National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Guidance for the derivation of environmental risk limits

Part 1. Introduction and definitions

version 1.0

Colophon

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1 Introduction and scope of the document

This report forms the guidance document for the derivation of environmental risk limits used in environmental policy in the Netherlands. The previous version of the guidance was published in 2007 and combined the existing European methodology with national guidance for those aspects that were not addressed in the European guidance documents [1]. Since then, the European legislation for new and existing substances became obsolete and new European guidance was introduced in 2008 for those compounds falling under REACH. In addition, a new European technical guidance document for the derivation of water quality standards under the Water Framework Directive (WFD) was published in 2011 [2]. As a consequence, an update of the 2007-guidance was needed.

In previous years environmental risk limits were derived for all environmental compartments simultaneously, considering soil, (ground)water, sediment and air together. Nowadays, the need for risk limits or quality standards is driven more and more by a compartment specific approach: the need for regulating a compound with respect to water quality does not necessarily mean that standards for soil and air are also needed. Moreover, compartment specific guidance became available at a European level, making national guidance partly obsolete and causing consistency problems to some extent, e.g. with respect to terminology.

In view of the above, it was decided to publish the updated guidance in the form of separate chapters that are digitally accessible only. The present document serves as a general introduction to these chapters. It provides general information on the historical background and formal process of standard setting in the Netherlands and discusses some aspects that are relevant for all other parts of the guidance, i.e. addresses general methodological concepts that are applicable irrespective of the environmental compartment.
This guidance presents the current state of the art with respect to environmental risk limit derivation and environmental standard setting in the Netherlands. The documents are meant to be living documents that will be revised when needed in view of technical or procedural changes. Revisions are subject to scientific review and should be agreed upon by the responsible Ministry of Infrastructure and the Environment.

2 A short history of environmental quality standards in the Netherlands

2.1 Introduction

The Netherlands have a relatively long history of environmental quality standards. The first official water quality standards date back to the late 60's of the past century [3]. Over the years, scientific developments and policy needs have influenced methodology. At the same time, the regulatory context for risk assessment of substances shifted from a national to a European level. For a proper understanding of the standards that are addressed in this guidance, this introduction provides a short history of the development of standard setting in the Netherlands.

2.2 Maximum Permissible and Negligible Concentration

In 1985, a risk based approach was adopted as the main principle of environmental protection in a policy document that was presented to the parliament [4]. In this policy document, two risk levels were introduced that are still used to date: the maximum permissible concentration (MPC), indicated in Dutch as '*maximaal toelaatbaar risiconiveau*' (MTR) and the Negligible Concentration (NC), indicated as '*verwaarloosbaar risiconiveau*' (VR). Below the NC, negligible risks are considered to be present and no action is needed. Above the MPC, intolerable risks are expected and action is prescribed. Between NC and MPC, there is room for improvement, and policy should be aimed at ultimately reaching the NC (see Figure 1).

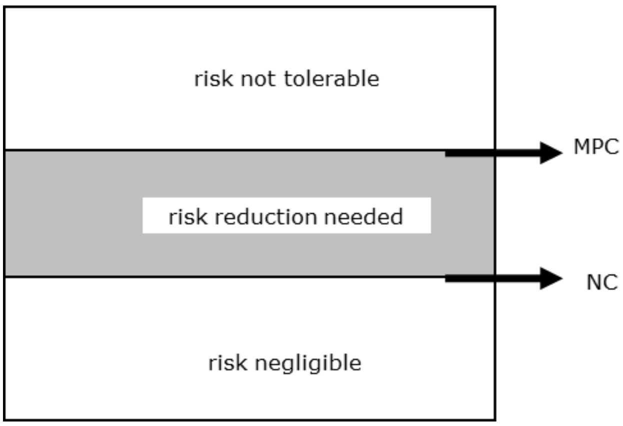

Figure 1 Risk based concept of environmental policy in the Netherlands. MPC = maximum permissible concentration, NC = negligible concentration.

In the appendix to the 1985-policy document, the risk levels were defined with respect to human health. For compounds for which a threshold level for adverse effects can be determined, the MPC for humans was set at the Acceptable Daily Intake (ADI) or Tolerable Daily Intake (TDI). For substances without a threshold (genotoxic carcinogens), the MPC was set to an increased probability of death of 10^{-6} per year (10^{-4} on a life-time basis). The NC was defined as 1% of the MPC, taking account of the fact that, while setting standards for single compounds, simultaneous exposure to multiple substances occurs in reality [4,5]. In a follow-up, the MPC for the environment was added and defined as the concentration which protects at least 95% of the species in an ecosystem, thereby protecting the function of the ecosystem [6]. Similarly to the human risk assessment, the NC for the ecosystem was set to 1% of the MPC.

The 95% protection level is associated with the use of Species Sensitivity Distributions (SSDs). The SSD-method is used to predict the sensitivity of a whole community on the basis of the results of laboratory data on individual species and enables to estimate the fraction of species in the community that is potentially affected given a certain exposure level. The method was developed by Van Straalen and Denneman [7] and modified later on (e.g. Aldenberg and Jaworska and Wagner and Løkke [8,9]). The initially proposed 5% cut-off level as the basis for standard setting was generally adopted. In the various guidance documents for Dutch standard setting that were published later on, the SSD-method was advised when at least four ecotoxicity data were available for species and/or functional parameters such as microbial or enzyme activity [10-14]. If fewer data were available, assessment factors were applied to the lowest ecotoxicity endpoint, assuming that this would at least guarantee a similar level of protection.

The definitions for MPC and NC have been maintained in the Dutch policy on substances over the years, although sometimes phrased in a slightly different way. In 1997 and 1999 [15,16], the definitions of MPC and NC were presented as follows:

'The MPC is defined in the policy on substances as the scientifically based standard for a substance that indicates at which concentration in an environmental compartment:

1. no effect to be rated as negative is to be expected for ecosystems;
2a no effect to be rated as negative is to be expected for humans (for non-carcinogenic substances);
2b for humans no more than a probability of 10^{-6} per year of death can be calculated (for carcinogenic substances).

The MPC is derived per substance. With the MPC for ecosystems it is envisaged to protect the species within an ecosystem. It is assumed that the ecosystem will be protected.'

'The NC is the lower limit for a substance and in principle derived as 1/100 of the MPC. The factor of 100 between MPC and NC is chosen because many substances are encountered simultaneously in the environment. It is particularly meant to account for the possible effects of combination toxicity. Although it seems desirable to differentiate the fixed factor of 100 (e.g. to substance group and/or environmental situation), it is decided based on advises of the Health Council[1] and Soil Protection Technical Committee[2] to maintain the factor of 100 between MPC and NC.'

[1] Gezondheidsraad, http://www.gezondheidsraad.nl/
[2] Technische Commissie Bodem, http://www.tcbodem.nl/

2.3 Serious Risk Concentration

Apart from the MPC and NC, the Dutch policy on substances uses the Serious Risk Concentration (SRC) as an additional risk limit. The SRC is primarily used in soil policy, where it is used as input for the derivation of the so-called intervention values. Intervention values are concentrations in soil, sediment or groundwater above which measures should be taken. The intervention values are based on a combination of human toxicological and ecotoxicological risk limits. For humans, the intervention value uses the MPC-level according to the definition given above, while for ecosystems the SRC is used. The SRC for ecosystems is defined as the concentration at which 50% of the species is potentially affected.

2.4 Harmonisation and integration of exposure routes

From the early start of method development [14], the harmonisation of quality standards among the environmental compartments has been a key issue in Dutch policy. Soil, (ground)water, sediment and air are interconnected and after primary emission to soil, water or air, compounds will be distributed to the other compartments depending on the characteristics of the substances and the environment. Harmonisation in this context means that the environmental quality standard for one compartment should offer adequate protection for organisms in another compartment after distribution of the substance. From this perspective, quality standards for soil were derived on the basis of experimental data, and compared with soil standards that were calculated from aquatic ecotoxicity data using information on sorption by means of equilibrium partitioning (see ERL Report 09), and the lowest value was usually taken forward. Similarly, for volatile substances, risk limits for water, sediment and soil were harmonised with risk limits for air based on human inhalation toxicity [13].

Harmonisation between compartments was seen as a primary aim of standard setting, as can be seen from the name that was given to the process of formalisation of environmental quality standards: 'Integrated Standard Setting for Substances', indicated in Dutch as *Integrale Normstelling Stoffen* (INS). Under the flag of INS, environmental quality standards have been developed and published for several hundreds of substances (see e.g. [15,16]). In practice, the concept of harmonisation has been primarily applied to convert standards between water and soil (vice versa), and to derive quality standards in case experimental data were absent (e.g. for soil and sediment). To date, the latter use of equilibrium partitioning is still applied, but the harmonisation of standards was abandoned in 2004 when the decision was made to follow the European developments [17].

Another aspect of integrating standards has been the inclusion of secondary poisoning in the final standard for soil or water. In 1994, RIVM published proposals for quality standards for water and soil that included the potential risks for birds and mammals due to consumption of water and/or soil organisms [18], based on the work of Romijn et al. [19,20]. Using this method, critical toxicity data for birds and mammals were back-calculated to safe concentrations in prey based on assumptions on daily food intake. The concentrations in prey were in turn recalculated into corresponding MPCs in water and/or soil using information on bioconcentration and bioaccumulation. One of the discussion points was whether or not these back-calculated MPC-values should be added to the dataset for direct ecotoxicity, leading to one MPC that covered both aspects, or that both types of MPC should be kept separated and the lowest one chosen as the final value. Where originally the datasets were kept separated [18], the approach of a combined dataset was chosen later on [11,13,21].

2.5 International developments: consequences for methodology

In 2003, a revision of the Technical Guidance Document (TGD) in support of the European evaluation of new[3] and existing substances[4] and biocides[5] was published [22-24]. Partly parallel to the revision of the TGD, initial methods were published in 2002 and 2005 for deriving water quality standards in the context of the European Water Framework Directive (WFD[6]) [25,26]. Where on the one hand harmonisation among member states was achieved by issuing European guidance documents, the development of framework specific guidance led to a compartment specific approach in which the Dutch principle of harmonisation of standards between water, sediment and soil was no longer appropriate from a policy point of view. In 2004, the responsible Ministries decided that internationally derived standards such as the Predicted No Effect Concentrations (PNECs) for new and existing substances, or water quality standards as derived under the WFD, would be the starting point for national quality standards. In case such standards were not available, the European methodology should be followed. It was explicitly stated that harmonisation between compartments was no longer performed, although this would be promoted among member states [17].

As a consequence, the process of standard setting was renamed to '(Inter)national Standard Setting for Substances' [17], but the terminology of MPC and NC was maintained. The definitions of MPC and NC were adapted from the 1989-version, i.e. the 95% protection level for species in ecosystems was again explicitly mentioned. Although the methodology of the TGD and WFD was in line with the approaches of the Netherlands to a large extent, adopting this guidance resulted in some major changes:

- equilibrium partitioning was only applied as a surrogate when no or not enough experimental ecotoxicity data were available to derive standards instead of using it as a default approach for harmonisation between water, sediment and/or soil,
- SSDs were only used in case of rather extensive datasets of at least 10 endpoints for at least eight different taxonomic groups, instead of the usual four values,

[3] Commission Directive 93/67/EEC on Risk Assessment for new notified substances
[4] Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances
[5] Directive 98/9/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market
[6] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

- secondary poisoning was assessed separately from direct ecotoxicity instead of integrated into one dataset,
- indirect exposure of humans was introduced as a third exposure route, next to direct ecotoxicity and secondary poisoning,
- in some cases, ecotoxicity data on microbial or enzymatic processes (functional endpoints) and data relating to effects on species or populations (structural endpoints) were combined into one dataset, instead of deriving separate risk limits for processes and species, respectively.

As a result of the decision to use the TGD and to implement the WFD guidance, an updated guidance document for the derivation of environmental risk limits was published in 2007 [1]. Although the concept of quantitative harmonisation between compartments was abandoned, the methodology for the respective compartments was harmonised as much as possible. An example of this was the choice to adopt the cancer risk level of 10^{-6} on a life-time basis as proposed under the WFD also for the derivation of MPC-values for soil and air (see section 4.5 for further information on this topic). In this way, the 2007-guidance combined the European methodology with national guidance for those aspects that were not addressed in the international guidance documents.

2.6 Developments since 2007

With the implementation of REACH, the European legislation for new and existing substances became obsolete and for compounds falling under REACH the TGD was replaced by REACH guidance documents in 2008. A similar process has led to separate technical guidance documents for biocides. In addition, a new European technical guidance document for the derivation of water quality standards under the Water Framework Directive was published in 2011 [2], and guidance documents for the risk assessment of plant protection products have been updated [27,28].

Although largely building on previous guidance, these updated guidance documents also include new scientific developments. One prominent example is the viewpoint that water quality standards derived on the basis of laboratory ecotoxicity tests represent dissolved concentrations instead of total concentrations, another is the inclusion of more sophisticated methods to address bioavailability in the context of standard setting. More importantly, the current situation illustrates the ongoing tendency that guidance development is primarily taking place within the respective European regulatory frameworks. These frameworks deal with specific compartments (e.g. WFD and European air quality directive) or consider all compartment within the context of a particular use (e.g. industrial chemicals under REACH, biocides and plant protection products under the respective regulations). Frameworks differ with respect to their policy aims, definition of protection goals, conceptual approaches, dossier requirements and/or timeframes for implementing scientific developments. Although harmonisation between frameworks is certainly an issue in Europe, the current situation is that substance and compartment specific guidance differs between regulatory frameworks.

As a consequence of the above described developments in Europe, an update of the 2007-guidance was needed which resulted in the present series of documents. This updated guidance reflects the technical changes in methodology, but also follows the European tendency towards a compartment and framework specific approach. In general, harmonisation between methodologies is sought for as much as possible. The national derivation of risk limits for water is fully compatible with the European methodology under the WFD, which has led for example to a more stringent risk level for genotoxic carcinogens, see section 4.5. For those aspects that are not (fully) addressed in the WFD-guidance, methods developed in other frameworks are inserted into the Dutch guidance, e.g. concerning the use of SSDs and mesocosms, and the implementation of secondary poisoning (see ERL Report 03; ERL Report 07).

It should also be noted that while a harmonised European policy exists for water and to some extent for air, the environmental policy regarding soils and sediments is fully member state specific. As a result, the terminology used for water follows the European guidance and differs from that for the other compartments (see further 3.1). However, although water quality policy has a strong European component, national policy aims may require additional risk limits that are used for specific purposes on a national scale. This is for instance the case for the NC, which may still play a role as a long-term policy goal and was used for e.g. deciding on the need to regulate substances in national legislation under the WFD [29,30]. Other formerly used national risk limits, such as the SRC, are no longer used for water, but derivation may still be necessary to derive equivalent risk limits for groundwater or for soil using equilibrium partitioning (see ERL Report 09). A full overview of relevant risk limits per compartment is given in section 3.2.

The national policy towards environmental management is subject to review. In the near future, hundreds of individual pieces of Dutch legislation will be brought together into one over-arching regulatory framework aiming at an integrated approach towards the management and use of the environment. This system review will also cover standards for the quality of the natural environment; this may potentially change the way national environmental risk limits will be implemented in policy decisions [31].

2.7 Procedural aspects

The formal procedure for standard setting in the Netherlands has been updated in 2013 to reflect the latest developments regarding organisational and policy aspects. In short, the procedure has the following steps:

1. Start of the procedure: the Ministry of Infrastructure and the Environment (IenM) commissions RIVM to derive risk limits, or a private party asks for a proposal to be considered
2. Derivation of risk limits according to the guidance document(s)
3. Review of the proposal by the Scientific Advisory Group on standard setting: scientific peer review by experts from

academia, research institutes and stakeholders regarding underlying data and methodology
4. Finalizing and publication of the scientific report taking account of the conclusions of the peer review
5. Policy advice by the Working Group on standard setting: consideration of e.g. socio-economic aspects and (inter)national developments by the responsible Ministries
6. Formal approval of the standards by the Steering Committee on standard setting.
7. Publication of the standards at the website 'Risico's van stoffen', which is the official website for information on standards for substances in the Netherlands[7]

The full procedure (in Dutch) is published on the website Risico's van Stoffen. Note that this procedure refers to water and air only, a separate policy process exists for soil, sediment and groundwater.

[7] http://www.rivm.nl/rvs/

3 Routes of exposure and terminology

3.1 Risk limits or quality standards

In the Netherlands, there has always been a clear distinction between scientifically based advisory values, indicated as environmental *risk limits*, and the final regulatory values, indicated as environmental *quality standards*. According to the procedures laid down in 2004, standards are set by the responsible Ministries primarily on the basis of a scientific advice, but other (socio-economic) aspects may be taken into account as well. It may happen that the final standard deviates from the scientifically based risk limit. Therefore, the national guidance documents and reports based thereon refer as much as possible to the derivation of risk limits, the word *standard* is preferably not used to avoid the suggestion that this policy step has already been taken. However, for water special considerations are made, see below.

3.1.1 Special considerations for water

As indicated in the previous chapter, the MPC (*MTR* in Dutch) has since long been used in environmental quality policy. With the implementation of the Water Framework Directive (WFD), new quality standards were introduced to cover both long- and short-term effects resulting from exposure:

- a long-term standard, indicated as the annual average environmental quality standard (AA-EQS) and normally based on chronic toxicity data, and
- a short-term standard, referred to as a maximum acceptable concentration EQS (MAC-EQS) which is based on acute toxicity data.
- a standard for the protection of surface water intended for drinking water abstraction ($QS_{dw, hh}$)
- a standard for the protection of sediment ($EQS_{sediment}$)

The terms AA-EQS and MAC-EQS are used in the European priority substances directive 2013/39/EU[8]. The derivation of the $QS_{dw, hh}$ and $EQS_{sediment}$ is discussed in the WFD-guidance [2], but these standards are not set at a European level. In the Netherlands, standards for sediment are not implemented in national legislation under the WFD, but risk limits are used in other legal frameworks e.g. local risk assessment, remediation policy and evaluation of re-use of dredged materials (see ERL Report 04). Standards for surface water intended for drinking water abstraction are included in national legislation as far as they concern the implementation of the former and existing European Directives 75/440/EEC and 98/83/EC, respectively.

Although in the 2007-guidance the methodology of the WFD was adopted, the terminology of EQS was not taken over, for the reason described above: using these abbreviations might suggest that the values presented in scientific reports had already been approved as

[8] Richtlijn 2013/39/EU van het Europees Parlement en de Raad van 12 augustus 2013 tot wijziging van Richtlijn 2000/60/EG en Richtlijn 2008/105/EG wat betreft prioritaire stoffen op het gebied van het waterbeleid.

official standards. For this reason the terms MPC_{water} and MAC_{eco} were used in the 2007-guidance. However, due to the literal translation of MPC into the Dutch equivalent MTR, it was not clear for the audience (stakeholders) that the resulting risk limits differed from the 'old' ones regarding methodology, and people interpreted the values as not being derived according to the WFD-methodology. As a result, it was also not clear that compliance check had to be performed according to the WFD-methodology, i.e. using the annual average and peak concentration, respectively, instead of the 90^{th} percentile that had been previously used for comparison of monitoring data with the regulatory standard.

To overcome this confusion, it was decided for water to follow the terminology of the WFD-guidance and refer to EQS instead of MPC. Still, the values that are derived based on the present guidance should be interpreted as being risk limits, in a sense that they are scientific advisory values that will be used as a basis for standard setting. A similar situation exists for the risk limits derived by experts during the European process of setting EQS for priority (hazardous) subtances under the WFD. For sediment, the term MPC is maintained. The status of the results should be made clear when publishing reports in which risk limits are derived.

3.2 Nomenclature

The following abbreviations are used for the respective risk limits and quality standards:

MPC =	Maximum Permissible Concentration (see 2.2)
NC =	Negligible Concentration (see 2.2)
SRC =	Serious Risk Concentration (see 2.3)
EQS =	Environmental Quality Standard, terminology used under the WFD (see 3.1.1)
AA-EQS =	Annual Average EQS (see 3.1.1)
MAC-EQS =	Maximum Acceptable Concentration EQS (see 3.1.1)
QS =	Quality Standard that is not reflected in the final generic standard for surface water

Each type of risk limit is indicated by the main abbreviation given above, followed by a subscript that indicates the compartment and exposure route considered. The abbreviations used are listed below:

air	= air
biota	= fish eaten by humans / predators
dw	= intended for drinking water abstraction
eco	= direct ecotoxicity for organisms
fw	= freshwater
grw	= groundwater
hh	= human health
hh food	= indirect exposure of humans via food
secpois	= secondary poisoning of predatory birds / mammals
sediment	= sediment
soil	= soil
sw	= saltwater
water	= fresh and saltwater

For example, the MPC for air based on human exposure is indicated as $MPC_{air, hh}$, the MPC for groundwater based on ecotoxicity is indicated as $MPC_{grw, eco}$, the Quality Standard for surface water intended for drinking water abstraction is indicated as $QS_{dw, hh}$. For further information, the reader is referred to the respective chapters of the guidance.

3.3 Risk limits and exposure routes considered

The aim of environmental policy is that humans and ecosystems are protected against adverse effects (see section 2). Environmental quality standards therefore consider direct and indirect exposure of both humans (where relevant) and organisms in an ecosystem. This, however, does not apply to the SRC (see 2.3) and the MAC-EQS (see 3.1.1), which refer to direct ecotoxicity only. When deriving the MPC for groundwater, effects on groundwater organisms are taken into account, but also the use for drinking water abstraction. For the $AA\text{-}EQS_{water}$, ecotoxicity to water organisms is evaluated and fish consumption by humans and predatory birds and mammals is taken into account when relevant in view of the characteristics of the compound. For soil, human health aspects are integrated at the level of the Intervention values (see 2.3), but for the purpose of this guidance, we also present a method to derive an MPC that includes exposure of predatory birds and mammals that feed on earthworms; exposure of humans by consumption of vegetables, and milk and meat from cattle that may have been exposed due to feeding on grass from contaminated soil are taken into account in specific cases. For sediment, however, only direct exposure of sediment organisms is considered, because direct contact of humans with sediment is not considered critical for risk limit derivation. For air, the opposite is true: although in some cases plants have been shown to be sensitive towards volatile compounds, in the majority of cases information on ecosystem effects will be lacking and the risk limits for air will be based mainly on human inhalation toxicity.

Table 1 summarises the risk limits and exposure routes that are considered for each compartment.

*Table 1 Types of risk limits and exposure routes considered for the respective compartments. Compartments/routes indicated with * are subject to trigger values: derivation of risk limits depends on the characteristics of the compound.*

Compartment	Name of risk limit	Route considered
Air	MPC NC	– humans via inhalation – ecosystem: plants
Soil	MPC NC	– humans via consumption of vegetables, meat, milk* – predatory birds / mammals via earthworms* – soil organisms
	SRC	– soil organisms
Groundwater	MPC NC	– humans via drinking water – groundwater organisms
	SRC	– groundwater organisms
Sediment	MPC NC SRC	– sediment organisms
Water	AA-EQS NC	– humans via fish consumption* – predatory birds / mammals via fish* – water organisms
	MAC-EQS SRC	– water organisms
	$QS_{dw, hh}$	– humans via drinking water

4 General approaches

4.1 Assessment factor approach

According to the principles of the TGD, REACH and WFD-guidance, risk limits are initially derived on the basis of standard laboratory tests, by applying an assessment factor (AF) to the lowest credible endpoint. The AF is applied to account for the uncertainty relating to the translation of laboratory data to the field situation, e.g. the variation within and between laboratories, the variation within and between species, and the translation of acute endpoints to long-term exposure. This method is indicated as the deterministic or AF-approach. Different AF-schemes are applied for the respective risk limits (e.g. MPC, EQS, SRC_{eco}), accounting for the different time frame and protection level aimed at. The AF depends on the number and type of data available, lower assessment factors may be used when more data on additional taxonomic groups and/or long-term studies are available. For example, for derivation of a chronic risk limit, an AF of 1000 is applied to a single acute endpoint, while the AF may be reduced to 10 when long-term toxicity data are available from three species across three trophic levels. Useful lines of evidence that may be used to inform the extrapolation (and possibly influence the size of AF applied) include mode of action data, effects data from the field, and background concentration data for naturally occurring substances [2]. Moreover, data on the toxicity to other organisms than the standard species, representing as such different trophic levels, taxonomic groups, traits or feeding strategies broaden the knowledge on the substance to be assessed and may justify reduction of the AF. If enough data are available, statistical methods can be applied.

4.2 Statistical extrapolation

As indicated in section 2.2, Species Sensitivity Distributions (SSD) have since long been used for standard setting in the Netherlands. For this statistical method, the reliable toxicity data per species are ranked and a model is fitted. From this, the concentration that protects a certain proportion of species (typically 95%) can be estimated (the HC5). For the construction of SSDs, the computer program ETX 2.0 [32] can be applied, but other programs may be used as well. Following international agreements, the data requirements for applying the SSD-method to aquatic data have been extended to at least 10 endpoints for individual species from at least eight different taxonomic groups. Although not explicitly stated in the TGD and REACH guidance, this requirement is also considered for soil. As a consequence, the application of SSDs for standard setting is limited to relatively data-rich substances. When the criteria are met and an SSD can be constructed, the HC5 based on chronic NOEC or L(E)C10-values is used for derivation of the MPC and/or AA-EQS. The HC5 based on acute studies may be used for derivation of the MAC-EQS. For derivation of the SRC for soil or water, the HC50-level is used (see 2.3).

In case of substances with a specific mode of action (e.g. plant protection products), constructing an SSD for the specifically sensitive species group may be considered when enough data are available. SSD-models explicitly account for differences in sensitivity between species, but a further AF is applied to the HC5 arising from model extrapolation to account for 'residual' uncertainties that are not accounted for by the SSD model. If the conditions to use the SSD-method for the derivation of quality standards are met, it should always be used. However, risk limits should also be derived using the AF method, and, where valid data exist, also using model ecosystems (see 4.3).

4.3 Semi-field or field data

In some cases, information from semi-field experiments or field monitoring data may be present. The majority of semi-field experiments involves aquatic micro- or mesocosm studies into the effects of pesticides on freshwater communities, although some examples are present of other substance groups and/or ecosystem types (e.g. metals, saltwater applications). Extensive guidance is available for designing and performing aquatic semi-field experiments, and for evaluation and interpretation of results [28,33-36]. The endpoints from a valid and relevant micro- or mesocosm study may be used with an AF to derive a water quality standard, or to underpin the AF used in the deterministic- or SSD-approach. For the terrestrial compartment, the use of model ecosystems has been promoted (see e.g. [37]), but application and use in standard setting is limited to date. Field monitoring data are generally not used directly for standard setting, but may be used in some cases for justification of the AF.

4.4 Data for species and processes

As indicated in section 2.5, the treatment of structural and functional endpoints was changed to some extent with the introduction of the TGD [22-24]. Previously, both types of data had been kept separated, resulting in two risk limits of which the lowest was taken forward as final value. In the TGD and REACH, microbial tests (e.g. nitrification or respiration), or enzymatic processes (e.g. urease activity) are considered to represent an additional trophic level next to plants, arthropods, and earthworms when using the AF-approach. However, it can be argued that data on species and processes cannot be combined into one SSD because they are not a random sample from the same normal distribution of species. Separate SSDs are thus constructed for species and processes, provided that the requirements with respect to the number of data points are met. An exception is when a functional endpoint is derived for isolated strains of bacteria or fungi, e.g. when respiration of *Pseudomonas putida* is measured. In that case, the test result can be treated as a single species endpoint and added to the dataset for species. Generally the lowest value for either species or process will be selected as the final risk limit. However, this choice should be made on a case-by-case basis, especially when different methods are applied. When enough data are available to apply statistical extrapolation for species, but not for processes, there is a chance that a single low value for processes overrules a large quantity of data on species. This may be a reason not to choose the lowest value (see e.g. risk limit derivation for fluoranthene in [38]).

4.5 Risk levels for genotoxic carcinogens

The MPC for genotoxic carcinogens has been set to the concentration in the environment at which an increased probability of death of 10^{-6} per year exists. This is equivalent to 10^{-4} on a life-time basis. The NC was defined as 1% of the MPC, being 10^{-8} per year or 10^{-6} on a life-time basis [4-6,15-17]. These risk limits are derived by means of the so-called quantitative cancer risk assessment-method (QCRA), also indicated as non-threshold extrapolation. For this, the occurrence of tumors in experimental animals (and sometimes in humans) are expressed as a percentage and extrapolated to the above mentioned probability level. Basic assumption of the non-threshold extrapolation is that any increase of the dose, increases the chance to develop cancer. The choice of the acceptable level (10^{-6}, 10^{-5}, 10^{-4}) is a policy decision and differs between frameworks and countries. The use of QCRA is subject of scientific debate. Under REACH, genotoxic carcinogens may be evaluated using the non-threshold approach, but a threshold approach using a Tolerable Daily Intake (TDI) is also allowed provided that sufficiently high safety factors are applied. When a non-threshold approach is used, it is recommended to use a life-time risk level of 10^{-6} for the general public [39]. The same risk level is used for derivation of the QS for human exposure via fish under the WFD [2]. Apparently, the acceptable level for humans under REACH and WFD is more stringent than the level of the MPC in the Netherlands and is in fact similar to the level of the NC. At the same time, the derivation of the QS for direct ecotoxicity under the WFD is comparable to the former MPC.

4.6 Derivation of the Serious Risk Concentration (SRC)

As indicated in section 2.3 and Table 1, the SRC in this guidance only refers to effects on ecosystems. For this, direct effects on organisms and indirect effects on predatory birds and mammals are taken into account. For derivation of the SRC_{eco} both acute and chronic toxicity data should be tabulated. In general, the SRC_{eco} is the geometric mean of all available chronic toxicity data. This can be calculated by hand, but when the SRC_{eco} is to be reported with confidence limits, the computer program ETX 2.0 [32] is used to calculate the median HC50 and its 90% confidence interval. The HC50 is equal to the geometric mean of log-normally distributed toxicity data. When no or few chronic data are available, a comparison is made with the geometric mean of acute toxicity data. In principle, an acute-to-chronic ratio (ACR) of 10 is applied to the acute toxicity data to compare acute L(E)C50s with chronic NOECs (or EC10s). If enough information on the ACR for the specific compound or endpoint is available, deviation of this factor of 10 may be possible on a case-by-case basis, but should be fully justified [40].

The SRC_{eco} is always taken as the geometric mean of (either acute or chronic) toxicity data, irrespective of whether these data are log-normally distributed or not. If the data from which the SRC_{eco} is calculated do not fit a log-normal distribution, it suffices to note this briefly in the report section where the SRC_{eco} derivation is presented. The factors and conditions used for deriving SRC_{eco} are shown in more detail in the guidance for the respective compartments.

For compounds that accumulate in the food chain, the SRC is also calculated on the basis of secondary poisoning. More information is given in ERL Report 07.

4.7 Derivation of the Negligible Concentration (NC)

In the 2007-guidance, it was stated that it is unclear whether ecotoxicological as well as human-toxicological endpoints should be taken into account for the derivation of the NC. Probably the confusion was raised because in a policy document of 1998, reference was made to the MPC in the context of effects on humans, and to the NC in the context of effects on 'the environment' [41]. In the 2001-guidance, the NC was only mentioned in the context of ecotoxicological data [13]. This can be explained by the fact that effects on humans were not taken into account in the derivation of environmental risk limits at that time, but were integrated at a later stage in the process when harmonising risk limits for volatile substances and/or deriving Intervention values for soil [13].

However, from the first policy documents from 1985 and 1989 [4,6] it is clear that the NC was developed first for human health, and later on also adopted for the ecosystem. This is confirmed by the definitions of MPC and NC [15-17], where the protection of human and ecosystem health is mentioned in one sentence. Therefore, the NC is derived as 1/100 of the MPC or AA-EQS, irrespective whether this value is derived on the basis of direct ecotoxicity, secondary poisoning or consumption of food by humans. There is one exception to this rule: if the AA-EQS for water is based on human exposure via fish, and the human toxicological risk limit is based on an added cancer risk level of 1 per 10^6 on a life-time basis, the NC is not derived, since in that case the AA-EQS already meets the risk level represented by the NC (see 4.5)
Further guidance on the derivation of the SRC and NC can be found in the respective chapters. Specific guidance on metals will be developed in due time.

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List of abbreviations

AA-EQS	annual average environmental quality standard
ACR	acute-to-chronic ratio
ADI	acceptable daily intake
AF	assessment factor
EC	effect concentration
EQS	environmental quality standard
ERL	environmental risk limit
HC5	hazardous concentration for 5% of the species
HC50	hazardous concentration for 50% of the species
IenM	Dutch Ministry of Infrastructure and the Environment
INS	Integrale/Internationale Normstelling Stoffen
LC	lethal concentration
MAC-EQS	maximum acceptable concentration EQS
MPC	maximum permissible concentration
MTR	maximaal toelaatbaar risiconiveau
NC	negligible concentration
NOEC	no observed effect concentration
PNEC	predicted no effect concentration
QCRA	quantitative cancer risk assessment-method
QS	quality standard
REACH	Registration, Evaluation and Authorisation of Chemicals
RIVM	Rijksinstituut voor Volksgezondheid en Milieu
SSD	species sensitivity distribution
SRC	serious risk concentration
TDI	tolerable daily intake
TGD	technical guidance document
VR	verwaarloosbaar risiconiveau (=negligible concentration)
WFD	Water Framework Directive