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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a

Directive of the European Parliament and of the Council on marine equipment and repealing Directive 96/98/EC

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Contents

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

Identification

Lead DG: DG MOVE

Subject: Impact Assessment (IA) accompanying the revision of Council Directive 96/98/EC of 20 December 1996 on marine equipment[1] (hereinafter MED).

Agenda Planning/WP reference: 2008/TREN/004 - simplification

1.1. Organisation and timing

Work on the present Impact assessment started back in 2008, following the reform of the EU reference legislation governing the free movement of goods[2]. While a general alignment of the internal market legislation with the new legislative framework took place in 2011, the specificities of the marine equipment sector made it advisable to carry out a separate exercise that could take those into account.

An Impact Assessment Steering Group (IASG) was established in September 2008 for the preparation of this IA to which all Commission departments concerned were invited. The following departments took part in the group's meetings: ENTR, ENV, TRADE and SG. The IASG met on 27 October 2008, 19 February 2009, 31 March 2009, 8 July 2009, 23 March 2012 and for the last time on 12 July 2012.

1.2. External expertise

In September 2008, DG TREN called upon the European Maritime Safety Agency (hereinafter "EMSA") to provide technical assistance in the preparation of this IA. Additional research has been carried out by the Agency based on the IAB opinion of 11 September 2009.

1.3. Consultation of stakeholders

Since the coming into force of the MED in 1997[3], the Commission and EMSA have organised regular meetings with the relevant stakeholders (principally the Member States and Notified bodies) in order to provide training and guidance as well as sharing best practices relating to the implementation of MED.

In addition the following steps have been taken specifically for the improvement of the Directive in question:

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1 Council Directive 96/98/EC of 20 December 1996 on marine equipment (OJ L 46, 17.2.1997, p. 25–56)

2 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;
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,
Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

3 The deadline for transposition was fixed at 1 January 1999.

Questionnaire sent to the Member States by EMSA in September 2008, asking for data and figures on the most significant points concerning the implementation of the Directive. [4]

Questionnaire sent to the Member States, Industry and the MarED[5] Group of notified bodies - in early October 2008, in preparation of the stakeholder meeting. The questionnaire contained a preliminary analysis and questions concerning the scope of the Directive, Notified bodies, Market Surveillance, Safeguard Clause and Intellectual Property Rights.

Formal stakeholder consultation by the Commission[6] - On 27 November 2008 at a meeting held in Brussels. The Commission also received written contributions from six Member States and three industry representatives following the stakeholder consultation.[7]

In April 2012, all stakeholders were contacted again by the Commission to see whether the organisations wanted to endorse their 2008 positions or not, or provide fresher views on the possible amendments of the directive or new data.[8] The answers received largely confirmed the problems already examined in 2009, and provided clearer examples of the issues associated with the rigidity of the existing mechanism for the alignment of the Directive with the IMO changing standards.[9]

Throughout the preparation of this impact assessment, continuous consultation has been held with the marine equipment sector through their representatives in Brussels (the European Marine Equipment Council).[10] Bilateral contacts have also been held with two sub-sectoral associations who approached the Commission on specific issues.

Consultation of the stakeholders has shown that a) the Directive is necessary in order to provide a legal framework capable of ensuring both an appropriate level of safety and the free movement of marine equipment within the Community; and b) the Directive is nevertheless in need of an in-depth revision. Criticism from the stakeholders on the current working of the MED focused around four main areas:

(1) The Directive mechanisms do not work well because they do not tie in well with the particular circumstances of the marine equipment sector.

(2) There is limited supervision of the implementation of the Directive by Member States due to resource scarcity/available expertise.

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4 The results of this survey are attached in Annex 1.

5 MarED – co-ordination group for the Notified bodies assigned by the Member States to carry out the conformity assessment procedures referred to in the MED. The MarED Website contains information about the MarED Group, Notified bodies and the Directive.

6 The group of stakeholders invited to comment was formed by the Member States, Iceland and Norway (flag States administrations), MarED Group on notified bodies and the equipment manufacturers.

7 The minutes of the stakeholders' meeting of November 2008, are attached in Annex 2 and will be available for consultation on the maritime safety webpage of DG MOVE .

8 Observations were submitted by five Member States and three industrial associations as well as the notified bodies.

9 The replies received in the second consultation are summarised in Annex 3 and will be available for consultation on the maritime safety webpage of DG MOVE.

10 Consultation with EMEC was considered indispensable given the importance of SMEs in the sector, which due to their size and scarce resources, would find it difficult to make their position known to the Commission. Indeed, in this way it has been possible to question individual companies through EMEC and obtain inputs which are representative also of the SMEs points of view.

(3) Complexity, time delays and unclear roles cause uncertainty for the Member States, Notified bodies and equipment manufacturers.

(4) Wherever the Directive deviates from standard international and/or IMO practice, this translates into operational difficulties for the operators, e.g. when the respectively applicable requirements differ or when transition arrangements do not coincide.

In general, while meaningful qualitative input was received from the stakeholders, this was not accompanied by quantitative information from either the industry or the Member States.

All in all, stakeholders (including SMEs) have been fully able to contribute to the current proposal for the review of the MED. Their views have been assessed and appropriately taken into consideration.

The standards set in the "General principles and minimum standards for consultation of interested parties by the Commission" have been met.

1.4. The key aspect of data availability[11]

There is not one sector-based (NACE[12]) classification covering the sector of marine equipment. This means that in many cases no uniform data is collected centrally, hence making this sector much harder to monitor than ship construction.

Furthermore, different definitions are used in different data sources making it difficult to arrive at “hard” estimations. Marine equipment manufacturers are often also suppliers of other industries (e.g. automotive, aviation, etc.) or are still integrated into the shipyards like in Italy. This should be taken into account when interpreting the data presented in the present IA.

It is worth mentioning that, according to a study undertaken by the Commission[13], no studies have been done at European level to look at employment in this sector, whereas only a few such studies have been carried out at the national level. For most countries, it is not possible to obtain figures relating to employment in the sector.

Lastly, the surveillance and control activities of the Member States face considerable difficulties given the specific features of the sector[14] and have not therefore produced comparable quantitative information. This makes it very difficult to gauge precisely the effectiveness of enforcement

The second stakeholder consultation, while confirming the qualitative perceptions made in the past, has not yielded any significant quantitative, up-to-date input. **In light of this, the present IA and its conclusions are based on the best available sector-related data, even though being occasionally incomplete.** Similarly, as a result of the known lack of data, it has been considered it would not be possible to carry out a meaningful, separate ex-post evaluation exercise to supplement stakeholders' input without incurring further serious delays.

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11 This part is largely based on the findings of the *Study on the Competitiveness of the European Shipbuilding Industry – 2009*, prepared for the Commission - http://ec.europa.eu/enterprise/sectors/maritime/files/fn97616_ecorys_final_report_on_shipbuilding_competitiveness_en.pdf.

12 Statistical Classification of Economic Activities in the European Union.

13 See "competitiveness" study, *op.cit.*

14 See Annex 4.

1.5. Results of the consultation of the Impact Assessment Board

A first draft report for this IA was submitted to the Impact Assessment Board (IAB) on 16 July 2009. The IAB asked for a resubmission of the IA report in its opinion of 11 September 2009. The IAB's recommendations led to significant shortening and complete restructuring of the initial draft, as well as to the improvements in a number of key aspects.

A revised version of the IA report has been resubmitted to the IAB on 20 July 2012. The revised document takes into account the recommendations of the IAB in the following manner:

- The report has been brought in line with the standard structure of Commission Impact Assessments, including a clearer description of the different steps, a refined but shorter problem description pointing at the importance of the different issues and a market description.

- The sections on policy options, impacts, comparison of options and monitoring and evaluation have been strengthened. Objectives have been regrouped and simplified and policy options have individually been mapped to objectives identified.

- The report now places greater emphasis on safety considerations in the analysis of options.

The IAB sent its second opinion on 28 August 2012, with a number of recommendations for inclusion in the final version of this impact assessment. As a result of these recommendations, the baseline scenario has been strengthened, more explicit references to input from stakeholders have been included and the assessment of policy options in regard of simplification and reduction of administrative burden has become more detailed (with specific reference to quantitative estimations), while the monitoring aspects have been given more attention in order to resolve the problems associated with data availability in view of a future ex-post evaluation.

2. CONTEXT

A detailed description of the market for marine equipment is provided in Annex 4.

2.1. Current EU legal framework for placing marine equipment on board ships - the MED

Shipping accidents are a matter of serious concerns to the EU, in particular those that cause loss of human life and pollution of seas and coastlines. It is vital to ensure that safety requirements and standards of marine equipment keep up with the latest trends, especially as new technologies, materials and manufacturing processes are constantly being developed while lessons keep being learnt from experience.

In order to ensure high safety levels in the performance of the equipment carried on board ships, international conventions adopted under the auspices of the International Maritime Organization (IMO) require marine equipment to conform to certain safety regulations. These

are mostly enshrined in the main maritime conventions themselves[15] together with their protocols and amendments, as well as in a number of other IMO instruments.

In this context, the MED has laid down common standards which provide a harmonised interpretation and implementation of the above mentioned IMO rules for the performance of marine equipment to be placed on board ships flying the flag of the EU Member States. Through this framework, the objective of this Directive is to contribute to safety at sea, to prevent marine pollution and to ensure the free movement of marine equipment within the EU.

The legislative technique used in MED to achieve its policy objectives is largely based on the principles defined in the *New Approach* for the area of free movement of goods.[16] Nevertheless, the MED has implemented a number of specific solutions which deviate from mainstream *New Approach* legislation due to the specificities of the marine equipment sector:

- marine equipment has to fulfil IMO international standards. Flag states are expressly required to issue a certificate of approval by the IMO conventions described above. The Directive has the specific objective to ensure compliance with this obligation as well as mutual recognition of these certificates between Member States.

- marine equipment encompasses some categories of equipment, which are also within the scope of Directives other than the MED (e.g. fire extinguishers, electronic material, protective equipment, pyrotechnics), the requirements of which may differ from, or even be incompatible with, those of the IMO.

This is described in more detail in Annex 5, which provides a description of the *New Approach* and a comparison between this and the MED.

2.2. Evolution of the EU reference legislation governing the free movement of goods

Experience over the years with the implementation of EU legislation in the area of free movement of goods has highlighted certain weaknesses and shown that the effectiveness of the system can still be improved. In 2008, the *New Approach*[17] was subject to a revision which led to the **New Legislative Framework** (hereinafter the "NLF") for the marketing of products.[18]

The IA accompanying the revision of the *New Approach* identified and fully analysed the problem areas which are common to *New Approach* directives, namely lack of confidence in notified bodies and in the whole notification process in general; weaknesses in market surveillance and efficient and consistent enforcement of the directives, inconsistencies and legal uncertainty in the current regulatory framework and misunderstanding of the value and role of CE marking. This IA has also identified and analysed a number of policy options to

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15 See Annex 13

16 The New Approach revolutionised the way legislation is written by moving away from complex and detailed prescriptive technical requirements and, instead, fixing only the essential public interest requirements to which products must comply to protect the public goals of health and safety. Other innovative features of this legislative technique include the setting up of appropriate conformity assessment procedures and the introduction of CE marking.

17 Impact assessment on the proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products and a Decision on a common framework for the marketing of products, SEC 2007(173).

18 Annex 7 contains a description of the elements of the NLF.

address the above problems across various sectors. Decision 768/2008/EC, which was adopted as a result of this analysis, provides a set of policy measures considered being the most adequate cross-sectorally, and which cover four main pillars: market surveillance, conformity assessment of products, CE marking and a set of measures for use of legislation.

The NLF leaves little flexibility to the co-legislators on the choice of tools for eliminating the malfunctions and inefficiencies of legislation based on the New Approach. Article 2 of Decision 768/2008/EC clearly says that Community legislation in the area of free movement of goods "*shall have recourse to the general principles set out in [the said] Decision and to the relevant reference provisions of Annexes I, II and III [to that Decision]"* while *"[departing] from those general principles and reference provisions if that is appropriate on account of the specificities of the [marine equipment] sector[…]"*[19]

Pursuant to this substantive reform, the Commission proposed the alignment of 10 technical harmonisation directives in 2011. As mentioned above, due to its important specificities, the MED was not included in this mainstream alignment, but remained a separate exercise.

3. PROBLEM DEFINITION

3.1. Description of the problem

As indicated above, criticism expressed by stakeholders in the public consultation on the current working of the MED focused on two main areas:

3.1.1. The MED suffers from weak implementation and enforcement mechanisms

The stakeholders' consultation conducted in the context of the revision of MED has confirmed that the marine equipment sector shares the same problem areas with other New Approach directives: unequal implementation in the Member States, ineffective market surveillance and misuse of safeguard clause. As a consequence, as suggested by stakeholders, the current legal framework defined by MED does not sufficiently ensure the complete application and implementation of IMO standards in the EU, possibly leading to safety risks and inefficient functioning of the Internal Market for marine equipment[20]. Annex 6 explains in greater detail how the problem areas common to New Approach directives materialise in the marine equipment sector.

The identified malfunctions of the MED system, which are shared with other New Approach Directives, stem from the fact that the MED has not yet incorporated the corresponding regulatory remedies provided by the NLF. This concerns four main pillars: market

[19] See also recital 7 of Decision768/2008/EC.

[20] Indeed, during the stakeholder consultation held in 2009, industry representatives highlighted the need for more effective action against non-compliant products and called for specific measures against IPR violation and counterfeit. Similarly, Member States complained about the difficulties faced by market surveillance authorities and the lack of transparency between administrations themselves, calling for specific action in the field. As regards notified bodies, Member States administrations highlighted the need for better audit and monitoring and pointed at the lack of maritime expertise among accreditation bodies, calling for a set of clear requirements to be included in the Directive – a point with which industry representatives concurred, while highlighting the need to avert unfair competition and control underperforming bodies. The second consultation carried out in 2012 confirmed that the views of both industry and Member States as regards these problems remained unchanged; with stakeholders insisting on different aspects needing improvement in all three fronts (notified bodies, market surveillance, safeguard clause).

surveillance, conformity assessment of products, CE marking and a set of other standard measures to be used in future internal market legislation.

However, in view of the explicit provision contained in Article 2 of Decision 768/2008/EC, addressing the malfunctions of the New Approach directives means mandatory alignment of MED on the provisions of the NLF, and notably on Decision 768/2008/EC and Regulation 765/2008/EC. Against this background, and taking into the specificities of the marine equipment, the problem discussed in this IA is not *if* MED should be aligned with the NLF, but *how* to align. In this respect,

- The main objective of the NLF is to contribute to the design, implementation and improvement of a flexible regulatory framework providing access to the single market while protecting essential public requirements. It follows that trade-offs can be expected between the goal of ensuring cross-sectoral legislative coherence through the alignment to NLF on the one hand, and the goal of optimising the functioning of the internal market for marine equipment, on the other hand.

- The wording of Article 2 of Decision 768/2008 leaves no doubt that departure from the NLF needs to be justified on precise grounds of specificities of the sector concerned. In the case of marine equipment, the specific features of the product indeed have a strong influence on the capacity of the legislation to reap the full benefits of EU harmonisation legislation and therefore it may be reasonable to consider MED-specific solutions in specific areas. This aspect has been confirmed by the public consultation.

The table below identifies and discusses which provisions of the NLF may see their effectiveness affected by the specificities of the MED in a way that the full benefits of harmonisation legislation would not be attained by its direct application.

Table 1: Influence of marine equipment specificities on the effectiveness of NLF main provisions

	Content of NLF provisions	*Possible influence of marine equipment specificities*
Market surveillance		
Common EU framework	Regulation (EC) 765/2008 improves market surveillance through explicit requirements for Member States to carry out and organise market surveillance activities in respect of the principle of subsidiarity. Market surveillance is organised and performed at two main stages: - national surveillance authorities monitor that products placed on their market comply with the provisions of Community harmonisation legislation transposed into the national legislation; structured controls are carried out at the EU borders; - national surveillance authorities take action, when necessary, either to bring non-compliant products into compliance, to remove unsafe products from the market and /or to ban them, or in justified cases to destroy them.	No significant influence. However, in the particular context of the marine equipment sector, the quality of surveillance authorities' work becomes a matter of critical importance. Surveillance authorities must in any case have a good mix of maritime expertise and expertise in the technical fields covered by the Directive.
More effective post-market control mechanism	Regulation (EC) 765/2008 defines market surveillance measures to be carried out by the surveillance authorities. These include: to organise random and spot checks; to require all necessary documentation from the manufacturer in order to be able to evaluate product conformity; when justified, to enter the manufacturer's premises and take samples for testing, and in extreme cases to destroy products. Market surveillance is put in the hands of a single national authority and subject to structured planning and implementation.	The relevant market for the legislator is not the marine equipment sold in the EU territory, but rather the marine equipment due to be installed on board ships flying the flag of an EU Member State. Equipment due to be installed on board non-EU ships falls outside the scope and objectives of the MED (and hence outside the scope of this IA) even if sold within EU territory. Conversely, equipment to be placed on board EU ships may or may not physically enter the EU territory. As a result, - controls at the borders and within EU territory become less relevant and; - market surveillance becomes more difficult than in the case of other products. Moreover, in the marine equipment sector, national authorities (suffering a chronic dearth of resources) need to

		make expertise available in a very diverse range of technical fields (as the MED covers a vast range of equipment e.g. from upholstery to radars) and gain access to very specialised test labs.
Safeguard clause procedure	The safeguard clause procedure has been reorganised and streamlined. The new procedure ensures that the relevant enforcement authorities are informed about dangerous products and that similar action is taken against that product in all Member States. The Commission ensures that these measures do not constitute disguised obstacles to the free movement of products.	The great diversity of the equipment covered by the MED calls for equally diverse technical expertise, which may be beyond the Commission's or even EMSA's resources. This may cause delays and difficulties in the assessment of safeguard clauses.
Conformity assessment of products		
Common EU framework	The NLF clarifies and develops the rights and obligations of notified bodies, and strengthens the control mechanisms in the hands of the Member States and the Commission.	No significant influence. However, in the particular context of the MED, as described above, the quality of notified bodies' work becomes a matter of critical importance. Notified bodies must in any case have a good mix of maritime expertise and expertise in the technical fields covered by the Directive.
Essential requirements	The NLF recommends specific product legislation to avoid, wherever possible, going into technical detail and to limit itself to the expression of essential requirements. However, where health and safety, the protection of consumers or of the environment, other aspects of public interest, or clarity and practicability so require, detailed technical specifications may be set out in the legislation concerned.	Marine equipment has to meet the requirements of the international conventions, the relevant resolutions and circulars of the IMO, and the associated relevant international testing standards. These instruments contain detailed technical requirements against which the flag State must approve any equipment placed on board ships flying the latter's flag. However, the said international instruments leave very considerable latitude for flag States in the interpretation and application of the relevant requirements. Some requirements which are important for safety do not muster sufficient consensus to be made mandatory and thus are approved as recommendations or guidelines only. In the absence of a harmonising instrument, this might lead to very significant differences between Member States and potentially affect both safety and the smooth functioning of

		the internal market.
Notification of conformity assessment bodies	The Decision (EC) 768/2008 foresees stronger clearer rules on the requirements for the notification of conformity assessment bodies (testing, certification and inspection laboratories) including the increased use of accreditation; a system to ensure that assessment bodies provide the high quality services that manufacturers, consumers and public authorities need.	No influence
Conformity assessment procedures	Decision (EC) 768/2008 provides a simple, coherent and complete menu to select the most appropriate module(s)/procedure(s) for the specific area of activity. A conformity assessment procedure covers both design and production phases. The assessment of the conformity of the product in question may be carried out either by the manufacturer himself or by a (manufacturer's in-house or external) conformity assessment body, depending on the provisions of the modules selected by the relevant sectoral legislative instrument.	IMO requirements are based on certification by or on behalf of the flag State. Modules not compatible with this premise must be excluded. Furthermore, the particular circumstances of marine equipment make the sector vulnerable to notified bodies' conflicts of interest, thus making it advisable not to allow for in-house notified bodies.
CE marking	The Decision (EC) 768/2008 confirms the fundamental requirement to use the CE marking and clarifies its meaning. In addition the CE marking[21] is to be protected as a trade mark, which will give authorities and competitors additional means to take legal action against abuse.	The overlap with other internal market Directives applicable to marine equipment requires a mechanism to identify the products specifically built for their use on board EU ships and conforming to the specific requirements of the IMO.
Set of measures for use in legislation	Common EU legal framework	
Obligations of actors in the distribution chain	The Regulation (EC) 765/2008 establishes common obligations for manufacturers, importers, distributors. **Importers and distributors** must check that products bear the CE marking, are accompanied by the required documents and carry the name of the manufacturer and the importer (if relevant). **Importers** must furthermore check that the manufacturer outside the EU has applied the correct conformity assessment procedure and establish a link to the manufacturer that allows the technical documentation to be obtained when it is requested by authorities. They must carry out sample tests on products which they have supplied, when this is appropriate in	The share of marine equipment which is actually placed on the market is small, with most of them being fixed on board ships in the shipyards. Equipment imported for installation on board non-EU ships is not relevant for the Directive.

[21] The CE marking is an indication that the products comply with the essential requirements of the applicable directives and that the products have been subject to a conformity assessment procedure provided for in the directives.

	the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non-conforming products and product recalls and keep distributors informed about such monitoring. In addition to the obligations that the current legislation already imposes on **manufacturers**, they must provide instructions and safety information in a language easily understood by consumers and end-users. Furthermore, they are subject to the same obligations on sample testing and product monitoring as importers. New obligations are introduced for **all economic operators** to ensure *traceability of products* throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document. Furthermore every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it. This obligation does not include sales to end-users.	
Harmonised definitions and procedures (save the CE marking)	The Regulation (EC) 765/2008 establishes harmonised definitions and procedures among the NLF directives.	No influence

The table above shows that, for some key components of the application and enforcement mechanisms of MED, the specificities of the marine equipment either have an influence on the effectiveness of the solutions provided by the NLF or are simply not compatible with them, thus making it necessary to deviate from these solutions.

3.1.2. The process of transposition of IMO rules into national law creates legal uncertainty and imposes excessive burden upon the industry and national administrations

In the course of the stakeholders' consultation, both industry representatives and the Member States complained about the difficulty to establish, on the basis of the Annexes to MED and of the amending legislative acts (Commission Directives), which requirements apply to particular pieces of marine equipment at a given time. The main elements of criticism were that:

- The date of entry into force of the requirement and the date of validity of certificates is not specified;
- The information on the most updated version of the annexes to MED is not available in an easily readable form online;
- Manufacturers are not notified in time of upcoming changes in standards;
- The automatic update clause is too rigid, especially as regards testing standards, leading to massive and unnecessary re-certification of stocks even if construction and performance requirements remain unchanged;
- The directive's Annex is at present not suited to meet the needs of both industry and national authorities. The current update mechanism does not allow the Commission to e.g. address equipment components if and when necessary, include production standards, introduce elements of flexibility for Member States' implementation, etc.

The resulting *legal uncertainty*[22] is compounded by the fact that safety requirements and standards of marine equipment as laid down in the Directive annexes do not necessarily keep up with the latest trends. Therefore, equally important are the inherent safety risks in the application of obsolete requirements to marine equipment, as the update of the latter is in most cases due to safety risks newly identified or the approval of more effective technologies to address known risks. Furthermore the risk of detention of ships by foreign port authorities for non-compliance with applicable IMO standards increases significantly. Finally, it must be taken into account that many items of marine equipment are installed into larger integrated systems (e.g. engines, navigational systems, etc.) which may have been designed for components meeting the newest standards and which therefore could suffer from installation problems or low performance.

The resulting confusion for manufacturers, customers and national authorities can lead to unwanted mistakes and failures to conform to the requirements in force[23]. Moreover, this may render the management of stocks (at least part of which are kept overseas) extremely difficult

[22] Problems with legal certainty were highlighted by industry and administrations, especially as regards the administration of the Annex, both in 2009 and 2012. Indeed, the problems suffered by the MED in this respect were a central theme in the answers received in the second consultation, held in 2012.

[23] In extreme cases, EU ships, national authorities, notified bodies and other operators may be forced not to apply the Directive correctly in order to avoid all these problems

and indeed more costly, as well as lead to re-certification gluts due to limited capacity on the side of the labs and notified bodies. [24]

The Commission has estimated (see Annex 12) that the current system may result in a burden of up to €6-7 million a year for the marine equipment industry only, of which approximately 2/3 may correspond to lost return on investment and stock management, while up to 1/3 could directly derive from double certification.

This situation stems from two main causes:

The legislative technique chosen to keep up pace with the development of IMO requirements is complex

As indicated above, marine equipment has to meet the requirements of the international conventions, the relevant resolutions and circulars of the IMO, and the relevant international testing standards. The MED therefore deviates from the principle of essential requirements defined in the *New Approach* so that IMO standards are applied and implemented in a harmonised way across Europe.

Currently, Annex A.1 to the MED contains the list of the specific construction and performance requirements to be met, as well as the mandatory testing standards to be used, in the conformity assessment of marine equipment due to be placed on board EU ships. This Annex is periodically updated in order to keep up with the legislative production of the IMO and, as appropriate, of the international and European standardization bodies[25]. The updates take the form of Commission Directives adopted in accordance with the regulatory procedure with scrutiny. The updates are then transposed into national legislation of each Member State within a period of twelve months. [26]

As an additional means to keep pace with the constant development of requirements and standards by IMO and the international/European standardisation bodies, the Directive includes a so-called "automatic update" mechanism. According to this, the performance and testing standards listed in Annex A.1 apply in any case in their up-to-date version – regardless of their explicit update in the Annex. However, in practice, this mechanism has proven quite ineffective for the following reasons:

- not all standards are simply amended but sometimes outright replaced;
- new items need to be incorporated into the Annexes;
- not all new amendments to the relevant instruments have a clearly identifiable date of entry into force; lastly, because even if this date exists, the amendments may contain "grandfathering clauses" not necessarily aligned with the principles of the directive

[24] This is a point which has been made by both the industry and the Member States, especially in the course of the second consultation.

[25] The International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the European Committee for Standardization (CEN), the European Committee for Electro-technical Standardization (CENELEC), and the European Telecommunication Standards Institute (ETSI)

[26] This was the case for the four most recent amendments of Directive 96/98/EC. Although in the first three amendments the transposition period was fixed at six months, this has proven insufficient for the Member States and it is now an established practice to have a twelve months' transposition period for each update.

and thus rendering very confusing the regime to be applied to the existing stocks. The net result of this is a significant degree of legal uncertainty and uneven practices among Member States, such that the automatic update mechanism cannot be relied on to replace a frequent, actual update of the annexes.

In summary, these two mechanisms work in such a way that:

1. Where a new standard replaces, amends or supplements an existing standard which is listed in Annex A.1 to the Directive, it will apply automatically on the date of its entry into force even without explicit change in the Directive's Annex. The immediate consequence of this is that what is listed in Annex A.1 may not coincide with what is actually applicable.

2. When a new standard does not fulfil the conditions under point 1, or does not have a date of entry into force, it will not apply until explicitly included in the Directive at the next periodic update of Annex A.1. The immediate consequence of this is that a new standard may not be applicable in the EU even if it is already applicable internationally.

The transposition process of IMO requirements into national law is lengthy

IMO normally leaves a reasonable time between the adoption of safety requirements and their entry into force, ranging in most cases between twelve and twenty-four months. To be effective, the EU transposition system should be capable of bringing the new requirements into national legislation within that time window. However, in practice, this is not the case. Experience has shown that the time lag between the update of instruments and international standards by IMO and the transposition of those into national law may easily reach 30 months per update (including update by the Commission and transposition by national authorities).

Box 2 illustrates the problems related to the currently process of transposing IMO rules into European and national legislation in the extreme case of the 4th amendment of the MED.

Box 2: Case study on the fourth amendment of Annex A

Work on the 4th amendment started at the beginning of 2005, that is, barely two years after the 3rd amendment[27]. At a moment of a particularly intensive activity of the IMO in the production of technical specifications for marine equipment, it soon became apparent that:

– Where new requirements had been adopted by the Organization, it was sometimes particularly difficult for the specialists to identify in a clear-cut manner their exact scope and the exact sequence of the application of new and old requirements depending on the type of ship and date of construction or putting into service. This was for instance the case of the items concerned under the IMO high-speed craft code, and extended to a significant portion of Annex A.1.

– The laborious and time-consuming process of identifying the correct requirements combined with the length of the formalised procedures involved made the process of adoption extremely time consuming, to the point that IMO requirements changed again while the technical discussion still went on. As a result, a number of items needed to be examined anew before their incorporation in the revised Annex.

– The adoption of the 4th amendment in these difficult circumstances required, in addition to countless rounds of online technical discussion coordinated by EMSA, examination of the dossier at three formal committee meetings and two specific committee expert meetings.

[27] Adopted in September 2002

Eventually, adoption was only possible by leaving the update of a number of items for the following amendment, at the inevitable cost of making part of the 4th amendment obsolete already on the very day of its adoption. Similarly, even if the transposition time was cut to the bare minimum, for some other items the requirements in the revised Annex would become obsolete even before their transposition into national law. The cascade effects of the difficulties experienced in the 4th amendment are highlighted by the fact that a total 16 items added anew in the 4th amendment to Annex A.1 were subsequently modified in the 5th amendment, adopted less than a year afterwards. This was clearly very disturbing for both the industry and national administrations.

For economic operators, the delay between the entry into force of international requirements and the time when it can legally be placed on the market may also have implications in terms of cost at different levels. In the first place, it delays the return on the investment for the company that has developed the new marine equipment. In addition, a too lengthy process for approval of new marine equipment undermines the rate of innovation in the sector. As a result, long transposition delays have a negative effect on the overall profitability of the sector, especially as it is composed mainly by small and medium enterprises.

Moreover, the lengthy process of periodic update of the Directive's Annex adds to the confusion. In effect, due to the time lag between the entry into force of international requirements and their enforcement within the EU, the industry is left in a situation of significant uncertainty as to the substantial and testing requirements actually applicable - especially in the case where there is significant departure from the practice in third countries.

3.1.3. Conclusion

Experience with the working of the MED highlighted certain implementation and enforcement weaknesses common to *New Approach* Directives that can be addressed by aligning the MED on the NLF as foreseen by the co-legislators. However, in light of the specificities of the marine equipment, a key issue is whether MED-specific solutions are also needed in some areas. In addition, the transposition process of IMO rules into national law creates legal uncertainty and imposes excessive burden upon the industry and national administrations because of a long and complex legislative technique – making it very difficult to keep up with the production of technical requirements by the International Maritime Organisation.

For these reasons, the MED does not ensure the complete application and implementation of IMO and other standards by Member States, leading to safety risks and inefficient functioning of the Internal Market for marine equipment.

3.2. Stakeholders affected

The global competitive advantage of **European marine equipment manufacturers** relies greatly on innovation, having regard to the relatively low labour costs and other advantages that often benefit their competitors in the emerging countries.[28] The weakness of market surveillance and the safeguard procedures therefore affect European manufacturers disproportionately.

The current transposition procedure, which often leads to the temporary coexistence of conflicting rules at EU and global levels, is also source of administrative burden and costs related to the manufacturing of products according to two or more standards. The inefficiency of certification by notified bodies is finally source of costs, delays, and can distort

[28] Shipbuilding IPR Study, *op. cit.*

competition between manufacturers. Given the strong links between the marine equipment sector and the **shipyards**, the latter are equally affected.

It must be borne in mind that **SMEs**, which are a majority among the EU marine equipment industry, are particularly vulnerable to the current problems as they have to face fierce competition in distant markets in a strongly regulated environment – where changes in regulation are very frequent. The industry has to adapt to the decisions made by a plethora of regulators (IMO, EU, national authorities), having little if any information on those decisions which in practice turn out to be uncoordinated both in timing and in content. Changes may have noticeable impacts on research and development investments, production planning or the management of stocks. These impacts may become important for SMEs, which find it harder to gain access to capital markets in order to adapt and stay competitive. The costs associated with the late implementation of IMO requirements in the EU (reduced return on R&D investment, costs of double certification) represent a heavier burden for SMEs (given e.g. that the cost of one type approval does not depend on the volume of production).

Ship passengers and crews are affected by the safety problems such as the presence on ships of counterfeit products of unknown performance (resulting from the ineffectiveness of market surveillance), possible use in the same mechanical unit of parts conforming with different standards (when new standards are not transposed in time), and the use of products certified by potentially incorrectly performing notified bodies. In case these problems lead to a major maritime accident, its consequences (eg. oil spill) could be felt by the inhabitants of coastal regions.

Finally, the ineffectiveness of the transposition system is source of administrative costs for the **public administration and governments**.

3.3. Baseline scenario

It is expected that the marine equipment sector will be affected by two trends in the foreseeable future. On the one hand, shipyards will gradually become final assembly facilities only, while most value added activity will continue migrating to the marine equipment sector. In this rising market, the share of Europe will however be declining (according to available sources, it would have already fallen to 31% in 2010 from 36% in 2005). Part of the reason is that many European players delocalise production to Asia where most of their customers – the shipyards – are located. As an effect, the problems related to market surveillance will become more acute in the future as an even larger fraction of the equipment will be manufactured and fitted on board European ships outside the physical borders of the EU.

The possible future enlargement of the EU to maritime countries such as Croatia and Turkey would significantly increase the fleet covered by MED rules and slightly increase the share of the EU in the global marine equipment market. At the same time, the increase in the number of EU Member States will further complicate the process of transposing IMO rules into EU and national legislation, exacerbating current problems.

The lack of data makes it impossible to measure the magnitude of these problems and hence to complete this assessment with the analysis of a set of meaningful quantitative indicators.[29]

[29] It is expected that, in the future, this problem will be resolved. In effect, the Commission has recently commissioned a study on the competitiveness of the sector, which is expected to provide an in-depth analysis of the market and examine the foreseeable evolution of the marine equipment industry.

A mechanism for a more efficient yearly update of MED Annex A has been initiated by EMSA at the request of the Commission as from 2008. This mechanism is based on a continuous monitoring of the essential requirements and testing standards for marine equipment and a Web based tool developed in order to facilitate the EU Member State contributions. Unfortunately, whatever the efficiency of these improvements is, it appears that the delay involved by the "amendment" procedure is still too important, as the time needed for a new IMO requirement to become effective within the national legal orders of the Member States continues to exceed significantly the window left by the IMO for its worldwide implementation. Annex 12 shows that the total costs incurred by the industry due to the delays in the transposition of IMO requirements into the MED can be estimated at approximately 6 to 7 million € per year of delay; in the baseline scenario, these costs should be expected to grow concomitant with the expectedly growing production of safety standards by the IMO, given the Organisation's ambitious work programme.

The EU procedure for the transposition of IMO rules will be affected by the changes introduced by the Treaty on the Functioning of the EU (TFEU). Currently, as stipulated by Articles 17 and 18.3 of MED, the annexes to the Directive are amended in accordance with a Regulatory Committee Procedure with Scrutiny. This will need adaption to the new Treaty provisions. Whether their fate is to become implementing acts (with an associated examination committee procedure) or, more plausibly, delegated acts[30], this should not bring about any significant reduction in the length of the procedures relative to the current state of affairs. Indeed, technical consultation with the Member States, be it at an expert or at a committee level, would continue to be necessary – as would transposition of each new Annex into the Member States' national legal orders.

In conclusion, the analysis of the baseline scenario seems to indicate that the problems concerning MED will grow in the future, making it even more urgent to review sub-optimal rules.

3.4. Does the EU have the right to act?

3.4.1. Legal basis

The EU transport policy, including maritime safety policy, has a well-established Treaty base in Article 100 of the TFEU (*ex* Article 80) upon which Directive 96/98/EC is based. This proposal modifies existing EU legislation principally to reflect the reform of the New Approach on which MED is partly based. The review uses the reference provisions provided in the Annexes to Decision 768/2008/EC, in line with Article 2 of the said Decision which stipulates that "Community 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." In some points, the proposal departs from the provisions of the Decision, which is justified in light of the rest of Article 2 of the Decision "Community 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".[31]

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30 The Commission has committed to replace, by 2014, all PRAC provisions by a reference to Delegated Acts in line with the Article 290 TFEU.

31 Point (5) of the recital to Decision 768/2008/EC actually mentions marine equipment as one of the sectors for which specific adaptations of the common principles and reference provisions are needed.

3.4.2. Subsidiarity

As the Commission already identified in its 1995 proposals, direct application of the IMO regulatory framework by the Member States in the absence of Community harmonisation had led to significant barriers to the free movement of goods, mostly stemming from a) the broad discretion left by the IMO instruments to the flag state, b) the production of additional national requirements and c) the divergences in the certification methods. At the same time, the resulting divergences in national regulations had led to uneven degrees of safety and environmental protection.

At the time it was established that harmonisation by the EU resolves these problems, as it results in a clearly identified set of requirements and uniform certification procedures capable of ensuring a high level of safety and of environmental protection. Moreover, unlike the international system, the EU offers the advantage of a judicial enforcement system – without which the effectiveness of those requirements and procedures would be seriously undermined.

The 2004 and 2007 enlargements have considerably increased the size of the Single Market and nearly doubled the number of Member States, making harmonisation even more necessary that before. At the same time, the expected steady increase in maritime transport volumes, and the enlargement of the EU to Member States having large fleets – notably Cyprus and Malta – has increased the importance of fixing and enforcing a common high level of safety and environment protection.

3.4.3. Proportionality

The EU does not harmonise itself the detailed technical specifications applicable, which are decided at the IMO level with full contribution of the Member States. It merely identifies in a clear way what specifications and technical standards of the IMO should be applied.

It is legitimate to enquire whether harmonisation could be achieved with soft law or mutual recognition. The Agreement between the European Community and the United States of America on the mutual recognition of Certificates of Conformity of marine equipment[32] can serve as an example of the limited effectiveness of such an approach. The agreement is based on the verification of the equivalence of the respectively applicable standards and the mutual recognition of certifications bodies and procedures. Given that both parties implement the IMO standards, a significant degree of convergence might have been expected. However, it appears that so far agreement has been reached, in this agreement, on the recognition of roughly 1/3 of the marine equipment listed in Annex A.1 to MED; for the rest, European and American rules have been deemed too divergent to make mutual recognition possible. This confirms the above mentioned Commission's findings of 1995, and clearly shows that in order to ensure the smooth functioning of the Internal Market and the full recognition of marine equipment between Member States, only a mandatory legislative approach can be effective – which is why only legislative options are analysed in what follows.

4. OBJECTIVES

This section defines the general and specific policy objectives of the proposed initiative and verifies their consistency with other EU horizontal objectives.

[32] OJ L 150/46, 30.04.2004.

4.1. Policy Objectives

4.1.1. General objectives

Pursuant to Articles 90 and 91 TFEU, the Common Transport Policy (CTP) should contribute to the broader objectives of the Treaties. 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[33] while ensuring a high level of safety at sea and prevention of marine pollution[34];

- 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.

4.1.2. Specific objectives

Based on the problem and related root causes set out in section 2 above, the twofold general objective can be translated into 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 market surveillance, conformity assessment of products and obligations for actors in the distribution chain;

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

The above specific objectives are sufficiently precise and inevitably contain the specific areas where measures are necessary. Therefore, it does not appear necessary to break them down into operational objectives.

[33] Art. 26 par. 1 TFEU on ensuring the functioning of the internal market as further explained in Art. 28 and 29 TFEU on the free movement of goods.

[34] Art. 91 par. 1(c) TFEU on improving transport safety read in conjunction with Art. 100§2 TFEU, and Art. 11 TFEU on integrating environmental requirements into the definition and implementation of the Union's policies and activities.

Table 2: Mapping problem, drivers and objectives

Problems		*General objectives*	
The MED suffers from weak implementation and enforcement mechanisms, leading to safety risks and inefficient functioning of Single Market for marine equipment.		To enhance implementation and enforcement mechanisms of MED, thereby guaranteeing an efficient functioning of the internal market for marine equipment while ensuring a high level of safety at sea and prevention of marine pollution.	
The transposition process of IMO rules into national law imposes excessive burden upon the industry and national administrations and legal uncertainty about what standard is applicable.		To simplify the regulatory environment while guaranteeing that IMO requirements are applied and implemented in a harmonised way across the EU.	
Drivers		***Specific objectives***	
D1	The MED has not been aligned, in a way that is compatible with the specific features of the sector, with the tools provided for by the NLF as regards: - market surveillance; - CE marking; - conformity assessment of products; - tools for use of legislation (obligations for actors in the distribution chain, harmonised definitions, etc) .	*SO1*	to define an optimal way to align MED on the NLF in the field of: - market surveillance; - CE marking; - conformity assessment of products; - tools for use of legislation (obligations for actors in the distribution chain, harmonised definitions).
D2	The legislative technique for transposing international safety standards for marine equipment into national law is complex and lengthy.	*SO2*	to simplify, clarify and shorten the transposition process of IMO standards into the European and national legal frameworks

4.2. Coherence with horizontal policies

4.2.1. New Legislative Framework

The objective of the proposed initiative clearly contributes to the objectives laid down in the *New Legislative Framework* which is the tool for harmonising across all sectors European legislation concerning the certification of products in the internal market and, hence, to facilitate the free movement of goods.

4.2.2. Better regulation strategy

The objective of the proposed initiative is fully in line with the *Better Regulation* Strategy[35], the *Smart Regulation* Communication[36] and the efforts to reduce administrative burden illustrated by the activities of the High Level Group of Independent Stakeholders on Administrative Burdens (the so-called "Stoiber Group").[37]

35 See: http://ec.europa.eu/governance/better_regulation/index_en.htm.

36 See COM/2010/0543 final.

37 See:http://ec.europa.eu/enterprise/policies/smart-regulation/administrative-burdens/high-level-group/index_en.htm.

5. POLICY OPTIONS

In light of the above and on the basis of the stakeholders' consultation, the Commission has identified four policy options – besides the baseline scenario – that combine specific EU actions across the two areas for action described in section 2 above. All policy options have been designed to be able to address both specific objectives defined in section 4.

Policy Option 1 would foresee the discontinuation of EU action. Under this option, the EU would abandon the specific regulation of the Internal Market for marine equipment which would then be governed by the general principles of the Treaty, including the principle of mutual recognition, and, where applicable, relevant horizontal legislation such as Regulation (EC) No 764/2008 - also part of the NLF. The latter regulation establishes procedures aimed at framing how authorities in the Member States monitor compliance with national technical rules on goods not covered by the harmonised Community rules.

Policy Option 2 would foresee a maximum alignment of the MED on the NLF, where departure from the latter's provisions would be kept to those issues where it is considered indispensable in any case – namely specific marking;

Policy Option 3 would take the form of a conditional alignment of the MED on the NLF, where additional MED-specific solutions would be introduced to optimise the effectiveness of the instrument, namely in the areas of IMO requirements and standards, obligations of economic operators, use of conformity assessment modules, product traceability and safeguard clause. These areas would largely be the same where the MED currently departs from the New Approach.

Policy Option 4 would represent a minimum alignment of the MED on the NLF, while still being inspired by the latter. It would build upon Policy Option 3 by adding the possibility of creating a MED-specific EU authority for market surveillance and one for notified bodies which would replace the national systems. This set of MED-specific measures could be considered in theory in order to channel maritime expertise into the Directive's control mechanisms in the two areas mentioned. In other words, these two additional measures would seek, compared to Policy Option 3, to combine the beneficial effects of pooling resources with the need to ensure familiarity with the maritime and shipbuilding/ship repair markets, their operation and their regulation at an international level. Policy Option 4 would therefore abandon the choice made in the NLF to maintain these two key functions in the hands of national authorities, pooling resources cross-sectorally at national level in the first place and ensuring mutual support, cross-fertilisation and coordination of national authorities at an EU level by means of EU-wide cooperative structures or the Commission itself.

5.1. Pre-screening of policy options

The Commission performed a preliminary screening of the above options on the basis of their effectiveness in addressing current problem drivers and of their efficiency. In parallel, the coherence of the possible policy options with the principles of subsidiarity and proportionality has been assessed. This pre-screening enabled the Commission to exclude PO 1 and PO 4 from in-depth assessment for the following reasons.

Policy Option 1 – Discontinuation of EU action

Under this option, Member States would apply IMO mandatory requirements for marine equipment based on their own individual assessment of the international conventions and

depending on what specific conventions and instruments they are a party to. Each Member State would decide on the procedures leading to the delivery of a type-approval certificate to each item of equipment. Finally, Member State administrations would deliver the certificates either directly or through classification societies or other types of bodies/laboratories for testing and certification.

Abrogation of the MED would mean that the rigidities introduced by the current formulation of the MED would be removed. Furthermore, marine equipment would benefit from a more developed legal framework for non-harmonised products, where objections based on the quality of accredited certification bodies would no longer be possible and a structured procedure would protect manufacturers in the case of technical decisions made in another Member State[38].

However these advantages are clearly outweighed by the problems that abrogation would bring about. In the absence of an enforceable, harmonised system, the risk of competition at the expense of safety is particularly acute in the specific circumstances of the maritime sector, and the safety benefits brought about by this Directive would run a serious risk of being reversed. Manufacturers would be obliged to produce several versions of their product for Member States applying the international Conventions differently or at different times. Divergence in the interpretation and application of international conventions would not only have an impact on safety, but also on the good functioning of the Internal Market: even in the absence of objections as to the quality of notified bodies, problems would arise from diverging application of the compulsory testing standards - with the result that Member States would become reluctant to mutually accepting their respective conformity certificates without additional national controls. Control over certifying bodies and market surveillance would either remain as is or would be further relaxed. Free movement of goods would inevitably be affected – as had been the case in the past. In the long term the situation within the EU could become somewhat comparable to the current state of affairs in the trade with the USA under the mutual recognition agreement in force, and thus only one fraction of the products currently covered by the MED would truly benefit from mutual recognition and move without problems between Member States.

For these reasons, the discontinuation of EU action has not been retained for in-depth assessment.

Policy Option 4 - minimum alignment of the MED on the NLF

Preliminary analysis of this option by the Commission soon made it apparent that:

- While unification of market surveillance is clearly not seen by the Member States as a need[39], one stakeholder only has suggested a centralised approach for the licensing and control of notified bodies.

- Compatibility with existing national structures and coherence with the parallel, cross-sectoral coordination would become difficult;

[38] See in particular Articles 5 to 8 in Regulation 764/2008

[39] Indeed, in the second consultation one national administration claimed for the clear identification of an *"expert body or organization in charge of coordination of the EU market surveillance, which would also provide support to Member States in establishing the surveillance system, and define for every product the method of conformity assessment".*

- Cooperation with third countries would be rendered more difficult by the existence of parallel, MED-specific structures;

- The volume and diversity of products covered by market surveillance and the number of notified bodies under the MED would put such a task beyond reach, in terms of resources, of the Commission or EMSA.

In addition:

For market surveillance:

- The vast range of products covered by the MED makes cross-sectoral expertise as indispensable for market surveillance as is maritime expertise itself. Indeed, the MED covers items as diverse as protective equipment, electronics, pressure vessels, pyrotechnics, etc.

- Moreover, as mentioned above, marine equipment manufacturers usually serve more than one market and do not necessarily direct their production to ships only; thus extracting the marine equipment sector from a cross-sectoral market surveillance structure would automatically affect the both systems' effectiveness.

For notified bodies

- Similarly, while notified bodies need to have specific maritime expertise in order to be able to certify marine equipment, their activities are seldom limited to the maritime domain and the reasons of potential shortcomings need not be linked to one particular area of activity;

In light of the above, the Commission has considered that these policy measures were both ineffective and disproportionate relative to the simpler method of incorporating the marine equipment sector and its associated expertise into the general framework created by the NLF in the two areas under consideration, thus reaping the benefits of both resource pooling and cross-sectoral cooperation. Moreover, these policy measures would become very difficult to justify under the prism of subsidiarity, as a priori they can be expected to bring no net added EU value to the Member States' action.

The above confirms that the reasons which led the Commission's choice for the NLF's general case, clearly justified in the original impact assessment[40], remain valid for the specific case of the MED.

For these reasons, Policy Option 4 has not been retained for in-depth assessment.

5.2. Description of retained Policy Options

In light of the above, the Commission has identified two policy options - besides the baseline scenario - that constitute viable policy alternatives for achieving the objectives.

The table below summarises in detail the content of the envisaged possible policy options and highlights their main differences.

[40] See Annex 8

Table 3: Description of retained Policy Options

	Policy Option 2 *maximal alignment to NLF*	*Policy Option 3* *conditional alignment to NLF*
Specific Objective 1: to find an optimal way to align MED on the NLF		
Market surveillance		
Common EU framework	Word by word transposition of NLF provisions into MED	Same as PO2
More effective post-market control mechanism	Word by word transposition of NLF provisions into MED	Same as PO 2 + Introduction of the possibility to use electronic tags to give better tools to market surveillance for detecting non-conforming equipment.
Safeguard clause procedure	Word by word transposition of NLF provisions into MED	Same as PO 2 + Additional provisions adapting the administration of the safeguard clause, making it possible for the Commission to decide to limit its assessment to the respect of due procedure by the Member State concerned.
Conformity assessment of products		
Essential requirements	Word by word transposition of NLF provisions into MED - current annexes to MED to be abandoned; compliance with IMO requirements[41] turned into "essential requirement".	Mandatory technical norms including mandatory and non-mandatory IMO requirements as well as European and international testing standards developed by European and international standardisation organisations on the basis of the IMO requirements.
Notification of conformity assessment bodies	Word by word transposition of NLF provisions into MED	Same as PO2
Conformity assessment procedures	Word by word transposition of NLF provisions into MED	Selective use of conformity assessment modules, whereby notably modules A and C (corresponding to the possibility of conformity assessment of products by in-house Notified Bodies) are not retained.
CE marking	No alignment, CE marking replaced by a wheelmark	No alignment, CE marking replaced by a wheelmark
Toolbox of measures for use in legislation		
Obligations of actors in the distribution chain	Word by word transposition of NLF provisions into MED	Adaption of obligations of actors in the distribution chain, reflecting the irrelevance of concentrating on the small share of marine equipment which is actually placed on the

[41] Consequently, non-mandatory requirements, recommendations and guidelines would not be covered by this essential requirement.

		market within the EU territory. Manufacturers: same as in PO2 Importers and distributors: identification and registration; cooperation with market surveillance authorities (information, documentation, removal of risks, etc.)
Harmonised definitions and procedures (save the CE marking)	Word by word transposition of NLF provisions into MED	Same as in PO2.
Specific Objective 2: to simplify, clarify and shorten the transposition of amendments to IMO standards into the European and national legal frameworks		
-/-	No transposition into EU legal order; IMO requirements in the form of essential requirements directly applicable in Member States. International and European standards are optional and give presumption of conformity.	Transposition of IMO requirements through implementing or delegated Regulations, which do not require transposition into national legislations. Testing standards (whether developed by IMO or by standardisation bodies) are mandatory.

6. ANALYSIS OF IMPACTS

6.1. Preliminary remarks

The two policy options considered in this IA report constitute alternative ways of aligning MED on the NLF.

As said above, the impacts of the alignment of sectoral legislation on the NLF have already been assessed in two IA reports, namely the one accompanying the *Communication on alignment of ten technical harmonisation directives to 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*[42], and obviously the one accompanying the *Proposals for the revision of the New Approach*[43].

For this reason, the assessment of impacts of the policy options will rely to a certain extent on these analyses. Most of the impacts identified in the above-mentioned documents are indeed very relevant for PO 2 given that the latter, except for the CE marking, foresees maximum alignment to the NLF. Part of the impacts of the NLF is also pertinent for PO3 which foresees a conditional alignment to the NLF. Besides, the assessment also builds upon the results of the stakeholders' consultation.

In light of the scarce availability of quantitative data explained above, a qualitative assessment is predominant.

42 SEC(2011)763

43 SEC(2007)173.

6.2. Economic impacts

6.2.1. On the functioning of the Internal Market for marine equipment

Common EU framework

Both policy options would import the relevant NLF provisions word by word. The MED would thus benefit from the significant evolution which the NLF represents relative to the baseline, with clear, structured and effective obligations for market surveillance authorities.

Market surveillance and safeguard clause

In PO2 and PO3, the alignment of market surveillance to a common EU framework should ensure a more uniform and sufficiently rigorous level of market surveillance across Member States compared to the baseline. This common EU framework should contribute also to a better protection of both consumers and professionals from unsafe products.

However, in addition to the more effective post-market control mechanism contained in PO2, PO3 also foresees the possibility to use electronic tags. These will facilitate detection of counterfeit and control of equipment already placed on board by both flag and port States. Given that marine equipment may or may not physically enter the EU territory before being placed on board EU ships, this additional measure gives PO3 a slight edge over PO2 in terms of effectiveness of market surveillance. [44]

Furthermore, the alignment of the MED's safeguard clause mechanism with the NLF in PO2 will ultimately lead to the adoption of equivalent measures across the EU in relation to products presenting a risk. However, in PO2, the variety of marine equipment and hence the diversity of technical expertise required is likely to render more difficult and time-consuming the assessment by the Commission of whether or not a national measure restricting the free movement of a product is justified. This drawback of PO2 is overcome in PO3 by allowing the Commission to limit its intervention to examining the respect of due procedure by the Member States – and thus examine the substance of the case only when justified.

Conformity assessment of products

PO2 and PO3 will include stricter requirements that will constitute a common benchmark for the assessment of NB throughout the EU regardless of the country in which they are active and of the specific NB providing the service. Moreover, according to the revised notification process, the notifying authority in a given MS will be able to scrutinise and object to notifications put forward by another MS. Therefore NB will be subject to more transparent and more coherent assessment and this will strengthen the conditions for a level playing field. Compared to the baseline, PO2 and PO3 will enhance equally the quality of (and hence confidence in) the conformity assessment of products.

[44] Logically, the effectiveness of electronic tags as a tool to render market surveillance more efficient largely depends on the penetration of this measure. While it is not excluded to make the use of electronic tags mandatory for all or part of the equipment falling under the scope of the MED, it is not the purpose of this IA to examine the optimal intensity of this particular measure and the most conservative approach, i.e. optional use, has been taken as the working hypothesis. In any case (see Annex 14) it is clear that RFID technology presents enormous advantages for the manufacturers at a very low cost, and it is therefore reasonable to expect that the use of electronic tags will spread very quickly as soon as it is made possible, even if not mandatory.

However, compared to PO2, PO3 operates a choice in the available conformity assessment procedures by excluding the possibility for manufacturers to assess themselves the conformity of their products - hence avoiding possible conflicts of interest and, again, providing a more level playing field. While it is true that for very specialised products it is the manufacturer itself who can provide the best expertise and testing facilities, on the whole this is a healthy measure given that (see below) the entire process of conformity assessment, production control, delivery and installation on board may happen at very distant locations and under significant pressure from the shipyards; moreover, self-certification would hardly tie in with the IMO requirement for the flag State to approve the equipment placed on board.

Obligations of actors' in the distribution chain

In PO2, the MED will include clear obligations applying to all actors throughout the EU that are likely to eliminate the current differences in national legislation and to create a more even level playing field among actors. However, the additional obligations placed on actors in the distribution chain (obligations on importers and distributors concerning post-marketing controls and conditions of transport as well as those which mirror the obligations of the manufacturer) can be seen as disproportionate in PO2 compared to the baseline, in light of the relatively small share of products actually placed on the market. The reason for this is twofold:

- In the first place, when placed on board and subsequently throughout its lifetime marine equipment is subject to control by the public authorities, be it the flag State[45] or, while in service, also the port States.

- Secondly, and more importantly, for a majority of products the figures of the importer and the distributor, as well as their respective associated obligations are meaningless: the items are sold directly to the ships or to the building/repair yards who will install them on board – in most cases outside the EU territory. Only a fraction of the products (namely those imported and distributed into EU territory by commercial operators other than shipyards) would actually benefit from the above mentioned obligations. These measures would therefore generate an important, unjustified asymmetry between products (or even between different batches of the same product, depending on where they are placed on board) and place an uneven burden on operators, while in practice having insignificant effect.

PO 3 would limit the obligations incumbent on the operators to a level which would be more commensurate with the specificities of the marine equipment sector, concentrating on: a) the obligations of the manufacturers, as it is the manufacturer who is ultimately responsible for the safety of the product; and b) those obligations incumbent on the other operators (importers and distributors) which are specifically conceived to facilitate the task of market surveillance authorities – i.e. identification, access to information and documents and removal of risks.

Harmonised definitions

Both PO2 and PO3 would import the definitions contained in the NLF, which is not expected to have any influence on the functioning of the internal market.

Uniform interpretation and implementation of IMO requirements and testing standards developed by standardisation bodies

[45] Or by classification societies acting on the flag State's behalf

PO 2 proposes to turn compliance with IMO requirements into an essential requirement. Compared to the baseline scenario, only mandatory IMO requirements would be covered by this provision. This would be a generic provision: there would be no list of specific requirements applicable to each item of equipment. Furthermore, non-mandatory IMO requirements as well as non-mandatory testing standards developed by European and international standardisation organisations would not be covered by the essential requirement; similar to the NLF, compliance with European standards, and in this case also international standards, would simply provide a presumption of conformity.

Careful formulation of this framework (together with a number of accompanying measures such as lists of IMO requirements and international/European standards being published and kept up-to-date by EMSA) could greatly reduce, but never completely remove Member States' discretion both in the determination of the specific requirements and in the conduct of the assessment process; as a result, divergences between Member States in the application of the MED should be expected to appear sooner or later, which in turn would render mutual recognition more difficult.

The distortions to the Internal Market caused by this measure would be partly – but not entirely – mitigated by the alignment on the NLF, which will raise the overall trust in the quality of the work of NB. Conversely, market surveillance would become more difficult in the face of divergences in the basic requirements. The final outcome, in terms of the functioning of the Internal Market, would be probably worse in PO2 than in the current situation.

Under PO 3, the MED would make technical norms mandatory, including IMO requirements as well as technical standards - as it is currently the case. The technical norms will then be transposed into national law through implementing or delegated Regulations. The legislative framework will thus be completely harmonised, as is also the case today. This new technique will allow timely transposition of the applicable requirements and standards into the national legal orders, thereby ensuring consistency between the MED system and the IMO practice. Therefore, any incentives for operators to deviate from the harmonised framework[46] will be removed. The final conclusion is that PO3 should be expected to slightly improve the functioning of the internal market relative to the baseline.

6.2.2. On operating costs and administrative burden[47]

For economic operators

Under PO2, the **additional obligations** for the operators (especially distributors and importers)[48] would translate into an important additional administrative burden and hence costs for the said operators, which would be disproportionate (especially for the large number of SMEs in the sector) in light of the expected low benefits in terms of compliance rates. As has been explained this is due to the fact that, in the marine equipment sector, most of the products are never placed on the market and economic operators have so far had little reason or incentive for putting in place costly follow-up strategies for their products. [49] This aspect is

[46] See section 3.1.2

[47] See annex 9 for a detailed assessment

[48] See section 5.2

[49] Contrary to the conclusions drawn the IA report on the Communication on alignment of ten technical harmonisation directives [See SEC(2011) 763] in which the Commission concluded that the additional

a considerable drawback of PO 2 compared to the baseline. Better adapted obligations on economic operators in PO3 would increase operating costs for economic operators compared to the baseline, but in a much lesser extent than in PO2 and, more importantly, this additional burden would be commensurate with the associated safety benefits.

Thus e.g. the **traceability obligations** of the NLF, which would be transposed into the MED in both Policy Options, would require manufacturers and importers to indicate on the products their names, addresses and batches or serial numbers. This would inquire some costs, which shouldn't however be too high. Anyway, manufacturers are already obliged by legislation in place to indicate their names on the products, while batches and serial numbers are normally used for internal management reasons.

PO3 also includes a specific measure to facilitate market surveillance, namely the introduction of electronic tags. As discussed in Annex 14, the costs of electronic tags (the use of which only needs to be made possible but not necessarily compulsory for the manufacturers) is marginal[50], while the associated benefits are very considerable both in terms of safety and in terms of IPR protection.

The undeniable simplification of **conformity assessment** requirements in both Policy Options would reduce the costs of conformity certification for marine equipment manufacturers. However, in the case of PO2 where the applicable requirements are not harmonised, divergences among Member States could lead to uncertainty and re-assessment requirements, and the risk that in some cases several versions of the same product may have to be manufactured cannot be excluded; this means that the final costs for the manufacturers could be actually higher than today. For ship operators, the lack of recognition of certificates issued by other Member States, together with difficulties in the identification of the applicable requirements by Port State Control officers, could lead – in extreme situations – to the detention of ships, causing very high costs.

In comparison with the baseline, PO 3 foresees the abandoning of the conformity assessment module H (full quality assessment), which is in theory extremely expensive for manufacturers in the case of marine equipment. But even under the existing MED, this module – although allowed – was never used. The gains of the measure in terms of operating costs are close to zero.

Both Policy Options contain measures shortening the time needed for the **implementation of IMO requirements** within the European legal framework. In PO 2, this objective is achieved by eliminating the need to transpose IMO standards into the MED, while the Member States still have to transpose these into their national legal orders. In PO3, the same objective is achieved by eliminating the need to transpose the IMO standards into national legislation. Each of the solutions should reduce the time necessary for the changes to become applicable in Europe to the limits imposed by IMO. This will put an end to a certain extent to the current situation which, according to the Commission estimates, may result in administrative burden of up to €6-7 million a year for the marine equipment industry only.

In the absence of transposition of IMO requirements into the EU legal order in PO2, a certain number of differences in the implementation of IMO requirements by the Member States, be in in terms of content or in terms of timing, will inevitably remain despite the fact that PO2

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obligations would not increase in a significant way the overall costs of economic operators, since the new provisions merely codify what is already normal practice for a responsible firm.

[50] Between €0,1 and €0,3 per unit

also foresees the creation of a website clarifying the rules in place at each given moment. Therefore, PO2 will probably not be able to completely remove the administrative burden generated by these differences, especially in terms of double certification, as described above.

Under PO3 standards would remain codified in the EU legislation rather than being separately transposed into the 27 legal systems of the Member States as it would be the case in PO2. This will allow PO3 to be considerably more effective than PO2 and bring about considerable improvement relative to the current situation, as the burden for national administrations as regards the administration of the Directive's Annex would be reduced to a minimum.

For notified bodies

The strengthening of NB control and requirements foreseen in both Policy Options is not expected to lead to any additional operating costs and/or administrative burden on those NB which already act in accordance with high professional standards. Indeed, the relevant benchmark for the assessment of conformity assessment bodies has already been codified within EN and ISO standards.[51] The costs would be much more significant for those NB which currently perform poorly, but their efforts to comply with higher quality standards should be actually considered as benefits of both policy options. Following the alignment on the NLF, MED would also provide the national authorities with a stronger legal basis to exclude underperforming conformity assessment bodies from the single market.

The introduction of information obligations in both Policy Options is expected to lead to an additional – but overall negligible- administrative burden (i.e. basically the costs of transmitting the required information). This information will only be provided on an ad hoc basis as required by the nature of the information itself (i.e. information on refusals, restrictions, suspensions and withdrawals of certificates to be addressed to the notifying authority, and information on negative conformity assessment results to be addressed the other NB). Furthermore, NBs are free to choose the format of the transmission of information.

Compared to the baseline, PO 2 proposes to remove the restrictions in the choice of conformity assessment modules. Currently, a number of so-called modules (notably modules A and C) which foresee self- certification by the manufacturer, are not allowed in the marine equipment sector; neither is the use of in-house notified bodies. The major advantage of self-certification or using in-house NB is the high level of expertise available inside the manufacturing companies, which in some cases is lacking in many of the independent NB. Moreover, potential synergies within the companies could lead to cost savings compared to the baseline. However, self-certification would probably give raise to problems for ships in third countries, as these might not accept it as a valid method to comply with the flag State approval requirement in the international conventions. In the case of in-house notified bodies, safety would also probably be affected given their high exposure to conflict of interests in the particular circumstances of the sector. PO3 would remove both possibilities, thus representing higher costs for the manufacturers but also reducing the risks for the fleet.

6.2.3. Impact on SMEs[52]

Among the measures foreseen, none are specifically addressed to SMEs, or have a specific impact on them. However, in the same way as SMEs are particularly vulnerable to the MED

[51] See SEC(2001)763, footnote 69 for the complete list of the relevant standards.

[52] See strengthened SME test in Annex 10, which includes the explanation of why micro-enterprises should not be excluded from the scope of the proposed initiative.

system's weaknesses[53], one should expect the benefits and drawbacks of both options to be particularly felt by SMEs. The introduction under PO3 of the possibility to use electronic tags, an effective and very economical way to improve the effectiveness of market surveillance, is expected to help reduce counterfeit – a problem which is very acutely felt by SMEs.

SMEs, which are less equipped to face unfair competition from non-compliant products, will particularly benefit from improvements in market surveillance under both PO2 and PO3.

Under PO2, the burden of the extended obligations foreseen for importers and distributors should also be felt mainly by SMEs; while under PO3, the removal of obligations whose benefits are considered less significant will work particularly in favour of SMEs without detriment to safety.

The improvement of the safeguard procedure in both PO2 and PO3 will reduce the exposure of SMEs to the costs associated with lengthy procedures where they are currently placed in a particularly weak position. This effect will be more acute in the case of PO3, especially as regards potential reputational damage, as the specific measures foreseen constitute a strong incentive for a fairer procedure already at national level.

SMEs should particularly benefit of the simplification foreseen under PO2 by the recourse to IMO requirements in the form of essential requirements only – accompanied by informative instruments as to the applicable standards. However, this would come at the cost of greater uncertainty in the absence of clear-cut lists of requirements enshrined in an enforceable instrument, a problem resolved under PO3 with the adoption of delegated/implementing regulations. Again, these effects – both favourable and adverse – would be magnified for SMEs, which have more difficulty in gaining access to information on requirements and standards.

Under both PO2 and PO3, SMEs would greatly benefit from a system which would drastically reduce the time needed for IMO requirements to become applicable in the EU and thus a) improve return on R&D investments and b) reduce the costs associated with multiple certifications.

6.2.4. On the competitiveness of economic operators

Competitiveness of economic operators analysed below refers to the ability of firms to sustain and gain in market share through their cost and pricing policy, innovative use of production factors and novelties in product characteristics.[54] [55]

Enforcement system

Under PO2 and PO3, the more effective enforcement of MED through better market surveillance and better supervised NB activity resulting in higher quality of compliance controls will help defend the competitiveness of compliant firms against unfair competition. This aspect concerns in the first place notified bodies: it will become more difficult and risky for lenient or sub-standard NBs to certify products which in reality do not meet the stringent standards required by the law. In the second place, non-conforming equipment (or equipment

[53] See section 2.3

[54] "Operational guidance for assessing impacts on sectoral competitiveness within the Commission Impact Assessment system" SEC(2012)91.

[55] A study of the impact on the sector's competitiveness under the prism of the main areas identified in the "LeaderShip 2015" initiative is provided in Annex 11

in breach of intellectual property rights) will be more easily detected if placed on the market or installed on board EU ships – from which it will be removed. Since European manufacturers have a comparative advantage in high value added, innovative and reliable products[56], more effective enforcement of MED should be particularly beneficial for them.

Traceability of products

In addition, compared to the baseline, the introduction of requirements on traceability and cooperation with surveillance authorities for all economic operators in both policy options will help the former to trace non-compliant products and stop their circulation. [57] [58] PO3 incorporates the possibility of using an additional tool for market surveillance authorities, i.e. the electronic tag, to trace in a more efficient way non-compliant products. Thanks to this additional element in PO3, the level of protection of Intellectual Property Rights is likely to increase, protecting better marine equipment' manufacturers and stimulating thereby also research and innovation.

Obligations of actors in the distribution chain

Furthermore, the introduction of clear obligations for importers and distributors regarding the compliance of *marketed* products (more effective *post-market* control) in PO2 will allow action at all levels of the supply chain. This action will then help defend the competitiveness of compliant firms from unfair competition. However, these additional obligations in PO2 will only increase the rate of compliance for products placed on the market; they will not affect the vast majority of marine equipment, which is placed on board ships without ever being marketed in the European Union, while probably coming at a net cost for the operators concerned as has been described above.[59] Compared to PO2, better adapted obligations in PO3 will reduce the burden on operators without significantly affecting the effectiveness of the system.

Conformity assessment

For both options, a strengthened, more effective framework for conformity assessment will greatly increase the pressure on any unscrupulous manufacturers who could be tempted to turn the weaknesses of the current system into a competitive strategy and place substandard products in the market. Conversely, compliant, quality-conscious manufacturers and notified bodies will see their position strengthened. Since the competitive advantage of European manufacturers resides notably in the high quality of their products, they could be proportionately more affected than their global competitors. This effect should be clearly more noticeable in PO3 than in PO2, given that under the latter marine equipment would not need to comply with non-mandatory IMO requirements and international/European technical standards.

6.2.5. Impact on public authorities[60]

Compared to the baseline, the measures concerning clear obligations for all economic operators and clearer market surveillance procedures in both Policy Options are expected to

[56] See section 2.1.1 above.
[57] See SEC(2007) 173.
[58] See SEC(2011) 763.
[59] See section 2.2.1.2 above, indent "Market surveillance".
[60] See Annex 9 for detailed assessment

substantially increase the effectiveness of public authorities' enforcement activities, while they are not expected in general to have negative budgetary consequences.

The new traceability obligations on operators will make it easier for market surveillance authorities to obtain documentation and information from manufacturers and importers and to identify non-compliant products, including from third countries. This may actually reduce the investigation costs of the authorities, while better cooperation between national administrations within a European market surveillance framework, will increase the efficiency and reduce the costs of market surveillance bodies. This impact is even more important in Policy Option 3 which incorporates the possibility to use electronic tags[61] in order to better trace non-compliant products.

In addition, the new safeguard procedure in the NLF contains a much more detailed description of the steps that the authorities have to take to deal with products presenting a risk. Most notably, it specifies when the relevant information should be exchanged in order to be useful for cross-border authorities: this will allow surveillance authorities to work more efficiently, as efforts already undertaken in one Member State will not have to be duplicated. Compared to PO2, PO3 would include a mechanism to simplify the safeguard procedure before the Commission, with a consequential positive impact for this and the administration(s) concerned.

In PO2, by turning into an essential requirement the compliance to IMO requirements, there is no longer need to transpose the latter into EU legal order. As described above, national administrations will no longer be required to contribute to the preparation of the periodic updates of the directive's Annex, but will still need to identify the relevant IMO requirements and transpose them into their national legal orders. Conversely, the legislative technique proposed in PO3 that would ensure transposition of IMO requirements through implementing or delegated Regulations does not require any longer transposition into national law – although national administrations would still participate in the preparation of the implementing or delegated acts. All in all, PO2 should not have any noticeable impact on national administrations or slightly increase their costs, while PO3 should bring about net savings. Costs for the Commission would be lower as well for both Policy Options compared to the baseline, with PO3 being more costly because transposition into EU legal order would still be necessary under this Policy Option.

6.2.6. Impact on users and passengers

Users and passengers in general will benefit from greater levels of safety as described in section 6.3 below. This impact is likely to be more important in PO3 than in PO2 compared to the baseline because of the higher potential of PO3 in terms of traceability of non-compliant products.

Due to the overall limited impact of alignment on costs, the new obligations on economic operators and NB are not expected to give rise to price increases for users/passengers. If, for specific products, moderate price increases occur, it is expected that the latter would be largely offset by the benefit of greater confidence in product quality.

[61] See Annex 14

6.2.7. Third countries and international relations

Neither PO2 nor PO3 contain trade-related measures, the matter falling completely out of the scope of the MED.

6.3. Environmental and Social impacts

The expected improvement of market surveillance together with an enhanced system for conformity assessment in both policy options is expected to strengthen the implementation of IMO standards across the EU. This is likely to help in reducing the number of non-compliant products on the market and thus the number of products potentially dangerous to the safety of passengers/ users and the environment.

More precisely, changes brought to the system of certification and to the enforcement of MED can therefore be expected to have a concomitant, indirect, but clearly positive impact on health, on safety and on the protection of the marine and coastal environment. This impact should result in a perceptible improvement relative to the current situation for both PO2 and PO3.

In addition, the shortening of the procedure for transposing IMO requirements (be it in PO2 or PO3) will accelerate the application in the EU of the latest safety norms, with a likely positive impact on the level of safety and on the protection of the marine and coastal environment compared to the baseline scenario.

The positive impact described above will be mitigated in PO2 by several elements. First, the unrestricted choice of conformity assessment modules in PO 2, including those which imply the certification of products by in-house NB, can have a negative impact on the quality of assessment. Second, the choice of turning compliance with IMO requirements into an essential requirement in PO2 implies that non-mandatory requirements, testing standards from standardisation bodies, recommendations and guidelines would not be covered by this essential requirement and their implementation is not guaranteed. This is likely to have a negative impact on safety compared to the baseline. Similarly, given that IMO requirements will not be transposed into EU legal order in PO2, fully uniform application of IMO safety standards for marine equipment within the EU will no longer be ensured in PO2. As a result, PO2 will not be able to achieve the same high standards for marine equipment as PO3, and thus the risks to health, safety and environment will be higher.

In the case of PO3, a fast and uniform EU procedure will give more certainty and have a positive influence on manufacturers' expectations, thus facilitating the availability of more advanced, safer products in the market and further reducing the risk of attracting stocks of obsolete products which could otherwise still be placed on board ships of EU flags lagging behind. Furthermore, the introduction of electronic tags to replace or supplement the *wheelmark* (PO 3) will increase the efficiency of market surveillance, therefore contributing to the detection and elimination of equipment (e.g. counterfeit) which is dangerous for health and safety.

6.4. Simplification of the regulatory environment

The use of the consistent and updated terminology provided for in the NLF will address the current problems of inconsistencies and legal uncertainty. It will reduce the administrative costs and burden linked to the need to conform to incompatible pieces of legislation.

As mentioned above, the choice made in PO3 not to include module H (full quality control) into the list of allowed conformity modules is aimed at eliminating from MED the reference to a provision which was anyway never used.

The changes to the method of transposing changes to IMO requirements are the main simplifying element. PO3, which eliminates the most burdensome procedure of transposing changes to MED into national legislation, seems the most interesting. PO2, and the elimination of the need to transpose rules into European legislation, has also its advantages, which must however be weighed against the distortions of the internal market it brings - noting that the need for MS to identify the applicable IMO requirements and transpose them into their national legal orders will remain. For the industry, both policy options would offer the opportunity to improve return on investment in the development of new products meeting the latest IMO requirements and, more markedly under PO3, a reduction in the current costs deriving from double certification. As is shown in annex 12, the respective savings for the industry could potentially reach 4 to 7 M€ for PO2against 6 to 7 M€ for PO3. Although these are relatively moderate figures when compared to the sector's overall turnover, it must be taken into account that the improvement would be particularly felt by SMEs which in extreme cases might at present be facing double certification costs reaching 1% of their turnover.

6.5. Conclusion

Both policy options propose the alignment of MED on the NLF. This will bring considerable positive impacts – compared to the baseline – which have been assessed in the IA on the NLF and summarised above. The difference between options 2 and 3 lies with the specific provisions concerning marine equipment. The following table provides a qualitative appreciation of the impacts of these measures in each of the policy options compared to the baseline.

Table 4: Qualitative assessment of the expected impacts of PO2 and PO3

	Policy Option 2	*Policy Option 3*
Economic impacts		
Internal market		
Common EU framework	++	++
More effective post-market control mechanism	++	+++
Safeguard clause procedure	++	+++
Conformity assessment of products	++	+++
Obligations for actors in the distribution chain	-	++
Harmonised definitions	=	=
Uniform interpretation and implementation of IMO requirements	--	=

Operating costs and administrative burden		
Economic operators	++	+++
Notified bodies	=	=
SMEs	+	++
Competitiveness of economic operators		
Enforcement system	++	+++
Traceability of products	+	++
Obligations of actors in the distribution chain	-	=
Conformity assessment	++	+++
Public authorities	=	++
Users and passengers	=	=
Third countries and international relations	=	=
Social impacts		
Safety	++	+++
Environmental pollution		
Marine pollution	++	+++
Simplification of the regulatory environment	+	+++

Legend: = baseline or equivalent to the baseline
+ to +++ low to high improvement compared to the baseline
- to - - - low to high worsening compared to the baseline

7. COMPARISON OF OPTIONS

The analysis above has shown that the different policy options have clear implications in terms of the related socio-economic and environmental impacts.

This section provides for an assessment of how the said policy options will contribute to the realization of the policy objectives, as set in Section 3, in light of the following evaluation criteria:

- Their effectiveness in relation to the objective;
- Their efficiency in reaching the objectives;
- Their coherence with overarching EU objectives, strategies and priorities.

7.1. Effectiveness in relation to specific objectives

The analysis contained in the preceding sections shows that both options represent a very substantial alignment of the MED on the NLF. PO2 would result in a virtually complete alignment, while PO3 would slightly deviate from the mainstream NLF solutions. However, the specific measures contained in PO3 allow the MED to better serve the general objective of 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, by better adapting to the particular features of the sector. This is mainly the case of the strengthened enforcement and control mechanisms (better market surveillance, simplified safeguard clause) and a system that ensures that all relevant IMO requirements (mandatory or not) as well as international and European standards are implemented within the EU, without differences between Member States in terms of timing, content or practice. By comparison, under PO2 such differences between Member States could appear and significantly develop over time, to the point that the situation could deteriorate compared to the baseline. As a result, the objective of optimal alignment is clearly better met by PO3.

Both policy options would allow shortening the transposition process to a period of time compatible with the deadlines given by the IMO. The difference between the options is that PO3 eliminates the most burdensome and confusing need to transpose amendments into the 27 legal systems of the Member States, while PO2 leaves it untouched. For this reason, PO3 should be preferred over PO2.

Table 5: Effectiveness of envisaged policy options in light of objectives

	Baseline	*Policy option 2*	*Policy option 3*
To define an optimal way to align MED on the NLF	0	Low	High
To simplify, clarify and shorten the transposition process of IMO standards in national legal orders	0	Medium - IMO standards directly applicable, but not in a harmonised way	High

7.2. Efficiency

As is shown in the preceding sections, PO3 offers more effective solutions at less costs and administrative burden for the different stakeholders relative to PO2, along with a stronger beneficial effect on competitiveness (particularly as regards SME's). PO3 therefore emerges as the most efficient course of action.

7.3. Coherence with the overarching EU objectives, strategies and priorities

As highlighted in Table 4 above, both policy options would on the whole bring about considerable improvements in terms of maritime safety and protection of the marine environment. Both options would result in a simplified legal framework, favouring the competitiveness of the EU marine equipment industry. However, it has been shown that the best results should be expected from PO3 in all fields, while PO2 might not be able to deliver in terms of smooth functioning of the internal market.

7.4. Conclusion

The table below summarizes the results of the comparison of policy options in terms of effectiveness, efficiency and coherence.

Table 6: Comparison of Policy Options

	Effectiveness	*Efficiency*	*Coherence*
Baseline	no	no	no
Policy Option 2	low	low	medium
Policy Option3	high	high	high

In light of the above, PO3 overall rates better than PO2 and is therefore the preferred option.

8. MONITORING AND EVALUATION

Once aligned with the new regulatory framework for the marketing of products, the MED will fully benefit from the latter's monitoring and evaluation mechanism[62]. There is indeed no need to develop independent mechanisms for the MED but it is necessary to envisage an active and substantial contribution from the marine equipment sector to the monitoring and evaluation mechanisms.

As regards the specific measures envisaged in addition to the alignment the following activities have been foreseen in order to verify their effectiveness and gather feedback from the stakeholders:

- As a result of the reform more informative data will be obtained from the market surveillance activities and similarly EMSA will continue to refine the production of statistics on the implementation of the directive. The possibility to include this sector in the Commissions statistical work programme will be examined.

- Contacts with the industry will continue beyond the adoption of the amending instrument and become standard practice; this will include workshops with the industry on the implementation of the amended MED. One main aim of this cooperation will be to develop methodologies for the production of relevant data on the marine equipment market which can underpin future assessments.

- The activities of the MARED Group of notified bodies are an important forum for discussion between the Commission, EMSA the industry and the Member States on the implementation of the directive, and provide most valuable feedback on operational issues.

- A specific agenda item on MED is included in the meetings of the COSS Committee several times per year which allows having productive exchanges of views with the Member States and examining ways to improve the functioning of this directive.

[62] See in particular SEC(2011)1376 final, pages 55-56

- In addition to the above measures, EMSA will continue to organise workshops for technical discussion and training activities with the Member States in order to refine Member States practise and obtain their feedback.

- Based on this, **an ex-post evaluation will be organised within 5 years** of the entry into force of the new system, with the objective to measure safety benefits, gauge with as much precision as possible the impact on the sector and its competitiveness, assess the costs and benefits for the different stakeholders, identify potential malfunction and carry out a comparative analysis of the EU system against that of a selected group of third countries.

  – For this purpose, a system of indicators will be developed based on those already foreseen for the body of directives already aligned with the NLF (including e.g. number of products checked, number of non-compliant products among those checked, type of non-compliance found, number of non-compliant products whose manufacturer was identified; or, as regards notified bodies, number of notifications, information derived from notified body assessments, frequency of reassessment, objections, de-notifications, etc.)[63]. Furthermore, a limited number of additional indicators will be developed in order to cater for MED specificities. Thus e.g. the time taken for IMO requirements to become effective in national legal orders will be systematically monitored; the possibility to refine the input provided by Port State Control statistics in order to render them more meaningful for the assessment of the MED implementation will also be examined, e.g. as regards the use of electronic tags.

- Preparatory arrangements, particularly as regards the work of EMSA and the MARED group, as well as contacts with the industry and Member States will start immediately so that a system capable of producing relevant information and data can be in place within one year of the entry into force of the new system.

[63] *Id.*

ANNEX 1

Results of the questionnaire sent to Member States

EMSA
European Maritime Safety Agency

EMSA's Questionnaire to EU Member States

In early October 2008, EMSA sent a questionnaire to the EU MS to prepare a background document that will form the basis of the impact assessment for the update of the MED.

I. Audit of Notified Bodies to MED

II. Market Surveillance for MED

III. Safeguard Clause of MED

IV. Intellectual Property issues of products under MED

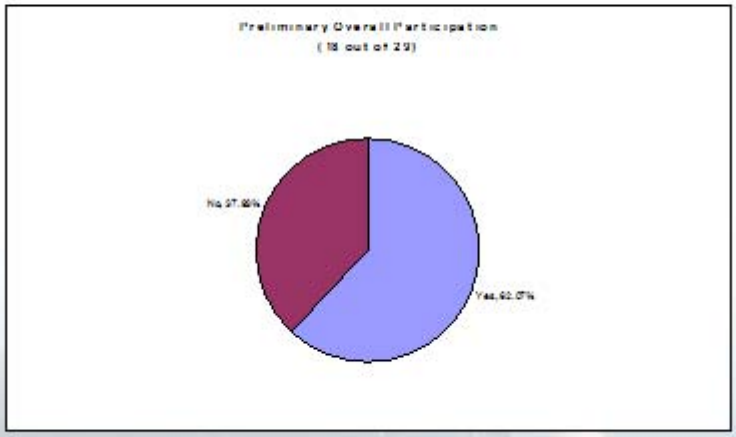
V. MED Annex A. Extension of coverage and update frequency

The following slides present the preliminary findings up to the middle of November 2008

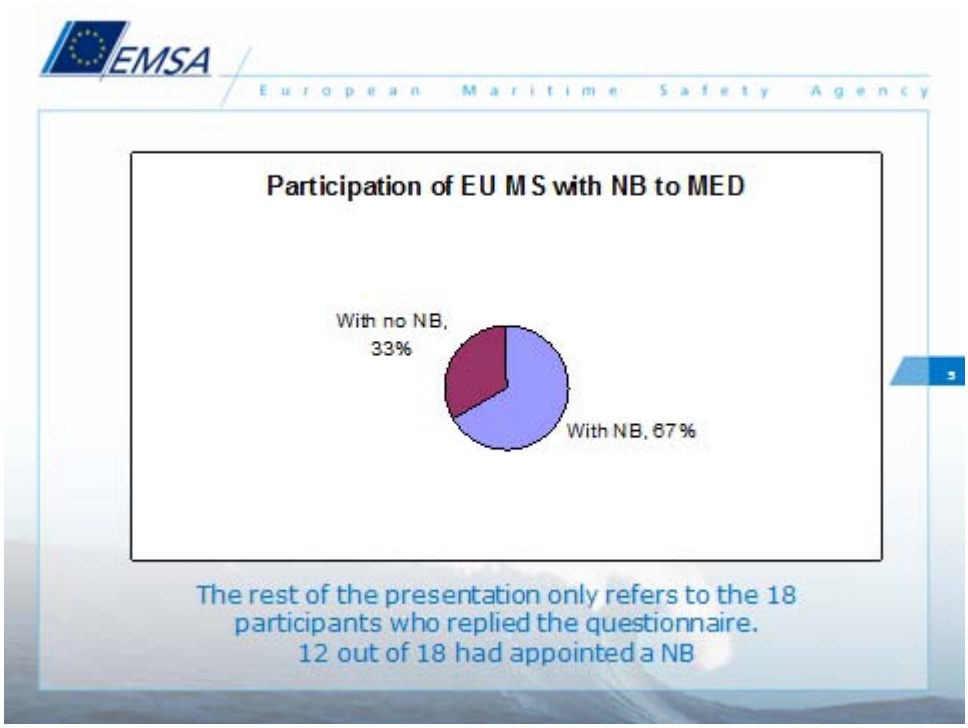
3

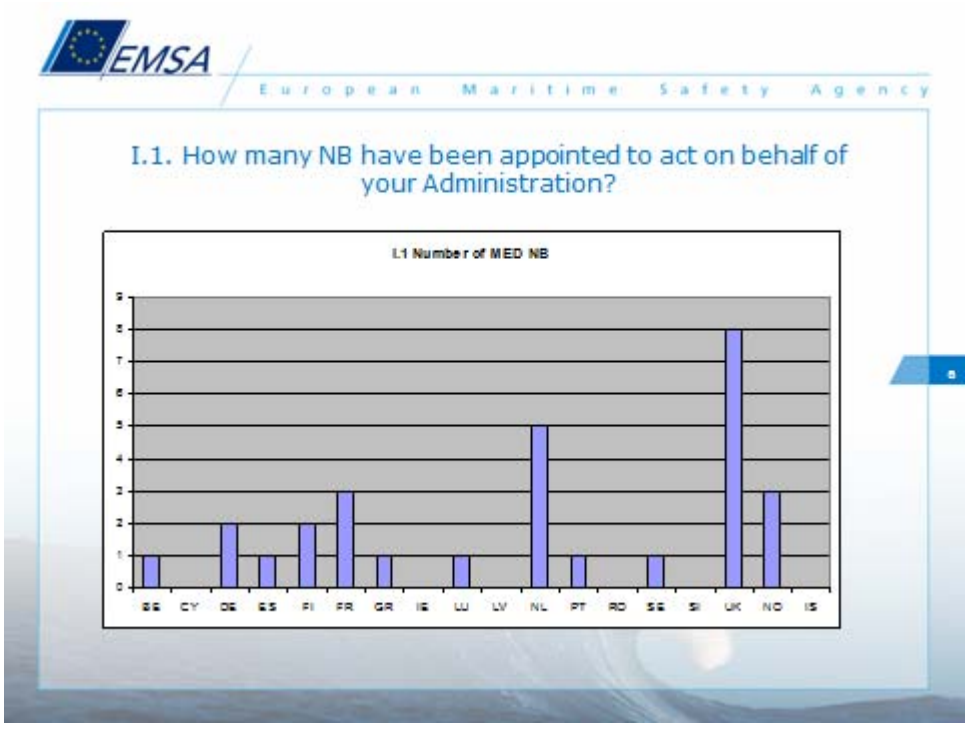
EMSA
European Maritime Safety Agency

Preliminary Overall Participation



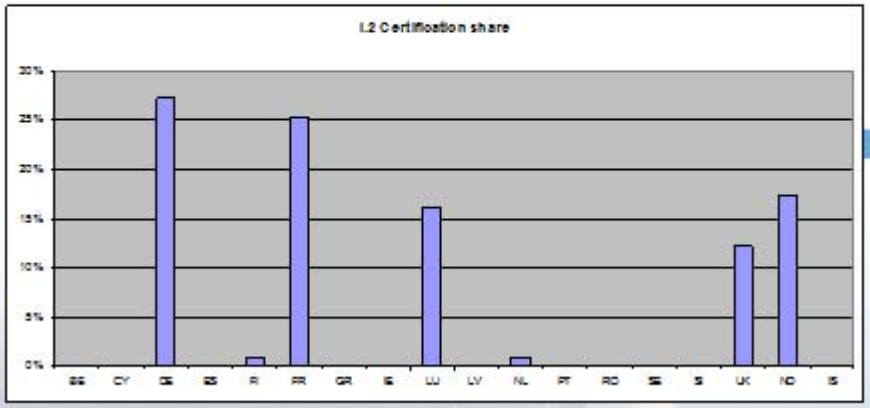
4


EMSA
European Maritime Safety Agency
Participation of EU MS with NB to MED
With no NB, 33%
With NB, 67%
The rest of the presentation only refers to the 18 participants who replied the questionnaire.
12 out of 18 had appointed a NB


EMSA
European Maritime Safety Agency
I.1. How many NB have been appointed to act on behalf of your Administration?
I.1 Number of MED NB
BE CY DE ES FI FR GR IE LU LV NL PT RO SE SI UK NO IS

EMSA
European Maritime Safety Agency

I.2. How many products have been approved by the Notified Bodies acting on behalf of your Administration?

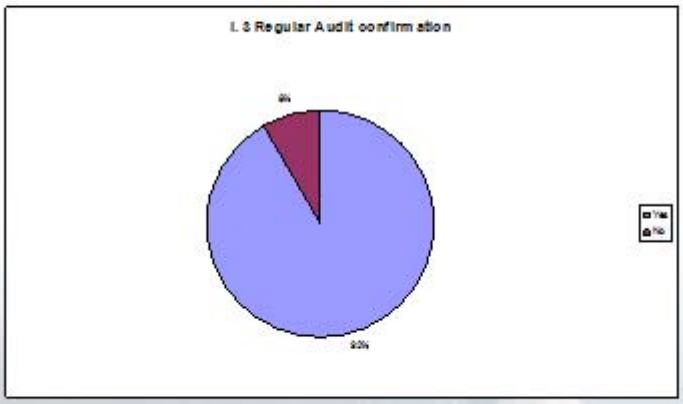


MarED Data Base: 28,000 certificates

7

EMSA
European Maritime Safety Agency

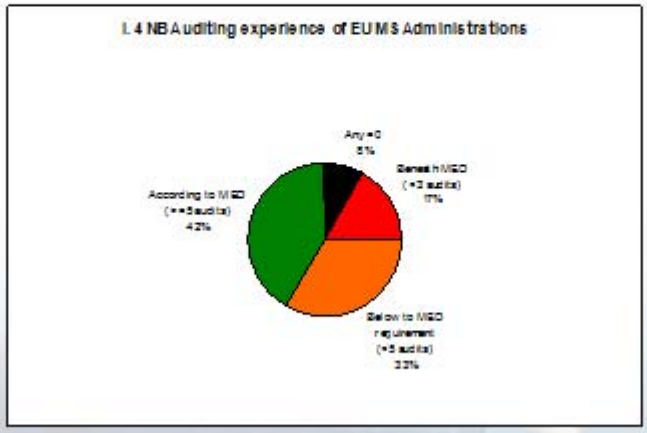
I.3. Can it be confirmed that the audits have been performed within the intervals provided for in Article 9.2?



8

EMSA
European Maritime Safety Agency

I.4. How many audits per NB has your Administration carried out?



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EMSA
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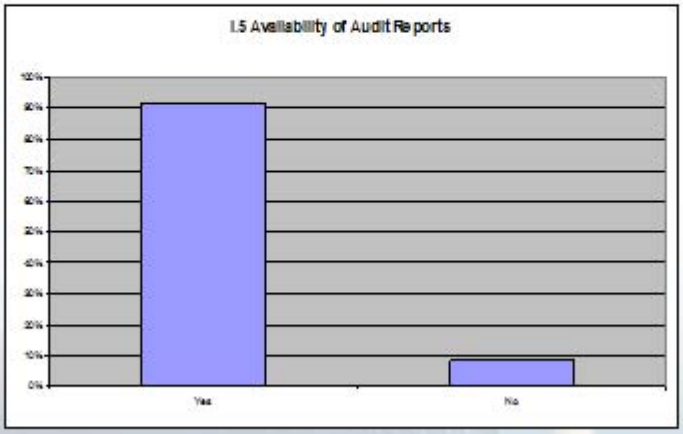
I.5. Are the audit records kept?



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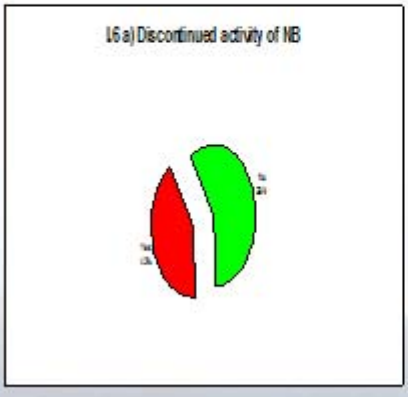
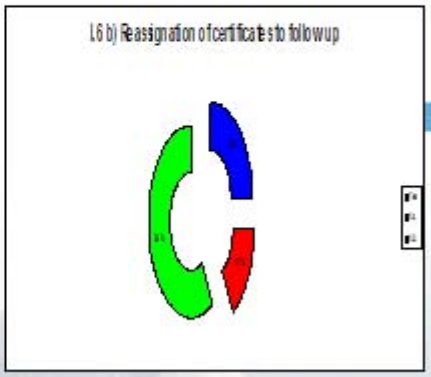
EMSA
European Maritime Safety Agency

I.6. a) Has any NB discontinued its activities?
b) If so, has your Administration reassigned the follow up of existing certificates?





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EMSA
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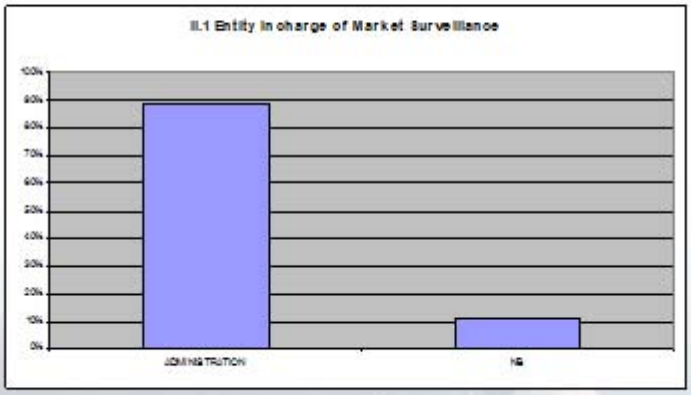
II.1. Which Authority in your Administration is responsible for Market Surveillance?



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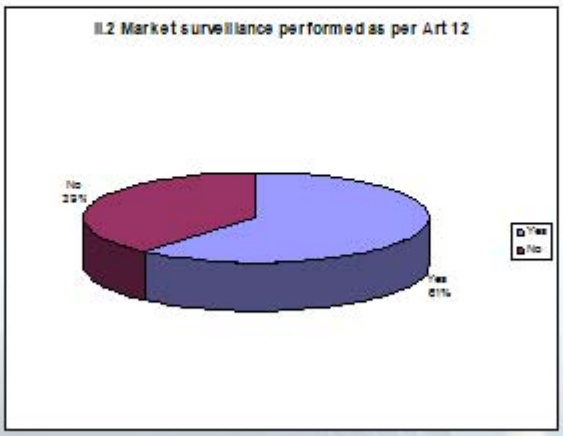
EMSA
European Maritime Safety Agency

II.2. Can it be confirmed that market surveillance is carried out as per Article 12?



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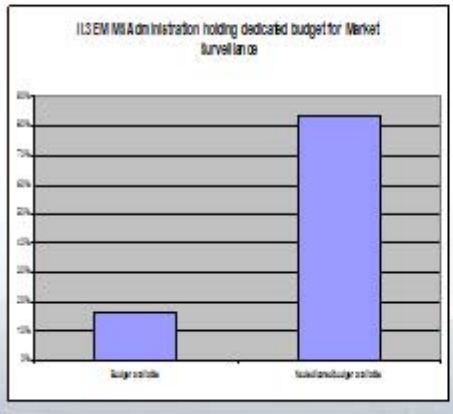
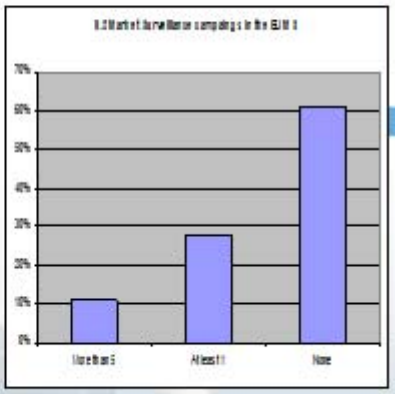
EMSA
European Maritime Safety Agency

II.3. Please state the annual budget for Market Surveillance campaigns and how many campaigns has your Administration performed concerning Marine Equipment since the adoption of the MED.





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II.5. Concerning your available resources for performing Market Surveillance, please describe the number of people, the cost and duration for each campaign.

Nearly all of the Administrations do not have dedicated resources for Market Surveillance.

Most of the approach to is performed by Port State Control Officers and in few cases the Administration Officials have visited factories

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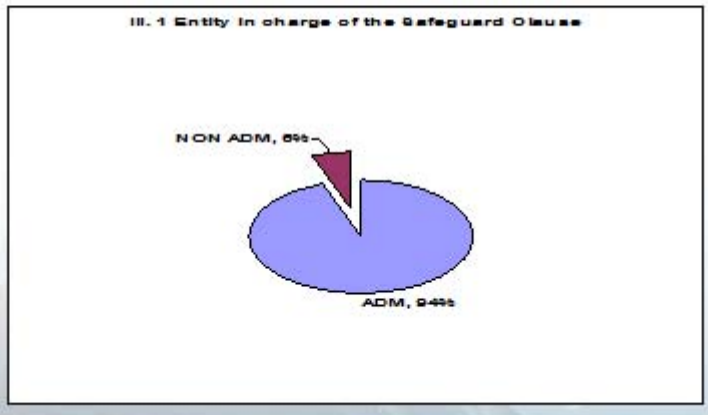
III.1. Which authority in your Administration is responsible for Safeguard Clause cases?



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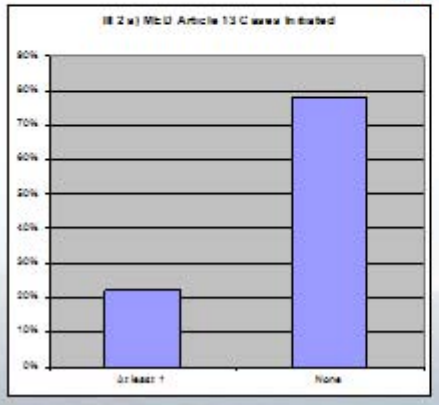
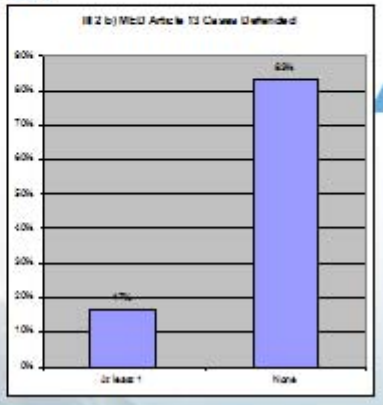
III.2. How many cases has your Administration:
a) initiated,
b) defended,
concerning the procedure stated at the "Safeguard Clause" as per MED Article 13?





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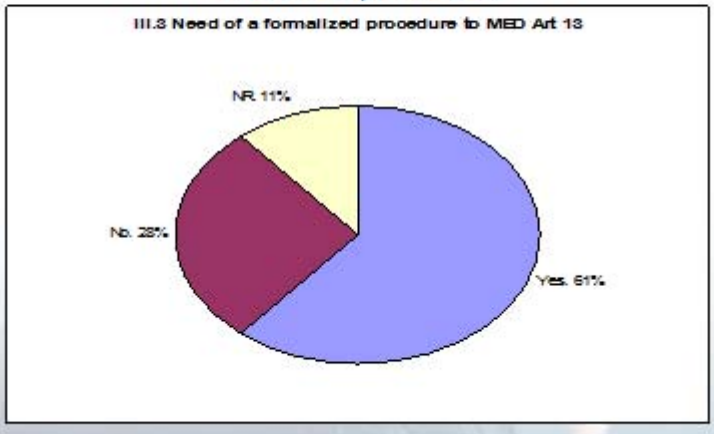
III.3. Would the Safeguard Clause Article 13 benefit from a formalized procedure?



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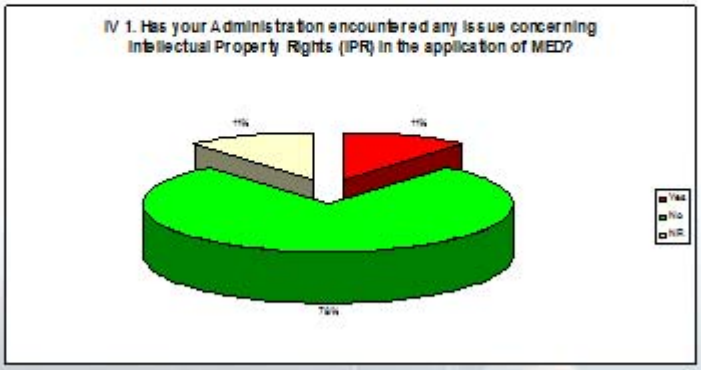
IV.1. Has your Administration encountered any issue concerning Intellectual Property Rights (IPR) in the application of MED?



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Impact of Intellectual Property Rights (IPR)

Scale of the problem

- Almost 90% of original and IP-protected vulnerable products are subject to counterfeiting.
- Counterfeited parts are certified, put onto the market and installed aboard vessels.

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(Source: in-house information available within an IP law firm)

Example:

- A manufacturer of booster plate systems estimates that 50 to 70% of the products which are marketed in countries where IP Law is not protected or enforced are counterfeited or manufactured in violation of existing IP rights.
- This results in 50 to 70% of new building assembled in those countries being equipped with counterfeited equipment which is relevant to safety.

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Impact of Intellectual Property Rights (IPR)

Consequences

Direct Consequences:

- the lowering of safety conditions on an increased number of new building;
- economic losses for manufacturers.

Indirect consequences

- the weakening of the capacity of high-end suppliers to contribute to the maintaining of safety;
- the undermining of the MED certification system: the credibility of European certificates issued for fake products would be called into question in case of accidents.

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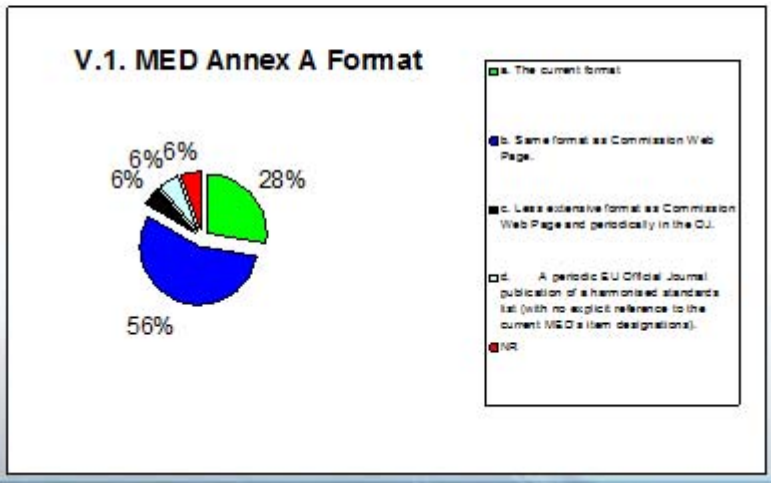
V.1. Concerning the presentation of technical references and update cycle of Annex A, would your Administration prefer:



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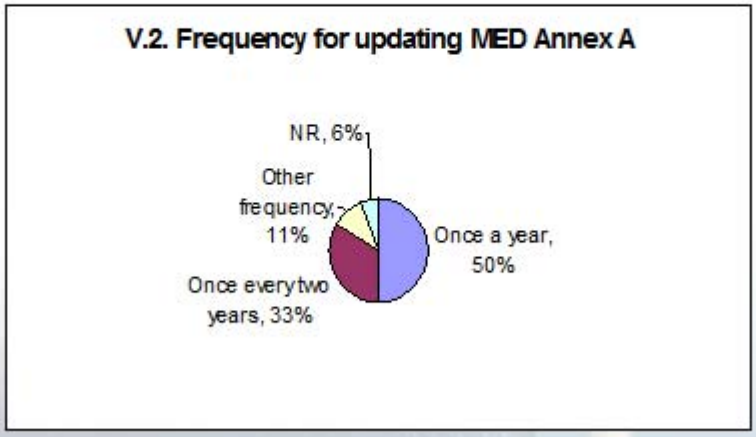
V.2. Please indicate what you consider the most suitable frequency for updating the MED Annex A.



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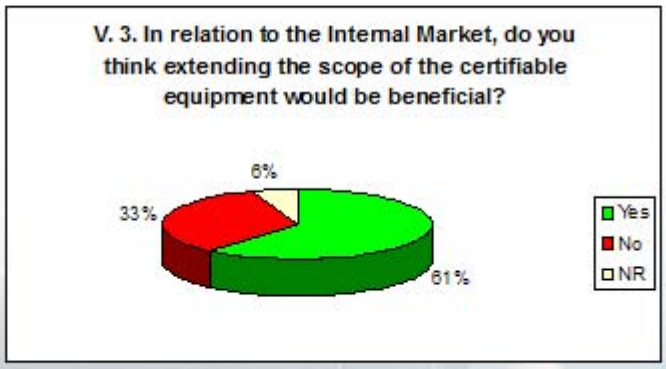
V.3. In relation to the Internal Market, do you think extending the scope of the certifiable equipment would be beneficial, provided that relevant European Harmonized Standards (ie. IMO, ISO, IEC, ITU, ETSI, CEN, CENELEC etc.) for marine equipment exist?



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ANNEX 2

Minutes of the stakeholders' meeting on the revision of the Marine Equipment Directive

Subject: Stakeholder Consultation on the revision of the Marine Equipment Directive 96/98/EC, Brussels, 27 November 2008

Background

After nearly ten years of implementation of Directive 96/98/EC on marine equipment (MED), a number of issues have been raised by the stakeholders concerning the scope and operation of the MED. The general conclusion of the stakeholder meeting on 27 November 2008 is that there is a need for improvement as regards uniformity of application, legal certainly, as well as efficient mechanisms to implement the MED for all parties concerned.

Minutes of the meeting

Industry comments (morning session)

1. Scope Annex A

- Annex A should remain;
- If Annex extended beyond SOLAS this might have market supply implications;
- Currently we are having different interpretation of standards;
- Add a 7th column stating date of entry into force for every item and the date of validity of certificates;
- Need of more functional division of the Annexes;
- Make Annex A available on the web and update it constantly with the latest testing standards;
- Produce forecasts for manufacturers to be aware (before the entry into force) in advance on changes concerning standards;

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. .
Office: DM28 3/23. Telephone: direct line (32-2) 2 961608. Fax: (32-2) 2 969066
S:\08\SK\MED\Stakeholder Consultation\Stakeholder consultation MED271108.doc
E-mail: sonia.karasavvidou@ec.europa.eu

- Convert Annex A into a Regulation or a Commission decision with direct applicability;
- Provide legal certainty as regards implementation dates.

2. Notified Bodies

- To give legal status to MarED Group of NB;
- Uniform criteria for auditing with a common methodology. The COM to have a role;
- Support accreditation by a 3rd party;
- Manufacturers would like to identify which NB are good service providers and which are not;
- To preclude NB to promote unfair competition;
- To set up a formal complain procedure against NB in case of substandard service provided.

3. Market Surveillance

- No actions have been taken against non compliant equipment;
- MS must have the obligation to provide resources to carry out Market Surveillance;
- Following Market Surveillance campaigns a positive list of tested equipment should be publish on the Internet.

4. IPR

- EMEC stated that the issue of MED certificates basically ignores the IPR;
- EMEC feels that the mechanisms considered to protect IPR are electronic tagging and requirement to provide IPR information in the type approval dossier;
- NB stressed that they should be restricted to their actual competences and not to act as the MED police;
- Good operation of the safety mechanisms would lead to safety of products and protect from counterfeit;
- There are failures and mistakes in the list of approved equipment.

Member States administrations comments (afternoon session)

1. Scope Annex A

- UK: in favour of the 7th column stating date of entry into force for every item and the date of validity of certificates. A forecast on standardization should be provided. Annexes considered vital.
- LU: Annex A to be put apart of Directive, upload on a website but first measure legal implications.
- FR: Annex A upload on a website. Also in favour of adding a 7th column stating the date of entry into force for every item. Personal Protection Equipment to be put out of MED. Scope to be reduced.
- DK: Scope should remain unchanged. In favour to upload Annex A on a website.
- EL: Equipment in service must be reviewed. Annex A update every two years-more flexible procedure. Upload Annex A on a website indicating also the entry into force of any amendments. Certification procedures should be better described.
- ES: Upload Annex A on a website but first check legal certainty. Manufacturers should be recommended to use the most updated version of the standards, even if these are not quoted in the Annex and enhance competitiveness. In favour of the 7th column stating date of entry into force for every item. Merging columns 4, 5 and 6 is also an option.
- PT: To make updates via the website. Annex A should be converted into a Regulation or Commission Decision in order to have direct applicability.
- CY: The scope of Annex A should not be extended. A regulation would be better than a Directive. CIRCA site could be a good tool instead of another website application.

2. Notified Bodies

- FR: Does not believe in the Accreditation system. Accreditation bodies are lacking maritime expertise. Regardless if accreditation is set up in the EU, the EU MS should keep the right to intervene.
- ES: ES supports FR. It also offers human expertise concerning maritime knowledge to set up accreditation and audit teams.
- DE: Welcomes the MED revision initiative. The notification criteria should be part of the directive. This way it would be easier to monitor NB

performance and competences. The model of the Class Directive could be used in this case.

- UK: MED already addresses the use of the EN 45000 series to ensure the right notification of NB. There is a concern as regards lack of maritime expertise in the Accreditation Bodies. Supports DE and the need to develop specific quality standards.

3. Safeguard Clause. Article 13

- NO: MS must be capable to identify major shortcomings.
- FR: Article 13 is an initial question concerning only the professional staff. When a problem is identified and is repeated then the COM should be alerted. The COM should provide a pool of independent experts and lead a coordination process and develop cooperation among administrations.

4. Market Surveillance

- DE: There is lack of transparency from others administrations. DE has taken initiatives for surveillance. Surveillance should be a coordinated action in the EU and EMSA should have a supervisory role.
- DK: Asked if EMSA has taken any action concerning Market Surveillance.
- FR: Control should be done by sampling methods. FR would like to have the right to request the Declaration of Conformity (DoC) on board of every ship. The DoC is not on board every ship and currently in many cases it is impossible to identify who is the responsible to put the product into the market.
- UK: In favour of making compulsory use of official templates for DoC and Technical Files. Also in favour of facilitating the access to the concerned documentation on board.
- CY: The PSC Officers have problem in finding the Marine Equipment certificates when there are changes of ownership.
- MS and MARED unanimously supported that each product should precisely define the conformity checking file.

5. IPR

- UK: In favour of the tagging system and to take advantage of this kind of technology.

- FR: can share the experience of containers labelling for assessment of the suitability of using RFID tags.
- CY: Wandered what should be the consequences to the ships if the DoC is missing and what would be the impact of the DoC being required on board.

Conclusion of the meeting

The Commission thanked all participants for their contributions and invited them to provide their additional written comments by 15/12.

Sonia Karasavvidou

ANNEX 3

Results of 2nd Stakeholder consultation

Respondents:

- 5 EU/EEA MS Administrations: France, the Netherlands, UK, Norway and Croatia
- 4 Industry stakeholders: MarED Group of MED NB, EMEC, CIRM and Holland Shipbuilding.

In relation to:

- Technical Annexes
- Notified Bodies
- Market Surveillance
- Safeguard Clause
- Intellectual Property Rights
- Other aspects.

1. TECHNICAL ANNEXES

MS provided the following comments:

- Provisions for allowing MS for early application of the amendments of certain requirements provided by the international regulations e.g MSC 1319 lifeboat hooks.
- Provisions to take timely corrective action if a standard is no longer appropriate. The directive assumes that standards will keep in line with the IMO requirement, but this is not guaranteed. A standard is only published if there is consensus.
- Provisions that allow mitigating action when a standard affects a large number of product changes e.g. IEC 60945. A change that required retest would likely create market difficulty.
- COM to foster changes to Directive 96/98/EC on equipment for which detailed testing standards already exist in international instruments.
- Column 5, to facilitate control, to indicate the proposed amendments to IMO instruments to verify that the requirements for equipment are met.

- In column 6, to adapt the evaluation of the module for type conformity to the type of marine equipment. The recast of the directive should pay particular attention to matching the modules of conformity assessment and the article to which reference is made (column 2) and possibly to forecast the necessary tailoring to the functions of the article.

- Beyond the existing procedures for prototypes (Module B quality assessment), to add a column 7, referring to production standards already existing in international instruments, to make them mandatory . For example, for life-saving appliances, the reference to Resolution MSC81 (70) part 2 of the IMO could be cited, or the item A.1/1.2, ISO 24408 as standard to follow up factory production .

- To add a clause stating that the standards laid down by Directive 96/98/EC (other than those listed in the IMO instruments that apply according the version quoted in the IMO instrument), when modified, are not applicable immediately, so as to leave time to adapt to industry in the production of marine equipment. Indeed, the approach of the current directive is that of "standard date", which implies an immediate adjustment of the equipment. Such a clause would allow time to adjust to industry for the establishment of standard and to modify the launch of a production. This rule applies only to standard added by the European Commission, other than the standards listed in the IMO instruments.

- To add provisions to clarify in Appendix A that, for vessels under construction, regulatory requirements are those in effect at the date of keel laying of the ship, provided that they have not entered into force for too long before the installation of the equipment.

- In the interest of safety, IMO sometimes encourages contracting governments to apply certain international instruments (ie performance standards or testing standards) as early as possible in advance of their legal entry into force. However due to the mechanism of the present directive, MS are not allowed to give effect to such encouragement. Quite recently we have seen a dilemma with respect to the application of the new LSA Code requirements in IMO resolution MSC.32(89), encouraged for early application trough MSC.1/Circ.1393.

- Since the Annex to the Directive is often amended (for instance three last amendments were adopted in September 2009, October 2010 and September 2011) it is very difficult to determine which equipment is allowed on the market. COM to add the 7th column stating date of entry into force for every item and the date of validity of certificates.

- To make a regularly updated Annex A available on the web or to give the legal relevance to the web data base created by the MarED group of the Notified Bodies.

Industry provided the following comments

- Provisions to insert marine equipment into Annex A.1 of MED should clearly be defined and consequently all marine equipment being in compliance with these requirements should be listed in Annex A.1, whether there are products available on the market or not; these provisions could be: carriage requirements based on international instruments, requirement of type-approval based on international

instruments, existing IMO-Performance Standards, existing and applicable testing standards.

- Clear provisions should be defined to shift marine equipment from Annex A.1 of MED to Annex A.2.

- A change in a test standard will make the approval invalid from one day to the other (date of publishing the standard) and subsequently the equipment cannot be installed before a notified body has issued a new type approval. It must be observed that these changes concern all manufacturers, resulting in a general problem for business. Grandfathering clauses of up to 2 years should be considered.

- The right sequence in the process to come to the wheel mark is not always clear: preferred sequences is as follows: Type approval, Production Survey, DOC, affixing Wheel mark. In case of an update of [testing standards in] the MED and its annexes, is it necessary to get a new type approval certificate for a product [even] in the case that there are no amendments to the [construction and performance] requirements of that specific product. In that specific case an issue of a new type approval certificate should not be necessary, or it should be automatically issued, and not be treated as a new type approval.

- To keep clarity in the legal process and updates of the MED, it is not preferable to give the MarED group a legal status. Issues brought up by the MarED group should be handled by the Committee.

2. NOTIFIED BODIES

MS provided the following comments

- Directive in its Art 9 requires MS to designate organizations, Notified Bodies, who will carry out type approval work on their behalf. It could be beneficial if the Directive includes provision on the steps which need to be taken when NB ceases its activities voluntarily and as a result of insolvency.

- Provisions to request material that documents the results of tests and the conformity assessment procedures required by article 5 of directive 96/98 and carried out by a Notified Body not designated by the requesting EU MS Administration other than the appointing one.

- Article 12 cf. articles 5, 6 and 9 establishes the framework for some kind of control that a piece of equipment actually conforms to the requirements contained in relevant international conventions and related standards. Although article 12 authorizes the flag state to request inter alia the manufacturer to provide inspection/testing reports of equipment installed on board, some administrations would prefer that every MS subject to the authority of a relevant article of the reformed directive 96/98, legally can request any NB to disclose all documents relevant for the assessment for conformity required by article xx cf. article yy (numbers of revised articles 5 and 10 of directive 96/98) of directive yyyy/nnnn (identification of revised 96/98).

- The criteria for Notified Bodies and the system of their accreditation is insufficient. Therefore it is suggested the introduction of the approach similar to the one used under Directive 2009/15/EC.

Industry provided the following comments

- The reporting of data to the MarED-databse should be an obligation to all NBs.

- It should be clarified, how far the European accreditation scheme should have influence to the MED, e.g. whether there should be an obligation to all NBs to hold an accreditation for their work etc.

- Accreditation of test houses. Notified bodies do not always accept the accreditation of test houses. In these cases accreditation by the Notified Body is necessary or re-test at another, NoBo-accredited, test house . This will come with extra cost and time for the manufacturers. It should be more clear which accreditation of test houses should be accepted by Notified Bodies.

- In case of showing to a notified body that the equipment fulfils the requirements, the equipment manufacturers are of the opinion that lab testing done at the manufacturers account, should only be verified by the notified body and not be checked by doing testing by an external lab (or at the NoBo lab) compulsorily. This only increases cost. If the NB can be satisfied that the tests are done well, this should be enough to fulfil the requirements.

3. MARKET SURVEILLANCE

MS provided the following comments

- With regard to the facilities already installed on board, the directive does not specify what rule should apply when these devices are subject to change (change of parts, replacement part not identical). It should be ensured that the European Commission maintains its position on changes of equipment in service. The position of the European Commission that the equipment is in use, once installed, are the responsibility of the flag, but did not specify the nature of the modification.

- Better cooperation and coordination of Member States' administrations is necessary, which entails establishment of mechanisms and sufficient resources providing the basis for efficient surveillance.

- Information on every product not in accordance with the Directive should be made available on the Internet and measures taken against the ones responsible for the distribution of such products.

- To appoint an expert body or organization in charge of coordination of the EU market surveillance, which would also provide support to Member States in establishing the surveillance system, and define for every product the method of conformity assessment.

- To make available guidelines or recommendations for the surveillance of equipment on the market, i.e. on-board vessel equipment, or setting up new requirements as a

proposal of on-board vessel equipment, since this would enable a more harmonized approach to the surveillance.

4. SAFEGUARD CLAUSE

MS provided the following comments

- To change Article 13 paragraph 2 of Directive 96/98/EC, to provide a maximum period for objection to the Commission following a safeguard clause of a Member State. Indeed, when a Member State ascertains that equipment referred to in Appendix A1 of the directive is likely to endanger the health and / or safety of the crew, and although this equipment is Wheel marked that Member State shall take all appropriate provisional measures to remove the equipment market and then to inform the other Member States and the European Commission to conclude on the validity of provisional measures taken by the Member State. The period within which the European Commission must make its decision should be specified.

5. INTELLECTUAL PROPERTY RIGHTS

Industry provided the following comments

- Measures should be in place to identify counterfeited products. For instance, the manufacturers should provide IP ownership information when applying for certificates. Such information should be recorded in a systematic manner which the notified body and Class can use later to double check the authentication of the application. Whenever there is any suspicious application (e.g. exactly the same product but by different producers), the notified body should contact the related producers for further proof. In addition, if feasible, a database should be established by a competent independent body for notified body and Class to check the authentication of the information provided by the manufacturers.

- State of the art technology (e.g. RFID tags) should be used in marking and identifying MED equipment. Certificates issued by notified body and Class should be printed with security measures so that it is difficult for the counterfeiting manufacturers to counterfeit the certificates.

- To set up a positive list of tested equipment following market surveillance, a "black list" should also be published to reveal counterfeiting MED equipment (and its manufacturers) as well as those which have caused safety and environmental problems.

OTHER ASPECTS.

MS provided the following comments

- Clarification of the term "placed on board" and "installed on board" – when the equipment is required to have a valid type approval certificate: date when the keel was laid; date of equipment delivery (equipment is sometimes delivered 6 months in advance of vessel survey or the ship programme may be delayed after the equipment is delivered); date of installation of equipment (the ships are built in blocks, thus e.g. a

radar antenna may be installed on the mast but the mast may not be on the ship at the time of installation).

- Provision which MS can apply, when product listed under Annex A.1 is not available on the market.

- To amending Article 18 to take into account the new comitology rules. In this case, taking into account that, in accordance with Article 2 of Regulation 182/2011, the examination procedure applies to the adoption of acts implementing environmental, safety and security, or protection of health or safety of persons, animals or plants.

Industry provided the following comments

- The rights and obligation of all parties involved should be clearly defined, e.g. manufacturer, notified body, COSS, market surveillance, etc.

- In analogy to international instruments, e.g. SOLAS, MARPOL, COLREG etc., also MED should contain regulations regarding the possibility to grant exemptions from MED under very strict restrictions (to avoid a misuse of exemption possibilities), e.g. for the case, that marine equipment is listed in Annex A.1 of MED but no products are available on the market.

- The obligation to report withdrawn applications should be deleted, because a withdrawn application by the applicant has no influence to the market yet, and instead of that an obligation to report suspensions of certifications and withdrawal of certifications should be inserted.

- EU should always strive to a world-wide level playing field. At this moment the directive is only EU based. Creating a level playing field for example via IMO or treaties with countries would be of great benefit for the EU based companies.

- At this moment the definition of a community ship still gives some uncertainty. Especially for ships, like (auxiliary) war ships, which do not have to comply with SOLAS and MARPOL requirements. It is not always clear whether these ships are community ships or not.

ANNEX 4:

Marine equipment in a nutshell

Marine equipment is the key supply industry of shipyards and of the whole maritime industry, including off-shore activities. Whereas several product and service categories can be distinguished within the sector, no standard categorization of marine equipment supplies exists. The term "marine equipment" is defined by the European Marine Equipment Council as all products and services supplied for the building, conversion, and maintenance of ships (seagoing and inland).

Main groups and categories of marine equipment

Categories	Marine equipment systems
Propulsion/power systems	1. Propulsion, power generating systems 2. Auxiliary Power generating systems 3. Auxiliary Systems
	4. Electrical systems, plants and cables
Navigation/communication/control (electrics & electronics) equipment	5. Instrumentation, control and navigation systems 6. Communications and Entertainment Systems 7. Lightning Systems 8. Steering Systems 9. Special Ship Operation Systems
Cargo related equipment	10. Mooring, Deck Machinery Systems 11. Cargo Systems
"Hotel" and related equipment	12. General Outfitting Components 13. Heat, Ventilation, Air Conditioning Systems
	14. Accommodations Systems
Other miscellaneous	15. Safety and Life Saving Systems, Environmental Protection Systems 16. Other Systems 17. Materials

Source: ECORYS *et al.*, Study on Competitiveness of the European Shipbuilding Industry, *op. cit.*

Only some thirty years ago most of the shipbuilding work was carried out at the shipyards themselves. Since then however an increasing trend can be observed towards outsourcing and subcontracting of activities. Nowadays it is assessed that 50-70% of the value added comes from external subcontractors and suppliers (many of whom are regarded as marine equipment suppliers), whereas for more complex ships this can be as high as 70-80%.[64]

Shipyards are therefore major partners of marine equipment manufacturers. Thanks to the sector's diversification strategy, when a reduction in ship orders occur, marine equipment manufacturers can partly compensate the reduced demand from this side with services and maintenance activities, as well as supplies to other industries.

[64] See "competitiveness" study, *Op. cit.*

According to a study undertaken for the Commission, between 2000 and 2005 the total annual worldwide marine equipment market (turnover) was estimated at €60 billion. Of this, around €35 billion concerns naval marine (military) equipment, while some €21 billion relate to the marine equipment in the commercial shipbuilding sector.[65] Taking into account supplies to the oil and gas sector[66], an additional turnover of some €50 billion per annum can be added. This would bring the total turnover to over €100 billion. Industry sources give different figures, calculating turnover at € 46 billion in 2008.[67]

Europe has a relatively strong position in marine equipment worldwide and acts as a net exporter. The European marine equipment industry is a high value added sector. The industry derives its competitiveness from innovative and reliable high quality products. However, many production facilities in Europe are in fact owned by Asian concerns nowadays. The global market share of the marine equipment sector in Europe is higher than the share of ship construction, reflecting the strong export position of this sector (export share of 46%). Within Asia, the shipbuilding nations Japan and Korea have the strongest position. Over the period 2000-2005 the Asian manufacturers (Japan and South Korea) accounted for some 50% of the marine equipment market as compared to 30-35% for the European Union.[68]

Contrary to the shipbuilding industry, the marine equipment sector is highly heterogeneous and consists of many small and medium-sized enterprises, which, according to a study carried out for the Commission in 2009[69], could account for up to 70% of the companies in the sector. There is no information available on SMEs' share in total sector turnover, but is assumingly more than 50%. Most of the existing innovations in the sector are developed by enterprises ranging from 50 to 200 jobs[70]. In total, estimates range from 5,000 to 6,000 companies in Europe (key European countries for marine equipment production are Germany, the UK, Norway, The Netherlands, Italy and France).[71] Inevitably, the relatively high presence of SMEs in the industry results in a number of vulnerabilities such as the presence of weak financial structures or the insufficient co-operation with other enterprises and/or universities on Research Development and Innovation.[72]

A study undertaken by the Commission[73] estimates that the European marine equipment industry employs directly more than 287,000 people whilst indirect employment would amount to about 436,000 people.

65 See "competitiveness" study, *Op. cit.* note 64.
66 As is done in certain definitions of the marine equipment industry
67 This will be the reference figure taken for the purposes of this IA.
68 See "competitiveness" study, *Op. cit.* note 64.
69 *Study on EU SMEs and subcontracting, October 2009*
70 *Id.*
71 See "competitiveness" study, *Op. cit.* note 64.
72 *Study on EU SMEs and subcontracting, Op. cit.*
73 http://ec.europa.eu/maritimeaffairs/studies/employment/summary_report.pdf

ANNEX 5

The New Approach and the MED

1. The New Approach

The Single Market for goods is one of the EU most important and continuing priorities which aims to create a user-friendly environment for businesses and consumers. Since the end of the 60s, the EU has developped original and innovative instruments to remove the barriers to free circulation of goods.

These instruments had a twofold objective. On the one hand they ensure that products available in Europe meet a high level of protection of public interests like health and safety, consumer protection or environmental protection. On the other hand they ensure the free movement of products by replacing national rules with a single harmonised set of conditions for the marketing of the products concerned that apply in all EU Member States.[74]

Among these innovative instruments, the **New Approach** to product regulation and the **Global Approach** to conformity assessment occupy an important place. The common thread between these complementary approaches is that they limit public intervention to what is essential and leave business the greatest possible choice on how they meet their public obligations.

The *New Approach* dated from 7 May 1985 limited legislation to cover only essential health and safety requirements of products. This simplification was a step forward in the legislative provisions which allowed all the technical elements for product specification to be covered in harmonised European standards, not the legislation itself, providing thereby a flexible, technology neutral and non-prescriptive means of regulation.

Box 7: Standard elements of New Approach directives[75]

- **Harmonisation**: limited to essential requirements that lay down the necessary elements for protecting the public interest.
- **Mandatory essential requirements**: Only products fulfilling the essential requirements may be placed on the market and put into service.
- **Presumption of conformity**: Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.
- **Conformity assessment procedure**: Before placing a product on the EU market, manufacturers must subject the product to a conformity assessment procedure provided for in the applicable directive with the veiw to affixing CE marking.

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74 The evolution of the EU's policy on technical harmonisation is outlined in detail in the impact assessment that accompanied the New Legislative Framework. SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

75 See in this respect *Guide to the implementation of directives based on, the New Approach and the Global Approach* (http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf).

- **Notified bodies**: Third party conformity assessment is carried out by notified bodies, which have been designated by the Member States among bodies that fulfill the requirements laid dwon in the directive and that are established on their territory.

- **CE marking**: is an indication that the products comply with the essential requirements of the applicable directives and that the products have been subject to a conformity assessment procedure provided for in the directives. Products in compliance with all provisions of the applicable directives providing for the CE marking must bear this marking.

- **Market surveillance**: National market surveillance shall monitor that products placed on the market comply with the provisions of the national legislation transposing the New Approach directives.

- **Safeguard clause**: Member States are obliged to prohibit or restrict the placing on the markets of products bearing the CE marking if the latter might compromise the safety and health of individuals or other public interests covered by the applicable directive.

The *Global Approach*[76] covers the various methods of examining a product to determine if it complies with the essential requirements of new approach directives, including any requirements relating to the design and manufacture of products.[77] The main principle of the global approach is that the manufacturer issues an EU declaration of conformity, declaring that the product satisfies the requirements of the applicable directives or conforms with an approved type.

Box 8: Basic elements for Conformity assessment

- manufacturers' internal design and production control activities;

- third party type examination combined with manufacturers' internal production control activities;

- third party type or design examination combined with third party approval of product or production quality assurance systems, or third party product verification;

- third party unit verification of design and production; or

- third party approval of full quality assurance systems.

2. Comparing MED with the New Approach

Some provisions of MED deviate however from the New Approach because of the particular features of marine equipment:

- First, marine equipment has to fulfil IMO international standards. Flag states are expressly required to issue a certificate of approval by the IMO conventions described above. The

76 The Global Approach was completed by Council Decision 90/683/EEC, which was replaced and brought up to date by Decision 93/465/EEC. These decisions lay down general guidelines and detailed procedures for conformity assessment that are to be used in New Approach directives.

77 It introduced a modular approach, which subdivided conformity assessment into a number of operations (modules). These modules differ according to the stage of development of the product (for example design, prototype, full production), the type of assessment involved (for example documentary checks, type approval, quality assurance), and the person carrying out the assessment (the manufacturer or a third party).

Directive has the specific objective to ensure compliance with this obligation as well as mutual recognition of these certificates between Member States.

- Second, marine equipment encompasses some categories of equipment, which are also within the scope of Directives other than the MED (e.g. fire extinguishers, electronic material, protective equipment, pyrotechnics), the requirements of which may differ from, or even be incompatible with, those of the IMO.

These features have a number of consequences on how the *New Approach* has been implemented in the field of marine equipment:

- Whereas the legislation on marine equipment is restricted to the requirements necessary to protect the public goals of health and safety as defined by IMO, compliance with the latter is not formulated as an 'essential requirement' in the meaning of the New Approach. Instead, the MED includes a detailed list of the mandatory requirements contained in the international conventions, the relevant resolutions and circulars of the International Maritime Organization (IMO), and the relevant international testing standards.

- As indicated above, these international requirements may either be substantially different, or go beyond those connected with the CE marking for similar products. For this reason, a specific MED marking (the *wheelmark*) has been put in place replacing the traditional CE marking for equipment falling under the scope of the MED.

- In order to comply with IMO requirements, conformity certificates for marine equipment must be issued by or on behalf of the flag State and not by the manufacturer of the product. This means that those conformity assessment modules provided under the *Global Approach*[78], which imply assessment by the manufacturer of the product, cannot be used for marine equipment.

[78] *The Global Approach*, which is one of the elements of the *New Approach*, provides various methods of examining a product to determine if it complies with the essential requirements of new approach directives.

ANNEX 6

Problematic areas common to New Approach directives, with a specific attention on marine equipment

The impact assessment accompanying the revision of the New Approach identified, described and fully analysed the problem areas which are common to New Approach directives[79], later confirmed by the Commission when preparing the alignment of ten sectoral Directives with the NLF[80]. Among the four areas identified, three are of particular importance for the MED, namely:

- lack of confidence in notified bodies and in the whole notification process in general;
- inefficient enforcement tools of the directive (market surveillance and safeguard mechanism);
- inconsistencies and legal uncertainty in the current regulatory framework.

The stakeholders' consultation conducted in the context of the revision of MED has confirmed that the marine equipment sector suffers from unequal implementation in the Member States, unequal market surveillance and misuse of safeguard clause.

i. Lack of confidence in notified bodies and in the whole notification process

Notified bodies (hereafter NB) are responsible for testing, inspecting and certifying equipment before it can be placed on board a community ship. They are notified by Member States to the Commission.

A number of problems in the functioning of the notified body system were highlighted in the NLF IA report for the ensemble of the internal market directives. Among these:

- Notified bodies provide their services as a commercial activity and are in competition with each other. Feedback from the industry had pointed to the fact that this competition is not always fair: the most frequent reason for unfair competition is the less rigorous implementation of procedures which can reduce the costs of NB by 30-75%. In this situation, "good" and law-abiding NBs loose business, and the general image and quality of the NB and their work are undermined. Manufacturers have an incentive to test their equipment with the less rigorous NB, and those who choose to do so gain a competitive advantage vis-à-vis manufacturers who undertake correct conformity assessment work.

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79 The NLF was accompanied by an impact assessment where these problems are presented and analysed in detail. See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf, pages 12-23 and 27-28.

80 See SEC(2011)1376 final, pages 16-30 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2011:1376:FIN:EN:PDF). A summary graph of these problems, with their causes and consequences, is provided in page 15. Worth noting is the recurrence of the same problems across sectors, as can be seen from the abundant supporting material cited both in this impact assessment and in SEC 2007(173), which includes answers to questionnaires, sectoral evaluation reports, RAPEX and market surveillance information as well as court cases.

- The final consequence is an increased risk of non-compliant products reaching the market (or being placed on board ships in the case of marine equipment).

- The NLF IA report identified the main reason in the lack of transparency and of harmonisation in the competence assessment and monitoring of NB, meaning in practice that NB are operating under uneven conditions inside the EU: accreditation is a precondition for notification in some Member States but not in others, monitoring is carried out more or less frequently (or not at all), etc…

The marine equipment sector is by no means immune to these problems. On the contrary, these are compounded by the very specific circumstances of the shipbuilding markets, concentrated in the Far East and characterised in recent years by the emergence of a plethora of shipyards with only elementary, still developing quality culture. Such a situation, from time to time encountered by the Commission's own inspectors, makes these shipyards vulnerable to pressure to reduce costs and meet their building schedule at the expense of quality – while being beyond reach of the traditional market surveillance techniques. It is true that verification *sur place* is carried out by flag State inspectors or classification societies, however these cannot – and it is not their role – substitute for a properly functioning, high-quality notified body system.

Box 1 – Inconsistency among Notified Bodies (NB)

The industry has highlighted that "In addition to the issue of potential conflicts between IMO and MED standards, difficulties in complying with the regulatory framework have been reported as a consequence of inconsistent interpretation by (NB) surveyors".

The divergences in the control of their notified bodies by national administrations are somehow reflected, in the marine equipment sector, in the results of the questionnaire sent to the Member States in 2008: since the entry into force of MED in 1999 only 42% of the notified bodies would have been audited five times or more, as would be expected; on the contrary, 33% would have been audited only three or four times, 17% less than three times and 8% would never have been audited.

ii. Weakness and difficulties in the enforcement of the directives

The two tools for the enforcement of New Approach Directives are market surveillance and the associated safeguard clause mechanism.

Market surveillance

A good level of market surveillance in each Member State is essential to ensure that only compliant products circulate on the market, and weaknesses in the organisation of market surveillance in one single Member State can seriously undermine the efforts taken by other Member States to keep non-compliant products from the market. Currently, the organisation of market surveillance differs strongly from one Member State to another. In the marine equipment sector, 39% of stakeholders indicate that administrations in their country don't carry out any market surveillance. Only 10% report about administations performing regular market surveillance campaigns.

As was highlighted in the IA on the NLF, competence of market surveillance authorities is limited to the national territory. Where action is needed beyond the border, authorities must rely on their colleagues in the other Member State. However, as there is not a sufficiently broad legal basis, cross-border co-operation in the EU does not work efficiently – the IA on

the NLF indicates that only 34% of stakeholders report having ever taken any action due to information provided by another Member State.

In the current situation, MED contains a generic clause allowing national administrations to carry out market surveillance, rather than laying down a specific obligation to do so. While in practice most national administrations do carry out market surveillance, this is affected by a dramatic dearth of resources. Moreover, market surveillance activity is limited to the marine equipment placed on the European market, which constitutes only a small fraction of the overall equipment on board community ships. Indeed most of the equipment is being placed on board wherever ships are built or repaired – most often outside the EU – and may never physically enter the EU territory. For the rest, market surveillance must largely rely on information drawn from port State control activities and from information received from the industry.

For the above reasons, market surveillance is unlikely to play its role of providing the national authorities with sufficient information to prevent the placing of non-compliant products on board Community ships. The results of the stakeholders' consultation concerning the violation of intellectual property rights (IPR) in the marine equipment sector seem to confirm this assumption: while the industry complained about massive counterfeit and violation of Intellectual property rights (according to the industry's own estimate , "almost any percentage from 100 down to not less than 80 percent of Korean marine equipment [could be] counterfeited and pirated", and other sources indicate similar problems in other Asian countries and in the EU itself), in contrast 78% of Member State administration declared never having been confronted with issues concerning IPR.

Safeguard clause mechanism

Under article 13 of MED, a Member State, if it discovers a piece of marine equipment non-compliant with the Directive, shall take interim measures to restrict it being placed on the market or being used on board a ship for which the Member State issues the safety certificates. The Commission is then responsible for verifying if the measures are justified or not.

Under this mechanism, Member States have no incentive to carry out an exhaustive procedure during market surveillance and all the way to the adoption of restrictive measures, since the final responsibility for the investigation lies with the Commission. Actually, Member States have a tendency to notify every restrictive measure at a very early stage, sometimes after only a superficial assessment as to whether the product really poses a risk to health and safety has been completed.

At the same time, the Commission does not have the necessary technical competence to evaluate the conformity of a product. The need for the Commission to rely on external expertise and the gathering of the information missing from the Member State's notification can both lead to considerable delays in the procedure. These can be extremely costly for compliant manufacturers, who must live for a long time under suspicion while the outcome of the Commission verification remains unknown. The case study in Box 1 illustrates the problems which arise from the inefficient safeguard clause mechanism.

Box 2: Case study on Korean pressure-vacuum valves

In February 2004, the Danish authorities notified the Commission their ban on a brand of high velocity pressure/vacuum relief valves of Korean origin. In its examination of the case the Commission found that:

a) a production error had rendered part of the production faulty and not in accordance with the type; however, this was not apparent from the documents submitted by the notifying authority but had been found and reported by the manufacturer itself following the ban;

b) for the rest of the production, the information provided by the notifying Member State (and also third parties) was inconclusive given the significant uncertainties surrounding the testing which reportedly led to the ban.

The Commission therefore supported the Danish ban for the part of the production which had been proven faulty and invited the parties to carry out new testing for the rest of the production.

The follow-up testing did not provide additional information in support of the original ban. The case was finally resolved by an agreement between the parties which included the voluntary replacement of the valves concerned by a full set of new models, fully re-tested, and a number of precautionary checks on the valves already installed on board Community ships.

The proceedings lasted nearly 40 months in total and required a significant involvement of the manufacturers, the notified body, the notifying authorities and the authorities of the Member State on whose behalf the MED certificate had been delivered, as well as EMSA and the Commission itself.

ANNEX 7

The elements of the New Legislative Framework

Two decades of operation of the New Approach revealed a number of areas where there still was room for improvement. Although New Approach was popular and supported in many sectors, it did not always guarantee a sufficient, perceptible level of confidence in the market place, whether for products manufactured in the EU or imported from third countries. This led to unequal implementation in the Member States, unequal market surveillance interventions, and misuse of safeguard mechanisms. In certain sectors, the consumers or end users also lacked trust in the validity and added value of the CE marking on products. Thus economic operators sometimes felt that they could not benefit from a level playing field on the market while consumers did not always feel that they were effectively protected.

With the aim of increasing the effectiveness of the system, its transparency as well as its smoother functioning for the benefit of all involved (manufacturers, conformity assessment bodies, authorities and consumers and users), the New Approach was therefore subject to a revision which in 2008 led to the **New Legislative Framework** (hereinafter the "NLF") for the marketing of products.[81] Its objective is to strengthen and complete the existing rules and to improve the way in which the requirements are actually applied and enforced in practice by business and authorities. The NLF consists of three instruments:

Regulation 764/2008[82] is intended to improve the free movement of goods in the "non-harmonised area" by reinforcing the application of the principle of the mutual recognition.

Regulation 765/2008[83] introduces better rules on market surveillance to protect both consumers and professionals from unsafe products, including imports from third countries. This particularly applies to procedures for products which can be a hazard for, health or the environment for instance, which in such a case will be withdrawn from the market. It also enhances the confidence in and quality of conformity assessments of products through reinforced and clearer rules on the requirements for notification of conformity assessment bodies (testing, certification and inspection laboratories) including the increased use of accreditation; a reinforced system to ensure that these bodies provide the high quality services that manufacturers, consumers and public authorities need. Finally, it improves the credibility and clarifies the meaning of CE marking. In addition the CE marking will be protected as a community collective trade mark, which will give authorities and competitors additional means to take legal action against manufacturers who abuse it;

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81 See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

82 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ L218 of 13.08.2008. For more information see http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/index_en.htm. This regulation

83 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L218 of 13.08.2008

Decision 768/2008[84] establishes a common legal framework for industrial products in the form of a toolbox of measures for use in future legislation. This includes provisions to support market surveillance and application of CE marking, amongst other things and it sets out simple common definitions (of terms which are sometimes used differently) and procedures which will allow future sectoral legislation to become more consistent and easier to implement. The provisions are split for legal reasons, but must be considered in parallel, as they are fully complementary and together form the basis of consistent legal framework for the marketing of products. The provisions of the Decision will be fed into existing Directives as and when they are revised - in effect, it is a basis for future regulation.

The initiative accompanied by this IA is a further step in the implementation of the goods package adopted on 9 July 2008 by the Council.

[84] 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, OJ L218 of 13.08.2008

ANNEX 8

Description of the elements of alignment on the New Legislative framework, as presented in the IA on NLF (SEC(2007) 173)

1. Creating a network of notified bodies and a horizontal group of notified bodies

To improve the co-ordination of conformity assessment activities in the different directives all notified bodies could be interlinked through a formal network. The presidents of the sectoral notified body groups could also be grouped into a horizontal co-ordination group under the chairmanship of the Commission, to address horizontal issues to ensure coherence and a consistently high quality of conformity assessment activities across all directives.49 The advantages of doing this are flexibility of approach, low cost and minimal resourcing needed for its implementation. There is, however, one important impediment to the effectiveness of this option. Participation in the notified body groups is, at present, not compulsory as a legal requirement, participation is purely voluntary. The idea would be to oblige participation of all notified bodies in their relative sector group (even in a 'virtual' way using web-based applications, to reduce costs for SMEs). For this reason, this option standing alone may not be sufficient to overcome the current problems.

2. Competence assessment and monitoring of notified bodies performed at national level based on a common EU legal framework and supported by a European infrastructure.

This option would build upon the current system (decentralised competence assessment and monitoring carried out under the responsibility of each Member State) and complete it with a common legal framework for accreditation and a co-ordination infrastructure at Community level.

Regulation at EU level will bring the current diverging national systems closer and provide the necessary framework for a more coherent and uniform implementation of accreditation at national level and its use in support of notification. As the non-regulatory measures taken so far have been insufficient to overcome the national differences, it is indispensable to opt for the regulatory solution. A common legal framework would harmonise the general rules for accreditation, such as the principle of non-competition, the public authority nature of accreditation, the rules on cross-frontier accreditation policy and oblige co-operation between the different Member States' accreditation bodies.

In order to ensure the coherent application of the accreditation framework, this option foresees a European infrastructure for accreditation that would steer and govern its implementation. This role could be taken over by the existing European Co-operation for Accreditation (EA). […] EA operates at EU level, promotes mutual recognition and acceptance of accreditation certificates thus contributing to the free movement of goods. Its system of peer evaluation provides greater coherence between accreditation bodies' practices and increases mutual confidence. The option would provide EA with public recognition and reinforce its structure and operation. As EA brings together representatives of national public authority organisations, it would therefore be in a position to guarantee the level of independence and technical capabilities required.

3. Electronic notification procedure

This option foresees the introduction of a legal basis for electronic notification on the website which would replace the obligation to publish the list of notified bodies in the Official Journal. The logical conclusion of this is, therefore, to abolish the publication in the Official Journal as a web based publication is quicker and more easily updateable.

4. Enhance co-operation of market surveillance authorities by extending the existing co-operation mechanisms

The existing co-operation mechanisms and information exchange tools could be extended without any need to change the existing framework. More than ten sectoral specific ADCO groups do presently exist, covering directives such as toys, personal protective equipment, machinery and construction products, etc. These groups provide a mechanism for Member States' market surveillance enforcement authorities to come together to exchange information regarding surveillance for a particular sector. This concept could be extended to cover all directives and their organisation and the working methods could be improved to exploit the existing the opportunities more efficiently.

The Commission could also establish an overarching horizontal group, complementary to the sector specific groups. Such a group could ensure that there is better coherence, co-ordination and co-operation across directives. However, to avoid duplication such a group should limit its operation to cover only horizontal aspects related to market surveillance, exchange of best practice from sector to sector and the identification of priority actions and specific fields for inter-sectoral co-operation. There could also be opportunities to share resources.

The big advantage of these measures is that they can be implemented using the existing legal and operational framework, with limited additional resource costs. However, the success of these groups depends on the active involvement and support from all Member States based upon what is currently a voluntary system. Participation in these activities does require resource allocation from member States which does incur a cost for them. In sectors where there is currently little or no market surveillance, measures such as ADCOs will not be sufficient to overcome the general problem that the legislation is not enforced.

5. More effective controls of the market place

More effective post-market control mechanism:

This option comprises of improving the organisation of market surveillance activities at the European level, to promote more coherency and efficiency of action. Reinforced co-operation and co-ordination mechanisms would be introduced, both at the national level and cross-border, in order for market surveillance to operate effectively throughout the whole Community.

In this context, the centralisation of certain activities or the setting up of an Agency could *a priori* be seen as options, given that there are already examples in certain sectors (eg. European Agency for Aviation Safety (EASA), European Maritime Safety Agency (EMSA), European Railway Agency (ERA) and the Food Veterinary office (FVO)). Whilst, there may be a case for a central organisation of market surveillance activities at the EU level in certain sectors, this option is unfeasible and unrealistic in the true horizontal context, due to the vast range of products to be covered and the organisation and vast expertise that would be necessary.

Similarly the complete harmonisation of market surveillance operation and requirements written into the legislation raises some questions with regard to subsidiarity, proportionality and the effectiveness point of view. Whilst such harmonisation would, without doubt, have a positive impact in aligning the level and rigour of market surveillance throughout the Community51 it would also lead to difficulties in maintaining flexibility for sector specific problems, flexibility to cope with different Member States' market structures and could, therefore, lead either to overkill of requirements or to gaps in the system. Furthermore, complete harmonisation would result in considerable costs for the adaptation of what are often well established and well functioning national structures and procedures.

6. Common EU framework on market surveillance setting out minimum requirements

This option consists of the creation of an EU legal framework which would set out minimum requirements for the organisation and operation of the national market surveillance system, combined with co-ordination mechanisms (as proposed in option B1). The framework requires the establishment of an effective and efficient organisation for national market surveillance, including, for example, sufficient resources, necessary powers, effective communication between authorities, etc. It also sets out certain obligations including the withdrawal of non-compliant products from the market, requirements to perform checks on products, to follow up complaints, to monitor accidents, to co-operate with economic operators etc.

Furthermore, it establishes an obligation to participate in horizontal EU co-operation activities and to provide mutual assistance, when necessary.

This option would also create a legal basis for enhancing the existing co-operation and co-ordination mechanisms, to build upon and improve what we already have in place. This would, therefore, ensure exchange of information and best practices, common projects and the sharing of resources. It would also provide for a single electronic information exchange system by extending the use of the current RAPEX system53 to products for professional use.

Under this option, the existing safeguard clause procedure would be rationalised. The idea is to split the safeguard procedure into an information exchange phase taking place at national level and a second phase taking place at Community level. In the first phase, Member States would inform each other of national measures taken to restricting the free movement of a product. The procedure would then be completed unless there were objections from other Member States. Only in the case of disagreement between Member States on the justification of the measure, would a decision be taken at the Community level.

7. Reinforcing traceability and the introduction of specific obligations for importers

This option would ensure that that market surveillance authorities can identify a responsible person in the EU and obtain the necessary information. The legislation would be amended to ensure traceability of a product and its supplier throughout the whole supply and distribution chain. The legislation would also specify the obligation of importers and distributors in more detail.

Traceability could be ensured by:

• Introducing a general obligation to appoint an authorised representative for products imported from third countries;

• Establishment of a registration system for manufacturers and importers;

• An obligation to identify the manufacturer and the importer of a product and an obligation on them to identify products they purchased and supplied on (except supplies to final users/consumers).

Specific obligations for importers and distributors could be introduced in the legal framework, clarifying that these operators must check whether the manufacturer has fulfilled his obligations. These obligations would take account of the role of these operators and would be minimum obligations applying in addition to those arising from national law.

8. Creation of a reference legal document

A better, more flexible solution is to establish a horizontal reference document containing standard terminology and procedures o which the individual legal instruments could be adapted in the future. Then, as sectoral texts are revised they can use this framework to include the harmonised elements appropriate for their sector.

ANNEX 9

Detailed assessment of impacts on operating costs and administrative burden

PO	Measure	Operating costs and administrative burden			Comments
		Economic operators	Notified bodies	Public authorities	
PO2, PO3	Harmonising definitions and procedures with other sectoral Directives in order to improve coherence	No	No	No	Measure of a strict legislative nature
PO2, PO3	Harmonised competence assessment and monitoring of Notified Bodies across the EU in order to improve the quality of their work	No	Negligible	Negligible	Competence assessment is an existing obligation: benchmark for conformity assessment bodies will not change; measure aimed at avoiding circumvention rather than creating new obligations. Moderate but temporary effort for NBs to produce new evidence may be necessary or negligible additional burden of transmitting information which is already in NB hands[85]. For public authorities, the new measure will facilitate implementation of obligations which also already exist and should, if anything, reduce their monitoring costs. Re-notification (if necessary) of bodies already complying with quality standards will be a mere formality.[86]

[85] See SEC(2011)1376 final, pp. 44-47
[86] See SEC(2011)1376 final, pp. 48-49

PO2, PO3	Enhancing cooperation of market surveillance authorities and setting out minimum requirements on market surveillance so that this becomes more effective and reaps the benefits of cross-sectoral action	No	No	Negligible	Market surveillance structure and obligations (cooperation, exchange of information, etc.) already exist under Regulation 765/2008. The MED will be integrated into these. Incorporation into single national structures should reduce the costs of administrations which now carry out sufficient market surveillance. If incorporation of the MED into these structures resulted in a net increase of the latter's activities, one should expect a moderate increase of the associated costs for administrations, which should however be partly offset by the economies of scale and the synergies of cross-sectoral control. The overall result is probably going to be a moderate increase in the costs for administrations.
PO2, PO3	Reorganisation of *safeguard clause procedure* to clarify how the relevant enforcement authorities are informed about dangerous products and ensure that equivalent action is taken against that product in all Member States	Negligible	No	No	Occasional effort for operators facing a more detailed procedure, however this contributes to ensuring fair treatment and avoid costs associated with incorrect technical assessment by surveillance authorities. For public authorities, the measure codifies what should already be good practice and application of basic legal principles. [87]
PO2, PO3	Reinforcing traceability of equipment in order to facilitate both market surveillance and port State control	Negligible	Negligible	No	Information already with notified bodies and manufacturers, and facilitating task of public authorities.[88]

[87] See SEC(2011)1376 final, p. 47
[88] See SEC(2011)1376 final, pp. 44-49

PO2, PO3	Using a "wheelmark" instead of the standard CE	No	No	No	Wheelmark already in the MED
PO2	Requirements on more effective post-market control mechanism and obligations by the economic operators (especially as regards post-market control mechanism)	Yes	No	No	Impact differs from general alignment, where it was considered that these requirements merely codify what should be good practice of operators working in accordance with recognised quality standards[89]. Given that other internal market directives focus on products which are *either* produced in EU territory *or* imported into it, similar obligations foreseen for manufacturers and importers are assumed not to overlap. In the case of the MED, none of these assumptions should be expected to hold given that a) marine equipment is in most cases directly installed on board at ship building or repair yards, where it is integrated into a higher system (the ship), itself certified by the flag State or a classification society on the latter's behalf; and b) only a fraction of the equipment to be installed on board EU ships is actually imported into EU territory. In practice, adopting post-market control requirements for economic operators would imply additional costs for these; these costs would be higher for the fraction of the equipment which is imported into EU territory as a result of the accumulation of obligations for manufacturers *and* importers. However, for the reasons given further up under a) and b), the practical benefits should be expected to be few – if any at all.

[89] See SEC(2011)1376 final, p. 42

PO2	Full alignment of the texts of the conformity assessment procedures. Allowing for conformity assessment by in-house bodies (conformity assessment modules A and C), which are not retained in the current MED	Negligible	No	No	Cost of certification against same standards and type of production with accredited labs does not change if an in-house NB is used. In this case, the manufacturer will benefit of economies of scale and better expertise – although these benefits will only accrue to manufacturers of a certain size, capable of maintaining a structure meeting the necessary standards, which are a minority in the market.
PO2	Abandoning the annexes to MED and turning respect of the IMO requirements into "essential requirements" constituting the reference in the NLF for conformity assessment. Norms produced by the standardisation bodies would be dealt with in the same way as in the NLF, thus only providing a presumption of conformity. Conformity assessment is made against mandatory technical norms created by European and international standardisation organisations and reflecting the IMO requirements	Between -4M€ and -7M€	No	Negligible	See Annex 12. Costs to industry generated by transposition delays would largely be removed, but double-certification costs would not completely disappear due to differences between Member States in the content and timing of implementation and uncertainty on applicable requirements. For Member States, transposition into national orders would still be necessary. Technical assessment in isolation would probably mean marginally higher costs for the national administrations.
PO3	Selective use of conformity assessment modules, whereby notably modules A and C (corresponding to the possibility of conformity assessment of products by in-house Notified Bodies) are not retained	No	No	No	Situation would not change relative to current MED practice.

PO3	Lightening of obligations of actors in the distribution chain, reflecting the small share of marine equipment which is actually placed on the market	No	No	No	Limiting obligations to what is proportionate for the sector renders valid the assumption that the measure merely codifies what should be good practice and therefore it should not be expected to generate any additional burden on stakeholders.
PO3	Introducing the possibility to use electronic tags to supplement or accompany the wheelmark gives better tools to market surveillance for detecting non-conforming equipment	No	No	No	Measure of a strictly technical nature; cost of RFID < €0.5 per unit largely compensated by the benefits[90]. Will facilitate task of surveillance and Port State Control authorities thus reducing their costs.
PO3	Adapting the administration of the safeguard clause, making it possible for the Commission to decide to limit its assessment to the respect of due procedure by the Member State concerned	No	No	No	Does not change material obligations on administrations or stakeholders while making procedure more efficient.
PO3	Transposing IMO requirements through implementing or delegated Regulations, which do not require transposition into national legislations and allow the Commission greater formal flexibility	Between -6M€ and -7M€	No	No	See Annex 12. For the Member States, the measure would imply an effective cost reduction given that, although technical consultation costs would continue to be incurred, transposition of requirements into national legal orders would no longer be necessary.

[90] See Annex XIV

ANNEX 10

***SME* test**

ASPECT	*COMMENTS*
(1) Consultation with SME representatives	Throughout the preparation of this impact assessment, continuous consultation has been held with the marine equipment sector through their representatives in Brussels (the European Marine Equipment Council). This was considered indispensable given the importance of SMEs in the sector, which due to their size and scarce resources, would find it difficult to make their position known to the Commission. Indeed, in this way it has been possible to question individual companies through EMEC and obtain inputs which are representative also of the SMEs points of view. Bilateral contacts have also been held with two sub-sectoral associations who approached the Commission on specific issues. These contacts have indeed helped the Commission gain a clearer insight on the nature of the problems affecting the MED.
(2) Preliminary assessment of businesses likely to be affected	**SMEs**, which are a majority among the EU marine equipment industry, are particularly vulnerable to the current problems as they have to face fierce competition in distant markets in a strongly regulated environment – where changes in regulation are very frequent. The industry has to adapt to the decisions made by a plethora of regulators (IMO, EU, national authorities), having little if any information on those decisions which in practice turn out to be uncoordinated both in timing and in content. Changes may have enormous impacts on research and development investments, production planning or the management of stocks. These impacts may become dramatic for SMEs, which find it harder to gain access to capital markets in order to adapt and stay competitive. The costs associated with the late implementation of IMO requirements in the EU (reduced return on R&D investment, costs of double certification) represent a heavier burden for SMEs (given e.g. that the cost of one type approval does not depend on the volume of production). SMEs are also particularly vulnerable to problems like the violation of IPR and counterfeit (directly linked to the failure of the market surveillance system) to the point that in extreme cases, as industry sources report, *"legitimate*

	manufacturers (particularly SMEs) are often and "silently" driven out of the market".
(3) Measurement of the impact on SME	Among the measures foreseen, none are specifically addressed to SMEs, or have a specific impact on them. However, one should expect the benefits and drawbacks of both options to be particularly felt by SMEs – these are assessed in detail in sections 5.2 and 5.3
(4) Assess alternative options and mitigating measures	At the end of the impact assessment, there was no indication that the selected option might result in a disproportionate burden for SME – on the contrary, SME's should benefit from the measures foreseen. Consequently, there is no element showing theneed for SME specific measures in order to ensure compliance with the proportionality principle
(5) Application to micro-undertakings	The MED concerns the application of international safety requirements to marine equipment and therefore no exceptions can be made based on the size of the producers or the ship operators. On the contrary, micro-undertakings can greatly benefit from a harmonised, well structured environment with a high degree of legal certainty.

ANNEX 11

Impact on competitiveness

The marine equipment sector remains a dynamic, innovative sector in the EU, with significant capacity to generate high value-added employment. Thus the potential impact of the policy options envisaged can be gauged against the main strategic factors which should allow the sector to stay competitive. Thus, looking at the main areas identified in the "LeaderShip2015" initiative[91]:

Impact of Policy Options on competitiveness

AREA	*IMPACT OF REVISION*
Establishing a Level Playing Field in World Shipbuilding	Neither PO2 or PO3 contain trade-related measures, the matter falling completely out of the scope of the MED.
Improving Research, Development and Innovation Investment	Neither PO2 nor PO3 contain specific RDI-related measures. However, both aim at improving return on investment by reducing delays in the transposition of international requirements. In this sense, both options should have a positive, if only marginal, impact.
Developing Advanced Financing and Guarantee Schemes	Neither PO2 or PO3 contain finance-related measures, the matter falling completely out of the scope of the MED
Promoting Safer and More Environment-Friendly Ships	Both PO2and PO3 contribute to four out of five recommendations made by the LeaderShip2015 advisory group, by: • Facilitating strict implementation of EU and international safety requirements, thus providing an "exportable" regulatory model. – A more transparent, uniform, efficient and independent system of conformity assessment. – Improvements in quality assessment of notified bodies and improvements in market surveillance, thus compensating for weaknesses in shipyard quality at world-wide level – Contributing to the strengthening of shipbuilding and repairing capabilities within the EU by improving the marine equipment industry's competiveness and capacity to offer state-of-the art technology to meet new safety

91 "LeaderSHIP 2015", Enterprise publications, October 2003

92 A good example is provided by the process to adapt EU legislation to the amended limits for sulphur content in marine fuels (COM(2011)439 final) where the possibility of recourse to scrubber technology, developed by EU manufacturers, has been key in meeting the challenges.

	and environmental protection challenges[92]
A European Approach to Naval Shipbuilding Needs	Neither PO2 or PO3 contain any measures in this field, the matter falling completely out of the scope of the MED
Protection of Intellectual Property Rights (IPR)	Although this area falls outside of the scope of the MED and is addressed by a specific EU strategy, more effective market surveillance will no doubt contribute to improving the protection of IPR in the hands of the EU marine equipment industry. As discussed in section 5.3, however, PO3, with the recourse to electronic tagging, should be better equipped for the task.
Securing the Access to a Skilled Workforce	Neither PO2 or PO3 contain any measures in this field, the matter falling completely out of the scope of the MED
Building a Sustainable Industry Structure	Neither PO2 or PO3 contain any measures in this field, the matter falling completely out of the scope of the MED

In conclusion, the contribution of the MED and the review options envisaged under this IA to preserving employment in the marine equipment industry is in any case indirect, and probably also marginal, although most probably also positive.

ANNEX 12

Impact of delayed adoption of MED updates on the industry

Continuation of the regulatory *status quo* is likely to generate additional costs to the industry deriving from the fact that, for a significant fraction of the products falling under the scope of the directive, it will have to produce against different standards for the EU market and for the international market. Discussion with industry representatives has highlighted that this increases production and certification costs, obliges manufacturers to keep higher stocks and reduces return on the investment incurred for the development of new products. However, this effect should be mitigated by the fact that there is a considerable lack of uniformity in the application of the IMO requirements by third states, which may oblige many manufacturers who are present in the world market to continue to produce anyway a high number of models.

A rudimentary estimation of the related impact could be as follows:

The EU marine equipment sector's rate of investment in R+D is particularly intensive and has been estimated at around 8% (with larger companies spending at least 10%[93]) of its annual turnover of €42 billion, of which 30% would relate to equipment certified under MED – that is, approximately € 1 billion

Working on the hypothesis that efficient annual updates could stabilise at a rate of 20% of change (items changed or added over total items in Annex 1), and using a return on investment of 4%, two calculations are possible:

- based on an EU fleet of 22% of the total world fleet, the potential lost return on investment would be: 1 billion x 0.20 x 0.22 x 0.04 = € 1.76 million per year of delay;

- based on the actual percentage of sales in the EU market, which is[94] approximately 54% of the total, the potential lost return on investment would be: 1 billion x 0.20 x 0.54 x 0.04 = 4.3 million per year of delay.

Thus one can estimate that every year of delay in the entry into force of new IMO requirements may be costing the industry in the region of €3 million plus administrative costs and overheads. Therefore the current system with inherent delays may be generating maximum costs of approximately €4 million to €5 million in terms of lost return on investment for the industry for each annual update.

Delay in the transposition of IMO requirements also generates double-certification costs which can be estimated as follows:

- During the last full yearly amendment periods (corresponding to the 4th, 5th and 6th amendments), an average of 8,500 new MED certificates have been issued per year. With a stable innovation rate of 20%, 1,700 certificates are issued against newly adopted requirements (while 6,800 correspond to ordinary periodic renewals).

93 Source: EMEC, 2010

94 Source: EMEC annual report 2009, p.7

– Among these 1,700 certificates, approximately 13% correspond to items newly added to Annex A.1 in each new annual update[95]. Thus an estimated 1,500 new certificates per year correspond to re-issuing of previous certificates following the update of existing requirements.

– Based on a standard 5-year period of validity for a MED certificate, 20% of these 1,500 certificates, that is 300 certificates, will have to be renewed for each year of delay in the transposition of new IMO requirements before they can be replaced by new certificates issued against the new requirements. Based on an estimated cost of 6,000€ per renewal[96], the total costs for the industry in terms of double-certification may amount to approximately 2M€ for each annual update.

Thus the total costs incurred by the industry due to the delays in the transposition of IMO requirements into the MED can be estimated at approximately 6 to 7 million € per year.

This is a relatively small cost compared to the sector's turnover. However, it must be borne in mind that these costs are not distributed evenly. **The cost of delays may become particularly significant for SME's,** some of which have only one or two products and a high rate of innovation. Sources from the industry indicated that duplication of certificates may represent up to 20% of the total certification costs linked to one single set of requirements[97]. This means that in extreme cases (low-value product, produced in reduced volumes, where the total certification costs may near 5% of the company's turnover), an SME could face double-certification costs reaching 1% of its annual turnover.

95 Average of last three annual updates

96 Source: EMEC – cost reported to be in a range of 6,000€ to 10,000€ per each new certificate

97 Source: EMEC, 2010

ANNEX 13

List of main international maritime conventions applying to marine equipment[98]

- 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)

[98] Convention texts can be obtained from the International Maritime Organisation (http://www.imo.org/Publications/Pages/Home.aspx)

ANNEX 14

Electronic tagging by means of RFID[99]

BASIC PRESENTATION OF THE RADIO-FREQUENCY IDENTIFICATION (RFID) TECHNOLOGY

For the purposes of this document, Radio Frequency Identification (RFID) is the use of an object (typically referred to as an RFID tag) applied to or incorporated into a product, for the purpose of identification and tracking using radio waves. Some tags can be read from several meters away and beyond the line of sight of the reader.

Radio-frequency identification comprises *interrogators* (also known as *readers*), and *tags* (also known as *labels*).

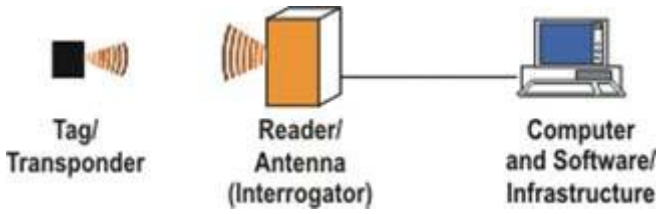
A basic RFID system consists of three components:

- An antenna or coil

(5) A transceiver (with decoder)

- A transponder (RF tag) electronically programmed with unique information

Figure 5: electronic tag system



- The antenna emits radio signals to activate the tag and to read and write data to it.
- The reader emits radio waves in ranges of anywhere from one inch to 100 feet or more, depending upon its power output and the radio frequency used. When an RFID tag passes through the electromagnetic zone, it detects the reader's activation signal.
- The reader decodes the data encoded in the tag's integrated circuit (silicon chip) and the data is passed to the host computer for processing.

Most RFID tags contain at least two parts. One is an integrated circuit for storing and processing information, modulating and demodulating a radio-frequency (RF) signal, and other specialized functions. The second is an antenna for receiving and transmitting the signal.

There are generally three types of RFID tags:

- active RFID tags, which contain a battery and can transmit signals autonomously,

[99] Source: EMSA

- passive RFID tags, which have no battery and require an external source to provoke signal transmission, and,

- battery assisted passive (BAP) which require an external source to wake up but have significant higher forward link capability providing great read range.

The Electronic Product Code (EPC) Global standard defines four classes of tags as class 1, class 2, class 3 and class 4. Each successive class has higher functionality than the previous one and is also backward compatible. [100]

RFID has many applications, for example, it is used in enterprise supply chain management to improve the efficiency of inventory tracking and management.

The first patent to be associated with the abbreviation RFID was granted in 1983 but today the technology is quite mature and RFIDs are easy to conceal or incorporate in a range of items. For example, in 2009 researchers at Bristol University successfully glued RFID micro transponders to live ants in order to study their behavior. This trend towards increasingly miniaturized RFIDs is likely to continue as technology advances. However, the ability to read at a distance is limited by the inverse-square law.

The record for the smallest RFID chip is at 0.05mm x 0.05mm. The Mu chip tags are 64 times smaller than the new RFID tags. Manufacture is enabled by using the Silicon-on-Insulator (SOI) process. These "dust" sized chips can store 38-digit numbers using 128-bit Read Only Memory (ROM). A major challenge is the attachment of the antennas, thus limiting read range to only millimeters.

Potential alternatives to the radio frequencies (0.125–0.1342, 0.140–0.1485, 13.56, and 840–960 MHz) used are seen in optical RFID (or OPID) at 333 THz (900 nm), 380 THz (788 nm), 750 THz (400 nm). The awkward antennas of RFID can be replaced with photovoltaic components and IR-LED on the ICs.

CURRENT USE IN TRANSPORTATION AND LOGISTICS

Logistics and transportation are major areas of implementation for RFID technology. RFID is currently used in a variety of applications such as the following:

- Yard management, shipping and freight and distribution centers are some areas where RFID tracking technology is used. Transportation companies around the world value RFID technology due to its impact on the business value and efficiency.

- The North American railroad industry operates an automatic equipment identification system based on RFID. Locomotives and rolling stock are equipped with two passive RFID tags (one mounted on each side of the equipment); the data encoded on each tag identifies the equipment owner, car number, type of equipment, number of axles, etc. The equipment owner and car number can be used to derive further data about the physical characteristics of the equipment from the Association of American Railroads' car inventory database and the railroad's own database indicating the lading, origin, destination, etc. of the commodities being carried.

[100] Apart from these four classes, sometimes class 5 is also referred by users in the industry which are nothing but RFID readers

- Aerospace applications that incorporate RFID technology are being incorporated into networks architecture. This technology serves to help facilitate more efficient logistics support for systems maintenance on-board commercial aircraft.
- Pieces of luggage passing through an airport are individually tagged with RFID tags as they navigate the airport's baggage handling system, which improves efficiency and reduces misplaced items.

The RFID technology has also already been implemented in the maritime transport sector notably for container tracking. Systems based on RFID enable the identification of containers over long distances and in demanding environments such as a port area. RFID help in real-time identification and tracking of containers, reaching new levels of traceability and control.

For example, the Port of Singapore Authority (PSA) deployed thousands of RFID transponders into its container yard to create a multi-dimensional tracking grid as early as 1993. The PSA tracks many thousands of multi-ton cargo containers daily, and also manages arrivals and departures of up to 50 ships. PSA spent close to $910 million in 1993 on development projects. A centralized system manages the placement and location of containers. Nowadays, the PSA is ranked the number one port worldwide.

In Europe, the Port of Rotterdam is one of the largest operators of container handling systems in Holland's massive port of Rotterdam. Buried RFID transponders guide automated guided vehicles (AGVs). Deployment of this system began in 1990 using the Texas Instruments technology.

POSSIBILITIES OFFERED BY RFID IN THE MED CONTEXT AND ADDED VALUE COMPARED TO THE PREVIOUS TECHNOLOGIES.

1. The Radio Frequency Identification (RFID) added value compared to the previous technologies.

Concretely, Radio frequency identification (RFID) is a generic term that is used to describe a system that transmits the identity (in the form of a unique serial number) of an object wirelessly, using radio waves. It's grouped under the broad category of automatic identification technologies.

Unlike ubiquitous UPC bar-code technology, RFID technology does not require contact or line of sight for communication. RFID data can be read through the human body, clothing and non-metallic materials.

The data transmitted by the tag may provide identification or location information, or specifics about the product tagged, such as price, colour, date of purchase, etc. RFID quickly gained attention because of its ability to track moving objects.

To retrieve the data stored on an RFID tag, a reader is necessary. A typical reader is a device that has one or more antennas that emit radio waves and receive signals back from the tag. The reader then may pass the information in digital form to a computer system. It is possible that active or semi-passive RFID devices could be complemented with data storage capacity in order to include, for example, protected copies of the certificates.

2. RFID Wheelmark tag

Currently the Wheelmark must be legible, visible and indelible throughout the anticipated life of the equipment. The mark of today is a printed label or plate.

The Wheelmark indicates that a piece of equipment holds a Declaration of Conformity which is based on the certification issued by Notified Bodies (NB) acting on behalf of the Maritime Administrations. Consequently that piece of equipment is entitled to free movement on the Internal Market and to be used on board ships flying a Community flag.

Currently the Wheelmark is a passive label.

The control of equipment addresses two kinds of needs which are connected to the implementation of the MED and the operation in real scenarios:

- Priority need: to ensure that products comply with the requirements"
- Added value need: intended to the efficient use of resources and sources of information.

2.1 Priority need

MED stakeholders have different needs concerning access to information related to the equipment during trading and operations. This information is linked to the relevant legal basis given in MED, namely,

- Article 7. Standard versions used for approval
- Article 9. Status of the notification and qualification of the certifying NB.
- Article 10. Certificates on board and limitation of use.
- Article 11. Wheelmark. Authenticity might be verified on the spot.
- Article 12. Market surveillance: Coordination and a feasible approach.
- Article 13. Safeguard actions: For comprehensive identification of particular manufacturing facts and identification of the piece of equipment.
- Article 14. Temporary/innovative equipment limitations.

2.2 Added value:

This chiefly concerns the daily use of equipment in operation and involves the availability of the following information:

- Declaration of conformity.
- NB Certificates and associated testing reports.
- Full identification of the equipment available to crosscheck with information of the official list of approved equipment.
- Base of operation of the equipment and ownership.
- Control of the property rights and particular registration.
- Certainty of authenticity of the piece of marine equipment on board.
- Means to fight against fake equipment on board.
- Installation manual on board.

- Instruction manual on board.
- Maintenance manual on board.
- Service manual on board.
- Troubleshooting manual on board.
- Replacement manual on board.
- Hazardous handling warnings.
- Anticipated plan of control points on the piece of equipment for facilitating authorities to perform efficient Market surveillance visits and campaigns. (Categories of control points may be preset up: deep, medium, documentary).
- Recommended points of control for Market Surveillance Authorities.
- Recommended points of verification for Classification Societies (and Flag States).
- Information for Port State Control authorities and recommended points of verification.
- Allowed testing in operation.
- Forbidden testing in operation.

CONCLUSIONS

In view of the potential benefits of current technology on RFID, MED marking might be evolved to look the same but built to perform as a RFID tag. In that case RFID tags would offer the stakeholders a powerful resource of control and verification. Wheelmark performing as a RFID might be proposed to be used on a voluntary basis, however even in this case the concerns identified among Member states and the industry regarding counterfeit products is likely to lead to a wide use.

Embedded RFID would provide a simple and cost-effective solution to counterfeiting as well as to the problems associated with non-compliant products. RFID allows manufacturers to embed inconspicuous tags that typically cost 10-30 cents each directly into or onto their products or consumables. Once a tag is added to a product or consumable, it can then be encoded with a digital fingerprint using state-of-the-art cryptography that uniquely identifies the product or consumable.

The use of labels containing all the necessary information for management of the marine equipment will facilitate rapid access to the necessary documentation for every MED stakeholder. Evidently the limited need to archive and maintain documentation control will be an additional asset.

With the increase of verification and control possibilities, the fight against illegal equipment will be enhanced as per the use of RFID tags for Wheelmark. Future consideration could foresee the list of serial numbers within the current data base of approved marine equipment.