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Glossary

Term	Definition
AnNa project:	the EU Member States driven project in close cooperation with the
	European Commission to support the effective implementation of the ship
	formalities directive.
AEO	Authorised Economic Operator
AIS	Automatic Identification Systems
B2A	Business to Administration
B2B	Business to Business
CENELEC	European Committee for Electrotechnical Standardization
CISE	Common Information Sharing Environment
COMSAR	the Sub-Committee on Radiocommunications and Search and Rescue
CRMF	Common Risk Management Framework
CSP	EU Customs Security Programme
DAE	Digital Agenda for Europe
DGMOVE	Directorate General for Mobility and Transport
eFreight	
e-Manifest	The electronic cargo 'eManifest' with information on the status of goods is
-	considered a practical solution to achieve this.
EPC	Electronic port clearance
eMS group	Expert group on Maritime administrative simplification and electronic
civio group	information services, DG MOVE
EIS	European Index Server
EMSA	European Maritime Safety Agency
GMDSS	Global Maritime Distress and Safety Systems
EQF	European Qualifications Framework
FAO	Food and Agricultural Organisation
HACCP	Hazard Analysis and Critical Control Point
IALA	International Association of Lighthouse Authorities
IEC	International Association of Eighthouse Authorities International Electrotechnical Commission
IMO	International Maritime Organization which sets out a number of regulations
IIVIO	relating to navigation and ship to shore communications.
IMO-FAL	IMO Facilitation Committee
ITU	International Telecommunications Union
ISO	International Organization for Standardization
ISPS	International Ship Port Security Notification
LRIT	Long Range Identification and Tracking Systems
MSC	Maritime Safety Committee
MSW	Maritime Single Window
SSN	SafeSeaNet
NSW	National Single Window
PCS	Port Community System
PSW	Port Single Window
RFD	Reporting Formalities Directive - A Directive of the European Commission coming
5	into force on 1/6/2015 dealing with the reporting formalities for ships arriving in
	and/or departing from ports of the MSs
SKEMA	Sustainable Knowledge Platform for the European Maritime and Logistics Industry,
	a European funded Project
SOLAS	International Convention for the Safety of Life at Sea, 1974

Term	Definition	
SAR	Search and Rescue	
SURPIC	Surveillance Picture	
TMSA	Tanker Management Self Assessment	
UN/CEFACT	UN Centre for Trade Facilitation and E-business - message standards for	
	ship to port state and port for clearance	
VTS	Vessel Tracking Systems	
VTS	Vessel Traffic Services	
WCO	World Customs Organisation	
WHO	World Health Organisation	
XML	Extensible Markup Language (XML) is a computer language that defines a set of	
	rules for encoding documents in a format that is both human-readable and	
	machine-readable	

Executive Summary

- The report examines current policy, legislation and standards and various requirements in order to facilitate the e-maritime agenda. Whilst there is extensive regulation in terms to operations, more work is needed to address the particular issues of information exchange.
- Co-operation, integration, standardised definitions and processes are common themes in the development of this agenda. Policy and legal development must also take account of issues of transparency, security of information and confidentiality issues.
- Regulation is required to ensure that these issues are taken seriously and that there is some element of legal redress.
- The report presents an extensive view of international and regional regulations, standards, policies and strategic developments that will have an impact on eMAR. The standardisation requirements of International Maritime and Regulatory bodies create the technical framework within which the eMAR standard messages are developed.
- Standardisation will play an important role in the uptake of new technologies. Standards
 need to be monitored to ensure that they are developed in an open, transparent and
 consensual manner with adequate participation of stakeholders. The e-Maritime concept is
 relevant to the international maritime industry and thus the aim, as far as possible, should
 be for international regulation and standards in consultation with international partners.
- A number of EU transport policies have a significant impact on e-Mar, particularly EU
 Maritime Transport Space without barriers and the "Blue Belt" for future free movements in and around the EU coast.
- This policy analysis concludes that the eMAR project is in line with the EU policy initiatives that address issues relating to the standard framework for information exchange, the national single window and the single transport document. The eMAR project will encourage the use of electronic communication between stakeholders in order to make the European maritime industry more efficient, safe and environmentally friendly. It will improve information use; knowledge creation; dissemination of new concepts; business process collaboration and overall competitiveness of the shipping business.
- The project lays down the foundations for the electronic messaging in this sector, but it is clear that there will still be a great deal of work for clarification after the project is completed.

1. Introduction

This report examines current legislation, policy, regulation and standardisation with respect to information exchange. More specifically, it seeks to establish overlaps and potential for harmonisation and simplification to better facilitate an e-maritime environment. For the purposes of this study, e-maritime is considered in the context of the eMAR Strategic Framework¹. The main focus is on ship- to- shore reporting to fulfil both navigational and administrative obligations as well as port communication.

The e-Maritime platform will be based on electronic standard messages which already are or are likely to become legal standards in the future. Although it is recognised that this project lays down the foundations for electronic messaging in this sector, a great deal will need to be done post project in order to establish and agree these standards. It is anticipated that Directorate General for Mobility and Transport (DGMOVE) will play a significant role in these discussions and the policy developments necessary to achieve efficient working in this area.

Many issues relating to policy and regulation were considered in the Periodic Study, which formed part of the SKEMA 'Sustainable Knowledge Platform for the European Maritime and Logistics Industry' project (2011). This work identified challenges concerning the use of electronic based interactions within the maritime industry and with other actors in the logistics chain. The SKEMA Periodic Study also considered policy options, which could facilitate the development of information exchange in the future. The study concluded that e-maritime had the potential to provide standardisation, interoperability and security of information exchanges that will establish foundations for cooperative networking strategies in intermodal operations. However, it also revealed that regulatory and policy development in this area could be problematic, since it must address issues of transparency, confidentiality, technical complexity, risk, and stakeholder buy-in.

This report builds on this work by highlighting the 'e-maritime related' standards at European and international level and the information required by the different stakeholder groups. It further discusses the developments required in order to achieve effective integration and the critical issues relating to electronic information transfer. The report reviews current transport policy developments that impact the e-Mar project activities and focuses on the Blue Belt policy: a single transport area for shipping international developments. In addition, it presents the regulatory regimes of the European Union, International Maritime Organisation, World Customs Organisation, World Health Organisation and standards of the International Standardisation Organisation that impact the e-Mar standardisation requirements, and have particular relevance to the eMAR project. These are the extensive topics of Sections 2, 3, 4, 5, 6 and 7, plus a matrix summarising them in Appendix II.

The report aims to give a thorough understanding of the current and upcoming developments in the field of information exchange that are relevant to the industry. The transfer of data and information is crucial to the progress of eMAR strategic framework. The interaction between the various systems lies at the heart of technological advancement for businesses and administrations. For this purpose, the project team will establish generic standard messages, suitable to all operators, and the European maritime industry will be invited to use them. These standard messages will be ready by

¹ e-Maritime Strategic Framework (EMSF) (Deliverable 1.3)

the end of the project to go through a standardisation process in order to become legal standards. It is expected that the legal standardisation of the standard messages in the eMAR Strategic Framework will take longer than the actual project duration. Therefore, an appropriate strategy will be implemented that will deal with the approach of various international bodies to standardise the eMAR standard messages.

2. Ship to Shore Communications: Navigation and Tracking

The international administrative domain is largely driven by the International Maritime Organization (IMO) which sets out a number of regulations relating to navigation and ship to shore communications in the International Convention for the Safety of Life at Sea, 1974 (SOLAS) Chapter V. IMO adopted a revised version of chapter V, updating it and incorporating new requirements, which entered into force in 2002.

Apart from Conventions, IMO has also issued a series of resolutions, codes and guidelines on navigation issues and performance standards for shipborne navigational and radio communications equipment. Although some of these are only recommendations, their acceptance is widespread. Others carry more weight as specific reference is made to them in the regulations of specific conventions.

In addition to IMO, other policy and regulation has come from the European Commission, especially in relation to Vessel Tracking Systems (see Section 2.2). Bodies such as the International Telecommunications Union (ITU), Inmarsat, and International Electrotechnical Commission (IEC) have also been instrumental in setting standards with respect to vessel navigation and monitoring.

The following sections explore regulations relating to ship reporting, Vessel Tracking Systems (VTS), Automatic Identification Systems (AIS), Long Range Identification and Tracking Systems (LRIT) and Global Maritime Distress and Safety Systems (GMDSS).

2.1 Ship Reporting Systems

Regulation 11 (SOLAS Chapter V) deals with Ship reporting systems. It states that IMO is the only recognized international body to provide guidelines and criteria for ship reporting system. National governments must comply with these criteria, but the development of the actual systems is a matter for national governments themselves. Ship reporting systems should be consistent with the United Nations Convention on the Law of the Sea (paragraph 8) and 'Any adopted ship reporting system shall have the capability of interaction and the ability to assist ships with information when necessary' (paragraph 6). Any initiation of establishing a ship reporting system is the responsibility of the Government or Governments concerned. All provision of guidelines and criteria developed by the IMO have to be taken into account. Reporting systems that were not submitted to the IMO for adoption do not need to comply with this regulation.

When two or more Governments decide to formulate proposals for a coordinated ship reporting system in accordance with Regulation 11, this should be done on the basis of agreement between them. Then the IMO disseminates details of the proposal to those Governments, which have a common interest in the area covered by the proposed system. Uniform procedures and operations should be adopted and established.

The master of a ship has to comply with the requirements of adopted ship reporting systems and report to the appropriate authority. The participation of ships in accordance with the provisions of adopted ship reporting systems is free of charge to the ships concerned. The IMO is responsible to ensure that adopted reporting systems are reviewed under the guidelines and criteria developed by the Organisation.

The communication among Ship Reporting Systems (SRS) is carried out by means of the GMDSS. Usually reports are sent to a coastal radio station and then they are passed on to the head office. The SRS contributes to the reduction of the time period counting from the moment of the last report and the beginning of search in cases when distress message has not been received. Depending on the reports time periods, in cases of justified suspicion of a vessel in peril, it may not be possible to define the search area of the appropriate size, which happens mainly in cases of agreed reporting. Therefore it is necessary to reduce the span of time between two reports. The eMAR platform will allow the transmission of essential data in order to follow the position of the sea traffic. By applying modern technological solutions, the application of the system on a European level is anticipated.

The SRS may be voluntary or obligatory. The voluntary systems are based on mutual solidarity, and they are usually set up in areas where unfavourable weather conditions prevail. The obligatory reporting systems rest on the stipulations of the SOLAS. In compliance with the SOLAS, the obligatory SRS may refer to all or some individual types of ships, excepting military and subsidiary merchant shipping, or some other non-commercial types of ships in charge of the Government. Ships masters are obligated to send in reports about the movement of the ship (sailing plan; position report; deviation report and final report).

In cases of real or possible sea contamination (pollution), there exists an obligation to report on dangerous goods; harmful substances and marine pollutants. The reports are sent on standard forms to the coastal radio stations, which pass them on to the head office and thus establishes the Surveillance Picture (SURPIC), which is always kept updated via the information coming from new reports.

2.2 VTS

Regulation 12 (SOLAS Chapter V) deals with Vessel traffic Services (VTS) which should be established where the volume of traffic or degree of risk justifies it (paragraph 2). Further guidelines can be found in the 'Guidelines on Vessel Traffic Services' adopted by the IMO by resolution A.857(20).

SOLAS Chapter V (Safety of Navigation) states that governments may establish VTS when the volume of traffic or the degree of risk justifies such services. The value of VTS in navigation safety was first recognised by IMO in resolution A.158 (ES.IV) Recommendation on Port Advisory Systems adopted in 1968. In 1985 IMO adopted resolution A.578 (14) Guidelines for VTS, which said that VTS was particularly appropriate in the approaches and access channels of a port and in areas having high

traffic density, movements of noxious or dangerous cargoes, navigational difficulties, narrow channels, or environmental sensitivity. All decisions were made by the ship's master and the guidelines also highlighted the importance of pilotage in a VTS. Revised guidelines for VTS, including Guidelines on Recruitment, Qualifications and Training of VTS Operators, were adopted as Assembly resolution A.857(20) in November 1997.

A revised SOLAS chapter V on Safety of Navigation was adopted in December 2000, and entered into force on 1 July 2002. Regulation 12 Vessel traffic services states:

- 1. VTS contribute to safety of life at sea, safety and efficiency of navigation and protection of the marine environment, adjacent shore areas, work sites and offshore installations from possible adverse effects of maritime traffic.
- 2. Contracting Governments undertake to arrange for the establishment of VTS where, in their opinion, the volume of traffic or the degree of risk justifies such services.
- 3. Contracting Governments planning and implementing VTS shall, wherever possible, follow the guidelines developed by the IMO. The use of VTS may only be made mandatory in sea areas within the territorial seas of a coastal State.
- 4. Contracting Governments shall endeavour to secure the participation in, and compliance with, the provisions of vessel traffic services by ships entitled to fly their flag.

Nothing in this regulation or the guidelines adopted by the IMO shall prejudice the rights and duties of Governments under international law or the legal regimes of straits used for international navigation and archipelagic sea lanes.

At European level, SafeSeaNet (SSN) was developed as a result of an EU Directive for establishing a Vessel Traffic Monitoring and Information System (2002/59/EC) amended by (2009/17/EC). The SSN system provides a European platform for maritime data exchange between EU maritime administrations promoting co-operation in preventing maritime pollution and accidents at sea. It includes a European Index Server (EIS), which is operated by the European Maritime Safety Agency (EMSA), with member States each having their own SSN applications.

On the basis of IMO Resolution A.949 (23) and following the work carried out jointly by the Commission, the European Maritime Safety Agency and the Member States, it was decided to lay down the basic provisions for accommodating ships in need of assistance in order to ensure a harmonised and effective implementation of this measure and clarify the scope of obligations of the Member States. Directive 2009/17/EC concerns only the amendment of Directive 2002/59/EC, most of the obligations it contains will not be applicable to Member States without sea shores and sea ports. Under this Directive Member States that are coastal States should be able to exchange information, which they gather in the course of maritime traffic monitoring missions. The Community maritime information exchange system SSN comprises a data exchange network, and a standardisation of the main information available on ships and their cargo. Thus it makes it possible to locate at source and communicate to any authority accurate and up-to-date information on ships in European waters, their movements and their dangerous or polluting cargoes, as well as marine incidents. In addition, the confidentiality of information sent to Member States pursuant to this

Directive should be ensured, and the Member States should use that information in compliance with this document.

SSN has undoubtedly improved the way in which information is made available to maritime administrations but will need to be integrated/ synchronised with the Single Window concept (discussed later in Section 3.2). There is an opportunity to increase the effectiveness of SSN by facilitating the flow of information between authorities of different member States in order to reduce the reporting burden (on-board ship), as well as provide vital information to coastal monitoring stations for ships en-route.

2.2.1 Initial developments associated with vessel traffic monitoring

In the maritime transport sector internationally, the concept of the Single Window has been used for some time, initially as Port Single Window to facilitate port state control. In Europe, in the last decade, National Single Windows (NSWs) have been developed to provide a single national interface for mandatory reporting by ships in European waters associated with the Vessel Traffic Monitoring (VTM) Directive (2002/59/EC). One of the main objectives of the VTM Directive is to guarantee that all Member States will be interconnected via the Community maritime information exchange system SSN in order to obtain a complete overview of the movements of ships and dangerous or polluting cargoes in European waters. Development pathways of NSWs differ from country to country but invariably are linked to Port Single Windows², which in turn are increasingly linked with Port Community Systems (PCS)³.

2.3 Navigation

Regulation 13 (SOLAS Chapter V) encourages uniformity in the establishment and operation of aids to navigation. It states that:

- 1. Each Contracting Government undertakes to provide, as it deems practical and necessary either individually or in cooperation with other contracting governments, such aids to navigation as the volume of traffic justifies and the degree of risk requires;
- In order to obtain uniformity in aids to navigation, the Contracting Governments have to take into account the international recommendations and guidelines when establishing such aids;
- 3. Contracting Governments undertake to arrange for information relating to aids to navigation to be made available to all concerned.

² Port Single Windows (PSW) providing information about the vessel to the authorities on a port level, B2A (Business to Administration); similar applications include Single Point of Contact (SPC)

³ Port Community Systems (PCS) supporting exchange of commercial and logistic messages in a port environment, B2B (Business to Business) services; similar applications include Cargo Community System (CCS)

Further work is taking place within the Maritime Safety Committee (MSC) on the "Development of an e-navigation strategy" (81st session MSC). 'The aim is to develop a strategic vision for e-navigation, to integrate existing and new navigational tools, in particular electronic tools, in an all-embracing system that will contribute to enhanced navigational safety (with all the positive repercussions this will have on maritime safety overall and environmental protection) while simultaneously reducing the burden on the navigator. As the basic technology for such an innovative step is already available, the challenge lies in ensuring the availability of all the other components of the system, including electronic navigational charts, and in using it effectively in order to simplify, to the benefit of the mariner, the display of the occasional local navigational environment. E-navigation would thus incorporate new technologies in a structured way and ensure that their use is compliant with the various navigational communication technologies and services that are already available, providing an overarching, accurate, secure and cost-effective system with the potential to provide global coverage for ships of all sizes.'

(http://www.imo.org/ourwork/safety/navigation/pages/enavigation.aspx)

2.4 Automatic Identification Systems (AIS)

Regulation 19 (SOLAS Chapter V) sets out the navigational equipment to be carried on board ships, according to ship type. Ships are required to carry automatic identification systems (AISs) capable of providing information about the ship to other ships and to coastal authorities automatically. The regulation states that AIS is to be fitted on board all ships of 300 gross tonnage and upwards engaged on international voyages, cargo ships of 500 gross tonnage and upwards not engaged on international voyages, and all passenger ships irrespective of size. This requirement became effective for all ships on 31 December 2004.

The IMO requirement defines the information to be supplied and sent by ships as:

- fixed, or static information, which is entered into the AIS on installation and need only be changed if the ship changes its name or undergoes a major conversion from one ship type to another
- dynamic information, which, apart from 'Navigational status' information, is automatically
 updated from the ship sensors connected to AIS equipment voyage-related information,
 which might need to be manually entered and updated during the voyage such as: ship's
 draught; hazardous cargo; destination and ETA; route plan (way-points); the correct
 navigational status; and safety related short messages.

Ships not required to fit AIS, such as pleasure craft and inland navigation vessels, may choose carry AIS on a voluntary basis. The AIS represents a communication system that operates on Very High Frequencies (VHF). The AIS instruments must be permanently in operation, except in some special cases (international agreements, rules or standards provide for the protection of navigational information). The purpose of the AIS is to:

- identify ships;
- help in the target follow-up;

- information exchange simplification, and
- provision of additional information for the purpose of collision avoidance.

The AIS is primarily meant for improving the Vessel Traffic Service (VTS). It realises the aims by means of the following possibilities:

- automatic data transmission to the adequately equipped coastal radio stations, other ships and aeroplanes, data about the identity of the ship, type of the ship, position, its course, speed, navigational state, and other pieces of safety information;
- automatic reception of such pieces of information from similarly equipped ships;
- supervision and monitoring of ships;
- data exchange with coastal radio stations.

A range of other standards have been developed by The International Association of Lighthouse Authorities (IALA), International Telecommunications Union (ITU), and International Electrotechnical Commission (IEC) which are listed in Table 1.

Table 1: Relevant regulations /standards documentation (Navigation)

- 1. ITU Radio Regulations, Appendix S18, Table of Transmitting Frequencies in the VHF Maritime Mobile Band
- ITU Recommendation on the Technical Characteristics for a Universal Ship-borne Automatic Identification System (AIS) Using Time Division Multiple Access in the Maritime Mobile Band (ITU-R M.1371) IMO SOLAS Chapter V, Regulation 19 (2.4) Carriage Requirements for ship-borne navigational systems and equipment
- 3. IMO Resolution MSC.74(69), Annex 3, Recommendations on Performance standards for universal automatic identification system (AIS), 1998
- 4. IMO Resolution A.917(22), Guidelines for the onboard operational use of ship borne automatic identification systems (AIS)
- IMO SN/Circular 227, Guidelines for installation of ship borne Automatic Identification System (AIS)
- 6. IMO SOLAS Chapter V, Annex 9, IMO Performance Standards for Navigational Equipment
- 7. IMO SOLAS Chapter V, Annex 11, Navigation Equipment new Ships
- 8. IMO SOLAS Chapter V, Annex 17, Guidelines to the Operation of AIS on Ships

- ITU-R Recommendation M.1371-1, Technical characteristics for a universal ship borne automatic identification system using time division multiple access in the VHF maritime mobile band, 2001
- ITU-R Recommendation M.1371-1, Technical Characteristics for a Class B ship borne automatic identification system using Carrier Sense Time Division Multiple Access in the VHF Maritime mobile band. (Draft to ITU).
- 11. IALA Recommendation on technical clarifications of ITU-R M.1371-1, Edition 1.4, December 2003
- 12. IALA Guidelines on universal ship borne automatic identification system (AIS), Volume I, Part I, Operational aspects
- 13. IALA Guidelines on universal ship borne automatic identification system (AIS), Volume I, Part II, Technical aspects
- 14. IALA Guidelines on universal ship borne automatic identification system (AIS), Volume II, Basic AIS Services, in preparation the AIS service
- 15. IALA Navguide, Edition 5, 2006
- 16. IEC 61993-2, Automatic identification system (AIS), Part 2: Class A ship borne equipment of the universal automatic identification system (AIS)
- 17. IEC 62287, Class B AIS using CSTDMA technology, CDV available
- 18. IEC 63320-1, AIS Shore Stations, CDV ready in July 2005
- 19. IEC 63320-2, AIS for AtoN, in preparation

Source: IMO

2.5 Long Range Identification and Tracking System (LRIT)

Long-range identification and tracking of ships provides ship identity and current location information in sufficient time for a Government to evaluate the security risk posed by a ship located off its coast, and to respond, if necessary. An active and accurate long-range identification and tracking system also has potential safety benefits, notably for maritime search and rescue. It can also pinpoint the location of a ship in distress as well as ships in the vicinity that could assist and save valuable response time.

SOLAS regulation V/19-1 on LRIT applies to ships constructed on or after 31 December 2008 with a phased implementation schedule for ships constructed before 31 December 2008. The regulation on LRIT establishes a multilateral agreement for sharing LRIT information for security and search and rescue purposes, amongst SOLAS Contracting Governments, in order to meet the maritime security needs and other concerns of such Governments.

The LRIT information that ships are required to transmit include the ship's identity, location and date and time of the position. However, there is no interface between LRIT and AIS so that only those entitled to receive such information will be able to access it and safeguards concerning the confidentiality of those data have been built into the regulatory provisions. Under the regulation, SOLAS Contracting Governments will be entitled to receive information about ships navigating within a distance not exceeding 1000 nautical miles off their coasts.

LRIT information is provided to Contracting Governments and Search and rescue services entitled to receive the information, upon request, through a system of National, Regional, Co-operative and International LRIT Data centres, using the LRIT International Data Exchange. Each administration should provide to the LRIT Data Centre a list of the ships entitled to fly its flag, which are required to transmit LRIT information, together with other salient details and should update without undue delay, such lists as and when changes occur. Ships transmit the LRIT information to the LRIT Data centre selected by their Administration.

Proposals for LRIT of ships, as a means of enhancing maritime security, were discussed during the development of the special measures to enhance maritime security which were adopted by the 2002 SOLAS Conference. It entered into force on 1 July 2004.

A number of specific resolutions have come out of the Maritime Safety Committee of IMO relating to LRIT which are shown in Table 2.

Table 2: Relevant regulation/standards documentation (LRIT)

Reference	Title	Date [adopted]
Resolution MSC.263(84)	Revised performance Standards and functional requirements for the LRIT of ships (revoking MSC.210(81), MSC.254(83)) https://extranet.emsa.europa.eu/images/stories/msc26384 revised performance standards.pdf	16/05/20 08
Resolution MSC.242(83)	Use of LRIT for Maritime Safety and Environment protection purposeshttps://extranet.emsa.europa.eu/download/lrit/MSC 254 (83).pdf	12/10/20 07
Resolution MSC.254(83)	Adoption of amendments to Resolution MSC.210(81)	12/10/20 07
2821st EU Council meeting	EU Council Resolution dated 2 October 2007	02/10/20 07
Resolution MSC.202(81)	Adoption of amendments to the international convention for safety of life at sea, 1974, as amended	19/05/20 06
Resolution MSC.210(81)	Performance standards and functional requirements for the long-range identification and tracking of ships	19/05/20 06
Resolution MSC.211(81)	Arrangements for the timely establishment of the long-range identification and tracking system	19/05/20 06
Resolution	Establishment, updating and retrieval of the information contained in the	25/11/19

A.887(21)	registration databases for the global maritime distress and safety system	99
	(GMDSS)	

Source: IMO

2.6 Global Maritime Distress and Safety Systems (GMDSS)

Global Maritime Distress and Safety Systems is another area which has received considerable attention by the regulators at international level. The GMDSS requirements are contained in Chapter IV of SOLAS on Radio communications and were adopted in 1988. The requirements entered into force on 1st February 1992 but provided for a phase-in period until 1 February 1999. GMDSS is a system based on the linking of Search and Rescue (SAR) authorities ashore with shipping in the immediate vicinity of a vessel in distress or in need of assistance. The main purpose is to automate and improve emergency communications for the world's shipping industry.

The IMO GMDSS Handbook provides an explanation of the principles upon which the GMDSS is based, the radio-communication requirements and recommendations for its implementation, the operational performance standards and technical specifications, and the procedures for and method of operation of the various radio services, which form the GMDSS.

A list of regulations and documentation are shown in Table 3.

Table 3: Relevant Documents Global Maritime Distress and Safety System (GMDSS)

- 1. List of Resolutions adopted by the Assembly, Council, FAL, LC, LEG, LP,
- MEPC, MSC, and TC Committee according to subject headings (12 November 2008), Section
 Maritime Safety
- 3. MSC.131(75) 2002. Maintenance of a continuous listening watch on VHF channel by SOLAS ships whilst at sea and installation of VHF DSC facilities on non-SOLAS ships
- 4. A.954(23) 2003. Proper use of VHF channels at sea
- 5. A.617(15) 1987. Implementation of the NAVTEX system as a component of the world-wide navigational warning service
- 6. A.617(15) 1987. Implementation of the NAVTEX system as a component of the world-wide navigational warning service
- 7. A.524(13) 1983. Performance standards for VHF multiple watch facilities
- 8. A.705(17) 1991. Promulgation of maritime safety information
- 9. A.706(17) 1991. World-Wide Navigational Warning Service
- 10. MSC.148(77) 2003. Revised performance standards for narrow-band direct-printing telegraph equipment for the reception of navigational and meteorological warnings and urgent information to ships

- 11. A.915(22) 2001. Revised maritime policy and requirements for a future global navigation satellite system (GNSS) A.880(21)
- 12. GMDSS Handbook technical details: 720 pp A4, product code: IC970E, ISBN: 978-92-801-4233-4. Also available on CD, product code: DC970E, ISBN: 978-92-801-7012-2., IMO, London
- 13. INTRODUCTION TO THE COSPAS-SARSAT SYSTEM, GC/S G.003
- 14. Issue 5 Revision 1, October 1999
- 15. IEC 60945, Maritime navigation and radio communication equipment and systems General requirements Methods of testing and required test results, October 2002
- 16. IEC 61097-4, Global maritime distress and safety system (GMDSS) Part 4: Inmarsat C ship earth station and Inmarsat enhanced group call (EGC) equipment Operational and performance requirements, methods of testing and required test results, November 1994
- 17. IEC 61097-5, Global maritime distress and safety system (GMDSS) Part 5: Inmarsat E Emergency position indicating radio beacon (EPIRB) operating through the Inmarsat system Operational and performance requirements, methods of testing and required test results, November 1997
- 18. IEC 61907-10, Global maritime distress and safety system (GMDSS) Part 10: Inmarsat B ship earth station equipment Operational and performance requirements, methods of testing and required test results, June 1996
- IEC 61907-13, Global maritime distress and safety system GMDSS) Part 13: Inmarsat F77 ship earth station equipment – Operational and performance requirements, methods of testing and required test results, May 2003

Source: IMO

The IMO Publication 'GMDSS Manual, 2009 edition' provides further detailed information on Radio communications. In addition the Sub-Committee on Radiocommunications and Search and Rescue (COMSAR) was instructed to review elements and procedures of the GMDSS and how they may be may be implemented.

3. Ship to Shore Communications: Administrative

Ship to shore communication and information exchange covers a wide range of reporting formalities required by the harbourmaster, customs and coastguard. Again much of this is covered by a wide range of regulation and legislation at international and European level. These administrative communications are the subject of the Reporting Formalities Directive (2010/65/EU) which requires a national single interface. This is discussed more fully in Section 3.2.

Directive 2010/65/EU repeals Directive 2002/6/EC. For the facilitation of the traffic and to reduce administrative burdens, the reporting formalities required by legal acts of the Union and by Member States need to be simplified and harmonised to the greatest extent possible. This Directive is without prejudice to the nature and content of the information required, and does not introduce any additional reporting requirements for ships not already under such obligation according to

legislation applicable in Member States. It deals only with how the information procedures can be simplified and harmonised, and how the information could be gathered more effectively.

3.1 Reporting Obligations

There are numerous B2A reporting obligations from ship to shore which broadly fall under the categories indicated in Table 4.

Table 4: Declarations for vessel call to port⁴ and EU Directives for Reporting Obligations from ship to shore

Actors	Information	Reporting Obligations
Between ship and	Entry and departure notification;	
harbourmaster:	Inward declaration;	-> Directive 2001/96/EC on Safe loading and unloading (Art. 7(1)b and 7(2)a
	Waste and residues notification;	-> Directive 2000/59/EC on port reception facilities (Article 6)
	 Security notification prior to entry (ISPS); Dangerous goods notification; 	-> Regulation 725/2004, Article 6
	IMO dangerous goods declaration;	-> FAL Form 7, Directive 2002/59/EC, Article 13
	Maritime declaration of Health.	-> International Health Regulations 2005, para 2.4
	Report of Inspection to the master	-> Directive 2009/16/EC Art.17
Between ship and customs:	IMO-FAL declaration: General declaration; Ship' stores declaration; Crew effects declaration; Crew list; Passenger list.	-> Regulation 562/2006, Schengen Borders Code: Article 7, Annex VI (3.1.2; 3.1.4; 3.2.3); FAL Form 6
	Dangerous goods manifest;	-> Directive 2002/59/EC Art. 13; FAL Form 7
	Cargo manifest;	-> FAL Form 2
	Collection of port dues;Collection of cargo dues.	

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⁴ Marnis: Research report on information management for authorities - Volume 4: Background information

Between ship and coastguards:	Entrance in and departure from territorial waters;	-> Directive 2009/16/EC Art. 9 and Directive 2002/59/EC Art. 4
	Report on dangerous cargo;	-> Directive 2009/17/EC on vessel traffic monitoring and information system, Art.12 and Art. 19(2)
	Report on position (AIS, LRIT)	

Source: Compiled by the authors

Many of these obligations are covered by various articles in EU Directives and Regulations. These are listed in more detail in Table 5

Table 5: EU Directives relating to Reporting Obligations from ship to shore

Directive 2000/59/EC generated waste and cargo residues Directive Article 7 (1)(b) – Estimated Time of Arrival (ETA), cargo and ship details Article 7 (2)(a) - Berth loading and unloading details Art. 9(1) Annex III as referred to in Art. 6 – Arrival notification 2009/16/EC Art. 17 - Vessel Inspection report Directive 2009/16/EC Directive Art. 19 - Art. 12 Dangerous/polluting goods declaration 2009/17/EC COM(2009) Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.3) - Regulation of the crew or the number of passengers Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		Reporting obligation
Directive 2001/96/EC Article 7 (1)(b) – Estimated Time of Arrival (ETA), cargo and ship details Article 7 (2)(a) - Berth loading and unloading details Art. 9(1) Annex III as referred to in Art. 6 – Arrival notification 2009/16/EC Art. 17 - Vessel Inspection report Art. 12 - Art. 12 Dangerous/polluting goods declaration Art. 19(2) - Dangerous Goods information COM(2009) Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	Directive	Art. 6 (with specification of notification in annex II) - Notification of delivery of ship-
2001/96/EC Article 7 (2)(a) - Berth loading and unloading details Directive 2009/16/EC Art. 9(1) Annex III as referred to in Art. 6 – Arrival notification 2009/16/EC Art. 17 - Vessel Inspection report Directive 2009/17/EC Art. 19(2) - Dangerous Goods information COM(2009) 11 final Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	2000/59/EC	generated waste and cargo residues
Directive 2009/16/EC Art. 17 - Vessel Inspection report Directive 2009/17/EC Art. 19(1) Annex III as referred to in Art. 6 – Arrival notification 2009/16/EC Art. 17 - Vessel Inspection report Art. 19(2) - Dangerous/polluting goods declaration COM(2009) Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	Directive	Article 7 (1)(b) – Estimated Time of Arrival (ETA), cargo and ship details
2009/16/EC Directive 2009/17/EC Art. 12 - Art12 Dangerous/polluting goods declaration COM(2009) 11 final PAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation 562/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	2001/96/EC	Article 7 (2)(a) - Berth loading and unloading details
Directive 2009/17/EC Art. 12 - Art12 Dangerous/polluting goods declaration Art. 19(2) - Dangerous Goods information COM(2009) 11 final PAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	Directive	Art. 9(1) Annex III as referred to in Art. 6 – Arrival notification 2009/16/EC
2009/17/EC Art. 19(2) - Dangerous Goods information Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	2009/16/EC	Art. 17 - Vessel Inspection report
COM(2009) Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	Directive	Art. 12 - Art12 Dangerous/polluting goods declaration
11 final 2000/59/EC or IMO FAL form 1, general declaration FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	2009/17/EC	Art. 19(2) - Dangerous Goods information
FAL form 2: Cargo Declaration - Arrival FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	COM(2009)	Notification according to Article 4 of Directive 2002/59/EC and Article 6 of Directive
FAL form 2: Cargo Declaration - Departure IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers	11 final	2000/59/EC or IMO FAL form 1, general declaration
IMO FAL form 3, ship's stores declaration IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		FAL form 2: Cargo Declaration - Arrival
IMO FAL form 4, crew's effects declaration Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation S62/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		FAL form 2: Cargo Declaration - Departure
Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation 562/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		IMO FAL form 3, ship's stores declaration
list Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		IMO FAL form 4, crew's effects declaration
Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6, passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 5, crew
passenger list Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		list
Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		Notification according Article 7 of Regulation (EC) No 562/2006 or IMO FAL form 6,
goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI(3.1.4) - changes to the composition of the crew or the number of passengers		passenger list
Form for providing security information prior to entry into a port of a Member State according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI(3.1.4) - changes to the composition of the crew or the number of passengers		Notification according Article 13 of Directive 2002/59/EC or Declaration of dangerous
according Article 6 of Regulation (EC) No 725/2004 Maritime declaration of health Regulation Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI(3.1.4) - changes to the composition of the crew or the number of passengers		goods (IMDG Code chapter 5.4) or FAL form 7: Dangerous goods
Maritime declaration of health Regulation 562/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI (3.1.4) - changes to the composition of the crew or the number of passengers		Form for providing security information prior to entry into a port of a Member State
Regulation 562/2006 Art. 7 - Annex VI (3.1.2) - crew and passenger list Art. 7 - Annex VI(3.1.4) - changes to the composition of the crew or the number of passengers		according Article 6 of Regulation (EC) No 725/2004
Art. 7 - Annex VI(3.1.4) - changes to the composition of the crew or the number of passengers		Maritime declaration of health
passengers	Regulation	Art. 7 - Annex VI (3.1.2) - crew and passenger list
	562/2006	Art. 7 - Annex VI(3.1.4) - changes to the composition of the crew or the number of
Art. 7. Appey VII (2.2.2). Nominal list of grow and passangers including:		passengers
Art. 7 - Armex Vi(3.2.3) - Norminal list of crew and passengers including.		Art. 7 - Annex VI(3.2.3) - Nominal list of crew and passengers including:
Regulation Article 6 (1) - Security info ship intending to enter a port of another Contracting	Regulation	Article 6 (1) - Security info ship intending to enter a port of another Contracting
725/2004 Government	725/2004	Government

Source: http://eur-lex.europa.eu/LexUriServ

3.2 National Single Windows (NSW)

3.2.1 Current EU Reporting Formalities Directive

A Single national interface/ window is now a requirement for maritime as part of the new EU Reporting Formalities Directive (2010/65/EU). This common reference point is a way of ensuring that operators have a single point of contact for all reporting requirements, relating to vessel and cargo movements, and that information is transmitted automatically to various national authorities.

However, interoperability between EU maritime transport information systems has, until recently, been limited, which in turn restricts possibilities for the wider integration of administration-to-business (A2B) services. There is also a general recognition from projects such as eFreight, that a hitherto lack of common reporting (transport document templates), or data structures, as well as an absence of established procedures for data sharing have led to unnecessary reporting duplication.

Directive 2010/65/EU of the European Parliament and of the Council of 20 October 2010 on reporting formalities for ships arriving in and/or departing from ports of the Member States will simplify administrative procedures through the rationalisation of reporting formalities and the general use of electronic means for the transmission of information.

The Directive requires that Member States carry out administrative formalities through an electronic single window by 1 June 2015. Furthermore, this information is to be made available to other Member States via the SafeSeaNet system. The Directive requires a close cooperation between the competent authorities, such as customs, border control, public health and transport authorities in order to continue to simplify and harmonise reporting formalities within the Union and make the most efficient use of electronic data transmission and information exchange systems. It states that the electronic systems of Member States have to be interoperable to a greater extent and by 1 June 2015 to ensure the smooth functioning of the European maritime transport space without barriers.

Ships that operate between ports situated in the customs territory of the Union are exempt from the obligation to send the information referred to in the FAL forms (FAL Convention). Exemptions from administrative formalities are also permitted on the basis of the ship's cargo, not merely on the basis of its destination and/or place of departure. A new temporary form is introduced to harmonise the information required for the prior Declaration of Security provided for by Regulation (EC) No 725/2004. Various legal acts of the Union requiring, for example, pre-notification formalities at the entry into ports, such as Directive 2009/16/EC, may impose different time limits for the accomplishment of these pre-notification formalities. The Commission will examine the possibility of shortening and harmonising these time-limits, taking advantage of ongoing progress in electronic data processing in the framework of the report to the European Parliament and the Council.

The measures defined in this Directive help achieve the objectives of the Lisbon Agenda. Access to SafeSeaNet and other electronic systems will be regulated in order to protect commercial and confidential information. The Member States and the Union institutions and bodies have to pay attention to the need to protect commercial and confidential information through appropriate access control systems.

The 'Single Windows' solution is also intended to facilitate *e-Customs*, which was introduced by 'Decision of the European Parliament and the Council No 70/2008/CE' on a paperless environment for customs and trade. The e-customs vision established an expectation of electronic declarations 'as a rule' on cargo movements between ports and between regional/ national jurisdictions.

The actions recommended by the Ship Formalities Directive (2010/65/EU) will contribute to the achievement of a European maritime transport space without barriers, particularly:

- Article 1 (Harmonising Administrative Procedures) the goal is to simplify the administrative procedures applied to maritime transport by standardizing the electronic transmission of information.
- Article 3 (Commission Member States co-operation) the goal is for the Member States to harmonise their reporting formalities and to co-operate with the Commission for the coordination of reporting formalities within the Union
- Article 5 (NSW) Member States need to implement a single entry point for all reporting obligations, using electronic data transmission.

3.2.2 Data Models

One of the main cornerstones for the development of SWs is the underlying Data Model and associated standard messages. Given the urgency of developing National Single Windows in all EU Member States, a number of projects have been working on such models. Notable examples are:

- the EMS group⁵ the group is to develop specifications and services for the electronic data exchange and single windows; to liaise with national stakeholders, paying also attention to multimodal and multidisciplinary aspects; to encourage the electronic data sharing and services within administrations and businesses. It assists the Commission in the implementation of the Reporting Formalities Directive 2010/65/EU.
- the AnNa project: the EU Member States driven project in close cooperation with the European Commission to support the effective implementation of the ship formalities directive. This project undertakes three major actions 1. Minimum data set based on which the requirements of Directive 2010/64/EU can be nationally fulfilled; 2. National scenarios and mechanisms for gauging national implementation; 3. Framework to identify the opportunities for standardisation and harmonisation. Expected results from some of the activities are: 1. Minimum Maritime Single Window features and capabilities; 2. Technical background and justification; 3. Master Plan June 2015⁶.

⁵ Expert group on Maritime administrative simplification and electronic information services, DG MOVE

⁶ See more details at: http://www.annamsw.eu/about.html

4. Port Communications

'Port' Single Windows have been around for a while now to facilitate information exchange within individual ports, but still need to become more widespread, particularly for smaller ports. The port single window should also be interfaced to the national or European level single windows. The main issue here is the information content. This standard may be national, but a European level standard is probably more appropriate. Consideration should also be given to the interface between ship/logistics and port single window. This should also cover the mechanisms by which the interface is made, e.g., through XML messages over electronic mail.

Standardisation of such processes and information would make it much easier to provide small ports with efficiency-enhancing tools at reasonable prices. It would also allow larger customer groups greater functionality for lower cost.

Many port and wider logistics information exchanges are taking place using various Port Community Systems (PCSs). Port Community Systems exchange messages in a wider port environment, having a commercial and logistic nature. These have a primarily B2B (Business to Business) purpose.

4.1 Electronic Port Clearance (EPC)

The IMO Facilitation Committee (FAL) decided in April 2013 to list ISO 28005 as a reference for XML based electronic port clearance systems in the FAL Compendium.

ISO 28005, "Security management systems for the supply chain – Electronic port clearance (EPC)"7, currently consists of two parts: Part 1 is "Message structures - Implementation of a maritime single window system" and part 2 is "Core data elements". ISO/PAS 28005-1:2012 allows different configurations of the single window (SW), from a minimum solution to support basic clearance requirements to a more complex system to facilitate more extensive cooperation between ship and shore organisations.

The standard has been developed through a number of EU-projects; finally eMS has been responsible for the finalisation of the standard and the work towards IMO FAL approval.

5. EU Transport Policy Developments

5.1 General Maritime Policy Developments

The EU maritime transport strategy 2018 recommends actions that will sustain the long-term competitiveness of the European shipping industry and cost-effective services⁸. Its strategic goals support also the developments of the EU integrated maritime policy.

Moreover, "The sustainable future for transport: Towards an integrated, technology-led and userfriendly system⁹ defines actions for the establishment of an intelligent and integrated logistics system, where development of ports and intermodal terminals as a key element becomes a reality.

⁷ http://www.iso.org/iso/catalogue_detail.htm?csnumber=61323

⁸ http://ec.europa.eu/transport/themes/strategies/2018_maritime_transport_strategy_en.htm

Also the EU Maritime Transport Space without barriers aims to simplify administrative procedures for maritime transport¹⁰ and will be further developed into a "Blue Belt" of free maritime movement in and around Europe. More policy developments that will support the blue economy and the e-MAR technology will facilitate the necessary changes are as follows:

- 1. A Commission initiative on maritime spatial planning and integrated coastal zone management;
- 2. A Common Information Sharing Environment (CISE)¹¹ for the surveillance of the EU maritime domain;
- 3. The Marine Strategy Framework Directive which introduces an ecosystem-based approach;
- 4. Actions in education and training financed by "Erasmus for All programmes" such as Knowledge Alliances and Sector Skills Alliances. It refers to instruments for facilitating the mutual recognition of skills and qualifications such as European Qualifications Framework (EQF)¹², and better anticipation of skills and labour market needs through European Sector Skills Councils and the EU Skills Panorama;
- 5. At a research level the future Horizon 2020 programme will target research and innovation on green transport, climate action and resource efficiency.

All these initiatives support further the development and progress of the Integrated Maritime Policy in the European Union and launch a process, which places the "blue belt" firmly on the agenda of the Member States. As a result, the Commission adopted Regulation (EU) No 177/2010 introducing streamlined procedures for the so-called "regular shipping services" (RSS) performed by authorised companies. Another part of the same policy is the e-Maritime initiative, which aims to foster the use of advanced information technologies for the maritime transport sector (in support of this initiative Directive 2010/65/EU was introduced).

In a broader context, the 2011 White Paper for the future of transport¹³ advocates a Single European Transport Area in which all residual barriers between modes and borders are to be eliminated. The Roadmap to a Single European Transport Area calls for the waterborne and rail sectors to absorb a 50% shift of medium-distance intercity passenger and freight traffic from roads by 2050. Also it calls for a Blue Belt in the seas around Europe, which would simplify the formalities for ships travelling between EU ports.

Furthermore the Digital Agenda for Europe (DAE) aims to help citizens and businesses of Europe to get the most out of digital technologies and deliver smart sustainable and inclusive growth. It contains 101 actions that are grouped in seven priority areas; encourages the use of digital technology and its business applications; create new public service infrastructures through

⁹ COM(2009) 279

¹⁰ COM(2009) 10

¹¹ COM(2010) 584

¹² http://ec.europa.eu/education/lifelong-learning-policy/egf_en.htm

¹³ COM(2011) 144 final

Connecting Europe Facility Fund¹⁴. It also addresses the issues of data security in the case of information flow exchanges between businesses and authorities.

Intelligent Transport Systems (ITS) Action Plan and Directive 2010/40/EU accelerate the deployment of innovative transport technologies across Europe. The aim is to establish interoperable and seamless ITS services for road transport and its interfaces with other modes of transport. Commission Regulation (EU) No 305/2013 supplements Directive 2010/40/EU to establish a harmonised provision for an interoperable EU-wide eCall¹⁵. The offered innovative solutions of e-Mar project will take into consideration the requirements of the ITS action plan.

Different regulatory requirements and liability regimes on regional and global levels exist simultaneously. In the maritime industry three different sets of rules have been utilised (The Rotterdam Rules; the Hamburg Rules and the Haque Rules). Various clauses have been developed over the years that have to be deemed too in developing the innovative e-Mar solutions.

5.2 Blue Belt: a Single Transport Area for shipping 6 - development of eManifest

Information relating to cargo, which is required by customs and other authorities are collected via a cargo declaration or "cargo manifest" transmitted by the shipping company. Despite the adoption of a standardised cargo declaration in the FAL Convention and the existence of an electronic format there is no harmonised structure for the cargo manifest agreed by the Member States to be used for electronic administrative clearance systems.

The electronic cargo 'eManifest' with information on the status of goods is considered a practical solution to achieve this. The eManifest would take the form of a harmonised and electronic cargo manifest further facilitating maritime transport for vessels calling at EU and also at third country ports¹⁷ by:

- Re-use of data previously provided
- Eliminating double/ triple reporting of same data to different authorities in departure/ arrival port of a ship

The eManifest will be implemented in a phased approach:

- Proof of Union Status and "Identification of post-Export goods" and the requirements of the maritime authorities are in the first phase
- Improvements for supply chain security (processes, interaction with Import Control Systems and data) will designed from the outset but implement in subsequent phases

¹⁴ http://ec.europa.eu/digital-agenda/digital-agenda-europe

¹⁵ http://ec.europa.eu/transport/themes/its/road/action_plan/

¹⁶ COM(2013) 510 final

¹⁷ Considerations for the Implementation of the eManifest; eManifest V1.0 Brussels, 13 September 2013

When the eManifest is lodged in a EU port, the Union status of the goods on board will be indicated and, if confirmed, customs controls would no longer be needed for Union goods apart from random checks. For the Proof of Union status, status information will be entered in the eManifest. The credibility of the information is either ensured by an Authorised Consignor for the Proof of status, or by endorsement of the status by customs.

Goods loaded at non-EU ports would by definition be non-Union goods and be mentioned as such on the eManifest. In addition, if a vessel calls at a third country port between two EU ports but Union goods remain on board, the goods will maintain their status as declared upon departure from the last EU port.

6. The EU and World Customs Organisation Regulatory Framework

Security measures for the customs were undertaken in 2003¹⁸ by the European Commission. The security amendment to the Community Customs Code was introduced in 2005 with three major changes:

- Requirement for providing information to the customs authority about the goods prior to the import to and export from the EU;
- Providing traders with trade facilitation measures (Authorised Economic Operator programme);
- Introduction of uniform Community risk-selection criteria for controls¹⁹.

This security amendment to the Code was fully implemented in 2006 and set out the operational details of the customs processes:

- A Common Risk Management Framework (CRMF) for the customs authorities to improve the risk-based control;
- Provisions for the Authorised Economic Operator programme;
- Providing customs with advanced information on goods brought into, or out of the European Union.

The amendment of the Code also serves to:

- Introduce electronic information exchange between customs administrations;
- Rationalise customs control, concentrating on safety and security at the place of entry or exit of goods into the Community;

Since January 2011, the advanced information declaration has been an obligation for companies trading goods, which means that all safety and security data has to be sent in advance, if not, the goods have to be immediately declared at the border of arrival. This usually avoids any delays of the customs clearance of consignments.

The EU Customs Security Programme (CSP) covers the implementation of all security measures, particularly the commonly agreed control standards and risk indicators, as well as the trade facilitation programme.

The Authorised Economic Operator status can be granted to any economic operator established in the EU as this certificate brings simplification of the customs rules and facilitates the customs control

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¹⁸ COM(2003) 452

¹⁹ See Regulation 648/2005

related to safety and security. There are different categories of AEO, so the type of certificates varies in accordance with the AEO category²⁰.

The WCO has developed the SAFE Framework of Standards to harmonise different sets of requirements of national customs administrations as a step to automate risk management activities (see Table 6). The WCO and the EU try to harmonise customs rules and simplify requirements. The EU's overall objective in its international relations is mutual recognition and reciprocity of security controls and standards and of business partnership programmes.

Table 6: WCO SAFE Framework of Standards

Group of Standards	Explanation
1.	Advance Electronic Information (to indentify high-risk shipments)
2.	Common targeting criteria and compatible communication
3.	Risk management systems
4.	Outbound security inspections at request of counterpart
5.	Modern inspection equipment
6.	Cargo Inspection Authority
7.	Integrated supply chain management
8.	High-risk cargo/container
9.	Performance measures
10.	Security assessments

Source: World Customs Organisation, 2011

6.1 External Trade Statistics

Extrastat Commission Regulation (EC) No 1917/2000²¹ Article 23 and 24 (amended by Commission Regulation (EC) No 1949/2005) deals with goods delivered to vessels. This concerns nearly exclusively exports. Goods intended for the consumption (by person & engine) on board of foreign vessels at national harbours or airports are reported with the simplified CN codes. The transmission of these CN codes to Eurostat is mandatory. Intrastat National Statistical authorities request from trade operators to provide data on goods delivered to vessels according to the specific CN codes.

Extrastat National Statistical authorities have the following possibilities:

²¹ http://eur-lex.europa.eu

²⁰ Guidelines on AEO

- direct collection of the CN codes via Customs;
- direct collection of the information via trade operators

Specific reporting procedures are applied for deliveries of products for the crew as well as for the operation of engines, machines and other equipment of vessels. It does not matter whether the vessels are managed or used for commercial, military or private purposes.

The codes ²²to be used in respect of exit ship supplies summary declarations should be the following codes, as defined in Article 24 of Regulation 1917/2000:

99302400: goods from CN chapters 1 to 24;

99302700: goods from CN Chapter 27;

99309900: goods classified elsewhere.

6.2 WCO Globally Networked Customs developments

The WCO Members recognised and confirmed the importance of connectivity. The Globally Networked Customs provides an overarching framework through which WCO members can apply a common and coordinated methodology to develop strategic and operational blueprints based on existing tools. This facilitates inter-connectedness among customs administrations via exchange of information arrangements.

7. The EU and World Health Organisation Regulatory Framework

Codex Alimentarius (Codex) created by the UN Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) develop food standards, guidelines and related texts such as codes of practices under the Joint FAO/WHO Food Standards to protect the health of customers, ensure fair trade practices in the food trade, and promote coordination of food standards by international organisations.

Any manufacturer that transports goods to another country within the EU has to comply with the EU Plant Health Regime. The overall aim of the EU plant health legislation is to ensure protection against harmful organisms that affect plants or plant products. This regime was established by Directive 2000/29/EC, which contains all measures and actions to be taken to prevent the introduction into and the spread within the EU. The Directive was amended in 2002 and introduced:

- improved import clearance procedures;
- harmonised fees for phytosanitary import inspections;
- updated some provisions of the Directive that build on international experience and instruments.

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²² TAXUD, Guidelines on Specific Commodity codes for air and ship supplies

Also manufacturers of wood packaging must meet the *International Standards for Phytosanitary Measures 15 (ISPM*15). The Regulation specifies the procedures used prior to export. The National Plant Protection Organisation (NPPO) of the exporting country has responsibility for ensuring that systems for exports meet the requirements set. It includes monitoring certification and making systems that verify compliance, and establishing inspection procedures. Exporters have to follow *ISPM 7: Export certification system, registration or accreditation and auditing of commercial companies* that apply the measures.

Since wood packaging materials are associated with almost all shipments, including those not normally the target of phytosanitary inspection, cooperation with agencies, organisations, etc. not normally involved with meeting phytosanitary export conditions or import requirements is important.

ISPM 7: Export Certification System – as part of the International Plant Protection Convention (IPPC), this standard requires all contracting parties to make arrangements to issue phytosanitary certificates that comply with the regulations of other contracting parties.

According to the Technical Regulation on Safety of Food Products from December 2011²³, non-processed food products of animal origin is subject to a veterinary and sanitary expertise before being issued into circulation on the customs territory of the EU unless otherwise established by the technical regulations, and has to be accompanied by a document containing information confirming its safety. Veterinary and sanitary expertise of non-processed food products has to be conducted with the purpose of:

- 1) establishment of conformity of the food products and the processes of production, storage, shipment, realisation and utilisation associated with the safety requirements;
- 2) establishment of veterinary security of production facilities;
- 3) the veterinary and sanitary expertise has to be conducted and its results registered in accordance with the laws of the EU member state as well as the Agreement of the Customs Union on veterinary and sanitary measures.

The European Commission has adopted on 6th May 2013 a package of measures to strengthen the enforcement of health and safety standards for the whole agri-food chain. The new rules follow a more risk-based approach thus allowing competent authorities to focus their forces on the more relevant issues. Member States will also be asked to fully integrate anti-fraud checks into their national control plans and to ensure that financial penalties in these cases are set at truly dissuasive amounts. More focus will be placed on high-risk trade coming from third countries and increased traceability of planting material on the internal market. Other institutions, including the European Parliament and the Council will consider the Commission's package of measures and will adopt their positions in due course. It is estimated that the package will enter into force in 2016.

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²³ See Technical Regulation of the Customs Union, http://ec.europa.eu/food/international/trade/docs/sps 880 en.pdf

7.1 ISO 22000 – Food Safety Management systems

ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by Codex. This international standard requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used are identified and assessed. ISO 22000 has been aligned with ISO 9001 (Requirements about the Quality management system). The ISO 22000 family contains a number of standards each focusing on different aspects of food safety management:

- ISO 22000:2005 overall guidelines for food safety management
- ISO/TS 22004:2005 guidelines for applying ISO 22000
- ISO 22005:2007 traceability in the feed and food chain
- ISO/TS 22002-1:2009 prerequisites for food manufacturing
- ISO/TS 22001-3:2011 prerequisites for farming
- ISO/TS 22003:2007 guidelines for audit and certification bodies

As many of today's food products cross national borders, international standards ensure the safety of the global food supply chain. In the EU, the European Food Safety Authority (EFSA) is responsible for the risk assessment regarding food and feed safety.

7.2 EU Veterinary Border Control

Since 1991 the EU has provided a harmonised legal framework for animal transportation by means of the adoption of Regulation (EC) 1/2005, in order to provide a level playing field for transport operators while ensuring a protection to the transported animals. Regulation 1/2005 amends Directive 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97. The Regulation applies to the transport of vertebrate animals transported in connection with an economic activity. The details of this Regulation mainly concern farmed animals such as cattle, pigs and horses and does not take the transport of other species such as dogs, cats, poultry, animals kept for scientific purposes and exotic species, into account.

Live animals or product of animal origin can only enter into the EU, if it has satisfactorily undergone the specific checks and a Common Veterinary Entry Document (CVED) is issued. There is a comprehensive body of EU legislation in place that deals with the veterinary border control (see Table 7 below)

Table 7: EU Legislation dealing with veterinary border control

Regulation/Directive/Decision	Explanation
Decision 2012/31/EU	Amending Annex I to Decision 2007/275/EC concerning the lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC
Regulation (EU) No 28/2012	Laying down requirements for the certification for imports into and transit through the EU of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009
Regulation (EU) No 809/2011	Amending Regulation (EC) No 2074/2005 as regards documentation accompanying imports of frozen fishery products directly from a freezer vessel
Decision 2011/215/EU	Implementing Council Directive 97/78/EC as regards transhipment at the border inspection post of introduction of consignments intended for import into the EU or for third countries.
Regulation (EU) No 142/2011	Implementing Regulation (EC) No1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive.
Regulation (EC) No 1069/2009	Laying down health rules as regards animal by- products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Decision 2009/821/EC	Drawing up a lsit of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces.
Regulation (EC) No 206/2009	Introduction into the Community of personal consignments of products of animal origin and amending Regulation (EC) No 136/2004.
Decision 2007/275/EC	Concerning list of animals and products to be subject to controls at border inspection posts under Council

	Directives 91/496/EEC and 97/78/EEC.
Regulation (EC) No 1/2005	Protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
Regulation (EC) No 882/2004	Official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
Council Directive 2004/68/EC	Laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC.
Regulation (EC) No 282/2004	Introducing a document for declaration of, and veterinary checks on, animals from third countries entering to the Community.
Regulation (EC) No 136/2004	Laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries.
Regulation (EC) No 998/2003	On the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC
Council Directive 2002/99/EC	Laying down the animal health rules governing production, processing, distribution and introduction of products of animal origin for human consumption
Decision 2001/812	Laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products intoduced into the Community from third countries.
Directive 97/78/EC	Laying down the principles governing the organisation of veterinary checks on products entering the Community from third country.
Decision 94/360/EEC	On the reduced frequency of physical checks of consingments of certain products to be implemented from third countries, under Council Directive 90/675.
Council Directive 92/65/EEC	Of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not

	subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 92/425/EEC
Council Directive 91/496/EEC	Laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries.

Source: http://ec.europa.eu/food/animal/bips/legis_en.htm

7.3 Current rules applicable for importing Active Pharmaceutical ingredient (API) into the EU (medicinal products for human use)

According to Directive 2001/83/EC, marketing authorisation holders in the EU are required to use active substances that are produced in accordance with the principles of Good Manufacturing Practice (GMP). Qualified Person (QP) signs a declaration stating that the active substance is manufactured in compliance with the detailed guidelines on GMP. If the active substance is imported into the EU, the importer (the finished product manufacturer) must ensure that the products have been manufactured in accordance with the standards. Based on the Directive 2011/62/EU and as one of the measures to fight against the falsified medicines that might be imported in the EEA (started from July 2013)²⁴, the EU authorities will require a GMP certification for every API imported into the EU. The certification should be issued by competent authority of the exporting country. The EU regulatory framework holds EU-based finished product manufacturers legally responsible for ensuring the full compliance with the newly published rules for API import.

7.4 International Health Regulations (IHRs) 2005

Ship Sanitation Control Exemption Certificate /Ship Sanitation Control Certificate are issued by the Authority to identify and record all areas of ship-borne public health risks and the required control measures to be applied. The certificates that are concerned with disease in a wider sense encompass both infection and contamination. The IHRs 2005 provide for ships engaged in international journeys to be issued with:

- Ship Sanitation Control Exemption Certificates where public health authorities have inspected a ship and found no evidence of infection or contamination, or of vectors or reservoirs of infection and contamination or of microbiological, chemical and other risks to human health, or signs of inadequate sanitary measures); or with
- Ship Sanitation Control Certificates (where the public health authorities are satisfied that procedures necessary to rid the ship of infection, contamination and/or their vectors/reservoirs have been effectively carried out).

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²⁴ See Guidelines from 7th March 2013 on Good Distribution Practice of Medicinal Products for Human Use

Prior to the arrival at the designated port, the Authority has to be presented with relevant documentation to assist with the completion of the Ships Sanitation Inspection. The documents to be presented are: 1) International Ship Port Security Notification (ISPS); 2) Port waste notification; 3) A copy of previous Ships Sanitation Certificate; 4) Maritime Declaration of Health.

A Maritime Declaration of health is the form used to provide information as follows: details of the ship; status of any Ship Sanitation Certification; number of passengers; previous ports visited; health questions, incl. whether anyone has died on board, anyone is sick, there is any case of disease which could be infectious and there is any condition that could lead to the spread of disease. This information ensures compliance with Article 37 of the IHRs 2005.

Health officials may grant quarantine clearance (pratique) provided the following are true:

- The Advance Notice of arrival form is received within the prescribed time;
- A "no change of health status" message is received within 12-24 hours of arrival;
- The Medical officer of Health or a Health Protection Officer is satisfied there is no quarantinable disease or other public health threat on board the ship.

The Medical Officer of Health will liaise with the incoming vessel prior to arrival to determine whether any measures are required to manage potential public health risks.

8. Development of legislation, regulation and standards

8.1 International scope

The e-Maritime concept is not confined to the European domain and as shipping is international, the aim should be for international standards where possible such as International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC). It should be noted that the World Trade Organization favours international standards over regional [WTO95]. Where it is more practical to implement legislation on a European level, it is generally recognized that European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) correspond to ISO and IEC.

Standards could also be developed independently of the standards organisations. Such standards are commonly referred to as "de facto" standards but do not have the same 'gravitas' as those which emanate from the official bodies.

8.2 Stakeholder buy-in

Buy-in requires involvement of relevant user groups at an early stage in terms of dissemination and demonstration of viability of regulation and standards. The fragmentation of the industry is such that there is no small group of organisations which encapsulates the majority of stakeholders.

Active user buy-in will ensure more rapid adoption of the e-Maritime concept at a much lower cost than if it has to be done through administrations and authorities alone. However, buy-in also requires that the benefits are clear and sufficiently large to defend necessary changes in organisations. It may be easier to get the concept adopted if it is done at an international level (See Section 8.1).

8.3 Trust and Transparency

An important development in the maritime industry is the increase of transparency, as seen by the voluntary reporting of more information such as:

- The introduction of Long Range Identification and Tracking.
- Voluntary reporting regimes such as Shipping KPI²⁵, Environmental impact reports or Tanker Management Self Assessment (TMSA).
- Increased port state control through Paris MoU and other similar agreements.
- Increased national and trans-national cooperation through, e.g., SafeSeaNet, port to port information exchanges, Equasis and other systems.

Transparency will, in most cases, lead to higher degrees of trust. e-Maritime, through this increased trust and better information availability can contribute significantly to more efficient legislation, contractual relationships and simplification of reporting requirements.

An important part of e-Maritime should be to provide mechanisms by which legislation could be semantically coded so that one can implement electronic systems to verify compliance with international, national and local laws and byelaws.

8.4 Quality of Information

There is in general no lack of information in the maritime domain today, but the problem is one of the quality and systematic retrieval of the data. This is similarly the case in ports, in shipping companies and in administrations. The situation is improving, but standard information models will be critical.

8.5 Enabling technologies

Standards will play an important role as the maritime business is an international activity and both plain interfacing and common understanding of information elements are necessary.

Surveillance and administrations' communication networks should also use standards. On the information exchange level, between regions or states, information models that can serve as common frameworks are needed. Also, standard data models and possibly messaging standards for exchange of information are needed in order to increase public-private cooperation.

Standards are also needed in the domain of e-Customs and e-Freight, but these standards should preferably be developed in those domains. Already, the WCO (World Customs Organisation) has developed a common data model for much of the customs clearance requirements world wide.

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²⁵ www.shipping-kpi.com

8.6 Systems Integration

SSN, e-Customs and other database systems basically represent information management and value adding services. So far, these systems have been based on a closed network between certain types of authorities so interoperability issues have been dealt with through design features in the respective systems and/or legislation. Thus, the syntax and semantics of information elements and services is fully defined by the context of the service and/or information used.

However, if the ambitions are to improve integration between systems and/or include other parties than authorities, one will need to consider at least information exchange standards. This may include information models, message formats and other features.

Information exchange between other administration parties should be included, such as flag state registries, port state control registers, conditions of class, certificate related information etc.

8.7 Safety, security and environmental risk management

Three types of standards are required to implement such applications:

- Information models to ensure accurate capture of compliant data into the applications so that reliable results can be provided. This applies to assessment, forecasts, statistical analysis and other features of such systems. Reliable input to the systems is necessary to provide useful results.
- Well defined rules for the calculation of safety, security and environmental risk. Some of this
 may be part of the e-Navigation domain, but standards should also be considered on EU
 level.
- Standard process definitions for the assessment of safety, security and environmental risks.
 Results of the assessments or forecasts could be used to influence existing processes and without a reference for such processes, different parties will reach very different conclusions.

In this context it should be noted that legislation and various authorities' regulations make references to entities in the maritime domain without a properly defined vocabulary. A dictionary of terms (ontology) would make it possible to provide semantically coded legislation in electronic format.

8.8 National single windows and port application

In terms of the development of National Single Windows (NSWs), the standards need to cover the following components:

 Message standards for ship to port state and port for clearance of ships. UN/CEFACT standards exist for most FAL forms, but these are not suitable for all ports and types of ships.
 New messages may also have to be developed to fit into new work processes in e-Maritime.

- Process standards for clearance. Currently, the implicit process standard is based on the FAL forms, but no clear semantics for exchange of clearance requests and acknowledgements are defined.
- Interface between national single window and port single window.
- Interface between ship/logistics and port single window.

8.9 Privacy, protection, and security of data

A prerequisite for trust and acceptance of these systems is that appropriate data protection measures are put in place against possible misuse and other data related risks. At the same time it is accepted that as different technologies do become the norm it affects the way in which we understand privacy. In this respect there must be continuous monitoring of the privacy and data protection through consultation and dialogue, and provision of guidance or regulation.

Information security is a major concern for most stakeholders. The security question is closely linked to that of trust and privacy mentioned above. It is recognised that such issues are often neglected at the design phase, and that integrating such features at a later stage is often costly and features to safeguard them at a later stage creates difficulties, is costly and can compromise the quality of the system. It is therefore essential that IT based components are designed from their inception with a privacy- and security-by-design mindset and comprehensively include user requirements.

Giving users a sufficient level of control improves their level of trust and plays an important role in the uptake of the technology.

9. Conclusions

The Deliverable 1.2 has three main objectives as per Description of Work. It aimed to present:

- 1) The regulatory regimes of international bodies and EU institutions;
- 2) Standardisation requirements and development strategies at EU and international level;
- 3) A review the transport policies that impact eMAR.

The report has examined current policy, legislation and standards and various requirements in order to facilitate the e-maritime agenda. More specifically, it has considered ship, ship-shore and port communications in the navigation, monitoring and administrative domains. Whilst there is extensive regulation in terms to operations, more work is needed to address the particular issues of information exchange. Co-operation, integration, standardised definitions and processes are common themes in the development of this agenda. Policy and legal development must also take account of issues of transparency, security of information and confidentiality issues. Regulation is

required to ensure that these issues are taken seriously and that there is some element of legal redress. Chapter 8 of this document explained these considerations in detail.

Moreover, the report has presented an extensive view of international and regional regulations, standards, policies and strategic developments that will have an impact on eMAR (see Appendix II, page 38). The standardisation requirements of International Maritime and Regulatory bodies create the technical framework within which the eMAR standard messages would be developed. The main chapters that focus on legal technicalities and frameworks are Chapter 2, 3, 4, 6 and 7. By Description of Work the standard messages are part of the e-Maritime Strategic Framework²⁶, which take into consideration these standards, risk management and operational concepts, processes and systems pertaining to the European transport system. The eMAR standard messages are expected to become legal requirements in the future. The project team is aiming to propose suitable candidates of messages to go through a full standardisation process. Also an appropriate strategy will be implemented for achieving either formal or de facto standardisation, which includes approaching the most suitable standardisation bodies.

Standardisation will play an important role in the uptake of new technologies. Standards need to be monitored to ensure that they are developed in an open, transparent and consensual manner with adequate participation of stakeholders. The e-Maritime concept is relevant to the international maritime industry and thus the aim, as far as possible, should be for international regulation and standards in consultation with international partners.

Suggested standards were discussed as part of the SKEMA Periodic Review of e-Maritime Initiative and a list is produced in the Appendix I: Summary of identified standards, page 36 of this document. The list presents a preliminary view of potential standards to be proposed.

Additionally, this Deliverable 1.2 has reviewed the EU transport policies that have a significant impact on e-Mar, particularly EU Maritime Transport Space without barriers and the "Blue Belt" for future free movements in and around the EU coast. The main chapter that focuses on policy developments is Chapter 5. The implementation of the eManifest application will be able to contribute to the development of the free movements and we recognise its importance for the eMAR project. When the eManifest is lodged in an EU port, the Union status of the goods on board will be indicated. When this is confirmed, customs controls would no longer be needed for Union goods apart from random checks. All status information will be entered in the eManifest.

This policy analysis further concludes that the eMAR project is in line with the EU policy initiatives that address issues relating to the standard framework for information exchange, the national single window and the single transport document. The eMAR project will encourage the use of electronic communication between stakeholders in order to make the European maritime industry more efficient, safe and environmentally friendly. It will improve information use; knowledge creation; dissemination of new concepts; business process collaboration and overall competitiveness of the

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²⁶ See Deliverable 1.3

shipping business. The e-Maritime platform will be based on electronic standard messages that will become legal standards in the future and on EU directives. Although it is recognised that this project lays down the foundations for the electronic messaging in this sector, it is clear that there will still be a great deal of work for clarification after the project is completed.

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<u>www.iec.ch</u> – International Electrotechnical Commission

www.iala-aism.org - The International Association of Lighthouse Authorities

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Appendix I: Summary of identified standards (adapted from SKEMA Periodic Review e-Maritime)

LIST OF POSSIBLE eMAR STANDARDS

Contents	Type and scope	Domain (Ship, Port, Logistics, Administration)
A general reference model or architecture for e-Maritime, defining roles, functions, processes, domains etc. Should be based on ARKRANS and MarNIS work. This should be a relatively high level model on which more detailed standards can be built. However, process models need to contain sufficient detail to ensure interoperability between the domains in e-Maritime.	Reference, de facto	All
Legal dictionary/Ontology for legal documents and commercial contracts	Reference, International	Administration
New standard contracts to make use of improvements in realisation e-Maritime.	Interoperability, EU/International	Transport and logistics
Standardised radio-communication facilities near shore and in port. Both frequencies and protocols must be agreed on.	Interoperability / Performance, EU/International	All
New work processes for integrated operations between maritime parties: Commercial part.	Process, de facto	All
New work processes for integrated operations between maritime parties: Administration part.	Process, EU legislation	All
Information model for interoperability between administrations' information networks and databases (SSN, SSN++, other surveillance and information networks). Can also be used for private-public data exchanges (see also single window standards).	Interoperability, International/EU	Administration, All
Service oriented architecture or similar standards for access to distributed services in the e-Maritime domain (see work done in Efforts).	Interoperability, EU/International	All
Standard assessment criteria for safety, security and environmental risk, based e.g., on Shipping KPI.	Performance, EU/International	Administration All
National single window implementation standard, implementation guideline or similar. Should also	Performance Interoperability	Administration, Ship,

consider port to port or similar exchanges.	International/EU	Port
Information and message models to fit the standard	Interoperability	Administration, Ship,
SW implementation guideline. Can be based on ISO	International	Port
28005-2		
Information and message models for interface	Interoperability,	Administration Port
between national/European single window and port	EU	
single window.		
Information and message models for interface	Interoperability,	Ship, Port
between ship and port single window.	EU/International	
Reference technical architecture for shipboard	Interoperability	Ship
monitoring and control systems with corresponding	International/EU	
information models (navigation, automation, safety		
etc.)		
Information models and message standards for	Interoperability	Ship Administration
electronic reporting and logging on board ships.	International/EU	
Information and message models for inter-domain	Interoperability,	Ship, Logistics
ship to shore communication (ship, owner, technical,	International/EU	
administrative etc.)		
Information and possibly message models for other	Interoperability,	Ship, Logistics
intra-domain communication. Scope needs to be	International/EU	
considered. e-Freight must be part of the framework.		
Performance standards for crew communication.	Performance,	Ship
	EU/International	
Information and message models for inter-domain	Interoperability,	Ship, Logistics
ship to shore communication (ship, charter, owner,	International/EU	
technical, administrative etc.)		

Appendix II: Summary of International Institutional Legislations and Standardisation Requirements

International	IMO – International	EU –	WCO –	WHO / ISPM –	ISO – Intern-
Institutional	Maritime	European	World	World Health	ational
Legislations	Organisation	Union	Customs	Organisation	Standardisa-
\rightarrow			Organisation	_	tion
			_		Organisation
\Leftrightarrow					_
Industry					
Dimension					
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Navigation	1. ITU Radio				
	Regulations,				
	Appendix S18				
	2. ITU				
	Recommendation on				
	the Technical				
	characteristics for a				
	Universal Ship-borne				
	Automatic				
	Identification System				
	(AIS) Using Time				
	Division Multiple				
	Access in the				
	Maritime Mobile				
	Band (ITU-R M.1371)				
	IMO SOLAS Chapter				
	V, Regulation 19				
	(2.4)				
	3. IMO Resolution				
	MSC.74(69), Annex				
	3, Recommendations				
	on Performance				
	standards for				
	universal automatic				
	identification system				
	(AIS), 1998				
	(113), 1330				
	4. IMO Resolution				
	A.917(22) Guidelines				
	for the onboard				
	operational use of				

ship borne automatic identification system (AIS) 5. IMO SN/Circular 227, Guidelines for installation of ship borne AIS		
6. IMO SOLAS Chapter V, Annex 9, IMO Performance Standards for Navigational Equipment		
7. IMO SOLAS Chapter V, Annex 11, Navigation equipment new ships		
8. IMO SOLAS Chapter V, Annex 17, Guidelines to the Operation of AIS on Ships		
9. ITU-R Recommendation M.1371-1, Technical characteristics for a universal ship borne automatic identification system using time division multiple access in the VHF maritime mobile band, 2001		
10. ITU-R Recommendation M.1371-1, Technical characteristics for a Class B ship borne automatic identification system		

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	using Carrier Sense Time Division Multiple Access in the VHF Maritime mobile band			
	11. IALA Recommendation on technical clarifications of ITU-R M.1371-1, Edition 1.4, 2003			
	12. IALA Guidelines on universal ship borne AIS, Vol. I, Part I, Operational aspects			
	13. IALA Guidelines on universal ship borne AIS, Vol. I, Part II, Technical aspects			
	14. IALA Guidelines on universal ship borne AIS, Vol. II, Basic AIS Services			
	15. IALA Navguide, Edition 5, 2006			
	16. IEC 61993-2, AIS, Part 2: Class A ship borne equipment of the universal AIS			
	17. IEC 62287			
	18. IEC 63320-1 AIS Shore stations			
	19. IEC 63320-2, AIS for AtoN			
LRIT (Long range identificatio	Resolution MSC.263 (84)			

		1	I	
n and				
tracking				
system)				
	Resolution MSC.242			
	(83)			
	Resolution MSC.254			
	(83)			
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	2821 st EU Council			
	Resolution, Oct 2007			
	, , , , , , , , , , , , , , , , , , , ,			
	Resolution MSC.202			
	(81)			
	(0-)			
	Resolution MSC.210			
	(81)			
	(01)			
	Resolution MSC.211			
	(81)			
	(01)			
	Resolution A.887			
	(21)			
	(21)			
GMDSS	1. Resolutions			
(Global	adopted by the			
Maritime	Assembly, Council,			
Distress and	FAL, LC, LEG, LP			
Safety				
Systems)				
	2. Section 4,			
	Maritime Safety,			
	Nov. 2008			
	3. MSC.131 (75)			
	2002			
	4. A.954 (23) 2003			
	5. A.617 (15) 1987			
	6. A.524 (13) 1983			
	7. A.705 (17) 1991			
	8. A.706 (17) 1991			

	1	I	Ī	Τ	T
	9. MSC.148 (77)				
	2003				
	10. A.915 (22) 2001				
	11. GMDSS				
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	the Cospas-Sarsat				
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	2002				
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	GIVID33, 140V 1337				
	17. IEC 61097-10				
	GMDSS, June 1996				
	18. IEC 61907-13,				
	GMDSS, May 2003				
Reporting		EU Directive			
obligations		2000/59/EC			
		EU Directive			
		2001/96/EC			
		EU Directive			
		2009/16/EC			
		EU Directive			
		2009/17/EC			
	IMO FAL Form 1	EU Directive		Maritime	
		2002/59/EC		Declaration of	
	IMO FAL Form 2	and		Health –	
		2000/59/EC;		International	
	IMO FAL Form 3	2000/33/10,		Health	
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	INAO FAL Forms 4	LC.	Dogulation	
	IMO FAL Form 4	EC	Regulation	
	IMO FAL Form 5	Regulation 562/2006;	2005	
	IMO FAL Form 6	EC		
		Regulation		
	IMO FAL Form 7	725/2004		
		723/2004		
		Regulation		
		562/2006,		
		Art. 7		
		Regulation		
		725/2004		
		Art. 6		
National		EU Directive		ISO/PAS
Single		2010/65/EU		28005-
Window				1:2012
Electronic				ISO 28005
Port				XML port
clearance				clearance
Intelligent		EU Directive		
Transport		2010/40/EU;		
Systems (ITS)		Regulation		
		305/2013		
Community		1. Regulation		
Customs		648/2005		
Code				
		2. Council		
		Regulation		
		2913/92;		
		2913/92,		
		3.		
		Commission		
		Regulation		
		2454/93;		
		4. Regulation		
		450/2008;		
		5. Decision		
		70/2008/EC		
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on
3. Risk
management
systems
Systems
4. Outbound
security
inspections
at request of
counterpart
5. Modern
inspection
equipment
6. Cargo
Inspection
Authority
/ Mariority
7. Integrated
supply chain

		management		
		0.115.15.25.1		
		8. High-risk cargo		
		9. Performance measures		
		10. Security assessments		
External Trade Statistics	Regulation 1917/2000; Regulation 1949/2005			
Plant Health Regime	Directive 2000/29/EC		ISPM15 Phytosanitary Measures; ISPM7 Export Certification System	
Health and Safety standards for the agri- food chain	New EU package will enter into force in 2016			ISO 22000 Food Safety Management System
				ISO 22005:2007 traceability in the feed and food chain
				ISO/TS 22002- 1:2009 prerequisites for food manufacturi ng
				ISO/TS 22001-

			3:2011 prerequisite for farming
			ISO/TS 22003:2007 audit and certification bodies
Veterinary Border Control	1. Decision 2012/31/EU		
	2. Regulation 28/2012		
	3. Regulation 809/2011		
	4. Decision 2011/215/EU		
	5. Regulation 142/2011		
	6. Regulation 1069/2009		
	7. Decision 2009/821/EC		
	8. Regulation 206/2009		
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	11. Regulation 882/2004		
	12. Council Directive		

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	Regulation		
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	Regulation		
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	Regulation		
	998/2003		
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	Directive		
	2002/99/EC		
	17. Decision		
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	18. Directive		
	97/78/EC		
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	94/360/EEC		
	20. Council		
	Directive		
	92/65/EEC		
	21. Council		
	Directive		
	91/496/EEC		
Rules for	Directive		
Importing	2001/83/EC;		
API into the			
EU	Directive		
(medicinal	2011/62/EU		
products for			
human use)			