

6.3: Predictive risk assessment approaches and tools

6.3. Predictive risk assessment approaches and tools

6.3.1. Environmental realistic scenarios (PECs) – Human

under review

6.3.2. Environmental realistic scenarios (PECs) – Eco

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Learning objectives:

You should be able to:

- explain the role of exposure scenarios in environmental risk assessment (ERA)
- describe the need for, and basic principles of defining exposure assessment goal
- link exposure and effect assessments and can describe the role of environmental scenarios in future ERAs

Keywords: pesticides, exposure, scenarios, assessment goals, effects

Role of exposure scenarios in environmental risk assessment (ERA)

An exposure scenario describes the combination of circumstances needed to estimate exposure by means of models. For example, scenarios for modelling pesticides exposure can be defined as a combination of abiotic (e.g. properties and dimensions of the receiving environment and related soil, hydrological and climate characteristics) and agronomic (e.g. crops and related pesticide application) parameters that are thought to represent a realistic worst-case situation for the environmental context in which the exposure model is to be run. A scenario for exposure of aquatic organisms could be e.g. a ditch with a minimum water depth of 30 cm alongside a crop growing on a clay soil with annual applications of pesticide using a 20-year time series of weather data and including pesticide exposure via spray drift deposition and leaching from drainpipes. Such a scenario would require modelling of spray drift, leaching from drainpipes and exposure in surface water, ending up in a 20-year time series of the exposure concentration. In this chapter, we explain the use of exposure scenarios in prospective ERA by giving examples for the regulatory assessment of pesticides in particular.

Need for defining exposure assessment goals

Between about 1995 and 2001 groundwater and surface water scenarios were developed for EU pesticide registration; also referred to as the FOCUS scenarios. The European Commission indicated that these should represent 'realistic worst-cases', a political concept which leaves considerable room for scientific interpretation. Risk assessors and managers agreed that the intention was to generate 90th percentile exposure concentrations. The concept of a 90th percentile exposure concentration assumes a statistical population of concentrations and 90% of these concentrations are lower than this 90th percentile (and thus 10% are higher). This 90th percentile approach has since then been followed for most environmental exposure assessments for pesticides at EU level.

The selection of the FOCUS groundwater and surface water scenarios involved a considerable amount of expert judgement because this selection could not yet be based on well-defined GIS procedures and databases on properties of the receiving environment. The EFSA exposure assessment for soil organisms was the first environmental exposure assessment that could be based on a well-defined GIS procedure, using EU maps of parameters like soil organic matter, density of crops and weather. During the development of this exposure assessment, it became clear that the concept of a 90th percentile exposure concentration is too vague: it is essential to define also the statistical population of concentrations from which this 90th percentile is taken. Based on this insight, the EFSA Panel on Plant Protection Products and their Residues (PPR) developed the concept of the exposure assessment goals, which has become the standard within EFSA for developing regulatory exposure scenarios for pesticides.

Procedure for defining exposure assessment goals

Figure 1 shows how an exposure assessment goal for the risk assessment of aquatic organisms can be defined following this EFSA procedure. The left part specifies the temporal dimensions and the right part the spatial dimensions. In box E1, the Ecotoxicologically Relevant type of Concentration (ERC) is defined, e.g. the freely dissolved pesticide concentration in water for

pelagic organisms. In box E2, the temporal dimension of this concentration is defined, e.g. annual peak or time-weighted average concentration for a pre-defined period. Based on these elements, the multi-year temporal population of concentrations can be generated for one single water body (E5) which would consist of e.g. 20 peak concentrations in case of a time series of 20 years. The spatial part requires definition of the type of water body (e.g. ditch, stream or pond; box E3) and the spatial dimension of this body (e.g. having a minimum water depth of 30 cm; box E4). Based on these, the spatial population of water bodies can be defined (box E6), e.g. all ditches with a minimum water depth of 30 cm alongside fields treated with the pesticide. Finally, then in box E7 the percentile combination to be taken from the spatio-temporal population of concentrations is defined. Specification of the exposure assessment goals does not only involve scientific information, but also political choices because this specification influences the strictness of the exposure assessment. For instance, in case of exposure via spray drift a minimum water depth of 30 cm in box E4 leads to about a three times lower peak concentration in the water than a minimum water depth of 10 cm.

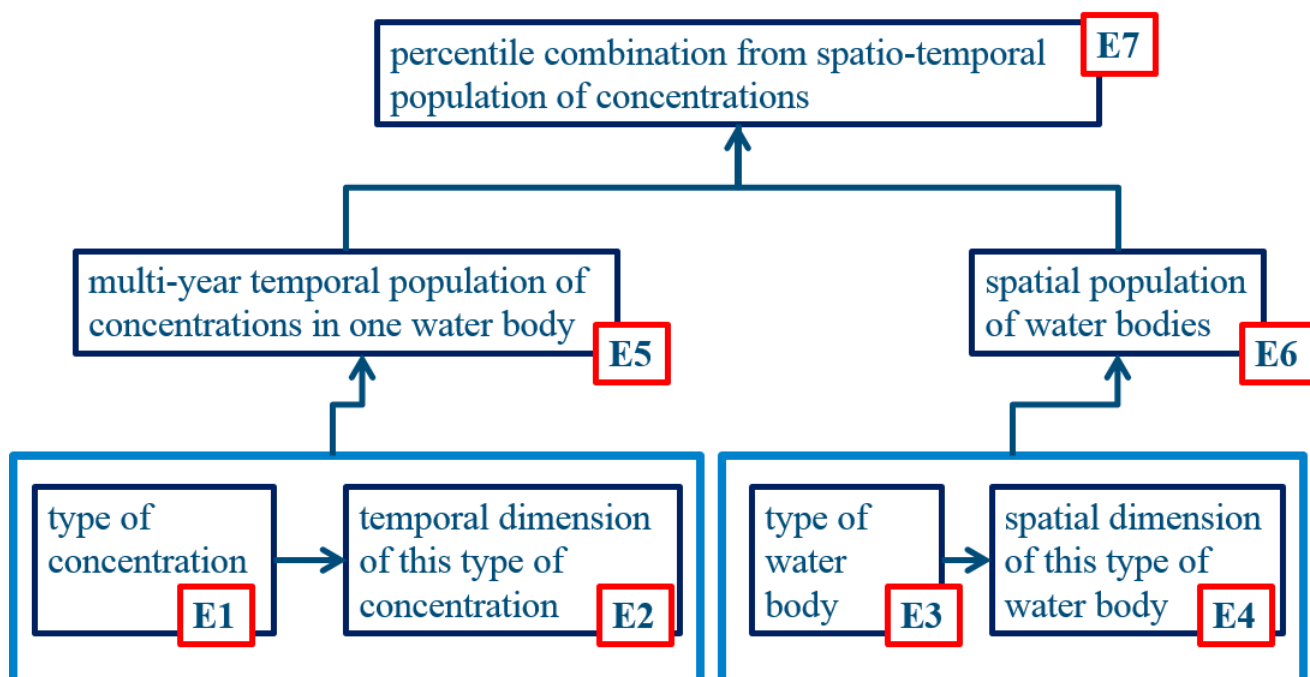


Figure 1. Scheme of the seven elements of the exposure assessment goal for aquatic organisms.

The schematic approach of Figure 1 can easily be adapted to other exposure assessment goals.

Interaction between exposure and effect assessment for organisms

Nearly all the environmental protection goals for pesticides involve assessment of risk for organisms; only groundwater and drinking water from surface water are based on a concentration of 0.1 µg/L which is not related to possible ecotoxicological effects. The risk assessment for organisms is a combination of an exposure assessment and an effect assessment as is illustrated by Figure 2.

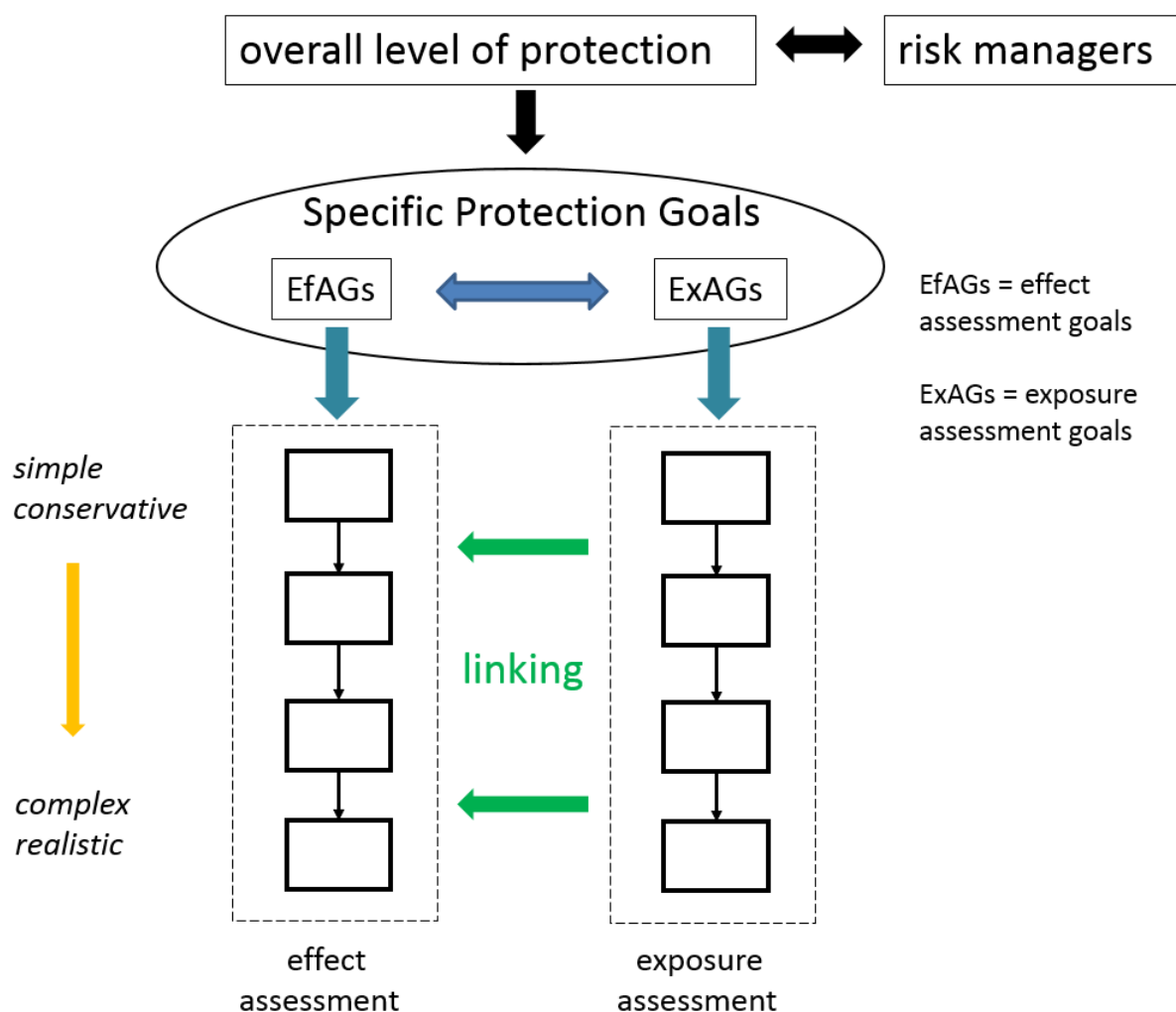


Figure 2. Overview of the risk assessment of organisms based on parallel tiered effect and exposure assessments.

Both the effect and the exposure assessment are tiered approaches with simple and conservative first tiers and less simple and more realistic higher tiers. A lower exposure tier may consist of a simple conservative scenario whereas a higher exposure tier may e.g. be based on a scenario selected using sophisticated spatial modelling. The top part of the scheme shows the link to the risk managers which are responsible for the overall level of protection. This overall level of protection is linked to the so-called Specific Protection Goals which will be explained in [Section 6.5.3](#) and form the basis for the definition of the effect and exposure assessment goals. So the exposure assessment goals and resulting exposure scenarios should be consistent with the Specific Protection Goals (e.g. algae and fish may require different scenarios). When linking the two assessments, it has to be ensured that the type of concentration delivered by the exposure assessment is consistent with that required by the effect assessment (e.g. do not use time-weighted average concentrations in acute effect assessment). Figure 2 shows that in the assessment procedure information flows always from the exposure assessment to the effect assessment because the risk assessment conclusion is based on the effect assessment.

A relatively new development is to assess exposure and effects at the landscape level. This typically is a combination of higher-tier effect and exposure assessments. In such an approach, first the dynamics in exposure is assessed for the full landscape, and then combined with the dynamics of effects, for example based on spatially-explicit population models for species typical for that landscape. Such an approach makes a separate definition of the exposure and effect scenario redundant because this approach aims to deliver the exposure and effect assessment in an integrated way in space and time. Such an integrated approach requires the definition of "environmental scenarios". Environmental scenarios integrate both the parameters needed to define the exposure (exposure scenario) and those needed to calculate direct and indirect effects and recovery (ecological scenario) (see Figure 3). However, it will probably take at least a decade before landscape-level approaches, including agreed-upon environmental scenarios, will be implemented for regulatory use in prospective ERA.

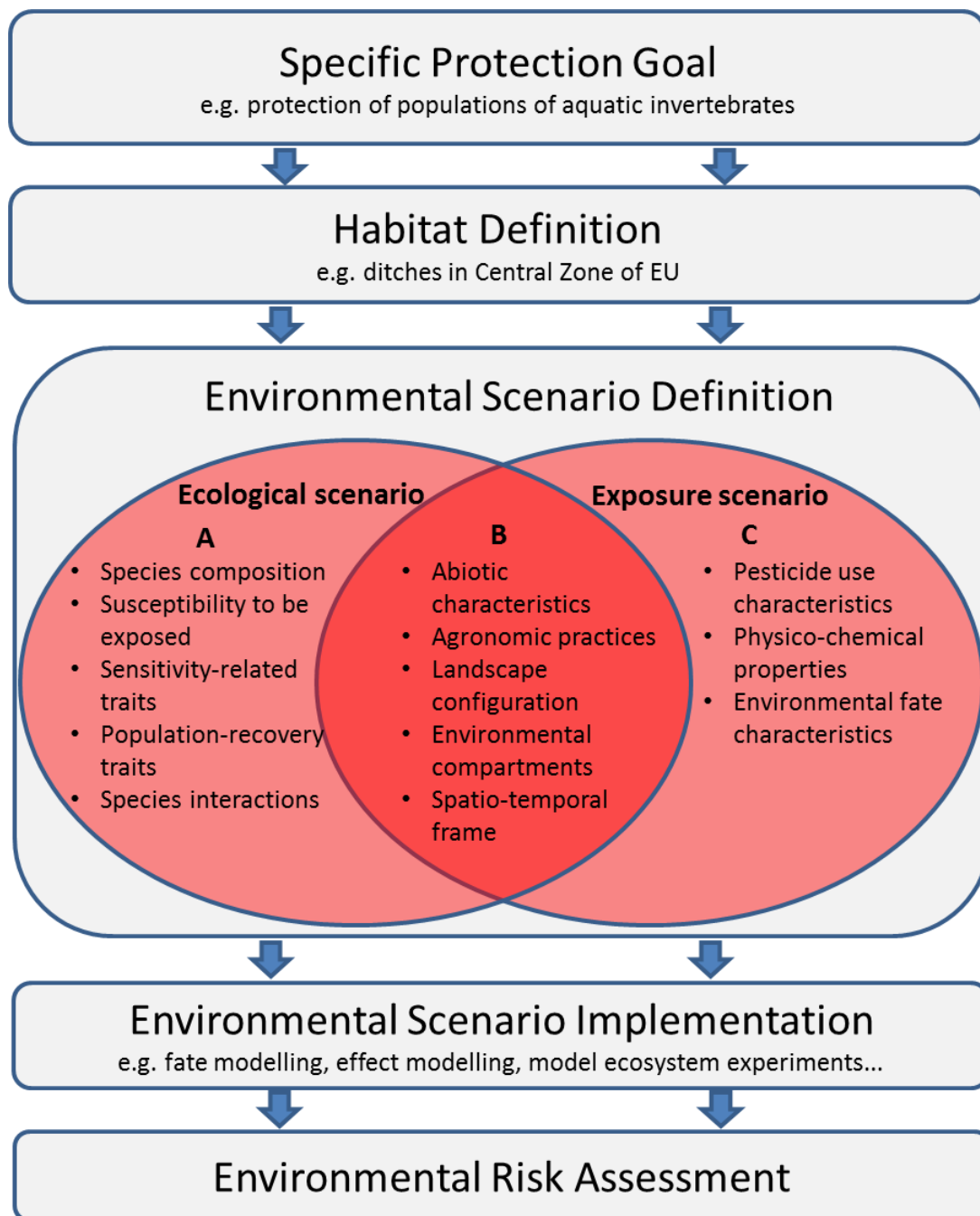


Figure 3. Conceptual framework of the role of an environmental scenario in prospective ERA (adapted after Rico et al. 2016).

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6.3.2. Question 1

Why is a detailed specification of exposure assessment goals needed ?

6.3.2. Question 2

Why does specification of the exposure assessment goals include political choices ?

6.3.2. Question 3

Why does the risk assessment of organisms consist of two parallel tiered schemes for effects and exposure ?

6.3.3. Setting reference levels for human health protection

in preparation

6.3.4. Setting safe standards

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Learning objectives

You should be able to:

- explain what a reference level for ecosystem protection is;
- explain the basic concepts underlying the assessment factor approach for deriving PNECs;
- explain why secondary poisoning needs specific consideration when deriving a PNEC using the assessment factor approach.

Key words: PNEC, quality standards, extrapolation, assessment factor

Introduction

The key question in environmental risk assessment is whether environmental exposure to chemicals leads to unacceptable risks for human and ecosystem health. This is done by comparing the measured or predicted concentrations in water, soil, sediment, or air, with a reference level. Reference levels represent a dose (intake rate) or concentration in water, soil, sediment or air below which unacceptable effects are not expected. The definition of 'no unacceptable effects' may differ between regulatory frameworks, depending on the protection goal. The focus of this section is the derivation of reference levels for aquatic ecosystems as well as for predators feeding on exposed aquatic species (secondary poisoning), but the derivation of reference values for other environmental compartments follows the same principles.

Terminology and concepts

Various technical terms are in use as reference values, e.g. the Predicted No Effect Concentration (PNEC) for ecosystems or the Acceptable Daily Intake (ADI) for humans (Section on [Human toxicology](#)). The term "reference level" is a broad and generic term, which can be used independently of the regulatory context or protection goal. In contrast, the term "quality standard" is associated with some kind of legal status, e.g., inclusion in environmental legislation like the Water Framework Directive (WFD). Other terms exist, such as the terms 'guideline value' or 'screening level' which are used in different countries to indicate triggers for further action. While the scientific basis of these reference values may be similar, their implementation and the consequences of exceedance are not. It is therefore very important to clearly define the context of the derivation and the terminology used when deriving and publishing reference levels.

PNEC

A frequently used reference level for ecosystem protection is the Predicted No Effect Concentration (PNEC). The PNEC is the concentration below which adverse effects on the ecosystem are not expected to occur. PNECs are derived per compartment and apply to the organisms that are directly exposed. In addition, for chemicals that accumulate in prey, PNECs for secondary poisoning of predatory birds and mammals are derived. The PNEC for direct ecotoxicity is usually based on results from single species laboratory toxicity tests. In some case, data from field studies or mesocosms may be included.

A basic PNEC derivation for the aquatic compartment is based on data from single species tests with algae, water fleas and fish. Effects on the level of a complex ecosystem are not fully represented by effects on isolated individuals or populations in a laboratory set-up. However, data from laboratory tests can be used to extrapolate to the ecosystem level if it is assumed that

protection of ecosystem structure ensures protection of ecosystem functioning, and that effects on ecosystem structure can be predicted from species sensitivity.

Accounting for Extrapolation Uncertainty: Assessment Factor (AF) Approach

To account for the uncertainty in the extrapolation from single species laboratory tests to effects on real life ecosystems, the lowest available test result is divided by an assessment factor (AF). In establishing the size of the AF, a number of uncertainties must be addressed to extrapolate from single-species laboratory data to a multi-species ecosystem under field conditions. These uncertainties relate to intra- and inter-laboratory variation in toxicity data, variation within and between species (biological variance), test duration and differences between the controlled laboratory set-up and the variable field situation. The value of the AF depends on the number of studies, the diversity of species for which data are available, the type and duration of the experiments, and the purpose of the reference level. Different AFs are needed for reference levels for e.g. intermittent release, short-term concentration peaks or long-term (chronic) exposure. In particular, reference levels for intermittent release and short-term exposure may be derived on the basis of acute studies, but short-term tests are less predictive for a reference level for long-term exposure and larger AFs are needed to cover this. Table 1 shows the generic AF scheme that is used to derive PNECs for long-term exposure of freshwater organisms in the context of European regulatory framework for industrial chemicals (REACH; see Section on [REACH environment](#)). This scheme is also applied for the authorisation of biocidal products, pharmaceuticals and for derivation of long-term water quality standards for freshwater under the EU Water Framework Directive. Further details on the application of this scheme, e.g., how to compare acute and chronic data and how to deal with irregular datasets, are presented in guidance documents (see suggested reading: EC, 2018; ECHA, 2008). Similar schemes exist for marine waters, sediment, and soil. However, for the latter two environmental compartments often too little experimental information is available and risk limits have to be calculated by extrapolation from aquatic data using the Equilibrium Partitioning concept. The derivation of Regulatory Acceptable Concentrations (RAC) for plant protection products (PPPs) is also based on the extrapolation of laboratory data, but follows a different approach focussing on generating data for specific taxonomic groups, taking account of the mode of action of the PPP (see suggested reading: EFSA, 2013).

Table 1. Basic assessment factor scheme used for the derivation of PNECs for freshwater ecosystems used in several European regulatory frameworks. Consult the original guidance documents for full schemes and additional information (see suggested reading: EC, 2018; ECHA, 2008).

Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels (fish, invertebrates (preferred <i>Daphnia</i>) and algae)	1000
One long-term EC10 or NOEC (either fish or <i>Daphnia</i>)	100
Two long-term results (e.g. EC10 or NOECs) from species representing two trophic levels (fish and/or <i>Daphnia</i> and/or algae)	50
Long-term results (e.g. EC10 or NOECs) from at least three species (normally fish, <i>Daphnia</i> and algae) representing three trophic levels	10

Application of Species Sensitivity Distribution (SSD) and Other Additional Data

The AF approach was developed to account for the uncertainty arising from extrapolation from (potentially limited) experimental datasets. If enough data are available for other species than algae, daphnids and fish, statistical methods can be applied to derive a PNEC. Within the concept of species sensitivity distribution (SSD), the distribution of the sensitivity of the tested species is used to estimate the concentration at which 5% of all species in the ecosystem is affected (HC5; see section on [SSDs](#)). When used for regulatory purposes in European regulatory frameworks, the dataset should meet certain requirements regarding the number of data points and the representation of taxa in the dataset, and an AF is applied to the HC5 to cover the remaining uncertainty from the extrapolation from lab to field.

Where available, results from semi-field experiments (mesocosms, see section on [Community ecotoxicology](#)) can also be used, either on its own or to underpin the PNEC derived from the AF or SSD approach. SSDs and mesocosm-studies are also used in the

context of authorisation of PPP.

Reference levels for secondary poisoning

Substances might be toxic to wildlife because of bioaccumulation in prey or a high intrinsic toxicity to birds and mammals. If this is the case, a reference level for secondary poisoning is derived for a simple food chain: water → fish or mussel → predatory bird or mammal. The toxicity data from bird or mammal tests are transformed into safe concentrations in prey. This can be done by simply recalculating concentrations in laboratory feed into concentrations in fish using default conversion factors (see e.g., ECHA, 2008). For the derivation of water quality standards under the WFD, a more sophisticated method was introduced that uses knowledge on the energy demand of predators and energy content in their food to convert laboratory data to a field situation. Also, the inclusion of other, more complex and sometimes longer food chains is possible, for which field bioaccumulation factors are used rather than laboratory derived values.

Suggested additional reading

EC (2018). Common Implementation Strategy for the Water Framework Directive (2000/60/EC). Guidance Document No. 27. Technical Guidance For Deriving Environmental Quality Standards. Updated version 2018. Brussels, Belgium. European Commission. circabc.europa.eu/ui/group/9...7a2a6b/details

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6.3.4. Question 1

What is a PNEC?

6.3.4. Question 2

How is a basic PNEC commonly derived in Europe?

6.3.4. Question 3

Why are assessment factors applied?

6.3.4. Question 4

Which aspects are covered by the assessment factor?

6.3.4. Question 5

Within the EU REACH/WFD regulatory framework, which assessment factor may be applied to derive a PNEC for freshwater if you have one LC₅₀ value for *Oncorhynchus mykiss*, one EC₅₀ value for *Daphnia magna*, one EC₁₀ value for *Oncorhynchus mykiss*, and one NOEC value for *Pseudokirchneriella subcapitata*?

6.3.5. Species Sensitivity Distributions (SSDs)

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Learning objectives:

You should be able to:

- explain that differences exist in the reaction of species to exposure to a chemicals;
- explain that these differences can be described by a statistical distribution;
- derive a Species Sensitivity Distribution (SSD) for sensitivity data;
- derive benchmark concentration from an SSD;

- derive a predicted impact from an SSD.

Keywords: Species Sensitivity Distribution (SSD), benchmark concentration, Potentially Affected Fraction of species (PAF)

Introduction

The relationship between dose or concentration (X) and response (Y) is key in risk assessment of chemicals (see section on [Concentration-response relationships](#)). Such relationships are often determined in laboratory toxicity tests; a selected species is exposed under controlled conditions to a series of increasing concentrations to determine endpoints such as the No Observed Effect Concentration (NOEC), the EC50 (the Effect Concentration causing 50% effect on a studied endpoint such as growth or reproduction), or the LC50 (the Effect Concentration causing 50% lethal effects). For ecological risk assessment, multiple species are typically tested to characterise the (variation in) sensitivities across species or taxonomic groups within the ecosystem. In the mid-1980s it had been observed that-like many natural phenomena-a set of ecotoxicity endpoint data, representing effect concentrations for various species, follows a bell-shaped statistical distribution. The cumulative distribution of these data is a sigmoid (S-shaped) curve. It was recognized, that this distribution had particular utility for assessing, managing and protecting environmental quality regarding chemicals. The bell-shaped distribution was thereupon named a Species Sensitivity Distribution (SSD). Since then, the use of SSD models has grown steadily. Currently, the model is used for various purposes, providing important information for decision-making.

Below, the dual utility of SSD models for environmental protection, assessment and management are shown first. Thereupon, the derivation and use of SSD models are elaborated in a stepwise sequence.

The dual utility of SSD models

A species sensitivity distribution (SSD) is a distribution describing the variance in sensitivity of multiple species exposed to a hazardous compound. The statistical distribution is often plotted using a log-scaled concentration axis (X), and a cumulative probability axis (Y, varying from 0 - 1; Figure 1).

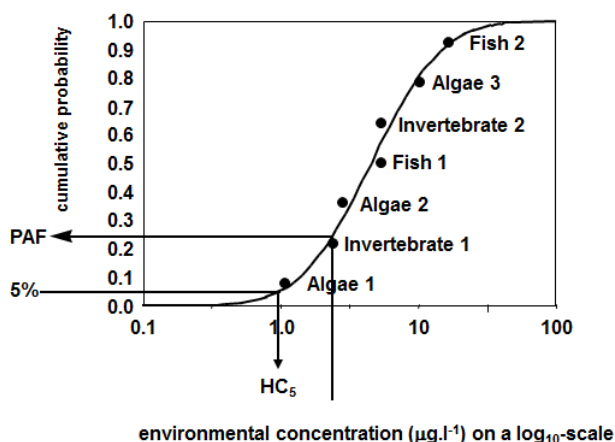


Figure 1. An species-sensitivity distribution (SSD) model, its data, and its dual use (from YàX, and from XàY). Dots represent the ecotoxicity endpoints (e.g., NOECs, EC50s, etc.) of different species.

Figure 1 shows that different species (here the dots represent 3 test data for algal species, 2 data for invertebrate species and 2 data fish species) have different sensitivities to the studied chemical. First, the ecotoxicity data are collected, and \log_{10} -transformed. Second, the data set can be visually inspected by plotting the bell-shaped distribution of the log-transformed data; deviations of the expected bell-shape can be visually identified in this step. They may originate from causes such as a low number of data points or be indicative for a selective mode of action of the toxicant, such as a high sensitivity of insects to insecticides. Third, common statistical software for deriving the two parameters of the log-normal model (the mean and the standard deviation of the ecotoxicity data) can be applied, or the SSD can be described with a dedicated software tool such as ET_X (see below), including a formal evaluation of the 'goodness of fit' of the model to the data. With the estimated parameters, the fitted model can be plotted, and this is often done in the intuitively attractive form of the S-shaped cumulative distribution. This curve then serves two purposes. First, the curve can be used to derive a so-called Hazardous Concentration on the X-axis: a benchmark concentration that can be used as regulatory criterion to protect the environment (YàX). That is, chemicals with different toxicities have different SSDs, with the more hazardous compounds plotted to the left of the less hazardous compounds. By selecting a protection level on the Y-axis-

representing a certain fraction of species affected, e.g. 5%-one derives the compound-specific concentration standards. Second, one can derive the fraction of tested species probably affected at an ambient concentration ($X \rightarrow Y$), which can be measured or modelled. Both uses are popular in contemporary environmental protection, risk assessment, and management.

Step 1: Ecotoxicity data for the derivation of an SSD model

The SSD model for a chemical and an environmental compartment (e.g., surface water, soil or sediment) is derived based on pertinent ecotoxicity data. Those are typically extracted from scientific literature or ecotoxicity databases. Examples of such databases are the U.S. EPA's Ecotox database, the European REACH data sets and the EnviroTox database which contains quality-evaluated studies. The researcher selects the chemical and the compartment of interest, and subsequently extracts all test data for the appropriate endpoint (e.g., EC_x -values). The set of test data is tabulated and ranked from most to least sensitive. Multiple data for the same species are assessed for quality and only the best data are used. If there is > 1 toxicity value for a species after the selection process, the geometric mean value is commonly derived and used. A species should only be represented once in the SSD. Data are often available for frequently tested species, representing different taxonomic and/or trophic levels. A well-known triplet of species frequently tested is "Algae, Daphnids and Fish", as this triplet is a requested minimum set for various regulations in the realm of chemical safety assessment (see section on [Regulatory frameworks](#)). For various compounds, the number of test data can be more than hundred, whilst for most compounds few data of acceptable quality may be available.

Step 2. The derivation and evaluation of an SSD model

Standard statistical software (a spreadsheet program) or a dedicated software model such as ETX can be used to derive an SSD from available data. Commonly, the fit of the model to the data set is checked to avoid misinterpretation. Misfit may be shown using common statistical testing (Goodness of Fit tests) or by visual inspection and ecological interpretation of the data points. That is, when a chemical specifically affects one group of species (e.g., insects having a high sensitivity for insecticides), the user may decide to derive an SSD model for specific groups of species. In doing so, the outcome will consist of two or more SSDs for a single compound (e.g., an SSD_{Insect} and an SSD_{Other} when the compound is an insecticide, whilst the SSD_{Other} might be split further if appropriate). These may show a better goodness of fit of the model to the data, but - more importantly - they reflect the use of key knowledge of mode of action and biology prior to 'blindly' applying the model fit procedure.

Step 3a. The SSD model used for environmental protection

The oldest use of the SSD model is the derivation of reference levels such as the PNEC ($Y \rightarrow X$). That is, given the policy goal to fully protect ecosystems against adverse effects of chemical exposures (see Section on [Ecosystem services and protection goals](#)), the protective use is as follows. First, the user defines which ecotoxicity data are used. In the context of environmental protection, these have often been NOECs or low-effect levels (EC_x , with low x , such as EC_{10}) from chronic tests. This yields an SSD-NOEC or SSD- EC_x . Then, the user selects a level of Y , that is: the maximum fraction of species for which the defined ecotoxicity endpoint (NOEC or EC_x) may be exceeded, e.g., 0.05 (a fraction of 0.05 equals 5% of the species). Next, the user derives the Hazardous Concentration for 5% of the species ($Y \rightarrow X$). At the HC_5 , 5% of the species are exposed to concentrations *greater* than their NOEC, but-which is the obverse-95% of the species are exposed to concentration *less* than their NOEC. It is often assumed that the structural and functional integrity of ecosystems is sufficiently protected at the HC_5 level if the SSD is based on NOECs. Therefore, many authorities use this level to derive regulatory PNECs (Predicted No Effect Concentration) or Environmental Quality Standards (EQS). The latter concepts are used as official reference levels in risk assessment, the first is the preferred abbreviation in the context of prospective chemical safety assessments, and the second is used in retrospective environmental quality assessment. Sometimes an extra assessment factor varying between 1 and 5 is applied to the HC_5 to account for remaining uncertainties. Using SSDs for a set of compounds yields a set of HC_5 values, which-in fact-represent a relative ranking of the chemicals by their potential to cause harm.

Step 3b. The SSD model used for environmental quality assessment

The SSD model also can be used to explore how much damage is caused by environmental pollution. In this case, a predicted or measured ambient concentration is used to derive a Potentially Affected Fraction of species (PAF). The fraction ranges from 0-1 but, in practice, it is often expressed as a percentage (e.g., "24% of the species is likely affected"). According to this approach, users often have monitored or modelled exposure data from various water bodies, or soil or sediment samples, so that they can evaluate whether any of the studied samples contain a concentration higher than the regulatory reference level (previous section) and, if so how many species are affected. Evidently, the user must clearly express what type of damage is quantified, as damage estimates based on an SSD_{NOEC} or an SSD_{EC50} quantify the fractions of species affected beyond the no effect level and at the 50%

effect level, respectively. This use of SSDs for a set of environmental samples yields a set of PAF values, which, in fact, represent a relative ranking of the pollution levels at the different sites in their potential to cause harm.

Practical uses of using SSD model outcomes

SSD model outcomes are used in various regulatory and practical contexts.

1. The oldest use of the model, setting regulatory standards, has a global use. Organizations like the European Union and the OECD, as well as many countries, apply SSD models to set (regulatory) standards. Those standards are then used prospectively, to evaluate whether the planned production, use or release of a (novel) chemical is sufficiently safe. If the predicted concentration exceeds the criterion, this is interpreted as a warning. Dependent on the regulatory context, the compound may be regulated, e.g., prohibited from use, or its use limited. The data used to build SSD models for deriving regulatory standards are often chronic test data, and no or low effect endpoints. The resulting standards have been evaluated in validation studies regarding the question of sufficient protection. Note that some jurisdictions have both protective standards as well as trigger values for remediation, based on SSD modelling.
2. The next use is in environmental quality assessment and management. In this case, the predicted or measured concentration of a chemical in an environmental compartment is often first compared to the reference level. This may already trigger management activities if the reference values have a regulatory status, such as a clean-up operation. The SSD may, however, be used to provide more detailed information on expected magnitude of impact, so that environmental management can prioritize most-affected sites for earlier remediation. The use of SSDs needs be tailored to the situation. That is, if the exposure concentrations form an array close to the reference value, the use of SSD_{NOEC} is a logical step, as this ranks the site pollution levels (via the PAFs) regarding the potentially affected fraction of species experiencing slight exceedances of the no effect level. If the study area contains highly polluted sites, that approach may show that all measured concentrations are in the upper tail of the SSD_{NOEC} sigmoid (horizontal part). In such cases, the SSD_{EC50} provides information on across-sites differences in expected impacts larger than the 50% effect level.
3. The third use is in Life Cycle Assessment of products. This use is comparative, so that consumers can select the most benign product, whilst producers can identify 'hot spots' of ecotoxicity in their production chains. A product often contains a suite of chemicals, so that the SSD model must be applied to all chemicals, by aggregating PAF-type outcomes over all chemicals. The model USEtox is the UN global consensus model for this application.

Today, these three forms of use of SSD models have an important role in the practice of environmental protection, assessment and management on the global scale, which relates to their intuitive meaning, their ease of use, and the availability of a vast number of ecotoxicity data in the global databases.

6.3.5. Question 1

What is the basic concept underlying SSD models?

6.3.5. Question 2

What is the main assumption underlying SSD models?

6.3.5. Question 3

What is meant by "the dual utility of an SSD model" in environmental protection, assessment and management?

6.3.5. Question 4

Given that the SSD model is a statistical description of ecotoxicological differences in sensitivity between species for a chemical, what is a critical step in the derivation and use of SSD model outputs?

6.3.5. Question 5

Does an SSD describe or explain differences in species sensitivity for a chemical?

6.3.6. Mixtures

under review

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