REVISION OF DIRECTIVE 96/98/EC ON MARINE EQUIPMENT

Results of 2nd Stakeholder consultation (13/4/2012 – 29/5/2012)

Written 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 amend 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.