



METALS ENVIRONMENTAL RISK ASSESSMENT GUIDANCE

FACT SHEET

MERAG

01

RISK CHARACTERIZATION: GENERAL ASPECTS

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The content of the MERAG fact sheets reflect the experiences and recent progress made with environmental risk assessment methods, concepts and methodologies used in Chemicals Management programs and Environmental Quality Standard setting (soil, water, sediments...) for metals. Since science keeps evolving these fact sheets will be update on a regular basis to take into account new developments. To be sure you have the most recent fact sheet on the current subject check our website: www.metalsriskassessment.org.

1. INTRODUCTION

In the risk characterization phase of a risk assessment, predicted or measured environmental concentrations are compared to the obtained toxicity values (effect thresholds) for each environmental compartment to identify potential risks. The current fact sheet presents the general building stones of a risk characterization strategy that will allow compliance in an anticipative way with forthcoming legislative obligations while ensuring, at the same time, that the best option for managing the potential risks presented by metals/metal compounds is considered. To this end, a tiered approach is advocated since data availability will depend to a large extent on the type of metal/metal compound under investigation, allowing for further refinement of the assessment (option 1: total → dissolved → bioavailable → biogeochemical or metallo-regions and option 2: deterministic → probabilistic → field validation). The incorporation of the bioavailability concept into the risk assessment context is dealt with in detail in fact sheets 5 and 6. In the latter fact sheets the total risk approach have been put forward as the scientific most appropriate way in assessing risks for metals. However, it is acknowledged that in some particular cases (e.g. setting of environmental quality standards) the use of the added risk approach may have its merits. Guidance on the use of the total risk approach versus the added risk approach is further elaborated in annex 1. The remainder of this fact sheet is mainly dealing with the general principles of risk assessment and explores more in depth of how risk assessments can be refined taking into account bioavailability or using probabilistic techniques.

Figure 1 outlines the generic tiered approach for the characterization of the potential risks to ecosystems associated with metals/metal compounds.

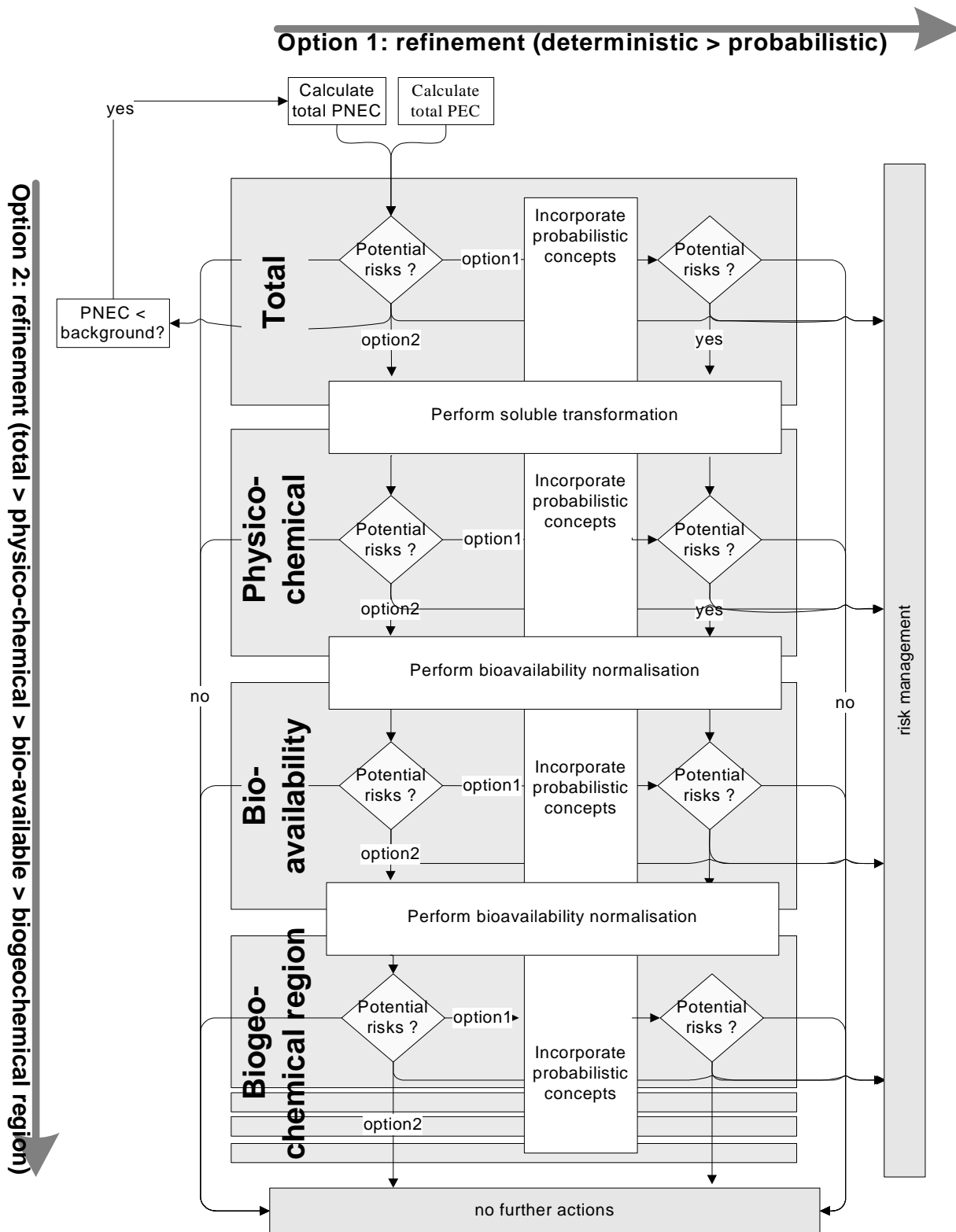


Figure 1: Generic tiered approach for performing the risk characterization for metals/metal compounds

The need and possibility for further refinement at every tier is governed by the availability of data, the remaining risk level and/or the magnitude of the assessment (e.g. small site in urban area versus large site in natural area).

Two dimensions are proposed for possible refinements (visualised as two axes in Figure 1). Option 1 deals with assessing the bioavailable fraction. Incorporation of the bioavailability concept could be performed at different levels of refinement (dissolved => bioavailable) but it should also be recognized that due to local or regional differences in geochemistry the physico-chemical parameters influencing bioavailability can be quite different. In a similar way metal background will vary to a large extent. A local or regional environmental compartment (water, soil, and sediment) is hence not characterised by one single set of abiotic factors/background, but is rather represented by range of abiotic factors/metal backgrounds. This variation in space and time may have a significant impact and should be taken fully into account in the risk assessment process. From the perspective of a risk assessment, it is therefore critical to understand which geochemical characteristics influence the toxicity of metals and metal compounds and as far as possible different (metallo) ecoregions should be identified and potential risks that metals may pose to a properly defined specific river/stream/lake (eco-regions) should be assessed. Since biology plays also an important role the concept may even be extended to include the premise that in the PNEC derivation those species that are not relevant for the ecoregion under investigation (biogeochemical region) should be excluded.

Currently guidance on the application of the ecoregion concept is being developed for the aquatic compartment (annex 1) but the same concepts would apply to the other environmental compartments (sediments and soil). As soon as guidance is available this will be incorporated in this fact sheet.

Next to option 1: total-biogeochemical region a second axis of refinement can be introduced i.e. option 2: deterministic vs probabilistic. In this second axis, the inherent spatial and temporal variability of exposure and the inter-species variability of effects are integrated and simplified into a single PEC and PNEC in a so called deterministic approach, in which the risk is subsequently quantified as a quotient of single values representing worst case estimates of both exposure (Predicted Environmental Concentration = PEC) and effect (Predicted No Effect Concentration = PNEC). In this first tier, exposure and effect results are often expressed as total concentrations if data availability is limited. However, total concentrations (dissolved and particulate) should only be used when no information is available on dissolved fractions¹) for the aquatic compartment. If no risks are identified at this stage, no further action is required. When sufficient data are available, single point estimates can be replaced by probability distributions which can be seen as more relevant since it allows assessors to cope with the variability observed both on the exposure and effects side of the risk assessment (i.e. running several realistic scenarios). In this way, probabilistic risk assessment (PRA) is a refined analysis as it allows evaluating the probability of occurrence and the magnitude of effect.

It should, however, be acknowledged that in order to perform a PRA additional effort in collecting data may be needed. Therefore with regard of the use of resources PRA may be more valuable when the risk boundary is approached and less valuable when the deterministic approach indicate a very low or very high risk. Finally, in addition to the PRA, a weight-of-evidence approach (e.g. field assessment, direct toxicity testing) can be used to validate the risk estimates (for more information on the weight-of-evidence approach see the fact sheet on this issue).

¹ refers to the fraction passing a filter of 0.2 µm and acidified with HNO₃

2. DATA-POOR VERSUS DATA-RICH APPROACH

The key question of environmental risk characterization of metals is to answer: "What is the likelihood (i.e. probability) of adverse effects occurring to exposed ecological systems due to exceedance of a toxicity level by an environmental metal concentration?" This question assesses both the probability of occurrence (exposure) and the magnitude of effects. However, for data-poor metals, the key question is usually simplified to: "Is it likely that adverse effects occur to exposed ecological systems due to exceedance of a no effect level by an environmental concentration?"

2.1 Deterministic approach (data-poor metals)

Environmental risks are typically estimated in a deterministic way using single point estimates for both exposure and effects. For example, the level corresponding to the protection of 95% of the species, i.e. the PNEC value, is compared to a reasonable worst case exposure concentration in the environment, i.e. the PEC value estimated as a high end value (e.g. 90th percentile) (see Figure 2). This is done separately for each of the environmental compartments of concern.

Inland environmental compartments that are distinguished in this regard are for example in Europe (TGD, 2003):

- Aquatic ecosystem (including sediment)
- Terrestrial ecosystem (including both the below- and above-ground compartments);
- Atmosphere;
- Top predators;
- Micro-organisms in sewage treatment plants

Marine environmental compartments:

- Aquatic ecosystem (including sediments)
- Top predators

The estimation of PEC and PNEC is considered in other fact sheets. A list of the different PEC/PNEC ratios that could be considered for the inland and marine environments is given in Table 1.

Table 1: Overview of PEC/PNEC ratios considered for inland risk assessment and marine risk assessment (indicated with * if applicable) for different geographical scales.

Local	Regional
$PEC_{local,water}/PNEC_{water}^*$	$PEC_{regional,water}/PNEC_{water}^*$
$PEC_{local,sediment}/PNEC_{sediment}^*$	$PEC_{regional,sediment}/PNEC_{sediment}^*$
$PEC_{local,soil}/PNEC_{soil}$	$PEC_{regional,agr-soil}/PNEC_{soil}$
$PEC_{stp}/PNEC_{micro-organisms}$	
$PEC_{local,oral,fish} vs PNEC_{coral}^*$	
$PEC_{local,oral,worm} vs PNEC_{coral}$	

The potential risks of the metal in each environmental compartment are calculated as a point estimate being the quotient of single values representing exposure and effects (i.e. PEC/PNEC or risk characterization ratio (RCR) ratio (also called Risk Quotient (RQ)). A RCR smaller than one indicates that no further actions are required. A RCR exceeding one suggests that the metal is present at levels that may pose a risk to ecological receptors. Further refinement on the exposure side (additional monitoring data, using site specific information instead of defaults) or a reality check of the derived PNEC value (e.g. if the PNEC is close to or even below reported background concentrations the PNEC could be revisited) could

take this concern away. If no further refinement by taking into account bioavailability is possible or feasible, risk reduction measures could be taken into consideration.

2.2 Probabilistic approach (data-rich metals)

2.2.1 General

Single point or deterministic modelling involves using a single “best guess” or “worst case” estimate of each variable within a model to determine the model’s outcome(s). “What if” scenarios are then conducted to determine how much that outcome might in reality vary from the model outcome (for example for metals, lower and upper estimates for partitioning coefficients are typically used in the exposure assessment). Probabilistic risk assessment is similar to “what if” scenarios in that it generates a number of possible scenarios. However, it goes one step further by effectively accounting for every possible value that each variable could take and weighting each possible scenario by the probability of its occurrence. Probabilistic risk assessment achieves this by modelling each variable within a model by a probability distribution. Guidance on probabilistic risk assessment methods can be found in US programs (ECOFRAM, 1999; EPA, 2001) and EU research programs on plant protection products (Hart, 2001; EUFRAM, 2005).

In a PRA the point estimates (PEC and PNEC), used in the deterministic approach, are replaced by probability distributions representing the inherent variability in both the exposure and effect parameters (see Figure 2). Variability represents inherent heterogeneity or diversity in a well-characterised population. Fundamentally a property of nature, variability is not reducible through further measurement or study.

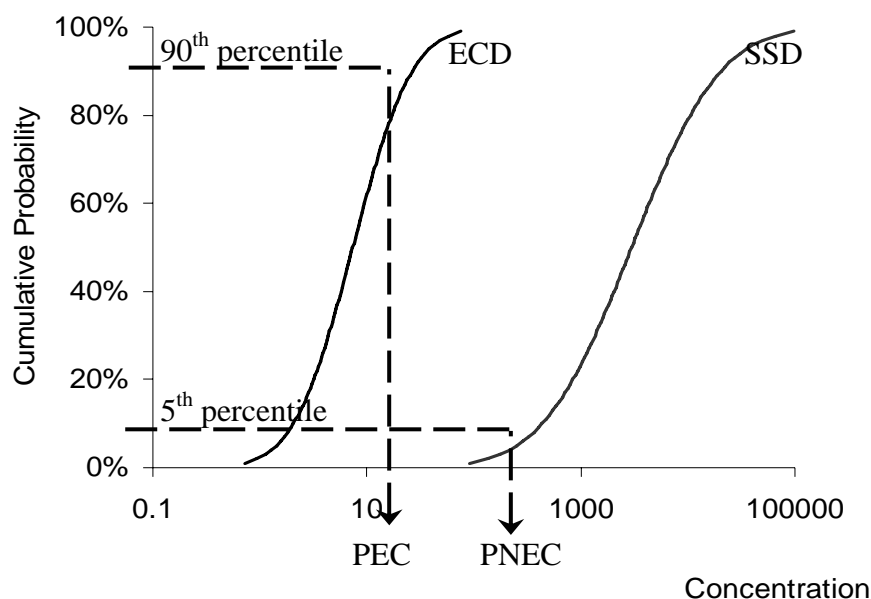


Figure 2: Visualisation of the deterministic concepts PEC (Predicted Environmental Concentration) and PNEC (Predicted No Effect Concentration) versus the probabilistic concepts of ECD (Exposure Concentration Distribution) and SSD (Species Sensitivity Distribution)

Temporal and spatial variations of metal concentrations in the environment are captured in a variability distribution, called the Exposure Concentration Distribution (ECD) (see Figure 2 left side). The different sensitivities of various species to a metal are described in a variability probability distribution called the Species Sensitivity Distribution (SSD) (see Figure 3 right side). Both ECD and SSD can be represented as probability density functions or cumulative probability distributions (Figure 3 presents cumulative probability distributions). Note that the probability distributions can have different interpretations depending on the data that were used to estimate them. For example, the probability distribution on the effects side could also represent the spatial variability of the PNEC due to spatial variability of bio-availability. Possible representations of the exposure and effects distribution are:

Exposure: - Spatial variations of the exposure concentration

- Temporal variations of the exposure concentration (e.g. at a local site)
- A combination of the representations above (as e.g. in a regional assessment)

Effects:

- Inter-species sensitivity (i.e. SSD, this is the most common form)
- Spatial/Temporal variability of PNEC (following variability in bio-availability)
- Intra-species sensitivity (dose-response curve of one species)
- A combination of the representations above

The guidance on the characterization of the ECD and the SSD is considered in respectively the facts sheets on exposure and effects assessment. Note that uncertainty represents partial ignorance or lack of perfect information about poorly characterised phenomena or models (e.g. sampling or measurement error), and can only partly be reduced through further research. Uncertainty is not visualised in Figure 2 because quantification of uncertainty is assessed in the uncertainty analysis fact sheet.

Figure 3 provides guidance on how to characterize and interpret probabilistic risk given the ECD and the SSD. Furthermore, guidance is given on how to determine the magnitude of effects and identify the sources of exposure (probability of occurrence) leading to potential risk scenarios. Several methods are possible, each with their strengths and weaknesses. Probabilistic risk assessment is an evolving field. The proposed set of methods reflects the current state-of-the-art.

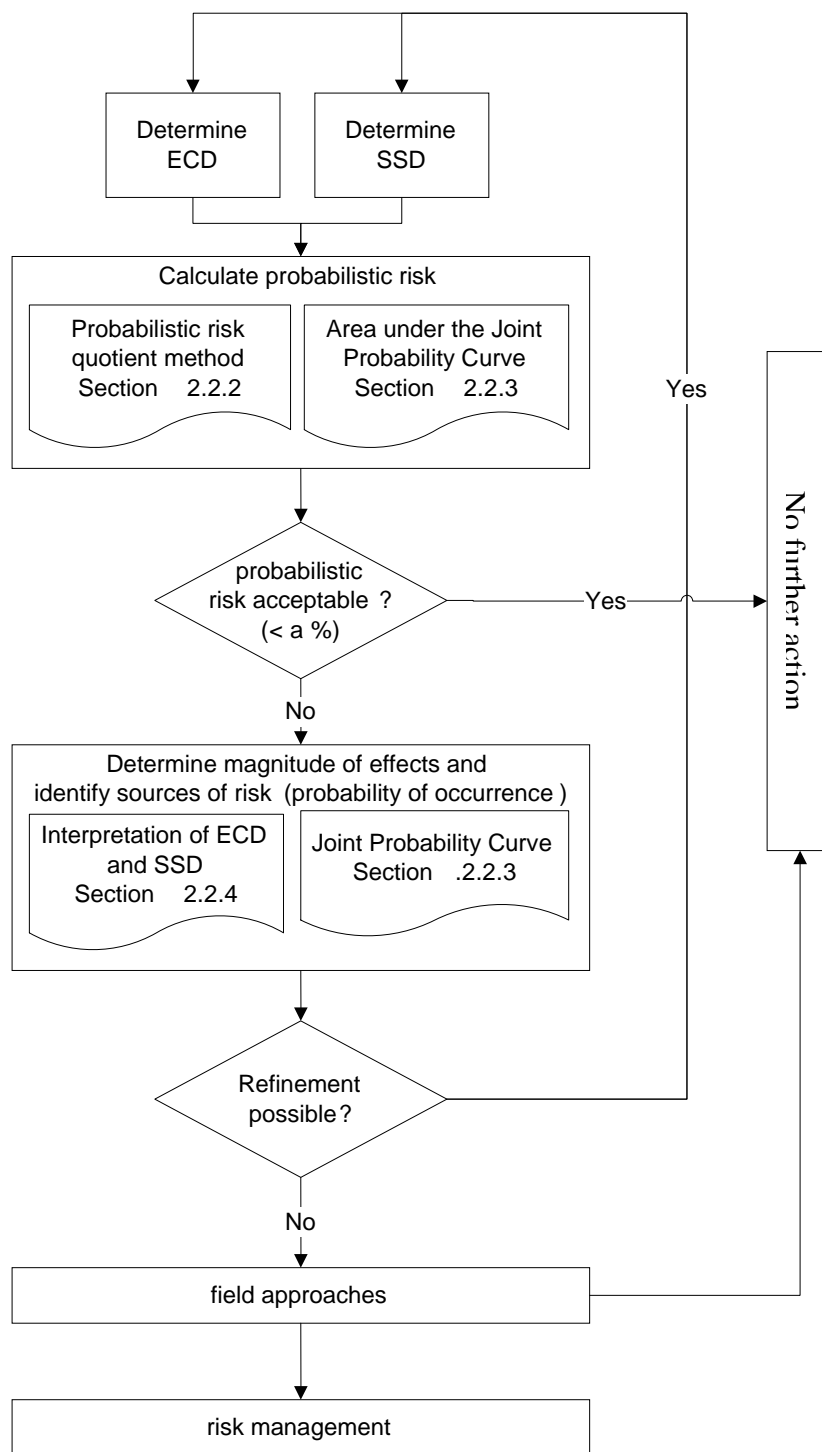


Figure 3: Guidance of risk characterization, interpretation and refinement (field approaches have not yet completely developed)

The first step is to calculate the probabilistic risk (see Figure 3). If the calculated risk level is acceptable, no further actions are deemed necessary (in analogy with the deterministic risk characterization). The probability of some randomly selected exposure concentration exceeding a randomly selected species sensitivity or toxicity value has been demonstrated to be a common measure of risk (an overview is given in Aldenberg et al., 2002). Guidance on how to derive exposure concentration or toxicity value (e.g. one

single species value or a geometric mean of values) can be found in the respective fact sheets on exposure and effects assessment.

$$Risk = P(Exposure\ Concentration > Toxicity\ Value)$$

where $P()$ denotes “the probability of”

The probabilistic risk can alternatively be defined as the probability that the risk quotient becomes larger than one. This can be written as:

$$Risk = P\left(\frac{Exposure\ Concentration}{Toxicity\ Value} > 1\right) = P(Risk\ Quotient > 1) \quad \text{Equation (1)}$$

This definition is intuitively easier to understand as it is an extension of the well-known and widely accepted Risk Characterization Ratio (RCR) or PEC/PNEC ratio of the deterministic risk assessment (see previous section). The main difference is that the inherent variability of exposure and effects quantified in the ECD and the SSD is considered instead of deriving point estimates as PEC and PNEC. Other probabilistic risk definitions, in which either the exposure concentration or toxicity value is fixed in combination with a probability distribution for respectively the toxicity value or exposure concentration, are also possible. For example, the Potentially Affected Fraction (PAF) has been considered as an alternative risk outcome. The PAF assessed the percentage of potentially affected species for a fixed exposure concentration.

The probabilistic risk definition, as defined in equation 1, is more general and considers all possible “what if”-scenarios. This comprises all possible combinations of the exposure concentration and the toxicity values (both toxicity values above and below the deterministic PNEC and both exposure concentrations above and below the deterministic PEC) because these combinations also occur in the real environment. Both (very) sensitive and insensitive species can be exposed to both low and high concentrations in a particular location/region or during a particular season. Or in other words, a probabilistic risk accounts for both the probability of occurrence (expressed by ECD) and the magnitude of effect (expressed by SSD).

Note that a probabilistic risk does not require the specification of the level of protection in the effects assessment (as e.g. 95% protection level in SSD) and the exposure assessment (as e.g. 90th percentile for PEC). Instead, an acceptability criterion only needs to be specified in the risk characterization phase. Acceptability criteria for risk management are currently still lacking. Ongoing and future research will however be able to cover this issue. An acceptable threshold on probabilistic risk could be defined at both the regional and local scale in order to compare it with the estimated probabilistic risk. If the estimated probabilistic risk is smaller than that threshold, no further action is needed. Identification of potential risks (when exceeding that threshold) could be a trigger for further in depth analysis (e.g. considering spatial variability; incorporation of bioavailability) as indicated in Figure 3.

A probabilistic risk does not decrease the actual risk. Instead, it provides a better risk estimate (because several realistic scenarios are run) and therefore allows the risk manager to differentiate risk statements such as e.g. “negligible risk”, “low risk”, “medium risk”, “high risk” or other categories (depending on a negligible, low, high risk probability) instead of the “no risk” (which is in fact a misnomer as no matter how small the risk is, it cannot become zero, it can only become negligible) or “potential risk” outcomes of a deterministic risk characterization.

Probabilistic risk assessment identifies those sites or periods in the year or those species at risk where further data collection is useful, if possible. It therefore focuses further research and efficiently allocates resources (scale and conditions under which risks may occur are limited). However, the validation of the outcome of the risk characterization should always be promoted. The probabilistic risk can be quantified using several methods (see Figure 3) of which the two most important ones, reflecting the current state-of-the-art, are a) the probabilistic risk quotient method (described in 2.2.2) and b) the area under the joint probability curve (described in 2.2.3). Mathematically, it can be shown that both methods result in the same

risk estimate (Aldenberg et al., 2002). Consequently, the two methods are equally valid and either method can be used to estimate the probabilistic risk. The risk assessor can therefore apply the method which is in his/her opinion easier to understand, apply and communicate.

Box 1: Thoughts and mis-thoughts on disadvantages of probabilistic risk characterization	
Criticism/disadvantage	Clarification
No common standard/consensus on methods to be used	True but can be resolved. Several frameworks in literature and ongoing initiatives strive for standardization and guidance (e.g. ECOFRAM, EUPRA, EUFRAM).
Data demanding	True but need to put this into context: probabilistic assessment is proposed as a higher tier assessment. Data-rich metals usually already cover sufficient data to start probabilistic assessment.
Complex output/complicated, difficult to communicate and interpret	True, this is clearly an issue for some of the probabilistic outputs (e.g. joint probability curve). However, some probabilistic concepts are easily accessible, interpretable and communicable because these are extensions of the deterministic concepts (e.g. exposure concentration distribution, species sensitivity distribution and risk quotient distribution).
How to deal with probabilistic risk in decision-making? (acceptability criteria)	Acceptability criteria for risk management are currently still lacking. Ongoing and future research will however be able to cover this issue.
Lack of experience	Wrong, on an academic level, there is a lot of literature illustrating probabilistic assessments. In risk assessment practice, there is already experience in other fields (e.g. EU Water Framework Directive, UK consenting of dangerous substances in discharges to surface waters, US EPA Superfund). In addition, "lack of experience" is a weak argument as it can be used against any scientific development.
Probabilistic risks contain less conservatism or are a mathematical artifact to decrease risk	Wrong, a probabilistic risk does not decrease the actual risk. Instead, it is a better estimate of the risk and therefore allows the risk manager to differentiate between different risk levels. Probabilistic methods deal with uncertainty differently (by separating it from risk characterization) and are for this reason a precautionary-driven approach (Verdonck et al., 2005).

Although probabilistic risk characterization significantly reduces several limitations of the deterministic risk quotient (because it's more realistic), they are still some remaining limitations that need further improvement (as illustrated by Verdonck et al., 2003). After all, a probabilistic risk integrates and therefore does not separate the magnitude of effect from the probability of occurrence. A management action may be different for a small magnitude (e.g. small percentage of species affected) and high occurrence probability compared to a high magnitude and small probability of occurrence.

For this reason, it needs to be quantified how many species will be impacted (i.e. magnitude of effect) and it needs to be identified which monitoring sites or exposure scenarios are resulting in a risk scenario (i.e. probability of occurrence). Depending on the type of data available and the problem formulation, several approaches can be considered: the ECD and SSD curve can be directly interpreted (see 2.2.4) or a Joint Probability Curve (JPC) can be derived and interpreted (see 2.2.3). If no further refinement is possible, risk management could be based on the interpretation of ECD/SSD curves or JPC to overcome the limitations of a probabilistic risk estimate. In this way, different management actions can be implemented depending on the probability of occurrence (ECD) in combination with the magnitude of effects (SSD).

2.2.2 Probabilistic risk quotient method

General case

This method is basically the direct translation of the mathematical definition of probabilistic risk (the probability of some randomly selected exposure concentration exceeding a randomly selected toxicity value):

$$Risk = P\left(\frac{Exposure\ Concentration}{Toxicity\ Value} > 1\right) = P(Risk\ Quotient > 1)$$

Exposure and effects are characterised by probability distributions i.e. respectively the ECD and the SSD. Many random samples are drawn (typically Monte Carlo¹ techniques are used) from both ECD and SSD distributions and for each set of samples, the ratio Exposure Concentration/Toxicity Value is calculated. All these ratios form the risk quotient distribution. And from the obtained risk quotient distribution, the probability that the exposure concentration exceeds the toxicity value or risk quotient exceeds 1 can be calculated (Figure 4). This probability of some randomly selected environmental concentration exceeding some randomly selected toxicity value for the metal/metal compound under consideration is equal to the probability that the risk quotient becomes larger than 1 and can therefore be regarded as a measure of adverse effects. More information can be found in Verdonck et al. (2003). In case the ECD and SSD are both (log)normally distributed, the lookup Table 5.3 of Aldenberg et al. (2002) can also be used. In the example of Figure 4, there is 13 % probability that any possible exposure concentration will exceed any possible toxicity value (both larger and smaller than the deterministic PNEC, derived as 5th percentile from SSD).

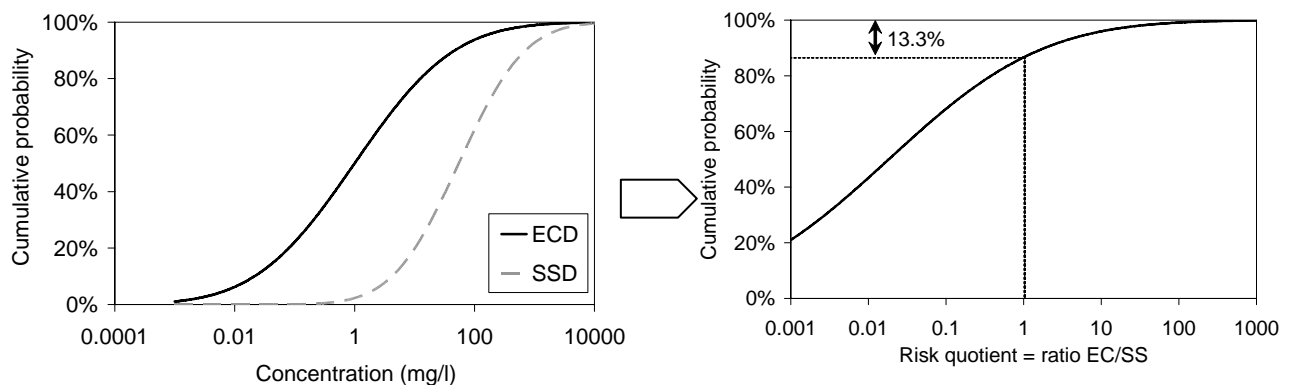


Figure 4: Probabilistic framework in case extensive exposure/effects data are available

Specific sub-cases

In literature, special cases of probabilistic risk (usually of a semi-probabilistic nature) are being used as well in which a fixed PEC or fixed PNEC are compared with a probability distribution, respectively a SSD or an ECD. These do not include all information on exposure and effects (and therefore are neglecting species with toxicity values smaller than PNEC are affected or exposure concentrations larger than PEC occur). These hybrid-versions could also add to the complexity of the interpretation of possible probabilistic outcomes. Nevertheless, they can be useful in case there is sufficient information to estimate a probability distribution for exposure or effects but data is lacking for respectively effects or exposure to estimate a probability distribution. Special attention should, however, be paid to the interpretation.

¹ In Monte Carlo analysis, point estimates in a model are replaced by probability distributions. Samples are randomly taken from the distributions and the model's results are combined, usually in the form of a probability density distribution or a cumulative density function

2.2.3 Joint probability curve

Another way of integrating the ECD and the SSD is through the use of so-called Joint Probability Curves (JPCs) (ECOFRAM, 1999; Giesy et al., 1999). In JPCs, the cumulative probabilities of the ECD and the SSD for each concentration are plotted in a graph. An example is given in Figure 5. For concentration a, the fraction of species affected, 20% (i.e. the cumulative probability of the SSD or the magnitude of effects), is plotted against the exceedance exposure probability 22% (i.e. the complement of the cumulative probability of the ECD) (see line a in Figure 5). The same exercise is repeated for concentration b and for any other concentration (see line b in Figure 5). The resulting JPC presents the fraction of species affected for each exposure exceedance or the exposure exceedance for each fraction of species affected. JPCs come in several forms. Aldenberg et al. (2002) gives an overview.

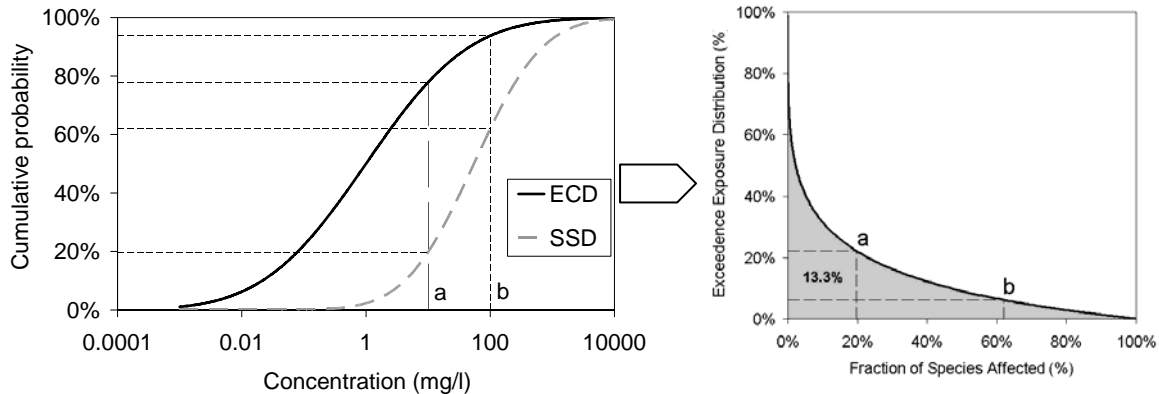


Figure 5: Exposure Concentration Distribution (ECD), Species Sensitivity Distribution (SSD) and Joint Probability Curve (JPC) (type cumulative profile plot) with its Area Under the Curve (AUC)

JPCs can be used for:

1. Calculation of the probabilistic risk: The area under the joint probability curve (shaded in Figure 5) is equal to the probabilistic risk and offers therefore an alternative way of calculating the probabilistic risk. This probabilistic risk (of an exposure concentration exceeding a toxicity value) is 13.3 % in the hypothetical example of Figure 5.
2. Exploration of the magnitude of effects versus probability of occurrence: All possible combinations of fraction of species affected (i.e. protection level) versus percentage exposure exceedance are plotted in one graph. The derivation of the JPC could offer a useful tool for communication of risks as it allows what-if questions to be addressed. It also provides the risk assessor and risk manager a method for assessing the effects of changes in assumptions, such as the choice of a different percentile from the species affected.

JPCs often involve interpretation and communication issues by non-experts. For this reason, the interpretation of the ECD and/or SSD curve is much easier and straightforward as risk assessors and managers are more familiar with these curves (see next section). The ECD and/or SSD curves contain the same information as in a JPC.

2.2.4 Interpretation of ECD and/or SSD curve

Some risk assessors prefer to interpret the ECD and SSD curves directly. One could define an acceptable effect level (fixed PNEC) and calculate the probability that the exposure concentrations exceed this level. An example is given in Doyle et al. (2003). Depending on the type and amount of data available, the fixed PNEC can be derived from assessment factors or when sufficient data are available from an SSD (as in Figure 6). In the hypothetical example, the exposure concentration in 42 % of the monitoring locations will exceed the PNEC (defined as 95% protection level). In addition, the monitoring locations or exposure scenarios leading to exceedance of the PNEC can also be identified.

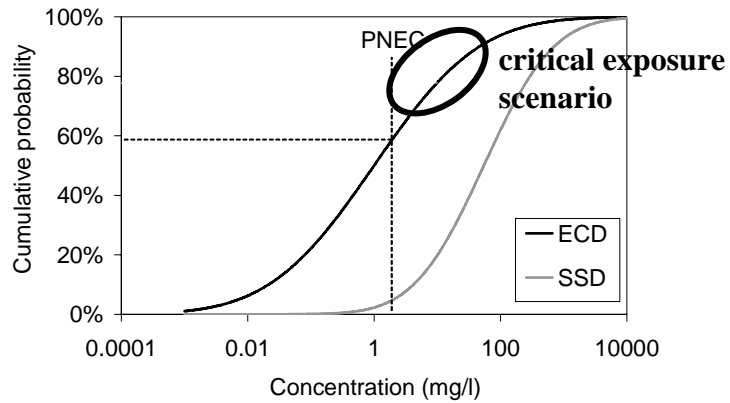


Figure 6: Exposure Concentration Distribution and Species Sensitivity Distribution

Similarly, an exposure level (fixed PEC) can be determined and the percentage of species affected can be calculated (no example shown here). It is recommended that this exercise is repeated for several exposure and effect levels for exploring the sensitivity of varying threshold levels respectively the probability of occurrence and the magnitude of effects. When only a fixed PNEC is compared with an ECD, although relatively easy to interpret, only gives one-sided view on the actual risk.

ANNEX 1: ADDED VS TOTAL RISK APPROACH AND ITS USE IN RISK ASSESSMENT AND/OR ENVIRONMENTAL QUALITY SETTING

1. INTRODUCTION

The presence of metals in the environment due to natural processes (resulting in a natural background concentration of metals in all environmental compartments, including organisms) and the chemical processes that affect the speciation of metals in the environment have implications for both the environmental exposure and effects assessment of metals and thus for the risk characterisation/environmental quality setting of metals in general.

In order to deal with the presence of a natural background different concepts have been developed such as the *Added Risk approach*¹ (ARA) or the *Total Risk approach* (TRA) concepts. The total risk approach assumes that "exposure" and "effects" should be compared on both the fraction compiling the natural and the added anthropogenic background. The risk characterisation can be done at different levels, for example, on total, dissolved, or bioavailable fractions. The added risk approach assumes that only the anthropogenic added fraction of a natural element that contributes to the risk for the environment should be regulated/controlled. Although this approach acknowledge that negative effects from the bioavailable fraction of the background concentration on some organisms in the ecosystem may occur or that organisms may even have become acclimated/adapted to it, from an environmental policy point of view such effects may be ignored and may even be regarded as desirable, since these effects may in theory lead to an increase in ecosystem differentiation or biodiversity (Crommentuijn et al, 1997). The maximum permissible concentration is calculated as the sum of a maximum permissible addition and the background concentration. In theory, the use of the added risk approach avoids as such the potential problem of deriving PNEC/EQS values below the natural background concentration, as could be the case when the total risk approach is used. In the added risk approach both the "Predicted Environmental Concentration"(PEC) and the "Predicted No Effect Concentration" (PNEC) are expressed as metals added by man, resulting in an "added Predicted Environmental Concentration" (PEC_{add})² and "added Predicted No Effect Concentration" (PNEC_{add})³, respectively.

Currently, no clear guidance is available on how to deal with elements that have a natural background concentration in the environment, such as metals. Both approaches have been used in the EU Risk Assessments context for metals: e.g. "added risk approach" (according to Struijs et al., 1997 and Crommentuijn et al., 1997) – cfr. Zn RAR - and the "total risk approach" – cfr. Cd RAR, Pb RAR and Cu RAR . In general it can be stated that the total risk approach may be the most scientifically defensible option in the context of a risk assessment, but for regulatory purposes (e.g. the setting of environmental quality standards) the added risk approach may have merits.

Guidance on the use of the total risk approach (TRA) and added risk approach (ARA) is further outlined in detail below.

¹ The concept was developed and published by : T. Crommentuijn et al. Maximum permissible concentrations and negligible concentrations for metals, taking backgrounds concentrations into account, Netherlands, Institute of Public Health and the Environment, RIVM, Bilthoven, RIVM report N° 601501001, 1997

² $PEC_{add} = PEC_{total} - C_{b,region/site}$

³ $PNEC_{add} = PNEC_{tot} - C_{b,culture\ medium}$

2. USE OF TRA AND ARA CONCEPTS IN THE CONTEXT OF CHEMICAL SAFETY MANAGEMENT (E.G. RISK ASSESSMENT AND ENVIRONMENTAL QUALITY STANDARD SETTING)

2.1 Application

Use in chemicals safety management

Potential environmental risks (RQ) are characterized based on the following quotient:

$$RQ = PEC_{add}/PNEC_{add}$$

Where $PEC_{add} = PEC_{tot} - C_{b_{site/region}}$ and $PNEC_{add} = PNEC_{tot} - C_{b_{culture\ medium}}$

With $C_{b_{site/region}}$ the background concentration of the specific site/region under investigation; $C_{b_{culture\ medium}}$ the metal concentration in the culture media.

Use in EQS settings

Although the same principles apply for EQS settings, the added risk approach is used somewhat differently. Indeed compliance of the monitoring data (PEC_{tot}) with the proposed EQS (i.e. PNEC) is estimated after addition of the $C_{b_{site/region}}$ to the $PNEC_{add}$. Compliance checking is therefore realized by comparing:

$PEC_{tot} - C_{b_{site/region}}$ with $PNEC_{tot} = PNEC_{add}$ (i.e. $PNEC_{tot} - C_{b_{culture\ medium}}$).

2.2 Further considerations when using the added risk approach

However, the added risk approach should be considered with caution for the following reasons:

- This approach ignores the possible contribution of the natural background ($C_{b_{culture\ medium}}/C_{b_{site/region}}$) concentration to the toxic effects of metals to ecological systems. As currently used in risk assessment exercises (e.g., Zn RAR) only the anthropogenic added fraction of a natural element that contributes to the risk for the environment is considered. However, organisms are not able to distinguish between the natural and the anthropogenic part of the metal present in the environment. Consequently, part of the natural background will be bioavailable and could therefore contribute to the total available metal concentration to which the organisms are exposed, and could therefore cause toxicity to the organisms.
- In order to use this approach correctly, the natural background of a particular location and/or a specific region ($C_{b_{site/region}}$) needs to be established. Limited knowledge of the geographical distribution of metal background concentration in ecological systems may hamper the proper implementation of the added risk approach. However, significant work is ongoing in relation to soil and sediments in the UK, Australia and some other countries. Significant efforts have been made to use extensive databases and intrinsic knowledge of the relationships between soil and sediment structural components and geogenic metal concentrations.
- To apply the added risk approach also involves correctly quantifying the metal concentration to which the test organisms are adapted/acclimatised ($C_{b_{culture\ medium}}$). Indeed, for several metals (particularly essential metals) a relationship has been demonstrated between the sensitivity of the organism and the culture condition metal concentrations. Organisms cultured in media with low metal concentrations (which is often the case in standard media) are generally more sensitive than when cultured in higher metal concentrations. However, organisms are often cultured in media (e.g. treated tap water or natural water) with varying metal background concentrations or even with unknown metal concentrations, which therefore complicates the proper implementation of the added risk approach. It must be stressed that culture media often differ from the standard test media used in the toxicity tests, suggesting that test organisms may not be acclimatised/adapted to the metal background concentrations in toxicity tests.
- The added risk approach 'pragmatically' accounts for the effects of acclimation/adaptation on the sensitivity of the organisms. Indeed, accounting for higher $C_{b_{site/region}}$ will result in higher EQS/ $PNEC_{total;site/region}$ values¹ (lower sensitivity) or lower potential risks² (lower sensitivity). This

¹ $PNEC_{total;site/region} = PNEC_{add} + C_{b_{site/region}}$

² Added Risks = $(PEC_{total;region/site} - C_{b_{site/region}})/PNEC_{add}$

approach therefore suggests a relationship between the natural background concentration of the site/region ($C_{b_{site/region}}$) and the sensitivity of the organisms.

- The remaining uncertainty on the effects assessment should be properly characterised/quantified. Indeed, the added risk approach 'allows (opens the door to)' the application of overly conservatism (e.g. using assessment factors, AF) as the reality check will always result in total EQS/PNEC values ($EQS/PNEC_{total;site/region}$) above background concentrations of the site/region under investigation ($C_{b_{site/region}}$)¹.

2.3 Further considerations when using the total risk approach

The total risk approach is based on the following assumptions:

- Contrary to the added risk approach, the total risk approach suggests the natural background ($C_{b_{culture\ medium}}/C_{b_{site/region}}$) concentration contributes to the toxic effects of metals on ecological systems. As currently used in risk assessment exercises (e.g. Pb VRAR), it assumes that the natural background is physiologically active on the toxicity.
- Following the reasoning that background concentration in culture media are generally lower than those encountered in the environment ($C_{b_{site/region}} > C_{b_{culture\ medium}}$), the total risk approach will be more conservative than the added risk approach (i.e. a lower RQ is noted in the added risk approach compared with the total risk approach).
- This results in EQS/PNEC settings based on organisms acclimatised/adapted towards metal background concentrations prevailing in culture media. Such metal concentrations in the culture media often do not reflect those encountered in the environment. Compared to natural levels occurring in the environment, such concentrations are generally low (or even deficient for essential elements). This therefore suggests a higher sensitivity of the organisms, thereby leading to conservative EQS/PNEC settings. Consequently, if background concentrations affect the sensitivity of the organisms, the total EQS/PNEC value only reflects adaptation/acclimation effects to metal background concentrations of the culture media. Ideally, the organisms should have been cultured under conditions relevant for the region under investigation.
- The remaining uncertainty surrounding the effects assessment should also be properly characterized/quantified. As a reality check, it is suggested to compare the total EQS/PNEC against the total natural background, in order to be able to check the environmental relevancy of the effects database used or the EQS/PNEC derived. A revision of the toxicity data set or the derivation approach (e.g. size of assessment factors) would be required if the EQS/PNEC total is below background concentration ($C_{b_{site/region}}$).

2.4. Proposed most scientific approach

Based on the above considerations, the most accurate and ecologically relevant risk characterisation should be made by establishing - on a site-specific-, watershed/basin- or regional basis - both exposure and effects data sets expressed as *bioavailable total fraction* in the environmental compartment/medium ($PEC_{bioavailable}$) and the bioavailable total no effect concentrations ($EQS/PNEC_{bioavailable}$). Tools for assessing and predicting metal bioavailability are available or are being developed for a number of metals (e.g. BLM model for water and the AVS-SEM model for sediment) including some of the metals considered in this document.

The bioavailability concept as described here above could be further extended to an even more refined approach where both geographical/geological and biological characteristics are considered. This approach is often called the "metallo-region driven approach" (or biogeochemical region concept).

This metallo-region approach arises from the fact that different ecoregions can be identified in terms of the physico-chemical characteristics and boundaries of the environmental compartment as well as in terms of their representative species. Within ecoregions, sub-ecoregions (also named metallo-regions) can be differentiated on the basis of the natural background concentration of the metal under consideration and the presence of well-defined abiotic factors that influence metal bioavailability. This concept therefore recognises that (bioavailable) background concentrations of a metal in a given ecoregion can differ from

¹ $PNEC_{total;site/region} = PNEC_{add} + C_{b_{site/region}} = (HC5_{add}/AF) + C_{b_{site/region}}$

one ecosystem to the other, resulting in different sensitivities to the toxic effects of metals due to acclimation or adaptation. This approach further suggests that instead of using 'generic' species sensitivity distributions, it is preferable to use 'endemic' test organisms representative for the natural environment under investigation to characterise the sensitivity of the ecosystem (Figure 1).

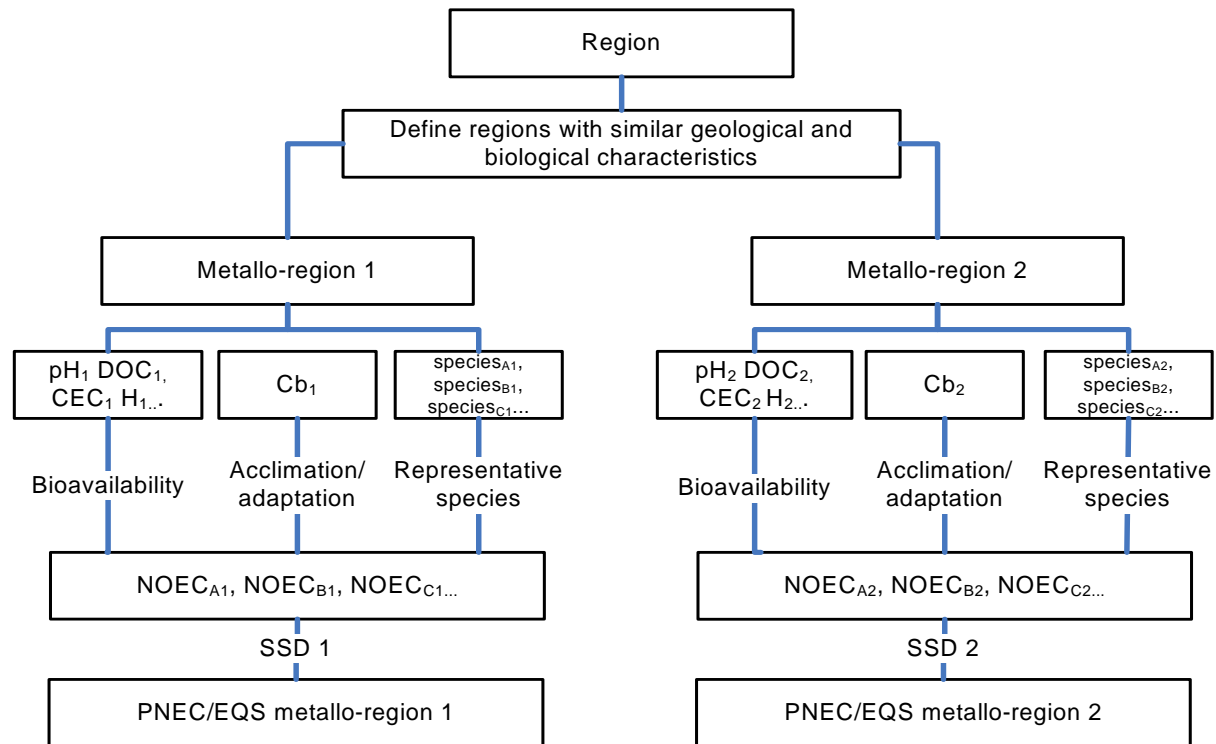


Figure 1: Schematic overview of the metallo-region concept.

The Metallo-region approach will further strengthen the understanding of the *metallo-region specific biodiversity* related to metal background levels. In overall the need for the Added Risk concept for the environmental risk assessments of metals within Chemical Safety Frameworks and EQS setting would in principle disappear when bioavailability can be fully integrated into both the effects and exposure estimation. An understanding and quantification of the natural metal background concentration will than mainly be required to determine the metallo-region classes relevant for the region(s) under assessment.

2.5 Proposed pragmatic tiered approach

Emerging regulatory initiatives (e.g., the Water Framework Directive) require that the metallo-region concept needs to be further developed in the near future. Consequently, in Figure 2 a tiered decision tree is presented to facilitate the expert judgment choice for either the Added Risk approach or the Total Risk approach in absence of metallo region models. The general idea in the decision process is that the actual choice can either be driven by data availability or by requirements set out in a regulatory context. If the data allows it preference should be given to the TRA with bio-availability incorporation (tier 2-3). However, if the data and/or models are not available the exercise could be started with approaches that require fewer resources and efforts, such as tiers 1 and 1'. In any event, if the effects data are considerably above the background concentration the difference between using the added or total risk approach could be negligible.

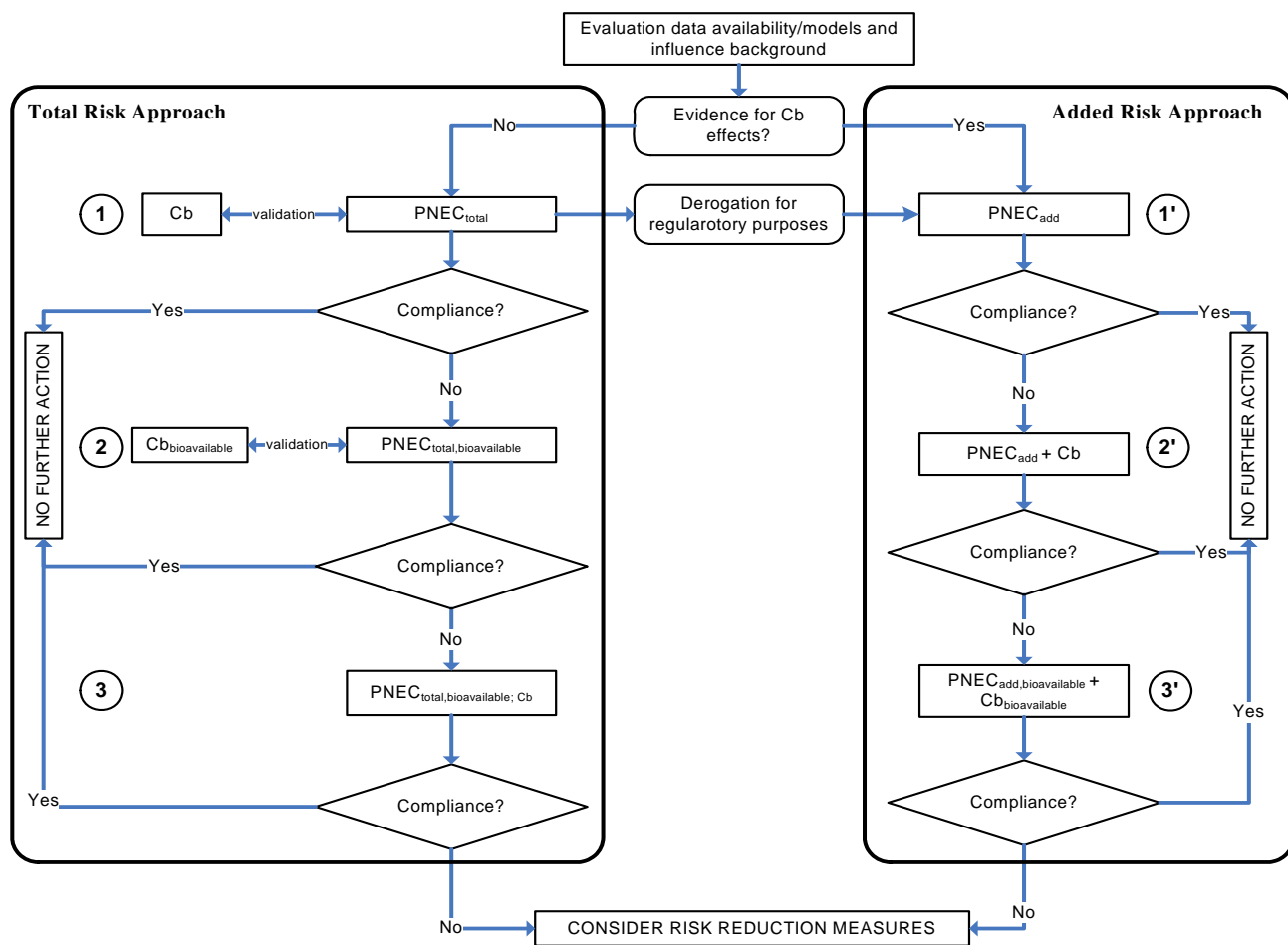


Figure 2: Tiered approach on potential application of total versus added risk concept.

The individual steps of the decision tree are described here below for both approaches.

Total Risk Approach

1) In case the effects of metal background on the sensitivity of organisms can not be demonstrated it is suggested to use the total risk approach. As a validation step, it is strongly recommended to check the ecological relevancy of the proposed PNEC value by comparing the total PNEC with the natural background of the site/region ($C_{b,site/region}$). A revision of both the dataset and/or the derivation approach would be required if the $PEC_{total} < C_{b,site/region}$. If for regulatory purposes, differences in background need to be taken into account, the added risk approach could be used (see 1'.)

Use in chemicals safety management

Potential environmental risks (RQ) are further characterised based on the following quotient:

$$RQ = PEC_{total} / PNEC_{total}$$

Use in EQS settings

Compliance checking is therefore checked by comparing:

$$PEC_{total} \text{ with } PNEC_{total}$$

2) If no compliance is reached a further refinement is possible when models are available to account for bioavailability. In case of the total risk approach both the NOEC and the background values should be corrected for bioavailability. As a validation step, it is strongly recommended to check the ecological relevancy of the proposed PNEC value by comparing the total bioavailable PNEC with the bioavailable natural background of the site/region ($C_{b_{site/region; bioavailable}}$). A revision of both the dataset and/or the derivation approach would be required if the $PEC_{total, bioavailable} < C_{b_{site/region; bioavailable}}$.

Use in chemicals safety management

Potential environmental risks (RQ) are further characterised based on the following quotient:

$$RQ = PEC_{total, bioavailable} / PNEC_{total, bioavailable}$$

Use in EQS settings

Compliance checking is therefore checked by comparing:

$$PEC_{total, bioavailable} \text{ with } PNEC_{total, bioavailable}$$

3) The most accurate and ecologically relevant approach would be to correct the effects/exposure data for both the effects of bioavailability and acclimation/adaptation ($\sim C_b$). As both the natural background concentration and the anthropogenic amount of the metal are considered as potentially contributing to toxic effects, the use of the total risk approach is recommended, resulting in a $EQS/PNEC_{total, bioavailable; C_b}$.

Use in chemicals safety management

Potential environmental risks (RQ) are characterised based on the following quotient:

$$RQ = PEC_{total, bioavailable} / PNEC_{total, bioavailable; C_b}$$

Use in EQS settings

Similarly, compliance of the proposed EQS with the monitoring data is based on the comparison between the site/region specific $PEC_{total, bioavailable}$ and the $PNEC_{total, bioavailable; C_b}$

Added Risk Approach

1) If the effects of metal background on the sensitivity of organisms have been demonstrated or need to be incorporated for regulatory purposes (e.g. Water Framework Directive), it is suggested to use the added risk approach. The first tier in compliance checking in a regulatory context when using added risk could be to compare the PEC total with the PNEC add. If the PEC_{total} is below the PNEC add then consideration of the background (as in 2') will only make this difference bigger. This simple first step would ensure only sites of concern are taken through the tiers.

Use in chemicals safety management

Potential environmental risks (RQ) are characterised based on the following quotient:

$$RQ = PEC_{total} / PNEC_{add}$$

$$\text{Where } PNEC_{add} = PNEC_{total} - C_{b_{culture medium}}$$

Use in EQS settings

Compliance checking is checked by comparing:

$$PEC_{total} \text{ with } PNEC_{add} \text{ (i.e. } PNEC_{total} - C_{b_{culture medium}} \text{).}$$

2) In the second tier both the PNEC and the background value are taken into account. . This approach also suggests the 'correct' estimation of the background concentrations.

Use in chemicals safety management

Potential environmental risks (RQ) are characterised based on the following quotient:

$$RQ = PEC_{add} / PNEC_{add}$$

Where $PEC_{add} = PEC_{total} - Cb_{site/region}$ and $PNEC_{add} = PNEC_{total} - Cb_{culture\ medium}$

Use in EQS settings

Compliance checking is checked by comparing:

$PEC_{total} - Cb_{site/region}$ with $PNEC_{add}$ (i.e. $PNEC_{total} - Cb_{culture\ medium}$).

3) In case the added risk approach is used and no compliance is reached and bioavailability can be taken into account, similar to the total risk approach both the NOEC and the background values should be corrected for bioavailability. However, care should be taken in how the background correction is done (see below).

Use in chemicals safety management

Potential environmental risks (RQ) are characterised based on the following quotient:

$$RQ = PEC_{add, bioavailable} / PNEC_{add, bioavailable}$$

Where $PEC_{add, bioavailable} = (PEC_{total} - Cb_{site/region})_{bioavailable}$ and $PNEC_{add, bioavailable} = (PNEC_{total} - Cb_{culture\ medium})_{bioavailable}$

Use in EQS settings

Compliance checking is therefore checked by comparing:

$PEC_{total, bioavailable} - Cb_{site/region, bioavailable}$ with $PNEC_{add, bioavailable}$ (i.e. $PNEC_{total, bioavailable} - Cb_{culture\ medium, bioavailable}$)

Conclusions

The above discussion shows that both the total and the added risk approach may be used for chemicals management purposes as well as for EQS setting. The added risk approach may be employed as a pragmatic solution facilitating risk management to accounting for the impact of background concentrations if strict data conditions are fulfilled and when more robust approaches (e.g., the metallo-region approach) are not available.

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