and Article 7 of Directive 94/55/EC or Article 6(1) and Article 7(1) and (2) of Directive 96/49/EC, shall be outside the scope of this Directive.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope

1. The purpose of this Directive shall be to enhance safety with regard to transportable pressure equipment approved for the inland transport of dangerous goods by road and by rail and to ensure the free movement of such equipment within the Community, including the placing on the market and repeated putting into service and repeated use aspects.

2. This Directive shall apply:

- (a) for the purpose of placing on the market: to new transportable pressure equipment as defined in Article 2;
- (b) for the purpose of reassessment of conformity: to existing transportable pressure equipment as defined in Article 2 which meets the technical requirements laid down in Directives 94/55/EC and 96/49/EC;

⁽¹⁾ Council Directive 84/525/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, steel gas cylinders (OJ L 300, 19.11.1984, p. 1).

⁽²⁾ Council Directive 84/526/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders (OJ L 300, 19.11.1984, p. 20).

⁽³⁾ Council Directive 84/527/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to welded unalloyed steel gas cylinders (OJ L 300, 19.11.1984, p. 48).

Article 2

Definitions

For the purposes of this Directive:

1. 'transportable pressure equipment' means:

- all receptacles (cylinders, tubes, pressure drums, cryogenic receptacles, bundles of cylinders as defined in Annex A to Directive 94/55/EC),
- all tanks, including demountable tanks, tank containers (mobile tanks), tanks of tank wagons, tanks or receptacles of battery vehicles or battery wagons, tanks of tank vehicles,

used for the transport of Class 2 gases in accordance with the Annexes to Directives 94/55/EC and 96/49/EC and for the transport of certain dangerous substances of other classes indicated in Annex VI to this Directive, including their valves and other accessories used for transport.

This definition excludes equipment subject to the general exemption principles applicable to small quantities and to the special cases provided for in the Annex to Directive 94/55/EC and the Annex to

Directive 96/49/EC as well as aerosol dispensers (UN number 1950) and gas cylinders for breathing appliances;

2. 'mark' means the symbol referred to in Article 10;
3. 'conformity assessment procedures' means those procedures set out in Annex IV, Part I;
4. 'reassessment of conformity' means the procedure for subsequent assessment, at the request of the owner or his authorised representative established in the Community or of the holder, of the conformity of transportable pressure equipment already manufactured and put into service before 1 July 2001 or, in the case of Article 18, within two years of that date;
5. 'notified body' means an inspection body designated by the national competent authority of a Member State in accordance with Article 8 and meeting the criteria of Annexes I and II;
6. 'approved body' means an inspection body designated by the national competent authority of a Member State in accordance with Article 9 and meeting the criteria of Annexes I and III.

Article 3

Conformity assessment or the placing on the Community market of new transportable pressure equipment

1. New receptacles and new tanks shall meet the relevant provisions of Directive 94/55/EC and 96/49/EC. The compliance of such transportable pressure equipment with these provisions shall be established by a notified body exclusively in accordance with the conformity assessment procedures set out in Annex IV, Part I, and specified in Annex V.
2. New valves and other accessories used for transport shall meet the relevant provisions of the Annexes to Directives 94/55/EC and 96/49/EC.
3. Valves and other accessories having a direct safety function in transportable pressure equipment, in particular safety valves, valves for filling and emptying and cylinder valves, shall be subject to a conformity assessment procedure at least as stringent as that undergone by the receptacle or tank to which they are fitted.

Such valves and other accessories used for transport may be subject to a different conformity assessment procedure separate from that used for the receptacle or tank.

4. Should Directive 94/55/EC and 96/49/EC not contain any detailed technical provisions for the valves and accessories referred to in paragraph 3, such valves and accessories must meet the requirements of Directive 97/23/EC and, pursuant to that Directive, be subject to a category II, III or IV conformity assessment procedure as laid down in Article 10 of Directive 97/23/EC according to whether the receptacle or tank belongs to category 1, 2 or 3 as laid down in Annex V to this Directive.

5. No Member State shall prohibit, restrict or impede the placing on the market or putting into service on its territory of transportable pressure equipment referred to in Article 1(2)(a) which complies with this Directive and bears the relevant mark provided for in Article 10(1) and (2).

Article 4

Conformity assessment for the placing on the national market of new transportable pressure equipment

1. By way of derogation from Article 3, Member States may authorise on their territory the placing on the market, transport and putting into service by users, of the receptacles — including their valves and other accessories used for transport — covered by Article 1(2)(a), the conformity of which has been assessed by an approved body.
2. Transportable pressure equipment the conformity of which has been assessed by an approved body may not bear the marking described in Article 10(1).
3. The approved body shall work exclusively for the group of which it is a member.
4. The procedures applicable to conformity assessment by approved bodies shall be modules A1, C1, F and G, as described in Annex IV, Part I.
5. The effects of this Article shall be monitored by the Commission and evaluated as from 1 July 2004. To this end, Member States shall forward to the Commission any useful information on the

implementation of this Article. If necessary the evaluation shall be accompanied by a proposal for amendment of this Directive.

Article 5

Reassessment of conformity for existing transportable pressure equipment

1. The conformity of the transportable pressure equipment referred to in Article 1(2)(b) with the relevant provisions of the Annexes to Directives 94/55/EC and 96/49/EC shall be established by a notified body in accordance with the conformity reassessment procedure set out in Annex IV, Part II, to this Directive.

Where such equipment was manufactured in series, Member States may authorise the reassessment of conformity with regard to receptacles, including their valves and other accessories used for transport, to be carried out by an approved body provided that conformity of the type is reassessed by a notified body.

2. No Member States shall prohibit, restrict or impede the placing on the market or putting into service on its territory of transportable pressure equipment referred to in Article 1(2)(b) which complies with this Directive and bears the relevant mark provided for in Article 10(1).

Article 6

Periodic inspection and repeated use

1. Periodic inspections of the receptacles, including their valves and accessories used for transport, referred to in Article 1(2)(c) shall be arranged by a notified or approved body in accordance with the procedure set out in Annex IV, Part III. Periodic inspections of tanks, including their valves and other accessories used for transport, shall be arranged by a notified body in accordance with the procedure laid down in Annex IV, Part III, module 1.

However, Member States may permit periodic inspections of tanks carried out on their territory also to be performed by the approved bodies which have been recognised for carrying out periodic inspections of tanks and which act under the supervision of a body notified under the procedure provided for in

Annex IV, Part III, Module 2 concerning periodic inspection through quality assurance.

2. The transportable pressure equipment referred to in Article 1(2) may be subjected to periodic inspection in any Member State.

3. No Member State may, on grounds concerning transportable pressure equipment as such, prohibit, restrict or impede the use (including filling, storing, emptying and refilling) on its territory of the following transportable pressure equipment:

- the equipment referred to in Article 1(2)(a) and (b) and the first indent of Article 1(2)(c), which satisfies the provisions of this Directive and bears the corresponding mark,
- existing gas cylinders bearing the conformity mark provided for in Directives 84/525/EEC, 84/526/EEC and 84/527/EEC and the mark and identification number referred to in Article 10(3) of this Directive indicating that it has undergone periodic inspection.

4. Member States may establish national requirements for the storage or use of transportable pressure equipment, but not for transportable pressure equipment itself or for the accessories needed during transport. Member States may, however, pursuant to Article 7, retain national requirements for connecting devices, colour codes and reference temperatures.

Article 7

National provisions

1. A Member State may retain its national provisions concerning devices intended for connection with other equipment and colour codes applicable to transportable pressure equipment until such time as European standards for use are added to the Annexes to Directives 94/55/EC and 96/49/EC.

However, where safety problems arise with the transport or use of certain types of gas, a short transitional period may be allowed, in accordance with the procedure laid down in Article 15, in order to enable Member States to retain their national provisions even after the European standards have been added to the Annexes to Directives 94/55/EC and 96/49/EC.

2. A Member State in which the ambient temperature is regularly lower than -20°C may impose more stringent standards as regards the operating temperature of material intended for use in the national transport of dangerous goods within its territory until provisions on the appropriate reference temperatures for given climatic zones are incorporated in the Annexes to Directives 94/55/EC and 96/49/EC.

Article 8

Notified bodies

1. Member States shall communicate to the Commission and the other Member States the list of notified bodies established within the Community which they have designated to carry out the new transportable pressure equipment conformity assessment procedures pursuant to Annex IV, Part I, to reassess the conformity of existing types or equipment with the requirements of the Annexes to Directives 94/55/EC and 96/49/EC pursuant to Annex IV, Part II, and/or to perform the task of periodic inspections pursuant to Annex IV, Part III, module 1 and/or to perform the task of surveillance pursuant to Annex IV, Part III, module 2. They shall also communicate the identification numbers assigned to them beforehand by the Commission.

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

2. Member States shall apply the criteria set out in Annexes I and II for the designation of notified bodies. Each body shall submit to the Member State which intends to designate it complete information concerning, and evidence of, compliance with the criteria in Annexes I and II.

3. A Member State which has notified a body shall withdraw such notification if it finds that the body no longer meets the criteria referred to in paragraph 2.

It shall forthwith inform the Commission and the other Member States of any such withdrawal of notification.

Article 9

Approved bodies

1. Member States shall communicate to the Commission and the other Member States the list of approved bodies established in the Community, which

they have recognised in accordance with the criteria of paragraph 2, for the purpose of carrying out periodic inspections of receptacles — including their valves and other accessories used for transport — referred to in Article 2(1), first indent, or conformity reassessment of existing receptacles — including their valves and other accessories used for transport — which conform to a type reassessed by a notified body, to ensure continued compliance with the relevant provisions of Directives 94/55/EC and 96/49/EC in accordance with the procedures laid down in Annex IV, Part III, module 1. They shall also communicate the identification numbers assigned to them beforehand by the Commission.

Member States using the option provided for in Article 6(1), second subparagraph, shall also communicate to the Commission and the other Member States the list of approved bodies established in the Community, which they have recognised for the purpose of carrying out periodic inspections of tanks.

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

2. Member States shall apply the criteria set out in Annexes I and III for the recognition of approved bodies. Each body shall submit to the Member State which intends to recognise it complete information concerning, and evidence of, compliance with the criteria in those Annexes.

3. A Member State which has recognised a body shall withdraw the approval if it finds that the body no longer meets the criteria referred to in paragraph 2.

It shall forthwith inform the Commission and the other Member States of any such withdrawal of approval.

Article 10

Marking

1. Without prejudice to the requirements for the marking of receptacles and tanks laid down in Directives 94/55/EC and 96/49/EC, receptacles and tanks satisfying the provisions of Article 3(1) and Article 5(1) shall have a mark affixed to them in accordance with Annex IV, Part I. The form of the mark to be used is set out in Annex VII. This mark shall be visibly and immovably affixed and shall be accompanied by the identification number of the

notified body which has performed the conformity assessment procedure on the receptacles and tanks. In the event of reassessment, this mark shall be accompanied by the identification number of the notified or approved body.

For transportable pressure equipment complying with Article 7(2), the identification number of the notified or approved body shall be followed by '-40 °C'.

2. New valves and other accessories having a direct safety function shall bear either the mark provided for in Annex VII hereto or that provided for in Annex VI to Directive 97/23/EC. Such marks need not be accompanied by the identification number of the notified body which carried out the conformity assessment on the valves and other accessories used for transport.

The other valves and accessories shall not be subject to any special marking requirements.

3. Without prejudice to the requirements for the marking of receptacles and tanks laid down in Directives 94/55/EC and 96/49/EC, for the purposes of periodic inspections, all transportable pressure equipment referred to in Article 6(1) shall bear the identification number of the body which performed the periodic inspection of the equipment to indicate that it may continue to be used.

With regard to gas cylinders covered by Directives 84/525/EEC, 84/526/EEC and 84/527/EEC, when the first periodic inspection is carried out in accordance with this Directive, the aforementioned identification number shall be preceded by the mark described in Annex VII.

4. For both conformity assessment and reassessment and for periodic inspections, the identification number of the notified or approved body shall be visibly and immovably affixed under its responsibility either by the body itself or by the manufacturer, or his authorised representative established within the Community, or by the owner or his authorised representative established in the Community, or by the holder.

5. The affixing of markings on transportable pressure equipment which are likely to mislead third parties with regard to the meaning or the graphics of the mark referred to in this Directive shall be prohibited. Any other marking may be affixed to equipment provided that the visibility and legibility of the marking in Annex VII is not thereby reduced.

Article 11

Safeguard clause

1. Where a Member State finds that transportable pressure equipment, when correctly maintained and used for its intended purpose, is liable to endanger the health and/or safety of persons and, where appropriate, domestic animals or property, during transport and/or use, notwithstanding the fact that it bears a mark, it may restrict or prohibit the placing on the market, transport or use of the equipment in question or have it withdrawn from the market or from circulation. It shall forthwith inform the Commission of any such measure, indicating the reasons for its decision.

2. The Commission shall enter into consultation with the parties concerned without delay. Where the Commission considers, after this consultation, that the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States.

Where the Commission considers, after this consultation, that the measure is unjustified, it shall immediately so inform the Member State which took the initiative and the owner or his authorised representative established in the Community or the holder, or the manufacturer or his authorised representative established within the Community.

3. Where transportable pressure equipment which does not comply bears the marking provided for in Article 10, the competent Member State shall take appropriate action against the person(s) who affixed the marking and shall so inform the Commission and the other Member States.

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

Article 12

Undue marking

Without prejudice to Article 11, where a Member State establishes that the marking described in Annex VII has been affixed unduly, the owner or his authorised representative established in the Community or the holder, or the manufacturer or his authorised representative established within the Community, shall be obliged to make the transportable pressure equipment conform as regards the provisions concerning the marking and to end the infringement under the conditions imposed by the Member State.

Should non-conformity persist, the Member State shall immediately inform the Commission thereof and take all appropriate measures to restrict or prohibit the placing on the market, transport or use of the equipment in question or to ensure that it is withdrawn from the market or from circulation in accordance with the procedure laid down in Article 11.

Article 13

Decisions leading to refusal or restriction

Any decision taken pursuant to this Directive which has the effect of restricting the placing on the market, transport or use or requires the withdrawal from the market or from circulation of transportable pressure equipment shall state the exact grounds on which it is based. Such Decision shall be notified forthwith to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in the Member State concerned and of the time limits to which such remedies are subject.

Article 14

Committee

The amendments necessary for adapting the Annexes to this Directive shall be adopted in accordance with the procedure laid down in Article 15.

Article 15

1. Where reference is made to the procedure provided for in this Article, the Commission shall be assisted by the Committee on the transport of dangerous goods set up under Article 9 of Directive 94/55/EC, hereinafter referred to as 'the Committee', composed of representatives of the Member States and chaired by a representative of the Commission.

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

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

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

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

Article 16

Adoption and publication

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 December 2000. They shall forthwith inform the Commission thereof.

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

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

Article 17

Implementation

1. Member States shall adopt no later than 1 July 2001 the provisions which they have adopted to comply with this Directive to transportable pressure equipment.

2. The date referred to in paragraph 1 shall be deferred for certain transportable pressure equipment for which there are no detailed technical specifications or for which adequate reference to the relevant European standards has not been added to the Annexes to Directives 94/55/EC and 96/49/EC.

The equipment concerned by any such deferral and the date on which this Directive becomes applicable to it shall be determined in accordance with the procedure laid down in Article 15.

*Article 18***Transitional arrangements**

Member States shall authorise the placing on the market and putting into service of transportable pressure equipment which complies with the regulations in force within their territory before 1 July 2001 until 24 months from that date and shall authorise the subsequent putting into service of such equipment placed on the market prior to that date.

*Article 19***Penalties**

Member States shall lay down a system of penalties for breaches of the national provisions adopted pursuant to this Directive and shall take all the measures necessary to ensure that those penalties are applied. The penalties thus provided for shall be effective, proportionate and dissuasive.

Member States shall notify the relevant provisions to the Commission not later than 1 December 2000 and shall inform it of any subsequent changes as soon as possible.

*Article 20***Applicability of provisions of other Directives**

As from 1 July 2001 or, in the case of Article 18, within two years of the date, the only provisions of Directives 84/525/EEC, 84/526/EEC and 84/527/EEC

to remain applicable shall be those of Article 1 and those of Annex I, Parts 1 to 3, of each of those Directives.

The provisions of Directive 76/767/EEC⁽¹⁾ shall no longer apply from 1 July 2001 or, in the case of Article 18, within two years of that date, for transportable pressure equipment falling within the scope of this Directive.

However, EEC pattern approval certificates for cylinders, issued pursuant to Directives 84/525/EEC, 84/526/EEC and 84/527/EEC shall be recognised as equivalent to the EC type-examination certificates provided for in this Directive.

Article 21

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

Article 22

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1999.

For the Council

The President

W. MÜLLER

⁽¹⁾ Council Framework Directive 76/767/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to common provisions for pressure vessels and methods of inspecting them (OJ L 262, 27.9.1976, p. 153). Directive as last amended by the 1994 Act of Accession.

ANNEX I

MINIMUM CRITERIA TO BE MET BY NOTIFIED OR APPROVED BODIES, AS REFERRED TO IN ARTICLES 8 AND 9

1. A notified inspection body or an approved inspection body that is part of an organisation involved in functions other than inspection must be identifiable within that organisation.
 2. The inspection body and its staff must not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities. In particular the staff of the inspection body must be free from any commercial, financial and other pressures which might affect their judgment, particularly from persons or organisations external to the inspection body with an interest in the results of inspections carried out. the impartiality of the inspection staff of the body must be guaranteed.
 3. The inspection body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform the technical and administrative tasks connected with the inspection and verification operations properly. It must also have access to the equipment required to perform special verifications.
 4. The staff of the inspection body who are responsible for inspection must have appropriate qualifications, sound technical and vocational training and a satisfactory knowledge of the requirements of the inspections to be carried out and adequate experience of such operations. In order to guarantee a high level of safety the inspection body must be in a position to provide expertise in the field of safety of transportable pressure equipment. The staff must have the ability to make professional judgments as to conformity with general requirements using examination results and to report thereon. They must also have the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.
 5. They must also have relevant knowledge of the technology used for the manufacturing of the transportable pressure equipment, including accessories, which they inspect, of the way in which the equipment submitted to their inspections is used or is intended to be used, and of the defects which may occur during use or in service.
 6. The inspection body and its staff must carry out the assessments and verifications with the highest degree of professional integrity and technical competence. The inspection body must ensure the confidentiality of information obtained in the course of its inspection activities. Proprietary rights must be protected.
 7. The remuneration of persons engaged in inspection activities must not directly depend on the number of inspections carried out and in no case on the results of such inspections.
 8. The inspection body must have adequate liability insurance unless its liability is assumed by the State in accordance with national laws or by the organisation of which it forms a part.
 9. The inspection body must itself normally perform the inspections which it contracts to undertake. When a inspection body sub-contracts any part of the inspection, it must ensure and be able to demonstrate that its sub-contractor is competent to perform the service in question and must take full responsibility for that sub-contracting.
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*ANNEX II***SUPPLEMENTARY CRITERIA TO BE MET BY THE NOTIFIED BODIES REFERRED TO IN
ARTICLE 8**

1. A notified body must be independent of the parties involved and therefore provide 'third party' inspection services.

The notified body and its staff responsible for carrying out the inspection must not be the designer, manufacturer, supplier, purchaser, owner, holder, user or maintainer of the transportable pressure equipment, including accessories, which that body inspects, nor the authorised representative of any of these parties. They must not be directly involved in the design, manufacture, marketing or maintenance of the transportable pressure equipment, including accessories, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of transportable pressure equipment and the inspection body.

2. All interested parties must have access to the services of the inspection body. There must be no undue financial or other conditions. The procedures under which the body operates must be administered in a non-discriminatory manner.
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*ANNEX III***SUPPLEMENTARY CRITERIA TO BE MET BY THE APPROVED BODIES REFERRED TO IN
ARTICLE 9**

1. The approved body must form a separate and identifiable part of an organisation involved in the design, manufacture, supply, use or maintenance of the items it inspects.
 2. The approved body must not become directly involved in the design, manufacture, supply or use of the transportable pressure equipment, including accessories inspected, or similar competitive items.
 3. There must be a clear separation of the responsibilities of the inspection staff from those of the staff employed in the other functions, which must be established by organisational identification and the reporting methods of the inspection body within the parent organisation.
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ANNEX IV

PART I

CONFORMITY ASSESSMENT PROCEDURES

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer, or his authorised representative established within the Community who carries out the obligations laid down in point 2, ensures and declares that transportable pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a written declaration of conformity.
2. The manufacturer must draw up the technical documentation described in point 3 and either the manufacturer or his authorised representative established within the Community must keep it at the disposal of the relevant national authorities for inspection purposes for a period of 10 years after the last of the transportable pressure equipment has been manufactured. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure equipment on the Community market.
3. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the Directive which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:
 - a general description of the transportable pressure equipment,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the transportable pressure equipment,
 - a description of the solutions adopted to meet the requirements of the Directive,
 - results of the design calculations, examinations carried out, etc.,
 - test reports.
4. The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity with the technical documentation.
5. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured transportable pressure equipment to comply with the technical documentation referred to in point 2 and with the requirements of the Directive which apply to it.

Module A1 (internal manufacturing checks with monitoring of the final assessment)

In addition to the requirements of module A, the following applies.

Final assessment must be performed by the manufacturer and monitored by means of unexpected visits by a notified body chosen by the manufacturer.

During such visits, the notified body must:

- ensure that the manufacturer actually performs final assessment,
- take samples of transportable pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the equipment samples.

Should one or more of the items of transportable pressure equipment not conform, the notified body must take appropriate measures.

On the responsibility of the notified body, the manufacturer must affix that body's identification number to each item of transportable pressure equipment.

Module B (EC type-examination)

1. This module describes the part of the procedure by which a notified body ascertains and attests that a representative example of the production envisaged meets the provisions of the Directive which apply to it.
2. The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community with a single notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative established within the Community, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described in point 3.

The applicant must place at the disposal of the notified body a representative example of the production envisaged, hereinafter called 'type'. The notified body may request further examples should the test programme so require.

A type may cover several versions of transportable pressure equipment provided that the differences between the versions do not affect the level of safety.

3. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the Directive which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:
 - a general description of the type,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the transportable pressure equipment,
 - a description of the solutions adopted to meet the essential requirements of the Directive,
 - results of the design calculations made, examinations carried out, etc.,
 - test reports,
 - information concerning the tests provided for in manufacture,
 - information concerning the qualifications or approvals.
4. The notified body must:
 - 4.1. examine the technical documentation, verify that the type has been manufactured in conformity with it and identify the components designed in accordance with the relevant provisions of the Directive.

In particular, the notified body must:

- examine the technical documentation with respect to the design and the manufacturing procedures,
 - assess the materials used where these are not in conformity with the relevant provisions of the Directive and check the certificate issued by the materials manufacturer,
 - approve the procedures for the permanent joining of pressure equipment parts or check that they have been previously approved,
 - verify that the staff undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved,
- 4.2. perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the requirements of the Directive;
- 4.3. perform or have performed the appropriate examinations and necessary tests to establish whether the relevant provisions of the Directive have been applied;
- 4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.
5. Where the type satisfies the provisions of the Directive which apply to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate, which should be valid for 10 years and be renewable, must contain the name and address of the manufacturer, the conclusions of the examination and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the notified body refuses to issue an EC type-examination certificate to the manufacturer or to his authorised representative established within the Community, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved transportable pressure equipment; these are subject to additional approval where they may affect conformity with the requirements of the Directive or the prescribed conditions for use of the equipment. This additional approval must be given in the form of an addition to the original EC type-examination certificate.
7. Each notified body must communicate to the Member States the relevant information concerning EC type-examination certificates which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn or refused.

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates must be held at the disposal of the other notified bodies.
9. The manufacturer, or his authorised representative established within the Community, must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of 10 years after the last of the transportable pressure equipment has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

Module B1 (EC design examination)

1. This module describes the part of the procedure whereby a notified body ascertains and attests that the design of an item of transportable pressure equipment meets the provisions of the Directive which apply to it.
2. The manufacturer, or his authorised representative established within the Community, must lodge an application for EC design examination with a single notified body.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative established within the Community, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described in point 3.

The application may cover several versions of the transportable pressure equipment provided that the differences between the versions do not affect the level of safety.

3. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the Directive which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:
 - a general description of the equipment in question,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the equipment,
 - a description of the solutions adopted to meet the requirements of the Directive,
 - the necessary supporting evidence for the adequacy of the design solution; this supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,
 - results of the design calculations made, examinations carried out, etc.,
 - information regarding qualifications or approvals.

4. The notified body must:

- 4.1. examine the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the Directive.

In particular, the notified body must:

- assess the materials used where these are not in conformity with the relevant provisions of the Directive,
 - approve the procedures for the permanent joining of pressure equipment parts or check that they have been previously approved,
 - verify that the staff undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved;
- 4.2. perform the necessary examinations to establish whether the solutions adopted by the manufacturer meet the requirements of the Directive;
 - 4.3. perform the necessary examinations to establish whether the relevant provisions of the Directive have actually been applied.

5. Where the design meets the provisions of the Directive which apply to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the name and address of the applicant, the conclusions of the examination, conditions for its validity and the necessary data for identification of the approved design.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the notified body refuses to issue an EC type-examination certificate to the manufacturer or to his authorised representative established within the Community, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved design; these are subject to additional approval where they may affect conformity with the requirements of the Directive or the prescribed conditions for use of the equipment. This additional approval must be given in the form of an addition to the original EC type-examination certificate.
7. Each notified body must communicate to the Member States the relevant information concerning EC design-examination certificates which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn or refused.

8. The other notified bodies may on request obtain the relevant information concerning:

- the EC design-examination certificates and additions granted,
- the EC design-examination certificates and additions withdrawn.

9. The manufacturer, or his authorised representative established within the Community, must keep with the technical documentation referred to in point 3 copies of EC design-examination certificates and their additions for a period of 10 years after the last of the transportable pressure equipment has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the community market.

Module C1 (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer, or his authorised representative established within the Community, ensures and declares that transportable pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a written declaration of conformity.
2. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured transportable pressure equipment to comply with the type as described in the EC type-examination certificate and with the requirements of the Directive which apply to it.
3. The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity for a period of 10 years after the last of the transportable pressure equipment has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure equipment on the Community market.

4. Final assessment must be subject to monitoring in the form of unexpected visits by a notified body chosen by the manufacturer.

During such visits, the notified body must:

- ensure that the manufacturer actually performs final assessment,
- take samples of transportable pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the equipment samples.

Should one or more of the items of transportable pressure equipment not conform, the notified body must take appropriate measures.

On the responsibility of the notified body, the manufacturer must affix that body's identification number to each item of transportable pressure equipment.

Module D (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the transportable pressure equipment concerned is in conformity with the type described in the EC type-examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in point 3 and be subject to surveillance as specified in point 4.
3. *Quality system*

- 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information on the transportable pressure equipment concerned,
- the documentation concerning the quality system,
- the technical documentation for the approved type and a copy of the EC type-examination certificate.

- 3.2. The quality system must ensure compliance of the transportable pressure equipment with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used,
- the examinations 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, reports concerning the qualifications or approvals of the personnel concerned,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2.

The auditing team must have at least one member with experience of assessing the transportable pressure equipment concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

- 4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- where applicable, special conditions linked to the approval of the system,
- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of 10 years after the last of the transportable pressure equipment has been manufactured, hold at the disposal of the national authorities:
 - the documentation referred to in the second indent of 3.1,
 - the adjustments referred to in the second paragraph of 3.4,
 - the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4, and in 4.3 and 4.4.
6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module D1 (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 3 ensures and declares that the items of transportable pressure equipment concerned satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in point 5.
2. The manufacturer must draw up the technical documentation described below.

The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the Directive which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- a general description of the equipment in question,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the equipment,
 - a description of the solutions adopted to meet the requirements of the Directive,
 - results of the design calculations made, examinations carried out, etc.;
 - test reports.
3. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in point 4 and be subject to surveillance as specified in point 5.
 4. *Quality system*
 - 4.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

 - all relevant information on the transportable pressure equipment concerned,
 - the documentation concerning the quality system.
 - 4.2. The quality system must ensure compliance of the transportable pressure equipment with requirements of the Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used,
- the examinations 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, reports concerning the qualifications or approvals of the personnel concerned,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

- 4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 4.2.

The auditing team must have at least one member with experience of assessing the transportable pressure equipment concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

- 4.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in 4.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

5. *Surveillance under the responsibility of the notified body*

- 5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 5.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

- 5.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

5.4. In addition, the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- where applicable, special conditions linked to the approval of the system,
- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

6. The manufacturer must, for a period of 10 years after the last of the transportable pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to in point 2,
- the documentation referred to in the second indent of 4.1,
- the adjustments referred to in the second paragraph of 4.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 4.3, in the last paragraph of 4.4, and in 5.3 and 5.4.

7. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the item of transportable pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to each product and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in point 4.

2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in point 3 and be subject to surveillance as specified in point 4.

3. *Quality system*

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information on the transportable pressure equipment concerned,
- the documentation concerning the quality system,
- the technical documentation for the approved type and a copy of the EC type-examination certificate.

- 3.2. Under the quality system, each item of transportable pressure equipment must be examined and appropriate tests must be carried out in order to ensure its conformity with the requirements of the Directive which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment,
- the examinations and tests to be carried out after manufacture,
- the means of monitoring the effective operation of the quality system,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2.

The auditing team must have at least one member with experience of assessing the transportable pressure equipment concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

- 4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- where applicable, special conditions linked to the approval of the system,
- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of 10 years after the last of the transportable pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to in the second indent of 3.1,
- the adjustments referred to in the second paragraph of 3.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4, and in 4.3 and 4.4.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E1 (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 3 ensures and declares that the transportable pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in point 5.

2. The manufacturer must draw up the technical documentation described below.

The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the Directive which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- a general description of the equipment in question,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the equipment,
- a description of the solutions adopted to meet the requirements of the Directive,
- results of the design calculations made, examinations carried out, etc.;
- test reports.

3. The manufacturer must operate an approved quality system for the final transportable pressure equipment inspection and testing as specified in point 4 and be subject to surveillance as specified in point 5.

4. *Quality system*

- 4.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information on the transportable pressure equipment concerned,
- the documentation concerning the quality system.

- 4.2. Under the quality system, each item of transportable pressure equipment must be examined and appropriate tests must be carried out in order to ensure its conformity with the requirements of the Directive which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment,
- the procedures used for the joining of parts,
- the examinations and tests to be carried out after manufacture,
- the means of monitoring the effective operation of the quality system,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the staff concerned.

- 4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 4.2.

The auditing team must have at least one member with experience of assessing the transportable pressure equipment concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

- 4.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorised representative established within the Community, must inform the notified body which has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in 4.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

5. *Surveillance under the responsibility of the notified body*

- 5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 5.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:
- the quality system documentation,
 - the technical documentation,
 - the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.
- 5.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.
- 5.4. In addition, the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:
- the category of the equipment,
 - the results of previous surveillance visits,
 - the need to follow up corrective action,
 - where applicable, special conditions linked to the approval of the system,
 - significant changes in manufacturing organisation, policy or techniques.
- During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.
6. The manufacturer must, for a period of 10 years after the last of the transportable pressure equipment has been manufactured, hold at the disposal of the national authorities:
- the documentation referred to in section 2,
 - the documentation referred to in the third indent of 4.1,
 - the adjustments referred to in the second paragraph of 4.4,
 - the decisions and reports from the notified body which are referred to in the last paragraph of 4.3, in the last paragraph of 4.4, and in 5.3 and 5.4.
7. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module F (product verification)

1. This module describes the procedure whereby a manufacturer, or his authorised representative established within the Community, ensures and declares that the transportable pressure equipment subject to the provisions of point 3 is in conformity with the type described:
- in the EC type-examination certificate, or
 - in the EC design-examination certificate,
- and satisfies the requirements of the Directive which apply to it.
2. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the transportable pressure equipment to comply with the type described:
- in the EC type-examination certificate, or
 - in the EC design-examination certificate,
- and with the requirements of the Directive which apply to it.

The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a declaration of conformity.

3. The notified body must perform the appropriate examinations and tests in order to check the conformity of the transportable pressure equipment with the relevant requirements of the Directive by examining and testing every product in accordance with point 4.

The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity for a period of 10 years after the last of the transportable pressure equipment has been manufactured.

4. *Verification by examination and testing of each item of transportable pressure equipment*

- 4.1. Each item of transportable pressure equipment must be individually examined and must undergo appropriate examinations and tests in order to verify that it conforms to the type and the requirements of the Directive which apply to it.

In particular, the notified body must:

- verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved,
- check the certificate issued by the materials manufacturer,
- carry out the final inspection and proof test or have them carried out and, where appropriate, examine the safety devices.

- 4.2. The notified body must affix its identification number or have it affixed to each item of transportable pressure equipment and draw up a written certificate of conformity relating to the tests carried out.

- 4.3. The manufacturer, or his authorised representative established within the Community, must ensure that the certificates of conformity issued by the notified body can be made available on request.

Module G (EC unit verification)

1. This module describes the procedure whereby the manufacturer ensures and declares that transportable pressure equipment which has been issued with the certificate referred to in point 4.1 satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to the equipment and draw up a declaration of conformity.
2. The manufacturer must apply to a notified body of his choice for unit verification. The application must contain:
 - the name and address of the manufacturer and the location of the transportable pressure equipment,
 - a written declaration to the effect that a similar application has not been lodged with another notified body,
 - technical documentation.
3. The technical documentation must enable the conformity of the transportable pressure equipment with the requirements of the Directive which apply to it to be assessed and the design, manufacture and operation of the transportable pressure equipment to be understood.

The technical documentation must contain:

- a general description of the equipment in question,
 - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the equipment,
 - results of design calculations made, examinations carried out, etc.,
 - test reports,
 - appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the staff concerned.
4. The notified body must examine the design and construction of each item of transportable pressure equipment and during manufacture perform appropriate tests to ensure its conformity with the requirements of the Directive which apply to it.
- 4.1. The notified body must affix its identification number or have it affixed to the transportable pressure equipment and draw up a certificate of conformity for the tests carried out. This certificate must be kept for a period of 10 years.
- 4.2. The manufacturer, or his authorised representative established within the Community, must ensure that the declaration of conformity and certificate of conformity issued by the notified body can be made available on request.

In particular, the notified body must:

- examine the technical documentation with respect to the design and the manufacturing procedures,
- assess the materials used where these are not in conformity with the relevant provisions of the Directive and check the certificate issued by the materials manufacturer,
- approve the procedures for the permanent joining of pressure equipment parts,
- verify the qualifications or approvals required,
- perform the final inspection, perform the proof test or have it performed and examine the safety devices if applicable.

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the transportable pressure equipment in question satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for the surveillance referred to in point 4.
2. The manufacturer must implement an approved quality system for design, manufacture, final inspection and testing as specified in point 3 and be subject to surveillance as specified in point 4.
3. *Quality system*
 - 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information concerning the transportable pressure equipment in question,
- the documentation concerning the quality system.

- 3.2. The quality system must ensure compliance of the transportable pressure equipment with the requirements of the Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the procedural and quality measures such as programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality,
- the technical design specifications, including standards, that will be applied,
- the design control and design verification techniques, processes and systematic measures that will be used when designing the transportable pressure equipment,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used,
- the examinations and tests to 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, reports concerning the qualifications or approvals of the personnel concerned,
- the means of monitoring the achievement of the required transportable pressure equipment design and quality and the effective operation of the quality system.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2.

The auditing team must have at least one member with experience of assessing the transportable pressure equipment concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of this surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,
 - the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests, etc.,
 - the quality records provided for in the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the staff concerned, etc.
- 4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:
- the category of the equipment,
 - the results of previous surveillance visits,
 - the need to follow up corrective action,
 - where applicable, special conditions linked to the approval of the system,
 - significant changes in manufacturing organisation, policy or techniques.
- During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.
5. The manufacturer must, for a period of 10 years after the last of the transportable pressure equipment has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in the second indent of the second paragraph of 3.1,
 - the adjustments referred to in the second paragraph of 3.4,
 - the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4, and in 4.3 and 4.4.
6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module H1 (full quality assurance with design examination and special surveillance of the final test)

1. In addition to the requirements of module H, the following apply:
- (a) the manufacturer must lodge an application for examination of the design with the notified body;
 - (b) the application must enable the design, manufacture and operation of the transportable pressure equipment to be understood, and enable conformity with the relevant requirements of the Directive to be assessed.

It must include:

- the technical design specifications, including standards, which have been applied,
 - the necessary supporting evidence for their adequacy. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf;
- (c) the notified body must examine the application and where the design meets the provisions of the Directive which apply to it issue an EC design-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the transportable pressure equipment;
- (d) the applicant must inform the notified body that has issued the EC design-examination certificate of all modifications to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design-examination certificate where they may affect conformity with the requirements of the Directive or the prescribed conditions for use of the transportable pressure equipment. This additional approval must be given in the form of an addition to the original EC design-examination certificate;
- (e) each notified body must also communicate to the other notified bodies the relevant information concerning the EC design-examination certificates it has withdrawn or refused.
2. Final assessment is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body must conduct examinations on the transportable pressure equipment.

PART II

CONFORMITY REASSESSMENT PROCEDURE

1. This procedure describes the method for ensuring that transportable pressure equipment placed on the market as defined in Article 1(2)(b) complies with the relevant requirements of Directive 94/55/EC and 96/49/EC.
2. The user must make available to a notified body information regarding transportable pressure equipment placed on the market which enables that body to identify the equipment precisely (origin, design rules and, for acetylene cylinders, also details of the porous mass). The user must, where appropriate, notify any prescribed restrictions on use, and forward any notes on possible damage or repairs which have been carried out.

The notified body must also check that valves and other accessories having a direct safety function ensure a level of safety in line with that defined pursuant to Article 3 of this Directive.

3. The notified body must check whether transportable pressure equipment which has been placed on the market affords at least the same degree of safety as the transportable pressure equipment referred to in Directive 94/55/EC and 96/49/EC. The check must be carried out on the basis of documents produced in accordance with point 2 and, where appropriate, of further inspections.
4. If the results of the above checks are satisfactory, the transportable pressure equipment must be subject to the periodic inspection provided for in Annex IV, Part III.
5. For receptacles manufactured in series, including their valves and other accessories used for transport, the relevant conformity reassessment operations relating to individual inspections of equipment, as indicated in points 3 and 4 above, may be carried out by an approved body provided that a notified body has previously carried out the relevant conformity reassessment operations indicated in point 3.

PART III

PROCEDURES FOR PERIODIC INSPECTION

Module 1 (periodic inspection of products)

1. This module describes the procedure whereby an owner or his authorised representative established within the Community or the holder ensures that the transportable pressure equipment subject to point 3 continues to meet the requirements of this Directive.
2. To meet the requirements referred to in point 1 the owner or his authorised representative established in the Community or the holder must take all measures necessary to ensure that the conditions of use and of maintenance ensure the continued conformity of the transportable pressure equipment to the requirements of this Directive, in particular so that:
 - the transportable pressure equipment is used as intended,
 - it is filled in appropriate filling centres,
 - any maintenance work or repairs are carried out,
 - the periodic inspections necessary are carried out.

The measures carried out must be recorded in documents and held at the disposal of the national authorities by the owner or his authorised representative established in the Community or the holder.

3. The inspection body must perform the appropriate examinations and tests in order to check the conformity of the transportable pressure equipment with the relevant requirements of the Directive by examining and testing every product.
 - 3.1. All transportable pressure equipment must be examined individually and appropriate tests, as set out in the Annexes to Directives 94/55/EC and 96/49/EC, must be carried out in order to check that it meets the requirements of those Directives.
 - 3.2. The inspection body must affix its identification number or have it affixed to each product being periodically inspected immediately after the date of periodic inspection and draw up a written periodic-inspection certificate. That certificate may cover a number of items of equipment (group certificate).
 - 3.3. The owner or his authorised representative established in the Community or the holder must keep the periodic-inspection certificate required under section 3.2, and the documents required under point 2 at least until the next periodic inspection.

Module 2 (periodic inspection through quality assurance)

1. This module describes the following procedures:
 - the procedure whereby the owner or his authorised representative established in the Community or the holder, who satisfies the obligations of point 2, ensures and declares that the transportable pressure equipment continues to meet the requirements of the Directive. The owner or his authorised representative established in the Community or the holder must affix the date of periodic inspection to all transportable pressure equipment and draw up a written declaration of conformity. The date of periodic inspection must be accompanied by the identification number of the notified body responsible for surveillance as specified in point 4,
 - the procedure whereby, in the case of periodic inspection of tanks performed by the approved body in accordance with the second paragraph of Article 6(1), the approved body which satisfies the obligations of the last paragraph of point 2, certifies that the transportable pressure equipment continues to meet the requirements of this Directive. The approved body must affix the date of periodic inspection to all transportable pressure equipment and draw up a periodic inspection certificate.

The date of periodic inspection must be accompanied by the identification number of the approved body.

2. The owner or his authorised representative established in the Community or the holder must take all steps necessary to ensure that the conditions of use and of maintenance are such as to enable the transportable pressure equipment to comply permanently with the requirements of this Directive and in particular that:

- the transportable pressure equipment is used as intended,
- it is filled in appropriate filling centres,
- any maintenance work or repairs are carried out,
- the periodic inspections necessary are carried out.

The measures carried out must be recorded in documents and held by the owner or his authorised representative established in the Community or the holder at the disposal of the national authorities.

The owner or his authorised representative established within the Community or the holder must ensure that the qualified staff and necessary facilities within the meaning of Annex I, points 3 to 6, are available for the purpose of the periodic inspections.

The owner or his authorised representative established in the Community or the holder or the approved body must operate an approved quality system for the periodic inspection and tests of the equipment as specified in point 3, and be subject to surveillance as specified in point 4.

3. *Quality system*

- 3.1. The owner or his authorised representative established in the Community or the holder or the approved body must lodge an application for assessment of his quality system for the transportable pressure equipment with a notified body of his choice.

The application must include:

- all relevant information on the transportable pressure equipment being submitted for periodic inspection,
- the documentation regarding the quality system.

- 3.2. Under the quality system, each item of transportable pressure equipment must be examined and appropriate tests must be carried out in order to ensure its conformity with the requirements set out in the Annexes to Directives 94/55/EC and 96/49/EC. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment,
- the examinations and tests to be carried out for the periodic inspection,
- the means of monitoring the effective operation of the quality system,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the staff concerned.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2.

The auditing team must have at least one member with experience of assessing the transportable pressure equipment concerned. The assessment procedure must include an inspection visit to the premises of the owner or of his authorised representative established in the Community or of the holder or of the approved body.

The decision must be notified to the owner or this authorised representative established in the Community or to the holder or the approved body. The notification must contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. The owner or his authorised representative established in the Community or the holder or the approved body must undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The owner or his authorised representative established in the Community or the holder or the approved body must inform the notified body which has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in 3.2 or whether a reassessment is required.

It must notify its decision to the owner or his authorised representative established in the Community or to the holder or the approved body. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the owner or his authorised representative established in the Community or the holder or the approved body duly fulfils the obligations arising out of the approved quality system.

- 4.2. The owner or his authorised representative established in the Community or the holder or the approved body must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, reports concerning the qualifications of the personnel concerned, etc.

- 4.3. The notified body must carry out periodic audits to make sure that the owner or his authorised representative established in the Community or the holder or the approved body maintains and applies the quality system and provide the owner or his authorised representative established in the Community or the holder or the approved body with an audit report.

- 4.4. In addition, the notified body may pay unannounced visits to the owner or his authorised representative established in the Community or the holder or the approved body. During such visits, the notified body may if necessary perform tests or have tests performed to verify if necessary that the quality system is functioning correctly. The notified body must provide the owner or his authorised representative established in the Community or the holder or the approved body with a visit report and, if a test has taken place, with a test report.

5. The owner or his authorised representative established in the Community or the holder or the approved body must, for a period of 10 years from the date of the last periodic inspection of the transportable pressure equipment, hold at the disposal of the national authorities:

- the documentation referred to in the second indent of the second paragraph of 3.1,
 - the adjustments referred to in the second paragraph of 3.4,
 - the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4 and in 4.3 and 4.4.
-

ANNEX V

MODULES TO BE FOLLOWED FOR CONFORMITY ASSESSMENT

The following table indicates which conformity assessment modules as described in Annex IV, Part I, are to be followed for the transportable pressure equipment defined in Article 2(1).

Category of transportable pressure equipment	Modules
1. Receptacles for which the product of the test pressure and the capacity is no more than 100 MPa × litre (1 000 bar × litre)	A1, or B in combination with C1
2. Receptacles for which the product of the test pressure and the capacity is more than 100 and no more than 300 MPa × litre (1 000 and 3 000 bar × litre respectively)	H, or B in combination with E, or B in combination with C1
3. Receptacles for which the product of the test pressure and the capacity exceeds 300 MPa × litre (3 000 bar × litre), and tanks	G, or H1, or B in combination with D, or B in combination with F

1. Transportable pressure equipment must be subject, at the choice of the manufacturer, to one of the conformity assessment procedures laid down for the category in which it is classified. In the case of receptacles or their valves or other accessories used for transport, the manufacturer may also choose to apply one of the set procedures for the higher categories.
2. As part of the quality assurance procedures, the notified body must, when making unannounced visits, take a sample of the equipment at the manufacturing or storage premises for the purpose of carrying out a check, or having a check carried out, in conformity to the requirements of this Directive. For this purpose the manufacturer must inform the notified body of the production programme planned. The notified body must make at least two visits during the first year of manufacture. The frequency of subsequent visits will be determined by the notified body on the basis of the criteria set out in point 4.4 of the relevant modules in Annex IV, Part I.

ANNEX VI

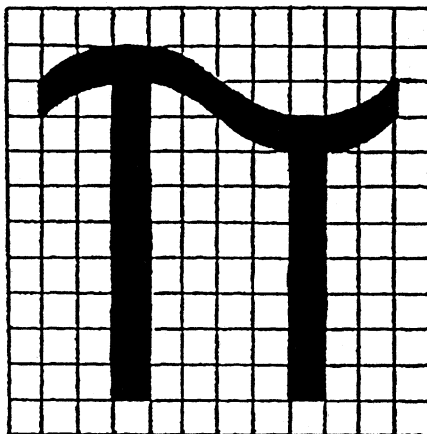
LIST OF DANGEROUS SUBSTANCES OTHER THAN THOSE IN CLASS 2 REFERRED TO IN
ARTICLE 2

UN number	Class	ADR/RID figures	Dangerous substances
1051	6.1	1	Stabilised hydrogen cyanide
1052	8	6	Anhydrous hydrogen fluoride
1790	8	6	Hydrofluoric acid

ANNEX VII

MARK OF CONFORMITY

The conformity mark shall take the following form:



If the mark is reduced or enlarged, the proportions of the above drawing must be respected.

The various components of the mark must have substantially the same vertical dimensions, which may not be less than 5 mm.

This minimum dimension may be waived for small devices.

COUNCIL DIRECTIVE 1999/37/EC
of 29 April 1999
on the registration documents for vehicles

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 75(1)(d) thereof,

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

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

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

Council Directive 91/439/EEC of 29 July 1991 on driving licences⁽⁴⁾ drives solely those categories of vehicles for which he is authorised; whereas such checking helps to improve road safety;

(1) Whereas the Community has adopted a certain number of measures that are intended to create an internal market consisting of an area without frontiers within which the free movement of goods, persons, services and capital is guaranteed in accordance with the provisions of the Treaty;

(2) Whereas all of the Member States require the driver of a vehicle registered in another Member State to hold the certificate of registration corresponding to that vehicle, in order for it to be permitted to use the roads on their territory;

(3) Whereas harmonisation of the form and content of the registration certificate will facilitate its comprehension and thus help towards the free movement, on the roads in the territory of the other Member States, of vehicles registered in a Member State;

(4) Whereas the content of the registration certificate must enable it to be checked that the holder of a driving licence issued pursuant to

(5) Whereas, as a prerequisite for registering a vehicle that has previously been registered in another Member State, all of the Member States require a document certifying that registration and the technical characteristics of the vehicle;

(6) Whereas harmonisation of the registration certificate will facilitate the re-entry into service of vehicles that have previously been registered in another Member State, and will contribute to the proper functioning of the internal market;

(7) Whereas Member States use a registration certificate consisting either of one single part or two separate parts, and whereas it is currently appropriate to allow both systems to coexist;

(8) Whereas differences remain between the Member States concerning the interpretation of the particulars contained in the registration certificate; whereas, in the interests of the proper functioning of the internal market and of the free movement and checks that these involve, it is therefore appropriate to specify in which capacity the persons named in the certificate may use the vehicle for which it was issued;

(9) Whereas, in order to facilitate those checks specifically intended to combat fraud and the illegal trade in stolen vehicles, it is appropriate to establish close cooperation between Member States, based on an effective exchange of information;

(10) Whereas it is appropriate to provide for a simplified procedure for adjusting the technical aspects contained in Annexes I and II

⁽¹⁾ OJ C 202, 2.7.1997, p. 13 and OJ C 301, 30.9.1998, p. 8.

⁽²⁾ OJ C 19, 21.1.1998, p. 17.

⁽³⁾ Opinion of the European Parliament of 28 May 1998 (OJ C 195, 22.6.1998, p. 21) Council Common Position of 3 November 1998 (OJ C 388, 14.12.1998, p. 12) and Decision of the European Parliament of 25 February 1999 (not yet published in the Official Journal).

⁽⁴⁾ OJ L 237, 24.8.1991, p. 1. Directive as last amended by Directive 97/26/EC (OJ L 150, 7.6.1997, p. 41).

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive shall apply to the documents issued by the Member States at the time of registration of vehicles.

It shall not prejudice the right of Member States to use, for the temporary registration of vehicles, documents which may not meet the requirements of this Directive in every respect.

Article 2

For the purposes of this Directive:

- (a) 'vehicle': shall mean any vehicle as defined in Article 2 of 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⁾ and in Article 1 of Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles⁽²⁾;
- (b) 'registration': shall mean the administrative authorisation for the entry into service in road traffic of a vehicle, involving the identification of the latter and the issuing to it of a serial number, to be known as the registration number;
- (c) 'registration certificate': shall mean the document which certifies that the vehicle is registered in a Member State;
- (d) 'holder of the registration certificate': shall mean the person in whose name a vehicle is registered.

Article 3

1. Member States shall issue a registration certificate for vehicles which are subject to registration under their national legislation. The certificate shall consist of either a single part in accordance with Annex I or two parts in accordance with Annexes I and II.

Member States may authorise the services they appoint to this end, in particular those of the manufacturers, to fill in the technical parts of the registration certificate.

⁽¹⁾ OJ L 42, 23.2.1970, p. 1. Directive as last amended by Commission Directive 98/14/EC (OJ L 91, 25.3.1998, p. 1).

⁽²⁾ OJ L 225, 10.8.1992, p. 72. Directive as amended by the 1994 Act of Accession.

2. Where a new registration certificate is issued for a vehicle registered prior to the implementation of this Directive, Member States shall use a certification model as defined in this Directive and may limit the particulars shown therein to those for which the required data are available.

3. The data given in the registration certificate, in accordance with Annexes I and II, shall be represented by the harmonised Community codes shown in those Annexes.

Article 4

For the purposes of this Directive, the registration certificate issued by a Member State shall be recognised by the other Member States for the identification of the vehicle in international traffic or for its re-registration in another Member State.

Article 5

1. For the purposes of identifying a vehicle in road traffic, Member States may require that the driver carry Part I of the registration certificate.

2. With a view to re-registering a vehicle previously registered in another Member State, the competent authorities shall require the submission of Part I of the previous registration certificate in every case and the submission of Part II if it was issued. These authorities shall withdraw the part(s) of the previous registration certificate submitted and shall keep the latter for a minimum of six months. They shall, within two months, inform the authorities of the Member State which delivered the certificate of its withdrawal. They shall return the certificate which they have withdrawn to those authorities if they so request within six months of its withdrawal.

Where the registration certificate consists of Parts I and II, and Part II is missing, the competent authorities in the Member State where the new registration has been requested may decide, in exceptional cases, to re-register the vehicle, but only after having obtained confirmation, in writing or by electronic means, from the competent authorities in the Member State where the vehicle was previously registered, that the applicant is entitled to re-register the vehicle in another Member State.

Article 6

Any amendments necessary in order to adapt the Annexes to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 7.

Article 7

1. Where reference is made to the procedure provided for in this Article, the Commission shall be assisted by the committee established by Article 8 of Council Directive 96/96/EC of 20 December 1996 on the approximation of the laws of the Member States relating to roadworthiness tests for motor vehicles and their trailers⁽¹⁾, hereinafter referred to as the 'committee', which shall consist of representatives of the Member States with a representative of the Commission in the chair.

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

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

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

If, within three months of the submission of the proposal to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 8

1. Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive by 1 June 2004. They shall notify the Commission thereof immediately.

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

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

The Commission shall communicate to the Member States all the models for registration certificates used by the national administration.

Article 9

Member States shall assist one another in the implementation of this Directive. They may exchange information at bilateral or multilateral level in particular so as to check, before any registration of a vehicle, the latter's legal status, where necessary in the Member State in which it was previously registered. Such checking may in particular involve the use of an electronic network.

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1999.

For the Council
The President
W. MÜLLER

⁽¹⁾ OJ L 46, 17.2.1997, p. 1.

ANNEX I

PART I OF THE REGISTRATION CERTIFICATE⁽¹⁾

- I. The overall dimensions of the registration certificate shall not be greater than an A4 format (210×297 mm) or a folder of A4 format.
- II. The paper used for Part I of the registration certificate shall be made secure against forgery by using at least two of the following techniques:
 - graphics,
 - watermark,
 - fluorescent fibres, or,
 - fluorescent imprints.
- III. Part I of the registration certificate may consist of several pages. Member States shall determine the number of pages in accordance with the information contained in the document and its layout.
- IV. The first page of Part I of the registration certificate shall contain:
 - the name of the Member State issuing Part I of the registration certificate,
 - the distinguishing mark of the Member State issuing Part I of the registration certificate, namely:

B	Belgium	L	Luxembourg
DK	Denmark	NL	Netherlands
D	Germany	A	Austria
GR	Greece	P	Portugal
E	Spain	FIN	Finland
F	France	S	Sweden
IRL	Ireland	UK	United Kingdom,
I	Italy		
 - the name of the competent authority,
 - the words 'Part I of the Registration Certificate' or, if the certificate consists of one part only, the words 'Registration Certificate', printed in large type in the language or languages of the Member States issuing the registration certificate; they shall also appear, after a suitable space, in small type in the other languages of the European Community,
 - the words 'European Community', printed in the language or languages of the Member State issuing Part I of the registration certificate,
 - the number of the document.
- V. Part I of the registration certificate shall also contain the following data, preceded by the corresponding harmonised Community codes:
 - (A) registration number
 - (B) date of first registration of the vehicle

⁽¹⁾ The certificate consisting of one part only will bear the words 'Registration Certificate', and there will be no reference in the text to 'Part I.'

- (C) personal data
 - (C.1) holder of the registration certificate:
 - (C.1.1) surname or business name
 - (C.1.2) other name(s) or initial(s) (where appropriate)
 - (C.1.3) address in the Member State of registration on the date of issue of the document
 - (C.4) Where the particulars specified in VI, code C.2 are not included in the registration certificate, reference to the fact that the holder of the registration certificate:
 - (a) is the vehicle owner
 - (b) is not the vehicle owner
 - (c) is not identified by the registration certificate as being the vehicle owner
- (D) vehicle:
 - (D.1) make
 - (D.2) type
 - variant (if available)
 - version (if available)
 - (D.3) commercial description(s)
- (E) vehicle identification number
- (F) mass:
 - (F.1) maximum technically permissible laden mass, except for motorcycles
- (G) mass of the vehicle in service with bodywork, and with coupling device in the case of a towing vehicle in service from any category other than M₁
- (H) period of validity, if not unlimited
- (I) date of the registration to which this certificate refers
- (K) type-approval number (if available)
- (P) engine
 - (P.1) capacity (in cm³)
 - (P.2) maximum net power (in kW) (if available)
 - (P.3) type of fuel or power source
- (Q) power/weight ratio (in kW/kg) (only for motorcycles)
- (S) seating capacity
 - (S.1) number of seats, including the drivers seat
 - (S.2) number of standing places (where appropriate)

VI. Part I of the registration certificate may, moreover, contain the following data, preceded by the corresponding harmonised Community codes:

- (C) personal data
 - (C.2) owner of the vehicle
 - (C.2.1) surname or business name
 - (C.2.2) other name(s) or initial(s) (where appropriate)
 - (C.2.3) address in the Member State of registration, on the date of issue of the document

- (C.3) natural or legal person who may use the vehicle by virtue of a legal right other than that of ownership
 - (C.3.1) surname or business name
 - (C.3.2) other name(s) or initial(s) (where appropriate)
 - (C.3.3) address in the Member State of registration, on the date of issue of the document
- (C.5), (C.6), (C.7), (C.8) where a change in the personal data given in points V, code C.1, VI, code C.2 and/or VI, code C.3 does not give rise to the issue of a new registration certificate, the new personal data corresponding to these points may be included under codes (C.5), (C.6), (C.7) or (C.8); they are then broken down in accordance with the references in points V, code C.1, VI, code C.2, VI, code C.3 and V, code C.4.
- (F) mass:
 - (F.2) maximum permissible laden mass of the vehicle in service in the Member State of registration
 - (F.3) maximum permissible laden mass of the whole vehicle in service in the Member State of registration
- (J) vehicle category
- (L) number of axles
- (M) wheelbase (in mm)
- (N) for vehicles with a total exceeding 3 500 kg, distribution of the technically permissible maximum laden mass among the axles:
 - (N.1) axle 1 (in kg)
 - (N.2) axle 2 (in kg), where appropriate
 - (N.3) axle 3 (in kg), where appropriate
 - (N.4) axle 4 (in kg), where appropriate
 - (N.5) axle 5 (in kg), where appropriate
- (O) technically permissible maximum towable mass of the trailer:
 - (O.1) braked (in kg)
 - (O.2) unbraked (in kg)
- (P) engine:
 - (P.4) rated speed (in min⁻¹)
 - (P.5) engine identification number
- (R) colour of the vehicle
- (T) maximum speed (in km/h)
- (U) sound level:
 - (U.1) stationary (in dB(A))
 - (U.2) engine speed (in min⁻¹)
 - (U.3) drive-by (in dB(A))

(V) exhaust emissions:

(V.1) CO (in g/km or G/kWh)

(V.2) HC (in g/km or g/kWh)

(V.3) NO_x (in g/km or g/kWh)

(V.4) HC+NO_x (in g/km)

(V.5) particulates for diesel (in g/km or g/kWh)

(V.6) corrected absorption coefficient for diesel (in min⁻¹)

(V.7) CO₂(in g/km)

(V.8) combined fuel consumption (in L/100 km)

(V.9) indication of the environmental category of EC type-approval; reference to the version applicable pursuant to Directive 70/220/EEC⁽¹⁾ or Directive 88/77/EEC⁽²⁾.

(W) fuel tank(s) capacity (in litres).

VII. Member States may include additional information (in Part I of the registration certificate), in particular they may add between brackets to the identification codes, as laid down under V and VI, additional national codes.

⁽¹⁾ Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles (OJ L 76, 6.4.1970, p. 1.), Directive as last amended by Directive 96/69/EC of the European Parliament and of the Council (OJ L 282, 1.11.1996, p. 64).

⁽²⁾ Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles (OJ L 36, 9.2.1988, p. 33). Directive as last amended by Directive 96/1/EC (OJ L 40, 17.2.1996, p. 1).

ANNEX II

PART II OF THE REGISTRATION CERTIFICATE ⁽¹⁾

- I. The dimensions of the registration certificate shall not be greater than an A4 format (210×297 mm) or a folder of A4 format:
- II. The paper used for part II of the registration certificate shall be made secure against forgery by using at least two of the following techniques:
 - graphics,
 - watermark,
 - fluorescent fibres, or,
 - fluorescent imprints.
- III. Part II of the registration certificate may consist of several pages. Member States shall determine the number of pages in accordance with the information contained in the document and its layout.
- IV. The first page of Part II of the registration certificate shall contain
 - the name of the Member State issuing Part II of the registration certificate,
 - the distinguishing mark of the Member State issuing Part II of the registration certificate, namely:

B	Belgium	L	Luxembourg
DK	Denmark	NL	Netherlands
D	Germany	A	Austria
GR	Greece	P	Portugal
E	Spain	FIN	Finland
F	France	S	Sweden
IRL	Ireland	UK	United Kingdom,
I	Italy		
 - the name of the competent authority,
 - the words 'Part II of the Registration Certificate', printed in large type in the language or languages of the Member States issuing the registration certificate; they shall also appear, after a suitable space, in small type, in the other languages of the European Community,
 - the words 'European Community', printed in the language or languages of the Member State issuing Part II of the registration certificate,
 - the number of the document.
- V. Part II of the registration certificate shall also contain the following data, preceded by the corresponding harmonised Community codes:
 - (A) registration number
 - (B) date of the first registration of the vehicle
 - (D) vehicle:

⁽¹⁾ This Annex is concerned only with registration certificates consisting of Parts I and II.

- (D.1) make
 - (D.2) type
 - variant (if available)
 - version (if available)
 - (D.3) commercial description(s)
 - (E) vehicle identification number
 - (K) type-approval number (if available)
- VI. Part II of the registration certificate may, moreover, contain the following data, preceded by the corresponding harmonised Community codes:
- (C) personal data
 - (C.2) owner of the vehicle
 - (C.2.1) surname or business name
 - (C.2.2) other name(s) or initial(s) (where appropriate)
 - (C.2.3) address in the Member State of registration, on the date of issue of the document
 - (C.3) natural or legal person who may use the vehicle by virtue of a legal right other than that of ownership
 - (C.3.1) surname or business name
 - (C.3.2) other name(s) or initial(s) (where appropriate)
 - (C.3.3) address in the Member State of registration, on the date of issue of the document
 - (C.5), (C.6) where a change in the personal data given in point VI, code C.2 and/or point VI, code C.3 does not give rise to the issue of a new Part II of the registration certificate, the new personal data corresponding to these points may be included under codes (C.5) or (C.6); they are broken down in accordance with point VI, code C.2 and point VI, code C.3.
 - (J) vehicle category
- VII. Member States may include additional information in Part II of the registration certificate; in particular, they may add between brackets to the identification codes, as laid down under points V and VI, additional national codes.
-

COUNCIL DIRECTIVE 1999/38/EC

of 29 April 1999

amending for the second time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work and extending it to mutagens

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 118a thereof,

Having regard to Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁽¹⁾,

Having regard to the proposal from the Commission⁽²⁾, submitted after consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

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

Acting in accordance with the procedure referred to in Article 189c of the Treaty⁽⁴⁾,

(1) Whereas Article 118a of the Treaty provides that the Council shall adopt, by means of Directives, minimum requirements for encouraging improvements, especially in the working environment, to guarantee a better level of protection of the safety and health of workers;

(2) Whereas, under the terms of that Article, such Directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings;

(3) Whereas germ cell mutagens are substances that can cause a permanent change in the amount or structure of the genetic material of a cell resulting in a change in the phenotypic characteristics of that cell, which may be transferred to descendent daughter cells;

(4) Whereas because of their mechanism of action germ cell mutagens are likely to have carcinogenic effects;

(5) Whereas vinyl chloride monomer is classified as a category 1 carcinogen under Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽⁵⁾;

(6) Whereas, for the sake of consistency and clarity, the essential provisions of Council Directive 78/610/EEC of 29 June 1978 on the approximation of the laws, regulations and administrative provisions of the Member States on the protection of the health of workers exposed to vinyl chloride monomer⁽⁶⁾ should be included in this Directive, without reducing the level of protection of the health and safety of workers;

(7) Whereas Directive 78/610/EEC can be repealed after implementation of this Directive;

(8) Whereas the carcinogenicity of oak and beech dusts has been confirmed in epidemiological studies on workers exposed; whereas it is highly probable that other types of hardwood dust can also cause cancer in humans; whereas therefore the workers concerned are exposed to a serious potential risk of developing cancer;

⁽¹⁾ OJ L 196, 26.7.1990, p. 1. Directive as amended by Directive 97/42/EC (OJ L 179, 8.7.1997, p. 4).

⁽²⁾ OJ C 123, 22.4.1998, p. 21.

⁽³⁾ OJ C 284, 14.9.1998, p. 111.

⁽⁴⁾ Opinion of the European Parliament of 22 October 1998 (OJ C 341, 9.11.1998, p. 134), Council Common Position of 22 December 1998 (OJ C 55, 25.2.1999, p. 39) and Decision of the European Parliament of 13 April 1999 (not yet published in the Official Journal).

⁽⁵⁾ OJ L 196, 16.8.1967, p. 1. Directive as last amended by Directive 97/69/EC (OJ L 343, 13.12.1997, p. 19).

⁽⁶⁾ OJ L 197, 22.7.1978, p. 12.

- (9) Whereas the precautionary principle should be applied in the protection of workers' health; whereas therefore Directive 90/394/EEC should be extended to cover all types of hardwood dusts;
- (10) Whereas further research is desirable into the carcinogenicity of other wood dusts; whereas the Commission is to bring forward proposals to protect the health of workers where a risk is identified;
- (11) Whereas Article 16 of Directive 90/394/EEC makes provision for the establishment of limit values in respect of all those carcinogens for which that is possible, on the basis of the available information, including scientific and technical data;
- (12) Whereas it is appropriate to fix such limit values for hardwood dusts; whereas the current limit values for vinyl chloride monomer should be reduced to reflect best minimum standards for technological practices which reflect feasibility factors while maintaining the aim of ensuring the health of workers at work;
- (13) Whereas workers must be effectively protected from the risks of developing cancer as a result of occupational exposure to hardwood dusts; whereas the aim of this Directive is not to restrict the use of wood either by replacing it with other materials or by replacing the use of certain types of wood with other types of wood;
- (14) Whereas compliance with the minimum requirements on protection of the health and safety of workers from the specific risk related to carcinogens is intended not only to ensure the health and safety protection of each individual worker but also to provide a level of minimum protection for all workers in the Community;
- (15) Whereas a consistent level of protection from the risks related to carcinogens has to be established for the Community as a whole, whereas that level of protection has to be set by a framework of general principles to enable Member States to apply the minimum requirements consistently;
- (16) Whereas the amendments contained in this Directive constitute a practical aspect of the realisation of the social dimension of the internal market;

- (17) Whereas, pursuant to Decision 74/325/EEC⁽¹⁾, the Advisory Committee on Safety, Hygiene and Health Protection at Work is to be consulted by the Commission with a view to drawing up proposals in this field,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/394/EEC is hereby amended as follows:

1. Article 1(4) shall be replaced by the following:

‘(4) As regards asbestos, which is dealt with by Directive 83/477/EEC (*) the provisions of this Directive shall apply when they are more favourable to health and safety at work.

(*) OJ L 263, 24.9.1983, p. 25. Directive as last amended by Directive 98/24/EC (OJ L 131, 5.5.1998, p. 11).’;

2. in Article 2, the following point shall be inserted after (a):

‘(aa) “mutagen” means:

(i) a substance which meets the criteria for classification as a category 1 or 2 mutagen set out in Annex VI to Directive 67/548/EEC;

(ii) a preparation composed of one or more substances referred to in (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 mutagen set out in either:

— Annex I to Directive 67/548/EEC, or

— Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;’;

(¹) OJ L 185, 9.7.1974, p. 15. Decision as last amended by the 1994 Act of Accession.

3. In Article 1(1), Article 3(1), (2), first and second indents, and (4), Article 5(5)(c), (d), (e) and (j), Article 6(a) and (b), Article 10(1), introductory wording, and point (a), Article 11(2), Article 14(3), Article 16(1) and Article 17(2), the word 'carcinogens' shall be replaced by 'carcinogens or mutagens';
4. in Article 2(b), Article 4(1), Article 5(2) and (5), heading and point (a), the word 'carcinogen' shall be replaced by 'carcinogen or mutagen';
5. in Annex I the following section shall be added:
- '5. Work involving exposure to hardwood dusts ⁽¹⁾;
- ⁽¹⁾ A list of some hardwoods is to be found in Volume 62 of the Monographs on the Evaluation of Carcinogenic Risks to Humans "Wood Dust and Formaldehyde", published by the International Agency for Research on Cancer, Lyon 1995;';
6. in Annex III, Part A shall be replaced by the following:

'A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EINECS ⁽¹⁾	CAS ⁽²⁾	Limit values		Notation	Transitional measures
			mg/m ³ ⁽³⁾	ppm ⁽⁴⁾		
Benzene	200-753-7	71-43-2	3,25 ⁽⁵⁾	1 ⁽⁵⁾	Skin ⁽⁶⁾	Limit value: 3 ppm (=9,75 mg/m ³) until three years after date in Article 2(1) of Directive 97/42/EC ^(*)
Vinyl chloride monomer	200-831	75-01-4	7,77 ⁽⁵⁾	3 ⁽⁵⁾	—	—
Hardwood dusts	—	—	5,0 ⁽⁵⁾ ⁽⁷⁾	—	—	—

⁽¹⁾ EINECS: European Inventory of Existing Chemical Substances.

⁽²⁾ CAS: Chemical Abstract Service Number.

⁽³⁾ mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

⁽⁴⁾ ppm = parts per million by volume in air (ml/m³).

⁽⁵⁾ Measured or calculated in relation to a reference period of eight hours.

⁽⁶⁾ Substantial contribution to the total body burden via dermal exposure possible.

⁽⁷⁾ Inhalable fraction; if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.

^(*) OJ L 179, 8.7.1997, p. 4.'

Article 2

Directive 78/610/EEC shall be repealed with effect from 29 April 2003.

Article 3

On the basis of the latest available scientific data, the Commission may within two years of the date of the adoption of this Directive, submit a proposal to the Council for the adoption of revised limit values for vinyl chloride monomer and hardwoods dusts in accordance with Article 118a of the Treaty.

Article 4

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 29 April 2003. They shall forthwith inform the Commission thereof.

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

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

Article 6

This Directive is addressed to the Member States.

Article 5

Done at Luxembourg, 29 April 1999.

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

For the Council

The President

W. MÜLLER
