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

Toxicological evaluation of mass flow limits for air emissions of substances of very high concern

RIVM Letter Report 601357014/2013

R van Herwijnen | M.P.M. Janssen

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

Toxicological evaluation of mass flow limits for air emissions of substances of very high concern

RIVM letter report 601357014/2013
R. van Herwijnen | M.P.M. Janssen

Colophon

ISBN:

R van Herwijnen
M.P.M. Janssen

Contact:
René van Herwijnen
Centre for safety of substances and products
rene.van.herwijnen@rivm.nl

This investigation has been performed by order and for the account of Ministry of Infrastructure and the Environment (I&M), Directorate General for the Environment and International Affairs, Directorate for Safety and Risks, within the framework of Policy support on priority substances

Rapport in het kort

Toxicologische evaluatie van grensmassastromen voor luchtemissies van zeer zorgwekkende stoffen

Een grensmassastroom is een maat die aangeeft welke hoeveelheid van een stof een bedrijf maximaal per uur mag uitstoten. Ze worden gebruikt bij de vergunningverlening voor emissies van stoffen. Het RIVM heeft onderzocht of de grensmassastromen bij de toelating van stoffen in de lucht voldoende beschermen tegen de risico's van zeer zorgwekkende stoffen. Het blijkt dat voor meer dan 99 procent van deze stoffen de bestaande grensmassastromen voldoende beschermen tegen schadelijke effecten. Bij de overige stoffen blijft de maximale overschrijding beperkt (minder dan een factor 10).

Zeer zorgwekkende stoffen zijn onder andere kankerverwekkende stoffen en stoffen die slecht afbreken, ophopen in organismen en giftig zijn (persistent, bioaccumulerend en toxisch, oftewel PBT-stoffen). Voorbeelden van zeer zorgwekkende stoffen zijn het oplosmiddel benzeen of gebromeerde brandvertragers.

Grensmassastromen worden gebruikt bij een eerste, eenvoudige beoordelingsstap voor de vergunningverlening van luchtemissies door bedrijven. Als de emissie van een bedrijf de grensmassastroom niet overschrijdt, is voor de vergunningverlening geen uitgebreide risicobeoordeling van deze emissie nodig.

De bestaande grensmassastromen zijn tot nu toe vooral gebaseerd op de mate waarin zuiveringstechnieken in staat zijn een stof te verwijderen. Om te toetsen of de huidige grensmassastromen inzetbaar blijven onder de nieuwe Omgevingswet, is vanuit toxicologisch oogpunt onderzocht in hoeverre ze veilig kunnen worden gebruikt. Hiervoor is de toxiciteit van zeer zorgwekkende stoffen vergeleken met de maximaal denkbare luchtconcentratie in de leefomgeving op basis van de bestaande grenswaarden. Omdat de gebruikte schattingen vanuit worst-case-situaties zijn berekend, worden negatieve effecten niet waarschijnlijk geacht.

Trefwoorden:
Grensmassastromen, Zeer zorgwekkende stoffen, Nationaal stoffenbeleid, Luchtemissies, Omgevingswet.

Abstract

Toxicological evaluation of mass flow limits for air emissions of substances of very high concern

A mass flow limit is a maximum amount of substance that is allowed to be emitted by an enterprise. They are used for permitting air emissions of substances. The RIVM has examined if they are protecting against the risks of substances of very high concern. The results have shown that for 99 percent of these substances the current mass flow limits are sufficiently protective against harmful effects. For the remaining substances the maximum exceedance is limited (less than a factor 10).

Substances of very high concern are for example carcinogenic substances or substances that are very persistent, accumulate in organisms and toxic (also called PBT substances). Examples are the solvent benzene and brominated flame retardants.

Mass flow limits are used in a first (simple) tier for the permission of air emissions by enterprises. When the emissions don't exceed the mass flow limit, a more extensive second tier assessment of the risks of the air emissions is not necessary.

Currently, the existing mass flow limits are based on the achievability of cleaning technologies. In order to be able to use the current mass flow limits under the new Dutch Environment Planning Act, it has been examined if they are safe from a toxicological point of view. For this, the toxicity of substances of very high concern has been compared with an estimated worst-case air concentration based on the current mass flow limits. Because of the worst-case approach, negative effects are not expected.

Keywords:
Mass flow limits, Substances of very high concern, Dutch national substances policy, Air emissions, Environment Planning Act.

Contents

Nederlandse samenvatting (Dutch summary)

Inleiding

Voor de vergunningverlening van luchtemissies van stoffen wordt in Nederland een stapsgewijze beoordeling uitgevoerd. In de eerste stap wordt de emissie bij de bron getoetst aan een grensmassastroom voor een stofklasse. Als de grensmassastroom niet wordt overschreden wordt de emissie toelaatbaar geacht en zijn verdere stappen in de beoordeling niet nodig. Bij overschrijding van de grensmassastromen wordt in de tweede stap een meer uitgebreide beoordeling uitgevoerd waarbij luchtconcentraties worden gemodelleerd die worden getoetst aan het Maximaal Toelaatbaar Risiconiveau voor lucht (MTR_{lucht}). Deze aanpak bespaart tijd en geld omdat bij beperkte emissies (kleine) bedrijven geen uitgebreide risicobeoordeling hoeven uit te voeren. De grensmassastromen zijn voornamelijk gebaseerd op technische haalbaarheid van zuiveringstechnieken en in mindere mate op basis van toxische eigenschappen van de stoffen. Vanwege wijzigingen in de Nederlandse regelgeving is er behoefte aan een betere toxicologische onderbouwing van de grensmassastromen voor de stofklassen voor zeer zorgwekkende stoffen (ZZS). Deze onderbouwing wordt uitgevoerd in dit rapport.

Zeer zorgwekkende stoffen

Middels het Nederlandse stoffenbeleid wordt ernaar gestreefd om zorgwekkende stoffen uit de leefomgeving te weren. Voor het behalen van dit doel worden Zeer Zorgwekkende Stoffen (ZZS) geprioriteerd als deze in Nederland worden geproduceerd, gebruikt of in het milieu worden aangetroffen. Bij vergunningverlening van luchtemissies wordt voor deze stoffen een minimalisatieverplichting (MVP) gehanteerd en geldt een grensmassastroom. Er zijn bij de vergunningverlening drie stofklassen voor minimalisatie verplichte stoffen: vaste stoffen (MVP 1), gas- of dampvormige stoffen (MVP 2) en extreem risicovolle stoffen (ERS), met ieder een eigen grensmassastroom. Voor de onderbouwing in dit rapport wordt onderzocht of de gehanteerde grensmassastromen voor de MVP klassen voldoende bescherming biedt tegen de toxische eigenschappen van ZZS-stoffen.

Methode

Voor het onderzoek zijn toxiciteitswaarden voor ZZS stoffen in lucht vergeleken met grensmassastromen. Hierbij is uitgegaan van stoffen die in het najaar van 2011 als zeer zorgwekkend zijn geïdentificeerd. De methodiek hiervoor werd eerder beschreven in RIVM rapport 601357004. Dit resulteerde in een verzameling van ongeveer 1200 stoffen en stofgroepen en deze zijn op basis van dampdruk ingedeeld in MVP 1 of MVP 2. Indeling als ERS is gebaseerd op een bestaande indeling als ERS onder de Nederlandse Emissierichtlijn voor lucht (NeR).
Voor de vergelijking werd voor zoveel mogelijk van de 1200 stoffen en stofgroepen een toxiciteitswaarde gezocht. De voorkeur hierbij was een Maximaal Toelaatbaar Risiconiveau voor lucht (MTR_{lucht}), omdat hieraan bij overschrijding van de grensmassastroom getoetst wordt. MTR_{lucht} waarden waren echter zeer beperkt beschikbaar en binnen het kader van dit project was het niet mogelijk voor alle ZZS-stoffen een MTR_{lucht} af te leiden, daarom zijn ook waarden uit andere kaders gebruikt. Hier betrof het bijvoorbeeld grenswaarden voor de werkplaats, waarden voor orale inname van stoffen in plaats van inhalatie, maar ook waarden afgeleid door buitenlandse overheden (bijvoorbeeld door de US-EPA). Waar nodig zijn deze waarden omgerekend naar een getal dat

vergelijkbaar is met een MTR_{lucht} (eenheid µg/m^3). De verzamelde getallen zijn niet voor individuele stoffen her-geëvalueerd. Als een stof-specifiek-toxiciteitsgetal niet voorhanden was, zijn standaard toxiciteitswaarden gebruikt.

Om de verzamelde toxiciteitswaarden voor lucht te vergelijken met de grensmassastroom (uitgedrukt in een maximale hoeveelheid stof die per uur uit een schoorsteen mag komen) moest de grensmassastroom omgerekend worden naar een blootstellingsconcentratie in de leefomgeving (immissie concentratie). Voor deze omrekening is een model gebruikt van een kleine bedrijfseenheid met een schoorsteen van 10 meter hoogte die 25 meter van de erfgrens staat. Op basis van de grensmassastroom en het model wordt dan een immissie concentratie bepaald bij de erfgrens op leefniveau. Het toxiciteitsgetal en immissie concentratie kunnen vervolgens met elkaar vergeleken worden.

Resultaat
De verkregen toxiciteitsgetallen en immissie concentraties zijn per MVP klasse met elkaar vergeleken. Slechts een klein aantal stoffen had een toxiciteitsgetal lager dan de immissie concentratie. In alle gevallen waren deze minder dan een factor 10 lager. Dit betrof minder dan 1% van de onderzochte stoffen. Voor een deel hiervan konden de lagere toxiciteitswaarden verklaard worden omdat bij het afleiden hiervan een strenger risico niveau is gehanteerd dan die voor het Nederlandse beleid geldt.

Discussie
De betrouwbaarheid van de uitgevoerde analyse is beperkt doordat de verzamelde toxiciteitswaarden van veel verschillende kaders en instanties afkomstig zijn. Daarnaast zit er ook een onzekerheid in de modellering van de immissieconcentraties. Er zijn echter ook een aantal factoren die de conclusie ondersteunen:

- er is in de meeste gevallen een worst case-scenario gehanteerd
- de sommatiebepaling van de NeR is niet meegenomen, hierdoor zijn effecten van stoffen zwaarder ingeschat dan bij de vergunningverlening
- het verlagen van toxiciteitswaarden afkomstig van grenswaarden met een extra factor 100, leidt tot bijna geen extra waarden die lager zijn dan de immissie concentratie.

Daarom kan worden gesteld dat het gebruik van grensmassastromen voor de MVP klassen voldoende beschermend is voor de risico's van emissies van de ZZS-stoffen. Uit de uitgevoerde analyse kan ook worden opgemaakt dat in veel gevallen de grensmassastromen zo laag zijn dat het overschrijden hiervan niet direct betekent dat er een risico is. In zo'n geval is het daarom zeer nuttig om de meer uitgebreide beoordeling uit te voeren waarbij wordt getoetst aan het MTR_{lucht} voor de individuele stoffen voor een betere inschatting van het risico.

Conclusies

- De bestaande grensmassastromen voor de MVP klassen zijn voldoende beschermend voor de risico's van emissie van Nederlandse Zeer Zorgwekkende Stoffen.
- Bij het overschrijden van een grensmassastroom is het nodig om aan het MTR_{lucht} te toetsen om te beoordelen of de emissie van de ZZS-stof tot een risico kan leiden.

Summary

Air emissions in the Netherlands are regulated in a tiered system. In the first tier, emissions at the source are assessed against mass flow limits for substance classes. When the mass flow limit is not exceeded by the emission, no further assessment is required. In the second tier a more complex assessment is performed where air concentrations are modelled in the surrounding environment and are assessed against substance specific risk limits. This approach saves time and money because (small) enterprises with low emission don't have to invest in time and expertise for the more complex second tier assessment. The mass flow limits are mainly based on technical achievability rather than toxicological aspects. Because of a policy change in the Netherlands, there is a need for a toxicological assessment of the existing mass flow limits of substance classes for substances of very high concern. This assessment is performed in this report.

Substances of very high concern
The Dutch policy on substances has the aim to reduce the amount of substances of very high concern emitted, with the ultimate aim to eliminate these substances from the environment. In order obtain this goal, a compulsory minimisation (MVP) is applicable for the emission of these substances. There are three classes for substances with compulsory minimisation (for particulate substances, for gaseous substances and for high risk substances), each with a class specific mass flow limit. For the assessment in this report is examined whether the existing mass flow limits are sufficiently protecting against the risk of substances of very high concern.

Methodology
In this study, toxicity values for substances, identified as of being of very high concern, have been compared with mass flow limits for the three minimisation classes. About 1200 substances and substance groups were identified following the methodology described in RIVM report 601357004. On the basis of their vapour pressure the substances have been classified as a particulate substance or gaseous substance. Classification as high risk substance is based on an existing list under the Dutch emission guideline (NeR).
For the identified substances and substance groups, as much as possible toxicity values were collected. Preference was given to Maximum Permissible Concentrations for air (MPC_{air}) since this is the risk limit that will be used when mass flow limits are exceeded. MPC_{air} values were only available for a few substances and therefore toxicity values from other frameworks (e.g. Occupational Exposure Levels or values from the US-EPA) were also collected. Where necessary, values have been recalculated to the unit of the MPC_{air} ($\mu g/m^3$).

In order to be able to compare the mass flow limits (expressed as maximum mass per hour to be emitted) with the collected toxicity values, these have been transferred into an exposure concentration in the environment (immission value) by modelling the emission from a theoretical small industrial unit with a chimney stack of 10 high located 25 meter from the border of the premises. The procedure described above resulted in two kind of values: one for exposure at the border of the premises based on the immission and one for the toxicity, that can be compared with each other.

Results
The results of the comparison indicated that for only a few substances (less than 1% of the dataset), the immission concentration at the mass flow limit is higher

than the toxicity level. In all these cases the difference was less than a factor 10.

Discussion
The toxicity values were combined from many different frameworks into one data set, in some cases this brings high uncertainties. Nevertheless, a worst case scenario has been used in general, a summation rule is used under the NeR and an examination of the use of additional assessment factors for values with the highest uncertainty did not indicate a higher risk. These facts support the conclusion that the mass flow limits for the minimisation classes are sufficiently protective against the risk of substances of very high concern. When the mass flow limits are exceeded, this does not immediately indicate that there is a risk. In such cases, it is recommended to proceed to the higher tier and further assess the risk of the emission through modelling and comparison against MPC_{air} values for the individual substances.

Conclusions

- The existing mass flow limits for the minimisation classes as used in the NeR are sufficiently protecting against the risk of emission of substances of very high concern.
- When mass flow limits are exceeded it is necessary to proceed to a higher tier (assessment of the emission against the MPC_{air}) in order to conclude whether or not there would be a risk by emitting the substance considered.

1 Introduction

Air emissions in the Netherlands are regulated in a tiered system. In the first tier, emissions at the source are assessed against mass flow limits for substance classes. When the mass flow limit is not exceeded by the emission, no further assessment is required. In the second tier, if emission is higher than the mass flow limit, a more complex assessment is performed where air concentrations are modelled in the surrounding environment that are assessed against substance specific risk limits (Maximum Permissible Concentrations for air - MPC_{air}). This approach saves time and money because (small) enterprises with low emission don't have to invest in expertise for the more complex second tier assessment.
The mass flow limits are mainly based on technical achievability rather than toxicological aspects. Three substance groups with mass flow limits are for substances of very high concern as defined by European legislation and treaties. Considering the toxicological aspects of these substances and because of a recent policy change (see Sections 1.2 and 1.3.2 below) there is a need for a toxicological assessment of the existing mass flow limits. This assessment is performed in this report.

In the next sections of this chapter more details are given on the Dutch substances policy and relevant Dutch legislation and regulations. In chapter 2 the methodology for the assessment is described. In chapter 3, the results are presented and discussed. In chapter 4, the final conclusions are given.

1.1 Objective

In this report, mass flow limits for air emissions of substances of very high concern are assessed against toxicological parameters for these substances.

1.2 Substances of very high concern

The aim of the Dutch policy on substances is to ban dangerous substances from the environment or, at least, to bring their concentration below a negligible risk limit. Since the implementation of this policy, substances have always been prioritised based on concern. In the autumn of 2011, the method for priority setting has been altered. Priority setting is now based on identification of a substance as being of very high concern and its relevance for the Netherlands. Being relevant is defined as being produced or used in the Netherlands or being detected in the Dutch environment. The criteria for substances of very high concern for the Dutch policy are similar as those laid down in article 57 of the REACH regulation (EU, 2006). The identification according to these criteria is expanded beyond REACH and the criteria have also been applied to substances that are not regulated under REACH such as pesticides and substances that are unintentionally released. This is described in RIVM report 601357004 (de Poorter et al., 2011) and is further elaborated in RIVM report 601357012 (van Herwijnen, 2013). In the course of 2013 a non-limitative list will be published with substances that have been identified as being of very high concern according to the identification method for the Dutch policy. This list will be published on the website "Risico's van Stoffen" (risk of substances): www.stoffen-risico.nl.

1.3 NeR, activities decree and environmental legislation

Emissions to air are largely regulated by the Dutch emission guideline (Nederlandse emissierichtlijn lucht - NeR) which was set up to harmonize all permits related to air emissions (InfoMil, 2013). Furthermore, the NeR has the aim to supply up-to-date information on technologies for emission reduction. The NeR is used as guideline for permit granting under Dutch environmental legislation. The system of the NeR is largely based on the German air pollution control regulation, the TA Luft.

Though the years, the NeR has been extended and has become an extensive document containing many aspects considering air emission. It has general emission targets as well as specific emission targets for specific industrial sectors. In the same time it is a guideline for the formulation of permits containing emission limit values, for emission monitoring and modelling of emissions.

As stated in the introduction of this chapter, the NeR handles a tiered approach. The mass flow limits (expressed in gram of substance per hour in the waste gas flow, to be considered as upper limits) of the first tier are mainly based on technical achievability of existing technologies for cleaning of air emissions but toxicological aspects were also considered. The risk limits, used in the second tier, are only based on toxicological parameters. The current substance categories and classes of the NeR are given in Table 1.

Table 1. Overview of current substance categories of the NeR.

Category	Classes
Substances with compulsory minimisation (MVP)	particulate substances (MVP 1)
	gaseous substances (MVP 2)
	high risk substances (ERS)
Dust	dust (S)
Inorganic substances - particulate	class 1 to 3 (sA)
Inorganic substances - gaseous	class 1 to 5 (gA)
Organic substances - particulate	solid organic (sO)
Organic substances - gaseous	class 1 to 3 (gO)

1.3.1 Minimisation classes of the NeR

As can be seen from Table 1, one of the substance categories in the NeR is for substances with a compulsory minimisation. Substances of very high concern as defined by European legislation and treaties are substances with compulsory minimisation and will be classified in one of the three classes: particulate substances (MVP 1), gaseous substances (MVP 2) or extremely hazardous substances (ERS). For these three classes different mass flow limits apply, these are presented in Table 2. When the (calculated) emission of an enterprise remains under the mass flow limit, no further risk assessment is necessary. In the case of exceeding, the emission will be assessed against the Maximum Permissible Concentration for a substance in air (MPC_{air}).

Table 2. Current mass flow limits in the NeR for substances with compulsory minimisation.

Class	Mass flow limit (g/hour)
Particulate substances (MVP 1)	0.15
Gaseous substances (MVP 2)	2.5
Extremely hazardous substances (ERS)	20 mg/year

1.3.2 *Future changes in the current regulations*

With the goal of streamlining and for a better connection with the changing environmental policy, the NeR will be separated in two parts. The emission limit section of the NeR will be part of the activities decree that contains conditions (e.g. emission reduction) for specific activities that do not require a permit.

Currently, a new Environment Planning Act is under construction that combines and simplifies regulations. The aim is to bring 40 sectorial laws, 150 governmental degrees and few hundred environmental regulations in the new Environment Planning Act. The activities decree will be one of the tools under this new Act.

2 Methodology

2.1 Introduction

The objective of this report is to assess mass flow limits for air emissions of substances of very high concern as defined by European legislation and treaties against toxicological parameters of these substances. For this purpose it is necessary to 1) identify these substances, 2) assign them to one of the minimisation classes, 3) find values for inhalation toxicity and 4) compare these toxicities against air concentrations caused by emissions at the level of the mass flow limits. In the next sections the different steps are described.

2.2 Selection of substances

Substances of very high concern were identified according to the methodology described in Section 1.2. This identification was performed in the autumn of 2011 and sources that were used were:

- The European directive on classification and labelling (EG1272/2008)(EU, 2008)
- The candidate list for REACH Annex XIV (EU, 2006)
- The European POP directive (EG 850/2004) (EU, 2004)
- The European Water Framework Directive (2000/60/EG) (EU, 2000)
- The list of chemicals for priority action of the OSPAR convention (OSPAR, 1992)

The different sources use different ways to describe a substance, i.e. one only names individual substances, other mention substances groups. Because of this, the identification resulted in a complex dataset with entries for about 1200 substances and substance groups. It was decided not to clean up this dataset but to handle the entries from the different sources separately unless they were clearly the same substance. As a result, the presence of substances groups and individual substances, and the presence of multiple CAS numbers for a substance, some substances may appear multiple times in the dataset. This is not considered a problem because the evaluation in this report concerns the range of the toxicity of all substances of very high concern and not the toxicity of individual substances. Only one substance from the dataset (asbestos) has not been used in the evaluation because this substance has its own legislation in the Netherlands. The final dataset contains a wide variety of kinds of substances, i.e. persistent organic compounds, pesticides, biocides, pharmaceuticals, complex organic mixtures, heavy metals, organometal substances, halogenated compounds, etc.

2.3 Assigning selected substances to a minimisation class

2.3.1 *Criteria for minimisation classes*

To assign a substance to one of the minimisation classes it is assumed that compulsory minimisation applies to all identified substances of very high concern. The difference between the class for particulate substances and gaseous substances is based on the definition for volatile organic substances as given in the NeR: having a vapour pressure of 10 Pa or more at 20°C. For volatile inorganic substances no definition is given but the same approach was taken as for volatile organic substances. In general there are only a few gaseous inorganic substances among the identified substances of very high concern. For assigning a substance as extremely hazardous substance, previous assignment as extremely hazardous (ERS) in the NeR was maintained. In the final assignment of substances to the minimisation classes policy decisions may play a role, that has not been taken into account for this report.

2.3.2 *Collecting physico-chemical properties*

As mentioned above, only the vapour pressure of a substance is needed to assign it to a minimisation class. These have been collected with the programme EPI-suite (US EPA, 2009). With this programme an estimation of the vapour pressure is made on the basis of a molecule structure. The programme also contains experimental values. When an experimental value is available, this was preferred over the estimated value. For experimental values determined for 25°C it was taken into account that the vapour pressure will be lower at 20°C and an estimation was made of the vapour pressure at 20°C. In some cases a molecule structure was not available and the substance was assigned to a minimisation class on the basis of expert judgement.

2.4 Collection of toxicity values

In order to compare toxicity of all entries within the dataset with the mass flow limits, it is necessary to express the toxicity values for all substances in the same units and transfer them to similar exposure parameters (e.g. amount of air inhaled per day for a lifetime). The most preferred value is the MPC_{air} (see Section 2.4.2) because this is the value that will be used in the risk assessment when the mass flow unit is exceeded. However, for the identified substances of very high concern only a limited number of MPCs for air is available. Within the framework of this project it was not possible to derive an MPC_{air} for every single entry in the dataset. Therefore, it was decided to collect comparable values from different national, foreign or international frameworks as well. Preference was given to parameters derived specifically for inhalation exposure (TCA, $CR_{inhalation}$ or OELs; see Sections 2.4.3 and 2.4.4). When these were not available, toxicity values for oral exposure (TDI, CR_{oral}) were converted to inhalation exposure. Values derived for frameworks relevant for Dutch policy were preferred over values derived in other (foreign) frameworks. Risk limits available in REACH dossiers (eg. DNELs) have not been used since it has been shown in a recent investigation that, in many cases, these deviate from those derived by national authorities (Bodar et al., 2013). The underlying data could however be used in the second tier assessment to derive an MPC_{air}.

When no value could be found for a substance, a standard value has been assigned on the basis of structural characteristics of the substance following the threshold of toxicological concern (TTC) concept. In the sections 2.4.2 to 2.4.6, the used toxicity values from the different frameworks will be described in order of preference. In Table 3 an overview is given of the different kind of values and how many values originate from each source.

Table 3. Overview of the risk limits used and their recalculation to a toxicity value for this report.

Risk limit	Recalculation [a]	Preference [b]	Number of values
MTR	x 1	1	40
TCA	x 1	2	181
$CR_{inhalation}$	x 1	2	42
OEL	/ (2 x 2)	3	79
TDI/ADI	x 70 / 20	4	77
CR_{oral}	x 70 / 20	4	14
TTC	x 1	5	771
Total			1204

[a] For the given formulas it is presumed that the same mass units are used.

[b] At equal preference, the lowest value of the two is selected.

The approach used, where values were selected from several frameworks, led to toxicity values based on different methodologies and underlying visions on the risks. In addition, the toxicological information demands may differ per framework. In the present report it was decided to follow this approach despite of the resulting uncertainties as the approach does provide a general view on the variation of the toxicity of the substances of very high concern.

As a consequence, many of the collected values should not be used in a risk assessment of individual substances without further evaluation of the value. Therefore, only general overviews are given in this report and the obtained values for individual substances are not reported.

2.4.1 *Assigning toxicity values to substances*

In general one toxicity value could be assigned to one entry in the dataset. In other cases the toxicity value for a basic element was assigned to the whole group with that element. For example, the toxicity value for nickel was assigned to more than 100 nickel compounds. It was more difficult to assign a toxicity value to substances that consist of multiple (toxic) components. In such cases, the toxicity value for the most toxic component was assigned. For example, for nickel diarsenide the TCA of nickel was assigned and for nickel triuranium decaoxide the MRL value for uranium soluble salts was used. For coal and oil derived substances, sometimes a toxicity values was available, in most other cases a TTC value was assigned.

2.4.2 *MPC*

The MPC is the Maximum Permissible Concentration as it is derived for the Dutch national substances policy. It is, as defined in VROM (1999, 2004), the standard based on scientific data which indicates the concentration in an environmental compartment for which:

1 no effect to be rated as negative is to be expected for ecosystems;

2a no effect to be rated as negative is to be expected for humans (for non-carcinogenic substances);

2b for humans no more than a probability of 10^{-6} per year of death can be calculated (for carcinogenic substances). Within the scope of the Water Framework Directive (WFD), a probability of 10^{-6} of cancer cases on a lifetime basis is used.

As a consequence, the MPC_{air} should be based on ecological- as well as human-toxicity. For the human part it is based on the TCA or $CR_{inhalation}$ (see next Sections). In case ecotoxicological data indicates that the ecosystem is more sensitive for a substance than humans, the MPC_{air} will be lower than the TCA. For most substances no ecotoxicological data for air exposure are available and the MPC_{air} is equal to the TCA or $CR_{inhalation}$.

For the Dutch policy indicative MPCs are also derived. These are not used for this report since many of them are not based on a toxicological value but on a conservative default (TTC) in combination with a deviant methodology. Because of this, they are considered extremely conservative (much lower than the TTC) and not comparable with "normal" MPCs.

The MPC_{air} is the risk limit that will be used to assess the risk of a substance when the mass flow limit is exceeded. Therefore the MPC_{air} is the most preferred value for the evaluation in this report. Also the fact that in principal human- as well as ecotoxicity is considered in this value, which is not the case in any of the other risk limits, plays a role in this preference. MPCs can be found on the website "Risico's van stoffen" (www.rivm.nl/rvs) or in an RIVM report (van Vlaardingen et al., 2007, Slooff et al., 1990, Bodar, 2008, van Herwijnen, 2009, Fleuren et al., 2009, van Herwijnen and van Veen, 2009, Verbruggen and van Herwijnen, 2011a, Verbruggen and van Herwijnen, 2011b). In case the website indicated that an MPC is in review, values of other frameworks (as described in Section 2.4.3 and 2.4.5) were selected in case these were lower.

2.4.3 *TCA and $CR_{inhalation}$*

2.4.3.1 TCA

The TCA (Tolerable Concentration in Air) is the highest concentration in air that does not affect health of the general public after lifelong exposure (70 years, 365 days/year, 24 hours/day). Special risk groups such as ill people, pregnant women, the elderly and children are considered when deriving these values. In general these values are equal to the MPC_{air} but not all TCA values reported by the RIVM (Baars et al., 2001, Bodar, 2008, Brand et al., 2011) have been used to set MPCs for the Dutch policy. RfCs from the US-EPA and Guidance values from the IPCS (International Programme on Chemical Safety of the World Health Organisation) are in principal derived according to a similar methodology and protection level (the whole population exposed for a lifetime) as for the TCA and were taken over without recalculation. The risk limits from the US-EPA and ICPS have been found though the website "Toxnet": toxnet.nlm.nih.gov (US-NLM, 2013)(accessed in December 2012 and January 2013). In some cases, MRLs originating from the US Agency for Toxic Substances and Disease Registry (ATSDR) have also been used. These are also derived for the whole population but cover chronic, as well as acute and intermediate exposure. The latter two have only been used when they were lower than other values available. Risk limits from the ATSDR were found though the website: http://www.atsdr.cdc.gov/toxprofiles/index.asp (ATSDR, 2013)(accessed January 2013). The Toxnet database also presents limit values derived by other organisations than the US-EPA (e.g. Health Canada) but these were not used because e.g. a Dutch value was already available.

2.4.3.2 $CR_{inhalation}$

The $CR_{inhalation}$ is comparable to the TCA but is it derived for genotoxic carcinogenic substances. For these substances, it is assumed that there is no threshold value below which there are no effects: any dose, however low, is associated with a certain cancer risk. Therefore, the $CR_{inhalation}$ is derived according to a different methodology where risk calculation to a certain acceptable risk level is applied. The Dutch policy is acceptance of one case per 1 000 000 exposed individuals per year, or 1 per 10 000 during one lifetime. In some cases other risk levels were applied in the past and are applied in foreign frameworks. For this report these were not transformed to the current Dutch policy (because it was not achievable to re-evaluate all gathered values on an individual substance base) but when different risk levels were derived the most appropriate to the current policy was taken over. As is the case for the TCAs, not all values reported by the RIVM (Baars et al., 2001, Fleuren et al., 2009, Smit, 2010, van Bruggen et al., 2010, van Herwijnen, 2009, van Herwijnen and van Veen, 2009, Verbruggen and van Herwijnen, 2011a, Verbruggen and van Herwijnen, 2011b) have been used to set MPCs. Risk Specific Concentrations (RSC) or Specific Risk Levels (SRL) of the IPCS and US-EPA have been taken over without any transformation. The values have been found though the website "Toxnet": toxnet.nlm.nih.gov (US-NLM, 2013)(accessed December 2012 and January 2013).

2.4.3.3 Use of TCA or $CR_{inhalation}$

In some cases a TCA as well as a $CR_{inhalation}$ is available for a substance. Then, the lowest of the two is used for the analysis in this report. Both TCA and $CR_{inhalation}$ are in general used to set MPC_{air} values and are therefore preferred over OELs that are set for the work place (see section 2.4.4).

2.4.4 Occupational Exposure Level

The Occupational Exposure Level (OEL) is the maximum acceptable concentration in the individual breathing space of an employee. A substance can be present as gas, vapour, aerosol or fibre. Because it concerns a labour situation the actual exposure to a substance is 8 hours a day. The presumed breathing volume in 8 hours is 10 m^3. In some cases, to prevent high exposures in a short period, exposure limits for 15 minutes have also been derived. For the analysis in this report only OELs derived for 8 hours of exposure are used.

OELs have been taken over from the European Scientific Committee on Occupational Exposure Limits (SCOEL)(SCOEL, 2013b, SCOEL, 2013a) or from the website of the Dutch social and economic council (Sociaal Economische Raad - SER; www.ser.nl, accessed January 2013). OELs from the SCOEL have been given the highest preference because they were extensively evaluated by all EU member states. On the website of the SER, public and private values are presented. The public values are those set in a legal context in the Netherlands, in general this concerns carcinogenic and inhalable allergenic substances without a safe threshold. There are also substances for which industry has to derive OELs themselves, for these substances "private" values are presented on the SER website that can be used by industry. These values are generally originating from other European national authorities or from classification programmes performed by the Dutch Health Council (www.gezondheidsraad.nl) but are not set in a legal context (for example because they have been cancelled). Considering the different sources for the OELs, an order of preference is used. Highest preference is given to the values of the SCOEL, second are public values from the SER website, and third "private" values on the SER website derived by the Netherlands but not officially endorsed. When any of these are not available for a substance, "private" values derived by other European authorities are used. In some cases there is a large variation in values derived by different authorities, then the lowest has been taken over as worst case. When the "private" values from the SER website are higher than a TDI or CR_{oral} based value (see section 2.4.5), the latter are preferred over the private OELs as worst case approach.

In order to be able to convert an OEL into a value that can be compared with a TCA, two factors have been used. At first the breathing volume is corrected from 10 m^3 for 8 hours to 20 m^3 for 24 hours (dividing by 2)(ECHA, 2012). Secondly there is a difference in the assessment factors used to derive OELs and TCAs with respect to the target population. Therefore an additional factor of 2 is applied. Possibly other factors may have played a role in setting the OELs, for example local effects, that are not standardly applied and being of a less conservative nature. For this reason, the TCAs derived from OELs are more prone to underestimate the 'actual' TCA, however data are lacking to apply substantiated correction factors to cover for this less conservative approach.
The recalculation taken forward in this report is as follows:
TCA = OEL/ (2 x 2).

2.4.5 *TDI and CR_{oral}*

2.4.5.1 TDI

The Tolerable Daily Intake (TDI) is an estimation of the amount of a substance than can be consumed daily during a lifetime without any negative health effects. For specific substance groups, like plant protection products or biocides, a comparable risk limit is derived. This is called the ADI. Apart from TDIs derived by the RIVM (Baars et al., 2001, Bodar, 2008, Brand et al., 2011, van Herwijnen and Smit, 2009, Dang and Smit, 2008, Tiesjema and Baars, 2009), RfD values of the US-EPA have been taken over without transformation as being a TDI. The risk limits of the US-EPA have been found though the website "Toxnet": toxnet.nlm.nih.gov.

2.4.5.2 CR_{oral}

The CR_{oral} is, like for inhalation, comparable to the TDI but derived for carcinogenic substances. The available risk levels have been taken over without transformation to the current Dutch air policy of 1:10 000 during a lifetime (see Section 2.4.3.2 for more details). When different risk levels were derived the most appropriate to the current Dutch policy was taken over. Apart from CR_{oral} values derived by the RIVM (Baars et al., 2001, Fleuren et al., 2009, Smit, 2010, van Herwijnen, 2009, van Herwijnen and van Veen, 2009, van Vlaardingen et al., 2007, Verbruggen and van Herwijnen, 2011a, Verbruggen and van Herwijnen, 2011b, van Bruggen et al., 2010), Risk Specific Doses (RSD) of the US-EPA and NSF International (following EPA guidelines) have been taken over without transformation as being a CR_{oral}. The risk limits of the US-EPA and NSF international have been found though the website "Toxnet": toxnet.nlm.nih.gov.

2.4.5.3 Use of TDI or CR_{oral}

For a substance, both a TDI and a CR_{oral} could be available. In those cases the lowest of the two values is used for the analysis in this report.
TDIs and CR_{oral} values have been recalculated to TCA-like values on the basis of route-to-route extrapolation. Meaning that a value that has been derived on the basis of oral exposure is recalculated as if the substance enters the body through inhalation. This kind of extrapolation is only acceptable for substances

where oral exposure and exposure through inhalation lead to the same effects (systemic toxicity). For substances that lead to local effects, e.g. skin irritation, the use of route-to-route extrapolation is not acceptable. Nevertheless for the analysis in this report route-to-route extrapolation is always applied in those cases where no MPC, TCA or $CR_{inhalation}$ was available since it was considered that it is better to have a substance specifically derived toxicity value which helps to get an indication of the variation in toxicity of the dataset than a value on the basis of the TTC concept (see section 2.4.6). Therefore, the TCA-like values calculated from a TDI might not be acceptable for the risk assessment of the individual substance but they are considered acceptable for the analysis in this report.

Recalculation is based on a body volume of 70 kg and a daily respiration volume of 20 m^3 following REACH guidance (ECHA, 2012) and presuming 100% absorption of the substance:
TCA (µg/m^3) = TDI (mg/$kg_{bodyweight}$/day) x 70 / 20

2.4.6 TTC

No toxicity value could be found for 771 out of the more than 1200 entries in the dataset. in those cases a standard value was given on the basis of structure characteristics following the concept of the Threshold of Toxicological Concern (TTC). This concept assigns substances to one of 5 substance classes and a substance gets a toxicity values belonging to this class. The five classes consist of three Cramer classes and two classes for carcinogenic substances. The three Cramer classes are arranged in order of toxicity from low (class I) to high (class III). Assigning a substance to a Cramer class is done (automatically) on the basis of an extensive decision tree (Patlewicz et al., 2008). An extensive explanation of the TCC concept can be found in Kalkhof et al. (2012).
The two classes for carcinogenic substances are separated on the basis of genotoxicity and non-genotoxicity. Assigning a substance to one of the carcinogenic classes has been done on the basis of annex VI of the European directive on classification and labelling of substances (EU, 2008). However, the directive does not distinguish between genotoxic and non-genotoxic carcinogens. Assigning a substance as genotoxic carcinogen is based on evaluations on carcinogenity of substances by the SCOEL (SCOEL, 2013b), information from De Jong and Janssen (2010) and by the Dutch Health Council (www.gezondheidsraad.nl). Furthermore substances classified as carcinogenic and mutagenic in annex VI of the European directive on classification and labelling (EU, 2008) are also considered to be genotoxic carcinogenic. Only one of these sources is sufficient to consider a substance as genotoxic carcinogen. Identification of compounds as genotoxic carcinogens could also be done on the basis of QSARs (Patlewicz et al., 2008). A first screening, however, indicated that several of the substances identified by the SCOEL (SCOEL, 2013b), Dutch health council (www.gezondheidsraad.nl) or De Jong and Janssen (2010) are not identified by the QSARs. The use of QSARs was therefore not preferred.

Originally the TTC concept was developed for oral exposure to substances. In Escher et al. (2010) air concentrations for inhalation exposure for the three Cramer classes are proposed. The values for general effects provided in this publication are used for this report. For the carcinogenic substances, Kroes et al. (2004) provided the values of 0.15 and 1.5 µg/person/day for genotoxic and non-genotoxic carcinogens respectively. The risk level considered in these values is 10^{-6} per lifetime. These values have been recalculated to 0.075 and

0.0075 µg/m^3 respectively on the basis of route-to-route extrapolation as described in Section 2.4.5. The used toxicity values for the TTC concept are presented in Table 4 and are based on toxicity data for general effects and not on systemic or local effects. It should be noted that the TTC values are based on a 5% percentile of the distribution of toxicological limit values within a specific class, therefore the TTC values can be considered worst case for most of the substances they are assigned to.

Table 4. Overview of toxicity values used for the TTC concept.

Substance class	TTC value (µg/m^3)	Reference
Cramer class I	3.6	Escher et al. (2010)
Cramer class II	0.48	Escher et al. (2010)
Cramer class III	0.18	Escher et al. (2010)
Non-genotoxic carcinogens	0.075	Based on Kroes et al. (2004)
Genotoxic carcinogens	0.0075	Based on Kroes et al. (2004)

2.5 Comparing the obtained toxicity value with the mass flow limit

The mass flow limit is a maximum amount of a substance emitted per hour (gram/hour) from an industrial unit (see also Section 1.3). The toxicity values collected for the analysis in this report are a maximum concentration in air inhaled by people living nearby or in the surrounding environment (µg/m^3). The latter is an immission concentration in air at street level and for the analysis in this report it is presumed that it is applicable at the border of the premises of the emitting facility. To be able to compare the two values, immission concentration at street level has been modelled from the existing mass flow limits.

2.5.1 Modelling of immission concentration from mass flow limits

For the modelling, a guideline for determining of immission concentrations has been used ("Handreiking bepaling van het immissieniveau" (RIVM, 2004)). The goal of this guideline is to help industry to determine their immission concentrations in a relative simple way. It is based on the Dutch national model for air emissions (Nieuw Nationaal Model (TNO, 1998)). The following assumptions have been made for the modelling of immission values for the analysis in this report: 'The emission scenario is a chimney stack of 10 meter in height located at 25 meter from the border of the premises. The emission from the chimney stack has no heath content and therefore the effective height of the chimney stack is equal to its actual height of 10 meter'. The emission scenario is schematically presented in Figure 1. For the selected emission scenario the distance of 25 meters gives the highest immission level. Table 2 of the guideline (RIVM, 2004) shows that a higher chimney stack would cause that the highest immission level is further away than 25 meters but this maximum concentration is lower. The chosen scenario is however not the most worst case since lower chimney stack heights (down to 0.1 meter) do give immission concentrations up to 5 times higher at a distance of 25 meter. These concentrations for the lower chimney stacks reduce within 75 meter to below the maximum concentrations for the 10 meter chimney stack. Furthermore, the chimney stack heights used in the modelling in RIVM (2004) range from 0.1 to 300 meter and the maximum emission concentrations for these heights differ a factor 300 000. Therefore our chosen scenario is considered a more realistic worst case scenario that still provides a maximum concentration higher than a factor 60 000 from the highest immission concentration for the highest chimney stack in the guideline.

According to Table 2 of the guideline (RIVM, 2004), with our scenario, an emission of 1 kg/hour will cause an immission concentration of 6.17 μg/m3. This linear conversion factor can be used to convert the mass flow limits into immission concentrations for the analysis in this report. The modelled immission values are presented in Table 5.

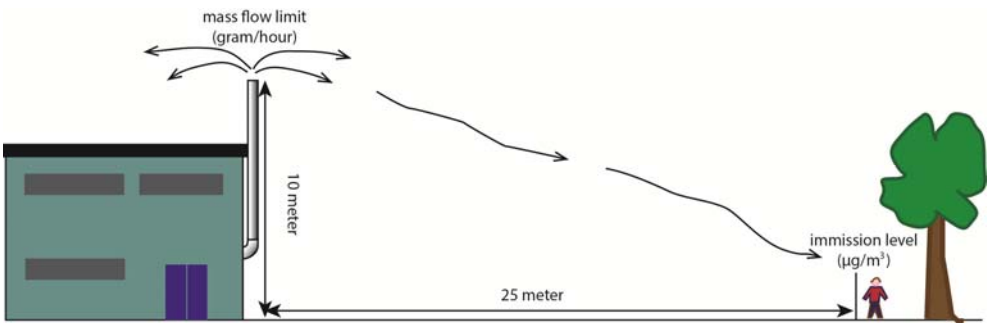

Figure 1. Schematic presentation of the chosen emission scenario for conversion of the mass flow limits into immission concentrations.

Table 5. Overview of the modelled immission concentrations at 25 meters from a 10 m high stack using the limit values as input for the emission.

Minimisation class	Mass limit value	Immission concentration ($\mu g/m^3$)
Particulate (MVP 1)	0.15 gram/hour	0.00093
Gaseous (MVP 2)	2.5 gram/hour	0.015
Extremely hazardous substances (ERS)	20 mg/year (= 0.0000023 gram/hour)	0.000000014

3 Results and discussion

The results of the comparison of the collected toxicity values with the modelled immission concentrations are presented separately for the different minimisation classes. The results for the particulate substances (MVP 1) are presented in Section 3.1, for the gaseous substances (MVP 2) in Section 3.2 and the results for the extremely hazardous substances (ERS) are presented in Section 3.3. In Section 3.4 all results are discussed. In this discussion, at first (Section 3.4.1) the most toxic substances are discussed for which the results indicate that their risk might be underestimated by the mass flow limits. Thereafter factors are discussed that could undermine (Section 3.4.2) or support the conclusions (Section 3.4.3). And finally the general discussion (Section 3.4.4) takes the facts from the previous sections into account.

3.1 Particulate substances

The variation of the substances of very high concern classified as particulate substances is presented in Figure 2. Vertically the toxicity value of the substances is given. Horizontally all substances are set with increasing toxicity from left to right. The blue dots indicate the values originating from MPC, TCA or $CR_{inhalation}$. The red dots are values originating from OEL, TDI, CR_{oral} or TTC. The red line indicates the immission concentration of the mass limit value for the particulate substances. The green lines indicate the levels of the TTC classes (see also Table 5). In total 597 of the entries in the dataset with substances of very high concern have been classified as particulate substance.

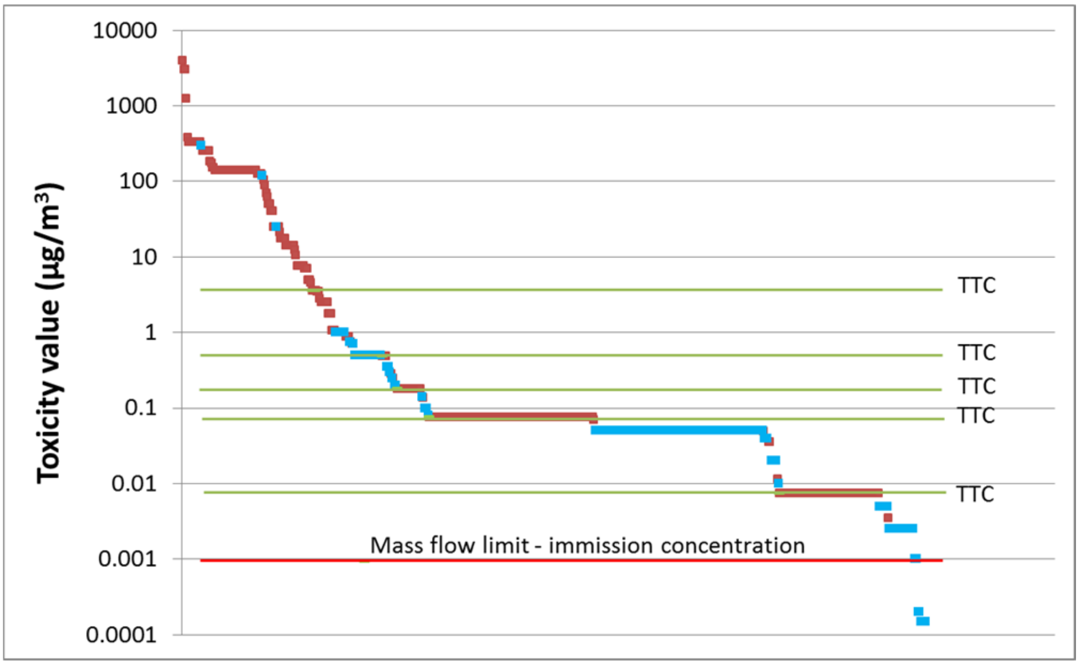

Figure 2. Overview of toxicity values for substances of very high concern classified as particulate substance. The blue dots indicate the values originating from MPC, TCA or $CR_{inhalation}$. See also text.

From Figure 2 can be seen that for only a few substances of very high concern the mass flow limit for the particulate substances underestimates the toxicity of the substance. This concerns two substances: 3,3'-dichlorobenzidine and benzidine. The difference to the converted mass flow limit is a factor 5 and 6.7 respectively. This indicates that relatively for less than 1% of the substances the toxicity could be underestimated.

3.2 Gaseous substances

The variation of the substances of very high concern classified as gaseous substance is presented in Figure 3. Vertically the toxicity value of the substances is given. Horizontally all substances are set with increasing toxicity from left to right. The blue dots indicate the values originating from MPC, TCA or $CR_{inhalation}$. The red dots are values originating from OEL, TDI, CR_{oral} or TTC. The red line indicates the immission concentration of the mass limit value for gaseous substances. The green lines indicate the levels of the TTC classes. In total 600 substances in the dataset with substances of very high concern have been classified as gaseous substance.

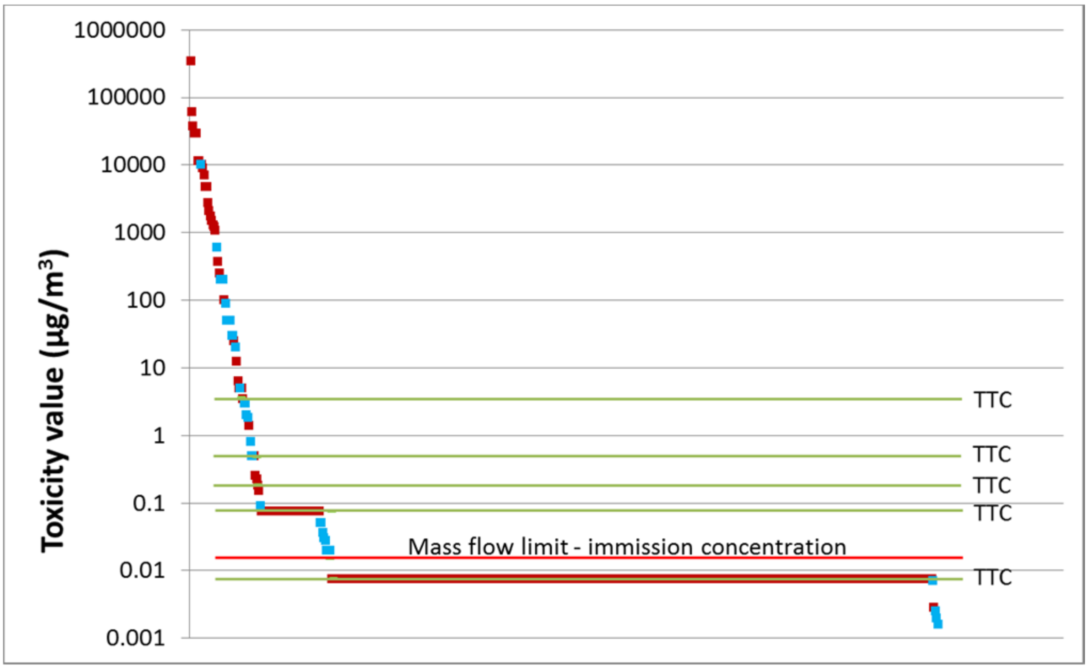

Figure 3. Overview of toxicity values for substances of very high concern classified as gaseous substance. The blue dots indicate the values originating from MPC, TCA or $CR_{inhalation}$. See also text.

A large number of substances in Figure 3 has a collected toxicity value lower than the immission concentration calculated for the mass limit value for the gaseous substances. The main part of these substances have however been given a toxicity value according to the TTC concept. The assigned (lowest) TTC-value is a factor 2 lower than the calculated immission concentration. Apart from this, this group consists for 481 out of 482 substances of oil derived fractions that have often been classified as carcinogenic because they might contain a carcinogenic component. The only other gaseous substance that has been assigned the lowest TTC value is 2,2'-bioxirane.

The five remaining substances lower than the immission concentration calculated for the mass limit value for gaseous substances (α,α,α-trichlorotoluene, chromyl dichloride, 1,2-dibromoethane, dimethylnitrosoamine en bis(chloromethyl) ether) are less than a factor 5 lower than this immission concentration. When the oil derived substances are not considered, the fraction of gaseous substances of very high concern for which the toxicity might be underestimated by the mass flow limit is less than 1%.

3.3 Extremely hazardous substances

The lowest toxicity value collected for substances of very high concern classified as extremely hazardous substances is 7 x 10^{-6} µg/m^3. This value is higher than the converted mass flow limit for this class (1.4 x 10^{-8} µg/m^3). This indicates that the mass flow limit for the extremely hazardous substances is sufficiently protecting.

3.4 Discussion

3.4.1 Substances with a toxicity value lower than the estimated immission

As indicated in Figure 2 and Figure 3, the immission concentrations resulting from the model estimation using the mass flow limits for both particulate and gaseous substances surpass the toxicity values for a few substances. In total this concerned seven entries in the dataset. Since this indicates a potential risk, the collected toxicity values for these entries were looked at in more detail. For four of the seven compounds (3,3'-dichlorobenzidine, benzidine, 1,2-dibromoethane and α,α,α-trichlorotoluene), the collected value was derived for another risk level than preferred (10^{-5} of 10^{-6} instead of 10^{-4} for lifetime exposure). This could occur because values for individual substances were not recalculated. One of the seven values was for chromyl dichloride, the selected toxicity value was for chromium compounds that are in general classified as particulate substance. Chromyl dichloride was classified as gaseous substance because of its vapour pressure but for the final assignment of substances of very high concern to the minimisation classes, chromyl dichloride is expected to be classified as particulate substance for being a chromium compound. In fact, this leaves only two compounds (dimethyl nitroamine and bis(chloromethyl)ether) with a toxicity value lower than the immission concentration modelled for their substance class. Therefore, since 433 entries had been assigned a toxicity value (i.e. a value based on TCA, TDI, OEL etc. and not a TTC), the actual percentage of substances for which the risk might be underestimated is less than 1% (0.46%). Even if only the substances were considered for which an MPC/TCA/$CR_{inhalation}$ is available, this percentage would still be 0.76%. In both cases, the difference of the collected value with the modelled immission concentration was less than a factor 10.

For the extremely hazardous substances, the difference between the immission value calculated from the mass flow limit and the toxicity values is more than factor 100 (immission concentration is lower).

For the gaseous substances, the lowest TTC value is also lower than the modelled immission value for this class. Many of the compounds with a TTC value are oil derived fractions of which the actual content of the carcinogenic component will in fact be only a few per cent of the total and the actual toxicity of the fraction will be lower than that of the carcinogenic component. Furthermore the TTC values for the carcinogenic substances are based on a risk level of 10^{-6} per lifetime (Kroes et al., 2004). This level is more conservative than the Dutch policy for air emissions that handles a level of 10^{-4} per lifetime.

3.4.2 *Influence of the recalculation of values on the conclusions*

For some substances MPC, TCA and/or $CR_{inhalation}$ were available as well as OELs. For such substances it was possible to compare the original MPC, TCA or $CR_{inhalation}$ with a value recalculated from the OEL or the TDI/CR_{oral}. Figure 4 shows the result of this comparison. On the horizontal axis, the MPC/TCA/$CR_{inhalation}$ is given and vertically the toxicity value derived from an TDI/CR_{oral} (▲) or OEL (◆). If for a substance the values obtained from the different sources would be the same, the diamond (◆) or triangle (▲) for the substance would be located on the red line. For the OELs it can be observed that almost all diamond are located (far) above the red line. This indicates that for a substance, the recalculated OELs are much less conservative than the real MPC/TCA values. For the recalculated TDI values this difference is smaller and these values are located above as well as below the red line.

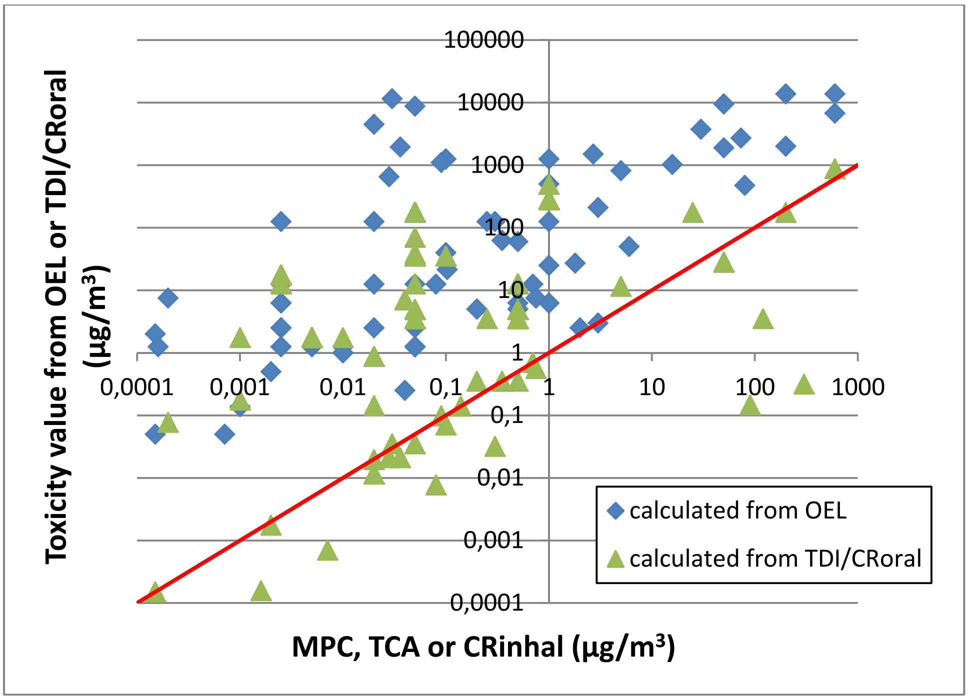

Figure 4. Difference between MPC/TCA toxicity values and those calculated from TDIs and OELs.

The range of recalculated TDI values (1.5 x 10^{-4} to 875 µg/L) is similar to the range of MPC/TCA/$CR_{inhalation}$ values (1.5 x 10^{-4} to 600 µg/L) for the same compounds. The averages differ from 106 to 6.2 respectively and the ratio between the two kind of values (TDI_{based}:MPC/TCA/$CR_{inhalation}$) differs from 0.001 to 7000. The toxicity values calculated from the OELs ranged from 5.0 x 10^{-2} to 13750 µg/m^3 where the range of the MPC/TCA/$CR_{inhalation}$ values is 1.5 x 10^{-4} to 600 µg/L. Also the average for the OEL derived values differs from 1025 µg/m^3 to 16 µg/m^3 for the MPC/TCA/$CR_{inhalation}$ values and the ratio between the two kinds of values (OEL_{based}:MPC/TCA/$CR_{inhalation}$) differs from 1 to 385000. For the OELs it can be concluded that there is an inherently difference between the derivation of the TCA and OEL that has not been covered by the recalculation. It should not be concluded that the OELs underestimate the potential risk of a substance, it could also mean that TCA values are overprotecting. The results don't contain enough details to draw a conclusion on this. For the TDI or CR_{oral}

could also be concluded that the conversion has a limited reliability. Since the reason for the differences of the converted values with the MPC/TCA/$CR_{inhalation}$ values is unknown, the calculations are not adapted.

Especially for the OELs, since the range of values is about a factor of 100 higher, it could be argued that the toxicity values calculated from an OEL are likely to underestimate the actual TCA or CR_{oral} that would be derived for a substance. In general could be stated that the OEL derived values could be divided by a factor 100 to get them in the same range as the MPC/TCA/$CR_{inhalation}$ values. For the particulate substances, this would not lead to any additional toxicity values below the calculated immission value. For the gaseous substances, four substances (urethane, nitrosopropylamine, aziridine and propyleneimine) would get a toxicity value lower than the immission value. There is a high variation in the origin of the OEL values and it can be assumed that an additional assessment factor of 100 is not realistic for all of these substances. For three of the four substances the used OEL value is set by the Dutch Health Council and it has been taken into account that the substances are genotoxic carcinogen and the same risk level is taken into account as for the Dutch substances policy. This means that the additional assessment factor of 100 would not be necessary. For the remaining substance (nitrosopropylamine) the used OEL originates from the Swiss government and the considerations taken into account for the derivation of the OEL are unknown. Nevertheless the substance is carcinogenic but probably not genotoxic carcinogenic and the toxicity value divided by 100 is already lower than the TTC for genotoxic carcinogenic substances based on a risk level of 10^{-6} per lifetime. Therefore it can be considered that an additional assessment factor for this substance is not realistic.
Nevertheless, the cases for the OEL and TDI/CR_{oral} derived values indicate that there is a relatively high uncertainty in these values. It is therefore considered better to base general conclusion on the collected MPC/TCA/$CR_{inhalation}$ values. The OEL and TDI/CR_{oral} derived values can be used as supporting information.

3.4.3 Cumulation rule

The granting of permits for air emission is done according to the NeR, where the "cumulation rule for emissions" (in Dutch: "sommatie bepaling") is applied. This means that before looking at the mass flow limit, all emission from substances in the same substance class are added up. Therefore, the mass flow limit is in general filled up by more than one substance. In our analysis it was presumed that the mass flow limit stands for the emission of one substance and the calculated immission value is therefore also for only one substance. Hence the actual immission value for a substance emitted in combination with other substances will therefore be even lower than the immission value used in our analysis. The actual protection level of the mass flow limits (taking possible synergistic effects not into account) is therefore higher than already assumed.

3.4.4 General discussion

In the above sections two aspects were addressed that indicated that potential risk of substances might be underestimated. It was considered more realistic to base the conclusions on the MPC and TCA/$CR_{inhalation}$ values collected. Furthermore, the differences in maximum immission concentrations between the emission scenario's in RIVM (2004) is a factor 300 000 and the maximum from our chosen scenario is only a factor 5 lower than the highest concentration reported. From this point of view it should also be considered that the range in the OEL and TDI/CR_{oral} derived toxicity values collected covers eight orders of magnitude (and ten when the OEL and TDI/CR_{oral} derived values would be included). This indicates that for the majority of the substances of very high concern the risk is more likely to be overestimated than underestimated. No toxicity value could be found for many substances and a TTC value was assigned. Also in this case it could be argued that a potential risk is missed since the TTC values are set at approximately the 5th percentile of the limit values of the substances included in the analysis to determine the TTC levels. Nevertheless it should be noted that the TTC values used are considered very conservative values and the lowest TTC value (based on a higher risk level than used for the Dutch policy) was only a factor two lower than the modelled immission value for the gaseous substances. These facts in combination with the cumulation rule as described in section 3.4.3 indicate that the risk of substances of very high concern as defined by European legislation and treaties is covered by use of the mass flow limits.

3.5 Conclusions

It can be concluded that when the mass flow limits are not exceeded, it is acceptable to grant a permission for air emission of substances of very high concern without a further risk assessment. The OEL and TDI/CR_{oral} derived values support this conclusion.

This analysis also shows that the mass flow limits are in general overprotecting for most substances. Because of their high level of protection, exceeding the mass flow limits does not necessarily indicate that there is a risk. Where the mass flow limit is exceeded it is nevertheless necessary to proceed to a higher tier (assessment of the emission against the MPC_{air}).

Acknowledgements

Joost Bakker, Emiel Rorije, Gerlienke Schuur, Wouter ter Burg and Marian Post are thanked for their assistance or support in the preparation of this report.

Literature

ATSDR. 2013. Toxic substances portal. Agency for Toxic Substances and Disease Registry.

Baars AJ, Theelen RMC, Janssen PJCM, Hesse JM, van Apeldoorn ME, Meijerink MCM, Verdam L, Zeilmaker MJ. 2001. Re-evaluation of human-toxicological maximum permissible risk levels. Bilthoven: RIVM. Report no. 711701025.

Bodar CWM. 2008. Environmental risk limits for dibutylphthalate (DBP). Bilthoven: RIVM. Report no. 601782009.

Bodar CWM, Smit CE, Post M, van Helmond CAM, Luit RJ. 2013. Validity of REACH risk limits in the Dutch policy framework on priority chemicals - Road-map Quality standard setting. Bilthoven: RIVM. Report no. 601357013.

Brand E, Bogte J, Baars BJ, Janssen PJCM, Tiesjema G, van Herwijnen R, van Vlaardingen PLA, Verbruggen EMJ. 2011. Proposal for Intervention Values soil and groundwater for the 2nd, 3rd and 4th series of compounds. Bilthoven: RIVM. Report no. 607711006.

Dang Z, Smit CE. 2008. Environmental risk limits for carbendazim. Bilthoven: RIVM. Report no. 601716014.

de Jong FMW, Janssen PJCM. 2010. Road-map Normstelling - Luchtnormen geordend. Bilthoven: RIVM. Report no. 601782026.

de Poorter LRM, Hogendoorn EA, Luit RJ. 2011. Criteria voor Zeer Zorgwekkende Stoffen. Bilthoven: RIVM. Report no. 601357004.

ECHA. 2012. Guidance on information requirements and chemical safety assessment - Part E: Risk Characterisation. Helsinki: European Chemicals Agency. Report no. ECHA-12-G-16-EN.

Escher SE, Tluczkiewicz I, Batke M, Bitsch A, Melber C, Kroese ED, Buist HE, Mangelsdorf I. 2010. Evaluation of inhalation TTC values with the database RepDose. Regulatory Toxicology and Pharmacology. 58: 259-274.

EU. 2000. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. In: Union E (Ed.) Brussels, European Union.

EU. 2004. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC. In: Union E (Ed.) Brussels, European Union.

EU. 2006. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Brussel, European Union.

EU. 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. In: Union E (Ed.) Brussels, European Union.

Fleuren RHLJ, Janssen PJCM, De Poorter LRM. 2009. Environmental risk limits for twelve volatile aliphatic hydrocarbons. An update considering human-toxicological data. Bilthoven: RIVM. Report no. 601782013.

InfoMil. 2013. Digitale NeR. Den Haag, Rijkswaterstaat, Ministerie van Infrastructuur en Milieu.

Kalkhof H, Herzler M, Stahlmann R, Gundert-Remy U. 2012. Threshold of toxicological concern values for non-genotoxic effects in industrial chemicals: re-evaluation of the Cramer classification. Archives of Toxicology. 86: 17-25.

Kroes R, Renwick AG, Cheesman M, Kleiner J, Mangelsdorf I, Piersman A, Schilter B, Schlatter J, van Schothorst F, Vos JG. 2004. Structured-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food and Chemical Toxicology. 42: 65-83.

OSPAR. 1992. Convention for the protection of the marine environment of the north-east atlantic. London, OSPAR Commission.

Patlewicz G, Jeliazkova N, Safford RJ, Worth AP, Aleksiev B. 2008. An evaluation of the implementation of the Cramer classification scheme in the Toxtree software. SAR QSAR Environ. Res. 19: 495-524.

RIVM. 2004. Handreiking bepaling van het immissieniveau - Versie 9 augustus 2004. RIVM- Available through: www.infomil.nl under the heading "hulpmiddelen bij de NeR".

SCOEL. 2013a. Consolidated indicative occupational exposure limits values (IOELVs). Brussels, European Commission - Employment, Social Affairs & Inclusion - Health and Saftety at work – The Scientific Committee on Occupational Exposure Limits (SCOEL).

SCOEL. 2013b. SCOEL recommendations. Brussels, European Commission - Employment, Social Affairs & Inclusion - Health and Saftety at work – The Scientific Committee on Occupational Exposure Limits (SCOEL).

Slooff W, Haring BJA, Hesse JM, Janus JA, Thomas R, van Beelen P, de Boer JLM, Boumans LJM, Buijsman E, Canton JH, Cremers PMA, van der Heijden CA, Knaap AGAC, Krajnc EI, Kramers PGN, Kreis IA, Kroese ED, Lebret E, Matthijsen AJCM, van de Meent D, van der Meulen A, Meulenbelt J, Taalman RDFM, Bijstra D, Bril J, Salomons W, van der Woerd KF. 1990. Integrated Criteria Document Arsenic. Bilthoven: RIVM. Report no. 710401004.

Smit CE. 2010. Environmental risk limits for benzyl chloride and benzylidene chloride Bilthoven: RIVM. Report no. 601714016.

Tiesjema G, Baars AJ. 2009. Re-evaluation of some humantoxicological Maximum Permissible Risk levels earlier evaluated in the period 1991-2001. Bilthoven: RIVM. Report no. 711701092.

TNO. 1998. Het Nieuwe Nationaal Model - Model voor de verspreiding van luchtverontreiniging uit bronnen over korte afstanden - Rapportage over het onderzoek Revisie Nationaal Model en de besluitvorming daarover in de begeleidingscommissie. Apeldoorn: TNO. Report no. R 98/306.

US-NLM. 2013. Toxnet - Database on toxicology, hazardous chemicals, environmental health, and toxic releases. US - National Library of Medicine.

US EPA. 2009. EPI Suite (computer program). Version 4.0. Washington, DC, U.S. Environmental Protection Agency (EPA) Office of Pollution Prevention Toxics and Syracuse Research Company (SRC).

van Bruggen M, Bodar CWM, Bos PMJ, van Belle NJC, Grievink L. 2010. Risicobeoordeling emissie ethyleenoxide in Zoetermeer. Bilthoven: RIVM. Report no. 609300017.

van Herwijnen R. 2009. Environmental risk limits for acrylonitrile. Bilthoven: RIVM. Report no. 601782015.

van Herwijnen R, Smit CE. 2009. Environmental risk limits for boron. Bilthoven: RIVM. Report no. 601782030.

van Herwijnen R, van Veen M. 2009. Environmental risk limits for 1,3-butadiene. Bilthoven: RIVM. Report no. 601782014.
van Herwijnen R. 2013. Handreiking identificatie Nederlandse zeer zorgwekkende stoffen. Bilthoven: RIVM. Report no. 601357012.
van Vlaardingen PLA, de Poorter LRM, Fleuren RHLJ, Janssen PJCM, Posthuma-Doodeman CJAM, Verbruggen EMJ, Vos JH. 2007. Environmental risk limits for twelve substances, prioritised on the basis of indicative risk limits. Bilthoven: RIVM. Report no. 601782003.
Verbruggen EMJ, van Herwijnen R. 2011a. Environmental risk limits for chrysene. Bilthoven: RIVM. Report no. 601357008.
Verbruggen EMJ, van Herwijnen R. 2011b. Environmental risk limits for benz[a]anthracene. Bilthoven: RIVM. Report no. 601357009.
VROM. 1999. Environmental risk limits in the Netherlands. A review of environmental quality standards and their policy framework in the Netherlands. The Hague: Ministry of Housing, Spatial Planning and the Environment.
VROM. 2004. (Inter)nationale Normen Stoffen. The Hague: Ministry of Housing, Spatial Planning and the Environment.

National Institute for Public Health
and the Environment
P.O. Box 1 | 3720 BA Bilthoven
www.rivm.com