National Institute
for Public Health
and the Environment

Letter report 601714012/2009
C.E. Smit

Maximum Acceptable Concentrations within the context of the Water Framework Directive

An initial evaluation

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RIVM Letter report 601714012/2009

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This investigation has been performed by order and for the account of Directorate-General for Environmental Protection, Sustainable Production Directorate (DP), within the framework of the project “Standard setting for other relevant substances within the WFD”

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Abstract

Maximum Acceptable Concentrations within the context of the Water Framework Directive - An initial evaluation

During the past two years, RIVM has derived environmental risk limits for a great number of compounds. These values are used as a basis to set Environmental Quality Standards (EQSs) as demanded in the Water Framework Directive (WFD).

The WFD distinguishes between two types of EQS: the Annual Average (AA-EQS) to protect against effects from prolonged exposure and the Maximum Acceptable Concentration (MAC-EQS) to protect against effects resulting from short term concentration peaks.

For ten compounds, the MAC-values were lower than the AA-EQS. The AA-EQS is based on chronic toxicity studies, which generally focus on more sensitive endpoints than acute toxicity test. It is assumed that the MAC-EQS cannot be lower than AA-EQS, because the latter is also protective for acute effects. It was therefore proposed to set the MAC-EQS equal to the AA-EQS.

RIVM was requested to present background information on these cases to be able to underpin future policy decisions. This report gives a further analysis of the derivation of the risk limits, aiming at identifying those factors that were important for each specific case. Furthermore, the methods for derivation of a MAC-EQS are compared for an initial evaluation of the robustness of the methods.

For eight compounds, it is advised to set the MAC-EQS equal to the AA-EQS, based on the scientific assessment as presented in this report. For two compounds, a revision may be considered anticipating on the new European EQS-guidance. The comparison of methods for MAC-derivation does not indicate that the assessment factor scheme should be revised.

Trefwoorden / Key words:
MAC-EQS, AA-EQS, environmental quality standards, WFD

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Rapport in het kort

Maximaal Aanvaardbare Concentraties volgens de Kaderrichtlijn Water – een eerste evaluatie

In de afgelopen twee jaar heeft het RIVM voor een groot aantal stoffen milieurisicogrenzen afgeleid. Deze waarden worden gebruikt als basis voor de Milieukwaliteitsnormen (MKN) zoals vereist in de Kaderrichtlijn Water (KRW).

De KRW onderscheidt twee soorten milieukwaliteitsnormen: de jaargemiddelde milieukwaliteitsnorm (JG-MKN), die bescherming moet bieden tegen effecten van langdurige blootstelling en de Maximaal Aanvaardbare Concentratie (MAC-MKN), gericht op kortdurende concentratie pieken.

Voor tien stoffen waren de voorgestelde MAC-waarden lager dan de JG-MKN. De JG-MKN is gebaseerd op chronische studies, die zich over het algemeen richten op gevoeliger eindpunten dan acute testen. Daarom is de aanname dat de MAC-MKN niet lager kan zijn dan de JG-MKN, de laatste is immers ook beschermend is voor acute effecten. In voorkomende gevallen is daarom voorgesteld de MAC-MKN gelijk te stellen aan de JG-MKN.

De opdrachtgever heeft gevraagd om een nadere analyse van deze normafleidingen. Dit om toekomstige beleidsbeslissingen rond het vaststellen van de uiteindelijke milieukwaliteitsnormen beter te kunnen onderbouwen. Daarnaast zijn de verschillende methoden voor de afleiding van de MAC-MKN vergeleken.

Voor acht stoffen blijft het advies om de MAC-MKN gelijk te stellen aan de JG-MKN. Dit rapport geeft hiervoor de technisch-wetenschappelijke onderbouwing. Voor twee stoffen kan, vooruitlopend op de aanpassing van de methodiek in Europees verband, een herziening worden overwogen. Er is geen aanleiding om het systeem van veiligheidsfactoren te herzien.

Trefwoorden / Key words:
MAC-MKN, JG-MKN, milieukwaliteitsnormen, KRW

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Preface and disclaimer

The present evaluation was prepared upon request of ir. Jelka Appelman, MSc, project coordinator at the Ministry of Housing, Spatial Planning and the Environment, Sustainable Production Directorate.

The cases that are discussed originate from RIVM-reports that were prepared within the context of the projects “Standard setting for other relevant substances within the WFD” and “International and national Environmental Quality Standards for Substances in the Netherlands” (INS).

The European guidance document on derivation of environmental quality standards within the context of the WFD is currently under revision. The derivation of the MAC is one of the subjects for which the revised guidance may lead to a quantitative change as compared to the current practice. According to the Dutch INS-guidance, a potential for bioaccumulation should be considered in the derivation of the MAC, and may lead to an additional assessment factor of 10. This factor is not considered any more in the new EU draft guidance document, and for the present evaluation it was assumed that this will also become the future practice. Final agreement on the EU guidance is, however, not yet reached. Any conclusions based on the absence or presence of the additional factor for bioaccumulation should therefore be considered as preliminary.

Formally speaking, RIVM itself does not derive Environmental Quality Standards (EQSs). RIVM derives Environmental Risk Limits (ERLs) that are scientifically derived advisory values. The Interdepartmental Steering Committee for Substances uses these values to set the final EQSs. The present analysis was also used in international meetings, where this formal distinction between ERLs and EQSs is not common knowledge. For matters of convenience, the general terminology as used in the WFD-guidance is applied, using “AA-EQS” and “MAC-EQS”, instead of the usual ERL-equivalents MPC_{water} and $MAC_{eco,\ water}$. It should be noted that despite this, the values mentioned in this report do not have the status of an official EQS as meant within the context of INS.

In some cases, this re-evaluation of the ERL-derivation raised discussion points or other issues that were not included in the original reports. Those reports have been discussed in the Scientific Advisory Group INS (WK-INS) and the results have been agreed upon by the members of this group. If on the basis of the present report there is a need to reconsider the original ERL-derivation, the program coordinator for derivation of ERLs at the RIVM should be consulted to maintain traceability and transparency.

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1 Introduction

1.1 Environmental Quality Standards: AA-EQS and MAC-EQS

With the implementation of the Water Framework Directive (WFD), member states of the European Union are required to set standards in order to guarantee a good water quality. The methodology for deriving Environmental Quality Standards (EQS) is described in an international guidance document (Lepper, 2005) and further elaborated by Van Vlaardingen and Verbruggen (2007) within the framework of the project "International and national Environmental Quality Standards for Substances in the Netherlands (INS)".
The WFD distinguishes between two types of EQSs in order to cover both long-term and short-term effects resulting from exposure to a chemical:

(i) an annual average concentration (AA-EQS) to protect against the occurrence of prolonged exposure, and
(ii) a maximum acceptable concentration (MAC-EQS) to protect against effects due to short term concentration peaks.

For priority substances, the average concentration determined in 12 monthly monitoring events should not exceed the AA-EQS. Peak concentrations may not result in annual average concentrations that are higher than the AA-EQS, but still may pose a potential risk to the ecosystem. Therefore, peak concentrations should not exceed the MAC-EQS at any occasion.

1.2 Methods to derive the MAC-EQS

The derivation of the AA-EQS is based on chronic toxicity data, the MAC-EQS relies on acute data. The initial derivation is performed by applying assessment factors (AFs) on the lowest NOEC or L/EC50, respectively. For the initial derivation of the MAC-EQS, Lepper (2005) gives the following guidance:

> *As standard method for the derivation of MAC-EQS the TGD provisions on effects assessment for substances with intermittent release may be used (section 3.3.2 of Part II of the TGD [3]). For exposure of short duration only short term effects may need to be considered. An assessment factor of 100 applied to the lowest L(E)C50 of at least 3 short term tests of three trophic levels is normally considered appropriate to derive the MAC-EQS for such situations. However, for substances with a potential to bioaccumulate the lowered assessment factor of 100 may not always be justified. For substances with a known non-specific mode of action interspecies variations may be low and therefore a factor lower than 100 appropriate. Expert judgement and justification of the decision regarding the assessment factor chosen is therefore required. In no case should a factor lower than 10 be applied to a short-term L(E)C50 value.*

This guidance was implemented in the INS-Guidance, resulting in the following assessment scheme (Van Vlaardingen and Verbruggen, 2007):

Table 1. Assessment factors to derive a $MAC_{eco, water}$

Toxicity data	Additional information	Assessment factor
Base set not complete	–	– [a)]
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	Potential to bioaccumulate [b)]	1000
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	Potential to bioaccumulate [b)]; AND known non-specific mode of action and low interspecies variation OR known mode of toxic action and most sensitive species included in data set	100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	No potential to bioaccumulate [c)]	100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, *Daphnia* and algae)	No potential to bioaccumulate [c)]; AND Acute toxicity data for different species do not differ by more than a factor 2 to 3[d)] OR known mode of toxic action and most sensitive species included in data set	10 [e)]

a: When the base set is not complete, a $MAC_{eco, water}$ can not be derived.
b: Potential to bioaccumulate is defined as the substance having an experimental BCF $\geq$ 100 $L.kg_{ww}^{-1}$ or an experimental BMF > 1 $kg_{ww}.kg_{ww}^{-1}$ or, if BCF and BMF are absent, a log $K_{ow} \geq 3$.
c: No potential to bioaccumulate is defined as the substance having an experimental BCF < 100 $L.kg_{ww}^{-1}$ and an experimental BMF $\leq$ 1 $kg_{ww}.kg_{ww}^{-1}$ or, if BCF and BMF are absent, a log $K_{ow} < 3$.
d: This guidance has been added within the INS framework. To assess the span of the acute toxicity data, all reliable acute toxicity data collected are used, with a minimum of three LC50 or EC50 values, for species representing each of the base set trophic levels (algae, *Daphnia*, fish). If the ratio of the highest and lowest L(E)C50 value is $\leq$ 3, an assessment factor of 10 should be applied, otherwise an assessment factor of 100 should be applied.
e: Lowest assessment factor to be applied.

For both the AA-EQS and MAC-EQS, refinements are possible by means of statistical extrapolation (Species Sensitivity Distribution; SSD) and/or by using mesocosm data. SSD and/or mesocosm should not be used independently from the AF-method. A comparison of results is always necessary in order to decide on the final EQS.

1.3 Aim of the present evaluation

1.3.1 Relationship between AA-EQS and MAC-EQS

There is an intuitive assumption that the MAC-EQS should be higher than the AA-EQS, because prolonged exposure generally induces effects at lower concentrations levels than short-term exposure. During the past two years, RIVM derived the equivalents for AA-EQS and MAC-EQS values for about 80 compounds, following the WFD-Guidance of Lepper (2005) as incorporated in the INS-Guidance by Van Vlaardingen and Verbruggen (2007). For ten compounds, the proposed MAC-EQS appeared to be lower than the AA-EQS.
The possibility of a MAC-EQS being lower than an AA-EQS is already indicated in the INS-Guidance. This is the case when the difference in acute and chronic values is smaller than the difference in AFs

(*e.g.* the MAC-EQS is derived from the lowest LC50 of 10 mg/L with AF of 100 = 0.10 mg/L, and the AA-EQS is derived from the lowest NOEC of 5 mg/L with AF 10 = 0.5 mg/L). According to the INS-Guidance, the MAC-EQS should be set equal to the AA-EQS, because it is not expected that acute toxic effects occur at concentrations that protect from chronic exposure.
It was felt necessary by the policy makers to have more background information on the reasons for the low MAC-values. RIVM was requested to investigate the derivation of the MAC-EQS again, aiming at identifying those factors that were important for each specific case.

1.3.2 Comparison of methods for MAC-derivation

The review of MAC-derivations offered also the opportunity to compare the different methods of MAC-derivation, *i.e.* Assessment Factor approach, statistical extrapolation and/or the use of mesocom data. The quantitative comparison of the resulting MAC-EQS-values, gives an impression of the robustness of the methodology.

1.3.3 Special note on terminology

Formally speaking, RIVM itself does not derive Environmental Quality Standards (EQSs). RIVM derives Environmental Risk Limits (ERLs) that are scientifically derived advisory values. The Interdepartmental Steering Committee for Substances uses these values to set the final EQSs. The present analysis was also used in international meetings, where this formal distinction between ERLs and EQSs is not common knowledge. For matters of convenience, the general terminology as used in the WFD-guidance is applied, using “AA-EQS” and “MAC-EQS”, instead of the usual ERL-equivalents MPC_{water} and $MAC_{eco,\ water}$. It should be noted that despite this, the values mentioned in this report do not have the status of an official EQS as meant within the context of INS.

2 Current developments within the EQS-guidance

2.1 Revised guidance for MAC-derivation

The guidance of Lepper (2005) is currently under revision. A draft version of the revised EQS-guidance document was released in December 2008 and circulated for EU member states' comments. A final draft is to be prepared after an expert group meeting in January 2009. Official acceptance of the revised EQS-guidance will require some additional time. As members of the expert group, representatives of RIVM and Waterdienst (Water Service, Ministry of Transport, Public Works and Water Management) contributed to a great deal to the guidance. With respect to the derivation of the MAC-EQS, the draft EQS-Guidance differs from the present INS-Guidance in that the additional AF of 10 for potentially bioaccumulative substances is no longer taken into account. A rationale for this was prepared by RIVM and is presented in the background document to the draft guidance of December 2008[1]. The new proposal for the AF-scheme for MAC-EQS derivation is presented below in Table 2, the accompanying text is copied from the draft EQS-Guidance:

"An assessment factor of 100 is applied to the lowest L(E)C50 where there are at least 3 short term tests using species from three trophic levels is normally considered appropriate to derive the MAC-QS. In this guidance, a distinction between compounds with and without bioaccumulation potential is no longer made (for rationale, see background document). Under some circumstances an AF less than 100 may be justified, e.g.

- *For substances which do not have a specific mode of action (e.g. acting by narcosis only), interspecies variations may be low and therefore a factor lower than 100 may be appropriate.*
- *For substances with a specific mode of action, the most sensitive taxa can be predicted with confidence, and representatives are present in the acute dataset, an AF less than 100 may again be justified.*
- *Where there is a good understanding of the relationship between acute and chronic toxicity (e.g. acute: chronic ratios for a range of species), the AF used to estimate the MAC may be selected to reflect this, or at least to ensure the MAC is not lower than the AA.*

In no case should a factor lower than 10 be applied to a short-term L(E)C50 value."

Table 2. Assessment factors to derive a freshwater MAC-EQS.

Toxicity data	Additional information	Assessment factor
Base set not complete	–	– [a)]
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae)		100
At least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae)	Acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions[b)] OR known mode of toxic action and representative species for most sensitive taxonomic group included in data set	10[c)]

[1]The draft guidance and background documents are available at http://ecb.jrc.ec.europa.eu/eg-eqs/

Notes to Table 2:
a: When the base set is not complete, a MAC-EQS can not be derived.
b: To assess the span of the acute toxicity data, all reliable acute toxicity data collected are used, with a minimum of three LC50 or EC50 values, for species representing each of the base set trophic levels (algae, *Daphnia*, fish). If the standard deviation of the log transformed L(E)C50 values is < 0.5, an assessment factor of 10 could be applied, otherwise an assessment factor of 100 should be applied.
c: Lowest assessment factor to be applied.

2.2 Remarks on assessment factors and acute to chronic ratios

2.2.1 Uncertainties covered by AFs

The AFs of 100 and 10 originate from the TGD assessment scheme for intermittent release (TGD, part II, section 3.3.2; EC, 2003). The TGD states that "*The assessment factor is designed to take account of the uncertainty that exists in extrapolating from the results of short-term laboratory toxicity tests to short-term effects that can be anticipated in the ecosystems*." In fact, the AFs cover several uncertainties: interspecies variation, extrapolation from laboratory to field, and extrapolation from the acute 50% effect level to an acute no- or 10% effect level. In addition, it should be noted that the TGD only refers to short-term effects. Long-term effects resulting from a single peak should, however, also be covered by the MAC-EQS. It is not clearly defined how the different factors contribute to the final AF. It is therefore hard to translate knowledge on different uncertainties into adapted AFs.

2.2.2 Considerations about the use of Acute to Chronic ratios (ACRs)

It may be argued that because the AA-EQS is based on chronic data and the MAC-EQS on acute, the difference between AA-EQS and MAC-EQS should somehow relate to the Acute to Chronic Ratio (ACR; see 3rd bullet above Table 2). When considering ACRs in relation to the derivation of the MAC-EQS, the following should be noted:

- The ACR is the ratio between the 50% effect level from short-term tests and the no effect level from long-term studies. The MAC-EQS, however, relates to a concentration without adverse effects, *i.e.* a NOEC or L/EC10. Therefore, multiplying the AA-EQS with the ACR does not result in the desired level of protection.
- Knowledge about the acute L/EC10 or NOEC might be helpful in decreasing the uncertainty related to the derivation of the MAC. These data are, however, often not presented and information on the steepness of the acute concentration response relationship can only be retrieved when raw effect data are available.
- The ACR relates to acute effects observed in short-term studies. The ACR does not given information on delayed effects of a short concentration peak.
- For compounds with a specific mode of action, ACRs may vary among taxa and even within taxa. Therefore, it is not possible to define *the* ACR for these compounds.
- The ACR only relates to effects on single species, and does not account for the complex interactions that take place at the ecosystem level (*e.g.* indirect effects on Daphnids due to elimination of algae).

3 Case studies: MAC-EQS below AA-EQS

3.1 Derived AA- and MAC-EQS

The MAC-EQS was in all cases derived using the Assessment Factor approach on the acute data. The AF-scheme as presented in Table 1 was used, including an AF to account for bioaccumulative properties, *i.e.* AFs of 1000, 100 or 10 could be applied according to the present INS-Guidance (Van Vlaardingen and Verbruggen, 2007). To determine whether the proposed changes in the assessment scheme lead to different conclusions, the new scheme from the draft EQS-Guidance as presented above in Section 2.1 was also considered.

In Table 3, an overview of the AA-EQS and MAC-EQS is given, the resulting values according to the new scheme are given where different form the original values. The underlying data are given in Appendix 1. A further evaluation of the derivation of the MAC-EQS for the ten individual compounds is given below.

Table 3. Summary of AA- and MAC-EQS values for 10 compounds. All values in µg/L.

Compound	AA-EQS	MAC-EQS[a]	MAC-EQS (new scheme)[b]	Reference
coumaphos	0.0034	0.00074	0.0074	Moermond et al., 2008
tolclophos-methyl	1.2	0.71	7.1	Moermond et al., 2008
monolinuron	0.15	0.1		Scheepmaker and Vonk, 2008
MCAA	0.58	0.48		Vos and Bodar, 2008
kresoxim-methyl	0.63	0.063	0.63	Van Leeuwen and Vonk, 2008
carbendazim	0.60	0.10		Smit and Dang, 2008
captan	0.34	0.034	0.34	Van Vlaardingen and Vonk, 2008
6 PPD	0.48	0.28		Van Vlaardingen et al., 2007
DNOC	9.2	0.66		Van Vlaardingen et al., 2007
aniline	1.5	1.0		Van Vlaardingen et al., 2007

a: with additional AF for potentially bioaccumulative compounds (log K_{ow} > 3 and/or BCF > 100 L/kg)
b: based on the draft EQS-Guidance, no additional AF for bioaccumulation

3.2 Discussion of individual cases

3.2.1 Coumaphos and tolclophos-methyl

The MAC-EQS derived according to the draft new method is higher than the AA-EQS because the AF of 10 for bioaccumulation is no longer applied.

3.2.2 Monolinuron

The MAC-EQS and AA-EQS are based on data for algae. Both EQSs are derived with an AF of 10, but the EC50 is lower than the NOEC. Strictly speaking, the AA-EQS should have been derived putting an AF of 100 on the EC50, leading to a AA-EQS of 0.01 µg/L, but this seems unrealistically low in view of the data. When derived in the same test, a NOEC which is higher than the EC50 is indicative of a large control variation and/or a not properly chosen test concentration range (spacing too large). Due to

the availability of data, the NOEC and EC50 in this case originate from two different experiments. The NOEC is by definition determined by the choice of the test concentrations, and a different concentration range in the NOEC-experiment would have led to different results.
Note that a similar situation occurred for Carassius auratus in the carbendazim dataset (Annex 1, Table A.6), but these values were not key-values for EQS-derivation.
This case illustrates that when data from the same species are key-values for both the AA-EQS and MAC-EQS, the NOEC and EC50 should preferably be obtained from the same study. When for the same species the NOEC is higher than the EC50, data should be thoroughly evaluated, and recalculation of an EC10 may be useful.

3.2.3 MCAA

The MAC-EQS and AA-EQS for MCAA are also based on algae data. The MAC-EQS is derived using an AF of 100 on the EC50 for algae, the AA-EQS by an AF of 10 on the NOEC. The derivation of risk limits is based on the EU-Risk Assessment Report prepared within the context of the Existing Substances Regulation (793/93/EEC). MCAA is used for various purposes, but the salt of MCAA is also known as an active ingredient of herbicides, which is also explicitly mentioned in the derivation of the AA-EQS. It may therefore be argued that the potentially most sensitive species group is represented in the dataset by means of algae. An AF of 10 may therefore be considered, which leads to a MAC-EQS > AA-EQS (4.8 vs. 0.48 µg/L).

It should be noted, however, that if the AF is lowered from 100 to 10, the MAC-EQS will be very close to the NOEC for algae. Both the NOEC and EC50 originate from a 72- or 96-hours study. If the MAC-EQS is close to or higher than the NOEC, it cannot be excluded be that a short-term peak induces effects. Taking this into account, it is reasonable that when the EQS-derivation is based on algae, the difference between MAC-EQS and AA-EQS is small, especially in case a steep concentration effect relationship is present.

3.2.4 Kresoxim-methyl and carbendazim

For kresoxim-methyl, the additional factor of 10 for bioaccumulation was used in the original MAC-derivation. When this factor is left out of consideration, the resulting MAC-EQS is equal to the AA-EQS, though derived on the basis of different values.
For these compounds, the AA-EQS is derived using mesocosm data, while the MAC-EQS is derived using the AF-method on laboratory data. Both compounds are fungicides, for which it cannot predicted beforehand which species group is most sensitive. The variation between species and within taxonomic groups is large, both on the acute and on the chronic time scale, and the sensitivity order of taxa may differ between acute and chronic exposure. Mesocosm studies may yield useful information for these compounds, provided that a wide range of species groups, representing different habitats, life histories and feeding strategies are present.
It should be noted that for carbendazim and kresoxim-methyl, additional laboratory and/or mesocosm data did not lead to large differences in AA-EQS as compared to the AF-method. For carbendazim, the AA-EQS was 0.34 µg/L based on laboratory data, 0.60 µg/L based on the mesocosms, and 0.24 µg/L based on an SSD. For kresoxim-methyl, the AA-EQS was 0.7 µg/L when derived using the lowest laboratory NOEC and 0.63 µg/L on the basis of mesocosm data. The mesocosm data thus merely confirmed the laboratory data and the main advantage is that uncertainty decreased.
If reliable mesocosm data had been available that could be used for MAC-EQS derivation (i.e. studies with pulse application), this might have led to different results, either by directly using the NOEC from the mesocosm, or by adjusting the AF from 100 to 10 because of additional information on sensitive species groups. It should be noted, however, that carbendazim is relatively persistent. This means that the concept of a peak exposure may not be fully applicable because a single application leads to prolonged exposure when water replacement rate is low.

3.2.5 DNOC

For DNOC, the situation is more or less comparable to the former two compounds. DNOC is a broad spectrum pesticide, it is applied as an insecticide/acaricide, but also as a herbicide. The broad use spectrum implies that it is not possible to identify one sensitive species group. Fish appear to be most sensitive on the acute time scale, while bacteria, protozoa and molluscs are most sensitive in chronic tests. In that respect, the low MAC-EQS reflects the uncertainty related to the data. The AA-EQS is derived using SSD on a wide range of species and is therefore considered most reliable. Additional data from laboratory studies that would allow for an SSD on acute data, or information from mesocosm studies with pulse exposure might lead to a different, or at least more reliable MAC-EQS.

3.2.6 Captan and 6 PPD

For captan, bioaccumulation was taken into account in the original MAC-derivation. Leaving the additional AF out of consideration results in a MAC-EQS that is equal to the AA-EQS, although derived from different data.
Captan and 6 PPD are both characterised by a very fast dissipation from the water phase ($DT_{50,hydrolysis}$ < 1 d). Due to this it is hardly possible to maintain constant concentrations, even when applying best technical measures. For both compounds, the EQS-derivation was therefore performed using endpoints that were based on measured concentrations. For captan, acute L/EC50s are very low, even in static tests where the compound is not longer present after 1 day. The time to effect is very short, indicating that effects are induced by a very short contact time. It is most likely that this also applies to 6 PPD, although less data are available for a thorough evaluation. The high toxicity cannot be attributed to metabolites, because they are less toxic than the parent. For captan, the available information further indicates that the acute concentration-response relationship for fish (the most sensitive species group) is very steep: for several species, the acute NOEC and LC50 differ by only a factor of two. In chronic studies, the NOECs for sublethal and lethal parameters are similar. This confirms the assumption that effects, whether observed in chronic or in acute studies, can be attributed to the initial contact with the test substance. In this respect, a low MAC-EQS is not unrealistic. It might even be argued that the MAC-EQS is the most relevant EQS, because under field conditions chronic exposure will not occur.

3.2.7 Aniline

Aniline does not seem to have a specific mode of action and the interspecies variation is high. This leads to an AF of 100. There is no obvious reason for the MAC-EQS being close to the AA-EQS, other than that the difference in EC50 and NOEC for the most sensitive species (*Daphnia pulex* and *D. magna*, respectively) is less than the difference in AFs. It may be possible that chronic data for *D. pulex* would have led to a slightly lower AA-EQS.

3.3 Conclusions

- For four compounds, tolclophos-methyl, coumaphos, kresoxim-methyl and captan, exclusion of the additional factor for bioaccumulation has influence on the derived MAC-EQS.
- Only for tolclophos-methyl and coumaphos, the new AF-scheme results in a MAC-EQS that is higher than the AA-EQS. Revision of the MAC-values for these two compounds may therefore be considered.
- For eight of the compounds, it is advised not to revise the originally derived MAC-EQS and thus to keep the MAC-EQS equal to the AA-EQS.
    - For monolinuron and MCAA, algae are the key species for the EQS-derivation. This triggers a specific focus on the evaluation of the relationship between acute and chronic endpoints. It is also reason to take expert judgement into account when deciding on the

choice of the assessment factors. If for algae the MAC-EQS is close to the NOEC, chronic effects cannot be excluded.

- For kresoxim-methyl, carbendazim and DNOC, the low MAC-EQS reflects the uncertainty as to whether the potentially most sensitive species are present in the acute dataset. For these compounds, the AA-EQS was derived by refined methods (SSD, mesocosms) which makes the AA-EQS most reliable.
- For captan and 6 PPD, it is most likely that effects in the chronic studies are induced by the initial contact with the compounds. Taking this into account, the MAC-EQS being set equal to the AA-EQS is realistic.
- For aniline, the only explanation for the MAC-EQS being lower than the AA-EQS is the fact that for the key-species the difference in acute and chronic endpoints is smaller than the difference in AFs.

4 Initial evaluation of derivation methods

In 2008, RIVM derived ERLs for 23 pesticides, based on data present submitted within the context of pesticide authorisation under Directive 91/414/EEC. For nine compounds, reliable mesocosm data were available that could be considered for the MAC-EQS, while for two compounds SSD could be applied. SSD was also applied for the MAC-derivation for 2,4,6-trichlorophenol.
The derivation of EQSs as performed by RIVM allows for a comparison of the various methods that can be used for derivation of the MAC-EQS. In this way, an initial evaluation of the robustness of each of the derivation methods can be performed. It can also be determined whether or not the AF-method generally leads to a more conservative MAC-EQS than the other methods.

4.1 Comparison of MAC-values

In Table 3, the results of the different derivation methods are presented for ten compounds. Bold values represent the final MAC-EQS value, taking account of the appropriate assessment factors. For the AF-method, values were adjusted to the new draft-guidance when needed. In most cases an AF of 3 was applied to the NOEC from a mesocosm study when one study was available. This factor is based on the evaluations of Brock et al. (2006). They conclude that in case one reliable study is present, this factor may be needed to cover variation at the level of the NOEAEC (No Observed Ecologically Adverse Effect Concentration = concentration at which effects are considered acceptable from a regulatory point of view). In order to account for the different protection goals of the WFD as compared to the assessment under Directive 91/414, putting this factor on the NOEC (thus without taking recovery potential into account) was considered justified. In case of SSDs, the default factor of 10 was applied to the HC5 based on acute L/EC50. For lambda-cyhalothrin, the value of 0.0065 µg/L represents the HC5 based on L/EC10 values without an additional assessment factor.

From Table 3 it can be seen that, except for fenoxycarb and teflubenzuron, the difference between methods is within the same order of magnitude when the revised assessment scheme is taken into account.

Table 3. Summary of MAC-EQS-values derived by different methods. Bold values represent the final MAC-values as reported in the original reference.

Compound	MAC-EQS [µg/L] derived by				ratio of MACs			Reference
	AF	AF new scheme[a]	mesocosm	SSD	meso/AF	SSD/AF	meso/SSD	
abamectin	**0.018**		0.016		0.89			Scheepmaker, 2008a
deltamethrin	3.1×10^{-5}		**3.0×10^{-4}**	5.7×10^{-4}[b]	10	18	0.5	De Knecht and Van Herwijnen, 2008
dodine	0.0069	0.069	**2**		290/29[a]			Smit and Van der Veen, 2008
esfenvalerate	**0.00085**	0.0085	NOEC < 0.01					Van Vlaardingen et al., 2008
fenoxycarb	5.2	52	**0.026**		0.005/0.0005[a]			Smit and Vonk, 2008
imidacloprid	0.1		**0.2**		2.0			Posthuma-Doodeman, 2008
lambda-cyhalothrin	0.00023		NOEC < 0.002	**0.00047**[c] 0.00065[d]		2.0 2.8		Van Leeuwen et al., 2008
teflubenzuron	0.05		**0.0017**		0.03			Scheepmaker, 2008b
pyriproxyfen	**0.026**		NOEC 5 (no insects)					Moermond, 2008
2,4,6-trichlorophenol	3.6	36		**32**		9/0.9[a]		Moermond et al., 2009

a: no longer taking account of the additional AF of 10 for bioaccumulation
b: based on HC5 of L/EC50 of arthropods with AF 10; requirements for SSD not met
c: based on HC5 of L/EC50 with AF 10
d: based on HC5 of L/EC10 of arthropods; no AF; requirements for SSD not fully met.

4.2 Discussion of individual cases

4.2.1 Abamectin

The MAC-EQS based on the mesocosm data is similar to that derived on the basis of laboratory data. In this case, two mesocosm studies were available which represented worst case exposure conditions. The lower value of the two NOECs was used without a further AF.

4.2.2 Dodine

A substantially higher MAC-EQS was derived based on the mesocosm study. This compound is a fungicide, and the observations made above for kresoxim-methyl and carbendazim also apply to this compound. The laboratory dataset was very limited with only the base set represented, and it is clear that a mesocosm study including a wide variety of species groups may change the outcome considerably.

4.2.3 Esfenvalerate

The mesocosm data for esfenvalerate could not be used because the lowest concentration induced effects. For this compound, the proposed change in the AF-scheme results in a 10-times higher MAC-value as compared to the original.

4.2.4 Fenoxycarb, teflubenzuron

The MAC-EQS based on mesocosm data is much lower than the value derived using acute laboratory data. This can be explained by the specific mode of action. These compounds are insect growth regulators, the effects of which only become apparent after prolonged observation. For this type of compounds, the duration of short-term studies is too short to detect delayed effects from a single peak. For fenoxycarb, this is clearly reflected by the extreme high ACR for *Daphnia magna* (> 7000).

4.2.5 Imidacloprid

The mesocosm resulted in a higher MAC-EQS, but the difference is not large.

4.2.6 Lambda-cyhalothrin

The lowest concentration in the mesocosm resulted in effects. The SSD based on acute L/EC50 resulted in a MAC-EQS that is a factor of two higher than that derived using the AF-method. The L/EC10-HC5 (without an additional AF) is only a factor of 1.4 higher than the L/EC50-HC5 with AF 10. Because this HC5-L/EC10 is based on two taxa only, it is not used for the final MAC-EQS.

4.2.7 Deltamethrin

The MAC-EQS based on the mesocosm is a factor of 10 higher than when based on laboratory data. The lowest laboratory LC50 was obtained in a flow-through experiment, while the mesocosm refers to a pulse application. It should further be noted that the majority of laboratory data was not considered valid because the very low solubility of deltamethrin (0.2 µg/L) was not taken into account in the studies (test concentrations were too high and/or chemical analysis was not performed). An SSD was also considered. This was originally constructed within the context of authorisation under Directive 91/414/EEC and does not comply with the criteria specified in the TGD. It was therefore not used for the final MAC-EQS.

4.2.8 Pyriproxyfen

The mesocosm study did not include insects, while this is the potentially most sensitive species group. It was therefore not used for MAC-derivation.

4.2.9 2,4,6-trichlorophenol

The MAC-EQS of 32 µg/L as derived using SSD was selected as the final MAC-EQS. This value is in good agreement with the MAC-EQS as derived using the AF-method, without the additional AF for bioaccumulation. In the original report, the MAC-EQS as derived using the "old" AF-method is 3.6 µg/L.

4.3 Conclusions

- In general, there is no reason to assume that the AF-method needs to be revised. Taking into account the proposed revisions in the draft EQS-Guidance, there is no indication that the AF-method is biased towards conservative values. The following should be noted:
    - for the specific group of insect growth regulators, acute data do not give information on delayed effects and cannot be used for derivation of EQSs; in general, for compounds with a (very) high ACR, the possibility of delayed effects should be considered.
    - for compounds which may affect different species groups, such as fungicides or broad spectrum pesticides, mesocosm studies, and/or additional laboratory data that allow for the use of the SSD-methods may lead to different results as compared to the AF-method; it cannot be predicted beforehand whether the refined MAC-EQS will be higher or lower than the initial value.

5 General conclusions

The following general conclusions on WFD MAC-EQS derivation can be drawn from this initial evaluation:

- In general, knowledge about the mode of action is essential for EQS-derivation and a MAC-EQS cannot be derived without a proper chronic dataset.
- When key values for the AA-EQS and MAC-EQS relate to the same species, and the L/EC50 is lower than the NOEC, the data should be re-evaluated and justified, and/or an EC10 should be derived instead of a NOEC to derive the AA-EQS.
- When the AA-EQS and MAC-EQS are based on algae, it should be noted that both the EC50 and NOEC for algae refer to a 72- or 96-hours toxicity test. Taking this into account it is reasonable that the difference between MAC-EQS and AA-EQS is small, especially when a steep concentration effect relationship is present.
- The time to effect in both acute and chronic studies can give valuable information as to whether the effects in chronic studies may be caused by an initial exposure to the test substance, rather than to prolonged exposure. If that is the case, it is reasonable that the MAC-EQS and AA-EQS are similar.
- Chronic studies that are rejected for AA-EQS derivation because concentrations were not kept constant, may give information on the occurrence of (delayed) effects due to a single peak.
- From the comparison of methods, it is concluded that there is no reason to assume that the AF-method is over-conservative. The following should be noted:
    - for the specific group of insect growth regulators, acute data do not give information on delayed effects and cannot be used for derivation of EQSs; in general, for compounds with a (very) high ACR, the possibility of delayed effects should be considered.
    - for compounds which may affect different species groups, such as fungicides or broad spectrum pesticides, mesocosm studies, and/or additional laboratory data that allow for the use of the SSD-methods may lead to different results as compared to the AF-method; it cannot be predicted beforehand whether the refined MAC-EQS will be higher or lower than the initial value.
- For potentially bioaccumulating compounds, the proposed revision of the EQS-Guidance may influence the outcome if the MAC-EQS is solely derived using assessment factors on acute data.

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Appendix 1. Underlying data used for EQS-derivation

The tables below represent the aggregated data tables taken from the individual reports. To facilitate comparison of acute and chronic data per species, species names have been added in case they were not already included in the original tables, and Acute to Chronic Ratios (ACRs) are added. Bold values indicate the key-values for EQS-derivation. The explanation to the EQS-derivation is also copied from the reports and presented in a box, the text is sometimes slightly changed for reasons of comparison between compounds.

A1.1 Coumaphos

Chronic taxon	species	NOEC/EC10 [µg/L]	Acute taxon	species	L(E)C50 [µg/L]	ACR
Crustacea	D. magna	0.034	Crustacea	D. magna	0.1	2.9
			Crustacea	G. fasciatus	0.15	
			Crustacea	G. lacustris	0.074	
			Crustacea	S. cerrulatus	0.1	
			Insecta	A quadricmaculatus	20	
			Insecta	A. teniorhynchus	30	
			Insecta	Hexagenia	427	
			Insecta	Hydropsyche	5.2	
Pisces	O. mykiss	11.7	Pisces	O. mykiss	1155	99
			Pisces	I. punctatus	840	
			Pisces	L. macrochirus	247	
			Pisces	M. salmoides	1100	
			Pisces	O. clarki	862	
			Pisces	P. reticulata	560	
			Pisces	R. heteromorpha	46	
			Pisces	S. namaycush	593	
			Pisces	S. vitreum vitreum	780	

Key values:
EC50 0.074 µg/L for *Gammarus lacustris*
NOEC 0.034 µg/L for *Daphnia magna*

Derivation of the $MPC_{eco,\ water}$
The base-set is not complete. But because toxicity data from azinphos-methyl show that algae are not sensitive to this group of compounds and chronic data are present for both crustaceans, mollusca and fish, it is allowed to derive $MPC_{eco,water}$ and $MPC_{eco,marine}$ using the chronic dataset. With these three species, and because crustaceans are the most sensitive taxonomic group in acute toxicity studies, an assessment factor of 10 can be applied for the $MPC_{eco,water}$ and because one of these NOECs is from a marine taxonomic group, for the $MPC_{eco,marine}$ an assessment factor of 50 can be used. The lowest NOEc is 0.034 µg/L for crustaceans. Thus, the $MPC_{eco,water}$ becomes $0.034 / 10 = 3.4 \times 10^{-3}$.

Derivation of the $MAC_{eco,\ water}$
The base-set for acute data is not complete, but it can be assumed that algae are not more sensitive than fish or Crustacea. The data for different species differ by more than a factor of 3. Since the BCF is higher than 100, this means that an assessment factor of 1000 should normally be used on the lowest L(E)C50 value (0.074 µg/L for crustaceans). However, the mode of toxic action is known (acetyl choline esterase inhibitor), and the most sensitive species are tested (crustaceans). These crustaceans are not likely to be exposed for a longer period of time due to slow desorption kinetics. An assessment factor of 100 instead of 1000 for the $MAC_{eco,water}$ is therefore justified. The $MAC_{eco,water}$ then becomes $0.074 / 100 = 7.4 \times 10^{-4}$ µg/L. This is however lower than the MPC_{water}, and thus the $MAC_{eco,water}$ is set equal to the MPC_{water} at 3.4×10^{-3} µg/L.

A1.2 Tolclophos-methyl

Chronic taxon	species	NOEC/EC10 [µg/L]	Acute taxon	species	L(E)C50 [µg/L]	ACR
Algae	S. subspicatus	261	Algae	S. subspicatus	712	2.7
Algae	S. quadricauda	32				
Crustacea	D. magna	26	Crustacea	D. magna	> sol	
Pisces	O. mykiss	12	Pisces	O. mykiss	738	62

Key values:
EC50 712 µg/L for *Scenedesmus subspicatus*
NOEC 12 µg/L for *Oncorhynchus mykiss*

Derivation of the $MPC_{eco, water}$
Acute LC50 values are only available for algae and fish. Acute values for *Daphnia magna* are above the solubility limit, so they can not be used to derive ERLs, but can be used to complete the base-set (…). With NOECs available from three trophic levels (algae, *Daphnia magna* and fish), an assessment factor of 10 can be applied to the lowest NOEC (12 µg/L for fish). This results in an $MPC_{eco,water}$ of 12 / 10 = 1.2 µg/L.

Derivation of the $MAC_{eco, water}$
No useful acute toxicity data for *Daphnia* are available, because effect concentrations in all *Daphnia* studies were above the water solubility. However, the performed studies show that the acute toxicity to *Daphnia magna* is low. The chronic toxicity studies show that tolclofos-methyl is not particularly toxic to *Daphnia magna* in long term experiments either. In contrast to the other organophosphorous pesticides, tolclofos-methyl is not an insecticide but a fungicide and acts by inhibition of phospholipid biosynthesis. Therefore, it seems justified to derive a MAC_{eco} although no useful acute data for crustaceans are available. With an assessment factor of 1000 on the lowest LC50 (712 for algae), the MAC_{eco} becomes 712 / 1000 = 0.71 µg/L.
When the final MPC_{water} is indeed set at 1.2 µg/L, the MAC_{eco} value of 0.71 µg/L is lower than the MPC_{water}, and should be adjusted to be equal to the MPC_{water} (1.2 µg/L).

A1.3 Monolinuron

Chronic taxon	species	NOEC/EC10 [mg/L]	Acute taxon	species	L(E)C50 [mg/L]	ACR
Bacteria	P. putida	11				
Cyanobacteria	M. aeruginosa	0.137				
Cyanobacteria	Nostoc spec.	0.26				
Algae	S. subspicatus	**0.0015**	Algae	S. subspicatus	**0.001**	0.67
Algae	S. quadricauda	0.125	Algae	Chlorella	0.20	
Crustacea	D. magna	0.95	Crustacea	D. magna	33	35
			Crustacea	C. roeselli	30	
			Annelida	T. tubifex	150	
			Insecta	C. tentans	12.5	
			Insecta	C. plumosus	100	
			Insecta	A. aegypti	75	
Pisces	O. mykiss	5.0	Pisces	C. punctatus	104.4	
			Pisces	C. mrigala	12.5	
			Pisces	C. carpio	74	
			Pisces	L. idus	74	
			Pisces	M. vittatus	28.6	
			Pisces	P. reticulata	46	
			Pisces	S. mossambicus	54	

Key values:
EC50 0.001 mg/L for *Scenedesmus subspicatus*, endpoint growth rate/cell density from 96-hours test with active substance.
NOEC 0.0015 mg/L for *S. subspicatus*, endpoint growth rate from 96-hours test with 50% formulated product.

Derivation of the $MPC_{eco, water}$
For monolinuron a complete base set for toxicity to freshwater organisms is available. Moreover, 7 long-term NOECs of three trophic levels (bacteria, algae, Crustacea and fish) are available. Therefore, the $MPC_{eco, water}$ is derived using an assessment factor of 10 on the lowest NOEC, i.e. the 72-h NOEC for *Scenedesmus subspicatus* of 0.0015 mg/L. The $MPC_{eco, water}$ is 0.0015 / 10 = 0.00015 mg/L (0.15 µg/L).

Derivation of the $MAC_{eco, water}$
The $MAC_{eco, water}$ may be derived from the acute toxicity data. Fifteen short-term values for three trophic levels (fish, Crustacea, Annelida, Insecta and algae) are available, monolinuron has no potential to bioaccumulate (log K_{ow} < 3 L/kg), the mode of action for the tested species is specific and the potentially most sensitive species group (algae) is included in the data set. Therefore, an assessment factor of 10 is applied to the lowest $L(E)C_{50}$, i.e. the EC_{50} for *Scenedesmus subspicatus* of 0.001 mg/L. The MAC_{eco} is derived as 0.001 / 10 = 0.0001 mg/L (0.1 µg/L).
However, because the $MPC_{eco, water}$ (0.15 µg/L) is higher, the $MAC_{eco, water}$ is put level with the $MPC_{eco, water}$ (see INS-Guidance, section 4.1.4) and becomes 0.15 µg/L.

A1.4 MCAA

Chronic taxon	species	NOEC/EC10 [mg/L]	Acute taxon	species	L(E)C50 [mg/L]	ACR
Bacteria	P. putida	2152				
Protozoa	T. pyriformis	16				
Algae	S. subspicatus	**0.0058**	Algae	S. subspicatus	**0.0481**	8.3
Algae	P. subcapitata	0.005	Algae	P. subcapitata	1.8	
Algae	S. quadricauda	0.13				
Crustacea	D. magna	32	Crustacea	D. magna	121	3.8
			Crustacea	B. calyciflorus	68.9	
Pisces	D. rerio	12.5	Pisces	D. rerio	370	30
			Pisces	L. idus	> 100	
			Pisces	P. promelas	145	
			Pisces	P. reticulata	369	

Key values:
EC50 48.1 µg/L for *Scenedesmus subspicatus*
NOEC 5.8 µg/L for *S. subspicatus*

Derivation of the $MPC_{eco, water}$
In the RAR, the algae are appointed as the most sensitive species to MCAA. This is not surprising, because MCAA is a known herbicide. The lowest long-term result is the NOEC of 5.8 µg/L for *Scenedesmus subspicatus*. This test is used for PNEC-derivation. An assessment factor of 10 was applied, because long-term studies are available for three different trophic levels. This lead to a $PNEC_{aquatic}$ of 0.58 µg/L. The $MPC_{water, eco}$ is equal to the $PNEC_{aquatic}$. Thus, $MPC_{water, eco}$ = 0.58 µg/L.

Derivation of the $MAC_{eco, water}$
The EC_{50}-value of 48.1 µg/L for *Scenedesmus subspicatus* is the lowest reported acute toxicity value in the RAR. This value is the geomean of two effect concentrations for growth rate. The base set is complete and MCAA is not bioaccumulative. Therefore, an AF of 100 is applied. The MAC_{eco} for fresh water is 48.1 µg/L/100 = 0.48 µg/L. However, this value is lower than the $MPC_{eco, water}$. Therefore, the $MAC_{water, eco}$ is set equal to the $MPC_{eco, water}$. The $MAC_{eco, water}$ = 0.58 µg./L.

Notes:
The chronic endpoints for P. subcapitata *and* S. quadricauda *refer to EC3-values. In the EU-Risk Assessment Report (EU-RAR), these values are considered as LOECs, and consequently the NOEC is reported as < 0.005 and < 0.13 mg/L, respectively. Within the context of INS, however, the EC3 is considered as a NOEC.*
B. calyciflorus *belongs to the rotifera.*
Both remarks do not change the original conclusions of the authors.

A1.5 Kresoxim-methyl

Chronic taxon	species	NOEC/EC10 [µg/L]	Acute taxon	species	L(E)C50 [µg/L]	ACR
Algae	P. subcapitata	15	Algae	P. subcapitata	490	33
Algae	A. bibraianus	**7**	Algae	A. bibraianus	**63**	9
Crustacea	D. magna	32	Crustacea	D. magna	293	9
Pisces	O. mykiss	32	Pisces	O. mykiss	830	26
			Pisces	L. macrochirus	3200	
			Pisces	C. carpio	808	

Key values:
EC50 63 µg/L for *Ankistrodesmus bibraianus*
NOEC 7 µg/L for *Ankistrodesmus bibraianus*
NOEC 1.9 µg/L from mesocosm with sufficiently chronic exposure.

Derivation of the $MPC_{eco, water}$
The base-set for freshwater toxicity data is complete. Chronic NOECs for three trophic levels are available for algae, Crustacea and fish. The lowest NOEC is 0.007 mg/L for the alga *Ankistrodesmus bibraianus*. An assessment factor of 10 can be used on the lowest NOEC (0.007 mg/L), and the initial $MPC_{eco, water}$ based on laboratory data is 0.007 / 10 = 0.0007 mg/L (0.7 µg/L).

From the mesocosmstudy, a NOEC of 1.9 µg/L is derived. (…). It is therefore in principle proposed to use an assessment factor of 3 on the NOEC instead of on the NOEAEC. Therefore, the $MPC_{mesocosm}$ becomes 0.63 µg/L.

The $MPC_{mesocosm}$ is in good agreement with the MPC based on laboratory data. The lower of the two is chosen as the final $MPC_{eco, water}$, which is therefore set to 0.63 µg/L.

Derivation of the $MAC_{eco, water}$
The $MAC_{eco, water}$ may be derived in the first instance from the acute toxicity data. Six short-term values for three trophic levels (fish, *Daphnia*, and algae) are available and kresoxim-methyl has a potential to bioaccumulate (BCF ≥ 100 L/kg). Therefore, an assessment factor of 1000 is applied to the lowest $L(E)C_{50}$, i.e. the EC_{50} for *Daphnia magna*: 0.293 mg/L. Therefore, the MAC_{eco} derived from toxicity data is 0.293 / 1000 = 0.000293 mg/L (0.293 µg/L). Since this value is below the MPC_{water} (0.63 µg/L), the $MAC_{eco, water}$ is set equal to the $MPC_{water.}$ Thus, the $MAC_{eco, water}$ is 0.63 µg/L.

Note that in the original derivation of the $MAC_{eco, water}$, the lowest EC50 is given as 0.293 mg/L for D. magna. The lowest EC50 is in fact 63 µg/L, which with the same reasoning would have led to a $MAC_{eco, water}$ of 0.063 µg/L.
This does not change the original conclusion of the authors.

A1.6 Carbendazim

Chronic taxon	species	NOEC/EC10 [µg/L]	Acute taxon	species	L(E)C50 [µg/L]	ACR
			Protozoa	T. pyriformis	6380	
Algae	S. subspicatus	10200				
			Algae	C. pyrenoidosa	340	
Turbellaria	D. lugubris	**3.4**	Turbellaria	D. lugubris	134	39
Clitellata	S. lacustris	21	Clitellata	S. lacustris	821	39
			Clitellata	D. digitata	980	
Gastropoda	B. tentaculata	103				
Gastropoda	P. planorbis	301				
Crustacea	G. pulex	10	Crustacea	G. pulex	55	5.5
Crustacea	D. magna	8.0	Crustacea	D. magna	234	29
Insecta	C. riparius	13.3				
Pisces	C. carpio	1000	Pisces	C. carpio	440	0.44
Pisces	O. mykiss	11	Pisces	O. mykiss	145	13
			Pisces	I. punctatus	**10**	
			Pisces	S. trutta	390	

Key values:
LC50 10 µg/L for Ictalurus punctatus
NOEC 3.4 µg/L for Dugesia lugubris
NOECs 1.79 and 3.3 µg/L from mesocosm studies with sufficiently chronic exposure, acute NOEC in mesocosm 2.17 µg/L (no fish).

Derivation of the $MPC_{eco, water}$

For carbendazim, a complete base set for toxicity to freshwater organisms is available. Moreover, long-term NOECs of at least three species representing three trophic levels are available. Therefore, the $MPC_{eco, water}$ is derived using an assessment factor of 10 on the lowest NOEC, i.e. the 21-d NOEC for *Dugesia lugubris* of 3.4 µg/L. The initial $MPC_{eco, water}$ based on laboratory tests is 3.4/10 = 0.34 µg/L.

NOECs of 3.3 and 1.79 µg/L are available from micro/mesocosm studies, that are considered valid for derivation of the MPC (….). Therefore an assessment factor of 3 is kept on the lowest NOEC, resulting in an MPC_{cosms} of 0.60 µg/L.

For comparison, the $MPC_{eco, water}$ is also derived applying Species Sensitivity Distribution (SSD) to the chronic data. (….). In view of the above listed points, there are reasons to apply an assessment factor to the HC_5, mainly because of the small dataset, the visual lack of fit and the large confidence interval. The remaining uncertainty is assumed to be covered by a factor of 3, leading to a MPC_{HC5} of 0.24 µg/L.

In the present case, the available information indicates that MPC_{HC5} is rather conservative. The MPC_{cosm} is 0.60 µg/L, which is over a factor of 5 lower than the lowest laboratory NOEC. It is considered justified to use the MPC_{cosm} and set the $MPC_{eco, water}$ to 0.60 µg/L.

Derivation of the $MAC_{eco, water}$

The $MAC_{eco, water}$ may be derived from the acute toxicity data. Fourteen short-term values for three trophic levels are available, carbendazim has no potential to bioaccumulate (BCF <100 L/kg), the mode of action for the tested species is non-specific and the interspecies variation is high. Therefore, an assessment factor of 100 is applied to the lowest $L(E)C_{50}$, i.e. the EC_{50} for *Ictalurus punctatus*: 10 µg/L. Therefore, the MAC_{eco} is initially derived as 10 / 100 = 0.1 µg/L. However, because the MPC_{water} (0.60 µg/L) is higher, the $MAC_{eco, water}$ is put level with the MPC_{water} and becomes 0.60 µg/L.

A1.7 Captan

Chronic taxon	species	NOEC/EC10 [mg/L]	Acute taxon	species	L(E)C50 [mg/L]	ACR
Algae	P. subcapitata	0.50	Algae	P. subcapitata	7.14	
			Crustacea	D. magna	3.44	
			Pisces	G. aculeatus	0.37	
Pisces	P. promelas	**0.017**	Pisces	P. promelas	0.065	3.8
			Pisces	O. mykiss	0.296	
			Pisces	L. macrochirus	0.072	
			Pisces	S. fontinalis	**0.034**	

Key values:
LC50 0.034 mg/L for *Salvelinus fontinalis*
NOEC 0.017 mg/L for *Pimephales promelas*

Derivation of the $MPC_{eco, water}$
For captan, the base set (algae, *Daphnia* and fish) is complete. Two long-term NOECs of two trophic levels (algae and fish) are available. Therefore, the $MPC_{eco, water}$ is derived using an assessment factor of 50 on the lowest NOEC, i.e. the 96-h NOEC for *Pimephales promelas* of 0.017 mg/L. The $MPC_{eco, water}$ is 0.017/50 = 0.00034 mg/L (0.34 µg/L).

Derivation of the $MAC_{eco, water}$
The $MAC_{eco, water}$ may be derived from the acute toxicity data. Seven short-term $L(E)C_{50}$ values for three trophic levels (fish, *Daphnia* and algae) are available, captan has a potential to bioaccumulate (BCF > 100 L/kg), the mode of action for the tested species is non-specific and the interspecies variation is high. Therefore, an assessment factor of 1000 is applied to the lowest $L(E)C_{50}$, i.e. the LC_{50} for *Salvelinus fontinalis*: 0.034 mg/L. Therefore, the MAC_{eco} is derived as 0.034/1000 = 0.000034 mg/L (0.034 µg/L). However, because the MPC_{water} is higher (0.34 µg/L), the $MAC_{eco, water}$ is put level with the MPC_{water} and becomes 0.34 µg/L.

A1.8 6 PPD

Chronic taxon	species	NOEC/EC10 [mg/L]	Acute taxon	species	L(E)C50 [mg/L]	ACR
Algae	P. subcapitata	0.22	Algae	P. subcapitata	0.668	3.0
			Crustacea	D. magna	0.23	
Pisces	P. promelas	0.024	Pisces	P. promelas	0.45	19
			Pisces	O. latipes	0.028	

Key values:
LC50 0.028 mg/L for *Oryzias latipes*
NOEC 0.024 mg/L for *Pimephales promelas*

Derivation of the $MPC_{eco, water}$
(….). Based on the argumentation outlined above, the base set for acute toxicity is accepted as complete. Data for three trophic levels are present, represented by algae, *Daphnia* and fish. Chronic data for two trophic levels are available: primary producers and secondary consumers, represented by algae and fish. This dataset allows for application of an assessment factor of 50 to the lowest NOEC. Note that the lowest LC50 is in the same range as the NOEC: 0.028 mg/L vs. 0.024 mg/L. If the lowest LC50 would have been lower than the lowest NOEC, an assessment factor of 100 should have been applied to the LC50 (EU-TGD guidance), which would have resulted in a lower MPC.
Based on the chronic test, the $MPC_{eco, water}$ is derived as 24/50 = 0.48 µg/L.

Derivation of the $MAC_{eco, water}$
6PPD has no bioaccumulation potential. The mode of action of 6PPD is not known, however, interspecies variation is not considered to be low: the range of acute toxicity test results spans a factor of 30. An assessment factor of 100 is applied to the lowest acute test result (LC50 of 28 µg/L for *O. latipes*) to derive the MAC_{eco}. MAC_{eco} = 28/100 = 0.28 µg/L.

A1.9 DNOC

Chronic taxon	species	NOEC/EC10 [mg/L]	Acute taxon	species	L(E)C50 [mg/L]	ACR
Bacteria	E. coli	100				
Bacteria	P. fluorescens	10				
Bacteria	P. putida	16				
Cyanobacteria	M. aeruginosa	0.69				
Algae	S. subspicatus	16	Algae	S. subspicatus	74	4.6
Algae	C. vulgaris	100				
Algae	P. subcapitata	1.0				
Algae	S. pannonicus	10				
Algae	S. quadricauda	22				
Protozoa	C. paramaecium	5.4	Protozoa	T. pyriformis	5.9	
Protozoa	E. sulcatum	5.4				
Protozoa	M. heterostoma	30				
Protozoa	U. parduczi	0.012				
Macrophyta	L. minor	0.32				
Coelenterata	H. oligactis	0.32				
Rotifera	B. calyciflorus	0.55				
Mollusca	L. stagnalis	0.032				
Crustacea	D. magna	0.21	Crustacea	D. magna	2.7	13
			Crustacea	D. pulex	0.15	
			Crustacea	G. fasciatus	1.1	
Insecta	C. pipiens	10	Insecta	P. californica	0.32	
Pisces	P. promelas	0.18	Pisces	P. promelas	1.9	11
Pisces	P. reticulata	1.0	Pisces	L. macrochirus	0.29	
Pisces	O. latipes	0.1	Pisces	O. mykiss	**0.066**	
			Pisces	S. salar	0.18	
			Pisces	D. rerio	4.7	
Amphibia	X. laevis	0.32				

Key values:
LC50 0.066 mg/L for *Oncorhynchus mykiss*

Derivation of the $MPC_{eco, water}$
The base set is complete and the set of chronic toxicity data fulfils the criteria for refined effect assessment: data for bacteria, cyanobacteria, algae, protozoa, macrophyta, coelenterata, rotifera, mollusca, crustacea, insecta, pisces and amphibia are present. The MPC is derived using refined effect assessment. (…). The sample of 23 toxicity test results passes all three tests on (log)normal distribution, indicating that the application of the extrapolation method is justified. A median HC_5 of 28 µg/L (90% confidence interval: 5.2 – 89 µg/L) is calculated for this DNOC. (….). Taking into account that several nominal values are included in the dataset and that there is one NOEC below the HC_5, we consider the application of an assessment factor of 3 valid. The MPC for DNOC is therefore equal to 27.5/3 = 9.2 µg/L (the non rounded off value of the HC_5 is used).

Derivation of the $MAC_{eco, water}$
DNOC has no bioaccumulation potential. The mode of action of DNOC is known, however, interspecies variation is not considered to be low since the range of acute toxicity test results spans over three orders of magnitude. An assessment factor of 100 is applied to the lowest acute test result (LC50 of 0.066 mg/L for *O. mykiss*) to derive the MAC_{eco}. MAC_{eco} = 66/100 = 0.66 µg/L.

A1.10 Aniline

Chronic taxon	species	NOEC/EC10 [mg/L]	Acute taxon	species	L(E)C50 [mg/L]	ACR
Bacteria	C. paramaecium	250	Bacteria	not specified	< 1	
Bacteria	E. sulcatum	24	Bacteria	not specified	53	
Bacteria	P. putida	130				
Bacteria	U. parduczi	91				
Algae	S. capricornutum	2	Algae	S. capricornutum	19	9.5
Algae	S. subspicatus	22	Algae	S. subspicatus	68	3.0
Algae	M. aeruginosa	0.16				
Crustacea	D. magna	0.015	Crustacea	D. magna	0.21	19
			Crustacea	D. cucullata	0.68	
			Crustacea	D. pulex	0.1	
			Crustacea	G. fasciatus	2.3	
Pisces	P. promelas	0.39	Pisces	P. promelas	68.6	176
			Pisces	D. rerio	42.9	
			Pisces	L. macrochirus	49	
			Pisces	O. mykiss	22.1	

Key values:
EC50 0.1 mg/L for *Daphnia pulex*
NOEC 0.015 mg/L for *D. magna* (mean of 3 values as reported in EU-RAR)

Derivation of the $MPC_{eco, water}$
The text in this section reflects the derivation presented in the EU-RAR. (….) In the EU-RAR, the mean value of the three NOECs for *Daphnia* is calculated and used as basic value for the effect assessment. It was stated that the NOEC of 4 µg/L should be used for the derivation of the PNEC because it is possible that effects occur at concentrations below 4 µg/L. As three *Daphnia* long-term tests are available that are regarded of equal value, it was considered to be most appropriate to use the arithmetic mean. Calculating the arithmetic mean of the three NOECs results in a value of 15 µg/L (the non-rounded off value was used in further calculations for INS purposes). For the derivation of the $PNEC_{aqua}$ an assessment factor of 10 was chosen, as reliable long-term tests are available for daphnids and fish. An effective NOEC on algae cannot be determined due to the rapid phototransformation of aniline in the presence of algae. However, as the nominal effect values from the algae tests are about 2-3 orders of magnitude higher than the NOECs from the *Daphnia* long-term tests, it can be expected with high probability that the effective algae NOEC is not below 15 µg/L. Therefore: $PNEC_{aqua}$ = $MPC_{eco, water}$ = 15 µg/L / 10 = 1.5 µg/L.

Derivation of the $MAC_{eco, water}$
For the derivation of the MAC_{eco}, an assessment factor of 100 is applied to the lowest EC50, because BCF < 100 L/kg, log K_{ow} < 3 and the base set is complete. The lowest EC50 is found for *Daphnia pulex*: 0.1 mg/L (….). The resulting MAC_{eco} is 1.0 µg/L.

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