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

Guidance for the derivation of environmental risk limits

Part 6. Risk limits for air

version 1.0

Colophon

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1 Introduction

1.1 Focus and risk limits considered

Risk limits for air are used as a basis for setting environmental quality standards for the protection of the general public and ecosystems that are exposed via outdoor air. The focus is not on deriving limit values for specific situations, e.g. worker exposure or indoor air quality. The following risk limits are derived:

- the Maximum Permissible Concentration (MPC_{air}), in Dutch designated as *Maximaal Toelaatbaar Risiconiveau (MTR)*, and
- the Negligible Concentration (NC_{air}), *Verwaarloosbaar Risiconiveau (VR)* in Dutch.

The MPC is defined in VROM [1,2] as the standard based on scientific data which indicates the concentration in an environmental compartment for which:

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 death of 10^{-6} per year can be calculated (for carcinogenic substances).

Note that “carcinogenic substances” means genotoxic carcinogens for which the risk values are derived by means of quantitative cancer risk assessment (QCRA), also indicated as non-threshold extrapolation.
The NC is defined as MPC/100. The factor of 100 is applied to account for combination toxicity.

1.2 Routes considered

Most risk limits will be derived on the basis of human toxicological data from inhalation studies, since for chemical substances only few ecotoxicity data for plants or animals are available that focus on exposure via air. However, if such data are available, they can be included. Two routes are considered for risk limit derivation:

- exposure of humans via inhalation;
- exposure of terrestrial animals and/or plants via air.

2 Derivation of risk limits

2.1 $MPC_{air, hh}$ - human toxicological risk limit for air

Human exposure via air is covered via the Tolerable Concentration in Air (TCA) or the inhalatory Cancer Risk ($CR_{inhalation}$) for genotoxic carcinogens. These are existing standards ($\mu g/m^3$) aimed at protection of humans from deleterious effects after continuous, lifetime exposure via air. If an established TCA or $CR_{inhalation}$ is not available for the substance investigated, the databases mentioned in ERL Report 02, may be searched for risk limits in air that can be used for this purpose. In principle, the RfC (reference concentration), derived by the US governmental organisations can be considered useful. These are included in the ITER-database (available via TOXNET, http://toxnet.nlm.nih.gov/), which includes risk estimates of the US EPA Integrated Risk Information System (IRIS), the US Agency for Toxic Substances and Disease Registry (ATSDR), Health Canada and the International Programme on Chemical Safety (IPCS) of the World Health Organization (WHO).

In most instances, the RfCs are developed for non-carcinogenic effects of substances, but may also be used for carcinogens which are non-genotoxic. For genotoxic carcinogens, the cancer risk values of IRIS may be used, considering the appropriate risk level. If a $CR_{inhalation}$ is not presented, the oral slope factor presented in IRIS may be used to estimate the $CR_{inhalation}$. In any case an expert in human toxicology should be consulted to verify the usefulness of the retrieved risk limit(s).

2.2 $MPC_{air, eco}$ – ecotoxicity via air

With respect to the ecotoxicological assessment, it is noted that the former EU TGD [3-5] and REACH guidance [6] do not give guidance for derivation of ecotoxicological risk limits such as a Predicted No Effect Concentration (PNEC) for chemicals based on exposure of terrestrial species via air. As a general approach, it is assumed that the standards for exposure of humans will be protective for the ecosystem as well, unless experimental data indicate otherwise. Some considerations on this aspect are included below.

2.2.1 Birds and mammals

Since experimental data on terrestrial mammals are used as a basis of the human-toxicological assessment, and additional safety factors are applied for the translation of (no) effect levels from mammals to humans, the assumption that the human-toxicological standard will be protective for mammals is justified. In general, the risks for birds are considered to be covered by mammals, although it is recognized that for inhalation toxicity this has not been proven due to the absence of data for birds. For the time being, in line with the other exposure routes, it is assumed that the human toxicological risk limits also cover the potential effects on birds.

2.2.2 *Other organisms*

For other organisms that may be exposed directly but are not considered for the derivation of human toxicological risk limits it is not clear if protection is ensured. No data are available for arthropods. For terrestrial plants, there are examples of species being affected at concentrations below human toxicological risk limits. For tetrachloroethylene, a PNEC for air based on plant studies of 8.2 µg/m^3 was derived in the European risk assessment in the context of the former existing substances Regulation 793/93/EC [7]. Based on the same dataset, De Jong et al. [8] derived an MPC for air of 9.2 µg/m^3. These values are considerably lower than the WHO Air Quality Guideline of 250 µg/m^3 which is based on human toxicological data. Ethene is another example of a compound for which terrestrial plants are sensitive [9]. There are also examples for pesticides for which plants are particularly sensitive, e.g. [10]. Another example of potentially relevant species are lichens, which are sometimes used as indicators for air pollution.

2.2.3 *Equilibrium partitioning*

De Jong et al. [8] also explored the derivation of risk limits for air by using equilibrium partitioning (EqP) from aquatic ecotoxicity data. Equilibrium partitioning is used as a tool for derivation of risk limits for soil or sediment from aquatic data, when toxicity data on terrestrial (or sediment) species are absent or insufficient. Applying EqP to convert aquatic data to soil can be justified because it is assumed that the exposure of soil inhabiting organisms also occurs via the water phase, i.e. the pore water fraction. This is not the case for organisms exposed via air and using equilibrium partitioning in fact introduces a kind of route-to-route extrapolation which is currently not validated. Therefore, an MPC for ecotoxicity via air is considered only when data obtained from tests with direct exposure via air are available.

2.2.4 *Assessment scheme for terrestrial plants*

In view of the above, this guidance only considers data for terrestrial plants for the derivation of ecotoxicological risk limits for air. If data on other organisms are available, they should be considered on a case-by-case basis. De Jong et al. [8] applied assessment factors (AF) similar to those used for other compartments, i.e. an AF of 1000 was applied on a short-term EC50. For the aquatic compartment, this factor is used if the base set (algae, *Daphnia*, fish) is complete. Experimental data for air, if available, will most likely be restricted to plants, and there is no conceptual framework to describe the “air ecosystem”. Therefore, additional factors to extrapolate to taxonomic groups other than plants are not included in the assessment scheme, but data can be used (see below). This is comparable to the strategy followed for terrestrial vertebrates.

For terrestrial plants the lowest endpoint per species is selected. If for a single species multiple comparable toxicity values are available for the same endpoint, the geometric mean is taken. Depending on the number of data, an assessment factor is applied to the lowest endpoint. According to the TGD, Species Sensitivity Distributions (SSD) may be applied to derive a PNEC for the ecosystem if chronic data are available that cover a wide range of species, including mono- and dicotyledons. In

this case, only plant data are considered to derive an MPC for the air compartment. If there are chronic data for at least 10 different plant species, an SSD can be applied. The assessment scheme is presented in Table 1.

Table 1 Assessment scheme for derivation of the $MPC_{air, eco}$ based on plant data.

Available data	**Assessment factor**
At least one short-term L(E)C50 for plants	1000
One long-term NOEC for plants	100
Two long-term NOECs for plants	50
Long-term NOECs for at least three plant species	10
Species sensitivity distribution (SSD) method (≥ 10 NOEC)	5-1 (to be fully justified case by case)
Field data or model ecosystems	Reviewed on a case by case basis

In the rare case experimental data on other taxa are available, these can be used as replacement for a plant NOEC (No Observed Effect Concentration), provided that also at least one plant NOEC is present in the dataset. A risk limit for air will not be derived solely on the basis of acute data for other species than plants.

2.3 Selection of the final MPC for the air compartment

The following MPC_{air} values can potentially be derived:
$MPC_{air, eco}$ which is the MPC_{air} based on ecotoxicological data;
$MPC_{air, hh}$, which is the MPC_{air} based on chronic inhalation.

The final value for the MPC_{air} is the lowest of the available MPC values.

2.4 Derivation of the NC for the air compartment

The NC_{air} is derived by dividing the MPC_{air} by a factor of 100.

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Appendix 1. 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 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