ZINC METAL

CAS No: 7440-66-6

EINECS No: 231-175-3

SUMMARY RISK ASSESSMENT REPORT

PART I - ENVIRONMENT

Final report, May 2008

The Netherlands

This document has been prepared by the Ministry of Housing, Spatial Planning and the Environment (VROM) in consultation with the Ministry of Social Affairs and Employment (SZW) and the Ministry of Public Health, Welfare and Sport (VWS), on behalf of the European Union.

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NOTE:

Part II (Human Health) of the Summary Risk Report for zinc metal has been published already in 2004 by the European Commission (see http://ecb.jrc.it).

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance zinc metal that has been prepared by The Netherlands in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

It is noted that in the context of Council Regulation (EEC) No. 793/93 risk assessments were carried out for zinc metal (CAS No. 7440-66-6), zinc distearate (CAS No. 557-05-1 / 91051-01-3), zinc oxide (CAS No.1314-13-2), zinc chloride (CAS No.7646-85-7), zinc sulphate (CAS No.7733-02-0) and trizinc bis(orthophosphate) (CAS No.7779-90-0). All six substances are EU priority substances within Council Regulation (EEC) No. 793/93. For each compound a separate RAR and Summary RAR have been prepared. It should be noted, however, that the RAR Zinc metal contains specific sections (as well in the exposure part as in the effect part) that are relevant for the other zinc compounds as well. For these aspects, the reader is referred to the RAR Zinc metal.

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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TABLES

1 GENERAL SUBSTANCE INFORMATION

See Part II – Human Health for data on ‘identification’, purity, impurities and additives’ and ‘physico-chemical properties’ of the substance.

Note: The following section on Classification and Labelling replaces the classification and labelling section that is included in Chapter 1 of the Human Health part of the Summary Risk Report for Zinc metal (published in 2004), as the classification and labelling mentioned below is now included in Annex 1 of Directive 67/548/EEC.

CLASSIFICATION AND LABELLING

At the September 2002 meeting, it was agreed no longer to classify stabilised zinc powder for physical chemical properties (flammability), but to keep the current classification for physical chemical properties (flammability) for pyrophoric zinc powder. It was agreed not to classify the powders for health effects. For zinc massive it was agreed not to classify for physical chemical properties and health effects.

Annex 1 of Directive 67/548/EEC contains a list of harmonised classifications and labellings for substances or groups of substances, which are legally binding within the EU.
For zinc metal the current Annex 1 classification and labelling (29^{th} ATP, 2004) is as follows:

Pyrophoric zinc metal powder and dust
Classification
F; R15-17
N; R50-53
Labelling
F; N
R15-17-50/53
S(2-)43-46-60-61

Stabilised zinc metal powder and dust
Classification
N; R50-53
Labelling
N;
R50/53
S60-61

Massive zinc metal
Not included in Annex 1 of Directive 67/548/EEC. The DG Environment is consulted for advice on classification and labelling of zinc in massive form. At the time the RAR Zinc metal was finalised this issue was still under discussion.

2 GENERAL INFORMATION ON EXPOSURE

2.1 PRODUCTION

Zinc metal is produced (>1000t/y) at around fifteen known sites in the European Union.

The total production volume of zinc metal in the EU is about 2,193,000 t/y (data for the year 1995), of which 98% was primary production from ores and 2% was secondary production from zinc containing scrap or residues. Around 80% of the primary zinc production involves the hydrometallurgical process and 20% the pyrometallurgical process. There is no detailed information on the imported or exported volumes of zinc in the EU, but as the EU consumption and production of zinc are very similar, the imported or exported volumes of zinc in the EU will be low.

2.2 USE PATTERN

Table 2.1 shows the industrial and use categories of zinc metal. One should realise that some use categories are probably more relevant to compounds made from zinc than to zinc metal itself, because it is not always possible to draw a clear border between those two options (e.g. chemicals, pigments). Zinc metal is mainly used in the EU in galvanising (39%), brass (25%), die casting alloy (12%), rolled/wrought zinc (12%), zinc powder/dust (3%) and other applications, i.e. the production of zinc compounds (9%). The quantitative estimates, mentioned between brackets, are from the year 1997. The two main types of use categories for zinc can be characterised as non dispersive use and use resulting in inclusion into or onto matrix.

Table 2.1 Industrial and use categories of zinc metal in the EU

Industrial category	**EC no.**	**Use category**	**EC no**
Chemical Industry: basic chemicals	2		
Chemical industry: chemicals used in synthesis	3	Intermediates Laboratory chemicals	33 34
Electrical/electronic engineering industry	4	Conductive agents	12
Personal/domestic	5	Absorbents and adsorbents	1
Metal extraction, refining and processing industry	8	Electroplating agents Others: Production of brass and other zinc alloys	17 55
Paints, lacquers and varnishes industry	14	Absorbents and adsorbents Colouring agents Corrosion inhibitors Reprographic agents	1 10 14 45
Others: Basic metal used in metal industry	15	Corrosion inhibitors Others: Pyrotechnical use	14 55

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 General introduction

The EU Technical Guidance Document (TGD, 2003) on risk assessment does not provide detailed information on how to deal with (essential) elements that have a natural background concentration in the environment, such as zinc. In the risk assessment reports (RARs) for zinc metal and zinc compounds, including the RAR for zinc metal, the "added risk approach" has been used. In this approach both the "Predicted Environmental Concentration" (PEC) and the "Predicted No Effect Concentration" (PNEC) are determined on the basis of the added amount of zinc, resulting in an "*added* Predicted Environmental Concentration" (PEC_{add}) and "*added* Predicted No Effect Concentration" ($PNEC_{add}$), respectively.

In the present environmental exposure assessment, the use of the added risk approach implies that the PEC_{add} values have been calculated from zinc emissions due to anthropogenic activities. In the local exposure scenarios for zinc metal that are presented in this RAR, the PEC_{add} values (which are expressed as zinc) are based on the local zinc emissions due to the production or use of zinc metal.

In the environmental effect assessment, the use of the added risk approach implies that the $PNEC_{add}$ values have been derived from toxicity data that are based on the added zinc concentration in the tests. Thus, the $PNEC_{add}$ is the maximum permissible addition to the background concentration. From the background concentration (Cb) and the $PNEC_{add}$, the PNEC can be calculated: $PNEC = Cb + PNEC_{add}$. It is emphasised that the $PNEC_{add}$ values were not derived from ecotoxicity data for zinc metal (which is poorly soluble), but derived from the combined ecotoxicity data for soluble zinc compounds, see further section 3.2.

Finally, in the environmental risk characterisation, the use of the added risk approach implies the evaluation of the PEC_{add} / $PNEC_{add}$ ratios. In case measured environmental concentrations are used in the risk characterisation, either the background concentration has to be subtracted from the measured environmental concentration (resulting in a "PEC_{add} / $PNEC_{add}$" ratio) or the background concentration has to be added to the $PNEC_{add}$ (resulting in a traditional "PEC / PNEC" ratio). See section 3.3.1 for additional explanation on the application of the added risk approach in the risk characterisation.

3.1.2 Environmental releases and fate

A general description about the release and fate of zinc in the environmental compartment is presented only in the RAR Zinc metal, but those data are applicable to all zinc compounds.

3.1.3 Local exposure assessment

The local environmental exposure assessment of zinc metal is based on the industrial releases of zinc during the following life cycle stages: *i)* production of zinc metal, *ii)* processing of zinc in galvanising industry ('continuous hot dip galvanising'(CHDG) and electro galvanising'' (EG)), *iii)* processing of zinc in brass, *iv)* formulation in zinc alloy and processing of zinc die casting, *v)* processing of rolled and wrought zinc, and *vi)* production of zinc powder and dust[2].

Production

For all 17 production sites of zinc metal, the exposure assessment is based on site-specific data that included the production tonnage and the emission to air and surface water receiving the effluent of the waste water treatment plant (WWTP). For a relatively large number of the production sites there were also measured local concentrations in air and in the receiving surface water and sediment. For the production stage there were about 30 different scenarios, based on either the site-specific emission data or on the measured concentrations.

Use categories (processing)

For most of the use categories (processing stages) actual local site-specific emissions were submitted and for some of the use sites there also were measured local concentrations. In addition, some generic scenarios were used for processing stages that were not covered fully by the site-specific information, for example for the galvanising processes (as about 26% and 14% of the CHGD and EG plants in the EU were not covered by the submitted site-specific data. For the use categories there were about 80 different scenarios, based on the site-specific emission data, generic scenarios or measured concentrations.

Additional data on local exposure scenarios

Because of the large number of local exposure scenarios, the added Predicted Environmental Concentrations, i.e. $Clocal_{add}$ and $PEClocal_{add}$ values ($(PE)C_{add}$s) for STP effluent, surface water, sediment, air and agricultural soil, based on the local exposure scenarios on the emissions of zinc due to the production or use of zinc metal, are <u>not</u> included in this Summary RAR. The local $(PE)C_{add}$s, which are expressed as zinc, have been used in the risk characterisation to calculate the local $(PE)C_{add}$ / $PNEC_{add}$ ratios (see section 3.3)[3].

It is noted that the PEC_{add}s for agricultural soil include the added regional background concentration ($PECregional_{add}$), according to the TGD equation $PEClocal_{add} = Clocal_{add} + PECregional_{add}$. The $PECregional_{add}$ for soil is 0.5 mg/kg wwt (calculated value). For STP effluent, the PEC_{add} is equal to the $Clocal_{add}$, as there is no regional PEC_{add} for STP effluent. For water and sediment, the $Clocal_{add}$ values (thus without the regional PEC_{add}) are used initially in the risk characterisation for water and sediment. i.e. initially only the $Clocal_{add}$ values have been compared with the corresponding $PNEC_{add}$. See section 3.3.1 for further explanation of the local risk characterisation.

It is noted that the $(PE)Clocal_{add}$s for air (atmosphere) have been left out of consideration in the environmental risk assessment, as no $PNEC_{add}$ could be derived for air (there are no useful data on the effects of airborne zinc on environmental organisms. The $(PE)Clocal_{add}$s for air have been used in the risk assessment of man indirectly exposed via the environment (see Human Health part).

[2] See the separate RARs for zinc oxide, zinc chloride, zinc sulphate, zinc phosphate and zinc distearate for the local exposure and risk assessments for the production and use of zinc compounds.

[3] It is noted that in the RAR Zn metal as well as in this summary RAR the following notations were used as synonyms regarding the local exposure concentrations:
$Clocal_{add}$ is used as synonym for local C_{add}, and, likewise, $PEClocal_{add}$ is used as synonym for local PEC_{add}.

3.1.4 Regional exposure assessment

A regional exposure assessment is described only in the RAR Zinc metal. The regional exposure assessment includes the industrial and diffuse emissions of all six current EU priority zinc compounds. In case of diffuse emissions it is not possible to distinguish between emissions from current EU priority zinc compounds and non-EU priority list zinc compounds. The diffuse emissions may thus also comprise emissions from other zinc compounds, as shown below in **Figure 3.1**.

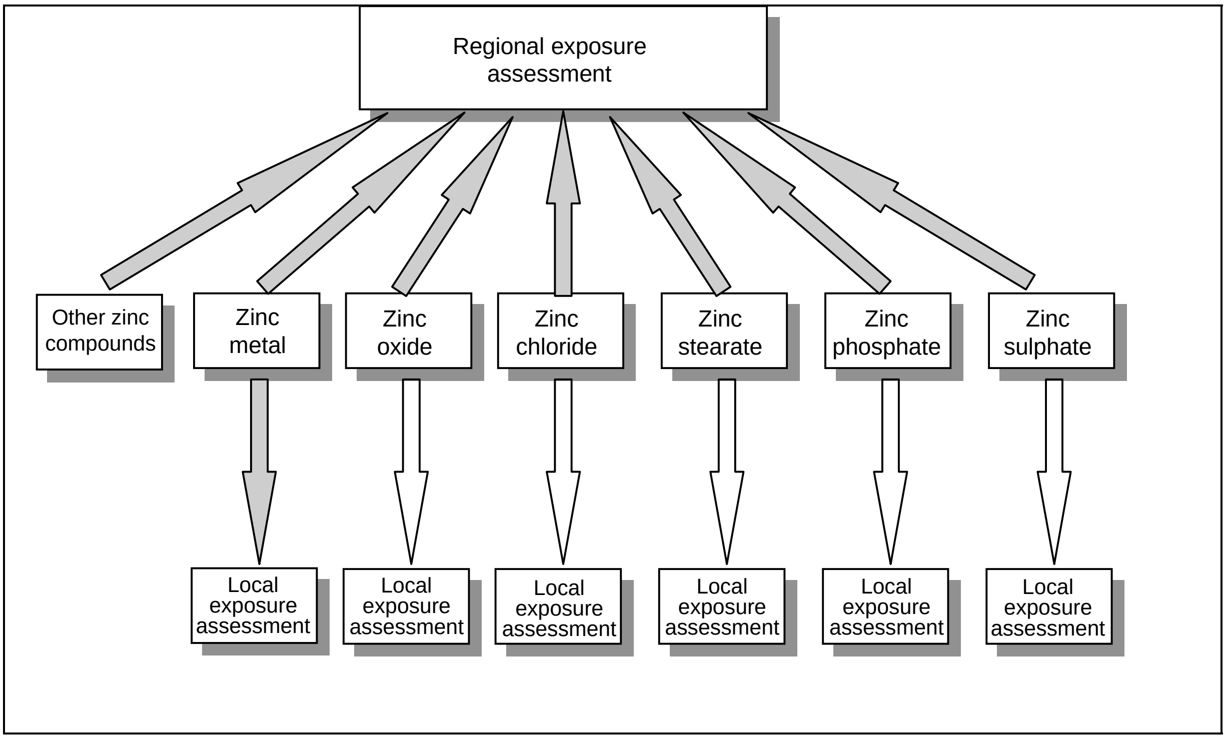

Figure 3.1 Theoretical outline for the regional and local exposure assessment for zinc metal and zinc compounds

In the regional exposure assessment, regional PEC_{add} values were calculated for the Netherlands as representative EU region and for a theoretical EU region[4]. The PEC_{add} values for the NL-region were calculated from the environmental zinc emissions in the Netherlands[5]. In addition, regional PEC_{add} values were calculated for a theoretical EU-region; these values were calculated from the continental (is total EU) zinc emissions. The calculated regional

[4] It is noted that in the RAR Zn metal the following notations were used as synonyms regarding the regional exposure concentrations:
$Cregional_{add}$ is used as synonym for regional C_{add}, and, likewise, $PECregional_{add}$ is used as synonym for regional PEC_{add}.

[5] The Netherlands was selected as representative EU-region, as for the Netherlands the most recent, extended and detailed information on environmental zinc emissions are available. Furthermore, the area of the Netherlands corresponds with that of a EU region (40,000 km^2) as defined in the EU TGD.

PEC_{add} values (expressed as zinc) for the theoretical EU-region and the NL-region are listed in **Table 3.1.** It is noted that based on the EUSES calculations the continental contribution to the regional PEC_{add} values is 29 % for water and 42 % for air. This is calculated based on the ratio between the regional and continental concentrations for water and air.

The calculated regional PEC_{add} values (to which the natural background concentrations have been added) have been compared with the measured regional zinc concentrations in the environment (monitoring data). Because of the very large number of measured regional zinc concentrations (especially in surface water, sediment, soil and groundwater) these data are <u>not</u> included in this summary RAR.

In NL <u>surface waters</u>, the measured concentrations are very similar to the calculated regional PEC_{add} values; only the measured concentrations in the river Meuse are substantially higher than the calculated PEC_{add}s (factor 2-3 higher). In surface waters in other EU regions, the measured concentrations (90-percentile values) substantially exceeded the calculated regional PEC_{add}s in several regions in France and Germany and in the Flanders region in Belgium (factor 2-5 higher). On the other hand, the 90-percentile concentration in Swedish waters was relatively low compared to the calculated regional PEC_{add}s (up to a factor of 2 lower). The comparisons of the measured and calculated concentrations in <u>sediments</u> show the same trend, i.e. measured concentrations that substantially exceed the calculated regional PEC_{adds} (factor of 2-3 higher).

The calculated regional concentrations (PEC_{add}) of zinc in <u>air</u> are 0.006 μg/m^3 (NL-region) and 0.01 μg/m^3 (EU-region). Recent monitoring data of the Netherlands (0.04 μg/m^3, annual average values for the Netherlands in 1997 and 1998) are found to be within the same order of magnitude, but nevertheless substantially higher than the calculated regional PEC_{add}s (around a factor of 5 higher). Available Belgian monitoring data are up to 2 or 3 orders of magnitude higher than the calculated regional PEC_{add}s, but the Belgian data are less recent and include monthly averages in addition to annual averages.

The zinc concentrations in <u>soil</u> are strongly related to the nature of the soil material (soil type). A comparison of the calculated PEC_{add} for agricultural soil with the measured concentrations in agricultural soil is performed in the regional risk characterisation for agricultural soil, see section 3.3.2.2.

In the regional risk characterisation (see section 3.3.2.2.) both calculated and measured data will be used to derive PEC_{add} / $PNEC_{add}$ values for the environmental compartments, but the emphasis will be on the large number of measured data from various EU regions. Only monitoring data from after 1995 will be used as they reflect the most representative situation. The reference year is 1998/1999 for the current zinc exposure assessment. Some very recent monitoring data (after 2000) will, however, be discussed in the regional risk characterisation to indicate the most recent trends in zinc levels in the environment.

The regional exposure and risk assessment also include data on measured zinc concentrations related to particular diffuse sources (especially corrosion and/or traffic), with special attention to “line sources” (road borders), although strictly speaking these data refer to local situations.

A further important issue included in the regional exposure and risk assessment is the (potential) accumulation of zinc in agricultural soils. See the risk characterisation (section 3.3.2.2) for the results for these issues.

Table 3.1 Calculated PEC_{add} values in theoretical EU-region and NL-region

	EU-region	NL-region
PEC_{add} air (µg/m^3)	0.01	0.006
PEC_{add} water (total-Zn; µg/l)	16.8 * 27.0 **	12.2 * 20.0 **
PEC_{add} sediment (mg/kg wwt) PEC_{add} sediment (mg/kg dwt)	268 696	194 504
PEC_{add} soil agricultural (mg/kg wwt) PEC_{add} soil agricultural (mg/kg dwt)	57 64	57 64
PEC_{add} soil natural (mg/kg wwt) PEC_{add} soil natural (mg/kg dwt)	0.9 1.0	0.5 0.6
PEC_{add} soil industrial (mg/kg wwt) PEC_{add} soil industrial (mg/kg dwt)	86 97	38 43

* $C_{suspended\ matter}$ 15 mg/l and $Kp_{suepended\ matter\ /\ water}$ 110.000 l/kg

** $C_{suspended\ matter}$ 30 mg/l and $Kp_{suepended\ matter\ /\ water}$ 110.000 l/kg

3.2 EFFECTS ASSESSMENT

3.2.1 Aquatic and terrestrial compartment

3.2.1.1 Zinc metal (powder)

Ecotoxicity data for zinc metal (powder) are limited. The aquatic toxicity data for zinc metal (powder), summarized below, were submitted by the industry as full test reports, but not included in the submitted zinc (metal) IUCLID data sheet (*ECB-version of 1 March 1995*). The data comprise short-term tests with freshwater algae, crustaceans and fish, fulfilling the required ecotoxicity dataset (base set). The three tests were performed with the same lot of zinc metal powder, having a median diameter of 13.4 µm and a purity of 98.4%. The results of these studies are based on the actual dissolved-Zn concentrations.
Terrestrial toxicity data for zinc metal were not submitted.

Aquatic toxicity – algae
A growth test with the alga *Pseudokierchneriella subcapitata* (formerly known as *Selenastrum capricornutum* resulted in a 72-h EC50 for dissolved zinc of 150 µg/l (endpoint: specific growth rate) and a 72-h NOEC for dissolved zinc of 50 µg/l (endpoints: specific growth rate and biomass). The test was performed according to OECD 201 and under GLP.

It is noted that similar growth tests have been conducted with the same algal species, using a soluble zinc compound or using “insoluble” ZnO as test compound (see Table 3.3.2.a in Annex 3.3.2.A of the RAR Zinc metal). These tests, all using soft to very soft artificial test media, resulted in comparable NOEC values if expressed as dissolved zinc, i.e. NOEC values for dissolved zinc in the range of 5-50 µg/l, regardless whether the soluble or the “insoluble” test compound was used.

Aquatic toxicity - invertebrates
A short-term *Daphnia magna* immobilisation test resulted in a 48-h NOEC for dissolved zinc of 150 µg/l. An EC50 could not be derived from the test results. The test was performed according to OECD 202 and under GLP.

It is noted that the 48-h NOEC from this short-term test is very similar or within a factor of 2 of a large number of NOEC values (endpoints: survival and/or reproduction) derived in long-term *D. magna* tests in which a soluble zinc salt was used as test compound (see Table 3.3.2.a in Annex 3.3.2.A of the RAR Zinc metal).

Aquatic toxicity - fish
In a 96-h acute toxicity test with the fish *Brachydanio rerio,* no effect was found for dispersed zinc powder at 100 mg/l (limit test). The actual dissolved-zinc concentration in this zinc powder dispersion was 2,360 µg/l. The test was performed according to OECD 203 and under GLP.

Environmental risk assessment approach
Zinc metal is much less water soluble than zinc salts such as zinc sulphate and zinc chloride. However, the results from the above-mentioned aquatic toxicity tests with zinc metal powder, although very limited with respect to the number of studies, indicate that zinc (ion) may be dissolved from zinc powder dispersions to a level that results in toxic effects to aquatic organisms. In addition, the test results -expressed as dissolved zinc- are similar to those from tests with soluble zinc salts. Once emitted into the environment, dissolved zinc from zinc metal will be transformed into other zinc species. The further speciation of zinc, which includes complexation, precipitation and sorption, depends on the environmental conditions. Therefore, emitted zinc metal and other emitted zinc species will contribute to the effect of the total amount of zinc in the environment, regardless of the original source or chemical form. For these reasons the risk characterisation for zinc metal is based on zinc, not on zinc metal as such, as explained also earlier in section 3.1 and in the RAR Zinc metal.

Because of the abovementioned approach, no effort has been made to retrieve additional ecotoxicity data on zinc metal.

3.2.1.2 Zinc

For a comprehensive overview of the aquatic and terrestrial toxicity of (soluble) zinc, see the RAR Zinc metal and especially the Annexes of that report; the Annexes include detailed data on the ecotoxicity data bases for (soluble) zinc.

In the Risk Assessment Report on Zinc metal, $PNEC_{add}$ values have been derived for zinc, on the basis of tests with soluble zinc salts (especially zinc sulphate or zinc chloride), using the “added risk approach” (see also earlier in section 3.1 of the present report for an explanation of the added risk approach). These $PNEC_{add}$ values for zinc are listed in **Table 3.2** and used in the risk characterisation (see section 3.3).

Table 3.2 $PNEC_{add}$ values for zinc (from RAR Zinc metal)

Environmental compartment	$PNEC_{add}$	$PNEC_{add}$ value, as Zn	Remark
Freshwater (Hardness ≥ 24 mg/L) (1)	$PNEC_{add,\ aquatic}$	7.8 µg/l 21 µg /l	Dissolved zinc Total zinc (2)
Freshwater (Hardness <24 mg/L) (1)	$PNEC_{add,\ aquatic}$ softwater	3.1 µg/l	Dissolved zinc
Freshwater sediment	$PNEC_{add,\ sediment}$	49 mg/kg dwt 11 mg/kg wwt	Dry weight of sediment (3) Wet weight of sediment (3)
STP effluent	$PNEC_{add,\ microorganisms}$	52 µg/l	Dissolved zinc
Soil	$PNEC_{add,\ terrestrial}$	26 mg/kg dwt 23 mg/kg wwt	Dry weight of soil (4) Wet weight of soil (4)

(1) Total hardness (mg/l), as $CaCO_3$.

(2) Total-Zn concentration: calculated from the $PNEC_{add,\ aquatic}$ of 7.8 µg/l for dissolved zinc, a C_{susp} of 15 mg/l (according to the TGD, 2003) and a Kp_{susp} of 110,000 l/kg.

(3) For the dry to wet weight normalisation of the $PNEC_{add,\ sediment}$ it is assumed that wet sediment contains 10% solids (density 2500 kg/m^3) and 90% water (density 1000 kg/m^3) by volume, i.e. 22% solids by weight. These properties are set equal to those of suspended matter, thus the $PNEC_{add,\ suspended\ matter}$ equals the $PNEC_{add,\ sediment}$ (according to the TGD, 2003).

(4) For the dry to wet weight normalisation of the $PNEC_{add,\ terrestrial}$ it is assumed that wet soil contains 60% solids (density 2500 kg/m^3) and 20% water (density 1000 kg/m^3) by volume, i.e. 88% solids by weight.

3.2.2 Atmosphere

There are no data to derive an ecotoxicological $PNEC_{(add)}$ for zinc in the air compartment.

3.2.3 Secondary poisoning

Based on data on bioaccumulation of zinc in animals and on biomagnification (i.e. accumulation and transfer through the food chain), secondary poisoning is considered to be not relevant in the effect assessment of zinc, see further the RAR Zinc metal.

3.3 RISK CHARACTERISATION

3.3.1 Local risk characterisation

3.3.1.1 Local risk characterisation – methods

In the first step of the risk characterisation, the local added Predicted Environmental Concentrations ($PEClocal_{add}$s) in the various environmental compartments are compared with the corresponding added Predicted No Effect Concentrations ($PNEC_{add}$s). In case this yields a PEC_{add} / $PNEC_{add}$ ratio above 1, the risk characterisation includes (if possible) a second step in which a bioavailability correction is made, see **Table 3.3** for a summary of the bioavailability correction methods applied and see RAR Zinc metal sections 3.3.2.1.1 (water), 3.3.2.2.1 (sediment) and 3.3.3.1.1 (soil) for a comprehensive explanation of the derivation and application of these bioavailability correction methods[6]. In all cases the bioavailability

[6] No bioavailability correction is done for the PEC_{add} in STP effluent. It is noted that in the main report (RAR Zinc metal) the notation PEC_{STP} has been used as synonym for the PEC_{add} in STP effluent.

correction is applied to the PEC_{add}, not to the generic $PNEC_{add}$, although for the resulting corrected PEC_{add} / $PNEC_{add}$ ratio it makes no difference whether the correction is applied to the PEC_{add} or to the $PNEC_{add}$.

- For <u>water</u> there is only a site-specific bioavailability correction, i.e. a bioavailability correction is only applied in case there are reliable site-specific data on the abiotic water characteristics that are needed to apply the BLM models. Bioavailability factors are being derived for two scenarios of abiotic conditions. One scenario refers to an average setting and the second one to a 'realistic worst case' setting. The highest bioavailability factor ($BioF_{water}$) is subsequently used in the risk characterisation by multiplying the original $(PE)C_{add}$ with this $BioF_{water}$. If a site has a discharge to seawater, no bioavailability correction is performed, as the BLM models were developed for freshwaters.
- For <u>sediment</u> the bioavailability correction is either site-specific (preference) or generic.
- For <u>soil</u> the bioavailability correction starts with the application of the generic lab-to-field correction factor (R_{L-F}) and if the corrected PEC_{add} / $PNEC_{add}$ ratio still is >1, then a further, site-specific bioavailability correction is applied.

Final conclusions of the risk assessment are based on the corresponding 'corrected' PEC_{add} / $PNEC_{add}$ ratios.

Table 3.3 Bioavailability corrections as applied in the EU RARs on zinc and zinc compounds

Compartment	***Added* Predicted Environmental Concentration (PEC_{add})**	
	Bioavailability correction (generic)	**Bioavailability correction (site-specific or region-specific)**
Water	None	Biotic Ligand Models (BLMs) for algae, Daphnia and fish (a)
Sediment	Factor of 2 (b)	Acid Volatile Sulphide (AVS) method (c)
Soil	Factor of 3 (d) (R_{L-F})	Regression lines for invertebrates, plants and microbial processes (e)

(a) Water – BLMs: Based on the relationship between toxicity of zinc and water characteristics, e.g. pH, dissolved organic carbon (DOC) and hardness (see RAR Zinc metal Section 3.3.2.1.1 for further explanation).

(b) The PEC_{add} (or measured concentration) for zinc in sediment is divided by a generic, AVS-related correction factor of 2 to obtain the bioavailable concentration of zinc (note that in the original description of this method in section 3.3.2.2.1 of the RAR Zinc metal it is stated that the PEC_{add} is multiplied with a factor of 0.5). The corrected PEC_{add} is subsequently used in the assessment of the PEC_{add} / $PNEC_{add}$ ratio.

(c) Sediment – AVS method: Based on the inverse relationship between toxicity of zinc and AVS content in sediment (see RAR Zinc metal Section 3.3.2.2.1 for further explanation). This method is also described as the SEM/AVS-method, as also the toxicity of other metals, i.e. Cd, Cu, Ni, Hg and Pb, referred to as Simultaneously Extracted Metals (SEM) is reduced by AVS.

(d) The PEC_{add} (or measured concentration) for zinc in soil is divided by a generic, ageing-related lab-to-field correction factor (R_{L-F}) of 3 to obtain the bioavailable concentration of zinc. The corrected PEC_{add} is subsequently used in the assessment of the PEC_{add} / $PNEC_{add}$ ratio.

(e) Soil – Regression lines: Based on the relationship between toxicity of zinc and soil characteristics, e.g. pH and cation exchange capacity (CEC) (see RAR Zinc metal Section 3.3.3.1.1 for further explanation).

For STP effluent and soil, the PEC_{add}s are compared in the first step of the risk characterisation with the corresponding $PNEC_{add}$s, as stated above.

For water and sediment, <u>initially</u> only the $Clocal_{add}$ values (thus without the $PECregional_{add}$) are compared in the first step of the risk characterisation with the corresponding $PNEC_{add}$s. At first the local aquatic risk characterisation thus focuses on the contribution of point sources to the potential risks, thereby neglecting the contribution of diffuse sources. If the regional PEC_{add} would have been added for sediment, all local scenarios would have resulted in $PEC_{add}/PNEC_{add}$ ratios larger than 1. This because the regional PEC_{add} for sediment already exceeds the $PNEC_{add}$ of 11 mg/kg wwt. This holds for both calculated and measured sediment concentrations. For this reason for <u>sediment</u> for all scenarios with a $Clocal_{add}/PNEC_{add}$ ratio between 0 and 1 a **conclusion iii*** will be drawn, indicating that due to (possibly) high added regional background concentrations a risk for sediment at local scale cannot be excluded. It has to be noted that this conclusion would not be influenced by applying the generic sediment bioavailability correction factor (BioF) of 0.5 in the second step of the risk assessment.

The situation is somewhat less pronounced for the surface water compartment. With a $PNEC_{add}$ of 7.8 µg/l the regional PEC_{add} / $PNEC_{add}$ would lie between 0.8 (regional PEC_{add} of 6.7 µg/l) and 1.1 (regional PEC_{add} of 8.8 µg/l). When using an (arbitrary) average bioavailability correction factor (BioF) of 0.6[7] in the second step of the risk assessment, these ratios would become, respectively 0.5 and 0.7. As a result of this, it is decided that for $Clocal_{add}/PNEC_{add}$ ratios between 0.5[8] and 1 a **conclusion iii*** will be drawn, indicating that due to (possibly) high (added) regional background concentrations a local risk for water cannot be excluded. For scenarios with a surface water $Clocal_{add}$ / $PNEC_{add}$ ratio < 0.5 the local contribution to the (added) regional background is assumed to be negligible (**conclusion ii**).

For those scenarios in which the involved process type does intrinsically not result in water emissions a **conclusion ii)** is drawn for water and sediment.

It is important to note that the above-mentioned distinction between a (normal) conclusion iii) and a conclusion iii*) is not only made because of transparency, but also because the regional background is due to a variety of zinc compounds (and thus not only the zinc compound specifically addressed in the local risk characterisation).

In the RAR zinc metal a general reflection is given on the uncertainties in the zinc risk assessments.

3.3.1.2 Local risk characterisation - results

Because of the large number of local risk characterisation scenarios, the $(PE)C_{add}$ / $PNEC_{add}$ ratios for all scenarios are not included in this Summary RAR, but the results and conclusions are summarised below. It is emphasised that the final conclusions of the local risk characterisation as summarised below are based on the 'corrected' PEC_{add} / $PNEC_{add}$ ratios (if applicable), as explained earlier in section 3.3.1.1

[7] See data in RAR Zinc Metal. Average of realistic worst case and average BioF for average NL data.

[8] A $Clocal_{add}$ / $PNEC_{add}$ of between 0.5 and 1 should theoretically also be corrected for bioavailability. This would give ratios between 0.3 and 0.6 when using the correction factor of 0.6. Such ratios could just raise the overall PEC_{add} / $PNEC_{add}$ ratio, thus including the regional background, to levels above one.

Aquatic compartment (including sediment)

STP-effluent
Production:
For 12 out of the 17 production sites of zinc metal the PEC_{add} in STP effluent (WWTP effluent) exceeds the $PNEC_{add}$ for microorganisms **(conclusion iii)**. For the other 5 production sites the PEC_{add} / $PNEC_{add}$ ratio is <1 (**conclusion ii).** All PEC_{add} values for the production sites (all using an industrial WWTP) are based on site-specific emission data.
Use categories:
In about 30% of the scenarios for the processing of zinc metal the PEC_{add} in STP effluent (WWTP effluent) exceeds the $PNEC_{add}$ for microorganisms (**conclusion iii**); these scenarios include 'galvanising-CHDG' (a number of individual sites and the additional generic assessment), 'galvanising-EG' (a number of individual sites and the additional generic assessment), 'brass' (a number of individual sites) and 'alloy and die casting' (a number of individual sites).
In the remaining 70% of the processing scenarios the PEC_{add} / $PNEC_{add}$ ratio is <1 **(conclusion ii).**

Surface water
Production:
For 10 out of the 17 production sites the local C_{add} (calculated concentration, based on site-specific emission data) and/or PEC_{add} (measured concentration, corrected for the natural background concentration) in surface water exceed the $PNEC_{add}$ for aquatic organisms **(conclusion iii)**. It is noted that for 5 out of these 10 sites the applied bioavailability correction did not result in a $(PE)C_{add}$ / $PNEC_{add}$ ratio <1 and that for the remaining 5 of these 10 sites no bioavailability correction could be applied, mostly because the effluent was discharged to seawater.
For the remaining 7 production sites the local C_{add} / $PNEC_{add}$ ratio is <0.5 and the local PEC_{add} / $PNEC_{add}$ ratio (available only for site no. 3) is <1 (**conclusion ii).**
All local C_{add} values for the production sites (all using an industrial WWTP) are based on site-specific emission data.
Use categories:
In about 25% of the scenarios for the processing of zinc metal the local C_{add} and/or PEC_{add} in surface water exceed the $PNEC_{add}$ for aquatic organisms (**conclusion iii**); these scenarios include 'galvanising-CHDG' (a number of individual sites and the additional generic assessment), 'galvanising-EG' (a number of individual sites and the additional generic assessment), 'brass' (a number of individual sites) and 'alloy and die casting' (a number of individual sites). It is noted that in half of these cases the applied bioavailability correction did not result in a $(PE)C_{add}$ / $PNEC_{add}$ ratio <1 and that for the remaining half of these sites no bioavailability correction could be applied.
In about 10% of the processing scenarios the local C_{add} / $PNEC_{add}$ ratio is between 0.5 and 1. In these cases a potential risk at the local scale cannot be excluded due to (possibly) high regional background zinc concentrations (**conclusion iii*).**
In the remaining 65% of the processing scenarios the local C_{add} / $PNEC_{add}$ ratio is <0.5 or the local PEC_{add} / $PNEC_{add}$ ratio is <1 (**conclusion ii**).

Sediment
Production:
For 8 out of the 17 production sites the local C_{add} (calculated concentration, based on site-specific emission data) and/or PEC_{add} (measured concentration, corrected for the natural background concentration) in sediment exceed the $PNEC_{add}$ for sediment organisms

(conclusion iii). It is noted that for these 8 production sites only the generic bioavailability factor of 2 (i.e. corrected $(PE)C_{add}$ = original $(PE)C_{add}$ divided by 2) could be applied; this correction did not result in $(PE)C_{add}$ / $PNEC_{add}$ ratios <1.
For 3 production sites the uncorrected local $(PE)C_{add}$ / $PNEC_{add}$ ratios were also >1, but the site-specific correction using the SEM/AVS-method resulted in $(PE)C_{add}$ / $PNEC_{add}$ ratios <0 (**conclusion ii).**
For the remaining 6 production sites the local C_{add} / $PNEC_{add}$ ratios are between 0 and 1; in these cases a potential risk at the local scale cannot be excluded due to (possibly) high regional background zinc concentrations (**conclusion iii*).**
Use categories:
In about 50% of the scenarios for the processing of zinc metal the local C_{add} and/or PEC_{add} in sediment exceed the $PNEC_{add}$ for sediment organisms (**conclusion iii**); these scenarios include 'galvanising-CHDG' (a number of individual sites and the additional generic assessment), 'galvanising-EG' (almost all individual sites and the additional generic assessment), 'brass' (almost all individual sites) and 'alloy and die casting' (a number of individual sites) and 'zinc powder/dust' (two individual sites). It is noted that in all these cases only the generic bioavailability factor of 2 (i.e. corrected $(PE)C_{add}$ = original $(PE)C_{add}$ divided by 2) could be applied; for these sites this correction did not result in $(PE)C_{add}$ / $PNEC_{add}$ ratios <1.
For 3 processing sites the uncorrected $(PE)C_{add}$ / $PNEC_{add}$ ratios were also >1, but the site-specific correction using the SEM/AVS-method resulted for two sites in $(PE)C_{add}$ / $PNEC_{add}$ ratios <0 (**conclusion ii).** For one of these three sites, however, also the corrected PEC_{add} / $PNEC_{add}$ ratio is >1 (**conclusion iii).**
In the remaining 50% of the processing scenarios the $(PE)C_{add}$ / $PNEC_{add}$ ratios are between 0 and 1; in these cases a potential risk at the local scale cannot be excluded due to (possibly) high regional background zinc concentrations (**conclusion iii*).**

Terrestrial compartment

Production:
For all production sites the local PEC_{add} for soil (agricultural soil) is below the $PNEC_{add}$ for terrestrial organisms (**conclusion ii**).
Use categories:
In 6 of the processing scenarios the local PEC_{add} in soil exceeds the $PNEC_{add}$ for terrestrial organisms (**conclusion iii**); these scenarios include 'galvanising-CHDG' (two of the individual sites and the additional generic assessment) and 'galvanising-EG' (two of the individual sites and the additional generic assessment). It is noted that in these cases only the generic soil correction factor of 3 (R_{L-F}: ageing-related lab-to-field factor) could be applied (i.e. corrected PEC_{add} = original $(PE)C_{add}$ divided by 3); in these cases this correction did not result in $(PE)C_{add}$ / $PNEC_{add}$ ratios <1.
For the remaining processing scenarios the local PEC_{add} / $PNEC_{add}$ ratios are all <1 (**conclusion ii**).

Atmosphere

Not applicable, as no ecotoxicological $PNEC_{(add)}$ for the air compartment could be derived.

3.3.2 Regional risk characterisation

3.3.2.1 Regional risk characterisation – methods

Regarding the derivation of regional (PE)C_{add} / $PNEC_{add}$ ratios, including the application of bioavailability corrections, the methods used in the regional risk characterisation are the same as those used in the local risk characterisation (see section 3.3.1.1).

Because of the large number of measured regional concentrations (monitoring data) and, hence, regional PEC_{add} values (PEC_{add} being the measured zinc concentration minus the natural background concentration of zinc), the large number of regional PEC_{add} / $PNEC_{add}$ ratios based on the measured data are not included in this Summary RAR, but the results and conclusions are summarised below. It is emphasised that the final conclusions of the regional risk characterisation as summarised below are based on the 'corrected' PEC_{add} / $PNEC_{add}$ ratios (if applicable), as explained earlier in section 3.3.1.1

3.3.2.2 Regional risk characterisation - results

Aquatic compartment (including sediment)

Surface water

Based on the calculated regional PEC_{add} values of 12.2 and 16.8 µg/l (total zinc; default $C_{suspended\ matteer}$ of 15 mg/l) for the NL-region and the EU-region **(see Table 3.1)** and the $PNEC_{add}$ for surface water of 21 µg/l (total zinc; default $C_{suspended\ matteer}$ of 15 mg/l suspended matter)(**see Table 3.2)**, the PEC_{add} / $PNEC_{add}$ ratios are 0.6 (NL-region) and 0.8 (EU-region), respectively. These PEC_{add} / $PNEC_{add}$ ratios refer to values without a bioavailability correction and would result in a conclusion ii.

However, based on the measured regional PEC_{add} values (average or 90-percentile concentrations in surface waters for the period 1995-1999) there are a number of regional EU surface waters with PEC_{add} / $PNEC_{add}$ ratios that are (substantially) >1. For many of these surface waters it is possible to apply a region-specific bioavailability correction. After this correction for bioavailability there are still a number of surface waters with PEC_{add} / $PNEC_{add}$ ratios >1 (most often in the range of around 2 to 4), resulting in a **conclusion iii** for these waters. This **conclusion iii** holds for surface waters (including some large rivers, e.g. the Meuse) in several EU regions, including the Netherlands, Belgium, France and Germany (it is noted that by far most data on measured zinc concentrations in surface waters are available for these EU Member States).

When the risk characterisation would be based on the most recent measured data (which are rather limited), the same trend in regional PEC_{add} values and, hence, PEC_{add} / $PNEC_{add}$ values is found, although in some EU surface waters the current conclusion iii would change in a conclusion ii and in some other EU surface waters the current conclusion ii would change in a conclusion iii.

Regarding the surface waters for which a **conclusion iii** was drawn, it is emphasised in the RAR Zn Metal that when deciding about (possible) emission reduction measures, the available information on potential zinc emission sources in that particular area, such as (former) mining activities, has to be carefully taken into account. To this aim the zinc industry executed a further analysis on the available regional monitoring data. The industry Annex (Annex 3.2.5) in which this analysis was reported was found by the Rapporteur to be useful to risk management because it sheds further light on the possible sources of zinc and zinc compounds that contribute to regional concentrations from monitoring studies. It is stressed, however, that this industry Annex has not been formally approved by either the Rapporteur or TC NES.

It is noted that a number of areas in e.g. the Nordic countries (Sweden, Norway and Finland) and parts of Spain are characterised by ‘soft water’ conditions (hardness <24 mg/l, as $CaCO_3$) for which the $PNEC_{add}$ for soft water should be applied. However, based on the available information it was difficult to assign distinct European areas where soft water conditions prevail. It was therefore decided that the entire risk characterisation for the soft water regions, had to be left out of account in the present generic risk assessment. This may be dealt with on a national/regional level during risk management (for guidance on application of the soft water $PNEC_{add}$, see RAR Zinc Metal Annex 3.3.2.C)

Sediment

Based on the calculated regional PEC_{add} values of 504 and 696 mg/kg dwt for the NL-region and the EU-region **(see Table 3.1)** and the $PNEC_{add}$ for sediment of 49 mg/kg dwt (**see Table 3.2)** , the PEC_{add} / $PNEC_{add}$ ratios are 10 and 14, respectively. These PEC_{add} / $PNEC_{add}$ ratios refer to values without a bioavailability correction. A site-specific bioavailability correction is not possible for these generic scenarios, thus only the generic bioavailability correction factor for sediment can be applied for these scenarios. This implies that the original PEC_{add} values are multiplied with a factor of 0.5, resulting in PEC_{add} / $PNEC_{add}$ ratios of 5 and 7, which are still substantially >1 **(conclusion iii).**

Based on the measured regional PEC_{add} values (average or 90-percentile concentrations in sediments for the period 1980-2000) there are a large number of regional EU surface waters with PEC_{add} / $PNEC_{add}$ ratios for sediment that are (substantially) >1. For most of these sediments only the generic bioavailability correction factor of 0.5 can be applied. After this bioavailability correction, almost all PEC_{add} $PNEC_{add}$ ratios are still >1 (most often in the range of 2-10), resulting in a **conclusion iii** for these sediments. This **conclusion iii** holds for sediments of surface waters (including some large rivers, e.g. the Meuse) in several EU regions, including the Netherlands, Belgium, France, Germany and Norway (it is noted that by far most data on measured zinc concentrations in sediments are available for these EU Member States). It is emphasised that for the Netherlands this conclusion is based on freshly deposited sediment and suspended matter (‘future sediment’).

For the Flanders (Belgium) sediment data base for which a site-specific bioavailability correction (SEM/AVS method) could be applied, the following conclusion can be drawn: in 41 % of the cases (77 out of 190 sampling points) the PEC_{add} / $PNEC_{add}$ ratio is >1 without any correction. In 9% of the cases the PEC_{add} / $PNEC_{add}$ ratio is still >1 after site-specific bioavailability correction (**conclusion iii**).

Line-source emissions: road borders

In surface waters alongside roads, especially alongside motorways with high traffic intensities, zinc emissions from traffic (especially from tyre debris) and corrosion (especially from street furniture such as crash barriers and lampposts) may result in high zinc concentrations in surface waters and sediments that receive (untreated) motorway runoff. Actually, high zinc concentrations have been measured in motorway runoff waters and sediments and also in sediments of streams receiving motorway runoff. In addition, effects on macroinverbrate diversity were found in streams along a motorway in the UK. Based on the available data it cannot be excluded that in surface waters along motorways PEC_{add} / $PNEC_{add}$ ratios for zinc in water and sediment are clearly >1 (also after a correction for bioavailability) and that adverse effects on aquatic ecosystems may occur due to the presence of zinc.

However, the amount of data on zinc concentrations in runoff water and sediments and especially in aquatic ecosystems alongside motorways is limited, as well as the field data on actual effects in aquatic ecosystems alongside motorways. In addition, together with zinc other substances (including other heavy metals and PAH) may contribute to the potential effects.
Balancing the available data and uncertainties a **conclusion i)** is considered most appropriate for aquatic ecosystems, including sediments, alongside motorways in the EU. Further work is needed to investigate the impact of zinc from traffic at a broader scale. Details of this conclusion i) program for water will be elaborated and will be linked with ongoing activities on this issue within the EU.

Terrestrial compartment

Non-agricultural soils
In the Netherlands and other EU Member States there are a number of areas which are highly contaminated with zinc (and other heavy metals) due to former industrial activities. Levels up to 1750 mg/kg dwt have for example been measured in Budel, the Netherlands. The contaminations are mostly due to historical emissions from zinc smelters etc. It is evident that in these areas the $PNEC_{add}$ for soil (26 mg/kg dwt) is exceeded by far. A great number of studies have indeed reported on occurring effects (e.g. disappearance of plant species) on terrestrial ecosystems in these areas. In most cases such areas are mapped out properly and local land development plans or sanitation measures have been (or should be) designed accordingly. In the present risk assessment it was therefore decided not to pay further attention to the regions affected by historical pollution.
High zinc levels in soil that strongly exceed the PEC_{add} were also measured around electricity pylons (data for the Netherlands: 200 to 650 mg/kg dwt in the topsoil; no further EU data). It should be stated, however, that for the Netherlands the observed high levels are most probably due to historical emissions. This because nowadays these galvanised steel pylons are coated in the Netherlands, which prevents zinc emissions via atmospheric corrosion. The situation in other EU Member States is unknown.
It is noted that the data in this section on “non-agricultural” soils also include data on agricultural soils, but that the zinc concentrations in these agricultural soils are mainly increased by industrial activities or corrosion and not by agricultural use (see below for data on agricultural soils in which the zinc concentrations are mainly increased by agricultural use).

Agricultural soils
Based on the calculated regional PEC_{add} value of 64 mg/kg dwt both for the NL-region and the EU-region **(see Table 3.1)** and the $PNEC_{add}$ for soil of 26 mg/kg dwt (**see Table 3.2)**, the PEC_{add} / $PNEC_{add}$ ratio is 2.5. This PEC_{add} / $PNEC_{add}$ ratio refers to the value without a bioavailability correction. A site-specific bioavailability correction is not possible for these generic scenarios, thus only the generic bioavailability correction factor of 3 (R_{L-F}: ageing-related lab-to-field factor) for soil can be applied for these scenarios. This implies that the original PEC_{add} value of 64 mg/kg dwt is divided by a factor of 3, resulting in a PEC_{add} / $PNEC_{add}$ ratio 0.8, which would result in a conclusion ii for agricultural soil.
The PEC_{add} of 64 mg/kg dwt is based on diffuse emissions to soil, with manure application being by far the major contributor of these soil emissions. The PEC_{add} has been calculated with the multi-media fate model SimpleBox (level III Mackay-type). This model predicts the concentration in topsoil (0-20 cm layer) after it has reached a steady-state concentration. The

model data on the relationship between time and the concentration as the percentage of such steady-state situation indicate that it would take almost 400 years before the agricultural soil concentration has reached 95% of its steady state.

The RAR Zinc metal also includes an alternative approach for the estimation of future, steady-state zinc levels in agricultural soil, based on a NL study. This approach, using a dynamic model, focuses on the actual balances between the input of zinc (manure, other fertilisers, pesticides, atmospheric deposition) and output of zinc (uptake by plants and leaching) in different combinations of soil type (sand, calcareous sand, clay, calcareous clay, loess, and peat) and agricultural use (grassland and arable land), based on detailed data for the Netherlands[9]. In this approach, the present zinc concentrations (measured data) and calculated future (steady-state) zinc concentrations are subsequently compared with the critical zinc limit in soil. This critical Zn limit in soil is based on the current $PNEC_{add}$ of 26 mg/kg dwt and the bioavailability corrections of the calculated PEC_{add} values (using the generic, ageing-related lab-to-field factor of 3 and the soil-type specific bioavailability corrections). The PEC_{add} values were corrected for the natural background zinc concentrations, taking into account the different soil types and soil layers (topsoil and subsoil). The main results and conclusions of this approach are the following:

- The current zinc concentrations in agricultural soils in The Netherlands exceed the critical zinc limit in 0.43% of the cases, based on measurements in approximately 5000 plots. Most of the plots in which the critical zinc limit is exceeded are being found in peat soils (2.4% of the peat plots). These plots only include historically polluted sites, such as the ‘Toemaakdekken’ (historical compost) or floodplain soils.
- In all combinations of soil type and agricultural use, there is a net accumulation of zinc in the soil, i.e. the input exceeds the output, which is in accordance with the results of earlier Dutch studies.
- In almost all combinations of soil type and agricultural use, the future concentrations will exceed the critical zinc limit, with average percentages for grassland and arable land of 50% and 55%, respectively. In grassland on sand and arable land on sand, the percentage of plots exceeding the critical limit for zinc are (very) low, with percentages ranging from 1% to 7%.
- The average time periods to reach the critical limit for zinc are 280 year in grassland and 650 years in arable land, with a total range of average time periods of 81 to 1704 years based on all calculations.
- When the zinc input is not based on the current Dutch data (assumed to remain constant over time), but on scenarios based on the application of manure applications strictly meeting the current EU standards for N input, i.e. 170 and 250 kg/ha/yr (170 kg/ha/yr is the current level of maximum levels of nitrogen that can be added to soils (Nitrates Directive 91/676/EEC) and 250 kg/ha/yr is the level of the derogation request from the Netherlands specifically for grassland), the percentage of plots at which the steady-state zinc concentration exceeds the critical zinc limit remains unaffected for arable land (55%). For grassland the percentage decreases from 50% to 40% when using a Zn input related to a maximum N input of 250 kg/ha/yr and it further reduces to 30% with the N target of 170 kg/ha/yr. Accordingly, complying

[9] In The Netherlands the input of zinc in agricultural soils is mainly caused by the application of manure (>90% in grassland and around 85% in arable land, based on actual (year 2000) Dutch nitrogen (N) application rates and the Zn/N ratio in manure) and the zinc input from this source may be about the highest in Europe. For most other EU countries the input of zinc in agricultural soils is mainly caused by the application of sewage sludge (not manure), but overall, the input of zinc in agricultural soils in the EU is considered to be comparable, regardless the main source.

with current EU standards for N application would result in a huge increase in the time periods for reaching critical levels in grassland, while the impact on arable land is negligible.

A more limited study in the United Kingdom also showed an accumulation of zinc in agricultural soils, receiving zinc input from sewage sludge or manure. This UK study used a simple linear extrapolation model in which zinc removal routes like leaching and uptake by crops were not addressed. Furthermore, the UK study used a critical zinc limit of 200 mg/kg dwt (being a background concentration of 88 mg/kg dwt and an added concentration of 112 mg/kg dwt, the latter being higher than the $PNEC_{add}$ of 26 mg/kg dwt derived in the RAR) and bioavailability was not taken into account. Hence, the validity and practicability of the UK study is therefore limited for the risk characterisation, but this UK study supports the conclusions of the NL study regarding the ongoing accumulation of zinc in agricultural soils.

Conclusion on agricultural soils

Diffuse zinc emissions to agricultural soil result in net accumulation rates in several EU areas with intensive agricultural activities. On the basis of the outcomes of the NL study it can be concluded that current manure application rates on agricultural soils will ultimately result in zinc concentrations (PEC_{add}) that exceed the critical zinc concentration ($PNEC_{add}$) in soil. This is expected to occur at a relatively large scale, i.e. in about 50% of the agricultural soils. However, the time period for reaching the critical zinc concentration in agricultural soils is estimated to be (relatively) long. On average, depending on the type of soil, it will take 100 to 500 years for grassland and 300 to 900 years for arable land. Complying with the EU standard for N-application on agricultural soils would significantly enhance the time scale for grassland, but not for arable land. The NL study is initially based on the situation for The Netherlands, but it is adequately substantiated that this scenario is representative (realistic worst case) for regions with a comparable, intensive agriculture in the European Union. It has to be recognised that substantial differences occur in manure, fertilizer, compost and sludge application rates between EU regions.

The CA meeting concluded that there is at present no need to implement risk reduction measures beyond those which are already in place (11^{th} Joint Meeting June 2005). A **conclusion ii)** is therefore drawn for agricultural soil at regional scale. The CAs concluded that there are no existing risks from zincs in agricultural soils. They also considered that existing legislation relating to sludge and manure management (86/278/EEC; 91/676/EEC; and 1831/2003) provide an adequate framework to address and prevent any future risks relating to zinc accumulation. It is, however, expected that the Commission will take the information provided in the risk assessment on zinc accumulation into account in future policy proposals relating to soil.

Line sources: road borders

Very high zinc concentrations (up to 1500 mg/kg dwt) have been measured in road borders alongside motorways in The Netherlands and other EU member states. The overall picture shows a clear accumulation of zinc in a rather thin top soil layer and a exponentially decreasing concentration over the distance from the curb of the road. Moreover, zinc levels are found to decrease with decreasing road intensity. Such levels largely exceed the $PNEC_{add}$ terrestrial of 26 mg/kg dwt, irrespective of which natural background concentration is chosen. In a number of cases the PEC_{add} / $PNEC_{add}$ ratios would also remain above 1 after the corresponding correction for bioavailability (ageing and soil-type). Very recently, however, a EU policy agreement was reached (CA decision 2003) about the formal distinction between the road technosphere and ecosystem. The agreed borderline of the road technosphere is dependent on the Average Daily Traffic Intensity (ADTI) and is definied as follows: motorways (ADTI > 60,000): 5-6 meters; regional roads (ADTI > 14,000): 3-4 meters, and urban roads (ADTI > 1,000): 1-2 meters. When applying these ranges on the available data set for zinc levels in soil road borders, it becomes clear that the observed zinc accumulation in road borders is mostly related to the technosphere. The data sets have been investigated at the level of individual data and in those cases where the zinc concentration in the 'ecosystem area' alongside roads is elevated compared to the prevailing natural background, the PEC_{add} / $PNEC_{add}$ ratio (corrected for bioavailability) would not be exceeded.

Conclusion on road borders
The available data set on monitoring data on zinc concentrations in soils alongside motorways is considered as sufficiently large and representative to draw conclusions. The data point to high zinc concentrations (PEC_{add} values) in the vicinity of the road at levels clearly exceeding the $PNEC_{add}$ even after correction for bioavailability. However, based on the recently agreed distinction of technosphere versus ecosystem, those sampling points with PEC_{add} / $PNEC_{add}$ ratios above 1 are found to lie within the technosphere. For this reason, based on the currently available data set a **conclusion ii)** is considered most appropriate for the terrestrial ecosystem area alongside EU roads.

Sludge
The rapporteur realises that STP sludge is not an official endpoint according to the TGD. Nevertheless some attention will be paid to the quality of sludge in comparison with current quality criteria for sludge for application as fertiliser on soil. Data on zinc concentrations in sludge from communal STPs in The Netherlands clearly show that in 1981 the majority of the sludge samples had a zinc concentration of more than 1500 mg/kg dwt, whereas in 1997 the majority falls within the class: >500 - 1000 mg/kg dwt. Sludge zinc levels from several other EU countries show more or less the same trend.
Despite the decreasing trend in sludge zinc levels, however, an important conclusion is that current sludge zinc concentrations from communal STPs still exceed the present-day operative Dutch quality criterion of 300 mg/kg dwt.

Atmosphere
Not applicable, as no ecotoxicological $PNEC_{(add)}$ for the air compartment could be derived.

3.3.3 Secondary poisoning

Not relevant (see section 3.2.3).

4 HUMAN HEALTH

See Part II – Human Health

5 RESULTS

5.1 ENVIRONMENT

(X) i) There is need for further information and/or testing

(X) ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already

(X) iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account

(X) iii*) A conclusion applied to local scenarios in which the local scenario merits conclusion (ii) but where (possibly) due to high regional background concentrations a local risk cannot be excluded.

The PNEC values for zinc metal have been derived in this report solely for the purposes of this risk assessment. They must not be used for other purposes, such as setting environmental quality standards or sanitation levels, without further in-depth consideration as to whether they are fit for that purpose. In every case the bioavailability correction, which has been used in the present RAR, should be incorporated as an essential part of the process.

5.1.1 Local

Conclusion (ii) is drawn for all local scenarios, including secondary poisoning, except those listed below.

Conclusion (iii) or (iii*) is drawn for the specified scenarios, because:

STP
- the PEC_{add} in STP effluent exceeds the $PNEC_{add}$ for microorganisms for a number of the production sites of zinc metal listed in Table 3.4.67 and a number of the processing scenarios of zinc metal listed in Table 3.4.67 **(conclusion iii)**.

Surface water
- the calculated $Clocal_{add}$ in water is greater than the $PNEC_{add}$ in surface water for a number of the production sites of zinc metal listed in Table 3.4.67 and a number of the processing scenarios of zinc metal listed in Table 3.4.67 **(conclusion iii)**. For some of the production sites of zinc metal the conclusion is based on surface water monitoring data**.**
- the $Clocal_{add}$ / $PNEC_{add}$ ratio is between 0.5 and 1 for a number of the processing scenarios of zinc metal listed in Table 3.4.67 (**conclusion ii)**, but a potential risk at the local scale cannot be excluded due to the possible existence of high regional background concentrations **(conclusion iii***).

Sediment

- the $Clocal_{add}$ in sediment exceeds the $PNEC_{add}$ in sediment for a number of the production sites of zinc metal listed in Table 3.4.67 and a number of the processing scenarios of zinc metal listed in Table 3.4.67 **(conclusion iii)**. For some of the production sites of zinc metal the conclusion is based on surface water monitoring data.
- the $Clocal_{add}$ / $PNEC_{add}$ ratio is between 0 and 1 for the remaining production sites of zinc metal and processing scenarios of zinc metal listed in Table 3.4.67 **(conclusion ii**), but a potential risk at the local scale cannot be excluded due to the possible existence of high regional background concentrations **(conclusion iii*)**.
- the sediment risk characterization at one processing site of zinc metal determined by the SEM/AVS method points to a potential risk for sediment-dwelling organisms **(conclusion iii**).

Soil

- $PEClocal_{add}$ / $PNEC_{add}$ ratios >1 exist for the terrestrial compartment at some processing scenarios of zinc metal listed in Table 3.4.67 **(conclusion iii).**

Annex 3.4.3 contains recent local exposure information for a number of zinc producers and users. **(Disclaimer: Industry Annex 3.4.3 was found by the Rapporteur to be useful to risk management because it sheds further light on the recent local exposure data. Annex 3.4.3 has not been formally approved by either the Rapporteur or TC NES.)**

5.1.2 Regional

Conclusion (i) is drawn, because:

- some measured or calculated zinc concentrations in surface waters and sediments alongside motorways in the EU exceed the corresponding $PNEC_{add}$. Due to a number of uncertainties additional information is needed to refine this part of the risk assessment.

Conclusion (ii) is drawn because:

- the risk assessment shows that risks related to terrestrial road borders, zinc accumulation in regional soils and all remaining regional scenarios (including aquatic) of zinc metal, except those listed below, are not expected.

Conclusion (iii) is drawn, because of:

Aquatic ecosystem, including sediment

- measured surface water concentrations indicated that the $PNEC_{add,\ aquatic}$ is exceeded in some, but not all, regional waters in the EU **(conclusion iii).** Sediment PEC_{add} / $PNEC_{add}$ ratios for some, but not all, EU regions point to a potential risk for sediment-dwelling organisms **(conclusion iii)**. This conclusion is based on both calculated and measured data, including SEM/AVS measurements for the Flanders region.

In regions where conclusion iii) is drawn, it is strongly recommended that the available information on known and potential sources of zinc emissions, and region-specific natural background concentrations of zinc are carefully taken into account before taking decisions about risk reduction measures. Annex 3.2.5 already provides some useful information from the side of industry on possible sources of zinc emissions for some regions where a conclusion iii) is drawn. **(Disclaimer: Industry Annex 3.2.5 was found by the Rapporteur to be useful to risk management because it sheds further light on the possible sources of zinc and zinc compounds that contribute to regional concentrations from monitoring studies. Annex 3.2.5. has not been formally approved by either the Rapporteur or TC NES.)**

The findings of this report are that the current uses of zinc and zinc compounds do not per se lead to the elevated regional levels found in surface water and sediment.
The elevated zinc levels in those waters and sediments, where they are found, may be caused by a combination of zinc and zinc compounds. The elevated levels come from various emission sources, including local industrial point sources, historical contamination, mining activities, geology and diffuse sources. The contribution of each of these sources may vary between regions.
Local industrial point sources may include industrial processes that use and emit zinc and zinc compounds, as well as other processes that are unintentional sources and are not directly connected with the zinc producing or using industries. These other processes are not examined in this report, but may nevertheless have emissions of zinc.

5.2 HUMAN HEALTH

See Part II – Human Health