COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment

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on the conclusion of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. SUMMARY

The European Community (EC) and the United States of America (US) have negotiated and initialled an agreement on mutual recognition of certificates of conformity for marine equipment, which should now be approved. The negotiations have been done according to the negotiation mandate given by the Council under the Action Plan for the Transatlantic Economic Partnership (TEP). The legal basis for the Agreement is Article 133 and 300 of the Treaty.

This Agreement has as its main objective the facilitation of EU-US trade in marine equipment. This is achieved by ensuring the recognition of certificates of conformity based on the equivalence between the Parties' respective regulations and conformity assessment requirements for a specific product. A Party will thus recognise certificates of conformity issued by the Conformity Assessment Bodies of the other Party on the basis of the technical regulations of that Party. This means a manufacturer can reach multiple markets on the basis of compliance with one set of regulatory requirements instead of multiple ones as would be the case without an Agreement. This can directly lead to a reduction of costs for manufacturers in terms of testing and certification. Indirectly it will also reduce costs that are related to the uncertainty and burden of contacting a conformity assessment body in the importing country, as well as the time delays this leads to in terms of getting a product on the market.

Basing the Agreement on equivalence of EU and US technical regulations is possible since both Parties have based their respective legislation (in the EU it is Directive 96/98/EC on marine equipment) on the Conventions of the International Maritime Organisation (IMO) and the relevant international standards. The Agreement also aims at promoting regulatory co-operation and efficiency.

The Commission and the US have carried out several detailed analyses of their respective technical regulations in view of determining equivalence where possible. The determination of equivalence has been done on the basis the EU and US implementation of the relevant International Instruments of the International Maritime Organisation (IMO). The products included in Annex II of the Agreement contain the initial results of the analysis and will be expanded as equivalence is determined for further products. The Agreement provides for mechanisms related to both maintaining and suspending equivalence while respecting the regulatory autonomy of the Parties.

In its assessment of the Agreement, the Commission draws the overall conclusion that the Agreement can offer substantial benefits to economic operators in terms of facilitating trade by reducing costs and burdens related to conformity assessment, can increase transparency and predictability in relation to regulations, will promote regulatory co-operation and will not compromise the regulatory objectives of the marine equipment directive, i.e. to enhance safety at sea and improve the prevention of marine pollution.

II. THE AGREEMENT

II.1 Basis for the Agreement

The Council endorsed the Action Plan for the TEP on 9 November 1998 and authorised the Commission to enter into negotiations with the US in view of concluding bilateral agreements in the field of, inter alia, technical barriers to trade. After consultation of the 133 Committee, and in accordance with the negotiation authorisation, the Commission commenced negotiations with the US on a mutual recognition agreement for marine equipment in September 1999. The Agreement was initialled on 21 March 2003.

The Community legal basis for concluding the Agreement is Article 133 and 300 of the Treaty.

II.2 Objective of the Agreement

The objective of the Agreement is the facilitation of EU-US trade in marine equipment. This is done by giving EU manufacturers the possibility of approving their products for the US market with a Conformity Assessment Body (CAB) located in the EU and according to the technical regulations of Directive 96/98/EC on marine equipment[1]. US manufacturers will, conversely, be able to approve their products for the EU market in the US on the basis of compliance to applicable US laws and regulations. This would reduce the costs related to testing and certification, which only has to be done once for several markets, and to the uncertainty, time and administrative burden of contacting approval bodies in the importing country.

The Agreement has also the aim of promoting regulatory co-operation and efficiency, but at the same time respecting the regulatory autonomy of the Parties. This is necessary in order to ensure the functioning of the Agreement and in particular that equivalence can be maintained while ensuring a high level of health, safety and environmental protection.

II.3 Text of the Agreement

The Agreement is composed of a main text, consisting of twenty-one articles in seven chapters, and three annexes. An article-by-article explanation and evaluation of the Agreement text follows hereunder. A more in-depth discussion on equivalence and the scope of the Agreement follows in the next chapter.

Preamble: This sets out the basic objectives and principles of the Agreement which is the facilitation of trade in marine equipment between the Parties.

Chapter 1 Definitions and Purpose

Article 1 Definitions: Sets out the definition of key terms that are necessary to ensure a clear understanding of the Agreement and also refers to ISO/IEC Guide 2 for definitions of general terms related to standards and conformity assessment.

Article 2 Purpose of the Agreement: This Article sets out the general objective of the Agreement - facilitating trade in marine equipment through the mutual recognition of

[1] OJ L 46, 17.2.97, p.25.

certificates of conformity and putting into place the necessary regulatory co-operation to ensure the well functioning of the Agreement.

Chapter 2 Mutual Recognition

Article 3 Basic Obligations: This Article, together with Articles 4, 6 and 10, is a key provision of the Agreement since it sets out the mutual recognition obligations and to which products it applies to. Each Party is obliged to accept the certificates of conformity that have been issued by a Conformity Assessment Body of the other Party in accordance with the legal requirements of that Party. This obligation applies only to the products that are listed in Annex II of the Agreement.

Article 4 Equivalence of Technical Regulations: This lays down the basis for the mutual recognition obligation, specified in Article 3, i.e. that equivalence between the respective EC and US technical requirements (e.g. performance requirements, testing standards, conformity assessment requirements) has been determined for a specific product. The basis for determining equivalence are the rules of the IMO related to marine equipment and the transposition of these rules into the respective technical regulations of the Parties.

Article 5 Marking: Lays down that the Parties maintain their respective requirements for marking, numbering and identification of products. In general, it could have been conceived that, since equivalence exists between the technical requirements for a product, the respective marking required in EU and US regulations would also be mutually recognised. However, it was considered better to maintain the respective marking requirements since there was a risk of causing confusion in particular for enforcement authorities as to what requirements a product complied to as denoted by its marking. The Article allows for the attribution of each other's marks and identification numbers.

Article 6 Conformity Assessment Bodies: This Article provides that the EU and US recognise, as Conformity Assessment Bodies (CAB), each other's bodies that have been recognised under their respective regulations. In this respect, the US Coast Guard (USCG) will be the only US Conformity Assessment Body since it is only the USCG that can issue certificates of conformity according to US law. The USCG will be carrying out this function together with the independent laboratories it has recognised under its regulations. From the EU perspective, all notified bodies that operate under the marine equipment directive are both eligible and recognised under the Agreement.

Chapter 3 Joint Committee

Article 7 Joint Committee: This establishes the Joint Committee that will administer the Agreement. The Joint Committee can take decisions to amend the Annexes of the Agreement, but will also serve as a forum for discussing technical issues and providing clarifications and guidance needed to ensure a proper functioning of the Agreement. The Article also allows for the establishment of Joint Working Groups which could provide, as necessary, expert advice to the Joint Committee on specific issues.

Chapter 4 Regulatory Co-operation

Article 8: Preservation of Regulatory Authority: Here it is made clear that the Parties do not relinquish their regulatory authority or autonomy with regard to the safety at sea or the prevention of marine pollution.

Article 9 Exchange of Information and Contact Points: This provides for the Parties to establish the necessary contact points and means for exchange of information. It also provides that the Parties are to publish on the World Wide Web the products that have been approved under their respective regulations.

Article 10: Regulatory Changes: This is an essential Article of the Agreement. Since equivalence is determined on the basis of EU and US regulations that are in effect at a certain point in time, equivalence needs to be re-examined when these regulations are amended or new ones are introduced that could affect equivalence. In this respect the Article states that the Parties shall base their regulations on the international instruments of the IMO. The Article sets out an obligation for the Parties to notify each other when regulatory changes take place and calls on them to consult each other. This article lays down that the Joint Committee is to consider whether equivalence is maintained when regulatory changes do take place and, in this respect, spells out what the outcome of the considerations will lead to: 1) that equivalence is maintained and the product is retained in Annex II of the Agreement; or 2) if equivalence is not maintained, the product is removes from Annex II of the Agreement; or 3) if agreement cannot be reached on whether equivalence is maintained or not, the possibility to suspend mutual recognition for that product.

Article 11 Regulatory Co-operation: This Article sets out that the Parties are to co-operate in the relevant international organisations with a view to establishing international rules for marine equipment. It also allows for bilateral EU-US regulatory co-operation, including, when necessary, examining their respective technical regulations in view of establishing equivalence for products that were not included within the scope of the Agreement upon its entry into force or for which equivalence has been discontinued or suspended. The Article also allows the Joint Committee to take decision to include products in Annex II once equivalence of the relevant technical regulations has been determined.

Article 12 Co-operation on Conformity Assessment: In view of maintaining confidence in the Conformity Assessment Bodies and the conformity assessment procedures of the Parties, this Article calls on the relevant authorities of the Parties to consult with each other and undertake other actions as necessary. The Article also calls on the Parties to encourage their Conformity Assessment Bodies to take part in co-operation and co-ordination activities.

Chapter 5 Surveillance and Safeguard Measures

Article 13 Surveillance of Conformity Assessment Bodies: This Article sets out that the Parties shall continuously monitor, through inspections and audits, the competence of their Conformity Assessment Bodies. The Article allows a Party to contest, based on objective reasons, the technical competence of a Conformity Assessment Body of the other Party.

Article 14 Market Surveillance: This Article spells out that the Agreement in no way limits the Regulatory Authorities of the Parties to take enforcement actions (e.g. prohibiting placement on the market or product recalls) against products that pose a danger to health, safety or the environment or otherwise do not comply with applicable regulations. The Parties will inform each other of such measures.

Article 15 Suspending Mutual Recognition: Lays down the procedures to be followed if one or both Parties considers that equivalence of the technical regulations for the products listed in Annex II has not or cannot be maintained. If equivalence is not maintained then the product is removed from Annex II and the mutual recognition obligations for that product are

suspended. The Parties undertake to co-operate in view of establishing equivalence again to the extent possible.

Article 16 Alert System: The Parties will set up a two-way alert system to inform each other of products that have been found not to comply with applicable to technical regulations or can pose an imminent danger to health, safety or the environment.

Chapter 6 Additional Provisions

Article 17 Confidentiality: This contains standard clauses and relates to protecting the confidentiality of information exchanged between the Parties or their Conformity Assessment Bodies.

Article 18 Fees: This Article ensures that fees are non-discriminatory and are not imposed for conformity assessment services already rendered by the other Party.

Article 19 Territorial Application: This is a standard Article. However, it should be noted that the special nature of the maritime sector has been taken into account with a reference to that the Agreement is applicable to ships in international voyage that are entitled to fly the flag of one the Parties or one of the Parties' Member States.

Article 20 Agreements with other Countries: The first paragraph of this Article provides that mutual recognition agreements between Parties to this Agreement and other countries shall have no force in regard to the other Party to the Agreement. According to the second paragraph the EC and the US undertake to examine the possibility of establishing a mutual recognition agreement on a multilateral basis.

Chapter 7 Final Provisions

Article 21 Entry into force, amendments and termination: These are standard provisions.

Article 22 Final Provisions: These are standard institutional and legal provisions. It can be noted that paragraph 2 calls on the Parties to assess the functioning of the Agreement on a regular basis and the first time no later than 2 years after its entry into force.

Annexes

Annex I Legislation, Regulations and Administrative Provisions: Refers to the basic legislative, regulatory and administrative provisions of the Parties related to marine equipment.

Annex II Product Coverage for Mutual Recognition: This Annex indicates specifically which products are within the scope of the Agreement. Only those products listed in Annex II are subject to the mutual recognition obligations described in Article 3. This Annex will develop as the programs and regulations of the Parties evolve. The products that are listed in this proposal represent an initial list of products for which equivalence could be determined at this point in time.

Annex III Regulatory Authorities: Lists the Regulatory Authorities of the Parties.

III DETERMINATION OF EQUIVALENCE AND PRODUCT COVERAGE

III.1 Basis for determining equivalence

As has been pointed out above, a key feature of the Agreement is that the mutual recognition obligation is based on that the respective EU and US technical regulations related to a specific product being equivalent. It is only once equivalence has been determined and is maintained that a product can be listed in Annex II of the Agreement and kept there. The reason this can be done is that both the EU and the US have to a very large degree based their respective technical regulations related to marine equipment on the international conventions on maritime safety and marine pollution prevention established within the IMO, in particular the SOLAS (Safety of Life at Sea) and MARPOL (Prevention of Pollution from Ships) Conventions, together with the relevant test methods (e.g. those of the International Telecommunications Union (ITU), the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC)) referred to in IMO Resolutions, Circulars, Codes etc.

In the EU marine equipment is regulated by Council directive 96/98/EC on marine equipment as amended, hereafter called the Marine Equipment Directive (MED). From the EU perspective, the potential product coverage of the Agreement is determined by Annex A.1 of the MED. In the US the majority of marine equipment is regulated by the US Coast Guard (USCG) in the US Code of Federal Register (CFR) 46 CFR Parts 159 to 165, while radio communication equipment and navigation equipment using radio is within the regulatory remit of the US Federal Communications Commission (FCC) in 47 CFR Parts 2 and 80.

Article 4, paragraph 2, of the Agreement states that

> "Determination of equivalence of technical regulations of the Parties shall be based on their implementation of the relevant International Instruments in their respective legislation, regulations and administrative provisions, except where a Party regards the Instrument would be an ineffective or inappropriate means of fulfilment of its regulatory objectives. In the latter case, equivalency shall be determined on a mutually acceptable bases."

In other words, the criteria for determining equivalence is the "degree" of implementation by the EU and US of the IMO requirements into their respective technical regulations for a specific product. The general rule is thus that the EU and US will base their technical regulations on the instruments of the IMO (also articulated in Article 10(1) of the Agreement). On an exceptional basis, and as allowed by the WTO Agreement on Technical Barriers to Trade, the Parties may choose not to use the IMO rules when these are deemed inappropriate or ineffective in terms of the regulatory objectives pursued. In such cases the criteria for determining equivalence must be agreed between the Parties. It should also be underlined that in determining equivalence all regulatory requirements related to a specific product must be examined and found equivalent - product requirements, testing and performance standards and conformity assessment procedures.

According to the definition of 'equivalence of technical regulations' in Article 1(1)(e) of the Agreement, EU and US technical regulations do not have to be identical, but must be sufficiently comparable to ensure that the objectives of their respective regulations are fulfilled. In other words, if the EU prescribes a standard in order to achieve a given level of safety or environmental protection, the US standard must be capable of ensuring the same level of safety and protection.

III.2 Determining product coverage

On the basis of the above, a number of detailed studies and analysis have been carried out to examine equivalence between EU and US technical regulations for marine equipment. The USCG carried out an analysis with regard to the products it regulates. This analysis was verified by the Commission who contracted, after an open public tendering procedure, an expert consultant to carry out the work. The Commission also contracted (as well after an open call for tenders) an analysis related to marine radio communication and navigation equipment. All these studies have been made publicly available.

The analysis and examinations made by the Commission and the US have led to the conclusion that the products listed in Annex II of the present proposal is an initial list of products for which there is equivalence. This list constitutes 43 product items, of which 11 are life saving appliances, 12 fire protection equipment and 20 navigation equipment. It should be pointed out that the final analysis has been made on the basis of the third amendment to the MED. Although the amending directive has not yet been formally adopted, its technical contents is known. In this respect, the MRA would have to enter into force in conjunction with the entry into force of the amending directive.

For the remaining products covered by the MED, it is considered that either equivalence can be determined after further technical examinations and this can be done with a relatively short timeframe after the entry into force of the Agreement (1-2 years), or equivalence cannot be determined within a foreseeable timeframe. There are approximately 50 equipment items that are candidates for future inclusion in Annex II of the Agreement, of which 24 are life saving appliances, 5 pollution prevention equipment, 10 fire protection equipment, 9 navigation equipment and 1 radio communication equipment. It is in particular within the area of radio communication equipment equivalence cannot be established. This is mainly due to that the US conformity assessment procedures for these products are at the moment not deemed to be equivalent to those prescribed by the MED and that the relevant US technical regulations are not always in line with the applicable ITU recommendations.

III.3 Maintaining equivalence and change in product coverage

The technical regulations of the Parties will evolve over time, in particular in response to new or amended IMO rules. When a technical regulation of a Party changes and this could affect equivalence, one needs to examine whether equivalence is maintained in terms of the new or amended regulations of one or both Parties. As described above, Article 10 of the Agreement sets out a mechanism of how changes to the technical regulations of the Parties is to be dealt with in terms of the Agreement. It should be underlined that nothing in the Agreement prejudices or limits the regulatory authority of the EU or the US in terms of pursuing their respective regulatory objectives and setting the level of protection they consider appropriate (see Article 8 of the Agreement).

Key elements in maintaining equivalence are, notification and exchange of information on regulatory development and offering the opportunity to consult on such developments, within the limits set by each Party's legislative procedures, and, of particular importance, regulatory co-operation and a shared commitment to the work of the IMO. As the general rule, co-operation on setting rules for marine equipment is to be done in IMO as well as in ITU, ISO and IEC. However, the Agreement also offers the possibility of bilateral EU-US regulatory co-operation and this will be necessary in view of not only maintaining equivalence, but can also contribute to improving the quality of regulations through the exchange of experiences and best practices.

One important element in the bilateral co-operation, which will heavily rely on the work at the international level, is setting out and carrying out a work plan for determining equivalence for those products that have not been listed in Annex II of the Agreement. Once such work has been finalised and both Parties are satisfied that equivalence of their respective technical regulations for a specific product has been determined, that product can be listed in Annex II by a decision of the Joint Committee (Article 11(4) of the Agreement).

It goes without saying that if equivalence cannot be maintained or found due to objective reasons, the product will be removed from or not listed in Annex II. For products that are removed from Annex II, the mutual recognition obligations of Article 3 of the Agreement will cease to apply, but the Parties shall continue to recognise previously issued certificates, unless reasons due to the protection of health, safety or the environment warrants otherwise. This may cause difficulties for economic operators, which may have to revert to seeking approvals with the importing Party. However, it should be made clear that the Agreement cannot prejudice or put into question the integrity of the regulatory objectives of the Parties.

IV. ASSESSMENT OF THE AGREEMENT

IV.1 General observations

In general, mutual recognition agreements have two objectives: facilitating trade by reducing costs related to conformity assessment and promoting regulatory co-operation and efficiency. The Commission considers that the Agreement presented for approval can fulfil those objectives for the reasons outlined below.

The Agreement is in a sense innovative since it is the first international agreement related to goods the Community would enter into that is based on equivalence with the regulatory requirements of another country.

In general terms the Agreement has the potential to offer substantial benefits to EU manufacturers and importers. An EU manufacturer, for a product covered by the Agreement, will be able to have direct access to the US market, in terms of regulatory requirements, on the basis of its compliance to EU requirements in the form of the MED. This means the manufacturer can reach multiple markets on the basis of compliance with one set of regulatory requirements and one approval instead of multiple ones as would be the case without an Agreement. This can directly lead to a reduction of costs for manufacturers in terms of testing and certification. Indirectly it will also reduce costs that are related to the uncertainty and burden of contacting a conformity assessment body in the importing country, as well as the time delays this leads to in terms of getting a product on the market.

As has been mentioned above and will be further expanded upon below, the Agreement will not affect the level of health, safety and environmental protection set respectively by the Parties. Although the Parties have a shared commitment to the work of the IMO and to base their respective regulations for marine equipment on the relevant International Instruments, the Agreement does not prejudice or compromise the regulatory autonomy or enforcement rights of the Parties.

IV.2 EC-US trade in marine equipment

The volume and value of trade in marine equipment between the EC and US has been difficult to assess due to the lack of official statistics. Table 1 below gives an indication of the trade in certain products..

Table 1: EC-US trade in certain marine equipment year 2000 (thousands of EUR)

Product and NC code	Import to EU	Export from EU
Radar apparatus (NC 85261090)	22 687	46 218
Signalling apparatus (NC 85318030)	8 7814	16 809
Radio navigational aid apparatus (NC 8569190)	150 391	36 208
Radio telegraphic or radio telephonic transmission apparatus (NC 85251050)	10 247	3 873
Direction finding compasses, including parts and accessories (NC 90141090 and 90149090)	115 987	97 025
Navigational instruments and apparatus (NC 90142090 and 901480)	251 361	202 668
Life jackets and life belts (NC 630720)	11 996	1 357
Vessels, incl. lifeboats (NC 89060091 and 89060099)	10 591	2 486
Inflatable rafts (NC 890710)	3 121	3 849
Signalling flares (NC 360490)	1 251	5 590

Source: Eurostat, COMEXT database

In assessing the potential impact of the MRA, an alternative approach to examining trade figures could be to look at the size of the respective markets for marine equipment. An indication of the size of the respective EU and US markets for marine equipment can be found by looking at the number of ships registered in the EU Member States and the US. This is illustrated in Table 3 below, which gives both the number of ships and the total gross tonnage (GT) of the EC and US registered fleets. In this respect, it should be kept in mind that the Agreement only applies to ships of the Parties that are to carry equipment that must be approved according to the IMO Conventions and that is in international voyage. Data on the number of ships that carry safety certificates according to the IMO Conventions has not been readily available. However, it is estimated that the very large majority (over 90%) of merchant ships carry a safety certificate. It should also be kept in mind that the figures below can include ships, for example those used for fishing or on inland waterways, which are covered by other Community directives.

It is primarily the number of ships that are of interest in assessing the market size for marine equipment since, for cargo ships in particular, the cost of equipping a ship with the IMO Convention required equipment does not vary much with the size of the ship. The greatest variation is between cargo and passenger ships, where passenger ships will necessarily bear a higher cost in relation to e.g. life saving appliances and fire protection equipment. Table 2 shows that the EC fleet is, in terms of numbers, double the size of the US and in particular the EC registered passenger ship fleet is considerably larger than that of the US.

Table 2: EC and US merchant fleets

	EC	EC % of world	US	US % of world
Total number of ships	10 973	12,5%	5 792	6,6%
Number of cargo ships	5 018	10,8%	429	1,0%
Number of other ships	5 955	14,4%	5363	13,0%
Of which passenger ships	744	24,6%	33	1,0%
Total gross tonnage of ships	62 572 051	11,2%	11 110 901	2,0%
Gross tonnage cargo ships	58 931 568	11,1%	9 283 757	1,8%
Gross tonnage other ships	3 640 483	12,4%	1 827 144	6,2%
Of which passenger ships	2 129 766	22,8%	107 612	1,2%

Source: Lloyd's Register of Shipping, World Fleet Statistics 2000

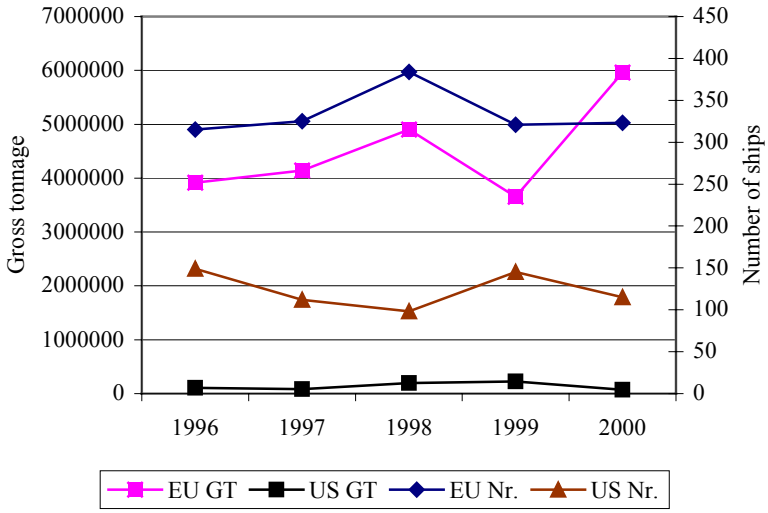
The figures in Table 2 give the number of existing ships which have already been fitted with the required marine equipment. It would therefore be useful to also look at the evolution of the number of ships under completion as this would give an indication of the potential market for marine equipment. These figures are given in Table 3 and illustrated in Figure 1. These figures clearly show that EU ship building, in terms of number of ships, is at least twice the size of the US.

Table 3: EU and US ships under completion 1996-2000 (number and gross tonnage)

	1996		**1997**		**1998**		**1999**		**2000**	
	Nr.	GT	Nr.	GT	Nr.	GT	Nr.	GT	Nr.	GT
EU	315	3 915 963	325	4 142 821	384	4 900 834	321	3 657 185	323	5 962 587
US	149	106 321	112	86 059	98	196 707	145	228 596	115	68 456

Source: Lloyd's Register of Shipping, World Fleet Statistics 2000

Figue 1: Number (Nr.) and gross tonnage (GT) of EU and US registered mechant ships under completion



Source: Lloyd's Register of Shipping, World Fleet Statistics 2000

IV.3 Conformity assessment costs related to marine equipment

It has been difficult to quantify the costs related to the type approval of marine equipment. The main reason for this is that the different marine equipment items within the scope of the MED cover a wide range of very differing technologies (cf. lifejackets and radar equipment), which will necessarily lead to varying approval costs. There are also a number of other costs, e.g. time to market, administrative burdens, uncertainty, which the MRA would have an impact on, but are very difficult to quantify. Industry sources have however given certain indications of the costs involved. These are given below for purely illustrative purposes and must be considered as "anecdotal" figures since they are not supported by verifiable quantitative data.

- In general terms it is estimated that the cost of equipping a ship with the IMO convention required marine equipment varies, depending on its type and size, between 10-25 % of its building cost.

- For a large passenger ship (cruise ship) that costs EUR 350 million to build, it is estimated that EUR 115 million (30%) relates to materials, equipment and approvals from classification societies required by IMO rules. Of the EUR 115 million, approximately EUR 90 million relate to different materials (related mainly to fire protection) and EUR 17 million to life saving, navigation and radio equipment. An interesting aspect that has been indicated was that a saving, in terms of costs related to the approval by the classification society, of up to EUR 25 million could be achieved by using materials and equipment that had already been approved. For cargo ships (container vessels), irrespective of size, it is estimated that it costs EUR 1 million to equip it with equipment required by IMO rules.

- Costs related to obtaining USCG approval for components for life-saving appliances are estimated to a minimum of EUR 50 000 and can take up to 2 years. Certain life

saving appliances, such as marine evacuation systems and davit launched high speed craft, must be tested under realistic circumstances, which can entail approval related costs of over EUR 1 million.

- With regard to marine radio and navigation equipment the general situation is that approval related costs are high, while the size of the market is limited. For example, for Inmarsat B SES, the approval cost are estimated to EUR 150 000 for a yearly world-wide market of 500 items representing a value of approximately EUR 13,5 million. A complete radar series carries approval costs of an estimated EUR 150 000 for a yearly world-wide market of EUR 175 million.

IV.4 Overall assessment

In making an overall assessment of the MRA the following main factors need to be considered:

- The cost/benefit of the MRA, for example in terms of its impact on trade, market access, reduction of costs etc. for EU manufacturers.

- The possible impact on EU regulatory objectives.

- The impact on other interested parties.

With regard to the cost/benefit, the information above, does not offer, in economic terms supported by quantitative data, a clear cut picture of the impact of the MRA on, for example, trade and cost reduction for manufacturers. However, the available information does give an indication that the costs related to equipping a ship with the IMO Convention required marine equipment are not negligible and the direct costs related to conformity assessment are considerable for many types of marine equipment. To this must be added indirect costs related to, for example, time to market, uncertainty and administrative burdens, which the MRA should also reduce but are difficult to quantify. The data in Tables 2 and 3 above show that the EU merchant fleet is much larger than that of the US, both in terms of existing ships and those under completion. This could be seen as an imbalance to the disadvantage of EU manufacturers of marine equipment. However, this needs to be seen in the overall market access situation. Furthermore, the Agreement can offer both EU and US manufacturers the possibility of being more competitive on each other markets. This should not only be to the advantage of EU marine equipment manufacturers, but also EU shipbuilders who should be able to reduce their costs (see above) and thus become more competitive on the world market.

In this context, it must be underlined that the MRA in itself will not guarantee benefits to economic operators. It offers possibilities for facilitating market access and reduction of costs, but it is up to the economic operators and in particular manufacturers to exploit the possibilities offered. It should also be pointed out that the use of the Agreement by business is voluntary. The relevant European industry federation have all given their support for the MRA. The Commission therefore assesses that the Agreement, can offer substantial benefits to manufacturers, in particular since it is based on equivalence between EU and US regulatory requirements - a manufacturer can reach several markets on the basis of one approval and one technical regulation.

With regard to the possible impact on EU regulatory objectives, the Agreement, in its Article 8, makes it very clear that the regulatory autonomy or authority of the Parties is not limited in any way. The Parties are free to pursue their respective regulatory objectives and set the level

of protection they consider appropriate. The Agreement is based on equivalence between EU and US technical regulations and it is from this the benefits to economic operators can accrue. If equivalence is not maintained, e.g. due to regulatory changes, these benefits could be lost. This could be perceived as acting as a deterrent for a Party to set a level of protection that is higher then the other Party, thus not allowing for equivalence to be maintained. The Commission assesses that this is very unlikely to happen for the following reasons: 1) as stated above, the Parties maintain their regulatory autonomy; 2) both the EU and US are strongly committed to basing their technical regulations on the rules of the IMO; 3) equivalence will be maintained on the basis of the amended regulations of one or both Parties, thus the Agreement is affected, or not, on the basis these amendments and not the other way around; 4) the MRA rests on a solid basis of regulatory co-operation.

As has been the experience with other MRAs concluded by the Community, co-operation has not only led to greater transparency in applicable regulations, but also an exchange of knowledge and experience between regulators which hopefully can lead to better use of regulatory resources and improved quality of regulations.

Furthermore, the Agreement does not prejudice or compromise the enforcement of the Parties' respective technical regulations on their territories. The two-way alert system foreseen by Article 16 of the Agreement could even help in increasing the efficiency of, for example, market surveillance activities, since more information on defective products would be made available to enforcement authorities.

It should be noted that the Transatlantic Consumer Dialogue (TACD)[2] has been quite critical of MRAs in general and the concept of equivalence of technical regulations. The main objections raised by the TACD relates to that MRAs, as well as equivalence, could lead to: 1) transfer of regulatory authority to foreign entities who may operate under different conflict of interest, transparency and liability rules; 2) privatisation of public functions; 3) loss of domestic regulatory control; 4) reduced levels of public participation in the regulatory decision making process; 5) increased opportunities for regulatory evasion by industry; and 6) reduction in levels of health, safety and environmental protection. For the reasons already mentioned above, the Commission cannot share the conclusions drawn by the TACD.

Concerning the possible impact on EU regulatory objective, the Commission therefore assess that the Agreement will not compromise the regulatory objectives of the MED, i.e. to enhance safety at sea and improve the prevention of marine pollution. The Agreement will not have a negative impact on the health and safety of crew, passengers or other persons or the marine environment.

In relation to the possible impact on other interested parties, it is mainly conformity assessment bodies and ship builders that could be affected. According to the Impact Assessment Form attached to this proposal, the MRA would offer EU conformity assessment bodies (the notified bodies under the marine equipment directive) the possibility of offering additional services to existing and new clients. However, the MRA could also mean that they could loose some business since US exporters no longer have to use their services in order to demonstrate compliance with directive 96/98/EC. As mentioned above, EU ship builders

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[2] The Transatlantic Consumer Dialogue is a forum of EU and US consumer organisations which develops and agrees joint consumer policy recommendations to the US government and European Union to promote the consumer interest in EU and US policy making.

should face reduced cost for marine equipment due to, inter alia, reduced conformity assessment costs and an increased competition between EU manufacturers and US exporters.

The Commission draws the overall conclusion that the Agreement can offer substantial benefits to economic operators in terms of facilitating trade by reducing costs and burdens related to conformity assessment, can increase transparency and predictability in relation to regulations, will promote regulatory co-operation and will not compromise the regulatory objectives of the MED, i.e. to enhance safety at sea and improve the prevention of marine pollution.

V. RELATIONS TO THE EFTA STATES, MEMBERS OF THE EUROPEAN ECONOMIC AREA

In accordance with the general information and consultation procedures set out in the EEA Agreement and its Protocol 12, the Commission has kept the EFTA/EEA States regularly informed about developments in the negotiations and has informed them of the final results of the negotiations.

VI. THE DRAFT COUNCIL DECISIONS

A proposal for two Council Decisions on the signature and the conclusion of the Agreement is attached.

The legal basis for both decisions is Articles 133 and 300 of the Treaty.

The Decision concerning the conclusion of the Agreement must also establish the appropriate Community procedure to enable the Commission, assisted by the special Committee to be designated by the Council, to represent the Community in the Joint Committee and in any Joint Working Groups that might be established.

VII. CONCLUSIONS

For the reasons outlined in this explanatory memorandum, the Commission proposes to the Council to adopt the two attached decisions.

2003/0078 (ACC)

Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133, in conjunction with the first sentence of the first subparagraph of Article 300(2) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The Commission has negotiated an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment,

(2) Subject to its conclusion at a later date, the Agreement, initialled in Brussels on 21 March 2003, should be signed.

HAS DECIDED AS FOLLOWS:

Sole Article

The President of the Council is hereby authorised to designate the person empowered to sign, on behalf of the Community, the Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment, subject to its conclusion at a later date.

Done in Brussels,

For the Council
The President

2003/0079 (ACC)

Proposal for a

COUNCIL DECISION

on the conclusion of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 in conjunction with Article 300, paragraph 2, first subparagraph, first sentence, paragraph 3, fist subparagraph, first sentence, and paragraph 4 thereof,

Having regard to the proposal from the Commission[3],

Whereas:

(1) The Agreement between the European Community and the United States of America on the mutual recognition of certificates of conformity for marine equipment has been signed, on behalf of the Community, on […], subject to its conclusion at a later date,

(2) The Agreement should be approved,

(3) The appropriate internal procedures should be established to ensure the good functioning of the Agreement; it is therefore necessary to delegate to the Commission the power to take certain decision for its implementation.

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement between the European Community and the United States of America on the mutual recognition of certificates of conformity for marine equipment is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person empowered to transmit, on behalf of the Community, the note provided for in Article 21(1) of the Agreement.

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[3] OJ C , , p. .

Article 3

1. The Commission, assisted by the special committee appointed by the Council, shall represent the Community in the Joint Committee provided for in Article 7 of the Agreement and in any Working Group that may be established according to Article 7(4) of the Agreement. The Commission shall proceed, after consultation with the above-mentioned special committee, to the notifications, exchanges of information and requests for information specified in the Agreement.

2. The position of the Community with regard to decisions to be taken by the Joint Committee shall be determined by the Commission, following consultation of the special committee..

3. A decision relating to terminating the Agreement according to Article 21(3) shall be taken by the Council, acting by qualified majority on a proposal from the Commission.

Done at Brussels,

For the Council
The President

ANNEX

Agreement

between the European Community and the United States of America on the mutual recognition of certificates of conformity for marine equipment

Preamble

The EUROPEAN COMMUNITY, and the UNITED STATES OF AMERICA, hereinafter referred to as "the Parties",

CONSIDERING the traditional links of friendship that exist between the United States of America (U.S.) and the European Community (EC);

DESIRING to facilitate bilateral trade in marine equipment and to increase the effectiveness of each Party's regulatory actions;

RECOGNISING the opportunities offered to regulators by the elimination of unnecessary duplication of their activities;

NOTING the shared commitment of the Parties to the work of the International Maritime Organization (IMO);

CONSIDERING that the aim of the Parties is enhancing safety at sea and the prevention of marine pollution;

RECOGNISING, on the one hand, that mutual recognition agreements can positively contribute to greater international harmonization of standards;

BEARING IN MIND, on the other hand, that the determination of equivalence must ensure that the fulfilment of the regulatory objectives of the Parties is fully respected and shall not lead to a lowering of their respective levels of safety and protection;

RECOGNISING that mutual recognition of certificates of conformity based on the equivalence of EC and U.S. marine equipment regulations is an important means of enhancing market access between the Parties;

RECOGNISING that agreements providing for mutual recognition are of particular interest to small and medium-sized businesses in the U.S. and the EC;

RECOGNISING that any mutual recognition also requires confidence in the continued reliability of the other Party's conformity assessments;

BEARING IN MIND that the Agreement on Technical Barriers to Trade, an agreement annexed to the Agreement Establishing the World Trade Organization (WTO), encourages WTO Members to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures, as well as to give positive consideration to accepting as equivalent technical regulation of other Members, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations;

HAVE AGREED AS FOLLOWS:

Chapter 1 Definitions And Purpose

Article 1

Definitions

1. The following terms and definitions shall apply to this Agreement:

(a) 'Regulatory Authority' means a government agency or entity that has the authority to issue regulations regarding issues related to safety at sea and prevention of marine pollution, that exercises a legal right to control the use or sale of marine equipment within a Party's jurisdiction, and that may take enforcement action to ensure that products marketed within its jurisdiction comply with applicable legal requirements. The Parties' respective Regulatory Authorities are identified in Annex III.

(b) 'Conformity Assessment Body' means a legal entity, whether a Regulatory Authority or a other body, public or private, that has the authority to issue Certificates of Conformity under a Party's domestic laws and regulations. For purposes of this agreement, the Parties respective Conformity Assessment Bodies are those referred to in Article 6.

(c) 'Technical regulations' comprise the mandatory product requirements, testing and performance standards and conformity assessment procedures laid down in the legislative, regulatory and administrative provisions of the Parties related to marine equipment, as well as any applicable guidelines for their application.

(d) 'Certificate of Conformity' means the document or documents issued by a Conformity Assessment Body of a Party certifying that a product fulfils the relevant legislative, regulatory and administrative requirements of that Party. In the U.S., this is the Certificate of Type Approval issued by the United States Coast Guard. In the EC, they are the certificates, approvals and declarations foreseen by Directive 96/98/EC.

(e) 'Equivalence of technical regulations' means that the technical regulations of the Parties related to a specific product are sufficiently comparable to ensure that the objectives of each Parties' respective regulations are fulfilled. Equivalence of technical regulations does not require that the respective technical regulations are identical.

(f) 'International Instrument' means the relevant international conventions, resolutions, codes and circulars of the International Maritime Organization (IMO), and the relevant testing standards.

2. Other terms concerning conformity assessment used in this Agreement shall have the meaning given elsewhere in this Agreement or in the definitions contained in Guide 2 (1996 edition) of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In the event of an inconsistency between ISO/IEC Guide 2 and definitions in this Agreement, the definitions in this Agreement shall prevail.

Article 2

Purpose of the Agreement

1. This Agreement establishes the conditions under which the importing Party's Regulatory Authority shall accept the Certificates of Conformity issued by the exporting Party's Conformity Assessment Bodies in accordance with the technical regulations of the exporting Party, hereinafter referred to as 'mutual recognition'.

2. This Agreement also lays down a framework for regulatory co-operation with the objective of maintaining and furthering mutual recognition between the EC and the U.S. of their respective regulatory requirements for marine equipment; of encouraging the improvement and evolution of regulatory requirements for the purpose of enhancing the safety at sea and the prevention of marine pollution; and ensuring a consistent application of this Agreement. This co-operation will take place fully respecting the Parties regulatory autonomy and their evolving policies and regulations as well as their shared commitment to the evolution of the relevant International Instruments.

3. This Agreement is intended to evolve as programs and policies of the Parties evolve. The Parties will review this Agreement periodically, in order to assess progress and identify potential enhancements to this Agreement as U.S. and EC policies evolve over time. Particular attention will also be given to the evolution of the International Instruments.

Chapter 2 Mutual Recognition

Article 3

Basic Obligations

1. With respect to each product listed in Annex II, the United States shall accept as complying with its own legislative, regulatory and administrative provisions as referred to in Annex I, without any further conformity assessment, Certificates of Conformity issued by the EC Conformity Assessment Bodies in accordance with the legislative, regulatory and administrative provisions of the EC.

2. With respect to each product listed in Annex II, the European Community and its Member States shall accept as complying with their own legislative, regulatory and administrative provisions as referred to in Annex I, without any further conformity assessment, Certificates of Conformity issued by the U.S. Conformity Assessment Body in accordance with the legislative, regulatory and administrative provisions of the United States.

3. The technical regulations applicable in the U.S. and the EC to each such product within the scope of this Agreement are specified in Annex II.

Article 4

Equivalence of Technical Regulations

1. The mutual recognition obligations referred to in Article 3 are based on the determination by the Parties that the technical regulations applicable to each product listed in Annex II are equivalent.

2. Determination of equivalence of technical regulations of the Parties shall be based on their implementation of the relevant International Instruments in their respective legislation, regulations and administrative provisions, except where a Party regards the Instrument would be an ineffective or inappropriate means of fulfilment of its regulatory objectives. In the latter case, equivalency shall be determined on a mutually acceptable basis.

Article 5

Marking

The Parties may maintain their respective requirements with regard to the marking, numbering and identification of products. With respect to the products listed in Annex II, the EC Conformity Assessment Bodies shall have the right to issue the marking and numbering required by the U.S. legislation and regulations, as allocated to them by the U.S. Coast Guard. The U.S. Conformity Assessment Body shall be given the identification number provided for in Directive 96/98/EC, as allocated to it by the European Commission, which shall be affixed next to the marking required by that Directive.

Article 6

Conformity Assessment Bodies

1. For the purpose of issuing Certificates of Conformity in accordance with the provisions of this Agreement, the following shall apply:

(a) The U.S. recognises the Notified Bodies that have been designated by the EC Member States under Directive 96/98/EC as Conformity Assessment Bodies;

(b) The EC and its Member States recognise the United States Coast Guard together with the laboratories it has accepted under 46 CFR 159.010, as a Conformity Assessment Body.

2. Each Party recognises that the Conformity Assessment Bodies of the other Party are authorised to perform the following procedures in relation to the legislative, regulatory and administrative provisions referred to in Annex I:

(a) testing and issuing of test reports,

(b) performing quality assurance functions or system certification.

3. The Regulatory Authorities of the Parties are responsible for the following procedures, but may delegate some or all of these functions to Conformity Assessment Bodies:

(a) reviewing equipment design and test results against identified standards,

(b) issuing Certificates of Conformity.

4. Prior to the entry into force of this Agreement the Parties shall exchange their respective lists of Conformity Assessment Bodies. The Parties shall inform each other promptly of any changes to their list of Conformity Assessment Bodies. The Parties shall maintain on the World Wide Web up-dated lists of their Conformity Assessment Bodies.

5. Each Party shall require that its Conformity Assessment Bodies to record and retain details of their investigations of the competence and compliance of their sub-contractors and maintain a register of all sub-contracting. These details will be available to the other Party on request.

6. Each Party shall require that its Conformity Assessment Bodies, upon request of a Regulatory Authority of the other Party listed in Annex III, make available to the Regulatory Authorities, copies of the Certificates of Conformity and related technical documentation they have issued.

Chapter 3 Joint Committee

Article 7

Joint Committee

1. The Parties hereby establish a Joint Committee consisting of representatives of each Party. The Joint Committee shall be responsible for the effective functioning of the Agreement.

2. Each Party shall have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimity. The Joint Committee shall determine its own rules of procedure.

3. The Joint Committee may consider any matter relating to the effective functioning of this Agreement. The Joint Committee shall have the authority to take decisions in the cases provided for in this Agreement. The Parties shall take the necessary measures to implement such decisions of the Joint Committee. In particular, the Joint Committee shall be responsible for:

(a) developing and maintaining the list in Annex II of products and associated legislative, regulatory and administrative provisions that the Parties have determined to be equivalent;

(b) discussing issues and resolving problems that may arise concerning the implementation of this Agreement, including concerns that technical regulations of the Parties applicable to a specific product in Annex II may no longer be equivalent;

(c) addressing technical, conformity assessment and technology issues in order to ensure a consistent application of this Agreement, in particular in relation to the relevant International Instruments;

(d) amending the Annexes;

(e) providing guidance and, if necessary, developing guidelines to facilitate the successful implementation and application of this Agreement;

(f) establish and maintain a work plan for aligning and harmonizing the technical requirements of the Parties;

4. The Joint Committee may establish Joint Working Groups comprised of appropriate Regulatory Authorities' representatives and appropriate experts deemed necessary, in order to address and advise the Joint Committee on specific issues related to the functioning of this Agreement.

Chapter 4 Regulatory Co-operation

Article 8

Preservation of Regulatory Authority

Nothing in this Agreement shall be construed to limit the authority of a Party to determine, through its legislative, regulatory and administrative measures, the level of protection it considers appropriate for enhancing safety at sea and improving the prevention of marine pollution, or otherwise act with regard to risks within the scope of this Agreement.

Article 9

Exchange of Information and Contact Points

1. The Regulatory Authorities of the Parties listed in Annex III will establish appropriate means of exchanging information on any regulatory problems concerning products subject to this Agreement.

2. Each Party shall designate at least one contact point, which may be the Regulatory Authorities listed in Annex III, to provide answers to all reasonable inquiries from the other Party and other interested parties such as manufacturers, consumers, trade unions, regarding procedures, regulations, and other matters related to this Agreement. The Parties shall exchange, and make publicly available, lists of contact points.

3. With regard to the exchange of information and notifications under this Agreement a Party shall have the right to communicate in its official language or languages. If a Party deems that information it receives must be translated into its official language or languages, that Party shall undertake the necessary translation and bear the cost.

4. Each Party agrees to make available to the public its list of products for which it has issued Certificates of Conformity under its respective legislative, regulatory and administrative provisions on the World Wide Web and update it on a regular basis.

Article 10

Regulatory Changes

1. When a Party introduces new technical regulations related to this Agreement, it shall do so on the basis of existing International Instruments, except when a Party considers the Instrument would be an ineffective or inappropriate means for fulfilment of its regulatory objectives.

2. Each Party shall notify the other Party of changes to technical regulations related to the subject matter of this Agreement at least 90 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a Party shall notify the other Party as soon as practicable.

3. The Parties and their Regulatory Authorities shall inform and consult with one another, as permitted by their respective laws and regulations, on:

(a) proposals to amend or introduce new technical regulations as laid down in their respective legislative, regulatory and administrative provisions referred in, or related to, provisions listed in Annexes I and II;

(b) timely incorporation of amended or new international instruments into their respective legislation, regulations and administrative provisions; and

(c) the renewal of existing and valid Certificates of Conformity when the renewal is required by amended or new legislative, regulatory and/or administrative provisions.

The Parties will provide each other the opportunity to comment on such proposals.

4. In the event of changes to the legislation, regulations, and administrative provisions referred to in Annex I and II, the Joint Committee shall consider whether or not the equivalence of the technical regulations with respect to products listed in Annex II has been maintained.

If it is agreed in the Joint Committee that equivalence is maintained, then the product shall be retained in Annex II.

If it is agreed in the Joint Committee that equivalence cannot be maintained, references to products and the relevant technical regulations for which equivalence cannot be maintained shall be removed from Annex II. The Joint Committee shall update Annex II by a decision to reflect the changes. Upon the discontinuance of mutual recognition, the Parties are no longer bound by the obligations referred to in Article 3 of this Agreement for the specific product. However, the importing Party shall continue to recognize previously-issued Certificates of Conformity for products that have been placed on the market of that Party prior to the discontinuance of mutual recognition, unless a Regulatory Authority in the Party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of the Agreement.

If the Parties, within the Joint Committee, cannot agree on whether or not equivalence of their technical regulations with respect to a product listed in Annex II is maintained, then mutual recognition with respect to that product shall be suspended according to the terms of Article 15.

5. The Parties shall make available on the World Wide Web an up-to-date version of Annex II.

Article 11

Regulatory Co-operation

1. The Parties agree to co-operate in the IMO and other relevant international organisation such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunications Union (ITU), with a view to establishing

and improving international rules for enhancing the safety at sea and the prevention of marine pollution.

2. The Parties will consider what technical work, data and information exchange, scientific and technological co-operation or other co-operative activities can be pursued between them with a view to improving the quality and level of their technical regulations applicable to marine equipment and making efficient use of resources for regulatory development.

3. For products that are not included in Annex II upon entry into force of this Agreement or for which equivalence of technical regulations has been discontinued or suspended, the Parties undertake to examine their respective technical regulations with a view to establishing, to the extent possible, mutual recognition. The Parties will set out a work program and time-table for alignment of their technical regulations, including the initiation of appropriate international standards work. The Parties shall endeavour to align their technical regulations to the extent possible on the basis of existing International Instruments in pursuit of the objective of their domestic legislation to enhance safety at sea and improve the prevention of marine pollution.

4. When the Parties have determined that equivalence can be established for a product and associated legislative, regulatory and administrative provisions, the Joint Committee shall take a decision to amend Annex II accordingly.

Article 12

Co-operation on Conformity Assessment

1. The Parties and their authorities responsible for conformity assessment issues shall consult as necessary to ensure the maintenance of confidence in conformity assessment procedures and Conformity Assessment Bodies. This can take the form of, for example, comparison of methods to verify and monitor the technical competence and ability of Conformity Assessment Bodies, and, with the consent of both Parties, joint participation in audits/inspections related to conformity assessment activities or other assessment of Conformity Assessment Bodies.

2. The Parties shall encourage their Conformity Assessment Bodies to take part in co-ordination and co-operation activities organised by the Parties either separately or jointly.

Chapter 5 Surveillance and Safeguard Measures

Article 13

Surveillance of Conformity Assessment Bodies

1. The Parties shall ensure that their Conformity Assessment Bodies are capable and remain capable of properly assessing conformity of products or processes, according to the applicable legislation, regulations and administrative provisions. In this regard, the Parties shall maintain, or cause to maintain, ongoing surveillance, as applicable, over their conformity assessment bodies and/or recognised laboratories, by means of regular audit or assessment.

2. In case a Party has objective reasons for contesting the technical competence of a Conformity Assessment Body of the other Party, it shall inform the other Party thereof. Such contestation shall be exercised when justified in an objective and reasoned manner. The other Party shall in a timely manner present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation. If necessary the matter shall be discussed in the Joint Committee. If agreement cannot be reached on the competency of the Conformity Body, the contesting Party may refuse to grant its marking and/or numbering to the contested Conformity Assessment Body and refuse to recognise the Certificates of Conformity issued by the contested Conformity Assessment Body.

Article 14

Market Surveillance

1. Nothing in this Agreement shall be construed to limit the authority of a Regulatory Authority to take all appropriate and immediate measures whenever it ascertains that a product may:

(a) although correctly installed, maintained and used for its intended purpose, compromise the health and/or safety of the crew, the passengers or, where applicable, other persons, or adversely affect the marine environment;

(b) not meet the legislative, regulatory, or administrative provisions within the scope of the Agreement; or

(c) otherwise fail to satisfy a requirement within the scope of the Agreement.

Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the Regulatory Authority takes such action, it shall inform the other Party no later than fifteen days of taking such action, providing its reasons for such action.

2. Nothing in this Agreement shall prevent the Parties from removing products from the market that do not in fact conform to a Parties' technical regulations.

3. The Parties agree that any applicable border inspections and checks of products which have been certified, labelled or marked as conforming with the importing Party's requirements specified in Annex I shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, the Parties agree that these shall be completed in no less a favourable manner than for like domestic products.

Article 15

Suspending Mutual Recognition

1. In case a Party considers that equivalence of technical regulations with respect to one or more products listed in Annex II is not being or cannot be maintained, it shall inform the other Party thereof and give the objective reasons for this. Any contestation of equivalence shall be discussed in the Joint Committee. If no decision is reached by the Joint Committee within 60 days of the referral to it the mutual recognition obligation with respect to such products shall be suspended by one or both Parties. The suspension shall remain in effect until agreement has been reached by the Joint Committee.

2. The Joint Committee shall update Annex II by a decision to reflect the suspension of mutual recognition for the products in question. The Parties agree to co-operate according to the terms of Article 11 in view of establishing equivalence again, to the extent possible.

3. Upon suspension of mutual recognition of technical regulations referred to in Annex II the Parties are no longer bound by the obligations referred to in Article 3 of this Agreement for the specific product. However, the importing Party shall continue to recognize previously-issued certificates of conformity for products that have been placed on the market of that Party prior to the suspension of mutual recognition, unless a Regulatory Authority in the Party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of the Agreement.

Article 16

Alert System

The Parties will put into place a two-way alert system between their Regulatory Authorities in order to inform each other of products that have been found not to comply with applicable technical regulations or can pose an imminent danger to health, safety or the environment.

Chapter 6 Additional Provisions

Article 17

Confidentiality

1. Each Party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this Agreement. In particular, neither Party shall disclose to the public, nor permit a Conformity Assessment Body to disclose, information exchanged under this Agreement that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

2. A Party or a Conformity Assessment Body may, upon exchanging information with the other Party or with a Conformity Assessment Body of the other Party, designate the portions of the information that it wishes to be exempt from disclosure.

3. Each Party shall take all precautions reasonably necessary to protect information exchanged under this Agreement from unauthorised disclosure.

Article 18

Fees

Each Party shall endeavour to ensure that fees imposed for services related to the subject matter of this Agreement shall be commensurate with the services provided. Each Party shall ensure that, for conformity assessment procedures covered under this Agreement, it shall charge no fees with respect to conformity assessment services provided by the other Party.

Article 19

Territorial Application

1. This Agreement shall apply, on the one hand to the territories in which the Treaty establishing the European Community is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

2. Without prejudice to paragraph 1, this Agreement applies to ships entitled to fly the flag of either Party, or one of the Parties' Member States, operating in international voyages.

Article 20

Agreements with other Countries

1. Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a

party not a signatory to this Agreement (a third party) shall have no force and effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures in the third party.

2. In view of furthering trade facilitation in marine equipment with other countries, the EC and the U.S. undertake to examine the possibility of establishing a multilateral agreement on the subject matter covered by this Agreement with other interested countries.

Chapter 7 Final Provisions

Article 21

Entry into force, amendments and termination

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of this Agreement.

2. This Agreement may be amended as specified in Article 7 or by the Parties.

3. Either Party may terminate this Agreement by giving the other Party six months notice in writing.

4. Following termination of the Agreement, a Party shall continue to accept the Certificates of Conformity issued by Conformity Assessment Bodies under this Agreement prior to termination, unless a Regulatory Authority in the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the Agreement.

Article 22

Final Provisions

1. This Agreement shall not affect the rights and obligations of the Parties under any other international agreement.

2. The Parties will review the functioning of this Agreement on a regular basis, the first time no later than two years after its entry into force.

3. This Agreement is drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic. In the event of inconsistencies of interpretation, the English text shall be determinative.

Done at…….., this……..day of……

For the European Community

For the United States of America

Annex I

Legislation, Regulations and Administrative Provisions

– **EC legislation, regulations and administrative provisions:**

Council Directive 96/98/EC of 20 December 1996 on marine equipment, as amended.

The Parties recognise that the "Guide to the Implementation of Directives Based on the New Approach and Global Approach" provides useful guidelines for the implementation of in particular conformity assessment procedures falling under this Directive.

– **U.S. legislation, regulations and administrative provisions:**

46 U.S.C. 3306

46 CFR Parts 159 to 165

Annex II

Product Coverage For Mutual Recognition

Life saving appliances

Product item identification	Applicable international instruments for construction, performance and testing requirements[4]	EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended	U.S. technical regulations
Lifebuoy self-activating smoke signals (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	LSA Code, sections 1.2, and 2.1.3; Recommendation on Testing, Part 1, paragraphs 4.1 to 4.5, and 4.8, and Part 2, section 4; IMO MSC Circ.980, section 3.3.	A.1/1.3	Guidelines for Approval of "SOLAS" Pyrotechnic Devices, October 1998
Rocket parachute flares (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	LSA Code, sections 1.2, and 3.1; Recommendation on Testing, Part 1, paragraphs 4.1 to 4.6, and Part 2, section 4; IMO MSC Circ.980, section 3.1.	A.1/1.8	Guidelines for Approval of "SOLAS" Pyrotechnic Devices, October 1998
Hand flares (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	LSA Code, sections 1.2, and 3.2; Recommendation on Testing, Part 1, paragraphs 4.1 to 4.5, and 4.7, and Part 2, section 4; IMO MSC Circ.980, section 3.2.	A.1/1.9	Guidelines for Approval of "SOLAS" Pyrotechnic Devices, October 1998
Buoyant smoke signals (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	LSA Code, sections 1.2, and 3.3; Recommendation on Testing, Part 1, paragraphs 4.1 to 4.5, and 4.8; and Part 2, section 4; IMO MSC Circ.980, section 3.3.	A.1/1.10	Guidelines for Approval of "SOLAS" Pyrotechnic Devices, October 1998

[4] "LSA Code" refers to the International Life-Saving Appliance Code adopted on 4 June 1996 (IMO Resolution MSC.48(66)). "Recommendation on Testing" refers to the IMO recommendation on Testing of Life-Saving Appliances adopted on 6 November 1991 (IMO Resolution A.689(17)) as amended on 11 December 1998 (IMO Resolution MSC.81(70).

Product item identification	**Applicable international instruments for construction, performance and testing requirements[4]**	**EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended**	**U.S. technical regulations**
Line-throwing appliances (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	LSA Code, sections 1.2, and 7.1; Recommendation on Testing, Part 1, section 9; and Part 2, section 4; IMO MSC Circ.980, section 7.1.	A.1/1.11	Guidelines for Approval of "SOLAS" Pyrotechnic Devices, October 1998
Rigid liferafts Note: The emergency pack is not covered by the Agreement	LSA Code, sections 1.2, 4.1 and 4.3; Recommendation on Testing, Part 1, paragraphs 5.1 to 5.16, and 5.20; IMO MSC Circ.811; IMO MSC Circ.980, section 4.2; IMO MSC Circ.1006 or other appropriate standard for hull or fire-retardant covering.	A.1/1.13	Rigid Liferaft – Coast Guard (G-MSE-4) Review Checklist, 27 July 1998
Automatically self-righting rigid liferafts Note: The emergency pack is not covered by the Agreement	LSA Code, sections 1.2, 4.1 and 4.3; Recommendation on Testing, Part 1, paragraphs 5.1 to 5.16, and 5.18 to 5.21; IMO MSC Circ.809; IMO MSC Circ.811; IMO MSC Circ.980, section 4.2; IMO MSC Circ.1006 or other appropriate standard for hull or fire-retardant covering.	A.1/1.14	Rigid Liferaft – Coast Guard (G-MSE-4) Review Checklist, 27 July 1998
Canopied reversible rigid liferafts Note: The emergency pack is not covered by the Agreement	LSA Code, sections 1.2, 4.1 and 4.3; Recommendation on Testing, Part 1, paragraphs 5.1 to 5.16, 5,18, and 5.21; IMO MSC Circ.809; IMO MSC Circ.811; IMO MSC Circ.980, section 4.2; IMO MSC Circ.1006 or other appropriate standard for hull or fire-retardant covering.	A.1/1.15	Rigid Liferaft – Coast Guard (G-MSE-4) Review Checklist, 27 July 1998
Float-free arrangements for liferafts (hydrostatic release units)	LSA Code, sections 1.2 and 4.1.6.3; Recommendation on Testing, Part 1, section 11; IMO MSC Circ.980, section 4.3.1;	A.1/1.16	46 CFR 160.062

Product item identification	**Applicable international instruments for construction, performance and testing requirements[4]**	**EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended**	**U.S. technical regulations**
Release mechanism for a. Lifeboats and rescue boats and b. Liferafts Launched by a fall or falls Limited to Davit-launched liferaft automatic release hook	LSA Code, sections 1.2 and 6.1.5; Recommendation on Testing, Part 1, section 8.2; and Part 2, paragraphs 6.2.1 through 6.2.4; IMO MSC Circ.980, section 6.1.3.	A.1/1.26	(Nothing in addition to international instruments)
Marine evacuation systems	LSA Code, sections 1.2 and 6.2; Recommendation on Testing, Part 1, section 12, IMO MSC Circ.980, section 6.2.	A.1/127	(Nothing in addition to international instruments)

Fire protection

Product item identification	Applicable international instruments for construction, performance and testing requirements*	EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended	U.S. technical regulations
Primary Deck coverings	FTP Code Annex 1, Parts 2 & 6, Annex 2; IMO Resolution A.687(17); MSC/Circ. 916; MSC/Circ. 1004.	A.1/3.1	(Nothing in addition to international instruments)
"A" and "B" Class division fire integrity, including: Bulkheads (without windows) Decks Fire doors (with windows no larger than 645 cm^2) Ceilings and linings	SOLAS II-2/3.2; II-2/3.4; FTP Code Annex 1, Part 3, and Annex 2; IMO Resolution A.754 (18); MSC/Circ.916; MSC/Circ.1004; MSC/Circ.1005.	A.1/3.11	(Nothing in addition to international instruments)
Non-combustible materials	SOLAS II-2/3.33; FTP Code Annex 1, Part 1, and Annex 2.	A.1/3.13	(Nothing in addition to international instruments)
Fire doors Limited to fire doors without windows or with total window area no more than 645 cm^2 in each door leaf. Approval limited to maximum door size tested. Doors must be used with a fire tested frame design.	SOLAS II-2/9.4.1.1.2, II-2/9.4.1.2.1, and II-2/9.4.2; FTP Code Annex 1, Part 3; IMO Resolution A.754 (18); MSC/Circ. 916; MSC/Circ. 1004.	A.1/3.16	(Nothing in addition to international instruments)

Product item identification	**Applicable international instruments for construction, performance and testing requirements***	**EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended**	**U.S. technical regulations**
Fire door control systems	SOLAS II-2/9.4.1.1.4; 1994 HSC Code 7.9.3.3; 2000 HSC Code 7.9.3.3; FTP Code Annex 1, Part 4.	A.1/3.17	(Nothing in addition to international instruments)
Surface materials and floor coverings with low flame-spread characteristics Limited to exposed surfaces of ceilings, walls, and floors. Does not apply to pipes, pipe coverings, or cables.	SOLAS II-2/3.29; 1994 HSC Code 7.4.3.4.1 and 7.4.3.6; 2000 HSC Code 7.4.3.4.1 and 7.4.3.6; FTP Code, Annex 1, Parts 2 & 5, and Annex 2; IMO Resolution A.653 (16); ISO 1716 (1973); MSC/Circ. 916, MSC/Circ. 1004 and MSC/Circ. 1008.	A.1/3.18	(Nothing in addition to international instruments)
Draperies, curtains and other suspended textile materials and films	SOLAS II-2/3.40.3; FTP Code Annex 1, Part 7.	A.1/3.19	(Nothing in addition to international instruments)
Upholstered furniture	FTP Code Annex 1, Part 8; IMO Resolution A.652 (16).	A.1/3.20	(Nothing in addition to international instruments)
Bedding components	FTP Code Annex 1, Part 9; IMO Resolution A.688 (17).	A.1/3.21	(Nothing in addition to international instruments)
Fire dampers	SOLAS II-2/9.4.1.1.8, and II-2/9.7.3.1.2; FTP Code Annex 1, Part 3; IMO Resolution A.754 (18); MSC/Circ. 916.	A.1/3.22	(Nothing in addition to international instruments)
Penetrations through 'A' class divisions by electric cables, pipes, trunks, ducts etc.	SOLAS II-2/9.3.1; FTP Code Annex 1, Part 3; IMO Resolution A.754 (18); MSC/Circ. 916, and MSC/Circ. 1004.	A.1/3.26	(Nothing in addition to international instruments)
Penetrations through 'B' class divisions by pipes other than steel or copper	SOLAS II-2/9.3.2.1; FTP Code Annex 1, Part 3; IMO Resolution A.754 (18); MSC/Circ. 916, and MSC/Circ. 1004.	A.1/3.27	(Nothing in addition to international instruments)

Navigation equipment

Product item identification	Applicable international instruments for construction, performance and testing requirements*	EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended	U.S. technical regulations
Magnetic compass	SOLAS V/19.2.1.1; IMO Resolution A.382 (X),; IMO Resolution A.694 (17); ISO 449 (1997), ISO 694 (2000), ISO 1069 (1973), ISO 2269 (1992), IEC 60945 (1996).	A.1/4.1	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.101.
Transmitting magnetic heading device (TMHD)	IMO Resolution MSC 86 (70) annex 2; IMO Resolution A.694 (17); ISO 11606 (2000), IEC 60945 (1996), IEC 61162.	A.1/4.2	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.102.
Gyrocompass	IMO Resolution A.424 (XI); IMO Resolution A.694 (17); ISO 8728 (1997), IEC 60945 (1996), IEC 61162.	A.1/4.3	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.103.
Echo-sounding equipment	IMO Resolution A.224 (VII) as amended by IMO Resolution MSC74 (69) Annex 4, IMO Resolution A.694 (17); ISO 9875 (2000), IEC 60945 (1996), IEC 61162.	A.1/4.6	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.107.
Speed and distance measuring equipment (SDME)	1994 HSC Code 13.3.2; 2000 HSC Code 13.3.2; IMO Resolution A.824 (19) as amended IMO Resolution MSC 96(72); IMO Resolution A.694 (17); IEC 60945 (1996), IEC 61023 (1999), IEC 61162.	A.1/4.7	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.105.
Rate of turn indicator	IMO Resolution A.694 (17); IMO Resolution A.526 (13); IEC 60945 (1996), IEC 61162.	A.1/4.9	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.106.
Loran-C equipment	IMO Resolution A.694 (17); IMO Resolution A.818 (19); IEC 61075 (1991), IEC 60945 (1996), IEC 61162.	A.1/4.11	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.135.

Product item identification	**Applicable international instruments for construction, performance and testing requirements***	**EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended**	**U.S. technical regulations**
Chakya equipment	IMO Resolution A.694 (17); IMO Resolution A.818 (19); IEC 61075 (1991), IEC 60945 (1996), IEC 61162.	A.1/4.12	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.136.
GPS equipment	IMO Resolution A.819 (19), IMO Resolution A.694 (17); IEC 60945 (1996), IEC 61108-1 (1994), IEC 61162.	A.1/4.14	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.130.
GLONASS equipment	IMO Resolution MSC 53 (66); IMO Resolution A.694 (17); IEC 61108-2 (1998), IEC 60945 (1996), IEC 61162.	A.1/4.15	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.131.
Heading control system HCS	SOLAS V/24.1; IMO Resolution A.342 (IX); as amended by IMO Resolution MSC 64 (67) Annex 3; IMO Resolution A.694 (17); ISO 11674 (2000), IEC 60945 (1996), IEC 61162.	A.1/4.16	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.110.
Automatic radar plotting aid (ARPA) (Radar equipment used with ARPA must have separate EU and U.S. certifications.)	IMO Resolution A.823 (19); IMO Resolution A.694 (17); IEC 60872-1 (1998), IEC 61162.	A.1/4.34	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.120.
Automatic Tracking Aid (ATA) (Radar equipment used with ATA must have separate EU and U.S. certifications.)	IMO Resolution MSC 64(67), Annex 4, Appendix 1; IMO Resolution A.694 (17); IEC 60872-2 (1999), IEC 60945 (1996), IEC 61162.	A.1/4.35	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.111.
Electronic Plotting Aid (EPA) (Radar equipment used with EPA must have separate EU and U.S. certifications.)	IMO Resolution MSC 64(67), Annex 4, Appendix 2; IMO Resolution A.694 (17); IEC 60872-3 (2000), IEC 60945 (1996), IEC 61162.	A.1/4.36	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.121.
Integrated bridge system	IMO Resolution MSC.64 (67) Annex 1; IMO Resolution A.694 (17); IEC 61209 (1999), IEC 60945 (1996), IEC 61162.	A.1/4.28	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.140.

Product item identification	**Applicable international instruments for construction, performance and testing requirements***	**EC technical regulations, item number indicated in Annex A.1 of directive 98/96/EC, as amended**	**U.S. technical regulations**
Voyage data recorder	IMO Resolution A.861(20); IMO Resolution A.694 (17); IEC 61996 (2000), IEC 60945 (1996), IEC 61162.	A.1/4.29	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.150.
Gyro compass for high speed craft	IMO Resolution A.821 (19); IMO Resolution A.694 (17); ISO 16328 (2001), IEC 60945 (1996), IEC 61162.	A.1/4.31	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.203.
Universal Automatic Identification System equipment (AIS)	IMO Resolution MSC.74 (69) Annex 3; IMO Resolution A.694 (17); ITU R. M. 1371-1 (10/00) IEC 61993-2 (2002), IEC 60945 (1996), IEC 61162	A.1/4.32	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.155. NOTE: In addition, the radio transmitter is required to be authorized by the U.S. Federal Communications Commission
Track control system	IMO Resolution MSC.74 (69) Annex 2; IMO Resolution A.694 (17); IEC 62065 (2002), IEC 60945 (1996), IEC 61162.	A.1/4.33	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.112.
Radar reflector	IMO Resolution A.384 (X); IEC 60945 (1996), ISO 8729 (1997).	A.1/4.39	Navigation and Vessel Inspection Circular NVIC 8-01, enclosure (4), 2/165.160.

Annex III

Regulatory Authorities

– **European Community**

Belgium	Ministère des Communications et de l'Infrastructure Administration des Affaires maritimes et de la Navigation Rue d'Arlon 104 1040 Bruxelles Ministerie voor Verkeer en Infrastructuur Bestuur voor Maritime zaken en Scheepvaart Aarlenstraat 104 1040 Brussel
Denmark	Søfartsstyrelsen Vermundsgade 38 C 2100 København Ø
Germany	Bundesministerium für Verkehr, Bau- und Wohnungswesen (BMVBW) Invalidenstraße 44 10115 Berlin
Greece	ΥΠΟΥΡΓΕΙΟ ΕΜΠΟΡΙΚΗΣ ΝΑΥΤΙΛΙΑΣ Γρ.Λαμπράκη 150 185 18 Πειραιας Ελλάς Ministry of Merchant Marine 150,Gr. Lampraki str. 185 18 Piraeus
Spain	Ministerio De Fomento Dirección General de la Marina Mercante. C/ Ruíz de Alarcón 1 ES-28071 Madrid
France	Le Ministère de l'Equipement, du Transport et du Logement Direction des affaires maritimes et des gens de mers 3, place de Fontenoy F-75700 Paris
Ireland	Maritime Safety Division Department of the Marine and Natural Resources Leeson Lane Dublin 2

Italy	Ministerio delle Infrastructure e dei Trasporti Unita di Gestione del trasporto maritimo Via dell'arte, 16 00144 - Roma
Luxembourg	Commissariat aux Affaires Maritimes 26 place de la Gare L-1616 Luxembourg
The Netherlands	Ministerie van Verkeer en Waterstaat Directoraat-Generaal Goederenvervoer (DGG) Directie Transportveiligheid Nieuwe Uitleg 1, Postbus 20904 NL-2500 EX Den Haag
Austria	Bundesaministerium für Verkehr, Innovation und Technologie Oberste Schiffahrtsbehörde Abteilung II/20 Radetzkystrasse 2 A-1030 Wien
Portugal	Ministerio do Equipamento Social Palacio Penafiel rua S. Mamede ao Caldas 21 1149-050 Lisboa
Finland	Liikenne- ja viestintäministeriö / kommunikationsministeriet PO Box 235 FIN-00131 Helsinki
Sweden	Sjöfartsverket S-601 78 Norrköping
United Kingdom	Maritime and Coastguard Agency Spring Place 105 Commercial Road Southampton SO15 1EG
Commission of the European Communities	Directorate General for Energy and Transport Maritime Safety Unit 200, rue de la Loi B-1049 Brussels

– **United States of America**

United States Coast Guard
Office of Design and Engineering Standards (G-MSE)
2100 Second Street S.W.
Washington DC 20593

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): External Trade Relations, including access to markets of non-Community countries

Activit(y/ies): Conformity assessment procedures and acceptance of industrial products

TITLE OF ACTION: AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE UNITED STATES OF AMERICA ON THE MUTUAL RECOGNITION OF CERTIFICATES OF CONFORMITY FOR MARINE EQUIPMENT

1. BUDGET LINE(S) + HEADING(S)

B7-8500 and A-7010

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): € 615950

2.2. Period of application:

The proposed Agreement is foreseen to be of unlimited duration.

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€

	Year 2003	2004	2005	2006	2007	Total	
Commitments	156700	106700	95850	95850	95850	550950	
Payments	156700	106700	95850	95850	95850	550950	

(b) Technical and administrative assistance and support expenditure*(see point 6.1.2)*

Commitments	40000	10000	5000	5000	5000	65000	
Payments	40000	10000	5000	5000	5000	65000	

Subtotal a+b							
Commitments	196700	116700	100850	100850	100850	615950	
Payments	196700	116700	100850	100850	100850	615950	

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

Commitments / payments	167140	169950	167380	167380	164700		

TOTAL a+b+c							
Commitments	363840	286650	268230	268230	265550	1452500	
Payments	363840	286650	268230	268230	265550	1452500	

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:[5]

The proposal does not involve any type of revenue.

3. BUDGET CHARACTERISTICS

Type of expenditure		**New**	**EFTA contribution**	**Contributions form applicant countries**	**Heading in financial perspective**
Non-comp	Diff	NO	NO	NO	**No 4**

4. LEGAL BASIS

Article 133 and 300 of the Treaty

Action Plan for the Transatlantic Economic Partnership as endorsed by the Council on 9 November 1998 and the ensuing negotiation mandate.

Proposal for a Council Decision on the conclusion of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment.

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention [6]

5.1.1. Objectives pursued

General objective: DG Trade has the task of conducting the European Union's commercial policy in accordance with the objectives set out in Article 131 of the Treaty: "to contribute, in the common interest, to the harmonious development of world trade, the progressive abolition of restrictions on international trade and the lowering of customs barriers". The common

[5] For further information, see separate explanatory note.
[6] For further information, see separate explanatory note.

commercial policy shall be based on uniform principles, particularly in regard to changes in tariff rates, the conclusion of tariff and trade agreements, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade such as those to be taken in the event of dumping or subsidies (Article 133(1) of the Treaty).

Specific objectives: The Community's external trade policy objectives in the field of standards and conformity assessment can be summarised as follows (see Commission Communication on the Community External Trade Policy if the field of Standards and Conformity Assessment[7]). First, to reduce technical barriers to trade in external markets and to prevent the emergence of new ones; and second, to encourage our trading partners to adopt standards and regulatory approaches based on, or compatible with international or European practice. These trade objectives have so far been pursued through a four-fold strategy. One of them is the negotiation of Mutual Recognition Agreements (MRAs).

EU manufacturers, when exporting to the US, must have their products approved by the USCG, which adds costs and delays in order to gain access to the US market. The MRA on marine equipment has thus the following two objectives: 1) the facilitation of EU-US trade in marine equipment; and 2) promoting regulatory co-operation and efficiency. This is achieved by ensuring the recognition of certificates of conformity issued by the Conformity Assessment Bodies of the Parties and setting up a framework for regulatory co-operation.

5.1.2. Measures taken in connection with ex ante *evaluation*

The New Transatlantic Agenda (NTA), adopted in 1995, provides a framework for EU-US partnership and co-operation across a wide range of activities under four broad chapters: promoting peace and stability, democracy, and development around the world; responding to global changes; contributing to the expansion of world trade and fostering closer ties; building bridges across the Atlantic. The Transatlantic Economic Partnership (TEP), launched in 1998, is an extension of the NTA and the TEP Action Plan calls for, in terms of bilateral EU-US co-operations, the removal of remaining barriers to trade. This Action Plan was endorsed by the Council on 9 November 1998 and at the same time the Council mandated the Commission to negotiate mutual recognition agreements with the US.

In view of implementing the TEP Action Plan the EU and the US, in consultation with their relevant stakeholders, identified a number potential projects, one them being a possible MRA related to marine equipment. Based on an initial assessment of EU and US technical regulations made by the USCG (this report has been publicly available and will be put of DG Trade's web-site), it was deemed both beneficial and feasible to start negotiations on a MRA based on equivalence of EU and US technical regulations related to marine equipment. After consultation of the Council 133 Committee negotiations started in September 1999.

5.2. Action envisaged and budget intervention arrangements

– ***The target population***

The target population are the manufacturing, exporting and importing companies, conformity assessment bodies, business associations, chambers of commerce and public institutions of the European Union, as well as passengers, ship builders and owners, which will benefit, or have an interest in the mutual recognition of certificates of conformity. For more details see the Impact Assessment Form attached to this proposal.

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7 COM(96)564 final.

– ***The specific objectives set***

Based on the objectives set out under point 5.1.1, the MRA has the following specific objectives:

– Avoid duplication of testing and certification by economic operators.

– Reduce costs and burdens (administrative, uncertainty, timing etc.), for in particular for small and medium-sized enterprises, related to conformity assessment requirements.

– Facilitation of access to the US market for EU products.

– Increased regulatory co-operation and co-ordination in relation to setting international rules for marine equipment. Better alignment of EU and US regulations to those international rules.

– Increased awareness of best regulatory practices.

– Reduced regulatory costs in relation to approval of US products.

– Increased efficiency in market surveillance and enforcement actions.

– ***The concrete measures to be taken to implement the action***

The general actions which will be pursued by the Commission services under the budget lines will mainly be the following:

– Actions related to the management of the Agreement and maintenance of the necessary degree of confidence, e.g. participation in Joint Committee meetings, taking part in regulatory co-operation projects.

– Actions related to the management and maintenance of Annex II of the Agreement which lists the products that are within the scope of the Agreement, e.g. analysis work on equivalence of EU and US technical regulations and technical co-operation work.

– Setting up of contact points for the exchange of information and establishing and managing a two alert system as foreseen in Articles 9 and 16 of the Agreement.

More specifically, the following implementation actions will be needed:

A. Participation in Joint Committee and co-ordination meetings

The necessary meetings will to a very large extent relate to meetings of the Joint Committee established under Article 7 of the Agreement. With regard to the frequency of Joint Committee meetings, it is expected that this will be more intense during the first one to two years of the Agreement, where up to 3 meetings per year could be required. Thereafter, the Joint Committee will need to meet on a regular basis (1-2 times per year) although this will depend on how the regulatory programs of the Parties evolve. Other meetings of technical experts need to be foreseen as well, also mainly in the initial phase of the Agreement. All these meetings will be attended by Commission officials and given the many times technical nature of these meetings, experts from Member State authorities and the Notified Bodies or

other appropriate experts. The meetings of the Joint Committee would take place alternatively in Brussels and Washington DC, USA. The cost for reimbursement of travel expenses for experts that assist the Commission services in meetings would be limited to travel and subsistence expenses.

B. Analysis of technical regulations

A core element of the mutual recognition obligations of the Agreement is the determination of equivalence of the respective EU and US technical regulations. These technical regulations will evolve over time to take into account developments within IMO, new technologies, new risks etc. For products that are included in the Agreement, analysis will have to be carried out whether applicable new or amended EU and US technical regulations are still equivalent. For products not yet covered, technical analysis of the technical regulations needs to be carried to determine whether those products could be brought within the scope of the Agreement. Based on previous experience, analysis of equivalence contracts are on average within the range of € 20-40.000. An average of 2 analysis per year are expected.

C. Information dissemination required by the Agreement

This relates, on the one hand, to information dissemination required by the Agreement and, on the other hand, information on and promotion of the Agreement to industry and conformity assessment bodies. With regard to the former, Article 6(4), 9(4) and 10(5) of the Agreement require the EU and US to make certain information available on the World Wide Web. The information required by Article 6(4) is already provided for within the framework of the marine equipment directive 96/98/EC. The other information activities relate to familiarising and promoting the Agreement with industry and conformity assessment bodies. This would mainly take to form of information publications and the organisation of workshops and conferences.

D. Two-way alert system

Article 16 of the Agreement calls on the Parties to set up a two-way alert system between their Regulatory Authorities in order to inform each other of products that have been found not to comply with applicable technical regulations or can pose an imminent danger to health, safety or the environment. The practical modalities for such a system will have to be agreed with the US once the Agreement has entered into force. However it can very well be envisaged that a system would function on the basis of electronic mail exchanges. Expertise in setting up such systems, including the necessary security features, might need to be contracted and the system maintained.

– ***The immediate outputs of the action***

Once the Agreement enters into force EU manufacturers can reduce their costs related to conformity assessment for access to the US market.

– ***The contribution of these outputs to the expected outcomes in terms of satisfying needs or solving problems***

The output described above will directly satisfy the objective of the Agreement, i.e. trade facilitation.

5.3. Methods of implementation

Under Article 133 of the Treaty the Community has exclusive competence for commercial policy and this agreement has been negotiated in accordance with a mandate of the Council of Ministers and in consultation with the 133 Committee. The Commission will, as proposed, be responsible for the implementation and management of the Agreement.

In view of ensuring legal certainty to economic operators that their certificates of conformity will be accepted by the other Party, a binding agreement is necessary. Other forms of agreements, e.g. memorandum of understanding, would not have offered this.

The choice of management method (Joint Committee) has been set out in the Agreement and constitute a minimum necessary for the proper functioning of the Agreement.

The nature of the Agreement requires close regulatory co-operation between the EU and the US, both bilaterally and in the different international organisations, the IMO in particular. However, as a "spin-off effect" this co-operation will also lead to increased knowledge and sharing of experiences and best practices with different regulatory approaches. For example , the US has already considered using a part of the marine equipment directive as basis for its new regulations for navigation equipment.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. Financial intervention

Commitments (in €)

Breakdown	Year 2003	2004	2005	2006	2007	Total	
Participation in meetings	21700	21700	10850	10850	10850	75950	
Analysis work	120000	80000	80000	80000	80000	440000	
Two-way alert system	15000	5000	5000	5000	5000	35000	
TOTAL	156700	106700	95850	95850	95850	550950	

6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)

	Year 2003	2004	2005	2006	2007	Total	
1) Technical and administrative assistance							
a) Technical assistance offices							

b) Other technical and administrative assistance: - intra muros: - extra muros: *of which for construction and maintenance of computerised management systems*							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications	40000	10000	5000	5000	5000	65000	
Subtotal 2							
TOTAL	40000	10000	5000	5000	5000	65000	

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[8]

(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated)

Commitments (in €)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 2003-2007)	Average unit cost	Total cost (total for years 1…n)
	1	2	3	4=(2X3)
Action 1: Participation external experts in meetings				
- *Meetings in Brussels*	Meeting	7[a]	2050[b]	14350
- *Meetings in USA*	Meeting	7[a]	8800[b]	61600
Action 2: Analysis work	Report	11	40000	440000
Action 3: Information	Publications	5	13000	65000
Action 4: Two-way alert system	Electronic messaging system	1	15000	15000
- *Setting up of system*		4	5000	20000
- *Maintenance of system*				
TOTAL COST				615950

Notes: a) Two meetings the first 2 years and thereafter one meeting per year; b) travel and subsistence expenses for 3 experts

[8] For further information, see separate explanatory note.

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

The needs for human and administrative resources shall be covered withing the allocation granted to the managing DG in the framework of the annual allocation procedure.

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A B C	1 0,5		1 0,5	*If necessary, a fuller description of the tasks may be annexed.*
Other human resources					
Total		1,5		1,5	

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the framework of the annual allocation procedure.

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials Temporary staff	162000	1,5 staff (€ 108000 per staff member per year)
Other human resources (specify budget line)		
Total	162000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount €	Method of calculation
Overall allocation (Title A7) A0701 – Missions staff - Joint Committee meetings - Other meetings	 18900 7650	 2 day meeting in Washington DC: travel: € 2400, per diem: € 2x150, 7 meetings 2003-2007 1 day meeting in Washington DC: travel: € 2400, per diem: € 150, 3 meetings 2003-2007
Total	26550	

The amounts are total expenditure for the period 2003-2007.

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

Monitoring and evaluation of the Agreement will be done primarily in relation to the foreseen results in terms of their effectiveness (how far the results of the Agreement have contributed to achieving its specific and general objectives; or performance against objectives). However, issues such as relevance of the Agreement (to what extent the Agreement's objectives are pertinent in relation to the evolving needs of the target population) and the utility of the Agreement (how the impacts of the Agreement compare with the needs of the target population), will also be addressed.

As an indicator for resources used, man-days spent by Commission officials dealing with issues related to the implementation of the Agreement.

With regard to evaluating the effectiveness of the Agreement (or performance against objectives), this can be measured both in relation to the trade facilitation objective and the regulatory co-operation objective.

With regard to trade facilitation and the expected results described in point 5.1.1 and 5.2 above, the following indicators could be used:

– Avoiding duplication of testing and certification. Number of certificates delivered to companies in accordance with the Agreement. This could be put into relation to the number of certificates delivered under the domestic systems before the Agreement entered into force.

– Reduction in costs. Savings (in EUR) due to avoiding duplicate testing and certification, estimated as the product of the average cost of testing and certification and the number of certificates issued in accordance with the Agreement. This is associated with certain difficulties due to the large number of products using different technologies thus impacting on the price of testing and certification. A case study approach could however give certain indications.

– Increased EU exports. Examine trade data before and after the entry into force of the Agreement. This indicator will be difficult to use due to, on the one hand, the impact of other variable (e.g. exchange rates, general economic trends) and, on the other hand, absence of official trade data for all types of marine equipment. This could also be included as part of a case study approach to carrying out an evaluation.

With regard to regulatory co-operation and the expected results described in point 9.1 above, the following indicator could be used:

– Regulatory co-operation. The number of specific EU and US technical regulations that can be determined as equivalence or alternatively the evolution of the number of products listed in Annex II of the Agreement.

– Enforcement efficiency. Number of alerts passed in the two way alert system. This could also be put into relation to the enforcement action taken, if any.

The issues of efficiency (how economically various inputs have been converted into outputs) could also be addressed, but considerable difficulties in assessing costs exist. Furthermore, the costs related to negotiating the Agreement (e.g. man-days spent by Commission staff,

consultations with Member States and industry, analysis work contracted, meetings with the US etc.) could be seen as a "sunk cost" since those costs would have been incurred whether an Agreement would have been concluded or not. With regard to the issue of efficiency it would be more relevant to evaluate this in terms of the management of the Agreement. This could be done in relation to the actions, procedures and measures taken both within the Community and those taken in relation or together with the US to ensure the well functioning of the Agreement (see also below).

8.2. Arrangements and schedule for the planned evaluation

Article 22(2) of the Agreement calls for that the functioning of the Agreement is reviewed on a regular basis and for the first time no later that 2 years after its entry into force. This evaluation is to be done by the Parties in conjunction and the elements that should be assessed would have to be agreed mutually. In this respect, the Commission could envisage proposing the following elements for assessment: progress in determining equivalence (expanding Annex II of the Agreement), functioning of Article 10 of the Agreement on regulatory changes, functioning of the two way alert system, co-operation between Conformity Assessment Bodies and assessing the possibility of establishing a multilateral agreement with other countries (Article 20(2) of the Agreement). It can very well be envisaged that the review of the functioning of the Agreement would take place on a biannual basis, however this would have to be agreed with the US.

The Joint Committee has as one of its functions to constantly evaluate the functioning of the Agreement. Within the Commission services and in co-operation with Member States in the 133 Committee monitoring and evaluation will be carried out according to the Commission staff working document "Guiding Principles on and a Vade mecum for the management of agreements on mutual recognition of conformity assessment".

The evaluation of the effectiveness of the Agreement, as described above, would with advantage take place in conjunction with the review of the Agreement done by the Parties. This could also take place on a biannual basis. With regard to the evaluation of the relevance and utility of the Agreement, this would preferably be done four years after its entry into force when enough experience has been gained.

With regard to specific activities, in particular those requiring financial resources, DG Trade requires that a project appraisal is made for all financial payments.

9. ANTI-FRAUD MEASURES

Specific methods of control (submission of interim reports, financial statements, expenditure statements, payment in instalments etc.) will be included in all contracts between the Commission and contractors/beneficiaries.

Analysis work, preparation of publications, arrangement of conference will, if not done by the Commission, be done under contracts that have been established following tendering procedures in accordance with the Commission's financial regulations. These contracts will require contractors to produce interim reports showing progress made and funds used and a final report approved by the Commission services before final payment is made. For certain activities, e.g. information workshops and conferences aimed at economic operators, grants can be envisaged after a call for proposals and in accordance with the Commission's

"Vademecum on Grant Management". Where appropriate, contracts also require contractors/beneficiaries to submit financial accounts certified by their auditors.

The reimbursement of travel expenses for experts assisting the Commission in the implementation of the Agreement will be done on the basis of invitations setting out the conditions for reimbursement and on the presentation of an invoice with original receipts. Commission staff will, as a general rule, be present at such meetings and if not close co-operation with the delegations of the Commission will check on the spot to ensure that work is carried out as required.

DG Trade has a system of internal controls with internal auditors. These controls intervene at the different stages related to the drafting, establishment, execution and closing of contracts. Furthermore, the new financial management circuits clearly describes and allocates responsibilities for all types of financial transactions.

Evaluations of contracts and the management of budget lines by external consultants are also carried out.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

TITLE OF PROPOSAL

Proposal for a Council Decision on the conclusion of an Agreement between the European Community and the United States of America on the Mutual Recognition of Certificates of Conformity for Marine Equipment

DOCUMENT REFERENCE NUMBER

THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

   Under Article 133 of the Treaty the Community has exclusive competence for commercial policy. The legislation is necessary to conclude the Agreement with the US on the mutual recognition of certificates for marine equipment. The Agreement has been negotiated and initialled by the Commission in accordance with negotiating mandate given by the Council on 9 November 1998.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

   – which sectors of business

   – which sizes of business (what is the concentration of small and medium-sized firms)

   – are there particular geographical areas of the Community where these businesses are found

   The business sectors, manufacturers (exporters and importers) and conformity assessment bodies, affected are those related to life saving appliances at sea, fire protection equipment used on board ships, marine pollution prevention and marine radio and navigation equipment. Table 1 below gives a picture of the whole maritime supplies industry in the Member States. It is estimated that approximately 20% of these activities could be related to the products covered by the MRA.

The figures in Table 1 indicate that companies in the marine supplies industry are small, with an EU average of 27 employees per company (varying between Member States from 5 to 46 employees per company) and export oriented, with an EU average of 46% of production going to export markets (varying between Member States from 10% to 80%).

Table 1: Maritime supplies industry in the EU (1999)

	Production Marine Supplies (MEURO)	Domestic Market (MEURO)	Export Market (MEURO)	Number of Employees	Number of Enterprises (est.)
Austria	14	3	11	203	13
Belgium	108	85	23	1 039	23
Denmark	1 003	605	398	13 098	381
Finland	869	574	296	9 622	516
France	1 606	978	629	18 875	675
Germany	5 217	2 248	2 969	58 739	1 269
Greece	502	440	62	10 350	381
Italy	1 966	1 238	728	23 035	960
Ireland	16	13	3	223	21
Luxembourg	10	2	8	33	6
The Netherlands	1 960	1 093	867	25 636	836
Portugal	87	79	9	2 319	504
Spain	1 315	1 047	268	19 198	1 665
Sweden	721	316	406	7 318	233
United Kingdom	3 837	1 608	2 230	47 374	1 382
EU	**19 231**	**10 329**	**8 907**	**237 062**	**8 865**

Source: Competitiveness and Benchmarking in the Field of Marine Equipment, study for the European Commission, DG Enterprise (ETD/98/502029).

3. What will business have to do to comply with the proposal?

It should be pointed out that the use of the Agreement by businesses is voluntary. For companies - manufacturers, importers and conformity assessment bodies - that wish to exploit the opportunities offered by the Agreement will need to make themselves acquainted with it. The Commission intends to inform and create awareness of the Agreement through publications (e.g. practical guides), workshops and conferences.

Manufacturers are already now taking the actions necessary to make use of the Agreement since they must comply with the EU marine equipment directive 96/98/EC for placing their products on the EU market. The Agreement will result, for those products covered, in that these actions will also give access to the US market without any further re-design, testing and certification.

4. What economic effects is the proposal likely to have?

Based on determining equivalence between specific EU and US technical regulations for marine equipment, the Agreement will permit EU manufacturers to test and certify their products in the EU to EU requirement for access to the US market. This will reduce costs directly related to duplicative testing and certification of a product in order to legally market it in the territory of the other Party. Since an EU manufacturer can use a conformity assessment body in the EU (instead of the US as would be the case without an agreement) will also reduce costs, burdens and uncertainty related to contacting a foreign body. Furthermore, it can be done within a

regulatory framework and according to technical regulations and standards EU manufacturers are already familiar with.

It can be expected that the EU conformity assessment bodies (the notified bodies under the marine equipment directive) can loose business opportunities since US exporters no longer have to use their services in order to demonstrate compliance with directive 96/98/EC. However, the Agreement can also provide them with new business opportunities in the form of the EU manufacturers which might previously have been deterred to exporting the US due the costs and burdens related to conformity assessment and acquiring the knowledge of a foreign regulatory system.

Due to the lack of verifiable data, it has been difficult to make a clear economic assessment of the Agreement. Indications from industry give that testing and certification costs for marine equipment are not negligible. The Agreement can help to reduce these and will thus not only benefit manufacturers of marine equipment but ship builders as well.

It is thus expected that the Agreement will have an overall positive effect on exports, employment, investment and competitiveness of EU companies.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

The Agreement does not contain specific measures to take into account of the particular situation of small and medium-sized firms, but by its nature and by reducing certification costs, which are the same for all firms, as well as uncertainty, the Agreement will potentially benefit small and medium-sized enterprises to a greater extent than larger firm.

CONSULTATION

6. List the organisations which have been consulted about the proposal and outline their main views.

The Commission services have on several occasions consulted with the relevant European industry federations: ILAMA, EMEC, ISSETA CIRM/EURONAV and ICOMIA, which have given their support to the Agreement. Representatives of trade unions (ETUC) and consumers (ANEC) have also been informed. The Commission services also organised a workshop in May 2000 with the objective of informing and discussing with all interested parties the issues involved with the marine equipment mutual recognition agreement. The workshop gathered 43 participants from 10 Member States, as well as from Norway and the US, representing a wide variety of interests (public authorities, manufacturers, consumers, conformity assessment bodies). The main conclusions from the discussion were the following:

- The promotion of a high level of safety at sea and the prevention of marine pollution must be a guiding principle towards a Mutual Recognition Agreement on Marine Equipment.

- IMO, as well as ISO, IEC and ITU, are the fora in which discussion and agreement on international rules and standards on marine equipment related to the safety at sea and the prevention of marine pollution should be made.

- Differences have appeared, for various reasons e.g. due to "gaps" in IMO standards, in EU and US marine equipment requirements although they are both based on the existing international instruments of the IMO. Equivalence between EU and US requirements must therefore first be established with a view to achieve the envisaged MRA+ concept.

- The USCG comparative study into EU and US marine equipment conformity assessment legislation and the verification study commissioned by the Commission services and carried out by Bureau Veritas is a solid basis on which to continue work towards a MRA on marine equipment, based on equivalence.

- Industry expressed a clear interest and benefit in the MRA concept based on equivalence (MRA+), but showed much less advantage in the "classical MRA" approach.

- Although a MRA is primarily a trade facilitation tool it will also act as a strong incentive for and promotion of regulatory co-operation and international harmonisation.

The Transatlantic Consumer Dialogue is a forum of US and EU consumer organisations which develops and agrees joint consumer policy recommendations to the US government and European Union to promote the consumer interest in EU and US policy making. The TACD has been quite critical of MRAs in general and the concept of equivalence of technical regulations. The main objections raised by the TACD relates to that MRAs, as well as equivalence, could lead to: 1) transfer of regulatory authority to foreign entities who may operate under different conflict of interest, transparency and liability rules; 2) privatisation of public functions; 3) loss of domestic regulatory control; 4) reduced levels of public participation in the regulatory decision making process; 5) increased opportunities for regulatory evasion by industry; and 6) reduction in levels of health, safety and environmental protection. The Commission cannot, for the reasons explained in the explanatory memorandum for this proposal, agree with the conclusions they draw.