

# Validity of REACH risk limits in the Dutch policy framework on priority chemicals

Road-map Quality standard setting

RIVM Letter Report 601357013/2013 C.W.M. Bodar et al.



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# Colofon

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#### **Abstract**

# Validity of REACH risk limits in the Dutch policy framework on priority chemicals

REACH is the European policy framework for the risk management of dangerous chemicals. Producers and importers provide risk limits below which the use of a chemical is assumed to be safe. For efficiency reasons national authorities want to use the REACH data as much as possible when executing the Dutch policy on priority chemicals. The policy goal is that the environmental concentrations of priority substances, for example chemicals causing cancer, in the Netherlands should be below the negligible (risk) concentration in 2030.

RIVM investigated the validity of REACH data in the Dutch policy framework on priority chemicals. The research was based on a sample of more than 200 chemicals. For a large number of chemicals the REACH dossiers were found not to contain risk limits. If risk limits were available, then industry relies on other figures than authorities. In most cases industry applies less stringent limits, sometimes with a substantial difference (factor of 100 or more). In those cases industry claims safe use of chemicals on values that deviate from the standards currently used by authorities to safeguard man and environment. Therefore carefulness is needed when transferring REACH risk limits to other frameworks, like the policy on priority chemicals in the Netherlands.

Above-mentioned differences may be caused because REACH and authorities found risk limits on different methods. In addition, authorities may not yet have implemented certain new insights, resulting in more conservative standards. However, industry's interpretation of key data on important characteristics of a chemical may also be different.

For, amongst others, local permit authorities it is important to realise that such differences and gaps may occur and that they should be further examined. RIVM gives a number of recommendations how stakeholders should handle REACH data in those cases for a better protection of man and environment. RIVM will prepare further guidance for this purpose.

#### Keywords:

REACH, risk limit, environmental quality standard, priority chemicals

# Rapport in het kort

# Bruikbaarheid van REACH-risicogrenzen in het Nederlandse prioritaire stoffenbeleid

REACH is de Europese regelgeving om risico's van schadelijke stoffen te beperken. Producenten en distributeurs leveren hiervoor zelf de gegevens aan over grenzen waaronder het gebruik van een stof veilig is. Het RIVM heeft in een steekproef van ruim 200 stoffen onderzocht in hoeverre REACH-gegevens ook voor andere beleidskaders kunnen worden gebruikt, zoals het prioritaire stoffenbeleid. Het blijkt dat REACH-risicogrenzen vaak niet één op één kunnen worden overgenomen.

#### Prioritaire stoffenbeleid

Het doel van het prioritaire stoffenbeleid is de concentratie van alle zeer schadelijke stoffen, zoals kankerverwekkende, in Nederland in 2030 dusdanig laag te krijgen dat het risico verwaarloosbaar is. Uit oogpunt van efficiëntie wil de overheid voor het Nederlandse prioritaire stoffenbeleid zo veel mogelijk gebruikmaken van de REACH-informatie.

#### Industrie gebruikt vaak ruimere grenzen

Het bedrijfsleven baseert risicogrenzen in de REACH-dossiers vaak op andere getallen dan de overheid. Doorgaans gebruikt de industrie ruimere grenzen, soms met een aanmerkelijk verschil, van een factor honderd of meer. In die gevallen baseert het bedrijfsleven de conclusies over veilig gebruik van een stof dus op waarden die afwijken van de normen die de overheid gebruikt.

# Risicogrenzen anders bepaald of afwezig in REACH

De verschillen tussen REACH en de overheid kunnen ontstaan doordat zij risicogrenzen op een andere manier bepalen. Ook kan het zijn dat de overheid bepaalde nieuwe inzichten nog niet heeft doorgevoerd. In dat geval pakken de overheidsnormen (die worden gebaseerd op risicogrenzen) strenger uit dan bij REACH. Bovendien interpreteert het bedrijfsleven bepaalde sleutelgegevens over stofeigenschappen soms anders dan de overheid. Het RIVM constateert ook dat voor een groot aantal stoffen de risicogrenzen ontbreken in de REACH-dossiers.

Het is vooral voor vergunningverleners van belang dat zij zich bewust zijn van de verschillen en hiaten, en deze nader onder de loep nemen. Het RIVM geeft enkele aanbevelingen hoe belanghebbenden in dergelijke gevallen het beste met REACH-gegevens kunnen omgaan om mens en milieu beter te beschermen. Hiervoor wordt onder andere een praktische handreiking opgesteld.

#### Trefwoorden:

REACH, risicogrens, milieukwaliteitsnorm, prioritaire stoffen

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# Summary

REACH generates a large amount of new or additional data on chemicals. This wealth of information could be useful in other policy frameworks on chemicals as well.

Risk limits and environmental quality standards are foreseen to play an important role in the redefined policy on priority chemicals in the Netherlands. The policy goal for these chemicals is that their environmental concentrations in the Netherlands should be below the negligible (risk) concentration in 2030. This negligible concentration differs from the risk limits contained in REACH dossiers (e.g., PNEC, DNEL and DMEL). However, where available, REACH risk limits can be converted into a negligible risk concentration. For reasons of efficiency, the starting point in the framework of the Dutch policy for priority chemicals is to use the risk limits from the REACH registration dossiers as much as possible. In this study we investigate the advantages and drawbacks of this approach. Will REACH indeed provide the information needed, and if yes, is it then simply 'copy and paste'? The redefined policy on priority chemicals states that legally established environmental quality standards should be preferred over REACH risk limits. This may seem straightforward, but discussions are to be expected in those cases where the prevailing standard significantly deviates from the REACH risk limit found in registration dossiers.

We conducted a 'meta-analysis' on a selected group of chemicals to answer abovementioned questions. The basis for this group of chemicals was the former list of priority chemicals in the Netherlands (207 substances). This is considered as a relevant 'sample' of which the results could be extrapolated to the group of priority chemicals within the current redefined policy framework for priority substances.

For more than half of the number of sample substances, a registration dossier was not available. If one or more registration dossiers were available, then in about one-third of the cases no risk limit for water was included. In 55 per cent of the cases there was no DNEL/DMEL for air. If a comparison could be made, it shows that in almost all cases the REACH values deviated from the national ones. For air in 95 per cent of the cases the REACH risk limit was numerically higher than the Dutch environmental quality standard. In 5 per cent of the cases the REACH value was lower than or equal to the standard. For water these percentages were 73 per cent and 27 per cent, respectively.

Our main message is that stakeholders should be aware that on the one hand

REACH is a great new source of information, but on the other hand REACH will often not generate appropriate data for the purpose of identifying acceptable risk limits. This may be due to a variety of reasons, both plausible and non-plausible ones. Plausible, for example, as the chemical substance does not fall under the REACH regulation or is not (yet) registered in REACH, or because there are principal, methodological differences between various policy frameworks. Non-plausible, for example, when there are no legal reasons not to submit a REACH-dossier or not to derive a risk limit, or when disregarding or missing a valid key study. These non-plausible reasons are in line with the results of other recent evaluations on REACH registration dossiers. One may anticipate discussions on risk limits and quality standards between

One may anticipate discussions on risk limits and quality standards between stakeholders, for example when handling permits or executing or implementing other parts of the redefined priority chemical policy framework. Our work also raises the more principle point that industry is claiming safe use of their chemicals with cut-off levels that in many cases differ from the ones that authorities are currently applying to protect man and environment from the risks of the same chemicals. This study addresses a number of issues that may be the

trigger for such dialogues, but, more importantly, we present a number of underlying reasons that may or may not explain these differences. This is expected to give input to these discussions. In addition, RIVM will prepare additional guidance on the usage of risk limits and environmental quality standards within the framework of priority chemicals in the Netherlands. These tools should provide further support to local and national authorities. This work may contain suggestions for REACH enforcement and control, but also for future evaluations of REACH in broader terms.

# Preface

# **Road-map Normstelling**

The Road-map Normstelling (Road-map Quality standard setting) is the long-range coordination scheme of the activities of RIVM to support the building of a new framework for setting environmental standards. The outputs of this Road-map contribute to the policy goals of the Ministry of Infrastructure and the Environment. This RIVM report 'Validity of REACH risk limits in the national policy framework on priority chemicals' is one of these outputs.

More information about the Road-map Normstelling: <a href="mailto:charles.bodar@rivm.nl">charles.bodar@rivm.nl</a>

# 1 Introduction

The Netherlands Ministry of Infrastructure and the Environment recently redefined its national policy on the risk management of priority substances (TK brief 29 juni 2011). Priority substances are those compounds that both meet the criteria of Substances of Very High Concern (SVHC) as defined in REACH (article 57)1 and are relevant for the Netherlands based on production, use and/or their actual presence in the environment. For these priority chemicals, the aim is that their environmental concentrations should be as low as possible on the long term, thereby not exceeding the negligible (risk) concentration (NC). The NC represents the concentration at which effects to ecosystems are expected to be negligible and functional properties of ecosystems are fully safeguarded. The NC is calculated by applying an additional factor of 100 to the Maximum Permissible (risk) Concentration (MPC). The MPC represents the concentration that protects man and environment from adverse effects due to chronic exposure. The NC includes a safety margin that pragmatically takes combination toxicity into account. The policy target is that in 2030 for all priority substances their concentrations in the environment are below the NC (inbetween target: in 2020 for 50 per cent of the priority chemicals this goals must

Various international policy frameworks, amongst others REACH and the Water Framework Directive (WFD), are already focused on the reduction of emissions for these substances. For chemicals falling under the REACH registration this means that the registrant should prove that for all identified/intended uses of a particular chemical the human and environmental risks are controlled towards acceptable levels. Emission reduction options can be part of the REACH-dossiers. WFD and REACH will thus contribute to meet the national policy targets, but additional emission reductions may in some cases nevertheless be needed (Van Herwijnen et al. (2010). Granters of permit applications play an important role in this national process.

For the implementation of the priority chemicals policy the availability of risk limits and/or environmental quality standards is an important issue. In the context of this report, environmental quality standards are values that have been officially set by the authorities. Risk limits are (scientifically) derived values that do not have such an official status. The introduction of REACH generated a large amount of data on chemicals, including risk limits such as the Predicted No Effect Concentration (PNEC), Derived No Effect Level (DNEL) and Derived Maximum Effect Level (DMEL). For each substance produced or imported in amounts > 10 tonnes per year the Chemical Safety Assessment should contain risk limits for the various protection targets (environment, workers and consumers).

Within the redefined national policy framework on priority chemicals a role is foreseen for these REACH risk limits. In case an environmental quality standard is missing for a particular substance, the use of the REACH risk limit should be considered in the permit or in enforcement strategies. It is emphasized, however, that already available legal or policy-approved quality standards should be preferred over the REACH risk limits.

Bodar et al. (2010) identified various relevant aspects for the generation of risk limits from REACH, including several points of interest when applying REACH risk

<sup>&</sup>lt;sup>1</sup> Zeer Zorgwekkende Stoffen (ZZS), as defined in De Poorter et al. (2011),

limits in other frameworks. Meanwhile the first REACH registration deadline for so-called phase-in substances has passed. For this batch of chemicals, the nonconfidential data (see Regulation EC/1907/2006, art. 118 en 119²) in the REACH-dossiers have been made publicly available through the website of the European Chemicals Agency (ECHA³). In this study the theoretical conclusions of the mentioned 2010-report are analysed 'in practice', and more specifically, the focus will be on the possibilities of the usage of REACH data in the redefined national priority chemicals policy framework. Two key questions will be addressed:

- 1. is it correct to assume that a REACH-registration dossier will provide alternative and usable information on risk limits in those cases where no environmental quality standard is available?
- 2. to what extent do REACH risk limits concur with already available legal or policy-approved environmental quality standards?

The first question is important because the presence of risk limits or standards is crucial for the implementation and execution of the policy framework on priority chemicals. If it shows that insufficient data become available from REACH, then potentially more efforts may be needed to generate data usable for permit authorities or to provide them with tools to generate such data in case EQS are lacking.

The second question relates to the above-mentioned starting point that when executing the policy, already available quality standards should be preferred over REACH risk limits. If large differences are revealed between current legal or policy approved standards on the one hand and REACH risk limits on the other hand, this implies that within REACH the safe use of chemicals is being controlled with limits that deviate from the values that the authorities intend to apply in the national policy framework on priority chemicals. This is a serious point of consideration, for example, at permit application, but it is also crucial to understand the potential reasons for the observed differences. Aim of this report is to highlight a number of aspects concerning the use of REACH data when further framing the redefined priority chemicals policy.

<sup>&</sup>lt;sup>2</sup> final consolidated version, 10 December 2011

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

# 2 Methods

### 2.1 Selection of chemicals

The primary focus of this study is an analysis at meta-level and not an in-depth analysis of the backgrounds of standard setting and/or derivation of REACH risk limits of individual chemicals. In some cases, however, individual chemicals will be mentioned for illustrative purposes. For such a meta-analysis it is needed to investigate a clearly defined group of chemicals. It was decided to execute the work on the former list of Dutch priority chemicals. The reasons are:

- 1. it is a limited group of substances related to a relevant policy framework ('well-defined sample');
- 2. it relates to chemicals for which in most cases relevant environmental quality standards (MPCs and NCs) are available;
- 3. it relates to chemicals that mostly meet the SVHC criteria (CMR, PBT, etc.), so there is a great chance that REACH-dossiers were submitted (deadline December 2010);
- 4. it relates to chemicals that are also relevant for the redefined priority chemicals policy framework. The outcomes of our study may be used to adapt its implementation.

The list of priority chemicals (2006) contains 207 entries. Some of those refer to groups of substances ('arsenic and arsenic compounds'), others to individual ones ('dichloromethane') or isomers of a chemical ('DDD, 2,4-isomere' and 'DDD, 4,4-isomere'). For reasons of simplicity we will not consequently discriminate between groups and individual compounds in this report. The entries 'fine particles' and 'course particles' are left out, as they do not refer to chemicals.

#### 2.2 Standards and risk limits used for comparison

REACH does not require the generation of a risk limit with a protection level that is equal or comparable to the NC, i.e. the target value of the priority chemicals policy framework. The safe use of a chemical is assessed in REACH with the PNEC for environment and either the DNEL or, in case of carcinogenic compounds without threshold, the DMEL for man. These protection levels equal the protection level of the Dutch MPC. The NC is defined as the MPC divided by 100 (NC=MPC/100). In order to make comparisons, this study therefore focuses on the MPC as legal or policy-approved quality standard and the REACH risk limits PNEC, DNEL and DMEL. This is done for the compartments freshwater and air. Risk limits for marine waters were not included because the number of marine environmental quality standards is limited, and it seldom occurs that there is a marine value, but no freshwater value for the same chemical. For air, in most cases the potential exposure of man, rather than ecosystem representatives determines the risk limit or standard. In practice this implies that if data are available for a comparison between REACH risk limits and Dutch standards, these comparisons are done between MPC and PNEC for freshwater, and between the MPC for air and inhalatory DNEL/DMEL for the general public.

#### 2.3 Information sources

The website 'Risico's van Stoffen' (RVS) (<a href="www.rivm/rvs.nl">www.rivm/rvs.nl</a>) is the official source for the current environmental quality standards (MPC, NC) in the Netherlands. All data on Dutch standards were retrieved from this website.

REACH dossiers were searched for in the ECHA database<sup>3</sup> via CAS-number and/or substance name (search was executed in Spring 2012). If a dossier was available, the risk limits were searched for in the dossiers by selecting 'ecotoxicological information' or 'toxicological information' in the menu (see Figure 1).

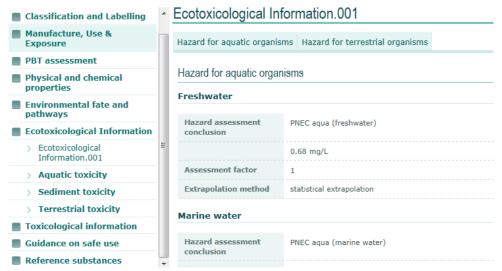


Figure 1. Example of the ECHA/REACH results screen in a REACH-dossier (screen shot 2013).

In case for a particular substance more than one dossier was available in the ECHA database, all individual values were used. When executing our study, information was disclosed for nearly all substances with a registration deadline of December 2010, *i.e.* substances meeting one or more of the following criteria: CMR cat. 1 and 2; > 1 tpa/R50-53; > 100 tpa/other; > 1000 tpa. In addition to data from the REACH-dossiers and the RVS-website we also investigated if for the particular chemical an EU Risk Assessment Report (EU-RAR) was made within the context of the former EC Regulation on Existing Chemicals 793/93. If so, the risk limits from the EU-RAR were also taken into account in the comparison.

All data for each individual chemical (or group) are presented in Tables A1 and A2 in Appendix 1.

# 3 Results and discussion

#### 3.1 Availability of REACH-dossiers

Out of a total of 207 former priority chemicals no REACH registration dossier could be found for 114 compounds (55 per cent) in the ECHA database (Figure 2). For 93 compounds (45 per cent) at least one dossier was available. In 28 cases (14 per cent) two or more dossiers were found, with a maximum of nine dossiers for the chemical methyloxirane.

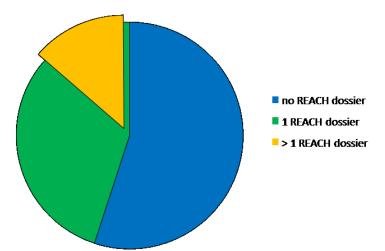


Figure 2. Availability of REACH-dossiers for a total of 207 entries on the list of former Dutch priority chemicals.

With respect to currently 'missing' dossiers, it should be mentioned that a number of substance categories is excluded from REACH registration obligations, either entirely or partly. There are several reasons for the 'missing' of dossiers. For example (for non-CMR chemicals), the registration deadline of the chemical is set later than December 2010, *i.e.* either 1 June 2013 or 1 June 2018. Further, the dossiers of the non phase-in substances that were notified under the former Substances Directive (67/548/EC) were not yet publicly available in the ECHA database. For those (groups of) substances that fall in these categories there is a clear, plausible reason why a REACH-dossier is currently lacking (see Text box 1). The detailed explanation of lacking REACH-dossiers for each individual substance is beyond the scope of this (meta)study.

# 3.2 Substance identity

For 49 out of the 207 entries (24 per cent) no MPC $_{\rm air}$  is found on the RVS-website and the same holds for the MPC $_{\rm water}$  in 50 cases (24 per cent). Examples are potassium bromate and lead acetate, lead diacetate and lead molybdate. For the compound lead environmental quality standards can be found on the RVS-website, whereas REACH-dossiers were submitted for lead (metal) and lead diacetate (metal ion). Both within REACH as in Dutch environmental standard setting frameworks choices have been made to group chemicals. In this case the standard for lead on the RVS-website covers various lead compounds. In the REACH-dossier of lead diacetate no risk limits are given, but they are available in the dossier on lead. Another example is vanadium pentoxide. At the RVS-website there is a water quality standard for vanadium in general, while there are separate

Text box 1. Substance categories being exempted from the registration requirements under REACH (Art 2).

### REACH does not apply to:

- radioactive substances
- substances under customs supervision
- non-isolated intermediates
- the carriage of dangerous substances
- waste (as no substance, preparation or article according to Art 3)
- chemicals exempted in the interests of defence

#### No registration duties for:

- substances with a production and/or import volume lower than 1 tonnes per year per manufacturer of importer
- substances used in human or veterinary drugs
- substances used as additive, flavouring agent, etc. in food or feed
- substances in Annex IV
- substances falling under Annex V
- registered substances, re-imported in the supply chain
- registered substances, recovered in the Community
- polymers
- plant protection products and biocidal products are considered as registered and evaluated according to Art 15 en 15; from a legal point of view they are not exempted from title II, registration duties under REACH.

### <u>Limited registration duties (Art 17 and 18):</u>

- on-site isolated intermediates
- transported isolated intermediates

REACH-dossiers for both vanadium pentoxide and vanadium. The latter dossier comprises the same ecotoxicity data as the dossier of vanadium pentoxide. These illustrations show that when searching information for a particular substance it is crucial that not only the CAS-number is used as search criterion, but also group names that may include that chemical. The other way around, if a risk limit is needed for a substance that may occur in several chemical forms, like metals, then these forms should be included in the search.

# 3.3 Availability of risk limits in REACH-dossiers

Out of 93 compounds with at least one REACH-dossier, 51 cases (55 per cent) do not contain a DNEL or DMEL, and in 33 cases (36 per cent) a PNEC freshwater is lacking (Figure 3). The dossiers without risk limits are not further studied on potential reasons for the lack of risk limits. This is without doubt a relevant issue, but it was outside the scope of this exploratory study. A plausible explanation could be that a particular route of exposure is not relevant with the intended use of the chemical, as there will be no emissions to that compartment. For example: the registrant does not include an inhalatory DNEL for the general public in the dossier, as for that particular chemical there is no discharge to outdoor air. In our study, we did not check whether in those cases the registrants actually give such exposure scenario waiving statement for not providing a DNEL/DMEL. However, according to REACH Annex 1 such exposure based waiving possibilities do not seem to be possible for the environmental PNECs.

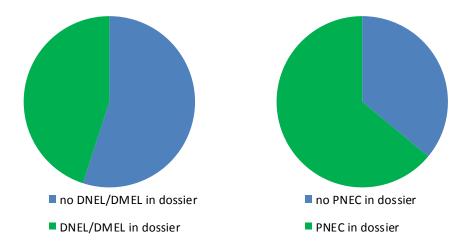


Figure 3. Presence or absence of a PNEC freshwater (left hand side) or DNEL/DMEL air (right hand side) in REACH-dossier.

#### 3.4 Differences between REACH-dossiers

As stated in section 3.1 there are 28 compounds with at least two dossiers. In these cases the results of the individual dossiers are separately presented in the Appendix. For the DNEL/DMEL risk limits in none of these cases differences were found between the dossiers: if there is more than one dossier, they all show the same DNEL/DMEL-value. More or less the same holds for the PNEC for water: if there are several dossiers, mostly only one of them presents a PNEC. In seven cases, several PNECs were found (25 per cent of the total number of compounds with two or more dossiers). In three of them the PNECs are equal, in two cases the difference is limited to a factor of less than 1.5 (28 and 40  $\mu$ g/L; 77 and 100  $\mu$ g/L). In the two remaining cases the difference amounts to more than a factor of 4 (130, 130 and 540  $\mu$ g/L) and almost 24 (80 en 1900  $\mu$ g/L).

# 3.5 Comparison DNEL/DMEL REACH and MPCair

For 25<sup>4</sup> compounds it is possible to compare the DNEL/DMEL from the REACH dossier with the current Dutch environmental quality standard for air. In 16 cases (64 per cent), the REACH value is more than a factor of 100 higher than the corresponding Dutch standard, in four cases (16 per cent) the difference amounts to a factor of 10-100. In another four cases the REACH risk limit is less than 10 times higher and in one case (4 per cent) the REACH value is equal to or below the Dutch environmental quality standard (see Figure 4).

<sup>&</sup>lt;sup>4</sup> As stated in section 3.2 for 42 (= 93-51) substances a DNEL or DMEL is available in the REACH dossier. However, only in 25 out of these 42 cases an actual comparison can be made, for example because a Dutch standard is missing for a particular compound (section 3.1)

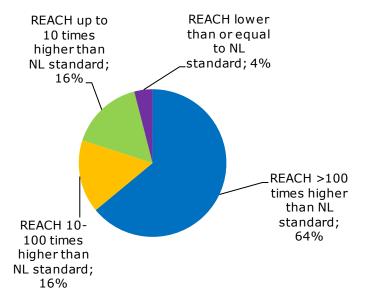


Figure 4. Difference between DNEL/DMEL-values for the general public from the REACH-dossier and the Dutch environmental quality standard for air (based on 25 entries on the list of former Dutch priority chemicals).

#### 3.5.1 Differences of more than a factor of 100

The group of chemicals with differences of more than a factor of 100 deserves further attention. In 14 out of 16 cases, the Dutch atmospheric environmental quality standard relates to a so-called 'indicative MPC' ('ad hoc MPC'), derived with the HUMANEX model. The HUMANEX model, which is no longer applied in the Netherlands, was used to integrate risk limits/standards for the compartments air, (ground)water, sediment and soil by means of equilibrium partitioning. It is known that this model on average results in very low (*i.e.* conservative) values (see also section 3.7). Re-evaluation of these standards may thus potentially result in higher values, and smaller differences as compared to the risk limits derived under REACH. However, for two substances the use of HUMANEX does not offer an explanation for the large difference between the REACH risk limit and the Dutch quality standard. In one case (tetrachloroethylene) the Dutch standard is set at a WHO-limit value, whereas in the other case (toluene) the Dutch standard was not based on HUMANEX.

#### 3.5.2 Other differences

Irrespective of the influence of the use of HUMANEX (see 3.4.1), it can be concluded that the DNEL/DMEL values from the REACH-dossiers are in most cases higher than the current Dutch air standards. There may be variety of explanations for these higher DNEL/DMEL values:

- 1. the derivation of the DNEL/DMEL is based on a different set of data.
- 2. the derivation of the DNEL/DMEL is based on the same data set, but on a different key study.
- the derivation of the DNEL/DMEL is based on the same data set and key study, but a different safety factor was applied. From an earlier internal RIVM study, it was concluded that in many cases other safety factors were used by registrants than those recommended in the REACH guidance (personal communication A. Muller, RIVM).

4. there is a difference in the interpretation of the mode of action. Should the chemical be regarded as a non-threshold carcinogen, and, if yes, which level of cancer risk should then be used?

A further investigation into the reasons for differences encountered for the individual substances is outside the scope of this exploratory study. It is noted that the latest version of the ECHA website displays some information on the derivation of the DNEL/DMEL (e.g. the critical endpoint and assessment factor) which can be used for this purpose. It should be realised, however, that an evaluation of the risk limit derivation in REACH requires specific skills with respect to human toxicological risk assessment. Furthermore, it is probably needed to consult confidential information to fully understand the choices made by the applicant.

# 3.6 Water: comparison REACH PNEC and MPC<sub>water</sub>

In  $49^5$  cases it was possible to compare the PNEC<sub>water</sub> from REACH with the Dutch MPC in water. There are more than one REACH-dossiers for a number of compounds with either the same or different PNECs (see section 3.2). These are separately taken into account in our comparison, which in total refers to 42 different compounds. Figure 5 shows that in 11 cases (22 per cent) the REACH risk limit is more than a factor of 100 higher than the Dutch standard. In nine cases (18 per cent) the difference amounts to a factor of 10-100 and for 16 compounds (33 per cent) the difference is lower than a factor of 10. Finally, in 13 cases (27 per cent) the REACH-value is equal to or lower than the Dutch environmental quality standard in water.

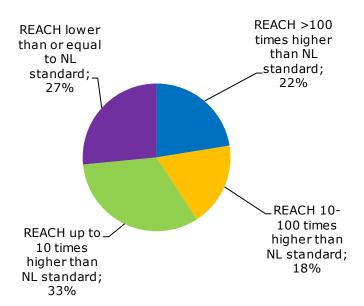


Figure 5. Differences between freshwater PNEC from REACH-dossiers and the Dutch environmental quality standard (based on 42 entries on the list of former Dutch priority chemicals).

The differences between PNEC and MPC for water are smaller than those between the inhalatory DNEL/DMEL and the MPC $_{air}$ . The reason is most probably that the national water quality standards were more often derived with a more

<sup>&</sup>lt;sup>5</sup> See footnote 4. Comparable situation for water.

refined methodology than the indicative method. Cases with a difference of more than a factor of 100 again mostly relate to an indicative MPC based on HUMANEX. There are also cases, however, in which HUMANEX resulted in a higher indicative MPC than would be expected on the available ecotoxicity data. The most illustrative example for this is the substance hydrochinon. For this substance the REACH PNEC<sub>water</sub> amounts to 0.11  $\mu$ g/L, whereas the indicative MPC for direct ecotoxicity is 0.04  $\mu$ g/L (factor of 2.9 difference). The current ad hoc MPC<sub>water</sub> based on HUMANEX is 49.6  $\underline{m}$ g/L, being more than 200 times higher than the PNEC from the REACH-dossier. This is caused by the integration of the human toxicological risk limit with that for ecotoxicity.

In a number of other cases, among which several priority chemicals included in Directive 2008/105/EC<sup>6</sup>, under the WFD, secondary poisoning or human consumption of fish were the critical exposure routes that determined the environmental quality standard in water. These exposure routes are not taken into account in the PNEC<sub>water</sub> from REACH that 'only' relates to direct ecotoxicity. Within REACH, potential risks for predators or man via indirect exposure are taken into account in the risk assessment, but no separate risk limits are derived for these routes. If the REACH PNECs would be compared with the corresponding values for direct ecotoxicity derived under national or European standard setting process, the differences would become smaller. In that case, the number of cases with a REACH value higher than the Dutch ones goes down from 73 per cent to 53 per cent. The number of cases with a difference of more than 100 decreases from 22 per cent to 14 per cent.

Although the differences become smaller, this still does not imply that in those cases the REACH risk limit can be used in policy or enforcement activities. The chemicals under consideration mostly meet the criteria for SVHC (*i.e.* CMR and/or PBT chemicals). Because of this, the exposure routes secondary poisoning and fish consumption have to be taken into account for standard setting following the current WFD methodology in addition to evaluating direct ecotoxicity to water organisms. This does not automatically mean that these exposure routes will eventually determine the overall standard, although this holds quite often for non-threshold carcinogens. However, these routes have to be evaluated in every case, which requires specific knowledge on both deriving an oral human risk limit and interpreting data on bioconcentration and bioaccumulation.

### 3.7 Comparison of REACH PNEC and EU-RAR PNEC

In 14 cases there is a PNEC water available from an EU-RAR. If present, the REACH PNEC mostly equals the PNEC in the EU-RAR. There are, however, some significant deviations. One of the two REACH-dossiers for benzene reports the PNEC of 80  $\mu$ g/L from the EU-RAR, that is also used for the derivation of the Dutch environmental quality standard, but the dossier data only refer to QSAR estimates that do not relate to this PNEC. The other REACH-dossier presents a PNEC of 1.9 mg/L, while the key-study from the EU-RAR (NOEC 0.8 mg/L) is included in the dossier, and is also classified as reliable. In this case the PNEC is more than two times higher than the lowest NOEC in the dossier (without safety factor). According to the information on the ECHA-website, the registrant has applied statistical extrapolation with an assessment factor of 1 instead of using the lowest NOEC with an assessment factor of 10 as was done in the EU-RAR. Another example is toluene: the PNEC water in the REACH-dossier amounts to 680  $\mu$ g/L, which is almost 10 times higher than the PNEC in the EU-RAR and the

<sup>&</sup>lt;sup>6</sup> This refers to chemicals assigned as priority chemicals or priority hazardous chemicals under WFD.

Dutch standard of 74 µg/L. Also in this case the key study from the EU-RAR (NOEC 0.74 mg/L) is included in the dossier. Again, applying statistical extrapolation without an assessment factor seems to be the reason for the difference. Whether these differences would in practice result in different conclusions when granting permits, etc. cannot be judged. Fact is, however, that these REACH-dossiers deviate from the conclusions earlier drawn by EU Member States, despite the fact that the underlying data are similar. Again, it is noted that an evaluation of the causes for the observed differences requires specific skills, and additional information that is not available in the public part of the dossier.

#### 3.8 Discussion

In this section we discuss a number of technical issues related to the availability of data from REACH and the observed differences between risk limits from REACH registration dossiers and Dutch quality standards. In addition, we shortly raise some other points, a.o. the comparison of our findings with those from other REACH-evaluation studies. Policy-related items are brought forward in Chapter 4 General conclusions and recommendations.

#### 3.8.1 Availability of information

The availability of substance information is strongly improved with the publication of the digital REACH-dossiers on the ECHA-website. Numerous internal data that was not publicly disclosed in the past, are now available. Although the dossiers on the ECHA-website include test summaries and not the original test reports, these summaries report much more details than before on test conditions, etc.

However, for almost half of the compounds in this study no REACH-dossier could be found. This relates to a certain extent (not further investigated) with the exemption rules for REACH registration, for example for plant protection products and (veterinary) drugs. In those cases there is a legal and sound argument for the absence of a dossier. Also under the redefined priority chemicals policy framework there will be chemicals beyond the REACH registration obligations. It is obvious that for these chemicals REACH will not generate risk limits.

In case a REACH-dossier is available, it does not provide a DNEL/DMEL in more than half of the cases. The same holds for the PNEC $_{\rm water}$  for more than one third of the substances. Only in case of DNEL/DMEL risk limits this may be explained by the fact that the registrant considers a particular exposure route as not relevant for a chemical (exposure based waiving: see section 3.2). This implies that the presence of a REACH-dossier does not guarantee the availability of 'ready-to-use' risk limits for these chemicals. We did not further examine if the dossier did contain any additional data that could be used to derive a risk limit or quality standard. Even if this would be the case then additional effort should be made to derive such value from the REACH information. ECHA has indicated that certain data entries cannot automatically be transferred from IUCLID to the public database. This may be the case, for example, if the registrant decides, wittingly or unwittingly, to include the risk limits for their substance in another numeric IUCLID field.

# 3.8.2 Differences between REACH risk limits and Dutch quality standards

The comparison between inhalatory DNEL/DMELs for the general public from the REACH-dossiers and the Dutch environmental quality standards for <u>air</u> points to large differences. In most cases the REACH risk limits numerically exceed the

current national standards. There may be several explanations as indicated in section 3.4.1.

One reason is the (former) use of the HUMANEX model when deriving indicative MPCs, resulting in very low values. The underpinning of these values is questionable. In addition, it should be realised that in most cases Dutch air standards were derived using a default value for human toxicity because adequate animal/experimental data were not present. The DNEL/DMELs in REACH-dossiers are mostly based on experimental studies. It is not clear, however, if the dossier includes all available information, and if the information has been correctly evaluated and applied. The dossiers do contain in any case more data than the data available for the derivation of indicative MPCs. Next to differences in availability of underlying data, differences in the evaluation and interpretation of studies, and the choice of correction- and safety factors may also play a role. There are indications (see section 3.4.2) that for the derivation of DNEL/DMELs in REACH other safety factors (e.g. correcting for interspecies differences) are used than recommended in the EU REACH guidance documents. This will, however, probably not result in large differences (within a factor of 5). Finally, different protection levels may have been applied for nonthreshold carcinogens  $(10^{-4}/10^{-5}/10^{-6})$ . Similar findings were also noted in the workshop on "Chemicals at the workplace: REACH and OSH in practice" held in October 2012 at ECHA (ECHA, 2012a). It was found that REACH risk limits are a meaningful source of information for downstream users in deriving their occupational exposure limits within the framework of the Chemical Agents Directive. Nevertheless, it was concluded that the DNELs and DMELs available in REACH dossiers and communicated down the supply chain in the Safety Datasheet should be treated with care. The main reasons are that the safety factors and correction factors applied are laid down in REACH guidance, but may be applied differently by registrants, and the (toxicological) points of departure may differ between various registrations for a single substance (the information basis and/or interpretation of key studies not necessarily being the same). Finally, the publicly disseminated information does not allow an easy verification of correction and assessment factors and points of departure. Also for the water compartment differences were shown between REACH risk limits and environmental quality standards (section 3.5). These differences were found to be not as large as for air. A major reason for differences encountered for the water compartment lies in the different 'receptors' to be protected. Whereas the PNEC from REACH is based on direct ecotoxicity, the WFD water quality standard additionally integrates secondary poisoning of (top)predators and human exposure via fish consumption. This is a serious point of attention, because for those chemicals that meet the SVHC-criteria, in all cases secondary poisoning and fish consumption should be examined carefully when deriving quality standards. These exposure routes are by definition not included in the REACH PNEC. This automatically results in a serious limitation in directly using PNECs from REACH in the redefined priority chemicals policy framework. The former use of the HUMANEX model when deriving indicative MPCs explains also for water a part of the observed differences.

#### 3.8.3 Other discussion points

We did not systematically investigate whether the contents of industry's REACH-dossiers differ from registration dossiers or risk assessments as prepared and/or assessed by authorities in other frameworks. The limited comparison for the  $PNEC_{water}$  with the former existing chemicals framework shows that there is mostly consistency. In those cases the information from the EU-RAR (EC regulation 793/93) is one-to-one transferred to the REACH-dossier. It should be

borne in mind, however, that REACH explicitly puts responsibility on the shoulders of producers/importers, and this may imply that one can deviate from conclusions on risk limits that were drawn before. This seems not so much related to the availability of other data, but to a deviating interpretation and use of them. Section 3.6 gives some examples on this for the compounds benzene and toluene (water). EU-RAR data thus seem to have been used in the REACH-dossiers. This in contrast to the derivations of environmental quality standards for priority and priority hazardous compounds under WFD.

In our study we did not find more than one DNEL/DMEL value for the same substance (or substance group). For the PNEC<sub>water</sub>, inconsistencies were observed between dossiers for the same compound. In general, these differences were not large, although in one case the PNECs in the respective dossiers differed by a factor of 24. A bigger issue is that it is not easily possible to see how the PNEC was derived. In some cases we were not able to link the PNEC to the most critical endpoint in the dossier. Bodar et al (2010) already referred to the possibility of disclosing more than one risk limit for the same compound in REACH. It appears to occur in practice and it goes without saying that it may cause difficulties in the near future, e.q., discussions on level playing field in EU. We put the issue forward to ECHA. ECHA reacted as follows: "The database displays the information by registration dossier in which it is contained. Manufactures or importers of the same substance have the obligation to submit certain information for the substance jointly to ECHA. However, under certain conditions or circumstances, companies may submit this information separately. The separate submission of data may result in the display of several entries in the database." The point was also discussed at the recent REACH-OSH workshop (see above) and by Püringer (2012; see below).

In the ECHA Evaluation report 2011, ECHA listed a large number of items that were found incomplete or missing in the dossiers for which a compliance check was carried out. Out of the 146 completed dossiers, 105 dossiers were concluded with a final decision requesting the registrant to provide further information. Additional information regarding identification and verification of the composition of the substance is most frequently asked for, exposure assessment and DNELs are among the other items that should be further addressed by the registrants (ECHA, 2012b). The European Commission recently reflected that the PNEC or DNEL derivation is one of the main identified shortcomings in the Chemical Safety Report (CSR) of evaluated REACH dossiers (European Commission, 2013).

Whereas the ECHA evaluation focused on a broad spectrum of issues, Püringer (2012) focused on occupational DMELs and evaluated the public information for 293 carcinogenic or mutagenic substances with a total of 368 registrations. He observed that for 61 per cent of the registrations no summary endpoint was available. When taking into account that the obligation to register is not applicable to part of the substances, still for 23 per cent of the substances with a full registration a limit value was lacking. Other conclusions from his evaluation seem to be in line with certain findings in our study, for example, a mismatch between the risk limit and the mode of action of the compound and differences between limit values for the same substance between dossiers.

# 4 General conclusions and recommendations

In Chapter 1 two study goals were defined:

- is it plausible to assume that in case no legal or policy-approved environmental quality standard is available, REACH will provide alternative risk limits?
- 2. to what extent are REACH risk limits in line with current legal or policy-approved environmental quality standards?

Based on this 'sample' with the former list of Dutch priority chemicals the following answers can be formulated:

- a REACH-dossier is lacking in more than half of the cases. If one or more
  dossiers are present then in 36 per cent percent of the cases no risk limit
  for water is included. In 55 per cent of the cases there is no DNEL/DMEL for
  air. In case official standards are lacking the REACH-dossiers will thus not
  provide relevant information for a considerable part of the investigated
  chemicals.
- 2. if a comparison can be done, it shows that for the <a href="atmospheric">atmospheric</a> compartment in 95 per cent of the cases the REACH risk limit is numerically higher than the Dutch environmental quality standard. In 5 per cent of the cases the REACH value is lower than or equal to the Dutch standard. For <a href="water">water</a> these percentages are 73 per cent and 27 per cent, respectively.

Our main message is that stakeholders should be aware that on the one hand REACH is a great new source of information for chemicals, but on the other REACH will not always generate the appropriate data and/or make it publicly available. This may be due to a variety of reasons, both plausible and non-plausible ones. Plausible, for example, as the compound does not fall under the REACH regulation, or because there are principal, methodological differences between various frameworks. Non-plausible, when there are no legal reasons not to submit a REACH-dossier or not to derive a risk limit, or when disregarding or missing a valid key study. Several of these shortcomings on the completeness and/or quality of REACH registration dossiers are in line with the results of recent evaluations by, amongst others, ECHA.

When executing the redefined priority chemicals policy framework in the near future the rule-of-thumb is that REACH risk limits will be used unless legal or policy-approved environmental quality standards are present. In the latter case these standards are binding. This study shows that for various reasons this general rule should be 'handled with care'. One may anticipate discussions on risk limits and quality standards between stakeholders, for example when handling permits or executing or implementing other parts of the redefined priority chemical policy framework. Our work also raises the more principle point that industry is claiming safe use of their chemicals with cut-off levels that in many cases differ from the ones that authorities are currently applying to protect man and environment from the risks of the same chemicals. This study addresses a number of issues that may be the trigger for such dialogues, but, more importantly, we present a number of underlying reasons that may or may not explain these differences. This is expected to give guidance to these discussions.

A crucial item is of course the issue of responsibility. This is beyond the scope of our study, but it notwithstandingly determines the way forward. Generally speaking, for the group of chemicals that is subject in our study (CMR, PBT,

etc.) authorities will remain responsible for risk management to safeguard man and environment. This to be done, however, in close interaction with other stakeholders, and making use as much as possible of information generated by others. Beyond doubt, REACH is a more than promising and useful source for that information supply.

RIVM is currently preparing additional guidance on the usage of risk limits and environmental quality standards within the framework of priority chemicals in the Netherlands. These tools should provide guidance to local and national authorities. Legal environmental quality standards should prevail in all circumstances, e.g. the WHO or WFD standards. When only a policy-approved standard is available, it is important to distinguish between indicative values based on the HUMANEX methodology and other values. In the former case, the derivation of a new value according to the revised methodology is essential (and also already accepted by policy makers). In that case, but also when no legal or policy-approved standard is available, a strategy should be made for potentially using the REACH risk limits with or without adaptation.

This study focused on the use of REACH information when executing the national policy on priority chemicals. We based our conclusions on a relatively small group of compounds. It seems useful to investigate to what extent these results can be extrapolated to a larger group of chemicals. Our work may also contain suggestions for REACH enforcement and control, but also for future evaluations of REACH in broader terms. As stated above, a number of our findings are in line with those recently reported by ECHA and the European Commission. Only a stringent following of the action points as recommended at European level will eventually result in an overall quality improvement of REACH dossiers

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# Appendix 1. Risk limits from REACH and Dutch standards

Table A.1. Availability and comparison of DNEL/DMELs (air-human) for priority substances (inhalation, general population). Partly in Dutch language. Search was executed in Spring 2012.

SUBSTANCE	REACH			NL-			REMARKS
				ERL MPC	Standard	key study	
	Dossiers			rir C		Study	
Anorganische fluoriden (µg/m3)	0				0.05		RvS: in herziening
Arseen en arseenverbindingen (μg/m3)	0				0.5		
Arsene pentoxide	0				n.d		
Diarsenic trioxide	1	nd			nd		
Arsenic acid	1	nd			nd		
Calcium arsenate	1	nd			nd		
Lead hydrogen arsenate	0				nd		
Beryllium	1	nd			nd		
Beryllium oxide		nd			nd		
Cadmium (µg/m3)	1	nd	nd	?	0.005		
Cadmium fluoride	0				nd		
Cadmium sulphide	1	nd			nd		
Trichlorobenzenes	0				nd		
1,3,5-Trichlorobenzene (µg/m3)	0				9.24		RvS: ad-hoc MTR
1,2,4-Trichlorobenzene (µg/m3)	1	nd	nd	10.3	10.3	N	RvS: ad hoc MTR
1,2,3-Trichlorobenzene (µg/m3)	1	nd			3.86		
1,4-Dichlorobenzene	1	nd			nd		
Hexachlorobnzene (µg/m3)	0				1.16E-4		RvS: ad-hoc MTR
Pentachlorobenzene (µg/m3)	0				0.071		RvS: ad-hoc MTR
Pentachlorophenol (µg/m3)	0				3.07E-5		RvS: ad-hoc MTR
Chromium (ng/m3)	1	nd			2.5		RvS: in revision
Chromylchloride	0				nd		
Chromiumoxide	2	nd			nd		
Chromium acid	0				nd		
Potassium dichromate	2	nd			nd		
Chromium(VI) verbindingen	0				nd		
DDD, 2,4'-isomeer (µg/m3)	0				2.63E-5		RvS: ad-hoc MTR
DDD, 4,4'-isomeer (µg/m3)	0				2.38 E-6		RvS: ad-hoc MTR
DDE, 2,4'-isomeer (µg/m3)	0				1.14E-5		RvS: ad-hoc MTR
DDE, 4,4'-isomeer (µg/m3)	0				1.35E-5		RvS: ad-hoc MTR
DDT, 2,4'-isomeer (µg/m3)	0				2.8E-8		RvS: ad-hoc MTR
DDT, 4,4'-isomeer (µg/m3)	0				4.32E-6		RvS: ad-hoc MTR
Dioxins	0				nd		
Aldrin (µg/m3)	0				3.63E-5		RvS: ad-hoc MTR
Dieldrin (μg/m3)	0				5.22E-5		RvS: ad-hoc MTR
Endrin (µg/m3)	0				1.07E-4		RvS: ad-hoc MTR

					RvS	Juine	REMARKS
			RAR		Standard	key	
				MPC		study	
11 ( ( 2)	Dossiers				0.405.4		
sodrin (µg/m3)	0				3.12E-4		RvS: ad-hoc MTR
Endosulphan (µg/m3)	0			<u> </u>	0.043		RvS: ad-hoc MTR
Alpha-endosulphan	0				nd		
Vonylfenolen	0			<u> </u>	nd		
p-nonylphenol (μg/m3)	0			<u> </u>	0.57		RvS: ad-hoc MTR
Octylfenolen	0				nd		
para-tert-octylfenol (µg/m3)	1	600		<u> </u>	2.11E-5		RvS: ad-hoc MTR
2,4,6-tri-tert-butylphenol	1	nd			1.03E-6		RvS: ad hoc MPC
ijn stof	?						
Phosfates (mg/m3)	6	0.9 / 0.9 / nd			nd		
Bis(2-ethylhexyl) phthalate (µg/m3)	2	nd / 670	nd	?	0.00724	?	RvS: ad hoc MPC
Dibutyl phthalate (mg/m3)	4	nd / 0.62	nd	0.00 01	nd	N	
Pentabroomdifenylether	0				nd		
lexabroombifenyl (μg/m3)	0				4.06E-6		RvS: ad-hoc MTR
Pentabroomethylbenzeen (µg/m3)	0				7.63E-6		RvS: ad-hoc MTR
?-Propeenzuur-(pentabroomfenyl)methylester (µg/m3)	0				7.43E-7		RvS: ad-hoc MTR
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (µg/m3)	1	174000	nd		0.0271	N	RvS: ad hoc MPC
,3,5-Tribroom-2-(2,3-dibroom-2-methylpropoxy)benzeen (µg/m3)	0				8.01E-6		RvS: ad-hoc MTR
Alkanes, C10-13, chloro (mg/m3)	1	8.7			nd		
Bromomethane (µg/m3)	0				100		
,2-Dibromoethane (ng/m3)	1	1150000	nd	2	0.0383		REACH: long term local effect. Also short term systemic effect: 2000000 ng/m3 / ERL: MPChuman,air
.,2-Dichloroethane (µg/m3)	1	nd	nd	nd	100		REACH: only DMEL (2.9 µg/m3) available // RvS: in revision
Dichloromethane (mg/m3)	3	nd / 88.3	nd				RvS: in revision
						/ N	
Hexachlorobutadiene (µg/m3)	0				3.90E-3		RvS: ad-hoc MTR
Pentachloroethane (µg/m3)	0				5.85E-2		RvS: ad-hoc MTR
.,1,2,2-tetrachloroethane (μg/m3)	0				94.2		RvS: ad-hoc MTR
etrachloroethylene (mg/m3)	1	34.5	nd	0.00 92	0.25	N	RvS: in revision
etrachloromethane (mg/m3)	1	1.6	nd		0.06	N	
.,1,1-Trichloroethane (mg/m3)	1	nd	nd	13	4.8	N	RvS: in revision
richloroethylene (mg/m3)	2	13.7 / nd	nd	nd	5	N/N	RvS: in revision
richloromethane (mg/m3)	1	0.18	nd	nd	0.1	N	
Bromoethylene (µg/m3)	1	nd			10.4		RvS: ad-hoc MTR
Chloroethylene (µg/m3)	3	nd	nd	0.03 6	100	N / N / N	REACH: in 2 registrations a DMEL available (0.002 mg/m3; 1.9 mg/m3) / RvS: in revision
2-Ethoxyethanol (ng/m3)	1	nd		ĺ	5.87		RvS: ad-hoc MTR
2-Ethoxyethylacetate (µg/m3)	0		1		3.57E-3		RvS: ad-hoc MTR
-Methoxyethanol (μg/m3)	1	1600	nd	0.01 24			RvS: ad hoc MPC
P-Methoxyethylacetate (µg/m3)	0				6.16E-4		RvS: ad-hoc MTR
2-Methoxypropanol (µg/m3)	0		İ		6.71E-4		RvS: ad-hoc MTR
Grof stof	?				nd		

SUBSTANCE	REACH		EU-		RvS		REMARKS
			RAR		Standard	key	
	Dossiers			MPC		study	
Hexachlorocyclohexane (µg/m3)	Dossiers				2.52E-5		RvS: ad-hoc MTR
gamma-Hexachlorocyclohexane (µg/m3)	0		1		2.32E-3 2.19E-4		RVS: ad-hoc MTR
	2	16.6 / nd	-	<u> </u>	nd		
Cobalt sulphate (µg/m3) Cobalt dichloride (µg/m3)	1	13.9	1		nd		REACH: DNEL for long-term local effects. Systemic effects not available REACH: DNEL for long-term local effects. Systemic effects not available
Copper (mg/m3)	1	18.2	nd	2	nd		REACH: short term systemic effect, for long term no sufficient data
Mercury (mg/m3)	1	0.004	nd	?	nd		REACH. Short term systemic effect, for long term no sunicient data
Lead (µg/m3)	1	nd	nd	1:	0.5		RvS: EU-grenswaarde
Lead acetate	<u>  1</u>	IIu	IIU		nd		RV3. LO-grenswadrue
Lead diacetate	11	nd			nd		
Lead molybdate	0	nu			nd		
Dilead dirhodium heptaoxide	0	+	<del>                                     </del>	<del>                                     </del>	nd	1	
Nickel (µg/m3)	1	0.02	nd	2	0.25	7	RvS: in revision, based on lifetime risk of 1:10.000
Dinickel trioxide	0	0.02	iiu	<del>l'</del>	nd	+	IN TOTAL DUSCO ON MICHINE HISK OF 1.10.000
Nickel monoxide (µg/m3)	1	0.02			nd	1	
Nickel sulphide (µg/m3)	1	0.02	1	1	nd	1	
Tetracarbonylnickel	0	0.02			nd	1	
2,3-Dinitrotoluene (µg/m3)	0				7.16E-5		RvS: ad-hoc MTR
2,4-Dinitrotoluene (µg/m3)	0				2.01E-6		RvS: ad-hoc MTR
2,5-Dinitrotoluene (µg/m3)	0				9.55E-5	1	RvS: ad-hoc MTR
2,6-Dinitrotoluene (µg/m3)	0				3.79E-5		RvS: ad-hoc MTR
3,5-Dinitrotoluene (µg/m3)	0				2.23E-4	1	RvS: ad-hoc MTR
Tributyltin	0				nd	1	INST dd Hoc FFFX
Tributyltin cation (µg/m3)	0				0.02		RvS: ad-hoc MTR
Tributylvinylstannane	0				nd		INST dd Hoc Fffix
Azocyclotin (µg/m3)	i o				2.64E-9		RvS: ad-hoc MTR
Fentin hydroxide (µg/m3)	0				1.31E-7		RvsS: ad-hoc MTR
Fentin acetate (µg/m3)	0				3.72E-9		RvsS: ad-hoc MTR
Epichlorhydrin (µg/m3)	2	1520 / nd	nd		0.189		RvS: ad hoc MPC
Methyloxirane (mg/m3)	9	nd / 1.7	nd	?	0.09	?	REACH: other 8 studies no data / RvS: Indicatieve norm
Oxirane (µg/m3)	6	nd .	nd	?	3	?	RvS: in revision
PCBs	0				nd		
PCTs	0				nd		
Anthracene (µg/m3)	1	nd			1.59		RvS: ad hoc MPC
Naphthalene (µg/m3)	1	nd			8.89		RvS: ad hoc MPC
Other PAHs	0				nd		
Heptachloronaphthalene (µg/m3)	0				2.30E-5		RvS: ad-hoc MTR
Hexachloronaphthalene (µg/m3)	0				5.05E-5		RvS: ad-hoc MTR
Octachloronaphthalene (µg/m3)	0				1.64E-5		RvS: ad-hoc MTR
Penthachloronaphthalene (µg/m3)	0				2.88E-5		RvS: ad-hoc MTR
Tetrachloronaphthalene (µg/m3)	0				7.46E-5		RvS: ad-hoc MTR
Trichloronaphtalene (µg/m3)	0				1.87E-3		RvS: ad-hoc MTR
Naphthalene, chloro derivs.	0				nd		
Zinc (mg/m3)	2	nd / 2.5			nd		
Chloroquine bis(phosphate) (µg/m3)	0				6.11E-7		RvS: ad-hoc MTR
Clotrimazole (µg/m3)	0				7.74E-7		RvS: ad-hoc MTR

SUBSTANCE	REACH		EU-	NL-	RvS	Same	REMARKS
	11271011					key	
				MPC		study	
	Dossiers						
Miconazole nitrate (μg/m3)	0				3.43E-7		RvS: ad-hoc MTR
Estradiol (µg/m3)	1	nd			1.03E-12		
Diethylstilbestrol (µg/m3)	0				1.39E-9		RvS: ad-hoc MTR
(20R,25R)-spirost-5-en-3β-ol (μg/m3)	0				9.03E-7		RvS: ad-hoc MTR
Estrone (µg/m3)	2				4.0E-9		RvS: ad hoc MPC
Ethinylestradiol (µg/m3)	0				8.44E-13		RvS: ad hoc MPC
Alachlor (µg/m3)	0				3.83E-4		RvS: ad hoc MPC
Atrazine (µg/m3)	1	nd			6.48E-6		RvS: ad hoc MPC
Aziridine (µg/m3)	3	nd			0.0498		RvS: ad hoc MPC
Chlordane (µg/m3)	0				9.86E-4		RvS: ad hoc MPC
Chlordecone (µg/m3)	0				2.16E-11		RvS: ad hoc MPC
Chlorfenvinphos (µg/m3)	0				2.3E-8		RvS: ad hoc MPC
Chlorpyrifos (ng/m3)	0				0.0194		RvS: ad hoc MPC
Dicofol (µg/m3)	0				5.29E-7		RvS: ad hoc MPC
Diuron (µg/m3)	1	nd			3.1E-7		RvS: ad hoc MPC
O-ethyl O-4-nitrophenyl phenylphosphonothioate (µg/m3)	0				3.03E-9		RvS: ad hoc MPC
Fenitrothion (µg/m3)	0				5.68E-6		RvS: ad hoc MPC
Fenvalerate (µg/m3)	0				8.65E-11		RvS: ad hoc MPC
Flucythrinate (µg/m3)	0				3.34E-10		RvS: ad hoc MPC
Heptachlor (µg/m3)	0				8.41E-5		RvS: ad hoc MPC
Heptachlor norbornene (ng/L)	0				4.19		RvS: ad hoc MPC
Isoproturon (µg/m3)	0				1.22E-4		RvS: ad hoc MPC
Methoxychlor (µg/m3)	0				0.019		RvS: ad hoc MPC
DNOC (µg/m3)	1	nd			9.94E-4		RvS: ad hoc MPC
Mirex (ng./m3)	0				5.73		RvS: ad hoc MPC
Nitrofen (ng/m3)	0				1.24		RvS: ad hoc MPC
Simazine (µg/m3)	0				3.01E-5		RvS: ad hoc MPC
Tetrasul (ng/m3)	0				2.92		RvS: ad hoc MPC
Toxaphene (µg/m3)	0				4.01E-6		RvS: ad hoc MPC
Triclocarban (µg/m3)	0				5.73E-9		RvS: ad hoc MPC
Trifluralin (ng/L)	0		1		2.62	1	RvS: ad hoc MPC
Acrolein (µg/m3)	1	nd	nd	0.5	0.5	N	No. da noci il c
Acrylonitrile (µg/m3)	1	60	nd	0.09		N	RvS: in revision / REACH: long-term local effects. DNEL for long-term systemc effects is 100 ug/m3.
Ammonia (mg/m3)	1	2.8			nd		REACH: DNEL for long-term local effects. DNEL for long-term systemic effects is 23.8 mg/m3.
Aniline (µg/m3)	1	nd	-	1	5.24E-4	<u> </u>	RvS: ad hoc MPC
Asbestos	0			1	100000		RvS: vezeleguivalenten/m3; norm in herziening.
Benzene (mg/m3)	3	nd	nd	0.09	0.005	2/2/	RvS: EU grenswaarde. Streefwaarde = 0.001 mg/m3
, ,	3					N	-
1,3 Butadiene (µg/m3)	2	nd	nd	0.03		N/N	MPC = TCA // Ad hoc MTR
2-Butenal (ng/L)	0	ļ		1	4.36	1	RvS: ad hoc MPC
Chloroacetaldehyde (µg/m3)	0	<b>.</b>		1	6.43E-2		RvS: ad hoc MPC
Chloromethylbenzene (µg/m3)	1	nd		1	1.65E-2		RvS: ad hoc MPC
Cyclododecane (µg/m3)	1	nd		1	9.28E-5		RvS: ad hoc MPC
1,5,9-cyclododecatrieen (μg/m3)	2	nd	l	1	1.53E-2		RvS: ad-hoc MTR

SUBSTANCE	REACH				RvS		REMARKS
			RAR	ERL MPC	Standard	key study	
	Dossiers			MFC		Study	
3,3'-dichloorbenzidine (µg/m3	0				6.81E-9		RvS: ad-hoc MTR
diethylsulfaat, diethylsulfaatester (µg/m3)	2	nd			5.11E-3		RvS: ad-hoc MTR
4-(dimethylbutylamino) difenylamine (µg/m3)	1	1700			1.32E-5		REACH: long-term systemic effects. RvS: ad-hoc MTR
dimethylsulfaat (µg/m3)	7	nd			1.83E-3		RvS: ad-hoc MTR
ethaandial (µg/m3)	1	20			0.0502		REACH: long-term, local effects; RvS: ad-hoc MTR
etheen (µg/m3)	2	nd			80		RvS: MTR in herziening.
ethyleenthioureum (µg/m3)	1	300			6.89E-9		REACH: long-term systemic effects; RvS: ad-hoc MTR
fenylhydrazine (µg/m3)	1	nd			4.96E-12		RvS: ad-hoc MTR
formaldehyde (µg/m3)	2	100 / nd			10		REACH: long-term local effects; RvS: MTR in herziening
formamide (µg/m3)	3	nd			1.06E-3		RvS: ad-hoc MTR
hexachloorcyclopentadieen (µg/m3)	0				1.22E-4		RvS: ad-hoc MTR
hexadecafluorheptaan (µg/m3)	0				6.95E-2		RvS: ad-hoc MTR
hexamethyldisiloxaan (µg/m3)	1	266000			0.0734		REACH: long-term systemic effects.RvS: ad-hoc MTR
hydrazine (µg/m3)	1	nd			2.35E-5		RvS ad hoc MTR
hydrochinon (µg/m3)	1	500			3.12E-10		REACH: long-term local effects / RvS: ad-hoc MTR
kaliumbromaat	1	nd			nd		,
koolmonoxide (µg/m3)	1	nd			10000		RvS: EU grenswaarde, 8-uur gemiddelde.
koolstofdisulfide (µg/m3)	2	nd / 752			26.3		REACH: long-term systemic effects, acute expossure DNEL was waived; RvS: ad-hoc MTR
methoxyazijnzuur (µg/m3)	1	nd			5.96E-6		RvS: ad-hoc MTR
o-toluidine, 2-aminotolueen, 2-methylbenzeenamine (µg/m3)	2	nd			3.90E-4		RvS: ad-hoc MTR
musk xyleen (µg/m3)	0				0.0756		RvS: ad hoc MTR
N,N-dimethylaceetamide (µg/m3)	1	7000			2.91E-7		REACH: long-term systemic effects; RvS: ad-hoc MTR
N,N-dimethylformamide (µg/m3)	2	nd			3.52E-4		RvS: ad-hoc MTR
2-naftylamine, 2-naftaleenamine (µg/m3)	0				5.95E-6		RvS:ad-hoc MTR
neodecaanzuur, ethenyl ester (µg/m3)	1	2500			2.27E-2		REACH: long-term systemic effects. RvS: ad-hoc MTR
nitrobenzeen (µg/m3)	2	nd	nd		2.04E-3		RvS: ad-hoc MTR
2-nitropropaan (µg/m3)	1	nd	nd		4.40E-2		RvS: ad-hoc MTR
N-methylacetamide (µg/m3)	1	7000	nd		1.45E-2		REACH: long-term systemic effects. RvS: ad-hoc MTR
ozon (µg/m3)	0				120		RvS: EU richtwaarde = hoogste 8-uurgemiddelde conc. Tevens: 18000 en 6000 = per uur
							t.b.v. vegetatie
pentachlooranisol (µg/m3)	0				4.60E-4		RvS: ad hoc MTR
pentachloorbenzeenthiol (µg/m3)	0				2.68E-4		RvS: ad-hoc MTR
radon (µg/m3)	0				nd		
stikstofoxiden (µg/m3)	0				30		EU-grenswaarde. Bescherming vegetatie
Styrene (mg/m3)	3	nd / nd / 10.2	nd	0.9	0.9	N / N / N	REACH: long-term systemic effects / MPC = TCA
telluriumslakken	1	nd	nd		nd	Ĺ	
Toluene (mg/m3)	1	56.5	nd	0.4	0.3	N	RvS: under revision / MPC based on NOAEC = 1125 mg/m3. This study not mentioned in REACH
2,6-tolueendiamine (µg/m3)	0				6.64E-7		RvS: ad-hoc MTR
2,6-tolueendiisocyanaat (μg/m3)	0			4.77 E-3	4.77E-3		RvS: ad-hoc MTR
trichloormethylbenzeen (µg/m3)	1	nd	nd		1.49E-4	1	RvS: ad-hoc MTR
5,6,6-tridecafluoro-6-iodo-1,1,1,2,2,3,3,4,4,5-hexaan (µg/m3)	0				6.89E-2		RvS: ad-hoc MTR
trifenylfosfine (µg/m3)	1	1000	nd	nd	3.43E-5	1	REACH: long-term systemic effects and long term local effects/ RvS: ad-hoc MTR
trifluorjoodmethaan (µg/m3)	0				6.99E-2		RvS: ad-hoc MTR

SUBSTANCE	REACH		RAR	NL- ERL MPC	Standard	REMARKS
	Dossiers					
3,3-(ureyleendimethyleen)bis (3,5,5-trimethylcyclohexyl) diisocyanaat (µg/m3)	0				9.28E-8	RvS: ad-hoc MTR
vanadiumpentoxide (µg/m3)	1	nd	nd		nd	
zwaveldioxide (μg/m³)	1	530	nd	nd	0.125*	RvS: EU grenswaarde algemene bevolking, 24-uurgemiddelde. REACH: long term local effects
						* Er is ook nog: 20 μg/m3 = bescherming ecosystemen / 350 μg/m3 = uurgemiddelde conc.
zwavelwaterstof	1	nd	nd		nd	

nd: not determined

Sources:

REACH: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

EU-RAR: http://esis.jrc.ec.europa.eu/

NL-ERL: searched via Google of paper version

RvS Standard: http://www.rivm.nl/rvs/

Table A.2. Availability and comparison of PNEC-water for priority substances. Partly in Dutch language. Search was executed in Spring 2012.

	REACH			EU- RAR		NL-ERL (MPC)		RvS Standar d		Same	REMARKS
SUBSTANCE	Dossiers	fresh- water	marine	fresh- water	marine	fresh- water	marine		marine	key study	
Anorganische fluoriden (mg/L)	0							1.5	nd	,	
Arseen en arseenverbindingen (μg/L	0							32	nd		
Arsene pentoxide	0							nd			
Diarsenic trioxide	1	nd	nd					nd	nd		
Arsenic acid (µg/L)	1	0.5	0.6					nd	nd		
Calcium arsenate	1	nd	nd					nd	nd		
Lead hydrogen arsenate	0	-						nd	nd		
Beryllium (ng/L)	1	nd	nd					9.2	nd		JG-MKN opgelost
Bervlliumoxide	1	nd	nd					nd	nd		
Cadmium (µg/L)	1	0.19	1.14	0.08- 0.19	nd	?	?	0.08- 0.25	0.2	?	JG-MKN / EU-RAR and RvS: depending on hardness
Cadmium fluoride	0			0.11				nd	nd		
Cadmium sulphide (µg/L)	1	0.19	1.14					nd	nd		
Trichlorobenzenes (µg/L)	0	0.13						0.4	0.4		JG-MKN totaal
1,3,5-Trichlorobenzene (µg/L)	0							0.4	0.4		JG-MKN totaal
1,2,4-Trichlorbenzene (µg/L)	1	nd	nd	4	nd	*	*	0.4	0.4	N	JG-MKN total
1,2,3-Trichlorobenzene (µg/L)	1	nd	nd	† <b>'</b>	iiu			0.4	0.4	.,	JG-MKN total
1,4-Dichlorobenzene (µg/L)	1	20	2	20	nd	6.9	2	250	nd	?	NL-ERL fresh: MPCsp,water
Hexachlorobenzene (µg/L)	0	20	_	20	iiu	0.5	_	0.01	0.01		JG-MKN totaal
Pentachlorobenzene (µg/L)	0				1		1	0.007	0.0007		JG-MKN totaal
Pentachlorophenol (µg/L)	0							0.4	0.4		JG-MKN totaal
Chromium (µg/L)	1	6.5	nd	nd	nd	?	?	3.4+AC	0.6+A		JG-MKN / RvS: AC is Backgroundconcentration
Chromylchloride	0							nd	nd		
Chromiumoxide	2	nd / 3.4	nd / 3.4					nd	nd		
Chromium acid	0	114 / 3.1	114 / 3.1					nd	nd		
Potassium dichromate (µg/L)	2	nd / 0.47	nd / 0.47					nd	nd		
Chromium (VI) verbindingen	0	, 01.17	,,					nd	nd		
DDD, 2,4'-isomeer (µg/L)	0								nd		RvS: ad-hoc MTR (totaal)
DDD, 4,4'-isomeer (ng/L)	0							0.4	nd		RvS: MTR opgelost. MTR totaal = 0.5 ng/L
DDE, 2,4'-isomeer (µg/L)	0							7.55E-4	nd		RvS: ad-hoc MTR
DDE, 4,4'-isomeer (ng/L)	0							0.4	nd		Troi da nociiin
DDT, 2,4'-isomeer (µg/L)	0							6.0E-6	nd		RvS: ad-hoc MTR totaal
DDT, 4,4'-isomeer (µg/L)	0							0.01	0.01		JG-MKN totaal
Dioxins	0		t	1	1		1	nd	nd		
Aldrin (µg/L)	0		<b>†</b>					0.01	0.005		JG-MKN totaal; Som van aldrin, dieldrin, endrin en isodrin
Dieldrin (µg/L)	0		<b>†</b>					0.01	0.005		JG-MKN totaal; Som van aldrin, dieldrin, endrin en isodrin
Endrin (µg/L)	0		t	1	1		1	0.01	0.005		JG-MKN totaal; Som van aldrin, dieldrin, endrin en isodrin
Isodrin (µg/L)	0		<b>†</b>	1	1		1	0.01	0.005		JG-MKN totaal; Som van aldrin, dieldrin, endrin en isodrin
Endosulphan (µg/L)	0	1	<b>-</b>	1	<u> </u>		1	0.005	0.0005		JG-MKN totaal
Alpha-endosulphan	0	1	<b>-</b>	1	<u> </u>		1	nd	nd		55 1 1111 (5664)
Nonylphenolen	0	1	1	+	1		+	nd	nd		

	REACH			EU-		NL-ERL		RvS		Same	REMARKS
				RAR		(MPC)		Standar			
SUBSTANCE	Dossiers	fresh-	marine	fresh-	marine	fresh-	marine	fresh-	marine	key	
		water		water		water		water		study	
p-nonylphenol (µg/L)	0							0.3	0.3		JG-MKN totaal
Octylfenolen	0							nd	nd		
para-tert-octylfenol (μg/L)	1	0.632	0.632					0.1	0.01		JG-MKN totaal / REACH: Intermittent releases 0.133 μg/L
2,4,6-tri-tert-butylphenol (ng/L)	1	nd	nd					0.195	nd		RvS: ad hoc MPC
Fijn stof	?										
Phosphates (mg/L)	6	1.7 / 1.7 / nd	0.17 / 0.17 / nd					nd	nd		
Bis(2-ethylhexyl) phthalate (μg/L)	2	nd	nd					1.3	1.3		JG-MKN totaal
Dibutyl phthalate (µg/L)	4	nd / 10	nd / 10	10	nd	10	1	10	1	Υ	
Pentabroomdifenylether (ng/L)	0							0.5	0.2		JG-MKN totaal
Hexabroombifenyl (µg/L)	0								nd		RvS: ad-hoc MTR totaal
Pentabroomethylbenzeen (μg/L)	0							1.95E-4	nd		RvS: ad-hoc MTR totaal
2-Propeenzuur-(pentabroomfenyl)methylester (µg/L)	0							8.48E-4	nd		RvS: ad-hoc MTR totaal
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (µg/L)	1	16	0.34	nd	nd	?	?	nd	nd		
1,3,5-Tribroom-2-(2,3-dibroom-2-methylpropoxy)benzeen (µg/L)	0							1.68E-3			RvS: ad-hoc MTR totaal
Alkanes, C10-13, chloro (μg/L)	1	0.5	0.15	0.5	nd	?	?	0.4	0.4		JG-MKN
Bromomethane (μg/L)	0							3.2	0.32		JG-MKN totaal
1,2-Dibromoethane (ng/L)	1	58100	5810	nd	nd	1.75	3.29	3.3	3.3		JG-MKN / ERL 1.75 ng/L = MPCdw,water 3.29 = MPChh food,water
1,2-Dichloroethane (mg/L)	1	1.1	0.11	nd	nd	1.1	1.1	0.01	0.01	Υ	JG-MKN
Dichloromethane (μg/L)	3	130 / 130 / 540	130 / nd / 194	nd	nd	1700	1700	20	20	N/N/ N	JG-MKN
Hexachlorobutadiene (µg/L)	0							0.1	0.1		JG-MKN totaal
Pentachloroethane (µg/L)	0							230	nd		MTR totaal en opgelost
1,1,2,2-tetrachloroethane (µg/L)	0							8	0.8		JG-MKN totaal
Tetrachloroethylene (µg/L)	1	51	5.1	51	nd	51	5.1	10	10	?	
Tetrachloromethane (µg/L)	1	220	22	nd	nd	12	12	12	12	N	JG-MKN
1,1,1-Trichloroethane (µg/L)	1	21	2.1	nd	nd	21	2.1	21	2.1	Υ	JG-MKN
Trichloroethylene (µg/L)	2	115 / 115	11.5 / nd	115	nd	120	12	10	10	N/N	JG-MKN
Trichloromethane (µg/L)	1	146	15	146	nd	150	150	2.5	2.5	?	JG-MKN
Bromoethylene (μg/L)	1	nd	nd					0.815	nd		RvS: ad hoc MPC
Chloroethylene (µg/L)	3	77 / 100 / nd	7.7 / 100 / nd	nd	nd	0.091	0.091	0.09	0.091	N / N / N	REACH: 77 verband PNEC-keystudy ? // 100 QSAR // JG-MKN
2-Ethoxyethanol (µg/L)	1	nd	nd					0.484	nd		RvS: ad hoc MPC
2-Ethoxyethylacetate (µg/L)	0							1.28	nd		RvS: ad-hoc MTR totaal
2-Methoxyethanol (µg/L)	1	10000	1000	nd	nd	970	nd	1.08	nd	N	RvS: ad hoc MPC
2-Methoxyethylacetate (µg/L)	0							1.34	nd		RvS: ad-hoc MTR
2-Methoxypropanol (µg/L)	0							0.681	nd		RvS: ad-hoc MTR
Grof stof	?							nd	nd		
Hexachlorocyclohexane (μg/L)	0							0.02	0.002		JG-MKN totaal
gamma-Hexachlorocyclohexane	0						1	0.02	0.002		JG-MKN totaal
Cobalt sulphate (μg/L)	2	0.51 / nd					1	nd	nd		
Cobalt dichloride (µg/L)	1	0.51	2.36					nd	nd		
Copper (µg/L)	1	7.9	5.2	nd	nd	?	?	3.8	nd	?	MTR totaal

			EU-		NL-ERL		RvS		Same	REMARKS
			RAR		(MPC)		Standar			
							d			
Dossiers		marine	fresh-	marine		marine		marine		
					water					
1				nd	?	?			?	JG-MKN opgelost
1	6.5	3.4	nd	nd	?	?			?	JG-MKN opgelost
0										
1	nd	nd					_			
U							_			
0							nd			
1	nd	nd					-	-		JG-MKN opgelost
0							nd	nd		
1	nd						nd	nd		
1	nd						nd	nd		
0							nd	nd		
0							0.3	nd		RvS: ad-hoc MTR totaal
0							118	nd		RvS: ad-hoc MTR totaal
0							0.599	nd		RvS: ad-hoc MTR totaal
0							0.0855	nd		RvS: ad-hoc MTR totaal
0							0.598	nd		RvS: ad-hoc MTR totaal
0							nd	nd		
0							0.0002	0.0002		JG-MKN totaal
0							nd	nd		
0							nd	nd		
0							0.005	0.0009		Som van trifenyltinacetaat, trifenyltinchloride en fentinhydroxide
0							0.005	0.0009		Som van trifenyltinacetaat, trifenyltinchloride en fentinhydroxide
2	10.6 / nd	1.06 / nd	nd	nd	0.65	0.065	0.65	0.065	N	JG-MKN totaal
										REACH: other 8 studies no data / RvS: ad-hoc MTR
-	~ -				2	?			?	REACH: other studies no data
0	/ 0 .	/ 0				i e	_			TENOTI Calci Scales iio aca
0										
1	nd	nd					_			JG-MKN totaal
1			2.4	nd	2.4	nd			Υ	JG-MKN totaal.
0										30 That total
0										RvS: ad-hoc MTR totaal
0										RvS: ad-hoc MTR totaal
0										RvS: ad-hoc MTR totaal
0										RvS: ad-hoc MTR totaal
n										RvS: ad-hoc MTR totaal
Ŭ										RvS: ad-hoc MTR totaal
•			<del>                                     </del>	<del>                                     </del>		<del>                                     </del>				TOTAL DE LA LICE LA
2	nd / 20.6	nd / 6.1	7.8	nd					?	RvS: JG-MKN opgelost, including backgroundconcentration (River Rhine)
0			1	1		1	5.72F-2	nd		RvS: ad-hoc MTR totaal
0	1	1								RvS: ad-hoc MTR totaal
0	1	1					4.88E-3	nd		RvS: ad-hoc MTR totaal
		•				<u> </u>				
	1 1 1 0 0 1 1 0 0 1 1 1 0 0 0 0 0 0 0 0	water  1	water  1	Dossiers   Freshwater   Marine   Freshwater   1	Dossiers   Fresh-water   Marine   Fresh-water   1	Dossiers   Marine   Marine	Dossiers   Freshwater   Marine   Freshwater   Marine   Freshwater   Marine   Marin	Dossiers   Freshwater   water   wate	Dossiers   Freshwater   marine   freshwater   water   water	Dossiers   Freshwater   Marine   Freshwater   Marine   Mater   Mater

	REACH			EU-		NL-ERL		RvS		Same	REMARKS
				RAR		(MPC)		Standar d			
SUBSTANCE	Dossiers		marine	fresh-	marine	fresh-	marine		marine	key study	
Diethylstilbestrol (µg/L)	0	water		water	-	water		water 48.6	nd	Study	RvS: ad-hoc MTR totaal
(20R,25R)-spirost-5-en-3ß-ol (µg/L)	0			1	<del> </del>	1		2.37E-3	nd		RvS: ad-hoc MTR totaal
(20κ,25κ)-spirost-3-eri-3b-0r (μg/L) Estrone (μg/L)	2	nd	nd	1	<del> </del>	1		0.322	nd		RvS: ad hoc MPC
Ethinylestradiol (ng/L)	2	nd	nd					0.322	0.0016		JG-MKN
Alachlor (µg/L)	0	IIu	IIu					0.010	0.0010		JG-MKN total
Atrazine (µg/L)	1	nd	nd	1	<del> </del>	1		0.6	0.6		JG-MKN total
Acidatine (µg/L) Aziridine (µg/L)	3	2.4 / nd	0.24 / nd					0.0	nd		RvS: ad-hoc MTR totaal
Chlordane (ng/L)	0	2.4 / 110	0.24 / 110					0.239	nd		MPC total
Chlordecone (µg/L)	0							8.98E-7	nd		ad-hoc MPC total
Chlorfenvinphos (µg/L)	0	-	1					0.966-7	0.1		JG-MKN total
	0										
Chlorpyrifos (µg/L)	0							0.03	0.03		JG-MKN total
Dicofol (ng/L)	0		0.000	<b>.</b>	<del> </del>			28.8	nd		RvS: ad hoc MPC total
Diuron (μg/L)	1	0.32	0.032	nd	nd	0.2	0.2	0.2	0.02		JG-MKN total / geen ERL, basisdocument is EQS Substance data Sheet
O-ethyl O-4-nitrophenyl phenylphosphonothioate (ng/L)	0							22.9	nd		RvS: ad hoc MPC total
Fenitrothion (ng/L)	0							9	nd		MPC total
Fenvalerate (µg/L)	0							4.08	nd		RvS: ad hoc MPC total
Flucythrinate (ng/L)	0							2.75	nd		RvS: ad hoc MPC
Heptachlor (ng/L)	0							0.5	nd		MPC total
Heptachlor norbornene (ng/L)	0							25.8	nd		RvS: ad hoc MPC
Isoproturon (µg/L)	0							0.3	0.3		JG-MKN total
Methoxychlor (μg/L)	0							5.0E-5	nd		RvS: ad hoc MPC total
DNOC (µg/L)	1	nd	nd					9.2	nd		JG-MKN total
Mirex (µg/L)	0							7.7E-4	nd		RvS: ad hoc MPC total
Nitrofen (µg/L)	0							26.3	nd		RvS: ad hoc MPC
Simazine (µg/L)	0							1	1		JG-MKN total
Tetrasul (µg/L)	0							0.121	nd		RvS: ad hoc MPC total
Toxaphene (µg/L)	0							2.67E-5	nd		RvS: ad hoc MPC total
Triclocarban (µg/L)	0							6.4E-4	nd		RvS: ad hoc MPC total
Trifluralin (µg/L)	0							0.03	0.03		JG-MKN total
Acrolein (µg/L)	1	0.1	0.1	0.1	nd	0.1	0.01	0.1	0.01	Υ	JG-MKN
Acrylonitrile (µg/L)	1	17	17	17	nd	0.036	0.036	8	nd	N	ERL: MPC ecowater = 17 μg/L //Lowest for hh foodwater chosen as overal MPC
Ammonia (µg/L)	1	1.1	1.1				1	nd	nd		
Aniline (µg/L)	1	1.2	0.12	1.5	nd	1.5	0.15	1.5	0.15	N	JG-MKN total
Asbestos	0	<u> </u>	1	1	1	T	1	nd	nd	1	
Benzene (mg/L)	3	nd / 0.08 / 1.9	nd / 0.08 / 1.9	0.08	nd	0.00075	7.5E-5		0.008	?	ERL: MPC ecowater = MPC ecomarine // RvS: JG-MKN
1,3 Butadiene (µg/L)	2	nd / 25.8		32.6	nd	0.062	0.062	0.062	0.062	N	RAR: based on QSAR, MPC-water based on MPC-hh food water // JG-MKN
2-Butenal (µg/L)	0		<b>†</b>	1	<u> </u>		<u> </u>	0.713	nd	1	RvS: ad hoc MPC total
Chloroacetaldehyde (ng/L)	0	<del> </del>	1	1	1			8.39	nd	1	RvS: ad hoc MPC total
Chloromethylbenzene (µg/L)	1	nd	nd	1	<u> </u>		<u> </u>	310	nd	1	IN ST. dd floc Fil C total
Cyclododecane (µg/L)	1	nd	nd	1	1		<u> </u>	3.08E-4	nd	1	RvS: ad hoc MPC total
1,5,9-cyclododecatrieen (µg/L)	12	nd	iiu	nd	1	1		1.47E-2	nd		RvS: ad-hoc MTR

	REACH			EU-	1	NL-ERL		RvS		Same	REMARKS
				RAR		(MPC)		Standar			
SUBSTANCE	Dossiers	fresh-	marine	fresh-	marine	fresh-	marine	fresh-	marine	key	
		water		water		water		water		study	
3,3'-dichloorbenzidine (ng/L)	0							0.0052	0.0052		RvS: wettelijk JG-MKN totaal
diethylsulfaat, diethylsulfaatester (µg/L)	2	nd		nd				1.23	nd		RvS: ad-hoc MTR
4-(dimethylbutylamino) difenylamine (μg/L)	1	0.37	0.037	nd				0.48	0.048		RvS: JG-MKN totaal / REACH: PNECaqua. PNEC intermit. releases = 0.28 μg/L
dimethylsulfaat (µg/L)	7	14 / 14 / 14 / nd	1.4 / 1.4 / nd	14				nd	nd		
ethaandial (µg/L)	1	319	31.9	nd				0.176	nd		RvS: ad-hoc MTR totaal
etheen (mg/L)	2	nd / 1.67	nd / 1.67	nd				8.5	nd		
ethyleenthioureum (µg/L)	1	26.4	2.64	nd				0.005	nd		
fenylhydrazine (µg/L)	1	nd		nd				1.22	nd		RvS: ad-hoc MTR
Formaldehyde (mg/L)	2	nd / 0.47	nd / 0.47	nd	nd	0.18	nd	0.18	nd	N	
formamide (mg/L)	3	0.5 / nd	0.5 / nd	nd				1.5	nd		RvS: ad-hoc totaal
hexachloorcyclopentadieen (µg/L)	0		,	0.03				3.61E-1	nd		RvS: ad-hoc MTR
hexadecafluorheptaan (µg/L)	0							1.54E-3	nd		RvS: ad-hoc MTR
hexamethyldisiloxaan (µg/L)	1	8	0.8	nd				3.07E-05			RvS: ad-hoc MTR
hydrazine (µg/L)	1	0.6	0.06	nd				0.0192	nd		RvS: ad-hoc MTR
hydrochinon (µg/L)	1	0.114	0.0114	nd				49600	nd		RvS: ad-hoc MTR
kaliumbromaat	1	nd		nd				nd	nd		
koolmonoxide	1	nd		nd				nd	nd		
koolstofdisulfide (µg/L)	2	nd / 10	nd / 1	nd				27.7	nd		RvS: ad-hoc MTR totaal
methoxyazijnzuur (µg/L)	1	nd	, -	nd				6.92E-1	nd		RvS: ad-hoc MTR
o-toluidine, 2-aminotolueen, 2-methylbenzeenamine (µg/L)	2	nd		nd				1.27	nd		RvS: ad-hoc MTR
musk xyleen (µg/L)	0			1.1				nd	nd		
N,N-dimethylaceetamide (mg/L)	1	0.5	0.0966	nd				0.32	nd		RvS: ad-hoc MTR
N,N-dimethylformamide (µg/L)	2	nd / 30000	nd / 3000	nd				0.684	nd		RvS: ad-hoc MTR
2-naftylamine, 2-naftaleenamine (µg/L)	0							9.90E-1	nd		RvS: ad-hoc MTR
neodecaanzuur, ethenyl ester (µg/L)	1	0.84	0.03	nd				0.0267	nd		RvS: ad-hoc MTR totaal
nitrobenzeen (µg/L)	2	38 / nd	3.8 / nd	38				22.7	nd		RvS: ad-hoc MTR
2-nitropropaan (µg/L)	1	nd	nd	nd				2.26E-1	nd		RvS:ad-hoc MTR
N-methylacetamide (mg/L)	1	0.5	0.05	nd				0.682	nd	?	RvS: ad-hoc MTR
ozon	0							nd	nd		
pentachlooranisol (µg/L)	0								nd		RvS: ad-hoc MTR
pentachloorbenzeenthiol (µg/L)	0							1.17E-3	nd		RvS: ad-hoc MTR
radon	0							nd	nd		
stikstofoxiden	0							nd	nd		
Styrene (μg/L)	3	nd / 28 / 40	nd / 28 / 40	40	nd	40	4.0	570	nd	N / N / ?	
telluriumslakken	1	nd	nd	nd				nd	nd		
Toluene (μg/L)	1	680	680	74	nd	74	7.4	74	7.4	?	$JG\text{-MKN}$ / Key study NOEC Ceriodaphnia = 740 $\mu g/L$ both in REACH and RAR.
2,6-tolueendiamine (μg/L)	0							0.690	nd		ad-hoc MTR totaal
2,6-tolueendiisocyanaat (µg/L)	0					0.0628	nd	0.0629	nd		ad hoc MTR totaal. Let op: Waarom factor verschil van 0.0001?
trichloormethylbenzeen (µg/L)	1	nd	nd	nd		2.19E-4	nd	2.19E-4	nd		ad hoc MTR totaal.

	REACH			EU- RAR		NL-ERL (MPC)		RvS Standar d		Same	REMARKS
SUBSTANCE	Dossiers	fresh- water	marine	fresh- water	marine	fresh- water	marine	fresh- water	marine	key study	
5,6,6-tridecafluoro-6-iodo-1,1,1,2,2,3,3,4,4,5-hexaan (μg/L)	0							2.07E-3	nd		RvS: ad-hoc MTR
trifenylfosfine (µg/L)	1	165	165	nd		0.00333	nd	0.00333	nd	?	ad hoc MTR totaal.
Trifluorjoodmethaan (µg/L)	0							2.03E-3	nd		RvS: ad hoc MPC
3,3-(ureyleendimethyleen)bis (3,5,5-trimethylcyclohexyl) diisocyanaat (µg/L)	0							0.00186	nd		ad hoc MPC total
Vanadiumpentoxide (μg/L)	1	7.6	2.5	nd		?	?	nd	nd		REACH: PNECaqua. PNEC intermittent releases = 6.93 μg/L
Zwaveldioxide	0							nd	nd		
zwavelwaterstof	1	nd		nd				nd	nd		

nd: not determined

#### Sources:

REACH: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

EU-RAR: http://esis.jrc.ec.europa.eu/

NL-ERL: searched via Google or paper version

RvS Standard: http://www.rivm.nl/rvs/