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Ships and marine technology — Risk assessment on anti-fouling systems on ships —

Part 2: Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances

Navires et technologie maritime — Évaluation des risques pour les systèmes antisalissure sur les navires —

Partie 2: Méthode d'évaluation des risques environnementaux maritimes pour les systèmes antisalissure sur les navires utilisant des substances actives biocides

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 8, *Ships and marine technology*, SC 2, *Marine environment protection*.

ISO 13073 consists of the following parts, under the general title *Marine environment protection — Risk assessment on anti-fouling systems on ships*:

— *Part 1: Marine environmental risk assessment method of biocidally active substances used for anti-fouling systems on ships*

— *Part 2: Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances*

— *Part 3: Human health risk assessment for the application and removal of anti-fouling systems (under development)*

Introduction

The attachment of fouling organisms such as barnacles and algae on the submerged parts of a ship's hull increases the propulsive resistance of the hull against water, leading to increased fuel consumption and accidental introduction of non-indigenous species to a foreign marine environment, which may cause significant and harmful changes. As a means of preventing such circumstances, an anti-fouling system that relies on biocidally active substances (e.g. anti-fouling paint) to prevent attachment of fouling organisms can be applied onto the hull of the ship. The harmful effects of organotin compounds used as biocides (historically used in anti-fouling paint) on marine organisms and human health have been of global concern. To prevent the continued use of these compounds, a legally-binding international framework regulating the use of anti-fouling systems containing harmful substances was enacted by the International Maritime Organization (IMO). Consequently, the International Convention on the Control of Harmful Anti-fouling Systems on Ships (the AFS Convention) was adopted at the IMO diplomatic conference held in London in October 2001, and entered into force in September 2008.

The Convention envisages handling various harmful anti-fouling systems within its framework and lays out a process by which anti-fouling systems can be risk assessed. Annexes 2 and 3 of the Convention include the list of information needed to determine whether an anti-fouling system is harmful to the environment and should be restricted from use on ships, but a marine environmental risk assessment method for making this decision is not provided. Furthermore, Resolution 3, adopted by IMO along with the AFS Convention recommends that contracting Parties continue to work in appropriate international fora for harmonization of test methods and assessment methodologies, and performance standards for anti-fouling systems containing biocidally active substance(s).

Based on this, there is a global need for an international method for conducting scientific environmental risk assessments for anti-fouling systems substituting organotin-based anti-fouling systems. This part of 13073 allows a pragmatic approach to introducing systems (i.e., self-regulation or approval systems) in countries where either no system exists, or a less developed system is in place and would allow such countries to improve protection of the aquatic environment.

Ships and marine technology — Risk assessment on anti-fouling systems on ships —

Part 2:
Marine environmental risk assessment method for anti-fouling systems on ships using biocidally active substances

1 Scope

This part of ISO 13073 specifies a risk assessment method that protects the marine environment from the potential negative impacts of anti-fouling systems intentionally using biocidally active substances applied to a ship during its service life. This method can also be modified for use in freshwater environments.

This part of ISO 13073 does not provide specific test methods for evaluating the hazards nor recommends usage restrictions for certain anti-fouling systems. It also does not provide an efficacy-evaluation method of the anti-fouling system using a specific substance.

The following uses of anti-fouling systems are also not covered by this part of ISO 13073:

— use at the application and removal stages, during new building, vessel maintenance and repair or ship recycling;

— use of systems intended to control harmful aquatic organisms and pathogens in ships' ballast water and sediments according to the International Convention for The Control and Management of Ships' Ballast Water and Sediments, 2004;

— use of anti-fouling systems applied to fishing gear, buoys and floats used for the purpose of fishing, and to equipment used in fisheries and aquaculture (nets/cages, etc.); and

— test patches of anti-fouling systems on ships and small panels for the purposes of research and development of anti-fouling systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13073-1:2012, *Ships and marine technology — Risk assessment on anti-fouling systems on ships — Part 1: Marine environmental risk assessment method of biocidally active substances used for anti-fouling systems on ships*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13073-1 and the following apply.

3.1
substance of concern
an intentionally added non-biocidal substance which is classified as acute or long-term hazard category 1 or 2 for "hazardous to aquatic environment" under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) and is released to the marine environment based on emission scenario(s)

4 Application

4.1 General

Risk assessment, as defined in this part of ISO 13073 and ISO 13073-1, is conducted for the protection of the marine environment. In order to confirm the risk of a biocidally active substance in an anti-fouling system, a risk assessment according to this part of ISO 13073 shall be conducted. In this part, the risk assessment is conducted for anti-fouling systems using biocidally active substances which have undergone the risk assessment given in ISO 13073-1. This assessment will identify the risk categorization of the anti-fouling system to allow decisions to be made on the use of this anti-fouling system in a certain environment.

This part of ISO 13073 provides a minimum guideline for the following uses:

— regulation of anti-fouling systems by government organizations;

— self-regulation or approval systems carried out for industry by industrial organizations or other third parties; and

— evaluations conducted for product development by the industry.

This part of ISO 13073 will enable the quantitative characterization of the environmental risk posed by an anti-fouling system on the marine environment and determine whether the environmental risk of the system is acceptable.

This part of ISO 13073 could be modified for assessing risk to freshwater environments such as rivers and lakes. Special attention should be given to defining the emission scenarios required for freshwater areas, and particular care should be taken to consider the effects on the species found in those environments.

4.2 Application considerations

This part of ISO 13073 provides a method for quantifying the marine (and freshwater, where necessary) environmental risk posed by an anti-fouling system, but does not directly regulate or approve the use or commercialization of the anti-fouling system. As a result of risk characterization of an anti-fouling system designated in Clause 8, a categorization into "possible high risk to the marine environment" does not necessarily mean a prohibition of its use. It may be accepted for use under certain conditions which demonstrates a reduction in the environmental exposure such as by use of additional mitigation measures, by refinement of the exposure assessment or by continuous monitoring of the relevant environment.

The risk assessment of the biocidally active substances that are in an anti-fouling system shall be conducted in accordance with ISO 13073-1 prior to making the assessment using this part of ISO 13073. Substances categorized as "low risk" or "relatively low risk" to the marine environment through the ISO 13073-1 risk assessment should generally be used in this risk assessment. In exceptional cases, special care shall be taken with the description designated in 5.1 when substances categorized as "risk of high concern" to the marine environment through the ISO 13073-1 risk assessment are used.

All data submitted by an applicant are, and shall remain, the property of the applicant under this part of ISO 13073. These data shall not be made available to other applicants without prior written approval from the owner of the data.

4.3 Structure and procedure of environmental risk assessment

The environmental risk assessment procedure consists of four components: review of the risk of biocidally active substance under ISO 13073-1, exposure assessment, representation of result of the hazard assessment, and risk characterization. The ratio of the predicted environment concentration (*PEC*) to the predicted no-effect concentration (*PNEC*) (*PEC/PNEC*) is used as a quantitative index for the risk assessment. The procedure is summarized in Figure 1.

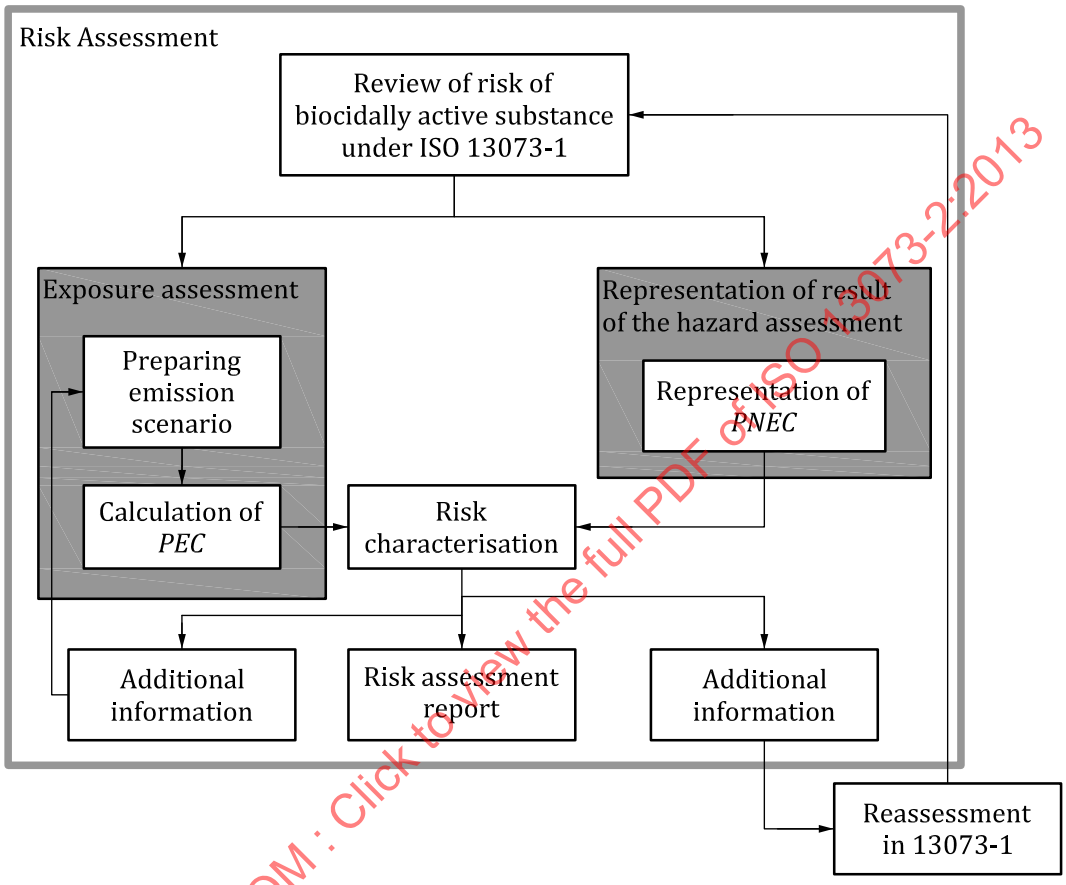

Figure 1 — Composition and schematic procedure of environmental risk assessment for anti-fouling systems on ships using biocidally active substances

5 Review of the risk of a biocidally active substance when used in the anti-fouling system

5.1 General

It shall be confirmed in accordance with the procedures in ISO 13073-1 that biocidally active substances intentionally added to an anti-fouling system are characterized as “low risk” or “relatively low risk” to the marine environment.

If any of the biocidally active substances is to be regarded as a “risk of high concern”, the use of the anti-fouling system may be considered for certain types of marine environments as described in 5.3, and this may result in restrictions on the use of such products or requirements for carrying out environmental monitoring. Such restrictions may (or may not) include restrictions in the environment where such products may be used, restrictions on the allowed maximum release rate, restrictions on the time period during which such products may be used (e.g. particular times of year), or restrictions in the type or size of the application area such as use in niche areas.

If the result of the risk categorization for the anti-fouling system identifies that all biocidally active substances are to be regarded as "low risk' or "relatively low risk", then the use of the anti-fouling system may be allowed. However, if any of the following applies, the same condition identified in the ISO 13073-1 risk assessment for the biocidally active substances shall also apply to the anti-fouling system.

a) A biocidally active substance is considered to have a relatively low risk tentatively for a certain period of time in ISO 13073-1.

b) A certain type of marine environment is considered to be a recipient of biocidally active substance(s) in ISO 13073-1.

5.2 Assessment when a biocidally active substance is tentatively deemed to have "relatively low risk"

If any of the biocidally active substances in the anti-fouling system is deemed to have a "relatively low risk" tentatively for a certain period of time as a result of the Level 1 assessment in Tier 2 in Annex B of ISO 13073-1:2012, a risk assessment of this anti-fouling system on the marine environment is also allowed tentatively for this period of time.

5.3 Assessment when a certain type of marine environment is considered to be a recipient of biocidally active substances

In this part of ISO 13073, exposure assessments of biocidally active substances are relevant only to those types of marine environments for which a risk assessment of biocidally active substances has been performed in accordance with ISO 13073-1. Results of a risk assessment conducted for a certain type of marine environment cannot be applied directly to other types.

For every new type of marine environment where an anti-fouling system is applied, a risk assessment specific to that type of marine environment shall be conducted.

NOTE For example, in the case of an anti-fouling paint for small boats and yachts, if an ISO 13073-1 exposure assessment has been conducted on a biocidally active substance "X" in this paint, for "waterways" and "open ocean" as the typical types of marine environment for application, and if it is suggested that "the substance X has relatively low risk to the marine environment", this anti-fouling paint is only deemed to have a relatively low risk to the marine environment for waterways and open ocean, even if the other biocidally active substances in that anti-fouling paint are assessed for other types of marine environments, such as harbours and marinas. In order to demonstrate the risk of the anti-fouling paint being relatively low risk also to harbours and marinas, the ISO 13073-1 exposure assessment of the biocidally active substance "X" needs to be conducted for harbours and marinas as additional environments for its typical application, and a low risk or a relatively low risk of the biocidally active substance "X" also to these types of marine environment needs to be indicated.

6 Exposure assessment

6.1 Preparing the emission scenario

The emission scenario is a set of parameters that define the sources and pathways of exposure, as well as use patterns of the biocidally active substance(s) in the anti-fouling system. The scenario enables the quantification of the distributions of the release to the environment by taking into account the physico-chemical parameters of both the substance(s) and the exposed environment.

6.1.1 Types of marine environments to be considered

With regard to the service life of an anti-fouling system used on ships, the characterization should be conducted for a marine environment where the biocidally active substance(s) are to be released. Types of marine environments to be considered may be as follows:

— open sea

— sea lane

— harbour

— marina

It may also be necessary to consider other bodies of water (e.g. a larger expanse of water).

Depending on the usage of products or receiving waters, it may not be necessary to consider all the environment types cited above. Nevertheless, provisions in 5.3 shall be observed.

6.1.2 Defining the emission scenario

Following the selection of the type(s) of marine environments under consideration, a representative scenario should be proposed that gives typical dimensions of the exposed environment. For example, the length, width and depth of a typical harbour should be defined. The emission scenario should provide enough information to enable the *PEC* to be calculated taking into account the relevant physico-chemical and hydrodynamic parameters of the defined scenario. The typical parameters to be considered when a scenario for modelling the *PEC* is defined, are given below:

a) the release rate of the biocidally active substance:

— release rate of biocidally active substance (the mass of biocidally active substance released per unit area and unit time)

NOTE Release rates determination methods are described in ISO 13073-1:2012, 5.2.

b) the parameters relating to emission:

— total number of ships at berth and total number of ships moving;

— proportion of ships moving;

— proportion of ships at berth;

— submerged surface area of ships (surface area per length class of ship); and

— percentages of the ships painted with the product.

c) the layout of the target sea area:

— the length and the width (or surface area), and depth of the target sea area; and

— the width and depth of the boundary between the target area and non-target area (e.g. exchange area, harbour mouth below mean sea level, depth in harbour entrance).

d) water quality:

— temperature;

— salinity;

— pH;

— silt concentration (silt fraction < 63 µm in mg/L);

— fraction organic carbon (organic carbon content (dry wt) of sediment);

— POC and DOC concentration [particulate and dissolved organic carbon (OC) concentration in mg OC/L); and

— suspended particulate matter in the water column.

e) hydrology:

— tidal exchange rate (in-flow and out-flow rate of water per unit time and unit cross section); and

— flow rate of rivers and streams connected to the target sea area (in-flow and out-flow rate of water per unit time and unit cross section).

f) environmental media:

— pH;

— depth mixed sediment layer; and

— dissolved organic carbon.

NOTE This list is not exclusive.

6.1.3 Requirements for setting parameters

All the parameters shall be set to give a realistic worst-case scenario. Examples of scenarios are given in the OECD EMISSION SCENARIO DOCUMENT (OECD 2005). When a scenario is produced, it is important to ensure that a realistic worst-case scenario is developed. For example, when risk to harbours is assessed, one would survey the dimensions of a suitable sub-set of harbours from the country of interest. Typical dimensions can then be defined based upon this sub-set of harbours for the country. Depending upon the size of the sub-set, the appropriate statistical measure should be chosen (e.g. average length, or 95th percentile length of the data set).

6.2 Determination of the PEC

The *PEC* for each emission scenario and each relevant environmental compartment should be determined using the parameters determined in 6.1.2 and 6.1.3 and the properties relevant to each biocidally active substance under consideration.

Typical parameters may include the following:

— degradation rate of the biocidally active substance (abiotic and/or biological);

— particle adsorption rate (or ratio of the biocidally active substance bound to particulates compared to the substance dissolved in seawater);

— organic-carbon partitioning coefficient (*K*oc);

— bioaccumulation factor of biocidally active substance.

In calculating the *PEC* a suitable mathematical model should be chosen which can determine the environmental loading by taking into account all the parameters defined in the scenario. Typically this is handled by a suitable computer program such as MAMPEC (Marine Antifoulant Model to Predict Environmental Concentrations). ISO 13073-1:2012, Annex H describes a number of validated models which could be used.

The organic-carbon partitioning coefficient (*K*oc) in suspended matter can be determined by adsorption studies (OECD TG 106) or measured by the HPLC-method (OECD TG 121).

Examples of average or typical values of the volume fraction of seawater in suspended solids, the volume fraction of solids in suspended matter, the density of the solid phase, and the mass fraction of organic carbon in suspended matter are listed in Technical Guidance Document (European Commission, 2003).

Where necessary, the *PEC* for predator and mammal (PEC_{pred}) should be determined using the parameters such as bioconcentration factor (*BCF*), mean fish consumption rate and the *PEC* for sea water (PEC_{SW}).

It is important that any models used to determine *PEC* are themselves appropriately validated. The validation report for the model should be an inherent part of the risk assessment report.

7 Selection of the appropriate PNEC

The *PNEC* used for the calculation of the risk assessment in ISO 13073-1 shall be identified for every biocidally active substance present in the anti-fouling system.

NOTE A toxicological interaction may theoretically occur among biocidally active substances in the receiving environment. Evaluation of the effects of such an interaction may be required for hazard assessment. However, there are no established scientific techniques or validated models for evaluation of such interactions. Therefore, if such toxicological interactions are of particular concern, an expert judgement on the potential interactions among their component substances may be required.

8 Risk characterization

In a risk assessment for an anti-fouling system with biocidally active substances, the risk to the marine environment throughout its service life shall be estimated on the basis of the ratio between *PEC* calculated from the exposure assessment and represented in *PNEC*, or *PEC*/*PNEC* ratio:

— for every biocidally active substance in it; and

— separately for each marine environment.

If *PEC*/*PNEC* ratio is equal to or greater than 1 for one or more of the biocidally active substance(s) in the anti-fouling system or for one or more of the assessed environment(s), the anti-fouling system is considered to have "possible high risk on the marine environment". If *PEC*/*PNEC* ratio is less than 1 for all of the biocidally active substances in the anti-fouling system and for every assessed environment, the anti-fouling system is considered to have "low risk to the marine environment".

9 Risk assessment of similar anti-fouling systems

The risk assessment of an anti-fouling system may take precedence for the risk assessment of other anti-fouling system(s) with similar formulations by reusing existing data through bridging and waiving. Such bridging and waiving can, for instance, be applied when the anti-fouling system contains the same active substance(s) and has the same or lower level of risk as the referred anti-fouling system, or in any case where bridging and waiving is scientifically and technologically justified as determined by expert judgement.

10 Substances of concern

Where the formulation of the anti-fouling product shows an inclusion of "substances of concern" as defined in 3.1, special attention shall be needed. A risk assessment shall be carried out for each of the substances of concern in accordance with this part of ISO 13073 if its concentration is high enough by itself to result in the anti-fouling product requiring to be labelled as "hazardous to the environment" under GHS rules.

11 Risk assessment report

Regarding the risk assessment conducted according to this part of ISO 13073, a risk assessment report shall be prepared including the information used for the assessment and the result. The minimum required information to be cited in the risk assessment report is described in Annex A.

Annex A
(normative)

Minimum information required for a risk assessment report

A.1 Minimum information required for a risk assessment report

This Annex provides a list of minimum data/information required to be included in the risk assessment report of the anti-fouling system submitted for application. These data and information are used to ensure an appropriate implementation of the environmental risk assessment.

Any relevant significant data and information, other than the requirement listed in this Annex, should be described in the risk assessment report.

If the bridging and waiving approach is used, a rationale shall be described in the risk assessment report.

Table A.1 — Minimum required information for the risk assessment report

Items	Data requirements
Applicant(s)	Name, address and point of contact for applicant(s)
	Name of manufacturer
Identity of product	Product name
	Product identification code number(s)
	Physical state and colour
	Product composition
Identity of each biocidally active substance(s)	Name of manufacturer and plant location(s)
	Common name and synonyms
	Chemical name (IUPAC)
	CAS number and other registry numbers
	Molecular and structural formula
	Molecular mass
	Concentration of biocidally active substances in the product
	Compliance statement for ISO 13073-1
Identity of each substance of concern	Name of manufacturer
	Common name and synonyms
	Chemical name (IUPAC)
	CAS number and other registry numbers
	Molecular and structural formula
	Molecular mass
	Concentration of substance of concern in the product
Effectiveness on target organisms and intended use for each biocidally active substance	Release rate and its determination method
	End user and application
	Service life time
Information on prediction about environmental concentration for each biocidally active substance	Model and parameters
	PEC
Hazard assessment for each substance	*PNEC*