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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

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

Partie 1: Méthode d'évaluation des risques environnementaux maritimes des substances actives biocides utilisées pour les systèmes antisalissure sur les navires

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13073-1 was prepared by Technical Committee ISO/TC 8, *Ships and marine technology*, Subcommittee SC 2, *Marine environment protection*

ISO 13073 consists of the following parts, under the general title *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*

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— *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)*

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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 possibly 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 of biocidally active substances for use in anti-fouling systems. This part of ISO 13073 provides 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 help such countries improve protection of the aquatic environment.

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This part of ISO 13073 is intended to be used for the positive evaluation of biocidally active substances for use in anti-fouling systems. For an evaluation of a biocidally active substance's entry onto Annex 1 of the AFS Convention, which is a negative listing, the methodology can be used but the evaluation should include an extensive assessment supported by the full data requirements established in the AFS Convention.

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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

1 Scope

This part of ISO 13073 specifies a risk assessment method that protects the marine environment from the potential negative impacts of biocidally active substances that are intentionally used in the anti-fouling system 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 a specific test method for evaluating the hazard and toxicity or usage restrictions of certain substances. This also does not provide an efficacy-evaluation method for an anti-fouling system using a specific substance.

The following are not covered by this part of ISO 13073:

— the risk assessment of biocidally active substances in anti-fouling systems during their application and removal during vessel maintenance and repair, new building or ship recycling;

— use of anti-fouling 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;

— 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);

— test patches of anti-fouling systems on ships for the purpose of research and development of anti-fouling products;

— the assessment of risk of biocidally active substances in cases of accidental releases, such as spillage during ocean transport or releases into the sea from rivers and/or coastal facilities.

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2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
acute test
exposure test on an aquatic species conducted for a short period (mostly for several dozen hours, although it varies among species), in order to obtain an LC_{50} or EC_{50} for fish fatality, abnormal behaviour of invertebrates, or inhibition of algal growth as the end point

2.2
anti-fouling system(s)
coating, paint, surface treatment, surface, or device that is used on a ship to control or prevent attachment of unwanted organisms

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2.3
assessment factor(s)
numerical factor that accounts for the uncertainty of extrapolating an effect concentration based upon experimentally derived hazard end points (for example, dose-dependent measures such as NOEC) to Predicted No-Effect Concentrations for use in environmental risk assessment

NOTE The hazard end point derived using a particular data point is divided by the assessment factor to define the PNEC for that particular biocidally active substance. It is equivalent to the “uncertainty factor” used in risk assessment for human health effects.

2.4
biocidally active substance(s)
substance having general or specific action such as mortality, growth inhibition, or repellence, on unwanted fouling organisms, used in anti-fouling systems, for the prevention of attachment of sessile organisms

2.5
chemical substance(s)
chemical element and its compounds in the natural state or obtained by any manufacturing process

2.6
chronic test
exposure test on an aquatic species conducted through most of its lifecycle, during its sensitive period (for fish, from fertilized eggs to the early life stage such as larvae and juveniles that take food), or for several generations, in order to obtain a *NOEC* for mortality, growth or reproduction as the end point

NOTE OECD Guidelines for Testing of Chemicals, Test Nos. 212 and 215 are not chronic tests.

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2.7
correction factor
numerical factor that accounts for the difference between the estimated release rate using a given method and the expected release rate from an anti-fouling system in-service; the estimated release rate using a particular method is divided by the correction factor to allow a more accurate and representative estimate to be made of the release rate to the marine environment

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2.8
emission scenario
set of parameters that define the sources, pathways and use patterns with the aim of quantifying the releases of a chemical or biocidally active substance into the environment

NOTE Emission scenarios are used in the risk assessment to establish the conditions on use and releases of the chemicals that are the bases for estimating the predicted concentrations of chemicals in the environment.

2.9
exposure assessment
procedure for evaluating the exposure of an organism, system or (sub)population to a biocidally active substance (and its degradants and/or metabolites), accounting for the exposure path, exposure amount, and concentration

2.10
harmful organism
any organism that has an unwanted presence or a detrimental effect on human activities, products they use or produce, animals or the environment

2.11
hazard assessment
process designed to determine the possible adverse effects of a biocidally active substance to which an organism, system or (sub)population could be exposed

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2.12
lowest-observed effect concentration
LOEC
lowest tested concentration of a test substance at which the substance is observed to have a significant effect when compared with the control

NOTE All test concentrations above the LOEC must have an effect equal to or greater than those observed at the LOEC.

2.13
marine environment
physical, chemical and biological features surrounding marine organisms, affecting the viability and bio-function of the organisms

NOTE Seawater and estuarine regions are included.

2.14
no-observed-effect concentration
NOEC
highest tested concentration of a test substance at which no statistically significant lethal or other effect is observed when compared with the control

2.15
predicted environment concentration
PEC
estimated concentration of a substance in a defined environment as quantified using exposure assessment

NOTE The substance is a biocidally active substance, a chemical substance, metabolite or any other relevant substance.

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2.16
predicted no-effect concentration
PNEC
concentration of a substance determined from hazard assessment by applying a suitable assessment factor, below which no adverse effect to a defined environment is anticipated

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2.17
release rate
representative value of the mass of biocidally active substance released in a day from the unit surface area of an anti-fouling system to water

NOTE Release rate is expressed in μg cm^{-2} day^{-1}.

2.18
risk
combination of the probability and the severity of an adverse effect due to a substance under certain conditions

2.19
risk assessment
process intended to quantitatively estimate the risk posed by exposure to a substance

NOTE 1 A quantitative assessment of environmental risk is defined as “environmental risk assessment”.

NOTE 2 In the case of low degradability and significantly high bioaccumulation, risk assessment is conducted without calculating PEC/PNEC ratio.

2.20
risk characterization
procedure to determine the risk level from the PEC/PNEC ratio calculated based on PEC calculated from exposure assessment and PNEC calculated from hazard assessment

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2.21
ships
vessels of any type whatsoever operating in the marine environment including hydrofoil boats, air-cushion vehicles, submersibles, floating craft, fixed or floating platforms, floating storage units (FSUs) and floating production storage and off-loading units (FPSOs)

2.22
worst-case scenario
realistic scenario in which organisms living in marine environment are expected to be most exposed to the biocidally active substance

2.23
50 % effective concentration
EC_{50}
concentration at which an effect is observed in 50 % of test organisms

2.24
50 % lethal concentration
LC_{50}
concentration at which 50 % of test organisms would die in an experiment

3 Application

3.1 General

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Risk assessment, as defined in this part of ISO 13073, is conducted for the protection of the marine environment.

The risk assessment shall be conducted for any degradates where there is evidence that they will be present in the environment at levels greater than 10 % mass of the parent compound from which they were formed.

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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 effects on the species found in those environments.

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 system for industry or industrial organizations;

— evaluations conducted for product development by the industry.

This part of ISO 13073 will enable quantitative characterization of the environmental risk posed by a biocidally active substance on the marine environment, and will determine whether the environmental risk of the substance is acceptable.

3.2 Application considerations

The following shall be taken into account when this part of ISO 13073 is used:

a) This part of ISO 13073 provides a method for quantifying the marine (and freshwater, where necessary) environmental risk posed by a biocidally active substance, but does not directly regulate or approve the use or commercialization of the substance. Classification of a substance into the category of “risk of high concern” does not directly mean prohibition of its use. It may be accepted for use under certain conditions such as under continuous monitoring of the substance or its metabolites in the environment.

b) This part of ISO 13073 does not include a method for a general risk assessment of industrial chemical substances. This is based on the assumption that it has already been accomplished by other methods.

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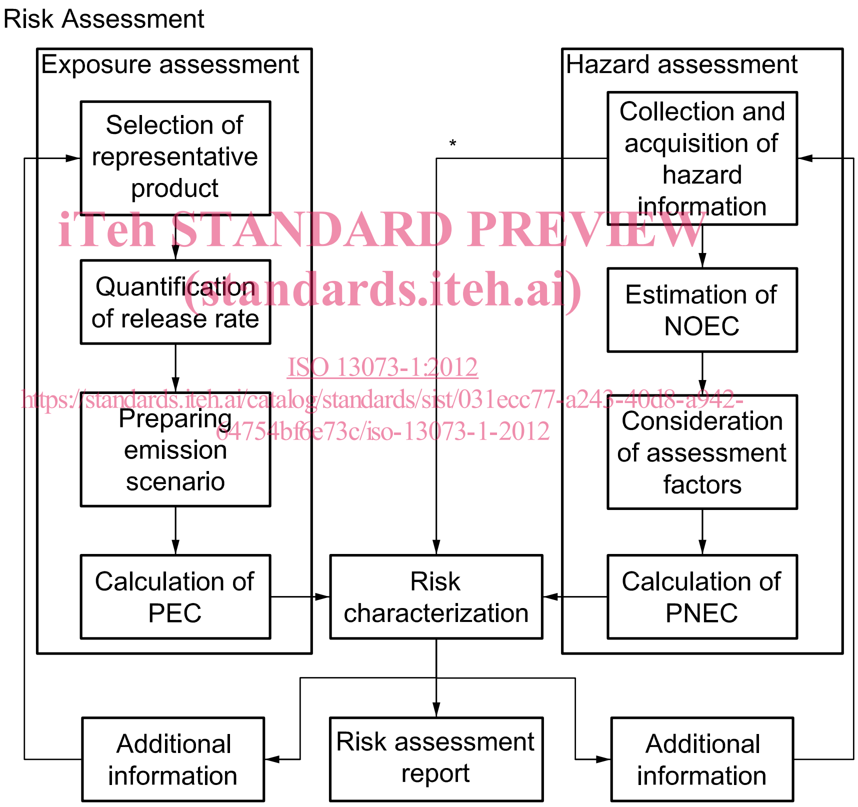
c) For regulatory systems with approval or evaluation procedures developed according to this part of ISO 13073 and with restriction of a substance classified as “tentatively low risk” under Level 1 of Tier 2, an appropriate sale period or quantity should be specified taking into account the severity of the potential effects on the exposed environment.

All data submitted by an applicant is, 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 Structure and procedure of environmental risk assessment

Environmental risk assessment consists of three procedures: exposure assessment, hazard assessment and risk characterization. Exposure assessment is a procedure used to obtain the PEC, and hazard assessment is used to obtain the PNEC. The ratio of the PEC to the PNEC (PEC/PNEC) is used as a quantitative index for the risk assessment. This procedure is summarized in Figure 1.

The risk characterization processes of the environmental risk assessment for organic and inorganic biocidally active substances used for anti-fouling systems on ships are provided in Annexes B and C, respectively.



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NOTE * An organic biocidally active substance is considered to be very bioaccumulative and with “risk of high concern” when its bioconcentration factor (BCF) is more than 2 000.

Figure 1 — Composition and schematic procedure of environmental risk assessment

5 Exposure assessment

5.1 Selection of representative product

A representative product (for example, an anti-fouling paint) for the exposure assessment shall be chosen from anti-fouling systems containing the biocidally active substance to be assessed. This product shall have a release rate as quantified according to 5.2.1. The risk assessment process can lead to a determination of

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the maximum release rate of that biocidally active substance which can be used in real products to maintain protection of the environment.

5.2 Quantification of release rate

There are three approaches to determining release rates: calculation, laboratory testing and field measurement.

5.2.1 Quantification method

The release rate of biocidally active substances into seawater from the anti-fouling system applied onto the ship shall be estimated.

There are several methods to estimate the release rate for the anti-fouling system. Examples of the existing calculation, laboratory and field methods are described in Table A.1.

It is preferable to select one of the methods in Annex A, but this part of ISO 13073 does not preclude the development and/or use of other quantification methods.

Appropriate correction factors should be applied to laboratory and calculated release rate data to enable the most reliable estimate of environmental release rates to be made.

NOTE The results of laboratory test methods described in Table A.1 do not generally reflect the environmental release rates for anti-fouling products in use, and they are not necessarily suitable for direct use in the environmental risk assessment. The mass-balance calculation method described in Table A.1 generally provides more realistic environmental release rates, which are more suitable for use in the environmental risk assessments than the results of the laboratory test methods. A suitable method is selected on a case-by-case basis.

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5.2.2 Test laboratory

When the release rate is estimated through measurements in testing laboratories, tests should be conducted at a laboratory that complies with ISO 17025 or at establishments with equivalent qualifications.

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5.3 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 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 and the exposed environment.

Examples of existing emission scenarios for anti-fouling products can be found in the OECD EMISSION SCENARIO DOCUMENT (OECD, 2005).

5.3.1 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 is to be released. Types of marine environments to be considered may be as follows:

— open sea;

— shipping 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.

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5.3.2 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 predicted environmental concentrations 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 per unit area and unit time).

b) 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 ships);
- — percentages of the ships painted with the product.

c) the layout of the target sea area:

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

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d) water quality:

- — temperature;
- — salinity;
- — pH;
- — silt concentration (silt fraction < 63 µm in mg/L);
- — fraction of organic carbon [organic carbon content (dry mass) of sediment];
- — POC and DOC concentration [particulate and dissolved organic carbon (OC) concentration in mg OC/L)];
- — 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);
- — 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:

- — depth of mixed sediment layer;
- — dissolved organic carbon.

NOTE This list is not exclusive.

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5.3.3 Requirements for setting parameters

All the parameters shall be set to give a realistic worst-case scenario. Examples of such 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, an appropriate statistical measure should be chosen (e.g. average length, or 95th percentile length of the data set).

5.4 Determination of PEC

The PEC for each emission scenario and each relevant environmental compartment should be determined using the parameters determined in 5.3.2 and 5.3.3 and the properties relevant to each specific 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 this substance dissolved in seawater);

— organic-carbon partitioning coefficient (K_{oc});

— bioaccumulation factor of the 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). Annex H describes a number of validated models which should be used.

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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).

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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 the Technical Guidance Document (European Commission, 2003).

Where necessary, the PEC for predators and mammals (PEC_{pred}) should be determined using the parameters such as BCF, mean fish consumption rate, and the PEC for seawater (PEC_{SW}).

It is important that any models used to determine the PEC are themselves appropriately validated. The validation report for the model should be made available as a part of the risk assessment report. Validated models for PEC determination are described in Annex H.

6 Hazard assessment

6.1 Setting of PNEC

6.1.1 Setting of PNEC in seawater ($PNEC_{sw}$)

6.1.1.1 $PNEC_{sw}$ estimation from chronic test results

When chronic test results are used, $PNEC_{sw}$ is calculated with the formula below.

$$PNEC_{SW} = \frac{NOEC_c}{AF} \quad (1)$$

where

$PNEC_{SW}$ is the PNEC in seawater (mg/L);

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$NOEC_c$ is the lowest NOEC obtained through chronic testing (mg/L);

AF is the assessment factor (see 6.2).

The lowest $NOEC_c$ obtained through each chronic test is used for the calculation of the $PNEC_{SW}$. The AF is determined based on the factors cited in 6.2.

According to many OECD Test Guidelines, test concentrations should be arranged in a geometric series unless otherwise stated in the relevant test guidelines. For example, a constant factor not exceeding 3,2 is required in OECD 210. In certain studies, the ratio between test concentrations may exceed the factor specified under the validated test methods. In this case, the average value of NOEC and LOEC (maximum allowable toxicant concentration, MATC) may be used as the NOEC.

6.1.1.2 $PNEC_{sw}$ estimation from acute test results

When acute test data are used, $PNEC_{SW}$ is calculated with the formula below:

$$PNEC_{SW} = \frac{L(E)C_{50}}{AF} \quad (2)$$

where

$PNEC_{SW}$ is the PNEC for seawater (mg/L);

$L(E)C_{50}$ is the 50 % Lethal Concentration (LC_{50}) or the 50 % Effective Concentration (EC_{50}) (mg/L);

AF is the assessment factor.

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The lowest $L(E)C_{50}$ obtained from the acute test data is used for the calculation of the $PNEC_{SW}$. The AF is determined based on the factors cited in 6.2.

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6.1.1.3 Considerations for data-rich substances

Many substances, particularly metals, are very data-rich with many and repeated studies being available both in the public domain and in protected data systems. Thus, evaluation of such a wide collection of data requires a complex screening and assessment of the studies using, for example, probabilistic techniques (6.1.1.4) to allow them to be used to establish a robust evaluation of the environmental risk posed by the use of such substances.

6.1.1.4 Typical statistical extrapolation techniques to be used

The method of choice for statistical extrapolation is the model that assumes a parametric distribution for the different chronic ecotoxicity data (no observed effect concentrations: NOEC's) observed on a number of species, belonging to an ecosystem. In order to estimate the uncertainty associated with the use of limited data sets, 95 % and 50 % confidence limits can be calculated for 5 % hazardous concentrations (HC5) value. The PNECs are usually set at the level of the 50 % lower confidence value of the HC5. These statistical extrapolation techniques are explained in the existing guidance such as the Technical Guidance Document (European Commission, 2003).

6.1.2 Setting of PNEC for sediment-dwelling organisms ($PNEC_{sed}$)

6.1.2.1 $PNEC_{sed}$ estimation from chronic test results

When chronic test results are used, $PNEC_{sed}$ is calculated with the formula below

$$PNEC_{sed} = \frac{Chronic_{sed}}{AF} \quad (3)$$

where

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