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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

revision of Council Directive 96/98/EC of 20 December 1996 on marine equipment

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

revision of Council Directive 96/98/EC of 20 December 1996 on marine equipment

Lead DG: DG MOVE

Executive summary

1. PROBLEM DEFINITION

Experience with the working of the Marine Equipment Directive (hereinafter referred to as "MED") highlighted certain implementation and enforcement weaknesses, mostly as regards: the quality and control of the work of the notified bodies (organisations carrying out conformity assessment procedures on the Member States' behalf); the obligations of the economic operators; the effectiveness of market surveillance activities; the safeguard mechanisms (which ensure that Member States take measures against non-compliant equipment, and that these measures are controlled in order to ensure that they do not constitute disguised obstacles to the free movement).

Given that the legislative technique used in MED to achieve its policy objectives is largely based on the principles defined in the *New Approach*[1] for the area of free movement of goods, the implementation and enforcement issues identified above are shared with all New Approach Directives.

To correct the malfunctions of the system, the *New Approach* was subject to a revision in 2008 which led to the **New Legislative Framework** (hereinafter the "NLF") for the marketing of products.[2]

Therefore, the problems identified for the MED 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. The impact assessment provides a detailed mapping of the NLF against MED specificities. Among these:

- Marine equipment must comply with the construction and performance requirements, and be tested in accordance with the testing standards, laid down by the IMO;
- Marine equipment must be approved by the flag State;

[1] For a description of the New Approach and its associated problems, see the Commission's 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).

[2] Annex 7 of the present impact assessment contains a description of the elements of the NLF.

- Marine equipment is not necessarily marketed in EU territory, but it is rather installed directly on board EU ships wherever these are built or repaired, or take supplies;

- Marine equipment includes many items which fall under the scope of other Internal Market directives, however the requirements of these are different from or incompatible with those of the IMO.

- 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.

Stakeholders affected include European marine equipment manufacturers, among which a large number of SMEs, shipyards, ship passengers and crews, as well as public administrations and governments.

2. ANALYSIS OF SUBSIDIARITY AND PROPORTIONALITY

Direct application of the IMO regulatory framework by the Member States in the absence of Community harmonisation would lead to 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 would lead to uneven degrees of safety and environmental protection.

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 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.

3. OBJECTIVES OF THE EU INITIATIVE

3.1. 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 while ensuring a high level of safety at sea and prevention of marine pollution;

- to simplify the regulatory environment while guaranteeing that IMO requirements are applied and implemented in a harmonised way across the EU, thereby contributing to ensuring that the conditions necessary for the competitiveness of the Union's industry exist pursuant to Article 173 TFEU.

3.2. Specific objectives

Based on the problem and related root causes set out in section 2 above, the twofold general objective can be translated into more specific objectives:

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

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

4. POLICY OPTIONS

The Commission has identified four policy options – besides the baseline scenario. All policy options have been designed to be able to address both specific objectives defined in section 3. The Commission performed a preliminary assessment of the 4 possible policy 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. As a result of this pre-screening, 2 policy options, besides the baseline scenario, have been retained for in-depth assessment.
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.

Table 1: 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 while taking into account the specificities of marine equipment**		
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[3] 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 market within the EU territory. • Manufacturers: same as in PO2

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

		• 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.

5. ASSESSMENT OF IMPACTS

The following table presents an aggregated qualitative assessment of of the expected economic, social and environmental impacts.

Table 2: 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

When compared with the baseline, both policy options have turned out to bring about positive impacts in most cases, particularly as regards the effectiveness of the control and enforcement mechanisms (notified bodies, market surveillance, safeguard clause). As a result of this, both policy options would on the whole result on more safety and better protection of the marine environment. The current system to transpose the IMO requirements into national legal orders would in both cases benefit from faster and more efficient mechanisms, centralised in the case of PO3 and left entirely to the Member States in the case of PO2.

However, PO2 has two important drawbacks. In the first place, replacing the current Directive's annexes by a generic requirement of compliance with the relevant international technical requirements and testing standards would in the long term negatively affect the smooth functioning of the internal market, as differences between Member States would inevitably build over time; this would also affect safety, as not all Member States would implement the latest requirements punctually, while the many valuable non-mandatory instruments produced by the IMO would be completely left aside. Secondly, an alignment of the obligations of economic operators on the NLF would result in an additional, disproportionate burden mainly for importers and distributors: these actors, who are only relevant for the small fraction of equipment which is imported into EU territory, would

nevertheless have to put in place an administrative structure which does not exist today and the benefits of which would not accrue to a majority of the products covered by the Directive – which are directly installed on board EU ships in ship building and repair yards, mostly outside the EU territory.

In contrast, PO3, thanks to its MED-specific solutions which are selectively adapted to the particular features of the marine equipment sector, proves more advantageous in several areas:

- The use of implementing or delegated regulations instead of the current Directive annexes provides a mechanism which is as fast as the solution envisaged under PO2, but without the above mentioned drawbacks for the Internal Market as the applicable requirements would remain fully harmonised at all times; moreover this system provides greater legal certainty for the operators and is cheaper for public administrations;

- Conformity checking improves thanks to the clear identification of testing standards, while the implementation of IMO non-mandatory instruments gives PO3 a clear edge in terms of safety;

- The possibility to use electronic tags improves the effectiveness of market surveillance and helps protect the manufacturers' IPR at a negligible cost;

- Better adapted obligations for economic operators removes unnecessary burdens;

- A simpler, faster safeguard clause mechanism removes unnecessary economic and reputational costs for compliant manufacturers.

6. COMPARISON OF OPTIONS

In terms of effectiveness, 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 in a harmonised way. In addition, 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.

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

As regards coherence with the overarching EU objectives, strategies and priorities, whereas both policy options would bring about improvements in terms of maritime safety and protection of the marine environment, and simplified legal framework, the best results should be expected from PO3, while PO2 might not be able to deliver in terms of smooth functioning of the internal market.

Table 3: 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.

7. 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. Specific measures have been envisaged in addition to the alignment in order to verify the effectiveness of the action and gather feedback from the stakeholders such as:

- As a result of the reform more informative data will be obtained from the market surveillance activities as well as from port state control. EMSA will continue to refine the production of statistics on the implementation of the directive and to organise workshops for technical discussion and training activities with the Member States..
- Contacts with the industry will continue including workshops on the implementation of the amended MED.
- Enhancing the activities of the MARED Group of notified bodies.
- Finally, an ex-post evaluation will be organised within [5 years] of the entry into force of the new system.