
Health Sub-Group

Maritime Declaration of Health – Business Rules

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Background

On 20 October 2010 Directive 2010/65/EU on reporting formalities for ships arriving in and/or departing from ports of the Member States (known as the Reporting Formalities Directive) was adopted, which repealed Directive 2002/6/EC. The purpose of the Directive is to “simplify and harmonise the administrative procedures applied to maritime transport by making the electronic transmission of information standard by rationalising reporting formalities.”

According to the provisions of Article 5, MSs shall accept the fulfilment of reporting formalities in **electronic format** and their transmission via a **National Single Window (NSW)** no later than **1st June 2015**. The Annex of the Directive lists 14 reporting formalities, which, when required in accordance with the legislation in a MS, are to be submitted through a NSW.

Among the reporting formalities resulting from international legal instruments (Part B) is the **Maritime Declaration of Health (MDH)** (paragraph 8). The form to notify the required information is defined in the International Health Regulations (IHR, 2005) Annex 8.

The reporting of the MDH through NSW was discussed at the 5th e-MS Group meeting (Brussels, 12 July 2012) which decided to set up a Health Sub-Group for the development of the business rules. 13 Member States volunteered to participate: Belgium, Bulgaria, Estonia, Finland, France, Germany, Italy, Latvia, Poland, Spain, Sweden, the Netherlands and the United Kingdom. In addition, DG SANCO has nominated Health experts. The EU Executive Agency for Health and Consumers, experts from the SHIPSAN project and the World Health Organisation also provided support.

The MDH shall, if required in accordance with national legislation, be submitted electronically only once (via the NSW) and made available to the Health competent authorities and relevant bodies at port level. The NSW concept at national level is introduced in order to gather the information more effectively. In defining the business rules of the MDH the Health Sub-Group considered the following principles:

- a. The inclusion of the MDH information into NSW should not only facilitate the legal obligations of the reporting formalities but should primarily satisfy the user requirements.
- b. The NSW has to meet the requirements of the Directive 2010/65/EU including the reporting formalities resulting from international instruments and national legislation.
- c. As soon as the business rules of the MDH will be defined, the results will be presented to the e-MS Group in charge of the implementation of the notifications and the Single Windows required by Directive 2010/65/EU in a harmonised way.

This report presents the business rules proposed by the Health Sub-Group to the e-MS Group for the integration of the MDH in the Single Windows.

Business Rules

1. Notification requirements

The legal framework is provided by the International Health Regulations (IHR) considering the scope of Directive 2010/65/EU:

- Article 37 of IHR states the legal obligation of the master of the ship to provide the MDH, if so required by the State Party;
- Article 37 of IHR also states that State Party may decide:
 - (a) to dispense with the submission of the MDH by all arriving ships; or
 - (b) to require the submission of the MDH only for ships arriving from affected areas or to require it from ships which might carry infection or contamination.
- The IHR Annex 8 provides the MDH form on which the ship master reports the health information on board required by the State Party. Some of the information is to be provided only upon request of the competent authority at the port of arrival in case of an event on board (list crew members, passengers or other persons). It is up to the MS to define which parts of the latter information is required and when.

Comments:

- The IHR defines ship as a “seagoing vessel on an international voyage” and international voyage is a “voyage between points of entry in the territories of more than one State”;
- The IHR adopts a flexible approach and allows state parties to establish which ships, on international voyages, are required to submit the MDH and which information is required to be provided on the MDH; therefore, there is no harmonised criteria for the submission the MDH in EU ports as this depends on the provisions established in the national legislation of each MS;
- According to the IHR, international voyages cover also the inland navigation. However, the reporting of the MDH must be analysed within the scope of Directive 2010/65/EU and inland navigation is not covered for the moment.

Business Rule 1: The MDH may be required by a MS, according to its national legislation, for ships on international voyages before the arrival at its first port of call in its territory, in particular for ships arriving from an affected area identified by the World Health Organisation or which might carry infection or contamination.

Business Rule 2: The MDH information required by the national legislation of each MS must be provided electronically to the NSW (excluding inland navigation¹).

2. Identification of ships

In the MDH ships are identified by the IMO number, the name and the registration number. The MS normally use the IMO number as the identifier of a ship. If the ship, which is required to send the MDH, does not have an IMO Number the MSs also use the MMSI number, the call sign, the name and registration. The IMO number and MMSI number are the most reliable identifiers because they are unique to each ship. The other parameters are not unique and may change even during a port visit. The number of ships which are required to submit the MDH and do not have an IMO or MMSI number is very limited.

Business Rule 3: In the development of the NSW a ship shall be identified as follows:

- a. The IMO number shall be considered as the "unique identifier", if available;
- b. The MMSI shall be considered as the "unique identifier" if the IMO number is unavailable;
- c. In the absence of the IMO number and MMSI number the following may be used as ship identifiers:
 - i. the call sign;
 - ii. the name; and
 - iii. national registration number.

3. Voyage related information

As regards to voyage data the MDH requires the ship to report from where it is arriving from and where it is sailing to. It also requires the list of ports of call from commencement of the voyage with dates of departure, or within the past thirty days, whichever is the shorter. In the majority of cases the last 10 ports of call, as required in the Security message, is sufficient to determine the ports visited by a ship. This list may provide more ports than if the ship reported only the ports of call since the commencement of the voyage.

The format of data of the ports of call and the dates will comply with the format agreed for other messages.

Public Health authorities when they require information on persons on board the ship should accept the crew list (FAL 5) and passenger list (FAL 6) provided by the ship for other reporting formalities. If applicable, for example, when the ship visited an affected area or any of the Health Question(s) is (are) answered with a "Yes", the competent authority may, in addition, request a list of crew members, passengers or other persons who have joined the ship since international voyage began or within past thirty days, whichever is shorter, including all ports and countries visited in this period.

¹ **Health sub-group recommendation:** consider including inland navigation in the future revision of the Directive 2010/65/EU

Re-using information which is provided by other reporting formalities and the harmonisation of the data elements is in line with the scope of the Directive 2010/65 to simplify and harmonise the administrative procedures by rationalising the reporting formalities.

Business Rule 4: The list of the last 10 calls at port facilities submitted as part of the Security notification will be re-used for the purpose of compiling the information required in terms of the MDH for reporting the previous ports of call. MS may, in compliance with the International Health Regulations, request for additional ports of call, if the ship called additional ports since the commencement of the voyage or within the last thirty days.

Business Rule 5: UN/LOCODEs with function “port” should be used to identify the ports. In any case, the competent authorities may declare additional location codes (not declared in the UNECE list with port function) to complete the list of their national ports (this is already the existing practice in SSN today). The UN/LOCODEs list is managed and maintained by the UNECE (following indications from national Governments) and with the active contributions of the national governments and commercial bodies. The SSN NCA shall be responsible for designation and management of UN LOCODES. The shipping industry should be informed of the proper use of the UN/LOCODEs list.

Business Rule 6: The ISO 8601UTC should be used for the date/time fields in the NSW. This is the date and time format currently implemented in SSN and defined in the business rules for other reporting formalities.

4. Classification of the information in the MDH

Article 8 of Directive 2010/65/EU requires MSs to take the necessary measures to ensure the confidentiality of commercial and personal information exchanged in accordance with the Directive.

Article 45 of the IHR also provides that health information collected or received by a State Party which refers to an identified or identifiable person shall be kept confidential and processed anonymously as required by national law. States Parties may disclose and process personal data where essential for the purposes of assessing and managing a public health risk.

Business Rule 7: The information included in the MDH is not considered as “classified” in accordance with the definition provided by Commission Decision 2001/844/EC and therefore does not require the NSW to be considered as a “classified” system. Nevertheless, this information shall be considered as sensitive and shall be protected from unauthorised access or disclosure by setting up the appropriate access rights. The personal data has to be protected in accordance with BR 11 and information that is considered commercially sensitive (e.g. cruise ship with an infectious outbreak), shall be protected in compliance with the rules of the MS.

5. Statement of responsibility

The signature of the master, (and of the surgeon, if available) is required on the MDH because he is the most knowledgeable of a situation on board a ship. However, Directive 2010/65 establishes that all reporting formalities are submitted in electronic format. Not all ships have the facility to send digital signatures. Therefore, the only way to implement

the Directive is to allow the agent (or any other representative of the ship) to submit the MDH to the NSW. It is important that the NSW is able to trace who has submitted the MDH related information.

Business Rule 8: Concerning the transmission of the MDH to the competent MS authorities, there is no need for a formal signature. The NSW has already the user's credentials of data provider (User ID & Password).

6. User Profiles

MS have to designate the competent authorities and organisations to perform functions related to the MDH. Consequently, it is the MS's responsibility to define the users entitled to deal with the MDH information based on of their specific organization at national level. The Competent Authority designated by the Member State will grant the relevant public health authority access rights to the MDH information and any other information received through other reporting formalities and which is relevant to it for processing the MDH. A MS may determine if it is useful that other public authorities also have access to MDH information.

Business Rule 9:

- a) The Competent Authority designated by the Member State is responsible for the assignment of access rights to the relevant local and national public health authorities to information in the NSW which is relevant for the processing of the MDH.
- b) Access rights to MDH information may also be provided to other public authorities.

7. Data Providing Process

According to Article 28(4) of the IHR, the persons responsible for providing the MDH are the officers in command of ships, or their agents. They shall report to the port as early as possible before arrival at the port of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board as soon as such illnesses or public health risks are made known to the officer. Article 37 of IHR states it is the obligation of the master of the ship to provide the MDH. The master of a ship is an officer in command of a ship.

The IHR does not provide fixed time frames for submitting the MDH but allows MS to determine if the MDH has to be delivered in advance (before its arrival in a port) or on arrival in a port. However, Article 4 of the Directive provides the time frame for submitting reporting formalities to the competent authority.

The NSW should allow updates to the MDH, either to provide an update of the situation on board or to correct inaccurate information up to the time of departure.

Business Rule 10:

- a) The MSs shall develop the appropriate data entry tools to allow the user (as identified in BR 8) to enter MDH information in the NSW.
- b) The MS shall develop mechanisms to ensure the non-repudiation and traceability of actions performed by users accessing the NSW.

- c) The timeframe for submitting the MDH is to comply with Article 4 of Directive 2010/65/EU:
- (a) at least 24 hours in advance; or
 - (b) at the latest, at the time the ship leaves the previous port, if the voyage time is less than 24 hours; or
 - (c) if the port of call is not known or it is changed during the voyage, as soon as this information is available.
- Updates on previously provided information may be accepted by the NSW to update or correct parts of the information previously transmitted. Updates may be allowed up to the departure time (ATD).
 - The MDH and the other reporting formalities information for that ship port call should be associated to an identifier of the port call. The identifier should be unique for all calls in the ports of the MS and guaranteed by the NSW.
 - Common data quality checking rules shall be applied in all systems. This is of particular importance to the NSW that is the entry point for all the information.

8. Data Distribution Process

The sub-group concluded that there is no requirement or identified need to exchange the MDH between MS, using SSN. The MDH information is mainly relevant to the Health authority in the port of call and access to such information should be provided in terms of BR 9.

9. Exemptions

The IHR does not provide for any specific exemptions but allows state parties to establish whether and which ships are required to submit the MDH. Therefore, the submission of the MDH depends on the provisions established in the national legislation of each MS.

Business Rule 11: The development of the NSW will take into consideration the provisions of the national legislation as regards to which ships are obliged to submit the MDH.

10. Data Storage and Data Availability

Business Rule 12: To maintain coherence with the requirements of other reporting formalities in the NSW, the same data storage requirements shall be applicable to the MDH information². The minimum periods for data storage (from the ship's departure) are:

² **Health sub-group recommendation:** Since there is no central database for the data storage of MDH information, the public health authorities highlighted that there is a real added value to organize the data storage of MDH information at the European level through links with database on vessels developed by the SHIPSAN project funded by the Public Health Executive Agency.

- Online: 2 months minimum;
- Offline: 5 years minimum.

Business Rule 13: The NSW system shall, as a minimum, maintain data availability, of 99% over a period of one year, with a maximum permissible period of interruption of 12h.

11. Personal Data Protection

Business Rule 14: The protection of personal data at national level shall be in line with national legislation for data protection and with Directive 95/46/EC. MS have to verify the compliance of the measures implemented for the protection of personal data in their NSW with the EU and their national legislations. For this purpose it is important to take into consideration BR 9 and 10(b).

12. Functionalities

The main purpose of implementing the MDH message in electronic format is to facilitate the clearance process for the ship. The types of functionalities that may be defined for the data processing may include several warning functionalities for the public health authority on:

- the completeness of the information provided;
- the validity of the Ship Sanitation Certificate (SSC);
- checks for specific answers to the health questions.

Business Rule 15: MSs should decide which functionalities to develop within the NSW for the MDH information.