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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

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*

— *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 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.

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.

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.

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

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.

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

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

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.

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

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 $\mu g\ cm^{-2}\ day^{-1}$.

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

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

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.

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.

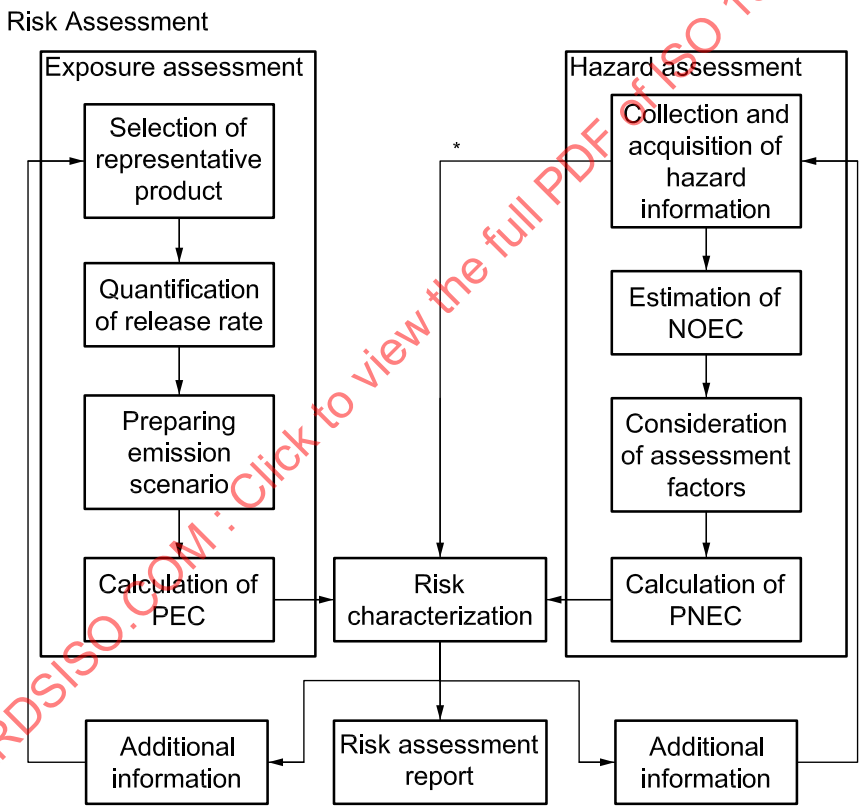
c) For regulatory systems with approval or evaluation procedures developed according to this part of ISO 13073 and with restriction of a substance classified as “tentatively low risk” under Level 1 of Tier 2, an appropriate sale period or quantity should be specified taking into account the severity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



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

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.

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.

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.

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:

   — 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).

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.

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.

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 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);

$NOEC_c$ 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.

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.

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

$PNEC_{sed}$ is the PNEC for sediment-dwelling organisms (mg/kg);

$Chronic_{sed}$ is the lowest NOEC obtained through the chronic test, the 10 % Lethal Concentration (LC_{10}) or the 10 % Effective Concentration (EC_{10}) (mg/kg);

AF is the assessment factor.

The lowest $NOEC_{sed}$ obtained through each chronic test or the lowest LC_{10} or EC_{10} obtained through each acute test is used for the calculation of the $PNEC_{sed}$. The AF is determined based on the factors cited in 6.2.

6.1.2.2 $PNEC_{sed}$ estimation from acute test results

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

$$PNEC_{sed} = \frac{L(E)C_{50}}{AF} \quad (4)$$

where

$PNEC_{sed}$ is the PNEC for sediment-dwelling organisms (mg/kg);

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

AF is the assessment factor.

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

6.1.3 Setting of PNEC for avian and mammalian species ($PNEC_{pred}$)

The PNEC for organisms in trophic levels higher than fish is calculated with the following formula:

$$PNEC_{pred} = \frac{Tox_{pred}}{AF} \quad (5)$$

where

$PNEC_{pred}$ is the PNEC for an organism of higher trophic level (mg/kg);

Tox_{pred} is the toxicity value for an organism of higher trophic level (mg/kg);

AF is the assessment factor.

The lowest value of either LC_{50} or NOEC for avian species or NOEC for mammals is set as Tox_{pred} and used to calculate the PNEC. The AF is determined based on the factors cited in 6.2.

6.2 Consideration of assessment factors

In order to adjust the uncertainty in calculating the PNEC that results from testing on a limited set of potential aquatic organisms, an assessment factor is incorporated into the PNEC based on the test type, number of tested species, and number of trophic levels covered by the test species.

Some examples of setting the assessment factor are described in Annex F; a combination of these methods/perspectives may be appropriate.

6.3 Determination of PNEC used for risk characterization

The PNEC to be used in a risk characterization calculation will be derived from the lowest experimentally determined value, either NOEC from chronic test data or $L(E)C_{50}$ from acute test data. This NOEC or $L(E)C_{50}$ is used in conjunction with the appropriate assessment factor derived from the entire ecotoxicology data set.

7 Risk characterization

7.1 General

Risk characterization for organic substances shall be conducted according to the tiered process described in Annex B. Risk characterization for inorganic substances shall be conducted under Annex C. The PNEC for organic substances is calculated using the toxicity data developed for each tier/level of the process. The risk level should be determined by calculating the ratio of PEC to PNEC (PEC/PNEC ratio). Both systems use a step-by-step approach to risk characterization utilizing the common approach described below.

Metallic complexes of organic compounds should undergo risk characterization to both Annexes B and C.

7.2 Data and information

7.2.1 Collection and acquisition of data and information

In order to conduct the assessment appropriately, data and information concerning the physico-chemical characteristics, environmental behaviour and hazardous properties of the biocidally active substances are required. Appropriate tests are described in Annexes B and C.

7.2.2 Reliability assessment of the collected data

7.2.2.1 Reliability assessment of data

Standard methodologies already exist for determining a reliability score to assess the data. One of such systems is the Klimisch scoring system (see D.4). Within this approach, consideration should also be given to a “weight-of-evidence” analysis.

7.2.3 Determination of any data gaps

If necessary, data gaps should be closed using as much information as possible from existing studies by applying the examples mentioned in OECD (2009). These include the following.

— Quantitative Structure-Activity Relationship (QSAR): a quantitative (mathematical) relationship between a numerical measure of chemical structure, and/or a physico-chemical property, and an effect/activity. QSARs often take the form of regression equations, and can make predictions of effects/activities that are either on a continuous scale or on a categorical scale. Thus, in the term “QSAR”, the qualifier “quantitative” refers to the nature of the relationship, not the nature of the end point being predicted. Caution should be used that only those QSAR techniques appropriate to class of the substances (e.g. organic or inorganic) are employed.

— Read-across argumentation: the technique for filling data gaps, where end point information for an untested chemical is predicted by using data on the same end point for a tested chemical, which is considered to be “similar” for some aspect (e.g. activity, property or structure). A read-across argumentation is feasible, where studies exist for an analogous substance to the one under consideration. If such an argument is substantiated, then the studies on one salt of an inorganic substance may be used for other salts of the same substance.

— Grouping approaches: the use of properties across a group of substances which show substantial similarities for the group as a whole.

Only valid studies should be used, and the most conservative value from these studies should be used to derive the PNEC. Data evaluated as “not reliable” or “of very low reliability” shall not be used for the risk assessment. Examples of guidance on data quality evaluation methods are provided in Annex D.

7.2.4 Test requirements

7.2.4.1 Testing methods

Tests shall be conducted according to internationally recognized test methods, or test methods equivalent to such methods (see Annex E), by an organization or a laboratory meeting Good Laboratory Practice (GLP) requirements or with the equivalent qualification.

7.2.4.2 Selection of test species

Test species relevant to the environmental compartment under evaluation should be chosen. For example, where a product is intended for use primarily in marine water, the use of marine species is preferable, however this does not rule out the use of freshwater species specified in the test methods shown in Annex E as long as this is taken into account when determining the assessment factor to be applied to the derived NOEC or L(E) C_{50} for determining the PNEC. For freshwater assessment, preference should be given to freshwater species.

7.2.4.3 Test omission

In certain circumstances, it may be acceptable to omit or replace some tests with other test results or methodologies. In all cases, scientifically justified reasons should be given for not conducting the test(s). Examples include the following:

— The study has been conducted on a chemically similar substance.

— It is impractical to test the target substance.

7.2.5 Data or information to be submitted

The applicant may submit the data or information evaluated as “not reliable” or “not assignable” according to the reliability assessment described in Annex D for ‘weight of evidence’ arguments or test omission justifications on the condition that the reliability assessment document on the data or information is attached.

The applicant shall submit any data indicating adverse effects or information that is of high significance to the protection of the marine environment, regardless of the reliability of the data (for example information on endocrine disrupting properties).

7.2.6 Consideration of animal protection

When an implementation plan is established for an additional test, consideration shall be given to animal protection, i.e. using the minimum number of vertebrate test animals. When considering whether a new test shall be conducted, it should be determined if such a test will significantly improve NOEC accuracy, before its implementation. The test shall not be conducted if the possibility is low.

7.3 Assessment results

The following terms are used to characterize the apparent risk of using the biocidally active substance.

7.3.1 Low risk

If the substance is assessed as “low risk”, the application of the anti-fouling system using the biocidally active substance on ships is regarded as having a risk to the marine environment which is considered negligible.

7.3.2 Risk of high concern

If the substance is assessed as “risk of high concern”, the ecological risk to the marine environment is considered to be high (more than negligible) and there is concern regarding the application of an anti-fouling system using that biocidally active substance.

7.3.3 Relatively low risk

If the biocidally active substance is assessed as “relatively low risk”, it means that ecological risk of the anti-fouling system using this substance on ships is not considered to be negligible in the marine environment, but it is deemed to be within an acceptable range.

7.4 Additional information obtained after last risk characterization

In cases where additional information has been made available after last risk characterization for a biocidally active substance assessed as “low risk”, “relatively low risk” or “risk of high concern” in a marine environment, a revised risk characterization shall be developed.

8 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 risk assessment report is described in the minimum required information to be cited in Annex G.

Annex A
(informative)

Systems for estimation of release rates of biocidally active substances from anti-fouling paints

A.1 Introduction

This Annex describes the main existing methods for estimating the release rate of biocidally active substance(s) from anti-fouling paints into seawater.

A.2 Examples of estimation method for release rate

Table A.1 provides the major methods for estimating the release rates of biocidally active substances from anti-fouling paints applied on ships, and the characteristics of these methods.

A.3 Estimation method

The determined release rate of the same biocidally active substance may vary depending on the estimation method. The selection of an estimation method is therefore significant. Refer to the published standards in the Bibliography for guidance on how the values estimated by different methods relate to the representative release rate values under any given emission scenarios (Finnie, 2006; IPPIC, 2009).

In principle, direct *in situ* measurement methods provide the best estimate of environmentally relevant release rates, but there is currently no practical standardized method available for routine use. The use of a calculation or laboratory method may provide release rate estimates that do not reflect the true release rate under environmentally relevant conditions.

The initial choice for release rate estimation would be “Mass-balance-calculation method”, which was developed for use in environmental risk assessment as it provides a realistic worst-case estimate of the release based upon the parameters of the dry paint film on ships. Accordingly, it is important that an appropriate dry film thickness is selected for the intended “in service” life of the coating. Where a biocidally active substance has yet to be used in a paint formulation, paint schemes (i.e. dry film thickness etc) can be approximated based upon the schemes of anti-fouling paints or systems already available.

It is also well known that the release rate of active substances depends on the relative flow rate of water (i.e. ship’s velocity) and that the release rate when ships are stationary is generally lower than that during navigation. Therefore, both the mass-balance calculation method and the laboratory method will generally provide significantly overestimated release rates for emission scenarios where the ship is largely immobile [e.g. the OECD’s marina or commercial harbour scenarios (OECD, 2005)]. For such particular cases, it is a pragmatic approach to make an appropriate correction on the release rate in order to refine the PEC determination for the emission scenario. Conservative correction factors of 2,9 for the mass-balance calculation method and 5,4 for the laboratory method have been recommended (Finnie, 2006; IPPIC, 2009). Although most of the laboratory tests are defined as “not for use in risk assessment” they could be used to obtain a release rate experimentally. Where there are concerns that the release rate is substantially overestimated (as in the current ASTM and ISO methods) then the use of an appropriate correction factor is recommended.

Table A.1 — Examples of estimation method for release rate of biocidally active substance

Type	Methods	Characteristics
Mass-balance calculation method	ISO 10890 Modelling of biocide release rate from anti-fouling paints by mass-balance calculation	The method is a generic empirical model of biocide release, which is based on the underlying fact that the total amount of biocide released by an anti-fouling paint cannot exceed the amount of biocide which was originally present when the paint was manufactured and applied. The method calculates the mean release rate over the lifetime of the paint. The calculated value should be considered as the maximum possible mean release rate over the lifetime of the paint. The method is applicable to any anti-fouling paint that releases any biocidally active substance.

Table A.1 *(continued)*

Type	Methods	Characteristics
Laboratory method	ASTM D5108-90 Organotin release rates from antifouling coating systems in seawater ASTM D6442-06 Standard Test Method for Determination of Copper Release Rate From Antifouling Coatings in Substitute Ocean Water ASTM D6903-07 Test method for determination of organic biocide release rate from antifouling coatings in substitute ocean water	These methods are standardized laboratory methods using a rotating cylinder device measuring the release rates during a given time of immersion (minimum 45 days) under specified conditions (T: 25 °C ± 1; salinity: 33 – 34 parts per thousand; pH: 7,9 - 8,1). The rotating-cylinder laboratory methods were initially developed to measure organotin and copper but have been since extended to cover a range of organic biocidally active substances. As described in these documents, caution should be exercised when using these methods to obtain a release rate for environmental risk assessments as the methods have occasionally been shown to significantly overestimate the release rate.
	ISO 15181-1 Determination of release rate of biocides from antifouling paints – General method for extraction of biocides ISO 15181-2 Determination of release rate of biocides from antifouling paints - Determination of copper-ion concentration in the extract and calculation of the release rate ISO 15181-3 Calculation of the zinc ethylene-bis (dithiocarbamate) (zineb) release rate by determination of the concentration of ethylenethiourea in the extract ISO 15181-4 Determination of pyridine-triphenylborane (PTPB) concentration in the extract and calculation of the release rate ISO 15181-5 Calculation of the tolylfluanid and dichlofluanid release rate by determination of the concentration of dimethyltolylsulfamide (DMST) and dimethylphenylsulfamide (DMSA) in the extract ISO 15181-6 Determination of tralopyril release rate by quantification of its degradation product in the extract	
Field method	SSCSD Dome Method (Finnie, 2006) Measuring *in situ* copper and organotin release rates using a dome placed on an immersed painted ship hull.	The published results demonstrate that the release rates measured in the field by this technique are significantly lower than those measured using laboratory methods. These results suggest that the laboratory methods above may overestimate organotin and copper release rates from anti-fouling paints and hence the environmental loading into the aquatic environment.

Annex B
(normative)

Details of risk characterization process of an environmental risk assessment for organic biocidally active substances used in anti-fouling systems on ships

B.1 Introduction

This Annex provides the decision-making process of the environmental risk assessment for organic biocidally active substances used in anti-fouling systems on ships (see Figure B.1). This aims to provide an appropriate environmental risk assessment for the protection of the marine environment.

B.2 The step-by-step approach

B.2.1 Start and end of the evaluation process

The risk characterization process starts from Tier 1, and proceeds stepwise to the end in Level 2 of Tier 2. The assessment is conducted in order of Tier 1, Tier 2, Level 1 and then Level 2, based on the criteria described in each step, until every biocidally active substance is defined as “Risk of high concern”, “Relatively low risk” or “Low risk” at the end of the evaluation process.

B.2.2 Tier system

The tier system in this Annex consists of 2 Tiers: Tier 1 and Tier 2.

It should be noted that, if any biocidally active substance does not meet the criteria described in Tier 1, it means that the substance could have adverse effects on the marine environment and additional studies are advised. Consequently, the minimum requirement necessary for the biocidally active substances to proceed to Tier 2 shall be the highest bioconcentration factor (BCF) for fish and aquatic invertebrates of less than 2 000.

NOTE BCF approximated by log P_{OW} (BCFp) can be used in place of this BCF except for Level 2 of Tier 2.

B.2.3 Level system

The level system in this Annex refers to the 2-stage assessment of biocidally active substances to complete Tier 2.

The assessment is conducted in steps from Level 1 to Level 2. For substances which are approved at Level 1 a predetermined period from the date of approval should be given in which the anti-fouling system may be used. During this period (hereafter referred to as “suspended period”), the applicant shall prepare data in order to apply for the approval in Level 2.

The suspended period may be set according to the volume, such as the production volume (including import volume) or usage amount of biocidally active substances so that they would not lead to any harm to the environment.

B.3 Tier 1

B.3.1 Data and information requirement

The data and information required in Tier 1 are described below.

a) A bioconcentration factor (BCF) in fish or aquatic invertebrates estimated through exposure tests or BCF approximated by log P_{OW} (BCFp);

b) A half-life estimated from simulated biodegradation test results;

c) All of the following primary degradation test results with a half-life estimated from them:

— hydrolytic degradation test;

— photolytic degradation test;

— biodegradation test in seawater;

d) Acute test results (LC_{50} and/or EC_{50}) for all of the following aquatic organisms:

— fish;

— invertebrates;

— algae;

e) Chronic test result (NOEC, LOEC and/or MATC) for the most sensitive species of fish or aquatic invertebrates;

f) The biocidal activity in degradation process of the initial dose;

g) PEC_{sw} and its calculation method;

h) Assessment factors and the grounds;

i) $PNEC_{sw}$ and its calculation method;

j) $PEC_{sw}/PNEC_{sw}$ ratio for respective environmental media.

Existing test methods to obtain these data are indicated in Annex E.

B.3.2 Criteria

In Tier 1, the biocidally active substance meeting all of the criteria (Table B.1) is determined as “Low risk”:

Table B.1 — Criteria of Tier 1

Bioaccumulation	Highest bioconcentration factor (BCF) in fish and aquatic invertebrates < 100
Degradation	Half-life for ultimate degradation calculated from the degradation test < 15 days, and Loss of biocidal activity is shown
Risk ratio	PECsw/PNECsw ratio < 1
NOTE 1 Ultimate degradation means mineralisation as determined by a surface-water simulation test series. Primary degradation means transformation of biocidally active substance. NOTE 2 If a substance is proven to be “readily degradable” as defined in the OECD 301 series, it is deemed to satisfy the half-life criterion above for degradation.	

B.3.3 Assessment

If the substance meets the criteria in B.3.2 and is assessed as “Low risk”, the ecological risk of the anti-fouling system using the biocidally active substance to the marine environment is considered to be low and the assessment is finalised.

If the substance is not assessed as “Low risk”, proceed to Level 1 of Tier 2, and continue the assessment with additional data and information.

B.4 Level 1 of Tier 2

B.4.1 Required additional data and information

In Level 1 of Tier 2, the following data and information are required in addition to the data obtained in Tier 1.

a) Refine PNEC by means of more chronic data:

b) K_{OC}:

— Adsorption/Desorption screening test for K_{OC}.

Test methods for obtaining the following data are described in Annex E.

Furthermore, BCFp, a bioconcentration factor (BCF) in fish or aquatic invertebrates approximated by a logarithm of *n*-octanol/water partition coefficient (log P_{OW}) may be used in place of a BCF estimated through exposure tests.

B.4.2 Criteria

In Level 1 of Tier 2, if the biocidally active substance meets either criteria (a) or (b) in Table B.2, it is assessed as “Tentatively classified as relatively low risk”.

Regarding the PEC/PNEC ratio criteria, in the case of PEC with low accuracy (e.g. due to limited types of marine environment considered, difficulty to calculate PEC for target media, and low reproducibility by the model used or significant variations in the results among the test methods for determination of release rate), lowering these criteria to less than 1 may be accepted.

Table B.2 — Criteria of Level 1 of Tier 2

	(a)	(b)
Bioaccumulation	Highest bioconcentration factor (BCF or BCFp) in fish and aquatic invertebrates < 100	Highest bioconcentration factor (BCF or BCFp) in fish and aquatic invertebrates < 1 000
Degradation	Half-life for ultimate degradation calculated from the degradation test < 60 days (simulation biodegradation test), and Loss of biocidal activity is shown	Half-life for ultimate degradation calculated from the degradation test < 15 days (simulation biodegradation test), and Loss of biocidal activity is shown
Accumulation to sediment	Maximum soil adsorption coefficient (K_p) < 2 000	
Risk ratio	PEC/PNEC < 1	
NOTE 1 In criteria for bioaccumulation, BCF approximated by log P_{OW} (BCFp) can be used in place of BCF. NOTE 2 Ultimate degradation means mineralisation as determined by a surface-water simulation test series. Primary degradation means transformation of biocidally active substance. NOTE 3 If a substance is proven to be “ultimate degradation” as defined in a simulation biodegradation test, it is deemed to satisfy the half-life criterion above for degradation.		

B.4.3 Tentative assessment

The assessment result in Level 1 of Tier 2 is tentative: the applicants, even when the biocidally active substance meets the criteria in B.4.2, shall apply again for the Level 2 assessment within the “suspended period” from the date of approval in Level 1.

B.5 Level 2 of Tier 2

B.5.1 Required additional data and information

In Level 2 of Tier 2, information on identification and quantification of degradation products is required in addition to the data acquired in Tier 1 and Level 1 of Tier 2.

Furthermore, the following data and information are required depending on the assessment criteria that could not be met in Level 1 of Tier 2. Bioconcentration factor (BCF) approximated by log P_{OW} shall not be used.

a) Risk characterization for degradation products (see B.5.2).

b) A bioconcentration factor (BCF) in fish or aquatic invertebrates estimated through exposure tests.

c) Refine PNEC by means of more chronic data.

d) Water/sediment degradation.

e) The risk assessment for predators due to secondary poisoning and for humans exposed via the environment:

— aves;

— mammals.

B.5.2 Required additional data and information on risk characterization for degradation products

Figure B.2 provides the process of risk characterization for degradation products of biocidally active substances. In this process, the following data are required for the degradation products more than 10 % of the initial dose of the biocidally active substance. The degradation tests shall be conducted according to the methods described in B.3.1 c).

a) Identification and quantification of degradation products more than 10 % of the initial dose;

b) Acute test (LC_{50} and/or EC_{50}) results for all of the following aquatic organisms or those obtained through quantitative structure-activity relationship (QSAR) approaches:

— fish,

— invertebrates,

— algae;

c) Chronic test result (NOEC, LOEC and/or MATC) for fish or aquatic invertebrates or those obtained through QSAR approaches;

d) PEC and its calculation method;

e) Assessment factors and the grounds;

f) PNEC and its calculation method.

B.5.3 Criteria

In Level 2 of Tier 2, the biocidally active substance meeting either of criteria (a) or (b) in Table B.3 is assessed as “Relatively low risk”.

Table B.3 — Criteria of level 2 of Tier 2

	(a)	(b)
Bioaccumulation	1 000 ≤ BCF < 2 000 and $PEC/PNEC_{(predator, mammal)} < 1$	BCF < 1 000
Accumulation to sediment	$K_p < 2\ 000$ or Ultimate degradation half-life < 15 day (water/sediment simulation test) or $PEC/PNEC_{(sediment)} < 1$	
Degradation	Loss of biocidal activity is shown.	
Risk ratio (degradation products)	All degradation products are less than 10 % of the initial dose or PEC/PNEC < 1 (degradation products ≥ 10 % of the initial dose)	
Risk ratio (biocidally active substance)	PEC/PNEC < 1	

NOTE 1 Ultimate degradation means mineralisation as determined by a surface-water simulation test series. Primary degradation means transformation of biocidally active substance.

NOTE 2 In the assessment for degradation products, risk assessment is made for all major metabolites (>10 % of the initial dose of the biocidally active substance). Degradation refers to the primary degradation. Toxicity data for PNEC of degradation products can be obtained through QSAR approaches.

Even if it was determined as “tentatively classified as relatively low risk” in Level 1 of Tier 2, the bioconcentration factor estimated through the exposure method and the risk characterization for degradation products shall be presented in Level 2 of Tier 2 after a certain period from the date of determination in Level 1.

B.5.4 Assessment

If the substance does not meet the criteria in B.5.3, it is assessed as “Risk of high concern”. If the substance satisfies the criteria in B.5.3, it is assessed as “Relatively low risk”. When the risk assessment is not sufficiently reliable, for example, with PEC of low accuracy (e.g. due to limited types of marine environment considered, difficulty to calculate PEC for target sea area, and low reproducibility by the model used or significant variations in results among the test methods to determine release rates), its application to certain ships can be limited to allow its re-assessment with additional results.

In Figure B.1, the following notes apply.

NOTE 1 Ultimate degradation means mineralisation as determined by surface-water simulation test series. Primary degradation means transformation of biocidally active substance.

NOTE 2 If any criterion with symbol “#n”(n = 1~4) cannot be satisfied, then the criterion in the next step with the same symbol is the only requirement to be looked at.

NOTE 3 For level 1 of Tier 2, BCF approximated by log P_{OW} can be used. However, this approximation is not allowed when it is difficult to estimate P_{OW}. Included among these chemicals are easily metabolisable compounds, compounds not easily soluble to fat but capable to be taken into the human body due to their affinity to specific components in the body such as proteins, organic metals and surfactants.

NOTE 4 In criteria for half-life, degradation refers to “ultimate degradation” as defined in a simulation biodegradation test.

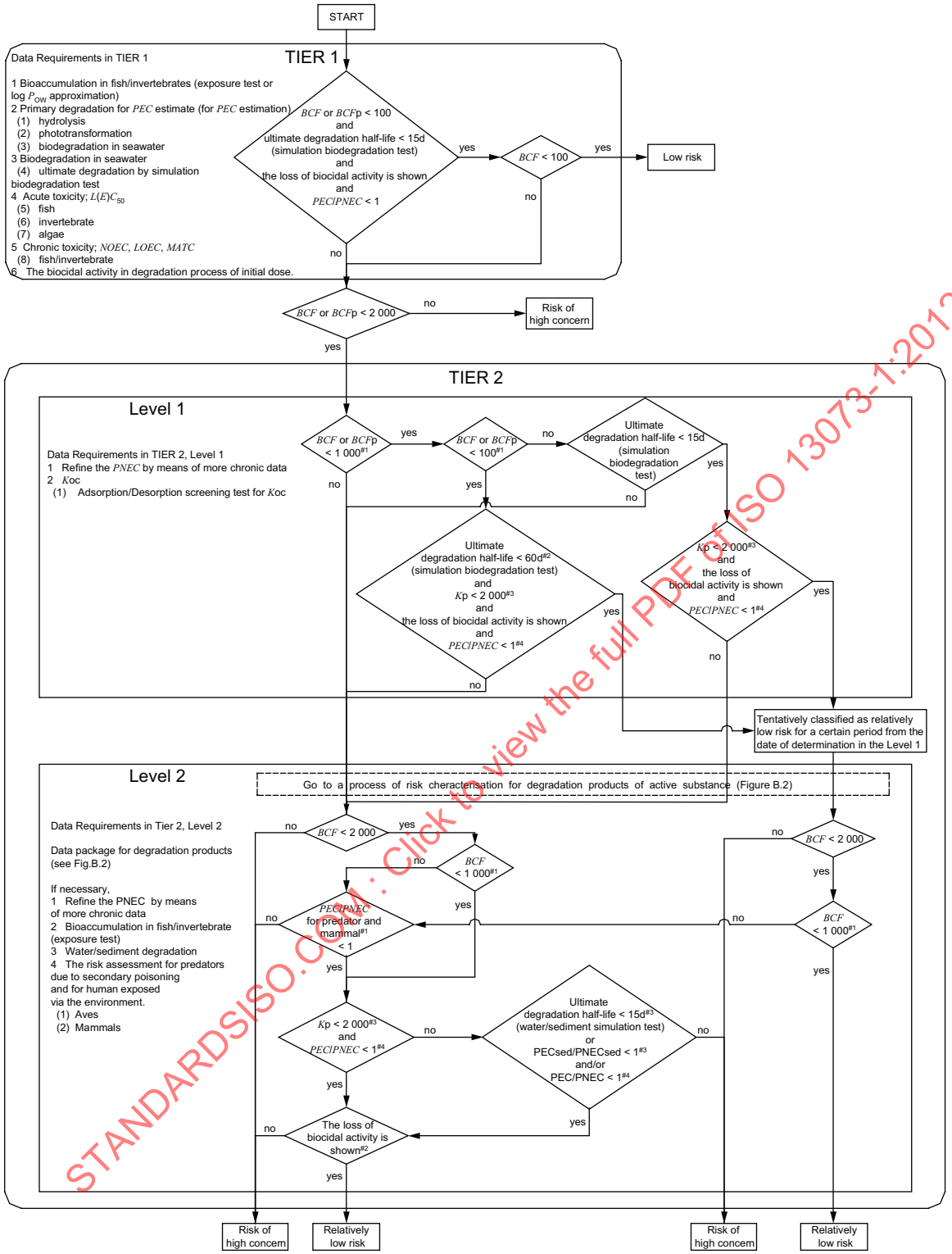
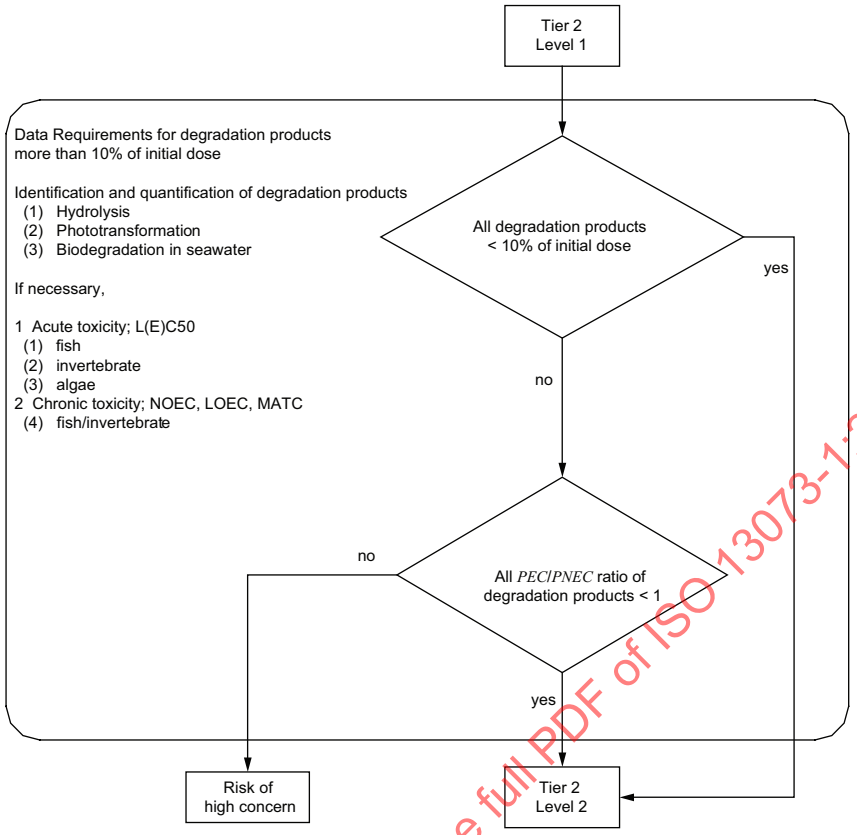


Figure B.1 — Process of risk characterization for organic biocidally active substances



NOTE 1 Toxicity data for PNEC of degradation products can be obtained through QSAR approaches.

NOTE 2 Degradation refers here to the primary degradation. Risk assessment for all major metabolites is conducted when degradation products are more than 10 % of the initial dose of the biocidally active substance.

Figure B.2 — Process of risk characterization for organic biocidally active substances

Annex C
(normative)

Issues to be considered for risk characterization for inorganic biocidally active substances used in anti-fouling systems on ships

C.1 Introduction

This Annex extends the consideration in Clause 7 to provide the decision-making process for an environmental risk assessment of inorganic biocidally active substances used in anti-fouling systems on ships. This aims to provide an appropriate environmental risk assessment for the protection of the marine environment. Inorganic substances are usually non-degradable, therefore specific consideration must be given to the points below. It is inappropriate to assess a non-degradable substance against the bioaccumulation and degradation criteria of Tier 1 defined in Annex B, as other mechanisms may be in place to limit these effects.

C.2 Approach to data-gathering and risk assessment for data-rich inorganic substances

Methodologies developed for synthetic organic substances are potentially inappropriate for assessing the risk of natural inorganic substances. They may not adequately address the properties of these substances and their interactions with biota such as:

— natural occurrence versus contamination;

— essentiality;

— homoeostatic control mechanisms;

— acclimatisation to diverse natural environments;

— bioavailability.

Many inorganic substances are very data-rich with many and repeated studies and, thus, evaluation of a wide collection of data requires a complex screening and assessment of the studies described in 6.1.1.3.

The risk assessment process for natural inorganic substances should be developed to allow the inclusion of information relating to factors such as natural occurrence, essentiality and bioavailability in order to derive a realistic assessment without compromising the protection of the environment.

C.3 Data gathering

The first stage in the process is the assembly of all available data, which should then be screened for quality and reliability.

The data and information required are described below. Details of example testing protocols are given in Annex E.

C.3.1 Physico-chemical properties

The data on physico-chemical properties indicated in Annex G are required.

C.3.2 Water/Sediment distribution

Although not explicitly mentioned in the OECD guideline 106 tier 2, the handling procedure can also be applied to sediments. An alternative method is the estimation of adsorption with HPLC (OECD Guidelines 121). It should be noted that for some substances the HPLC-technique is not yet fully validated.

C.3.3 The bioconcentration factor (BCF) in fish and/or aquatic invertebrates

An estimation of the intrinsic potential for bioconcentration of a biocidally active substance in aquatic organisms on the basis of the physical and chemical properties should be reported. Especially in the case of inorganic substances such as metals, an estimation on the basis of toxico-kinetic studies (including those on their metabolism where appropriate), residue studies or monitoring data on aquatic organisms (e.g. data on residues in tissues of aquatic organisms and on concentrations in the environment) or an available relevant study should also be reported.

The evaluation of aquatic bioconcentration should include an estimate of the bioconcentration factor related to an aquatic food chain, freshwater and/or marine, with an aquatic species and a fish-eating bird/predator.

It should be noted that for many inorganic substances, particularly metals, most organisms maintain a homoeostatic control mechanism and thus these studies may not be suitable.

Bioaccumulation for an appropriate species of fish and/or invertebrates shall be studied. Examples of the study methods are provided in Annex E.

C.3.4 Other data

The information required is described below:

a) Information on factors which will affect the bioavailability of the substance in differing environmental compartments and situations:

   — the effects of organic matter in the compartment;

   — the effects of particulate matter in the compartment;

   — the effects of pH in the aquatic compartment;

   — hardness in freshwater.

NOTE The main effects on bioavailability are water quality factors including but being not limited to the above.

b) Information on the natural occurrences of the substance in relevant environmental compartments and situations.

C.4 Assessment factors

Some examples of the methods for setting an assessment factor are described in Annex F.

For inorganic substances, there often exist a very large number and range of chronic studies for different taxonomic groups. It is thus possible to use statistical extrapolation methods to derive a PNEC, in which case lower assessment factors (typically 1-5) can be applied based upon the confidence in the size and quality of the data set.

C.5 Risk characterization and uncertainty analysis

C.5.1 Initial risk consideration

The initial risk characterization should be undertaken by deriving Predicted Environmental Concentration (PEC) and comparing this with a Predicted No-Effect Concentration (PNEC) for each environmental compartment. This comparison of the derived PEC versus the PNEC should be assessed with an understanding of uncertainties and data gaps to ensure that the outcome is sensible.

When reviewing the predicted risk (PEC to PNEC ratio) (see Figure C.1), it may be necessary to carry out further refinements. In this case an assessment should also be undertaken with attention given to particular aspects of the properties of natural inorganic substances as shown from C.5.1.1 to C.5.1.4. It may be necessary to utilize an exposure model which takes account of bioavailability in determining the risk quotient to be used.

NOTE Such a model is the Biotic Ligand Model (BLM), see C.5.2.

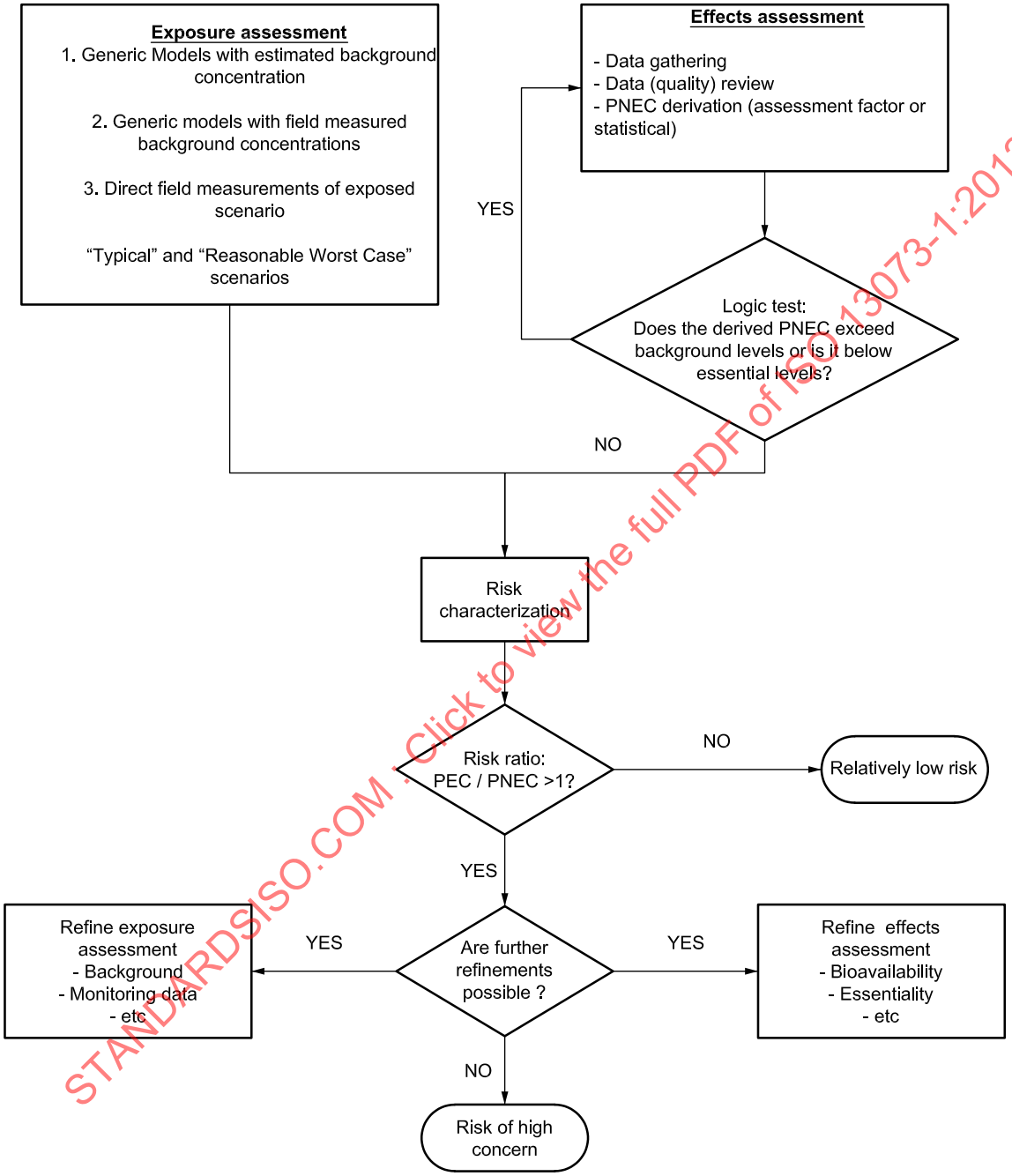


Figure C.1 — Process of risk characterization for inorganic biocidally active substance

C.5.1.1 Essentiality

Within a defined concentration window, organisms use their homoeostatic mechanisms to regulate the internal concentration of an essential element without experiencing excessive stress.

The derived PNEC cannot logically fall below this threshold and should be reviewed against this since, if the concentration of the essential metal falls below this threshold value, then effects from deficiency of the essential metal may arise.

C.5.1.2 Background concentrations

The derived PNEC cannot logically fall below the background concentration if information on this is available.

C.5.1.3 Adaptation

Organisms can naturally adapt to the concentration of metals in their environments. This effect must be taken into consideration when test doses for such organisms are set in the studies. The results from such studies should be carefully considered when their acceptability is determined.

C.5.1.4 Bioavailability

Generic exposure models return calculated total concentration and/or dissolved concentration.

Research has shown that the biological activity of, in particular, essential metals is reduced through interactions with, for example, dissolved organic carbon.

The resultant organo-metal complex may not be bio-available, therefore the total concentration determined by modelling may not be the most appropriate value to use to provide a true reflection of biological activity.

C.5.2 Modelling bioavailability of chemical forms of inorganic substances in the aquatic environment

Metal bioavailability and toxicity are recognized to be a function of water chemistry. For example, formation of inorganic and organic metal complexes and their sorption on particle surfaces can reduce metal toxicity. As a result, metal toxicity can be highly variable and dependent on ambient water chemistry.

The Biotic Ligand Model (BLM) was developed to estimate metal speciation and the effects on bioavailability. The BLM can be used to predict the amount of metal accumulated which is bioavailable at a given site under the specific conditions at that site.

C.5.3 Refined assessment

The risk assessment is an iterative process and may be refined by the derivation of further data at stage 1 or application of increasingly sophisticated methodologies at stage 2. Models such as BLM are under constant development, and may lead to increasingly sophisticated results. The assessment may also be further refined by additional effects data to allow a reduction of the assessment factor, or a refinement of the exposure assessment through verification by field measurements taken from a typical worst-case receiving environment.

Annex D
(informative)

Examples of guidance for determining data quality

D.1 Introduction

This Annex describes the examples of existing guidance for determining toxicity data quality of hazardous substances.

D.2 OECD guidance on data quality evaluation

Manual for Investigation of HPV Chemicals, Chapter 3, Data Evaluation:

http://www.oecd.org/document/7/0,3343,en_2649_34379_1947463_1_1_1_1,00.html

D.3 EU guidance on data quality evaluation

European Chemicals Agency, 2008. Guidance on information requirements and chemical safety assessment Chapter R.4: Evaluation of available information. Guidance for the implementation of REACH. May 2008 http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r4_en.pdf?vers=20_08_08

BPD Reference—European Chemicals Bureau (2008). Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market, Common Principles and Practical Procedures for the Authorisation of Registration of Product, Dossier Preparation and Study Evaluation.

D.4 Klimisch scoring scheme

Klimisch scoring scheme provides for four reliability categories:

a) Reliable without restrictions (score 1);

b) Reliable with restrictions (score 2);

c) Not reliable (score 3);

d) Not assignable (score 4).

Using this system all collated studies should be given a reliability score. Only categories with a score of 1 or 2 should be used in a risk assessment, whereas studies with a score of 3 or 4 may be used in support of, but not replacement of, the results of studies with score of 1 or 2.

European Chemicals Agency, 2008. Guidance on information requirements and chemical safety assessment Chapter R.4: Evaluation of available information. Guidance for the implementation of REACH. May 2008 http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r4_en.pdf?vers=20_08_08

NOTE OECD, Manual for Investigation of HPV Chemicals Chapter 3, where the original Klimisch scoring system is fully implemented.

Annex E
(informative)

Examples of testing methods

E.1 Introduction

This Annex describes examples of existing test methods for degradation, bioaccumulation, toxicity (acute and chronic), and sediment adsorption of substances.

E.2 Test species

Marine or brackish organisms should be selected as test species. If different aquatic environments are exposed, tests should be conducted with two species. For instance, in addition to a test with a freshwater species, test results for a saline or brackish water species should be submitted, whichever is relevant.

E.3 Ecotoxicological studies

The ability of the biocidally active substance or its degradation product(s) to damage the function and structure of biotic systems is to be clarified with a selection of ecotoxicity tests.

Effects in ecologically functional groups of producers, consumers and decomposers in relevant media (water, soil, and air) are addressed in these tests.

There is a need to report all potential adverse effects found during routine ecotoxicological investigations and to undertake and report such additional studies which may be necessary to investigate the probable mechanisms involved and to assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the biocidally active substance must be reported.

The species tested should be relevant to the environments likely to be affected due to the manner of use of the substance. Seawater species should be used if the substance is likely to influence directly or indirectly only estuarine or marine environments. If a marine or brackish water environment is affected and it is not the only aquatic target environment, then a toxicity test on a marine or brackish water species is required in addition to the tests on freshwater species.

In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of the biocidally active substance if stability permits. Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various toxicity tests specified.

As required by EC test methods, concentrations of the test substance should be measured at least at the beginning as well as at the end of the test. Normally, however, it will be necessary to monitor the concentrations more frequently. The LC_{50}'s, EC_{50}'s and NOEC's should be calculated based on the measured concentrations. However, where the measured concentrations are close to the nominal concentrations (i.e. $>$ 80 % of nominal), it is acceptable to calculate the LC_{50}'s, EC_{50}'s and NOEC's based on nominal concentrations of the tested substance. In other cases, the geometric average of measured concentrations should be used.

E.3.1 Acute toxicity test result for all of the following organisms

The tests should provide the acute toxicity values for mortality, immobilisation or growth inhibition, NOEC values, and details of observed effects.

When a toxicity test is conducted on aquatic organisms, it is useful to confirm solubility and stability of the substance in the test medium, as they may differ from those obtained under the water solubility test.

Fish shall be studied at least for one species, and a marine water species is preferred. If organisms are exposed in different aquatic environments, two species, one freshwater species and one marine species should be selected. *Cyprinodon variegatus* may be used as a marine species. Tests should be performed according to the EC method C.1 or the corresponding OECD guideline 203 (where a test with *Cyprinodon variegatus* is also possible). For marine species, e.g. US-EPA guideline OPPTS 850.1075 should be followed.

E.3.2 Chronic toxicity test

Chronic toxicity tests should include at least one on the most sensitive species identified from acute toxicity testing. Information on other taxonomic groups, trophic groups and species is especially important if statistical techniques such as those in 6.1.1.3 are to be used.

E.3.3 Food chain concerns

In the case of BCF equal to or greater than 1 000 but less than 2 000, additional tests should be considered for toxicity on aves and mammals (examples in Table E.7).

Table E.1 — Examples of degradation test methods

Study	References
Toxicity/bioassay of degradation products*	— Callow and Finlay (1995) A simple method to evaluate the potential for degradation of antifouling biocides. Biofouling 9: 153-165 — ISO 11348-3 Water quality — Determination of the inhibitory effect of water samples on the light emission of *Vibrio fischeri* (Luminescent bacteria test) — Part 3: Method using freeze-dried bacteria
Hydrolysis	— OECD 111: Hydrolysis as a Function of pH (EC method C.7.) — US-EPA OPPTS 835.2110 Hydrolysis as a function of pH
Phototransformation	— M. Lynch, Ed. Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides. In: Aqueous Photolysis, Chapter 10, pp. 28–30. SETAC -Europe Publication, 1995. — US-EPA OPPTS 835.2210 Direct photolysis rate in water by sunlight — OECD 316: Phototransformation of Chemicals in Water - Direct Photolysis
Biodegradation in seawater	— OECD 306: Biodegradability in Seawater — OECD 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test — ISO 14592-1 Water quality — Evaluation of the aerobic biodegradability of organic compounds at low concentrations — Part 1: Shake-flask batch test with surface water or surface water/sediment suspensions — ISO 14592-2 Water quality — Evaluation of the aerobic biodegradability of organic compounds at low concentrations — Part 2: Continuous flow river model with attached biomass — US-EPA OPPTS 835.3160 Biodegradability in sea water
Water/sediment degradation study	— OECD 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems — BBA guideline Part IV, 5.1 — BBA 1990a Hoeks/Dekker — US-EPA OPPTS 835.3180 Sediment/water microcosm biodegradation test
NOTE In ISO 13073-1, whether a biocidal activity is temporally reduced is identified with the luminescent bacteria test specified in ISO 11348-3 or the test method proposed by Callow and Finlay (1995), which is not validated.	

Table E.2 — Examples of bioaccumulation test methods

Study	References
Bioaccumulation in an aquatic organism	— OECD 305 Bioconcentration: Flow-Through Fish Test — US-EPA OPPTS 850.1710 Oyster BCF

Table E.3 — Examples of acute test methods

Study	References
Acute toxicity to fish	— OECD 203 Fish, Acute Toxicity Test (EC method C.1) — US-EPA OPPTS 850.1075 Fish acute toxicity test, freshwater and marine
Acute toxicity to invertebrates	— OECD 202 Daphnia sp. Acute Immobilisation Test (EC method C.2) — ISO 14669 Water quality — Determination of acute lethal toxicity to marine copepods (Copepoda, Crustacea) — US-EPA OPPTS 850.1020 Gammarid acute toxicity test — US-EPA OPPTS 850.1025 Oyster acute toxicity test (shell deposition) — US-EPA OPPTS 850.1035 Mysid acute toxicity test — US-EPA OPPTS 850.1045 Penaeid acute toxicity test — US-EPA OPPTS 850.1055 Bivalve acute toxicity test (embryo larval) — ASTM E724 Standard Guide for Conducting Static Acute Toxicity Tests Starting with Embryos of Four Species of Saltwater Bivalve Molluscs — ASTM E1463 Standard Guide for Conducting Static and Flow-Through Acute Toxicity Tests With Mysids From the West Coast of the United States — Bryant et al. 1985 as quoted in OECD DRP on Aquatic Testing Methods for Pesticides and Industrial Chemicals 1998 (brackish water mollusk Macoma baltica)
Growth inhibition test on algae	— OECD 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test (EC method C.3) — ISO 10253 Water quality — Marine algal growth inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum* — US-EPA OPPTS 850.5400 Algal toxicity, Tiers I and II
Inhibition to microbiological activity	— OECD 209 Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)
Aquatic plant toxicity	— US-EPA OPPTS 850.4400 Aquatic plant toxicity. (For marine/estuarine higher plants, Zostera Spp. could be tested.)

Table E.4 — Examples of chronic test methods

Study	References
Chronic toxicity to fish (reproduction/growth study)	— OECD 210 Fish, Early-Life Stage Toxicity Test — US-EPA OPPTS 850.1400 Fish early-life stage toxicity test — US-EPA OPPTS 850.1500 Fish life cycle toxicity
Effects on reproduction and growth rate of invertebrates	— OECD 211 Daphnia magna Reproduction Test — US-EPA OPPTS 850.1300 Daphnid chronic toxicity test — US-EPA OPPTS 850.1350 Mysid Chronic Toxicity Test — Danish standard 2209 (marine species) — Bryant et al. 1985 as quoted in OECD DRP on Aquatic Testing Methods for Pesticides and Industrial Chemicals,1998 (brackish water mollusk Macoma baltica)
Effect on sediment-dwelling organisms	— ASTM E1367-03 Standard Test Method for Measuring the Toxicity of Sediment-Associated Contaminants with Estuarine and Marine Invertebrates — ASTM E1611-00 Standard Guide for Conducting Sediment Toxicity Tests with Polychaetous Annelids

Table E.5 — Examples of sediment adsorption test methods

Study	References
Adsorption/desorption screening test	— OECD 106 Adsorption - Desorption Using a Batch Equilibrium Method (EC method C.18) — OECD 121 Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) — US-EPA OPPTS 835.1220 Sediment and soil adsorption/desorption isotherm

Table E.6 — Examples of physico-chemical property test methods

Study	References
Melting point, boiling point and relative density	— OECD 102 Melting Point/ Melting Range — OECD 103 Boiling Point — OECD 109 Density of Liquids and Solids — US-EPA OPPTS 830.7200 Melting Point/Melting Range — US-EPA OPPTS 830.7220 Boiling Point/Boiling Range — US-EPA OPPTS 830.7300 Density/Relative Density/Bulk Density
Surface tension	— OECD 115 Surface Tension
Flash-point	— EC method A.9 Flash-Point
Vapour pressure	— OECD 104 Vapour Pressure — US-EPA OPPTS 830.7950 Vapor Pressure

Table E.6 *(continued)*

Study	References
Water solubility	— OECD 105 Water Solubility — US-EPA OPPTS 830.7840 Water Solubility: Column Elution Method; Shake Flask Method — US-EPA OPPTS 830.7860 Water Solubility (Generator Column Method)
n-octanol/water partition coefficient	— OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method (EC method A.8.) — OECD 117 Partition Coefficient (n-octanol/water), HPLC Method — OECD 123 Partition Coefficient (1-Octanol/Water): Slow-Stirring Method — US-EPA OPPTS 830.7550 Partition Coefficient (n-Octanol/Water), Shake Flask Method — US-EPA OPPTS 830.7560 Partition Coefficient (n-Octanol/Water), Generator Column Method — US-EPA OPPTS 830.7570 Partition Coefficient (n-Octanol/Water), Estimation By Liquid Chromatography

Table E.7 — Examples of avian and mammal toxicological test methods

Study	References
Toxicity to aves	— OECD 205 Avian Dietary Toxicity Test — OECD 206 Avian Reproduction Test
Toxicity to mammals	— OECD 407 Repeated Dose 28-Day Oral Toxicity Study in Rodents — OECD 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents — OECD 409 Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents

Annex F
(informative)

Setting of assessment factors (AF)

F.1 Introduction

This Annex describes examples of existing methods for setting assessment factors (AF) used when calculating PNEC from chronic NOEC or acute toxicity data.

F.2 OECD Screening Information Data Sets (SIDS) manual

Assessment factors are used to adjust the effect concentration when there is a limited toxicity data set to estimate a PNEC. Assessment factors should be applied with care to acute data for substances which are suspected of having a specific mode of action, or which have a high log *K*ow or which significantly bioaccumulate. Assessment factors should reflect the following uncertainties and extrapolations.

a) intra-species and inter-species variations;

b) the extrapolation of acute toxicity towards chronic toxicity;

c) the extrapolation of laboratory results towards the field.

Several assessment factors proposed are summarized in Appendix 1 in Chapter 4 of the MANUAL FOR INVESTIGATION OF HPV CHEMICALS (OECD, 2007b). Assessment factors to be used in estimating PNEC from SIDS data are provided in the following paragraphs. These factors are summarized in Table F.1.

When only acute toxicity data in the SIDS are available, an assessment factor of between 100 and 1 000 is applied to the lowest L(E)C_{50} [i.e. case (a)]. A factor of 1 000 is a conservative and protective factor and applied when only limited data are available, i.e. this value may be reduced to 100 if evidence is available to suggest that this may be a more appropriate factor. Such evidence would include the following:

— availability of data from a wide variety of species including those which are considered to represent the most sensitive species;

— information, from structurally similar compounds or QSAR, to suggest that the acute to chronic ratio is likely to be low;

— information to suggest that the chemical acts in a non-specific or narcotic manner, with little inter-species variation in toxicity;

— information to suggest that the release of the chemical is acute or intermittent, and that the chemical would not be persistent in the environment.

When chronic toxicity data are available in addition to acute data, an assessment factor of between 10 and 100 is applied to the lowest NOEC [i.e. case (b)], taking the following into account:

— If chronic NOEC is available from one or two species representing one or two trophic levels (i.e. fish, Daphnia or algae), a factor of 100 or 50 is applied to the lowest NOEC. In this case, a PNEC value derived from chronic data should be compared to that derived from the lowest acute data. It is then the lowest value that is used in the assessment.

— If chronic NOEC's are available from three species representing three trophic levels (i.e. fish, Daphnia and algae), a factor of 10 is applied to the lowest NOEC. If there is convincing evidence that the most sensitive species has been tested, a factor of 10 may also be applied to the lowest NOEC from two species representing two trophic levels (i.e. fish and/or Daphnia and/or algae).

Use of different assessment factors should be clearly justified in the assessment report.

Table F.1 — Summary of proposed assessment factors for estimating a PNEC

Case	Data available	Range of assessment factor
(a)	EC_{50} algae (72 h) EC_{50} Daphnia (24-48 h acute test) LC_{50} fish (96 h)	100 – 1 000
(b)	NOEC Daphnia (14-21 d chronic toxicity test) NOEC algae (72 h) NOEC fish (chronic toxicity test)	10 – 100
NOTE 1 In case (a), all three acute data are included in the SIDS. NOTE 2 In case (b), NOEC algae is a SIDS element and NOEC Daphnia or NOEC fish is also included in the SIDS for certain chemicals.		

Reference: OECD (2007b)

F.3 Technical guidance document (TGD) for risk assessment conforming to the EU Biocidal Products Directive (BPD)

In Table F.2, evidence for varying the assessment factor should, in general, include consideration of the availability of data from a wider selection of species covering additional feeding strategies/life forms/taxonomic groups other than those represented by the algal, crustacean and fish species (such as echinoderms or molluscs). This is especially the case where data are available for additional taxonomic groups representative of marine species. More specific recommendations, as regarding issues to be considered in relation to the available data and the size and variation of the assessment factor, are indicated below.

When substantiated evidence exists that the substances may be disrupting the endocrine system of mammals, birds, aquatic or other wildlife species, it should be considered whether the assessment factor would be sufficient to protect against effects caused by such a mode of action, or whether an increase of the factor would be appropriate.

a) Use of a factor of 10 000 for acute toxicity data is conservative and protective, and ensures that substances with potential adverse effects are identified in the effect assessment. It assumes that each of the identified uncertainties described above makes a significant contribution to overall uncertainty.

   For any given substance, there may be evidence that this is not so, or that one particular component of the uncertainty is more important than any other. In these circumstances, it may be necessary to vary this factor. This variation may lead to a raised or lowered assessment factor depending on the evidence available. Except for substances with intermittent release, as defined in Section 2.3.3.4 of TGD for EU BPD, under no circumstances should a factor lower than 1 000 be used in deriving a PNEC water for saltwater from acute toxicity data.

   Evidence for varying the assessment factor could include one or more of the following:

   — Evidence from structurally similar compounds which may demonstrate that a higher or lower factor may be appropriate.

   — Knowledge of the mode of action as some substances by virtue of their structure may be known to act in a non-specific manner. A lower factor may therefore be considered. Equally, a known specific mode of action may lead to a higher factor.

   — The availability of data from a variety of species covering the taxonomic groups of the base set species across at least three trophic levels. In such a case, the assessment factors may only be lowered if multiple data points are available for the most sensitive taxonomic group (i.e. the group showing acute toxicity more than 10 times lower than for the other groups).

There are cases where a complete acute data set, even for freshwater algal, crustacean and fish species, will not be available, for example, for substances which are produced at < 1 t/a (notifications according to Annex VII B of Directive 92/32). In these situations, the only data may be acute $L(E)C_{50}$ data for Daphnia. In these exceptional cases, the PNEC should be calculated with a factor of 10 000.

Variation from an assessment factor of 10 000 should be fully reported with accompanying evidence.

b) An assessment factor of 1 000 applies where data from a wider selection of species are available covering additional taxonomic groups (such as echinoderms or molluscs) other than those represented by algal, crustacean and fish species if at least data are available for two additional taxonomic groups representative of marine species.

An assessment factor of 1 000 applies to a single chronic NOEC (freshwater or saltwater crustacean or fish) if this NOEC was generated for the taxonomic group showing the lowest $L(E)C_{50}$ in the acute algal, crustacean or fish tests.

If the only available chronic NOEC is from a species which does not have the lowest $L(E)C_{50}$ in the acute tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus, the effects assessment is based on the acute data with an assessment factor of 10 000. However, normally the lowest PNEC should prevail.

An assessment factor of 1 000 applies also to the lowest of the two chronic NOEC's covering two trophic levels (freshwater or saltwater algae and/or crustacean and/or fish) when such NOEC's have not been generated for the species showing the lowest $L(E)C_{50}$ of the acute tests.

This should not apply in cases where the acutely most sensitive species has an $L(E)C_{50}$ value lower than the lowest NOEC value. In such cases, the PNEC might be derived by applying an assessment factor of 1 000 to the lowest $L(E)C_{50}$ of the acute tests.

c) An assessment factor of 500 applies to the lowest of two NOEC's covering two trophic levels (freshwater or saltwater algae and/or crustacean and/or fish) when such NOEC's have been generated covering those trophic levels showing the lowest $L(E)C_{50}$ in the acute tests with these species. Consideration can be given to lowering this factor in the following circumstances:

— It may sometimes be possible to determine with a high probability that the most sensitive species covering fish, crustacea and algae has been examined, i.e. that a further longer-term NOEC from a third taxonomic group would not be lower than the data already available. In such circumstances, an assessment factor of 100 would be justified;

— a reduced assessment factor (to 100 if only one acute test, to 50 if two acute tests on marine species are available) applied to the lowest NOEC from only two species may be appropriate where:

1) acute tests for additional species representing marine taxonomic groups (for example echinoderms or molluscs) have been carried out and indicate that these are not the most sensitive group,

2) it has been determined with a high probability that chronic NOEC's generated for these marine groups would not be lower than that already obtained. This is particularly important if the substance does not have the potential to bioaccumulate.

An assessment factor of 500 also applies to the lowest of three NOEC's covering three trophic levels, when such NOEC's have not been generated from the taxonomic group showing the lowest $L(E)C_{50}$ in acute tests. This should, however, not apply in the case where the acutely most sensitive species has an $L(E)C_{50}$ value lower than the lowest NOEC value. In such cases, the PNEC might be derived by applying an assessment factor of 1 000 to the lowest $L(E)C_{50}$ in the acute tests.

d) An assessment factor of 100 will be applied when longer-term toxicity NOEC's are available from three freshwater or saltwater species (algae, crustaceans and fish) across three trophic levels.

The assessment factor may be reduced to a minimum of 10 in the following situations:

— where acute tests for additional species representing marine taxonomic groups (for example, echinoderms or molluscs) have been carried out and indicate that these are not the most sensitive

group, and it has been determined with a high probability that chronic NOEC's generated for these species would not be lower than that already obtained;

— where acute tests for additional taxonomic groups (for example echinoderms or molluscs) have indicated that one of these is the most sensitive group acutely and a chronic test has been carried out for that species. This will only apply when it has been determined with a high probability that additional NOEC's generated from other taxa will not be lower than the NOEC's already available.

e) A factor of 10 cannot be decreased on the basis of laboratory studies only. Statistical extrapolation methods for calculation of PNEC for marine organisms could be used when sufficient data are available. More information on these methods and the prerequisites to apply them for risk assessment purposes can be found in 6.1.1.3.

In Table F.4, the general principles of c) and d) in this subclause as applied to data on aquatic organisms should also apply to sediment data. Additionally, when there is convincing evidence that the sensitivity of marine organisms is adequately covered by that available from freshwater species, the assessment factors used for freshwater sediment data can be applied. Such evidence may include data from chronic testing of freshwater and marine aquatic organisms, and must include data on specific marine taxa.

Table F.2 — Technical guidance document (TGD) for risk assessment conforming to the EU Biocidal Products Directive (BPD)

Data set	Assessment factor
Lowest acute L(E)C_{50} from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels	10 000[a]
Lowest acute L(E)C_{50} from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels, + two additional marine taxonomic groups (e.g. echinoderms, molluscs)	1 000[b]
One chronic NOEC (from freshwater or saltwater crustacean reproduction or fish growth studies)	1 000[b]
Two chronic NOEC's from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish)	500[c]
Lowest chronic NOEC's from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels	100[d]
Two chronic NOEC's from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) + one chronic NOEC from an additional marine taxonomic group (e.g. echinoderms, molluscs)	50
Lowest chronic NOEC's from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels + two chronic NOEC's from additional marine taxonomic groups (e.g. echinoderms, molluscs)	10
Species sensitivity distribution (SSD) method (to be fully justified case by case)	5-1[e]
Field data or model ecosystems	Reviewed on a case-by-case basis
[a] See F.3 a). [b] See F.3 b). [c] See F.3 c). [d] See F.3 d). [e] See F.3 e).	

Reference: European Commission (2003)

Table F.3 — Assessment factors for calculating PNEC for marine sediment organisms from acute sediment toxicity tests in TGD or EU BPD

Available test results	Assessment factor
One acute freshwater or marine sediment test	10 000
Two acute tests including a minimum of one marine test with an organism of a sensitive taxa	1 000

Reference: European Commission (2003)

Table F.4 — Assessment factors for calculating PNEC for marine sediment organisms from chronic sediment toxicity in TGD of EU BPD

Available test results	Assessment factor[a]
One chronic freshwater sediment test	1 000
Two chronic freshwater sediment tests with species representing different living and feeding conditions	500
One chronic freshwater and one saltwater sediment test representing different living and feeding conditions	100
Three chronic sediment tests representing different living and feeding conditions	50
Three chronic tests with species representing different living and feeding conditions including a minimum of two tests with marine species	10

[a] See last paragraph of F.3

Reference: European Commission (2003)

Table F.5 — Assessment factors for calculating PNEC for organisms of higher trophic level in TGD of EU BPD

Available data	Duration of test	Assessment factor
LC_{50} bird	5 days	3 000
NOEC bird	chronic	30
NOEC mammal, food, chronic	28 days	300
	90 days	90
	chronic	30
NOTE If NOEC's both for birds and mammals are given, the lower of the resulting PNECs is used in risk assessment.		

Reference: European Commission (2003)

F.4 Assessment factors in ecological risk assessment of TSCA new chemicals by U.S.EPA OPTT

Table F.6 — Assessment factors in ecological risk assessment of TSCA new chemicals by US. EPA OPTT

Available data on chemical or analogue	Assessment factor
Limited (e.g. only one acute LC_{50} via SAR/QSAR)	1 000
Base-set acute toxicity (e.g. fish and daphnid LC_{50}s and algal EC_{50})	100
Chronic toxicity MATCs[a]	10
Field test data for chemical	1
NOTE 1 1 000 if only one acute value is available. NOTE 2 100 applied to the most sensitive species when the environmental base set of toxicity data (i.e. fish acute toxicity, daphnid acute toxicity, and green algal toxicity) are available. NOTE 3 10 applied to the lowest chronic value (ChV) for fish, daphnids, and algae. NOTE 4 1 applied to the chronic value (ChV) from a field study (e.g. pond) or from a microcosm study.	
[a] Maximum Acceptable Toxicant Concentration is the calculated geometric mean of LOEC and NOEC.	

Reference: Committee on Environment and Natural Resources of the National Science and Technology Council (1999)

Annex G
(normative)

Minimum information required for the risk assessment report

G.1 Introduction

This Annex provides the minimum data/information required to be included in the risk assessment report for a substance submitted for application. These data and information are used to ensure an appropriate environmental risk assessment has been conducted.

When conducting risk characterization with the step-by-step approach described in Annex B, new data and information, other than those already used or obtained in the preceding process, are added as necessary for each tier. For toxicity test data for aquatic organisms, chronic toxicity data may be added to refine PNEC and lower the assessment factor (AF).

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

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

Items	Data requirements	Organic			Inorganic
		Tier 1	Tier 2		
			Level 1	Level 2	
Applicant(s)	Name, address and point of contact for applicant(s)	X	X	X	X
	Name of manufacturer and plant location(s)	X	X	X	X
Identity of substance and products	Common name* and synonyms	X	X	X	X
	Chemical name (IUPAC)*	X	X	X	X
	CAS number* and other registry numbers	X	X	X	X
	Molecular and structural formula*	X	X	X	X
	Molecular mass*	X	X	X	X
	Methods of manufacture and purity of substance, and identity of material(s) and precursor(s) (e.g. UV/VIS, IR, NMR or MS)	X	X	X	X
	Identity of impurities and additives	X	X	X	X
Physical and chemical property	Melting point*, boiling point* and relative density*	X	X	X	X
	Vapour pressure*, flash-point and surface tension, if applicable	X	X	X	X
	Physical state and colour	X	X	X	X
	Water solubility* (effect of pH and temperature)	X	X	X	X
	Thermal stability and decomposition product(s)*	X	X	X	X
Analytical methods for detection and identification	Analytical methods, recovery rates and limits of determination of pure substance, isomers, impurities, additives and degradation products in/on: — seawater — sediment	X	X	X	X
	— animal body tissue and food	X	X	X	X