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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on marine equipment and repealing Directive 96/98/EC

(Text with EEA relevance)

{SWD(2012) 437 final}
{SWD(2012) 438 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Background

Marine equipment represents a significant fraction of the value of a newly built ship, and its quality and good operation are critical for the safety of the ship and its crew, as well as for the prevention of maritime accidents and pollution of the marine environment.

The international maritime safety conventions contain specific requirements for ships to be properly equipped; furthermore they require flag States to ensure that the equipment carried on board ships complies with certain safety construction and performance requirements and to issue the relevant certificates. To that end both the International Maritime Organization (IMO) and the international and European standardization bodies produce testing standards for marine equipment. The IMO develops the convention requirements and the testing standards, and keeps them up to date, by means of a number of instruments such as Codes, Resolutions and Circulars.

The international conventions and testing standards leave certain discretion to the flag administrations. Although in general IMO instruments containing requirements and testing standards become mandatory, the IMO tradition to work by consensus may from time to time lead to the adoption of important safety standards for marine equipment by means of non-binding instruments; for the same reason, some IMO instruments occasionally have exceedingly generous deadlines for their implementation or none at all.

In its proposal for a directive on marine equipment, back in 1995, the Commission clearly identified the problems encountered in the Internal Market as a result of this state of affairs and in the absence of EU harmonisation in the marine equipment sector[1]. Member States were reluctant to mutually accept their respective conformity certificates even in the presence of comparable requirements – not at least without additional national controls; the result was multiple approval procedures for the same marine equipment. The Commission noted how harmonisation would lead to the elimination of important administrative barriers and open the internal market to marine equipment certified in the Member States, with significant economies of scale.

Council Directive 96/98/EC of 20 December 1996 on marine equipment[2] (MED) thus laid down common rules to eliminate differences in the implementation of international standards by means of a clearly identified set of requirements and uniform certification procedures. Today, these common rules continue to be necessary to achieve a smooth operation of the internal market in the marine equipment sector while ensuring a high level of safety and of environmental protection.

1.2. Experience gained in the implementation of Directive 96/98/EC

The experience gained in the implementation of the MED has highlighted four areas where the existing Directive does not fully meet its objectives. These are:

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1 Cf. COM (1995) 269 final

2 OJ L 46, 17.2.1997, p. 25.

1.2.1. Identification of applicable requirements. The periodic amendment of Annex A of the directive

The specific technical requirements and testing standards applicable to equipment falling under the scope of the MED are listed in Annex A to the directive. Given the need to keep up with the legislative production of the IMO and, as appropriate, of the international and European standardization bodies, Annex A is in need of periodic updates.

IMO instruments and international standards normally leave a reasonable time between their adoption and their entry into force, ranging in most cases between twelve and twenty-four months. The system must be capable of bringing the new requirements into national legislation within that window, which is currently not the case. Until now, it has never been possible to fully meet the IMO deadlines, and the delay in the incorporation of the IMO requirements into the national legal orders of the Member States has reached peaks of several years.

This generates significant disturbance for the industry, which must produce to different standards for the European and international markets and has difficulties in identifying the applicable requirements. The risk of detention of European ships in foreign ports increases.

1.2.2. Quality of the work of the notified bodies

There is a clearly uneven, where not insufficient, degree of control of notified bodies by Member States administrations. The MED requirements on notified bodies currently do not provide detailed quality benchmarks for the notified bodies themselves or efficient ways of control for the Member States. Given that correctly functioning conformity checking procedures are the first and main line of defence to avoid the entry of non-compliant equipment in the market, concerns have been raised that these weaknesses may be confronting the industry with unfair competition from entities taking advantage of this situation.

1.2.3. Market surveillance

Marine equipment is mostly placed on board when the ship is built or repaired – anywhere in the world and mostly away from the EU's borders. Thus the marine equipment that actually enters the physical territory of the Member States is only a fraction of the equipment covered by the Directive.

However, the MED only allows market surveillance to take place on equipment not yet placed on board and contains no detailed framework – to the point that market surveillance appears as an option rather than an obligation. Therefore the system in the MED does not adapt to the reality of the market and in practice makes it very difficult for the Member States to carry out effective market surveillance.

Market surveillance is therefore unlikely to provide the national authorities with sufficient information to prevent the placing of non-compliant products on board EU ships. This has a direct, negative impact on safety while compliant manufacturers have to face the difficulties associated with unfair competition and counterfeit.

1.2.4. Safeguard clause

Experience has highlighted structural weaknesses in the safeguard clause mechanism as currently laid down in the MED. There is no incentive for a Member State to carry out an

exhaustive procedure during market surveillance and all the way to the adoption of restrictive measures, where sample testing is carried out independently and with sufficient guarantees of reliability. Nothing in the current text obliges the Member States to have a proper hearing of the manufacturer or put at its disposal any appeal mechanisms, let alone to seek voluntary correction of any shortcomings in the first place. This may lead, as in the above mentioned case, to premature notification to the Commission thus transferring to it the detailed examination of the substance. This also places on the Commission a burden which is well beyond its resources and technical capacities, even if the assistance of EMSA is taken into account.

Moreover, the current safeguard clause mechanism is burdensome and lengthy, and thus exposes manufacturers to significant reputational damage for long periods until the case is finally decided.

1.3. The new regulatory framework for the marketing of goods within the EU (NLF)

Regulation 765/2008/EC of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[3] lays down a common EU framework for accreditation and market surveillance. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC[4] sets out the common framework of general principles and reference provisions for the drawing up of EU legislation harmonising the conditions for the marketing of products (EU harmonisation legislation). According to Article 2, EU harmonisation legislation shall have recourse to the general principles set out in this Decision and to the relevant reference provisions of Annexes I, II and III. However, EU legislation may depart from those general principles and reference provisions if that is appropriate on account of the specificities of the sector concerned, especially if comprehensive legal systems are already in place.

1.4. Objectives of the proposal

1.4.1. General objectives

Pursuant to Articles 90 and 91 TFEU, the Common Transport Policy (CTP) should contribute to the broader objectives of the Treaties, and hence the free movement of goods, and include measures to ensure the safety of transport. Within the framework of CTP and taking into account the specificities of marine equipment, the general objective of the proposed initiative is twofold:

- to enhance the implementation and enforcement mechanisms of the MED, thereby guaranteeing the proper functioning of the internal market for marine equipment while ensuring a high level of safety at sea and prevention of marine pollution;
- to simplify the regulatory environment while guaranteeing that IMO requirements are applied and implemented in a harmonised way across the EU, thereby contributing to ensuring that the conditions necessary for the competitiveness of the Union's industry exist pursuant to Article 173 TFEU.

[3] OJ L 218, 13.8.2008, p. 30
[4] OJ L218, 13.8.2008, p.82

1.4.2. Specific objectives

This twofold general objective can be translated into more specific objectives:

- to find an optimal way to align MED on the New Legislative Framework (as required under Article 2 of Decision 768/2008/EC (the NLF Decision) while taking due account of the specificities of marine equipment in the field of market surveillance, conformity assessment of products and obligations of actors in the distribution chain.

- to shorten, simplify and clarify the transposition of amendments to IMO standards into the European and national legal frameworks.

2. RESULTS OF CONSULTATION WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

Further to regular contacts with stakeholders since the coming into force of the MED in 1997, stakeholders were consulted in 2008 when the revision exercise was launched, by means of questionnaires to the Member States, the industry and the MarED group of notified bodies. A formal stakeholder consultation meeting was held on 27 November 2008 in Brussels. In April 2012, all stakeholders were contacted again by the Commission in order to obtain fresher views on the possible amendments of the directive or new data. The answers received largely confirmed the problems already examined.

The impact assessment focused on two alternatives to the baseline (*statu quo*) scenario, namely maximum alignment with the NLF and conditional alignment; in this latter case allowing for a number of MED-specific measures in order to cater for the sector's particular features. The analysis showed that while on the whole both options were appropriate, conditional alignment was the most effective and less burdensome solution and at the same time it had the most positive overall economic, social and environmental impacts.

The Commission's Impact assessment board was consulted twice, namely in September 2009 and in August 2012. The remarks on the initial version led to an in-depth reformulation of the impact assessment, i.a. refining the problem description, restructuring policy options and shortening the document. In its second opinion, the Board formulated a number of additional recommendations which have been incorporated in the final document.

The complete assessment can be found in the impact assessment report accompanying this proposal and is also published online at: http://ec.europa.eu/governance/impact/index_en.htm .

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Legal basis

The legal basis for the proposal is Article 100 (2) TFEU.

3.2. Subsidiarity and proportionality principles

The principles of subsidiarity and proportionality are fully respected.

Harmonisation by the EU results in a clearly identified set of requirements and uniform certification procedures capable of ensuring a high level of safety and of environmental protection whilst fostering the smooth functioning of the internal market.

The objectives of the EU in the marine equipment sector cannot be sufficiently achieved by the action of the Member States alone; they can be better achieved thanks to EU action.

However, the proposed Directive does not contain the detailed technical specifications applicable to marine equipment falling under its scope, but limits itself to mandating compliance with the requirements and testing standards contained in the international instruments while providing a mechanism to implement those requirements and standards in a uniform way. While conformity-checking procedures are harmonised, implementation is left entirely to the Member States, who remain responsible for ensuring that marine equipment due to be placed on board EU ships meets the requirements of the Directive. In case restrictive measures are adopted by a Member State as regards non-compliant equipment, the Commission is required to intervene only if objections are raised against these measures within a reasonable time. Therefore EU action does not go beyond what is strictly necessary to achieve the objectives spelled out in section 2.3.

3.3. Choice of instrument

A Directive continues to be the most appropriate instrument in order to achieve the objectives of the proposal. The measures envisaged represent a major modification of the provisions contained in Directive 96/98/EC and therefore, in the interests of clarity, this Directive should be repealed and replaced by a new Directive.

4. BUDGETARY IMPLICATIONS

This proposal has no budgetary implications. The tasks devolved to the Commission, including those for which the assistance of the European Maritime Safety Agency is foreseen, are not expected to represent on the whole an increase in workload and will be carried out with existing resources.

5. CONTENT OF THE PROPOSAL

Article 1 defines the objectives of the proposal in line with the relevant objectives laid down in the Treaties, as referred to in section 1.4 of this memorandum.

The scope of the Directive is defined in **Article 3**. Marine equipment is installed on board ships wherever they are built, repaired or supplied. Although marine equipment is of course also traded within the borders of the EU, the scope of the Directive is defined by reference to equipment which is a) due to be installed on board a ship flying the flag of a Member State, and b) for which the approval of the flag State is required by the international conventions. Similarly, the application of concurrent Directives is excluded, as only the marine equipment directive can ensure that marine equipment installed on EU ships complies with the requirements in the international conventions and instruments.

The requirements for marine equipment are defined in **Article 4** by reference to the international conventions and instruments. As required by these, demonstration of compliance is confined to the specific applicable testing standards. Given the need to ensure continued

consistency with the international regulatory framework, these requirements and standards must apply in their up-to-date version; this automatic update is consistent with the general policy followed by the EU in the area of maritime safety. The automatic update does not apply to testing standards as experience has shown it may lead to disproportionate effects.

Article 5 reflects another distinctive element of the marine equipment sector, namely, that the flag State has the responsibility to ensure that only equipment which has been duly approved in accordance with the then applicable requirements of the international instruments is placed on board ships flying its flag. Equipment should remain in conformity with those requirements, unless requirements subsequently adopted by the IMO apply to equipment already placed on board ships.

Article 6 provides the basis for the free movement of marine equipment within the EU, based on the concept of mutual recognition between Member States of equipment complying with the requirements laid down in the Directive. **Article 7** governs the particular case of the transfer of a ship to a Member State's register based on the principle of compliance with the Directive requirements, but allowing for the acceptance of equivalent equipment in order not to place a disproportionate and unjustified burden on the ship owners or penalise EU flags.

Article 8 reflects the priority given to the international regulation of maritime safety, consistent with the global nature of shipping. However, it is necessary to ensure that failure by the IMO to produce appropriate standards does not impair the objectives of the Directive, and thus the Commission must be empowered to lay down appropriate specifications while awaiting the production of the international standards, by means of delegated acts.

Articles 9 to 11 deal with the wheel mark. As in the current Directive, a specific mark is necessary in order to distinguish equipment complying with the requirements in the international maritime safety conventions, which may be different from those contained in other EU harmonisation instruments applying to equipment which is similar in nature but is not for use or installation on board ships. However, the general principles governing the CE marking, in particular as laid down in Regulation 765/2008/EC, are applied *mutatis mutandis*. In order to facilitate control by the flag and port State authorities, and to combat counterfeit, Article 11 opens the possibility to use an electronic tag in addition to or in place of the wheel mark.

Articles 12 to 14 incorporate the reference provisions of Decision 768/2008 as regards the specific obligations of the economic operators. It must be taken into account that a) only a fraction of the marine equipment falling under the scope of the Directive is traded within EU borders, normally by ship yards and ship repairers, and b) as stated above, a specific mandate is placed on the Member States to ensure that only compliant equipment is installed on board ships flying their flags. As a result of this, a) for importers, the act of affixing the mark triggers the assumption of responsibilities and the effectiveness of their obligations, which must include granting access to their premises for national authorities carrying out market surveillance; b) the appointment of an authorised representative has been made compulsory for manufacturers located outside the EU; and c) in the case of importers and distributors, the respective obligations have been limited to those which are relevant for the sector, namely cooperation with market surveillance and, for importers, clear identification.

The conformity-checking procedures made available to manufacturers are listed in **Article 15** and further developed in **Annex II**. Among the modules foreseen in Decision 768/2008 of the European Parliament and of the Council on a common framework for the marketing of

products, only those modules which are consistent with the requirement for specific approval by the flag State as laid down in the international conventions and instruments have been retained. Slight adaptations in the text have been made for the same purpose. In order to facilitate the protection of legitimate intellectual property rights, all modules contain an obligation for the manufacturer to provide the notified body with a certified copy of the patent, license or document by which the applicant purports to have the right to make, use, sell or offer the marine equipment for sale or use its trademark; this document shall be made available to the competent courts upon request.

As regards the EU declaration of conformity, **Article 16** aligns the Directive with Decision 768/2008. Like the affixing of the wheel mark, the act of drawing up of a declaration of conformity will trigger the manufacturer's responsibilities and obligations under the Directive. Additional provisions ensure that copies of the declaration will be deposited with the relevant notified body and can always be found on board, which will greatly facilitate control by market surveillance authorities, the flag State and the Port State authorities – at the price of a negligible additional administrative burden.

Articles 17 to 26 as well as Annexes III to V incorporate the reference provisions of Decision 768/2008 as regards notification, notifying authorities, notified bodies and their respective regimes. This inclusion opens the possibility for the Member States to have recourse to accreditation – which could help resolve the chronic paucity of resources in national maritime administrations. Furthermore, in order to reinforce the control of notified bodies in a context where the entire process comprising design, testing, certification, production, delivery and placing on board of marine equipment may entirely happen outside the EU borders, two additional safeguards have been added to the standard Member States' monitoring obligations: in the first place, monitoring of notified bodies should occur at least every two years; secondly, the Commission[5] may participate in the audits as an observer. As regards notified bodies, the possibility of a manufacturer's in-house notified body has been discarded, given that it is not appropriate for the restricted choice of conformity-assessment procedures referred to above.

By virtue of **Articles 27 to 31**, the Directive is fully aligned with the general EU market surveillance framework, including as regards the safeguard procedure. Checks on board may be necessary and are therefore regulated in Article 27. Article 29 contains two additional specific elements which appear to be necessary in the marine equipment sector.

- If the Commission is satisfied that the technical assessment carried out by the Member State concerned has been fair and objective, it should not be obliged to repeat this evaluation when reviewing the restrictive measures adopted by that Member State as regards non-compliant equipment. The objective is to ensure that the burden placed on the Commission is commensurate with the means at its disposal and to encourage the Member States to ensure a fair procedure and take all measures conducive to an exhaustive and objective evaluation of the risks.
- It is necessary to cater for the possibility that shortcomings are identified in the IMO standards. In this case, a mechanism similar to that described under Article 8 is provided for.

[5] It must be recalled that, as stated in recital 17, the European Maritime Safety Agency assists the Commission in the implementation of the Directive and in carrying out the tasks entrusted to the former.

Articles 32 to 34 contain the specific regime in exceptional circumstances, largely taken from the existing Directive. This concerns exemptions in cases of technical innovation or for the purpose of testing and evaluation. More importantly, solutions are provided for the cases where ships cannot obtain supplies of wheel marked equipment in ports outside the EU in reasonable terms or where wheelmarked equipment has become unavailable in the market. In all these cases, the Member States may authorise the placing on board of non-wheelmarked equipment – subject to the necessary procedural constraints to ensure that these exemptions do not impair the objectives of the Directive.

Article 35 constitutes an essential part of the new Directive's architecture, with three distinctive elements:

- The requirement for marine equipment to comply with the specific design, construction and performance requirements laid down in the international instruments, including the relevant testing standards, as defined by the Legislator, will be uniformly implemented by empowering the Commission to identify from these instruments the requirements and standards corresponding to each item of equipment. This will be done by means of implementing acts. As shown in the impact assessment, the use of implementing Regulations is expected to resolve the problems of delay and legal uncertainty described above, *inter alia* given that transposition into the Member States' legal order will no longer be needed.
- Secondly, the Commission is also empowered to adopt common criteria and procedures for the application of these requirements and standards, a necessary measure to ensure that divergent interpretations by the Member States (e.g. in terms of time, scope or technical implementation) cannot have an impact on safety or on the smooth functioning of the internal market. In this respect, the preparatory work carried out by the group of notified bodies established by the Directive will be taken into account. In this case, the use of implementing acts has been considered the most appropriate course of action.
- Finally, the Commission is charged with the task of gathering and publishing a significant package of information. This codifies and expands existing practice and will facilitate the implementation of the Directive by all actors, as has been suggested during the stakeholder consultation.

Continued consistency of the new Directive with the international regulatory framework is ensured by means of the empowerment given to the Commission in **Article 36**, so that it can adopt delegated acts in order to update the list of relevant international conventions and of standardisation organisations as well as the references to international and European standards contained in the Directive. Aspecific criterion allowing the Commission to identify the relevant conventions (namely the requirement of flag approval of marine equipment) is provided, so that the update of the list by the Commission cannot constitute an indirect extension of the Directive's scope as defined in Article 3.

Article 40 provides for the repeal of Directive 96/98/EC and lays down the necessary transitional arrangements.

Articles 37(exercise of delegation), 38(committee procedures), 39 (transposition), 41 (entry into force) and 42 (addressees) contain standard legislative provisions.

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DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The global dimension of shipping calls for the Union to apply and support the international regulatory framework for maritime safety. The international maritime safety conventions require flag States to ensure that the equipment carried on board ships complies with certain safety requirements as regards design, construction and performance, and to issue the relevant certificates. To that end detailed performance and testing standards for certain types of marine equipment have been developed by the International Maritime Organization (IMO) and by the international and European standardization bodies.

(2) The international instruments leave a significant margin of discretion to the flag administrations. In the absence of harmonisation, this leads to varying levels of safety for products which the competent national authorities have certified as complying with the said conventions and standards; as a result, the smooth functioning of the Internal Market is affected as it becomes difficult for the Member States to accept equipment certified in another Member State to be placed on board ships flying their flags without further verification.

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1 OJ C , , p. .

2 OJ C , , p. .

(3) Harmonisation by the Union resolves these problems. Council Directive 96/98/EC of 20 December 1996 on marine equipment[3] thus laid down common rules to eliminate differences in the implementation of international standards by means of a clearly identified set of requirements and uniform certification procedures.

(4) There are other various instruments of Union law which lay down requirements and conditions, *inter alia* in order to ensure the free movement of goods within the Internal Market or for environmental purposes, for certain products which are similar in nature to equipment used on board ships, but which do not meet the international standards – which may substantially differ from the internal legislation of the Union and are in constant evolution. These products cannot therefore be certified by the Member States in accordance with the relevant international maritime safety conventions. Equipment to be placed onboard EU ships in accordance with international safety standards should therefore be regulated exclusively by this Directive, which should in any event be considered the *lex specialis*; furthermore, a specific marking should be established to indicate that the equipment bearing that mark complies with the requirements laid down in the relevant international conventions and instruments.

(5) Experience in the implementation of Directive 96/98/EC has shown that it is necessary to take additional measures in order to enhance the implementation and enforcement mechanisms of the said Directive and simplify the regulatory environment while guaranteeing that IMO requirements are applied and implemented in a harmonised way across the Union.

(6) Requirements should therefore be established for marine equipment to meet the safety standards laid down in the applicable international instruments, including the relevant testing standards, in order to ensure that equipment which complies with these requirements can circulate unimpeded within the Internal Market and be placed on board ships flying the flag of any Member State.

(7) Decision No 768/2008 of the European Parliament and of the Council on a common framework for the marketing of products[4] lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. This Decision constitutes a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products and a reference text for existing legislation. This general framework provides appropriate solutions to the problems identified in the implementation of Directive 96/98/EC. It is therefore necessary to incorporate the definitions and reference provisions of Decision No 768/2008 into this Directive by making the adaptations which are required by the specific features of the marine equipment sector.

(8) Given that marine equipment is placed on board ships at the time of their construction or repair all over the world, market surveillance becomes particularly difficult and cannot be effectively supported by border controls. Therefore it is necessary to provide market surveillance authorities and port State control officers with additional, specific means to facilitate their task, such as enabling the use of electronic tags to replace or supplement the wheelmark.

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[3] OJ L 46, 17.2.1997, p. 25.

[4] OJ L 218, 13.8.2008, p. 82.

(9) Similarly, the responsibilities of the economic operators should be laid down in a way which is proportionate and non-discriminatory for those who are established within the Union, taking into account that a significant fraction of the marine equipment falling under the scope of this Directive may never be imported and distributed in the territory of the Member States.

(10) Compliance with international testing standards could best be demonstrated by means of conformity-assessment procedures such as those laid down in Decision No 768/2008. However, only those conformity-assessment procedures which meet the requirements of the international instruments should be made available to manufacturers.

(11) In order to ensure a fair and efficient procedure when examining suspected non-compliance, the Member States should be encouraged to take all measures conducive to an exhaustive and objective evaluation of the risks; if the Commission is satisfied that this condition has been met, it should not be obliged to repeat this evaluation when reviewing the restrictive measures adopted by the Member States as regards non-compliant equipment.

(12) The use of marine equipment not bearing the mark of conformity may be allowed in exceptional circumstances, especially when it is not possible for a ship to obtain equipment bearing the wheel mark in a port or installation outside the Union or when equipment bearing the wheel mark has become unavailable in the market.

(13) It is necessary to ensure that the objectives of this Directive are not impaired by shortcomings in the applicable testing standards or in case the IMO failed to produce appropriate standards for marine equipment falling under the scope of this Directive. It is also necessary to adopt appropriate technical criteria so that electronic tags can be affixed and used in a safe and reliable way. Moreover, it is necessary to keep up-to-date a number of non-essential elements of this Directive, namely the list of international conventions laying down safety requirements for marine equipment contained in Article 2(3) and the references to specific standards contained in Annex III. The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should therefore be delegated to the Commission in respect of the adoption, on an interim basis, of harmonised technical specifications and testing standards and in order to amend the said lists and references. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(14) The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(15) In order to meet the objectives of this Directive, the international instruments should be uniformly implemented in the Internal Market. It is therefore necessary, for each item of marine equipment for which the approval of the flag State is required by the international conventions, to identify in a clear and timely way the design, construction and performance requirements as well as the associated testing standards laid down in the international instruments for that equipment, and to adopt common criteria and procedures for the implementation of those requirements and standards by notified bodies, Member State authorities and the economic operators. Moreover, it is

necessary to ensure that only in exceptional and duly justified cases equipment not bearing the wheel mark is allowed to be placed on board.

(16) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.[5]

(17) The Commission is assisted by the European Maritime Safety Agency, in accordance with Regulation (EC) […], in the effective implementation of relevant binding legal acts of the Union and in the performance of the tasks therein entrusted to the Commission;

(18) Since the objectives of this Directive, namely to enhance safety at sea and the prevention of marine pollution through the uniform application of the relevant international instruments relating to equipment to be placed on board ships, and to ensure the free movement of such equipment within the Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that article, this Directive does not go beyond what is necessary in order to achieve that objective,

(19) The measures to be adopted represent a major modification of the provisions of Directive 96/98/EC and therefore, in the interests of clarity, that Directive should be repealed and replaced by a new Directive.

HAVE ADOPTED THIS DIRECTIVE:

Chapter 1

General provisions

Article 1

Objective

The purpose of this Directive is to enhance safety at sea and to prevent marine pollution through the uniform application of the relevant international instruments relating to marine equipment to be placed on board EU ships, and to ensure the free movement of such equipment within the Union.

[5] OJ L 55, 28.2.2011, p. 13.

Article 2

Definitions

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

(1) "Marine equipment" means equipment falling under the scope of this Directive in accordance with Article 3.

(2) "EU ship" means a ship, for which safety certificates are issued by or on behalf of Member States under the international conventions, with the exception of a ship for which the administration of a Member State issues a certificate at the request of a third country's administration;

(3) "international conventions" means the conventions, together with their Protocols and Codes of mandatory application, adopted under the auspices of the International Maritime Organization (IMO) which lay down specific requirements for the approval by the flag State of equipment to be placed on board ships. This includes:

– the 1966 International Convention on Load Lines (LL66),

– the 1972 Convention on the International Regulations for Preventing Collisions at Sea (Colreg),

– the 1973 International Convention for the Prevention of Pollution from Ships (Marpol),

– the 1974 International Convention for the Safety of Life at Sea (Solas),

– the 2004 International Convention for the Control and Management of Ships' Ballast Water and Sediments (BWMC);

(4) "testing standards" means the testing standards for marine equipment set by

– the International Maritime Organization (IMO),

– the International Organization for Standardization (ISO),

– the International Electrotechnical Commission (IEC),

– the European Committee for Standardization (CEN),

– the European Committee for Electrotechnical Standardization (Cenelec)

– the International Telecommunication Union (ITU)

– the European Telecommunication Standards Institute (ETSI)

– the Commission, in accordance with this Directive,

– the Regulatory Authorities recognised in the mutual recognition agreements to which the Union is a party.

(5) "international instruments" means the international conventions, together with the resolutions and circulars of the International Maritime Organization giving effect to those conventions, and the testing standards;

(6) "wheel mark" means the symbol referred to in Article 9 and set out in Annex I or, as appropriate, the electronic tag referred to in Article 11;

(7) "notified body" means an organisation designated by the competent national administration of a Member State in accordance with Article 17;

(8) "making available on the market" means any supply of marine equipment on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(9) "placing on the market" means the first making available of marine equipment on the Union market;

(10) "manufacturer" means any natural or legal person who manufactures marine equipment or has marine equipment designed or manufactured, and markets that equipment under his name or trademark;

(11) "authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(12) "importer" means any natural or legal person established within the Union who places marine equipment from a third country on the EU market;

(13) "distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes marine equipment available on the market;

(14) "economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

(15) "accreditation" means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council [6];

(16) "national accreditation body" means national accreditation body as defined in Article 2 (11) of Regulation (EC) No 765/2008;

(17) "conformity assessment" means the process demonstrating whether marine equipment complies with the requirements laid down in this Directive, in accordance with Article 15;

(18) "conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(19) "recall" means any measure aimed at achieving the return of marine equipment that has already been placed on board EU ships;

[6] OJ L 218, 13.8.2008, p. 30.

(20) "withdrawal" means any measure aimed at preventing marine equipment in the supply chain from being made available on the market;

(21) "EU declaration of conformity" means a statement issued by the manufacturer in accordance with article 16;

(22) "product" means an item of marine equipment.

Article 3

Scope

1. This Directive shall apply to equipment to be placed on board an EU ship and for which the approval of the flag State administration is required by the international instruments.

2. Notwithstanding the fact that the marine equipment referred to in paragraph 1 may also fall within the scope of instruments of Union law other than this Directive, that marine equipment shall, for the purpose set out in Article 1, be subject only to this Directive .

Article 4

Requirements for marine equipment

1. Marine equipment that is placed on board an EU ship on or after the date referred to in the second subparagraph of Article 39(1) shall meet the design, construction and performance requirements of the international instruments as applicable at the time the said equipment is placed on board.

2. Compliance of marine equipment with the requirements referred to in paragraph 1 shall be demonstrated solely in accordance with the testing standards and by means of the conformity-assessment procedures referred to in Article 15.

3. The requirements and standards referred to in paragraphs 1 and 2 shall be implemented in a uniform manner, in accordance with Article 35(2) and (3).

4. The international instruments, with the exception of testing standards, shall apply in their up-to-date version, without prejudice to Article 5 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council [7].

Article 5

Application

1. When issuing, endorsing or renewing the certificates of the ships flying their flag in accordance with the international conventions, the Member States shall ensure that

[7] OJ L 324, 29.11.2002, p.1.

the marine equipment on board those ships complies with the requirements of this Directive.

2. Member States shall take the necessary measures to ensure that marine equipment on board ships flying their flag complies with the requirements in the international instruments which are applicable to equipment already placed on board. These requirements shall be implemented in a uniform manner, in accordance with Article 35(4).

Article 6

Functioning of the internal market

Member States shall not prohibit the placing on the market or the placing on board an EU ship of marine equipment which complies with this Directive, nor refuse to issue the certificates relating thereto to the ships flying their flag, or to renew the said certificates.

Article 7

Transfer of a ship to the register of a Member State

1. In the case of a ship which, irrespective of its flag, is not registered in a Member State but is to be transferred to the register of a Member State, that ship shall, on transfer, be subject to inspection by the receiving Member State to verify that the actual condition of its marine equipment corresponds to its safety certificates and either complies with this Directive and bears the wheel mark or is equivalent, to the satisfaction of that Member State's administration, to marine equipment certified in accordance with this Directive.

2. Unless the equipment either bears the wheel mark or the administration considers it to be equivalent, it shall be replaced.

3. Marine equipment which is considered equivalent pursuant to this Article shall be given a certificate by the Member State which shall at all times be carried with the equipment. It shall give the flag Member State's permission for the equipment to be placed on board the ship and imposes any restrictions or lays down any provisions relating to the use of the equipment.

Article 8

Standards for marine equipment

1. Without prejudice to Directive 98/34/EC of the European Parliament and the Council[8], the Union shall pursue the development by the IMO of appropriate international standards, including detailed technical specifications and testing standards, for marine equipment whose use or installation on board ships is deemed

[8] OJ L 204, 21.7.1998, p. 37.

necessary to enhance maritime safety and the prevention of marine pollution. The Commission shall monitor this development on a regular basis.

2. In the absence of appropriate international standards developed by the IMO for a specific item of marine equipment, the Commission shall be empowered to adopt, by means of delegated acts in accordance with Article 37, harmonised technical specifications and testing standards for that specific item of marine equipment when it is necessary in order to remove an unacceptable threat to safety or to the environment. Those specifications and standards shall apply on an interim basis and until such time as the IMO has adopted appropriate standards.

Chapter 2

The wheel mark

Article 9

The wheel mark

1. Marine equipment whose compliance with the requirements laid down in this Directive has been demonstrated in accordance with the relevant conformity-assessment procedures shall have the wheel mark affixed to it.

2. The wheel mark shall not be affixed to any other product.

3. The form of the wheel mark to be used shall be as set out in Annex I.

4. Use of the wheel mark shall be subject to the general principles set out in paragraphs 1 and 3 to 6 of Article 30 of Regulation (EC) No 765/2008, where any reference to the CE marking shall be construed as a reference to the wheel mark.

Article 10

Rules and conditions for affixing the wheel mark

1. The wheel mark shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

2. The wheel mark shall be affixed at the end of the production phase.

3. The wheel mark shall be followed by the identification number of the notified body, where that body is involved in the production control phase, and by the last two digits of the number of the year in which the mark is affixed.

4. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the wheel mark and take appropriate action in the event of improper use of the mark. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Article 11

Electronic tag

1. The wheel mark may be supplemented or replaced by an appropriate and reliable form of electronic tag. In such case, Articles 9 and 10 shall apply, as appropriate, *mutatis mutandi*.

2. The Commission shall adopt delegated acts, in accordance with Article 37, in order to identify the specific items of marine equipment which can benefit from electronic tagging, and to lay down appropriate technical criteria as regards the design, performance, affixing and use of electronic tags.

Chapter 3

Obligations of economic operators

Article 12

Obligations of manufacturers

1. By affixing the wheel mark, manufacturers shall take on responsibility for guaranteeing that the marine equipment to which the mark is affixed has been designed and manufactured in accordance with the requirements set out in Article 4 and shall undertake the obligations laid down in paragraphs 2 to 9 of this Article.

2. Manufacturers shall draw up the required technical documentation and have the applicable conformity assessment procedures carried out.

3. Where compliance of marine equipment with the applicable requirements has been demonstrated by the conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity in accordance with Article 16 and affix the conformity marking in accordance with Article 9.

4. Manufacturers shall keep the technical documentation and the EU declaration of conformity referred to in Article 16 for a period of time commensurate with the level of risk, and in no case less than the expected lifecycle of the marine equipment, after the wheel mark has been affixed on the last unit.

5. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in marine equipment design or characteristics and

changes in the requirements in the international instruments as referred to in Article 4, on the basis of which conformity of marine equipment is declared shall be adequately taken into account. When necessary in accordance with Annex II, they shall have a new conformity assessment carried out.

6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

7. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

8. Manufacturers shall ensure that the product is accompanied by instructions and all necessary information for safe installation on board and safe use of the product, including limitations of use, if any, in a language which can be easily understood by the end-users, together with any other documentation required by the international instruments or testing standards.

9. Manufacturers who consider or have reason to believe that a product which they have placed on the market or on board EU ships is not in conformity with the applicable requirements in the international instruments as referred to in Article 4, shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or recall it, if appropriate. In addition, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States, giving details, in particular, of the non-compliance and of any corrective measures taken.

10. Manufacturers shall, further to a reasoned request from a competent national authority, promptly provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority, and grant to that authority access to their premises for market surveillance purposes in accordance with Article 19 of Regulation (EC) No 765/2008. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article 13

Authorised representatives

1. A manufacturer who is not located in the territory of a Member State shall, by a written mandate, appoint an authorised representative.

2. The obligations laid down in Article 12(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of time commensurate with the level of risk, and in no case less than the expected lifecycle of the marine equipment, after the wheel mark has been affixed on the last unit;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Article 14

Other economic operators

1. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

2. Importers and distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

3. An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 12, where he places marine equipment on the market or on board an EU ship under his name or trademark or modifies marine equipment already placed on the market in such a way that compliance with the applicable requirements may be affected.

Chapter 4

Conformity assessment and notification of conformity assessment bodies

Article 15

Conformity assessment procedures

1. The conformity assessment procedures shall be as set out in Annex II.

2. Member States shall ensure that the manufacturer or his authorized representative carry out the conformity assessment, for a specific item of marine equipment, by using one of the options provided by means of implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 38(3), from among one of the following procedures:

(a) where the EC type-examination (module B) is to be used, before being placed on the market, all marine equipment shall be subject to:

– production-quality assurance (module D);

– product-quality assurance (module E); or

– product verification (module F);

(b) where sets of marine equipment are produced individually or in small quantities and not in series or in mass, the conformity- assessment procedure may be the EC unit verification (module G).

3. The Commission shall keep an up-to-date list of approved marine equipment and applications withdrawn or refused and shall make it available to interested parties.

Article 16

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the requirements laid down in accordance with Article 4 has been demonstrated.

2. The EU declaration of conformity shall follow the model structure set out in Annex III to Decision No 768/2008/EC. It shall contain the elements specified in the relevant modules set out in Annex II to this Directive and shall be continuously updated.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume the responsibility and undertake the obligations referred to in Article 12(1).

4. When marine equipment is placed on board an EU ship, a copy of the EU declaration of conformity covering the equipment concerned shall be provided to the ship, and shall be kept on board until the said equipment is removed from the ship. It shall be translated into the language or languages required by the flag State.

5. A copy of the EU declaration of conformity shall be provided to the notified body or to the bodies having carried out the relevant conformity-assessment procedures.

Article 17

Notification

1. Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

2. Notified bodies shall comply with the requirements laid down in Annex III.

Article 18

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 20.

2. Notified bodies shall be monitored at least every two years. The Commission may choose to participate as an observer in the monitoring exercise.

3. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body.

4. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Annex V. In addition it shall have arrangements to cover liabilities arising out of its activities.

5. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 4.

6. The notifying authority shall comply with the requirements laid down in Annex V.

Article 19

Information obligation on notifying authorities

1. Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of such bodies, and of any changes thereto.

2. The Commission shall make that information publicly available.

Article 20

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Annex III and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Directive.

Article 21

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Annex III , or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 22
Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, based on the information available to it or brought to its attention, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 23

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the procedures provided for in Article 15.

2. Where a notified body finds that the requirements laid down in accordance with Article 4 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

3. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 24

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

   (a) any refusal, restriction, suspension or withdrawal of a certificate;

   (b) any circumstances affecting the scope of and conditions for notification;

   (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

   (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the Commission and the Member States, on request, with relevant information on issues relating to negative and positive conformity assessment results. Notified bodies shall provide the other notified bodies carrying out conformity assessment activities covering the same products with information concerning negative and, on request, positive conformity assessment results.

Article 25

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 26

Coordination of notified bodies

1. The Commission shall ensure that appropriate coordination and cooperation between notified bodies are put in place and properly operated in the form of a sectoral group of notified bodies.

2. Member States shall ensure that the bodies notified by them participate in the work of the sectoral group, directly or by means of designated representatives.

Chapter 5

Union market surveillance, control of products, safeguard provisions

Article 27

EU market surveillance framework

1. As regards marine equipment, the Member States shall undertake market surveillance in accordance with the EU market surveillance framework laid down in Chapter III of Regulation (EC) No 765/2008, subject to the provisions of paragraphs 2 and 3 of this Article.

2. National market surveillance infrastructures and programmes shall take into account the specific features of the marine equipment sector, and in particular the responsibilities placed with the flag State administration by the international conventions.

3. Market surveillance may include documentary checks as well as checks of marine equipment which bears the wheel mark whether or not it has been placed on board ships. Checks of marine equipment already placed on board shall be limited to such examination as can be carried out while the equipment concerned remains fully functional on board. Checks of marine equipment placed on board ships flying the flag of a Member State other than that carrying out the checks shall be carried out in accordance with the relevant provisions of Directive 2009/16/EC of the European Parliament and the Council[9].

4. Where the market surveillance authorities of a Member State intend to carry out sample checks, they may request the manufacturer to make the necessary samples available at its own cost in the territory of that Member State.

[9] OJ L 131, 28.5.2009, p. 57

Article 28

Procedure for dealing with marine equipment presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that marine equipment covered by this Directive presents a risk to maritime safety or to the protection of the environment, they shall carry out an evaluation in relation to the marine equipment concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

   Where, in the course of that evaluation, the market surveillance authorities find that the marine equipment does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the marine equipment into compliance with those requirements, to withdraw the marine equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

   The market surveillance authorities shall inform the relevant notified body accordingly.

   Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory or to ships flying their flag, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union or, as necessary, placed or delivered to be placed on board EU ships.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, or otherwise fails to meet its obligations under this Directive, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the marine equipment being made available on their national market or placed on board the ships flying their flag, to withdraw the product from that market or to recall it.

   They shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant marine equipment, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either:

(a) failure of the marine equipment to comply with the applicable design, construction and performance requirements as laid down pursuant to Article 4;

(b) non-compliance with the testing standards referred to in Article 4 during the conformity-assessment procedure;

(c) shortcomings in the said testing standards.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the marine equipment concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within four months of receipt of the information referred to in paragraph 4, no objection has been raised by a Member State or by the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the marine equipment concerned, such as withdrawal of the product from their market, without delay.

Article 29

EU safeguard procedure

1. Where, on completion of the procedure set out in Article 28(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers that a national measure may be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

2. For the purpose of paragraph 1, where the Commission is satisfied that the procedure followed in the adoption of the national measure is appropriate for an exhaustive and objective evaluation of the risk and complies with the provisions laid down in Article 21 of Regulation (EC) No 765/2008, it may limit itself to examining the appropriateness and proportionality of the national measure in relation to the said risk.

3. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

4. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant marine equipment is withdrawn from their market, and, where necessary, recalled. They shall inform the Commission accordingly.

5. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

6. Where the national measure is considered justified and the non-compliance of the marine equipment is attributed to shortcomings in the testing standards referred to in Article 4, the Commission may confirm, modify or revoke the said measure by means of implementing acts in accordance with the advisory procedure referred to in Article 38(2). The Commission shall furthermore be empowered to adopt, by means of delegated acts in accordance with the procedure referred to in Article 37, interim harmonised requirements and testing standards for that specific item of marine equipment in order to remove the threat to safety or to the environment pending the modification of the testing standard concerned by the relevant international organisation.

7. Where the testing standard concerned is a European Standard, the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.

Article 30

Compliant products which present a risk to maritime safety or to the protection of the environment

1. Where, having performed an evaluation under Article 28(1), a Member State finds that although marine equipment is in compliance with this Directive, it presents a risk to marine safety or to the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the marine equipment concerned, when placed on the market, no longer presents that risk, to withdraw the marine equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the Union or placed on board EU ships.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the marine equipment concerned, the origin and the supply chain of the marine equipment, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures; for this purpose, Article 29(2) shall apply *mutatis mutandis.*

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 31

Formal non-compliance

1. Without prejudice to Article 28, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

   (a) the wheel mark has been affixed in violation of Article 9 or of Article 10;

   (b) the wheel mark has not been affixed;

   (c) the EU declaration of conformity has not been drawn up;

   (d) the EU declaration of conformity has not been drawn up correctly;

   (e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the marine equipment being made available on the market or ensure that it is recalled or withdrawn from the market.

Article 32

Exemptions based on technical innovation

1. In exceptional circumstances of technical innovation, the flag State administration may permit marine equipment which does not comply with the conformity assessment procedures to be placed on board an EU ship if it is established by trial or otherwise to the satisfaction of the flag State administration that such equipment is at least as effective as marine equipment which does comply with the conformity-assessment procedures.

2. The trial procedures shall in no way discriminate between marine equipment produced in the flag Member State and marine equipment produced in other States.

3. Marine equipment covered by this Article shall be given a certificate by the flag Member State which shall at all times be carried with the equipment and which gives the flag Member State's permission for the equipment to be placed on board the ship and imposes any restrictions or lays down any provisions relating to the use of the equipment.

4. Where a Member State allows marine equipment covered by this Article to be placed on board an EU ship, that Member State shall forthwith communicate the particulars

thereof together with the reports of all relevant trials, assessments and conformity-assessment procedures to the Commission and the other Member States.

5. Within twelve months of receipt of the communication referred to in paragraph 4, the Commission, if it considers that the conditions laid down in paragraph 1 are not met, may require the Member State concerned to withdraw the permission granted within a specified deadline. For this purpose, the Commission shall act by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 38(2).

6. Where a ship with marine equipment on board which is covered by paragraph 1 is transferred to another Member State, the receiving flag Member State may undertake the necessary measures, which may include tests and practical demonstrations, to ensure that the equipment is at least as effective as equipment which does comply with the conformity-assessment procedures.

Article 33

Exemptions for testing or evaluation

A flag State administration may permit marine equipment which does not comply with the conformity-assessment procedures or is not covered by Article 32 to be placed on board an EU ship for reasons of testing or evaluation, if the following cumulative conditions are complied with:

(a) the marine equipment shall be given a certificate by the flag Member State which shall at all times be carried with the equipment, state the said Member State's permission for the equipment to be placed on board the EU ship, impose all necessary restrictions and lay down any other appropriate provisions as regards the use of the equipment concerned;

(b) the permission shall be limited to a short period of time;

(c) the marine equipment shall not be relied on in place of equipment which meets the requirements of this Directive and shall not replace such equipment, which shall remain on board the EU ship in working order and ready for immediate use.

Article 34

Exemptions in exceptional circumstances

1. In exceptional circumstances, which shall be duly justified to the flag State administration, when marine equipment needs to be replaced in a port outside the Union where it is not practicable in terms of reasonable time, delay and cost to place on board equipment which bears the wheel mark, other marine equipment may be placed on board subject to paragraphs 2 to 4 of this Article.

2. The marine equipment placed on board shall be accompanied by documentation issued by a Member State of the IMO which is a party to the relevant conventions, certifying compliance with the relevant IMO requirements.

3. The flag State administration shall be informed at once of the nature and characteristics of such other marine equipment.

4. The flag State administration shall, at the earliest opportunity, ensure that the marine equipment referred to in paragraph 1, along with its testing documentation, complies with the relevant requirements of the international instruments and of this Directive.

5. Where it has been demonstrated that specific marine equipment bearing the wheel mark has become unavailable on the market, the flag Member State may authorise other marine equipment to be placed on board subject to the provisions of paragraphs 6 to 8 of this Article.

6. The authorised marine equipment shall comply, as much as possible, with the requirements and testing standards referred to in Article 4.

7. The marine equipment placed on board shall be accompanied by an interim certificate of approval issued by the flag Member State or by another Member State, stating the following:

   (a) the equipment bearing the wheel mark which the certified equipment is due to replace;

   (b) the exact circumstances under which the certificate of approval has been issued, and in particular the unavailability in the market of equipment bearing the wheel mark;

   (c) the exact design, construction and performance requirements against which the equipment has been approved by the certifying Member State;

   (d) the testing standards applied, if any, in the relevant approval procedures.

8. The Member State issuing an interim certificate of approval shall inform the Commission forthwith. If the Commission considers that the conditions of paragraphs 6 and 7 have not been met, it may require that Member State to revoke the said certificate or take other appropriate measures by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 38(2).

Chapter 6

Final provisions

Article 35

Implementing measures

1. The Member States shall notify to the Commission the name and contact details of the authorities in charge of the implementation of this Directive. The Commission shall draw up, periodically update and make public a list of these authorities.

2. For each item of marine equipment for which the approval of the flag State administration is required by the international conventions, the Commission shall identify by means of implementing acts the respective design, construction and performance requirements and the testing standards provided for in the international instruments.

3. The Commission may adopt by means of implementing acts common criteria and detailed procedures for the application of the requirements and testing standards referred to in paragraph (2).

4. The Commission shall, by means of implementing acts, identify the respective design, construction and performance requirements newly provided for in the international instruments and which apply to equipment placed on board before their adoption in order to ensure that equipment placed on board of EU ships complies with the international conventions.

5. The Commission shall set up and maintain a data base containing at least the following information:

   (a) the list and essential details of the conformity certificates issued under this Directive;

   (b) the list and essential details of the declarations of conformity issued under this Directive;

   (c) an up-to-date list of the applicable international instruments, requirements and testing standards, including any updates becoming applicable by virtue of Article 4(3);

   (d) the list and full text of the criteria and procedures referred to in paragraph 3;

   (e) the requirements and conditions for electronic tagging referred to in Article 11;

   (f) any other useful information with a view to facilitating correct implementation of this Directive by the Member States, the notified bodies and the economic operators.

   This database shall be made accessible to the Member States. It shall also be made available, in whole or in part, to the public for information purposes only.

6. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 38(3).

Article 36

Amendments

This Directive may be amended by the Commission, by means of delegated acts, in order to:

(a) amend the list of international conventions set out in Article 2(3), in order to include those conventions which require the flag State's approval of equipment to be placed on board ships flying its flag;

(b) update the references to international and European standards, as referred to in Annex III when new standards become available.

Those delegated acts shall be adopted in accordance with the procedure laid down in Article 37.

Article 37

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 8, 11, 29 and 36 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Directive.

3. The delegation of power referred to in Articles 8, 11, 29 and 36 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 8, 11, 29 and 36 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Article 38

Committee

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) established by Regulation (EC) No 2099/2002 of the European Parliament and of the Council[10]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

[10] OJ L 324, 29.11.2002, p. 1.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 39

Transposition

1. Member States shall adopt and publish, by [*one year after entry into force*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from [*one year after the date of entry into force*].

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

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

Article 40

Repeal

1. Council Directive 96/98/EC is repealed with effect from [application date].

2. The requirements and testing standards for marine equipment applicable on [application date] pursuant to the provisions of national law adopted by the Member States in order to comply with Directive 96/98/EC shall continue to apply until the entry into force of the implementing acts referred to in Article 35(2).

3. References to the repealed Directive shall be construed as references to this Directive.

Article 41

Entry into force

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

Article 42

This Directive is addressed to the Member States.

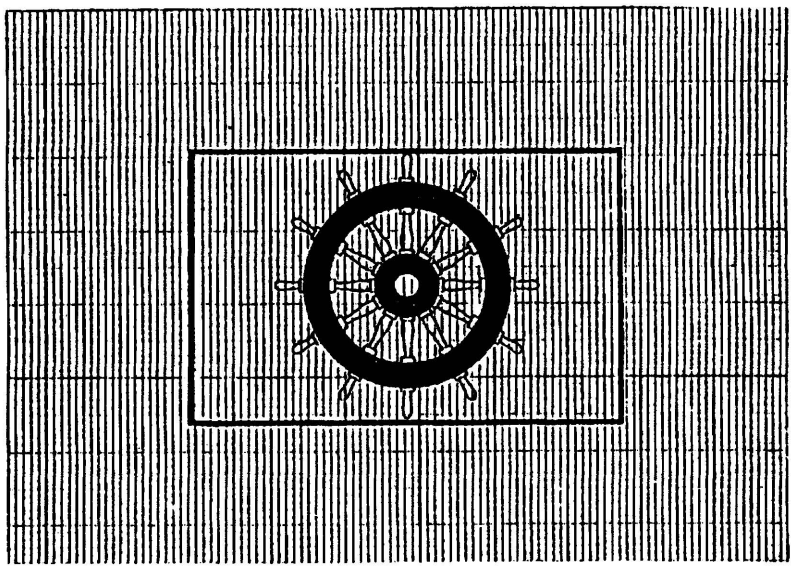
Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

Wheel mark

The mark of conformity must take the following form:



If the wheel mark is reduced or enlarged the proportions given in the graduated drawing must be respected.

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

That minimum dimension may be waived for small devices.

ANNEX II

Conformity assessment procedures

I. MODULE B: EC-TYPE EXAMINATION

1. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the requirements in the international instruments.

2. EC-type examination may be carried out in either of the following manners:

   – examination of a specimen, representative of the production envisaged, of the complete product (production type);

   – assessment of the adequacy of the technical design of the marine equipment through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type);

3. The manufacturer shall lodge an application for EC-type examination with a single notified body of his choice.

   The application shall include:

– a certified copy of the patent, license or document by which the applicant purports to have the right to make, use, sell or offer the marine equipment for sale or use its trademark, which, notwithstanding point 16 of Annex III, the notified body shall keep at the disposal of the competent courts;

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, 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. The technical documentation shall make it possible to assess the conformity of the marine equipment with the applicable requirements of the international instruments as referred to in Article 4, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the marine equipment. The technical documentation shall contain, wherever applicable, at least the following elements:

  – a general description of the marine equipment,

  – conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

(a) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the marine equipment,

(b) a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with this Directive, together with a description of the solutions adopted to meet the said requirements,

(c) results of design calculations made, examinations carried out, etc., and

(d) test reports;

– the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

– the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the marine equipment:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the marine equipment;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests in accordance with this Directive;

4.4. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific international instruments that apply to the marine equipment concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the international instruments, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the international instruments, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the marine equipment with the requirements of the international instruments or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for ten years after the last product has been manufactured.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

II. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the marine equipment concerned is in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the international instruments that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the marine equipment concerned.

The application shall include:

– a certified copy of the patent, license or document by which the applicant purports to have the right to make, use, sell or offer the marine equipment for sale or use its trademark, which, notwithstanding point 16 of Annex III, the notified body shall keep at the disposal of the competent courts,

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

– a written declaration that the same application has not been lodged with any other notified body,

– all relevant information for the marine equipment category envisaged,

– the documentation concerning the quality system,

– the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure that the products are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the international instruments that apply to them.

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

It shall, in particular, contain an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

– the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions 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, qualification reports on the personnel concerned, etc. and

– the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

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

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

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

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 shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

– the quality system documentation;

– the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the wheel mark set out in Article 9, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the international instruments.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for ten years after the last product has been manufactured. The declaration of conformity shall identify the marine equipment model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least ten years after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation referred to in point 3.1,

– the change referred to in point 3.5, as approved,

– the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

III. MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the marine equipment concerned is in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the international instruments that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the marine equipment concerned.

The application shall include:

- a certified copy of the patent, license or document by which the applicant purports to have the right to make, use, sell or offer the marine equipment for sale or use its trademark, which, notwithstanding point 16 of Annex III, the notified body shall keep at the disposal of the competent courts,
- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information for the marine equipment category envisaged,
- the documentation concerning the quality system, and
- the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type described in the EC-type examination certificate and with the applicable requirements of the international instruments.

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

It shall, in particular, contain an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

– the examinations and tests that will be carried out after manufacture;

– the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

– the means of monitoring the effective operation of the quality system.

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

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

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

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 shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

– the quality system documentation;

– the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in Article 9, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the international instruments.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for ten years after the last product has been manufactured. The declaration of conformity shall identify the marine equipment model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least ten years after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation referred to in point 3.1;

– the change referred to in point 3.5, as approved;

– the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

IV. MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the products concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the international instruments that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the international instruments that apply to them.

3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EC-type examination certificate and with the appropriate requirements of the international instruments.

The manufacturer shall provide the notified body with a certified copy of the patent, license or document by which the applicant purports to have the right to make, use, sell or offer the marine equipment for sale or use its trademark, which, notwithstanding point 16 of Annex III, the notified body shall keep at the disposal of the competent courts.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out, at the choice of the manufacturer either by examination and testing of every product as specified in point 4 or by examination and testing of the products on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every product

4.1 All products shall be individually examined and tested in accordance with this Directive, in order to verify conformity with the approved type described in the EC-type examination certificate and with the appropriate requirements of the international instruments.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for ten years after the last product has been manufactured.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot. All products in a sample shall be individually examined and tested in accordance with this Directive, in order to ensure their conformity with the applicable requirements of the international instruments and to determine whether the lot is accepted or rejected.

5.3. If a lot is accepted, all products of the lot shall be considered approved, except for those products from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for ten years after the last product has been manufactured.

5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. Conformity marking and declaration of conformity

6.1. The manufacturer shall affix the required conformity marking set out in Article 9, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product that is in conformity with the approved type described in the EC-type examination certificate and satisfies the applicable requirements of the international instruments.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities, for ten years after the last product has been manufactured. The declaration of conformity shall identify the marine equipment model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

V. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the international instruments that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

– a certified copy of the patent, license or document by which the applicant purports to have the right to make, use, sell or offer the marine equipment for sale or use its trademark, which, notwithstanding point 16 of Annex III, the notified body shall keep at the disposal of the competent courts,

– a general description of the product,

– conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

– descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

– a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with this Directive, together with a description of the solutions adopted to meet the said requirements,

– results of design calculations made, examinations carried out; and

– test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for ten years after the last product has been manufactured.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the international instruments.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in accordance with this Directive, in order to check the conformity of the product with the applicable requirements of the international instruments.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for ten years after the last product has been manufactured.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in Article 9 and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of the international instruments.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for ten years after the last product has been manufactured. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX III

Requirements to be met by notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in points 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the marine equipment it assesses.

4. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of marine equipment which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the marine equipment which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that marine equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services**.**

7. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

9. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it under this Directive and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

10. At all times and for each conformity assessment procedure and each kind or category of marine equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the marine equipment technology in question and the mass or serial nature of the production process.

11. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

12. The personnel responsible for carrying out conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the requirements, of the applicable harmonised standards and of the relevant provisions of EU harmonisation legislation and of its implementing regulations;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

13. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

14. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

15. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

16. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Directive

or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

17. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant EU harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

18. Conformity assessment bodies shall meet the requirements of standard EN4011 (ISO guide 65),

19. Conformity assessment bodies shall ensure that testing laboratories used for conformity-assessment purposes meet the requirements of standard EN17025.

ANNEX IV

Notification procedure

1. Application for notification

1.1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

1.2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the marine equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Annex III of this Directive.

1.3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Annex III .

2. Notification procedure

2.1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Annex III .

2.2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

2.3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and marine equipment concerned and the relevant attestation of competence.

2.4. Where a notification is not based on an accreditation certificate as referred to in section 1, the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Annex III to this Directive.

2.5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

2.6. Only such a body shall be considered a notified body for the purposes of this Directive.

2.7. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

3. Identification numbers and lists of notified bodies

3.1. The Commission shall assign an identification number to a notified body.

3.2. It shall assign a single such number even where the notified body is recognised as notified under several EU acts.

3.3. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

3.4. The Commission shall ensure that that list is kept up to date.

ANNEX V

Requirements to be met by notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.