RIVM report 601500001/2005

Comparison of the guidance documents in support of EU risk assessments with those for the derivation of EU water quality standards

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This investigation has been performed by order and for the account of VROM-BWL, within the framework of project 601500, 'Supporting International Environmental Quality Standards-water compartment'.

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Rapport in het kort

Vergelijking van richtlijnen ter ondersteuning van Europese risicobeoordelingen met richtlijnen voor de afleiding van Europese waterkwaliteitsnormen

Risico's van nieuwe en bestaande stoffen en van biociden worden in Europa beoordeeld aan de hand van het Technical Guidance Document (TGD) van de Europese Commissie. De Kaderrichtlijn Water verwijst naar de TGD voor het afleiden van waternormen. Daarnaast is in opdracht van de Europese Commissie het Fraunhofer rapport (FHI rapport) afgeleid van de TGD voor de normafleiding voor water. In onderhavig rapport worden de twee richtsnoeren vergeleken om verschillen in normafleiding te bestuderen. Verschillen in kaders, doelstellingen en methodologie worden beschreven, evenals verschillen van meer technische aard.

De risicobeoordeling volgens de TGD omvat beoordeling van effecten, beoordeling van blootstelling en risicokarakterisering. De beoordeling van milieu-effecten bleek grotendeels overeen te komen met de normstelling volgens het FHI rapport. De verschillen waren voornamelijk van technische aard. Volgens de Fraunhofer methode worden veilige waterconcentraties afgeleid van veilige doses of concentraties voor predatoren en mensen, terwijl volgens de TGD alleen een veilige waterconcentratie voor waterorganismen wordt berekend. Daarnaast bepaalt de risicobeoordeling volgens de TGD blootstelling via alle relevante routes, terwijl het FHI rapport alleen de waterroute in acht neemt. Het is daardoor theoretisch mogelijk dat de waternorm mens en dier niet voldoende beschermt tegen stoffen die voornamelijk via lucht of voedsel worden ingenomen.

Trefwoorden: Technical Guidance Document, Fraunhofer rapport, risicobeoordeling, normstelling, Kaderrichtlijn Water

Abstract

Comparison of the guidance documents in support of EU risk assessments with those for the derivation of EU water quality standards

Risks of both new and existing substances and of biocides in Europe are being evaluated using the Technical Guidance Document (TGD). The European Water Framework Directive refers to this document for establishing Environmental Quality Standards (EQSs) for water. Another guidance document for the derivation of EQSs was developed on the basis of the TGD by the Fraunhofer Institüt (FHI) on request of the European Commission. Our study, as documented in this report, aimed to elucidate differences between the two guidance documents. Besides describing the main differences in background, aim and methodology, we also considered discrepancies at a more technical level.

Risk assessment described in the TGD encompasses effect assessment, exposure assessment and risk characterisation. Determination of EQSs in the FHI document was found to overlap with the environmental effect assessment of the TGD. Differences were partly technical. Only one PNEC for water is derived following the TGD, whereas according to the FHI document, several EQSs for water are calculated from toxicity data for predators and human consumption of aquatic products. Additionally, risk assessment described in the TGD takes into account multiple exposure routes, while the FHI document only encompasses exposure via water. Therefore, it is theoretically possibly that adopting PNECs as EQSs for the water compartment will not fully protect human health in the case of substantial exposure via air or food.

Key words: Technical Guidance Document, Fraunhofer document, risk assessment, quality standards, Water Framework Directive

Preface

This report is part of the project ‘Supporting International Environmental Quality Standards-water compartment for BWL-VROM’ (RIVM-project 601500). We want to acknowledge Trudie Crommentuijn (Ministry of Housing, Spatial Planning and Environment, The Hague, The Netherlands) for supporting this RIVM-project.

The results as presented in this report have been discussed by the members of the ‘Setting International Environmental Quality Standards Advisory Group’ (WK-INS), who are acknowledged for their contribution. This advisory group provides a non-binding scientific comment on the final draft of a report in order to advise the steering committee of the project ‘Setting International Environmental Quality Standards in the Netherlands (INS, RIVM-project 601501) on the scientific merits of the report.

Peter van Vlaardingen, Charles Bodar, Dick Sijm and Mark Montforts (all SEC-RIVM) are acknowledged for reviewing this paper.

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Samenvatting

In november 2003 heeft de stuurgroep '(Inter)nationale Normstellingen Stoffen' besloten om op nationaal niveau het Technical Guidance Document (TGD) van de Europese Commissie (EC, 2003a) te volgen voor de normafleiding van stoffen. Daarnaast gaf de Europese Commissie de opdracht aan het Fraunhofer Instituut om een richtlijn voor de Kaderrichtlijn Water (KRW, Directive 2000/60/EC) te ontwikkelen voor normafleiding voor water (FHI rapport door Lepper, 2002 en 2004). Om eventuele verschillen in normafleiding volgens de twee richtsnoeren te doorzien, zijn de twee documenten vergeleken.

Het bleek dat de grootste verschillen liggen in de kaders en doelstellingen van de documenten. De TGD ondersteunt de EU-risicobeoordeling voor nieuwe en bestaande stoffen en biociden. Zo'n risicobeoordeling bestaat uit verschillende onderdelen, namelijk uit beoordeling van effecten, beoordeling van blootstelling en risicokarakterisering. Het FHI rapport omvat normstelling, die overlapt met de effectbeoordeling beschreven in de TGD.
De verschillen in doelstelling en kaders vertalen zich in andere aanpak en methodologie. Het FHI rapport is er op gericht om mens en milieu te beschermen voor vervuiling via de waterfase (direct of via aquatisch voedsel). De TGD houdt echter rekening met alle mogelijke blootstellingroutes tijdens de volledige levenscyclus van de stof.
In de TGD worden alle blootstellingsroutes geïntegreerd om daarna de totale blootstelling van mens en milieu te berekenen. Vervolgens wordt deze 'totale' blootstelling vergeleken met de veilige blootstellingsconcentraties om te bepalen over het gebruik of de productie van een substantie veilig is. In het FHI rapport worden veilige concentraties voor waterorganismen, predatoren en mensen individueel teruggerekend naar veilige waterconcentraties. De laagste, berekende veilige waterconcentratie wordt als norm genomen. De veilige concentratie in water, zoals afgeleid volgens het FHI rapport kan op deze manier echter lager uitvallen voor sommige stoffen, in vergelijking met de veilige waterconcentratie zoals afgeleid volgens de TGD, omdat de TGD alleen een veilige waterconcentratie bepaald voor waterorganismen.

Naast de verschillen in kader en doelstelling zijn verschillen van meer technische aard gevonden. Soms zijn de verschillen het resultaat van verschil tussen doelstelling van beide kaders. Bij de verschillen van meer technische aard moet worden gedacht aan het al dan niet inzetten van monitoringdata en van algentoxiciteitdata, het gebruik van fourageergebied van predatoren en het bepalen van de biobeschikbaarheid van metalen.
De verschillen tussen de TGD en het FHI rapport op detailniveau, van technische aard, kunnen over het algemeen worden overzien en worden opgelost. De verschillen op het vlak van risico voor mensen zijn echter complexer van aard. In de TGD wordt de blootstelling van mensen via alle mogelijke routes simultaan bezien en vergeleken met de veilige dosis. In het FHI rapport wordt alleen blootstelling via de waterroute in acht genomen. Voor de afleiding

van de waternorm volgens het FHI rapport is bepaald dat maximaal 10% van de veilige inname voor mensen mag plaatsvinden via directe wateropname en daarnaast mag maximaal 10% van de veilige dosis via aquatische producten worden ingenomen. In hypothetische gevallen van omvangrijke blootstelling via lucht of voedsel zou deze manier van normafleiding niet de veiligheid van mens en dier waarborgen.

Het huidige rapport heeft de verschillen tussen het FHI rapport en de TGD benoemd, maar het dient tot aanbeveling om een rekenkundige exercitie uit te voeren met stoffen met verschillende chemische eigenschappen om inzicht te krijgen in de praktische consequenties van de methodologische verschillen voor risico’s voor mens en milieu.

Summary

In November 2003, the Dutch Steering Committee 'Setting (Inter)national Environmental Quality Standards for the Environment' decided to follow the Technical Guidance Document (TGD, EC, 2003a) of the European Committee for the derivation of Environmental Quality Standards. Meanwhile, the European Committee had requested the Fraunhofer Institüt (FHI) to develop guidance for the derivation of Environmental Quality Standards for the water compartment for the Water Framework Directive (WFD, Directive 2000/60/EC) resulting in the FHI report (Lepper, 2002 and 2004). This report compared both guidance documents to analyse possible disparities.

Main differences were found between aims and frameworks of the documents. TGD is developed for risk assessment. The risk assessment exists of effect assessment, exposure assessment and risk characterization. The methodology described in the FHI report is aimed at setting quality standards, which partly overlaps with the effect assessment in the TGD. The FHI report aims to protect humans and the environment from contamination of the water phase, taking into consideration direct and indirect (aquatic food) uptake routes, whereas the risk assessment described in the TGD assesses human and environmental exposure via all possible routes and during the whole life cycle of a substance. The FHI report calculates safe water concentrations from the safe concentrations for aquatic organisms, in predators and humans. The lowest resulting water concentration is used as quality standard (EQS). In the TGD, all possible exposure routes are integrated to calculate the total exposure of humans and the environment. This total exposure is compared with the safe dose or concentration (PNEC) to determine if use or production of a substance is safe. It is postulated that EQSs determined following the Fraunhofer method may be lower in comparison of the PNEC derived for the water compartment following the TGD methodology for some substances, because the TGD calculates only one PNEC for water organisms.

Also, differences of more technical nature were found. At some instances, these differences resulted from differences between frameworks. Discrepancies of more technical nature were, for instance, use of monitoring data and algae toxicity data, foraging area of predators and bioavailability of metals. These differences at detailed level can be easily overseen and solved. However, disparities in the area of human risk are of another standard. The TGD assesses human exposure via different exposure routes simultaneously in order to compare exposure with the results of effect assessment. The FHI report only considers exposure via the aquatic environment, neglecting possible additive effects of substances taken in via other routes. Both the EQS for aquatic food intake and the EQS for water intake are restricted to 10% of the safe human consumption. In the hypothetical case of a high intake rate via air or agricultural products, human health may not be safeguarded by the 10% limits for the 2 aquatic uptake routes.

It is recommended to perform calculations for a few substances with different properties to gain insight in the practical consequences of the EQS derivation for risks to humans and the environment.

1. Introduction

Until 2004, Environmental Quality Standards (EQS) in the Netherlands were derived within the project Setting Integrated Environmental Quality Standards (INS). These Environmental Quality Standards were derived using the methods described in the INS Guidance document by Traas et al. (2001). In May 2003, the Steering Committee INS decided to consider PNEC-values from EU Risk Assessment Reports as being equivalent to Dutch EQSs, as the methods for deriving PNECs is roughly similar to the methods used for deriving EQSs. In addition, the Steering Committee INS decided in November 2003 to follow the European method for the derivation of Predicted No Effect Concentrations (PNECs) for setting EQSs. This method is laid down in the Technical Guidance Document of the European Commission (EC) (EC, 2003a). The Water Framework Directive (EC/2000/60) also referred to this document for the derivation of EQSs in Annex V paragraph 1.2.6. As a result, the name of the INS-project was changed from Setting Integrated Environmental Quality Standards' into 'International and National environmental quality standards for Substances in the Netherlands (INS)'. Meanwhile, the European Commission had also requested the Fraunhofer Institüt (FHI) to apply the TGD for the derivation of Environmental Quality Standards for the water compartment (Lepper, 2002 and 2004). A closer look at the methods in the TGD and the FHI report showed a lot of similarities, but also a number of differences which complicate the implementation of one single method for derivation of EQSs. By order and on the account of VROM/BWL, this document elucidates the differences between TGD and the FHI report with respect to the derivation of EQS. First, the main differences will be treated (Chapter 2). Discrepancies at more detailed level will be described in the Chapter 3 'Technical details'.

2. Differences in background, aim and methodology

2.1 Framework, objectives and endpoints

The Fraunhofer Institüt report (FHI report by Lepper, 2002 and 2004) is created as a guidance document for the derivation of surface water EQSs for priority substances within the Water Framework Directive (WFD). The WFD is a legislative framework, aiming to realise a good quality of all surface water and groundwater, in order to protect freshwater and marine ecosystems from adverse effects, as well as to protect human beings from all impacts on health by drinking water uptake or ingestion of food originating from aquatic environments. Article 6 of the WFD obligates Member States to designate river basin districts and areas needing specific habitats and species protection. Also, water bodies used for recreational purposes or for drinking water supply have to be assigned. The water quality aims for all water systems have to be formulated and these aims should be reached in 2015. For surface water and per type of water body, good chemical and good ecological situation is formulated, and for groundwater, good chemical and good quantitative situation is defined. The Member States are also obliged to monitor surface water and groundwater to obtain a coherent vision on water quality of each water district.
Measures should include the measures required by the following Directives:
(i) The Bathing Water Directive (76/160/EEC);
(ii) The Birds Directive (79/409/EEC);
(iii) The Drinking Water Directive (80/778/EEC) as amended by Directive (98/83/EC);
(iv) The Major Accidents (Seveso) Directive (96/82/EC);
(v) The Environmental Impact Assessment Directive (85/337/EEC);
(vi) The Sewage Sludge Directive (86/278/EEC);
(vii) The Urban Waste-water Treatment Directive (91/271/EEC);
(viii) The Plant Protection Products Directive (91/414/EEC);
(ix) The Nitrates Directive (91/676/EEC);
(x) The Habitats Directive (92/43/EEC);
(xi) The Integrated Pollution Prevention Control Directive (96/61/EC).
The legislative WFD is still elaborated upon. Scope, definitions, procedures and methodology are still evaluated and discussed (see e.g. priority substances non-paper on Article 16 of WFD; draft daughter directive, version 2, June 6th 2004).

In 1993, the Council of the European Communities adopted Council Regulation 793/93/EEC, also called the Existing Substances Regulation (ESR), thereby introducing a framework for the evaluation and control of existing chemical substances. The principles for the assessment of risks to man and the environment of existing substances were laid down in Commission Regulation (EC) 1488/94 and resulted in the Technical Guidance Document (TGD, 2003a). This document also supports Commission Directive 93/67/EEC on risk assessment for new

notified substances and since 2003 also the Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.
The risk assessment is carried out to assess all possible risks of a substance to humans and the ecosystem. Human populations under consideration are workers, consumers (users of products) and members of the general public exposed via the environment. The risk assessment may lead to several conclusions, copied below from the TGD (2003a).

Possible conclusions of the risk assessment for new notified substances (according to Article 3 of Directive 93/67):
(i) The substance is of no immediate concern and need not be considered again until further information is made available in accordance with Article 7(2), 8(3), 8(4) or 14(1) of Directive 67/548.
(ii) The substance is of concern and the competent authority shall decide what further information is required for revision of the assessment, but shall defer a request for that information until the quantity placed on the market reaches the next tonnage threshold as indicated in Article 7(2), 8(3) or 8(4) of Directive 67/548.
(iii) The substance is of concern and further information should be requested immediately.
(iv) The substance is of concern and the competent authority should immediately make recommendations for risk reduction.
Possible results of the risk assessment for existing substances (according to Article 10 of Regulation 793/93 and as extracted from Annex V of Regulation 1488/94):
(i) There is need for further information and/or testing.
(ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.
(iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.
Possible results of the risk assessment for active biocidal substances (according to Article 11 of Directive 98/8):
(i) Recommendation of an inclusion of the active substance in Annex I, IA or IB (the inclusion shall, where appropriate, be subject to certain requirements).
(ii) Recommendation of a non-inclusion of the active substance in Annex I, IA or IB.

Thus, the FHI report is used to determine EQS for the aquatic and marine environment (*maintenance of water quality*).
The TGD is used to assess whether a certain substance pose risk for the environment and humans and if pollution should be reduced (*risk assessment*).

Differences in aims and framework between TGD and the FHI report are expressed in deviations of approach, working area and products. The methodology described in the FHI report aims to protect humans and the environment from contamination of the water phase, taking into consideration direct and indirect (aquatic food) uptake routes, whereas the risk assessment described in the TGD assesses human and environmental exposure via all possible routes and during the whole life cycle of a substance. The EQS derivation following the FHI is described in datasheets and risk assessment according to the TGD is described in RARs (risk assessment reports). Table 1 summarises main differences between the 2 guidance documents.

Table 1. Summary of main differences between TGD and FHI report.

Guidance	TGD (EC, 2003a)	FHI report (Lepper, 2002, 2004)
Legislation	Various EU legislation[1]	WFD 2000/60 and daughter directive for priority substances
Aim	Risk assessment of substance	Quality Standards derivation for surface water
Evaluation reports	Risk assessment reports (EU-RAR)	Substance data sheets
Endpoints	Identification of risk of substance	EQS (AA, MAC)

2.2 Substances under consideration

The FHI report proposes the methodology for setting EQS for new notified substances, existing substances, plant protection products (PPPs), and biocides. The WFD (article 16) demands complete cessation or phasing out of discharge of priority hazardous substances and progressive reduction of priority substances. Priority hazardous substances and priority substances are further defined in the WFD and Annex III of FHI report presents a list of substances assigned as priority substance, priority hazardous substance and priority substance under review. For priority substances, EQSs are defined for all Member States. For the remaining, relevant substances, EQSs are defined per river basin district.
The TGD is a guideline for the risk assessment of new notified substances (Directive 93/67), existing substances (Regulation 1488/94), and biocides (Directive 98/8) and does not include the risk assessment for PPPs. The risks of PPPs are assessed according to the principles laid down in Council Directives 91/414/EEC and 97/57/EC.

2.3 General methodology

The FHI report proposes to apply internationally acknowledged effect assessment procedures used in the EU-risk assessment frameworks, thereby specifically referring to TGD 1996 and TGD draft version 2002 for new and existing substances and Council Directives 97/57/EC and to 91/414/EEC and the guidance document on aquatic ecotoxicology for PPPs[2].
Generally, the FHI report refers repeatedly to Part II, Chapter 3 of the latest version of the TGD available at the time of publication of the FHI report (Lepper, 2002) dealing with environmental risk assessment. Part II of the TGD deals with the assessment of environmental effects of soil and air pollution, with pollutant effects in water bodies, sediment and sewage treatment plants (STPs), with secondary poisoning and the calculation of predicted no effect concentrations (PNECs).
Within the FHI report, all direct and indirect exposure routes in and via aquatic systems are accounted for; exposure via water and sediment or via bioaccumulation as well as possible human exposure via drinking water and aquatic food uptake. Furthermore, all relevant types of toxicity are considered, i.e. for ecosystems direct and indirect toxicity and for man oral

[1] Legislation for new and existing substances and biocides [67/548/EEC, 93/793/EEC, 93/67/EEC, EC/1488/94 and 98/8/EC]
[2] http://europa.eu.int/comm/food/plant/protection/evaluation/guidance_en.htm (August 2004)

toxicity as well as carcinogenicity, mutagenicity and adverse effects on reproduction. In addition, effects on endocrine regulation in animals and man are evaluated. The safe levels or concentrations for benthic and pelagic organisms, for predators and humans are recalculated into safe concentrations in water. Generally, the resulting lowest water concentration is chosen as an EQS.

In the TGD, the procedure to carry out risk assessment is described. Risk assessment is the process determining if risks for humans and environment are present for certain substances. Risk assessment encompasses effect assessment, exposure assessment and risk characterisation. Effect assessment comprises identification of effects of concern and a dose – response assessment. Exposure assessment is the estimation of the concentrations to which human populations or environmental compartments are or may be exposed. Risk characterisation encompasses the estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance. The methodology followed for effect assessment within the TGD overlaps with the process of EQS determination in the FHI.
In the TGD, all routes of exposure in and via the aquatic systems and all relevant modes of toxicity are considered. Thus, not only aquatic exposure routes but also direct and indirect exposure through air and soil are included. No EQSs are derived but safe substance concentrations (PNECs) are compared with predicted concentrations (PECs) for the specific use and production of the substance at the relevant spatial scale, for the relevant environmental compartments and for the relevant human populations.

The calculation of EQS_{water} following the FHI report may result in lower PNECs in comparison to the PNECs in water derived in an EU-RAR. An example of this is shown in Figure 1 below, for SCCPs (short chain chlorinated paraffins), (EC, 2000). For the EU-RAR, a $PNEC_{secondary\ poisoning}$ is calculated of 16.6 mg/kg food (concentration in fish), the same value calculated following the FHI report. The $PNEC_{water}$ derived in the EU-RAR is 0.5 µg/l, which is the same value derived following the FHI report. However, the FHI report calculates an additional $PNEC_{water}$ based on $PNEC_{secondary\ poisoning}$ using a BCF (bioconcentration factor), resulting in an $EQS_{secondarypoisoning,\ water}$ lower than the $PNEC_{water}$, i.e. 0.41 µg/l. The TGD does not derive a $PNEC_{water}$ based on $PNEC_{secondary\ poisoning}$ but uses the $PNEC_{secondary\ poisoning}$ to compare with a $PEC_{secondary\ poisoning}$ for risk assessment of predators.

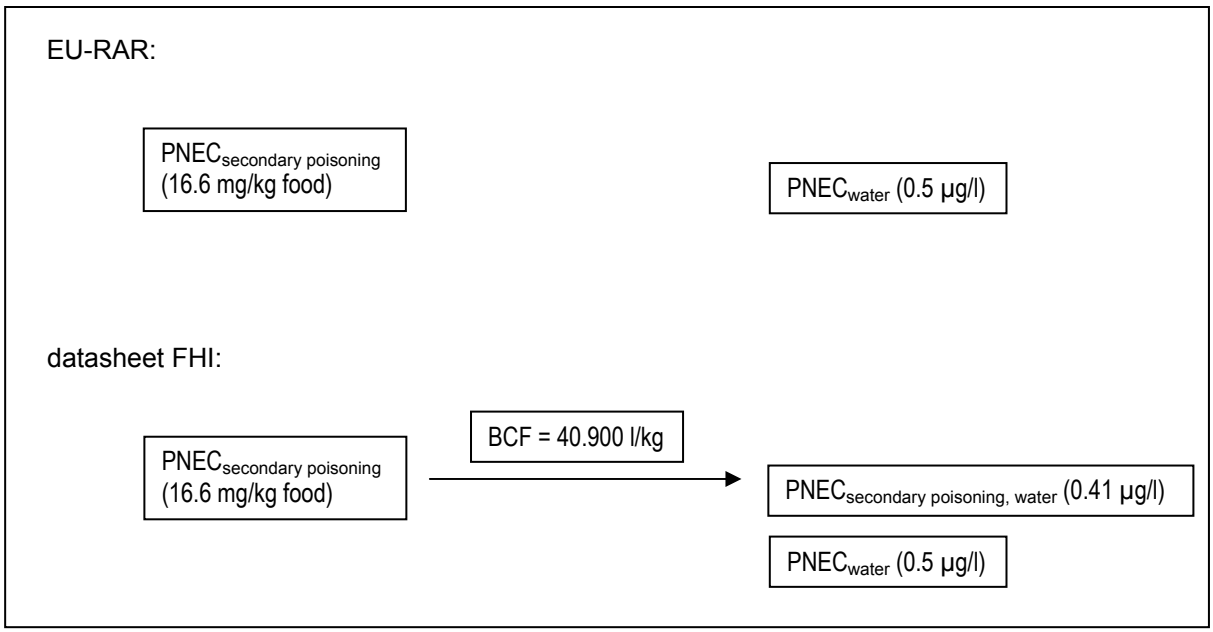

Figure 1 PNEC derivation in RAR and for EQS derivation following the FHI report for SCCPs.

2.4 Assessed compartments

In the TGD, the following compartments are distinguished for the inland environment: the aquatic (including sediment) and the terrestrial ecosystem (including groundwater), STPs and the atmosphere (Figure 2). Beside these compartments, the marine ecosystem is distinguished, which is separated in a benthic and a sediment part. For all compartments, risk assessment is carried out. However, triggers are specified for sediment and secondary poisoning effect assessment to avoid extensive testing.

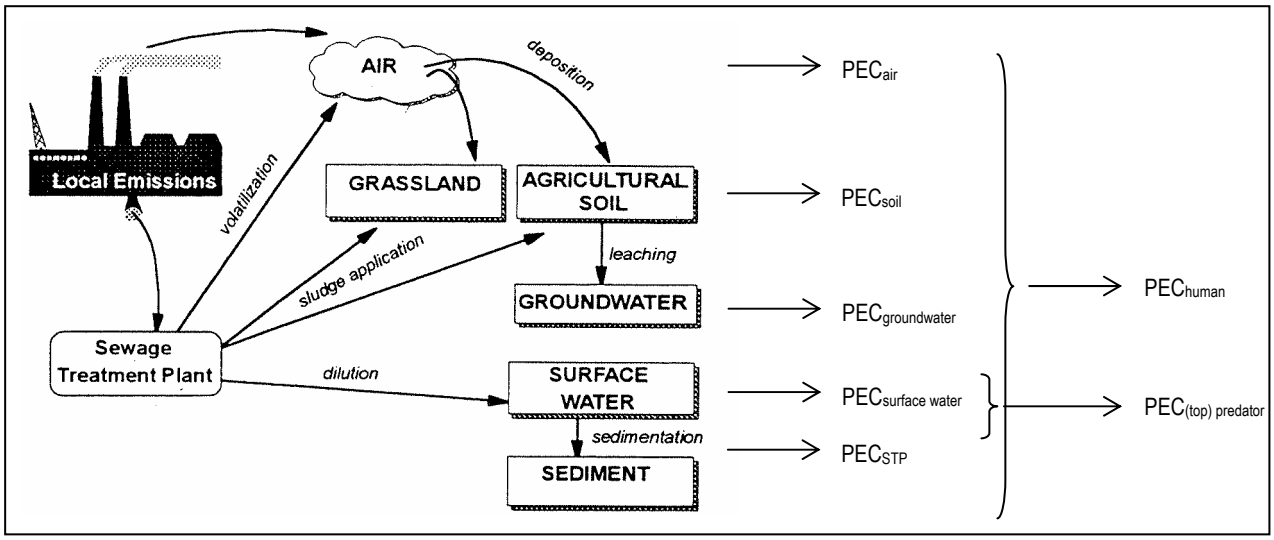

Figure 2 Exposure assessment of the different compartments in the TGD.

The FHI report also entails the aquatic and marine environment (including sediment), but distinguishes coastal, transitional and territorial waters among the fresh- and saltwater bodies

(definition given in WFD). Marine QS mostly are applied for transitional waters as well, due to lack of data. STP, terrestrial compartment and the atmosphere are not included in the EQS_{water} derivation. Groundwater, being a drinking water source, is also a protection target of the WFD. Groundwater has its own daughter directive, i.e. draft 2003/0210 (EC, 2003b). Daughter directive for priority substances in surface water is the non-paper, version 2, June 6th 2004 (EC, 2004).

According to Article 16(7) of the WFD, the Commission submits proposals for QS for water, sediments *or* biota. Article 2(35) defines an EQS as the 'concentration of a particular pollutant or group of pollutants in water, sediment or biota that should not be exceeded in order to protect human health and the environment'. Annex V of the WFD states that EQSs may be set for water, sediment or biota. According to Lepper (2002 and 2004), this suggests that derivation of EQS for all the mentioned compartments is optional, except for water. In terms of working economy it is therefore foreseen to derive a quality standard for each priority substance only for the water phase by default (Crane, 2003 and Lepper, 2002 and 2004). QS for a specific compartment may not be required if, based on the available scientific knowledge, there is no indication that a given substance poses a risk to this compartment. In Table 8.1a and 8.1b of the FHI report (or Table 1a and 1b of Annex V, see Annex of this document), environmental protection objectives, human health related protection objectives and triggers when to derive QS are formulated for the different compartments.

FHI report:	TGD:
freshwater environment (incl. sediment)	freshwater environment (incl. sediment) ▪ local (point sources) ▪ regional (multiple point and diffuse sources)
marine environment: (incl. sediment) ▪ coastal ▪ transitional ▪ territorial	marine environment: (incl. sediment) ▪ local (point sources) ▪ regional (multiple point and diffuse sources)
	air
	terrestrial environment
	sewage treatment plants

2.5 Technical details

In the sections below, differences between TGD and FHI report of a more detailed nature are described. Table 2 shortly presents differences between the 2 documents.

Table 2. Overview of differences of more detailed nature.

	FHI	**TGD**
Monitoring data	To check actual water quality	For PEC calculation
Monitoring living organisms	Not necessary according to FHI. According to WFD monitoring of biota is mandatory	Useful as estimation of secondary poisoning
Human risk	Exposure through drinking water and aquatic food intake, both routes estimated separately Risk estimated for consumers	Exposure through inhalation, soil ingestion, dermal contact, drinking water and consumption of crops, meat, milk and fish, simultaneously Estimation for consumers, workers and general public
Groundwater contamination	Aim is reaching good chemical status	Assessment of human exposure through drinking water and protection of groundwater community
Drinking water	Taking into consideration A1-values of 75/440/EEC and drinking water QS from 98/83/EC Uptake via drinking water <10% of threshold for human health	 Risk for human health integrated with other exposure routes Exposure assessment via drinking water produced from surface water or groundwater
Aquatic food consumption	Triggers for calculation of QS (R-phrases, cat. I-III, bioaccumulation potential) Uptake via aquatic food <10% of threshold for human health	Relevance of uptake route determined case-by-case Risk for human health integrated with other exposure routes
Partitioning between compartments	For derivation of QS sediment from QS water if no toxicity data for sediments organisms are available	For derivation of PNEC sediment from PNEC water if no toxicity data for sediments organisms are available. Partitioning processes between air and aerosol, air and water, and solids and water are taken into account during PEC calculations
Bioavailability in water	For hydrophobic compounds and metals, QS expressed as dissolved compound and concentration in suspended matter Total content is bioavailable	Dissolved compound is bioavailable (PEC and PNEC)
Foraging areas of predators	Does not fall in framework of WFD	Assumption that predators obtain 50% of prey in local area and 50% in regional area and that top-predators (only marine) obtain 10% of prey in local area and 90% in regional area
Persistent, bioaccumulative and toxic substances	Priority Hazardous Substances. Detection limit as Borderline QS	Special attention for assessment of persistency, bioaccumulation and toxicity potential
Metal bioavailability in sediments	AVS/SEM-approach rejected as generic approach	AVS/SEM-approach mentioned as example but no specific approach is proposed. The AVS/SEM is applied in certain RARs
Algae toxicity data	For PPPs considered as acute toxicity (EC_{50}) For new and existing substances and for biocides considered for both acute as chronic exposure (NOEC)	 Data are considered for both acute as chronic exposure
Assessment factors for PPP algae toxicity data	For new and existing compounds AFs depend on dataset For PPPs AF should not fall below 10	AFs depend on dataset
Marine environment	SPM concentration 3 mg/l	No SPM default for marine sediments mentioned
Microorganisms in STPs	Not included in EQS derivation	Included in risk assessment

2.5.1 Endpoints

The FHI report derives 2 kinds of QSs referring to 1) the annual average concentration (AA-QS) and 2) short-term concentration peaks, the so-called maximum admissible concentration QS (MAC-QS). The QSs are calculated on basis of toxicity data; the AA-QS on basis of NOECs and the MAC-QS on basis of L(E)C_{50}-values. The MAC-QS must not be exceeded any time and the AA-QS may be exceeded a certain percentage of time. If monitoring data exceed QSs, sources contributing to the pollution have to be identified and measures may have to be taken according to WFD.
The MAC-QS should be established to protect the aquatic ecosystem from peak concentrations of highly toxic chemicals. During a meeting of the Expert Advisory Forum (EAF) on 23rd of January 2002, no clear recommendation if and how to derive a MAC-QS was given. However, it was decided to derive an example for a MAC-QS for all substances on the working list as an exercise. Based on this exercise, a decision should be made later on if MAC-QSs are necessary and if so, if MAC-QSs should be statutory standards or a guidance value, and which trigger value should be used (Lepper, 2002). In article 5 of the proposed daughter directive on article 16 of WFD (version 2, July 7th 2004), Member States are obliged to identify source and reason for any exceedance of a MAC-EQS and to take appropriate remedial measures.
The current proposal how to derive a MAC-QS is to rely on the procedure described in the TGD for the effects assessment of intermittent releases (§3.3.2 Part II). TGD, Part II, § 3.3.2 states that normally a factor 100 is applied to the lowest of at least 3 short-term tests from 3 trophic levels. There may, however, be situations in which higher or lower assessment factor must be applied. For instance, in case of substances which are taken up rapidly by organisms a higher assessment factor has to be considered. In case of substances with a known non-specific mode of action, interspecies variation may be low and a lower assessment factor might be considered. For PPPs, the MAC-QS may be derived by taking the lowest relevant acute L(E)C_{50} and dividing it by the relevant short-term trigger. The short-term trigger is 100 for fish and invertebrates and 10 for algae.

The TGD is developed to predict environmental concentrations in the relevant compartments for specific uses and production of substances (PECs). The PEC is compared to effect concentrations from toxicity tests and modelling (PNECs) to determine if use and production under consideration pose toxicological risk. PECs may also be (partly) based on monitoring data. Use and/or production may be prohibited or a risk reduction strategy may be applied if risk is expected.
The PNECs safeguard from both acute and chronic exposure. In case of intermittent releases, defined as discharge less than once a month and for no more than 24 hours, the PEC_{local} is compared to a PNEC based on acute toxicity tests. For chronic exposure, the PEC is compared to a PNEC based on chronic toxicity tests.
For the derivation of PNECs, assessment factors are applied to toxicity data to account for intra- and inter-species variation, for intra- and inter-laboratory variation, for short-term to

long-term toxicity extrapolation and/or for laboratory to field impact extrapolation, if relevant. The same assessment factors are applied to toxicity data in the FHI for the derivation of the QSs.

2.5.2 Monitoring data

In the FHI report, EQSs for sediment organisms, predators and human exposure via drinking water and aquatic food uptake are recalculated to EQSs for water, thus necessitating monitoring of the water phase only. The WFD demands monitoring systems, which give a coherent vision on the water quality status of each water district.
Several Member States and NGOs have given their opinion on how to average monitoring data during an expert meeting in January 2002 (Brussels). The expert meeting revealed 2 preferred options; to aggregate monitoring data on an annual basis either as 90^{th} percentile or as arithmetic mean. The advantage of the annual arithmetic mean is that it is in line with Annex V of the WFD and with other Directives. The advantages of the 90^{th} percentile are that it is the only acceptable indicator with regard to the WFD objectives and that no problems exist to include data below the LOD (limit of detection). The FHI report (2002) states that a decision on how to calculate annual averages of monitoring data will be taken at a later stage, by the Expert Advisory Forum or by another competent body. According to the proposed daughter directive on Article 16 of WFD (version 2, July 7^{th} 2004), the annual average concentration is calculated as the annual arithmetic mean of the concentrations measured in the samples taken. In case more than one sample has been taken and analysed per water body per month, the 90^{th} percentile value is used as the monthly value for the calculation of the annual average.

Monitoring to check for quality standards is not addressed in the framework of the TGD. However, for the derivation of PEC, the TGD promotes integrated use of measured data and PEC calculation by using models. A list of quality criteria for use of existing data is given in Table 4 of § 2.2.1, TGD Part II. For regional PEC assessment, the mean of the 90^{th} percentiles of the individual sites within one region is recommended for regional PEC determination. If only maximum concentrations are reported, these should be considered as worst-case assumption. Use of mean concentrations can result in an underestimation of the existing risks. The TGD gives some considerations when using measured levels to derive a PEC from, for instance in case of waste-related releases.
The TGD warns for comparability of concentrations. For instance, PEC and PNEC in water may either reflect total concentrations or dissolved concentrations. Concentrations in sediment may depend on content of organic matter and particle size. For soil and sediment concentrations, concentrations normalised on particle size are recommended (§ 2.2.1, TGD Part II). No recommendation how to express concentrations in water is made.
Measurements below the LOQ should be considered on case-by-case basis. One approach could be to use a value of LOQ/2. However, this method may heavily influence mean and

standard deviation and therefore, other methods may be considered. For instance, by assuming that data below and above the LOQ follow the same frequency distribution.
The TGD considers samples of living organisms to provide an estimation of the body burden of biota and, accordingly, distribution via the food chain. The FHI reports that EQSs in organisms are transformed into EQSs in water so that monitoring of substance levels in organisms is not necessary. However, in article 13 of the proposed daughter directive on article 15 of the WFD, monitoring of biota (and sediment) is mandatory, for the assessment of long-term anthropogenic pressure and prevention of water body status from deterioration.

2.5.3 Human risk assessment

Human risk in the FHI report is assessed as intake of drinking water or of other products coming from the aquatic environment, considering oral toxicity, repeated dose toxicity, carcinogenicity, mutagenicity, effects on reproduction and endocrine disruption. Effect data to derive QS for human health are NOAEL (No Observed Adverse Effect Level), ADI (Acceptable Daily Intake) and TDI (Tolerable Daily Intake) values as identified following Council Regulation 793/93 (existing substances) or Council Directive 91/414 (PPP Directive) and also World Health Organisation (WHO)-values may be used. In addition, specific reactions to exposure such as cancer and endocrine disruption are taken into account.
Aquatic food intake and of drinking water consumption are not integrated in the EQS calculations, but separate EQSs expressed as water concentrations are derived for the 2 oral intake routes:

$PNEC_{human,oral}$	$->QS_{drinking\ water}$	$->QS_{water}$
	$->QS_{food}$	$->QS_{water}$

Both drinking water uptake and food uptake should not contribute more than 10% to the threshold level for humans.

The TGD is directed to investigate if risks of specific substances for different human populations are likely to occur. Human populations under consideration are workers, consumers (users of products) and members of the general public exposed via the environment. In Part I of the TGD, human exposure via inhalation of air, soil ingestion and dermal contact, via drinking water and via food consumption (crops, meat, milk, fish) are taken into consideration simultaneously in the exposure assessment (Figure 3). Each of these intake media is retrieved exclusively from within the contaminated system. The daily intake by humans is calculated by means of the daily intake values per exposure route. Exposure and acceptable intake are compared to determine if human health is at risk:

$PEC_{via\ air}$ $PEC_{via\ skin}$ $PEC_{drinking\ water}$ PEC_{food}	PEC_{human}	PEC_{human} versus $PNEC_{human}$: risk for human health?

Risks for human health can be estimated with several computer programs, which are described in Appendix III, Part I of the TGD (EC, 2003a). In the EUSES computer program, exposure rates for each exposure route are calculated, assuming that concentrations in all relevant compartments are in equilibrium. Output is uptake rate per exposure route and proportion of each uptake route is determined.
Indirect (environmental) exposure is principally assessed on two spatial scales: locally near a point source of the substance (worst-case), and regionally using averaged concentrations over a larger area. In the local assessment, all food products are derived from the vicinity of one point source, in the regional assessment, all food products are taken from the regional model environment. A generic indirect exposure assessment is used to indicate potential problems. In a case where the regional assessment indicates reason for concern, the assessment is refined. In cases where the local assessment does not indicate a potential risk, no further assessment needs to be conducted. The situation is less clear in the grey area where a regional assessment does not give reason for concern, but the local assessment does. No testing strategy is triggered by the indirect exposure assessment. Instead, when there is reason for concern in the local assessment only, a further analysis of the major exposure routes is performed to investigate the accuracy of the local exposure scenario.

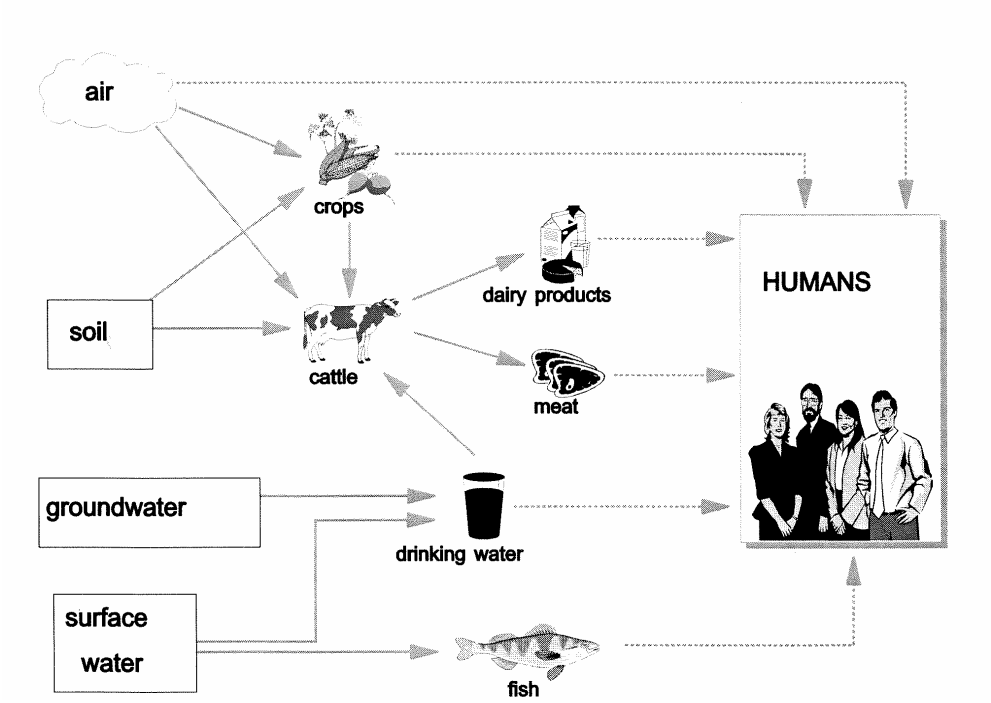

Figure 3 Schematic representation of exposure routes considered in human exposure (Fig. 5 of TGD, Part I).

2.5.4 Groundwater

The WFD requires the achievement of a good *chemical* status for groundwater. Good chemical status encompasses quantitative and qualitative aspects. In a proposal for daughter directive for the protection of groundwater against pollution (2003/0210 COD; EC, 2003b),

criteria are given for which pollutants quality standards have to be derived, for monitoring frequency and for the identification of significant upward trends. A groundwater body has good chemical status if nitrates are < 50 mg/l and PPPs are <0.1 µg/l (Annex I of proposal 2003/0210 COD). With regard to pollutants that are not covered by EU legislation, the proposed Directive requires Member States to establish threshold values by June 2006 at least for a number of chemicals listed in the proposed daughter directive (ammonium, arsenic, cadmium, chloride, lead, mercury, sulphate, trichloroethene and tetrachlorobenzene). These threshold values have to be defined at the national, river basin or groundwater body levels, thereby taking into account the great diversity of groundwater characteristics across the EU. For the assessment of the chemical status of groundwater bodies for which no QS are present yet, is referred to the WFD.
The FHI report was not directed to specify EQS derivation for groundwater, but for surface water only. However, for PPPs, the FHI report refers to Annex VI, § 2.5.1.2 of Council Directive 91/414/EEC (§5.2.2 of FHI report). There it is stated that the authorization of a PPP is not granted if the concentration in groundwater is expected to exceed the lowest of the limit values set in Council Directive 98/83/EC related to the quality of water intended for human consumption (i.e. 0.1 µg/l drinking water for an individual active substance); or the maximum concentration laid down by the Commission when including the active substance in Annex I; or, when that concentration has not been laid down, the concentration corresponding to one tenth of the acceptable daily intake (ADI) of the respective substance.

In the TGD (Part II, § 2.3.8.6), the concentration in groundwater is calculated to assess indirect exposure of humans through drinking water. For the calculation of groundwater levels, several numerical models are available (mainly developed for pesticides). However, these models require a characterisation of the soil on a high level of detail. Therefore, as an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken, as a worst-case assumption, neglecting transformation and dilution in deeper soil layers.
Groundwater ecosystem is also a protection aim in the TGD but currently it is not possible to carry out effect assessment for the groundwater community because no toxicity data for groundwater organisms are available.

2.5.5 Drinking water

The WFD demands the designation of water bodies that are used for collection of drinking water. The designated water bodies have to meet the requirements of Directive 80/778/EEC as amended by Directive 98/83/EC. For these water bodies, special statutory monitoring- and protection-obligations (EQS) are formulated (article 7 of WFD). In the FHI report, existing standards are used in respect to drinking water quality. The FHI (§ 8.3) refers to Council Directives 75/440/EEC (concerning the quality required of *surface water* intended for the abstraction of drinking water in the Member States) and 98/83/EC (on the quality of water intended for human consumption, *end product* drinking water).

In the FHI report, the A1-category of surface water as defined in Council Directive 75/440/EEC is considered as minimum QS. The A1-category is the quality of surface water that can be used as drinking water after simple physical treatment and disinfection, e. g. rapid filtration and disinfection. If surface water quality representing the A1-category is better than the QS required to safeguard the other objectives of protection, the A1-category should be adopted as QS for surface freshwater. If no A1-category is defined but a drinking water standard according to 98/83/EC is available and this drinking water standard is lower than the QS to safeguard the other objectives of protection, an assessment is performed with the objective to derive a QS ensuring the possibility of drinking water abstraction by simple treatment, with assistance of experts in drinking water processing technology.
If there are no A1-values or QS fixed in the context of 75/440/EEC or 98/83/EC available, provisional drinking water QS are calculated from oral toxicity tests using the following default settings: 2 L/day water uptake and body weight 70 kg (TGD values for drinking water uptake and male body weight). Uptake by drinking water should not exceed 10% of the threshold level for human health. See also table 2, copied from FHI report (Lepper, 2002 and 2004), showing human health related protection objectives and triggers.

In the TGD (Part I, Appendix III), exposure assessment of drinking water that is produced from surface water or groundwater is performed by modelling as described by Hrubec and Toet (1992). A complete removal of suspended particles from surface water and groundwater is assumed. Effects of the sewage treatment processes used for purification of groundwater and surface water, which are generally not intended for the removal of organic pollutants, are neglected. Two water treatment systems for surface water are distinguished: a system with storage in open reservoirs and a system with dune recharge.

2.5.6 Human consumption of food originating from aquatic environments

The QSs of the FHI have to safeguard human health through ingestion of contaminated food. QSs for human food consumption are calculated if triggers defined in the table below are met. Calculations are performed according to §3.8.3 of TGD, Part II, treating secondary poisoning assessment.
With respect to ‘seafood’ (the term ‘seafood’ is not further defined), the FHI report states that no standard approach or convention exists for ingestion of food originating from aquatic environments by humans (§ 8.4.3). Therefore, the practical approach has been adopted that the uptake of a substance via fishery products should not contribute to more than 10% of the relevant threshold level for humans (ADI/TDI/NO(A)EL).
The oral toxicity tests with mammals or birds are transferred into a $QS_{human,food}$ using AFs (assessment factors) derived from the TGD. The QS is transformed into a water concentration ($QS_{human.food.water}$) by applying a BCF (bioconcentration factor) and a BMF (biomagnification factor).

FHI report's human health related protection objectives and triggers to derive QS are summarised in table 3.

Table 3 Human health related protection objectives and triggers to derive QS. Copied from table 8.1b (Lepper, 2002) and Table 1b (Lepper, 2004).

Biota (Food consumption)	Drinking water abstraction from surface water
A QS is derived for substances: • being a known or suspected carcinogen (cat. I-III, R-phrases R45 or R40) • being a known or suspected mutagen (cat. I-III, R-phrases R46 or R40) • being a substance known or suspected to affect reproduction (cat. I-III, R-phrases R60, R61, R62, R63 or R64) • having the potential to bioaccumulate (experimental BCF ≥ 100 or BMF >1 (or logPow ≥ 3, for organic substances only)) plus harmful or (very) toxic if swallowed or in contact with skin (R-phrases R21, R22, R24, R25, R27 or R28); or R48 (danger of serious damage to health by prolonged exposure) Check for compliance of the proposed QS with the maximum permissible levels in fishery products seafood fixed by existing legislation (e.g. Council Regulation (EC) No 466/2001 for Cd, Hg and Pb).	Derivation of a QS referring to DW * abstraction only if the following cases apply (see section 4.2.4 for details): A 'A1 value' is fixed in Directive 75/440/EEC and this value is lower than the QS for other objectives of protection: ⇒ QS = 'A1 value' of CD 75/440/EEC No 'A1 value' is fixed in CD 75/440/EEC but a DW Standard is available in CD 98/83/EC and the DWS ** is lower than the QS for other protection objectives: ⇒ Assessment (Experts): Identification of the substance specific removal efficiency in DW processing. QS = DWS / Fraction not removable No A1 value or DW Standard exists for the substance concerned: ⇒ a) Calculation of a provisional DWS b) Assessment based on expert knowledge with regard to: 1. Removal efficiency of substance in DW processing; 2. toxicological appropriateness of the provisional DWS QS = appropriate DWS / Fract. not removable

* DW = drinking water; ** DWS = drinking water standard

Human exposure assessment via food consumption in the TGD is modelled to predict human exposure through the aquatic food chain. Relevance of human exposure via food consumption is determined on a case by case basis. Exposure through the food chain is integrated with possible other exposure routes. See human risk assessment above.

2.5.7 Partitioning

For model calculation of PEC according to the TGD, transport between the compartments is taken into account, when possible. In case of continuous release, equilibrium between the compartments is assumed. Partitioning processes between air and aerosol, air and water, and solids and water are described in § 2.3.5 Part II. The FHI report does not include partitioning processes between air and aerosol, air and water, and land and water, as the FHI report only considers exposure via water. However, for the derivation of a QS for sediment from the QS

for the water phase, the equilibrium partitioning method is applied if no appropriate toxicity test data for sediment organisms are available.

2.5.8 Bioconcentration to derive PEC_{oral} and $PNEC_{oral}$

In Table 8.1a of FHI, trigger-values of BCF ≥ 100 or BMF > 1 are given. Also, it is mentioned that if a reliable BCF is not available, a trigger of log K_{ow} ≥ 3 should be used, only in case of organic substances.
The TGD gives some more triggers as indication of bioaccumulation potential, i.e. a log K_{ow} ≥ 3; high adsorptive properties; substance belongs to a class of substances known to have potential to accumulate in living organisms and indications from structural features, together with a half-life > 12 hours (Part II, § 3.8.2).

As, according to the FHI report, for several reasons it is not desirable to perform routine monitoring of biota for compliance checking, a corresponding concentration in water is calculated as a surrogate standard (≈ $QS_{secpois.water}$), using the safe level in prey ($QS_{secpois.biota}$) and bioaccumulation data (bioconcentration factor (BCF) and biomagnification factor (BMF)) of the substance concerned. The calculation is done with a transformation of the formulae used in the TGD to calculate the PEC_{oral} (§ 3.8.3.4 and 4.3.3.2 of the TGD). Not only biomagnification in the prey of predators (BMF_1, as for freshwater) but also in the prey of top predators (BMF_2) is considered, to account for the longer food chains in the marine environment.
The FHI report gives a table to derive BMF-values from log K_{ow}- and BCF-values. The table heading (Table 5.3) refers to Table 21 of the TGD but one value differs between the 2 documents. The BMF-value for log K_{ow} 4.5 - <5 and BCF 2000 – 5000 is ‘2’ in Table 21 of the TGD and ‘3’ in Table 5.3 of the FHI (Lepper, 2002). In Annex V of the FHI (Lepper 2004), Table 21 of TGD, Part II, is copied correctly. The deviating number in Lepper (2002) is due to adjustment in the TGD (2003a) of the BMF value after printing of Lepper (2002).
The TGD gives some more guidance on which studies are acceptable to derive a $PNEC_{oral}$ from and the FHI report refers to the TGD, § 3.8.3.6, how to consider secondary poisoning in more detail.

2.5.9 Bioavailability in water

In the TGD, the concentration in surface water is calculated after complete mixing of the effluent outfall. To allow for sorption, a correction is made to take account of the fraction of substance that is adsorbed to suspended matter. The resulting dissolved concentration (PEC) is used for comparison with $PNEC_{water}$, assuming that in aquatic toxicity tests generally the entire amount of compound is bioavailable. However, when a substance is released to surface water predominately as particles (e.g. as precipitates or incorporated in small material pieces), this could lead to overestimation of $PEC_{surface\ water}$ or underestimation of $PEC_{sediment}$.
In the chapters on STPs in the TGD (Part II, § 2.3.7.1), it is reported that only the dissolved concentration is assumed to be bioavailable.

For metals in the local aquatic environment (PEC), as a first estimate it is assumed that the substance will dissolve up to its water solubility limit, and that this fraction will be the bioavailable form (Appendix VIII).
In the FHI report, it is intended to derive a quality standard for each substance only for the water phase by default. However, for hydrophobic or strongly adsorbing substances the QS is additionally expressed as concentration in suspended particulate matter (µg/kg). A trigger value of log $K_{p\ SPM\text{-}water} \geq 3$ is given to derive a QS expressed as concentration in particulate matter. Thus, for hydrophobic organic substances, the QS referring to water will be given for unfiltered water samples (µg/l) ('total' concentration) and for the corresponding concentration in suspended particulate matter (µg/kg) (see § 4.2.1 for transformation algorithms).
For metals, it was decided to compare toxicity test results of metals (added metal concentration is considered 100% bioavailable) with the total metal content in 'real world' water samples and not with the dissolved fraction only. This, because on the one hand not all of the metal in the dissolved fraction is bioavailable and on the other hand organisms may also take up metals from the particle bound fraction (§ 4.2.1). However, in § 8.6.4 it is reported that no decision is taken yet whether bioavailable metal in real world water samples is only the dissolved fraction or the total content of a metal in a water sample. In § 8.6.4 it is therefore proposed to calculate 2 MPAs (Maximum Permissible Addition); one referring to (dissolved) metal levels in water and one referring to levels in suspended particulate matter of EU standard water.
The 'position paper on the derivation of Quality Standards for 'water-total' and the recalculation of monitoring data to standard conditions for Priority Substances in the context of the Water Framework Directive' goes into more detail how and if to standardise QS to standard water (Anonymous, 2003). Figure 2 is adapted from this position paper.

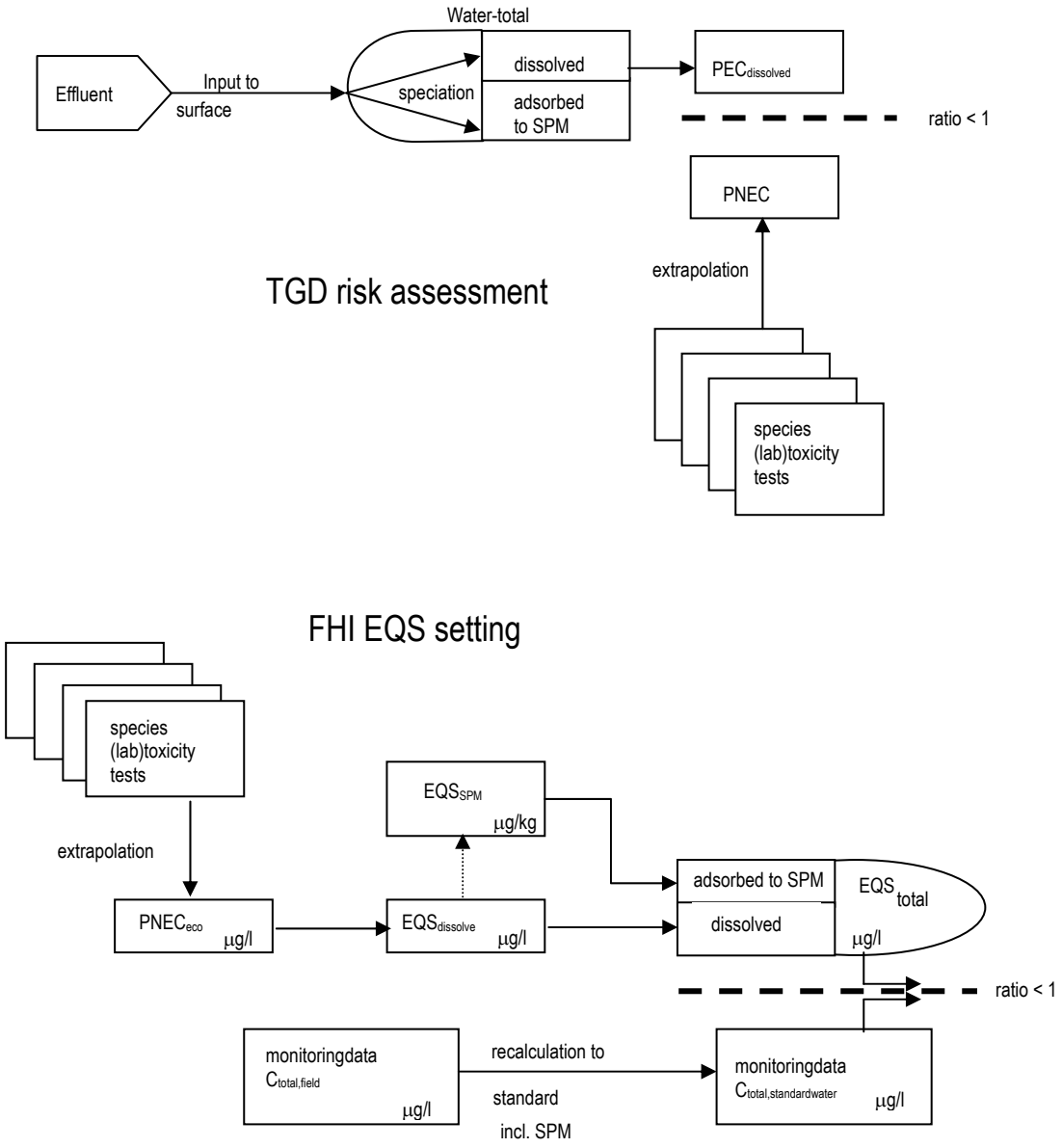

Figure 4. Dissolved and total water concentrations in TGD risk assessment and FHI EQS derivation. Figures 1 and 2 from Anonymous (2003).

2.5.10 Foraging areas of predators and top-predators

The FHI report refers to the TGD for calculation of secondary poisoning of predators and top predators in the marine environment. In short, the derivation of the $PNEC_{oral}$ for predators and top predators is explained.
The TGD has a special section devoted to the calculation of $PEC_{seawater}$ taking into account the preying areas of predators and top-predators. For predators, the worst-case assumption is made that they consume equal amounts of prey from the local and regional area. For the marine environment, top predators are also accounted for. It is assumed that top predators obtain their prey mainly from the larger-scale, regional marine environment, which is influenced by point source discharges to a lesser extent. As realistic worst case, a 90/10 ratio between regional and local food intake is taken for the calculation of $PEC_{seawater}$ for top predators.

Preying scales of predators and top predators are not discussed and not applied in the FHI report, falling out of the scope of the WFD.

2.5.11 Persistent, bioaccumulative and toxic substances

In § 8.4.1.2 and § 8.4.2.2, the FHI report states that QS are inappropriate to control risks of Priority Hazardous Substances (persistent, bioaccumulative and toxic substances) in the open sea and marine sediments of transitional, coastal and territorial waters and that the focus for this group of substances should be to reduce contamination of the marine environment. For man-made Priority Hazardous Substances, the detection limit should be defined as Borderline Quality Standard. Such a statement is not made in the TGD due to its different focus (risk assessment).

The TGD, however, does give special attention to PBT (persistence, bioaccumulation and toxicity) assessment (§ 4.4 Part II). The PBT assessment seeks to protect ecosystems where the risks are more difficult to estimate. The PBT assessment concerns the marine environment, which may not be adequately addressed by the traditional risk assessment methodologies. For PBT substances, a ‘safe’ concentration in the environment cannot be established with sufficient reliability. The PBT assessment is particularly developed to take into account the unacceptable high uncertainty in predicting reliable exposure and/or effect concentrations hampering quantitative risk. The PBT assessment basically consists of identification of PBT substances and evaluation of sources, major emissions and pathways to the marine environment, in order to establish the most effective measures.

2.5.12 Metals

Background concentrations of metals

In both TGD and FHI report the added risk approach is used. Background concentrations can be derived from measurements in pristine areas or from calculations according to both documents. The FHI report refers to background levels of metals for inland waters defined by Germany, Finland, the Netherlands and Sweden and to background levels in marine waters defined by Finland and Sweden. The TGD refers to surface water data from extensive national monitoring programs for the EC Regulation 76/464.

Bioavailability in water

In the FHI report, the QS refers to the bioavailable fraction. At time of FHI report publishing, it was not yet decided if only the dissolved fraction or the total content of metal in a water sample should be considered as bioavailable fraction. For the time being, 2 MPAs (Maximum Permissible Addition) are calculated, 1 referring to metal levels in water and 1 to levels in suspended particulate matter of standard EU water. In the TGD, dissolved concentrations are preferred, because these indicate the bioavailable metal fraction in the aquatic environment. In the draft RAR zinc (EC, 1999) this approach is applied. The TGD adds that it is of utmost importance that both PEC and PNEC are based on similar levels of availability in both exposure and effect assessment, taking the speciation into account.

Bioavailability in sediment

The SEM/AVS approach is not applicable as methodology for sediment quality standard setting of metals according to the FHI report (§ 8.6.5) and its use for a generic approach is not adopted. The AVS concept is mentioned in the TGD as example of formation of insoluble metalsulphides under unaerobic conditions, but it is not discussed how to deal with AVS information. The AVS concept is applied in the draft RAR for zinc (EC, 1999).

In FHI report Annex V, it is elaborated on the lack of scientific knowledge is available to quantitatively describe the influence of water quality parameters on bioavailability and long-term toxicity for the different aquatic life forms. Therefore, for the time being, no account of the influence of physico-chemical parameters on metal bioavailability is taken. For lead, mercury and nickel only long-term toxicity to different aquatic life forms has been considered.

2.5.13 Algae toxicity data for PPPs

The FHI report mentions in Annex V, p. 20 that for PPPs, only acute toxicity to algae (EC_{50}) is considered (following PPPRA, protocol for PPPs), whereas in the protocols for new and existing substances (ESRA) also the no-effect level (NOEC, EC_{10}) is taken into account, if respective data are available. The TGD (Part II, Table 15, p. 98) considers 72-hour (or longer) EC_{50}-values from algae studies as short-term results and 72-hour (or longer) NOEC-values as long-term results.
In the FHI report, safety factors for algal toxicity data are applied for new and existing substances derived from the TGD and for PPPs derived from PPPRA. For new and existing compounds, AFs from Table 16 (Part II, p. 101) of TGD are used, whereas for PPPs the AF for $EC_{50,\ algae}$ must not fall below 10. In the TGD, AF of 1000 are applied on acute toxicity data from at least three trophic levels. The AF applied to chronic toxicity data depends on the other available toxicity data.

2.5.14 Minor remarks

Calculation of PNEC using assessment factors

- Assessment factors (AFs) to derive a PNEC are identical in both guidelines and originate from TGD. The TGD gives a few more reasons to deviate from the basic AFs given in Table 16 (§3.3.1.1 TGD, Part II). For PPPs, other AF may be applied to algal toxicity data, compared to AFs applied to algal toxicity data of new and existing substances (see above 'Algae toxicity data').

Calculation of PNEC using statistical extrapolation techniques

- TGD and FHI report have the same data requirements and apply the same calculations.
- The TGD adds that a pre-selection of data should be performed in relation to realistic environmental parameters for Europe and states that test data applicable to the most sensitive endpoint should be taken as representative for the species.
- The TGD gives some more considerations to serve as an aid in judging reported effect concentrations or to recalculate them before use in statistical extrapolation techniques in order to calculate a PNEC (Part II, Table 15, p. 98).
- The TGD goes more into detail about testing data distribution for lack of fit.
- Although not reported in the FHI report, MAC-QSs also have been derived using statistical extrapolation (information from Priority Substance datasheets). The TGD does not use SSD extrapolation for acute toxicity data.

Default compositions

- The TGD defines a default composition for surface water, suspended matter, sediment and soil used in the calculation of PECs, presented in Table 5 of Part II, § 2.3.4. These are mostly copied for WFD effect assessment. However, for marine sediments a SPM concentration of 3 mg/l is proposed in the FHI (p.102). This value is not mentioned in the TGD.

Special highlighting of substances

- The TGD has special appendices devoted to metals, (Appendix VIII of Part II), petroleum substances (Appendix IX) and ionising substances (Appendix XI). These appendices are devoted to deviations in risk assessment procedures for these substances or to special considerations when treating these substances. Petroleum substances and ionising substances are not separately treated in the FHI report, but metals are.

Microorganisms in sewage treatment plants

- Microorganisms in sewage treatment plants (STPs) are included in the risk assessment described by the TGD (§3.4 of part II). In the FHI report, microorganisms in STPs are not incorporated in the derivation of EQS.

Sediment Quality Standards

- Both TGD and FHI report have formulated trigger values for sediment effect assessment. However, in the FHI report (Table 8.1*a*), log $K_{p,SPM\text{-}water} \geq 3$ is reported as trigger for substances to derive a QS for sediments and in the TGD (§ 3.5.2, Part II), log K_{oc} or log $K_{ow} \geq 3$ are recommended to use as trigger values for sediment effect assessment.

3. Conclusions and recommendations

The risk assessment described in the TGD encompasses effect assessment, exposure assessment and risk characterisation. The effect assessment overlaps with the determination of EQSs in the FHI report, because a great part of the TGD methodology is copied for the EQS derivation of the FHI report. Differences in methodology can partly be found at detailed level, described in the paragraphs on $PEC_{regional}$ and PEC_{local}, monitoring data, bioconcentration, bioavailability, metals, algae data and minor remarks. Consequences of most of these discrepancies can easily be overseen.
The situation is more complicated for the PNEC determination for the water compartment. Although PNEC calculation shows great similarities between the two guidance documents, final choice of safe water concentration following the Fraunhofer methodology can be different from the PNEC determined by the TGD in some cases. The FHI report calculates several safe water concentrations from safe food concentrations for predators, from safe sediment concentrations for sediment organisms and from safe intake levels for humans. The lowest resulting safe water concentration is used as EQS. In some instances, this will lead to lower EQSs in comparison to the PNECs for water derived following the TGD, depending on chemical properties and toxicity to mammals.
Additionally, the FHI report only considers exposure via water, whereas the TGD evaluates exposure via all relevant routes. The resulting PNECs of both methodologies serve different aims. The PNEC according to FHI methodology, which is translated into an EQS, is used as safe water concentration to safeguard both human health and the environment. The PNEC of the TGD is applied to compare with the calculated exposure via all possible routes. Thus, the PNEC of the TGD is not meant to be translated into a safe water concentration only, because this would ignore exposure of some protection targets through other routes, such as air or agricultural products. For the protection of human health, the EQS for aquatic food intake and the EQS for water intake are restricted to 10% of safe human consumption according to Fraunhofer methodology. In the hypothetical case of a high intake rate via air or agricultural products, human health may not be safeguarded by the EQS of the FHI.

This report aimed to elucidate discrepancies between the TGD and the FHI report. Disparities between framework and also discrepancies of more technical nature were elucidated. However, the practical consequences of the differences for EQS derivation can not be judged by a theoretical examination only, as performed during this study. Calculations following both methodologies with substances with different chemical properties and behaviour, together with investigations of RARs, are recommended to gain more insight in the extent of the consequences of the differences between the guidance documents. Routes other than aquatic routes could be estimated, assuming equilibrium between all compartments.

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Abbreviations

AA-QS	Annual Average concentration Quality Standards
ADI	Acceptable Daily Intake
AF	Assessment Factor
BCF	Bioconcentration Factor
BMF_1	Biomagnification Factor from water to prey of predator
BMF_2	Biomagnification Factor from prey of predator to predator
DW	Drinking Water
DWS	Drinking Water Standard
EC	European Commission
EC_{50}	Effective Concentration, median
EQS	Environmental Quality Standard
ESRA	Existing Substances Risk Assessment
FHI	Fraunhofer Institüt document
LC_{50}	Lethal Concentration, median
LOD	Limit of Detection
LOQ	Limit of Quantification
MAC	Maximum Acceptable Concentration
MAC-QS	Maximum Admissible Concentration Quality Standards
MPA	Maximum Permissible Addition
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PPP	Plant Protection Products
PPPRA	Plant Protection Products Risk Assessment
QS	Quality Standards
SCCP	Short Chained Chlorinated Paraffin
SPM	Suspended Particulate Matter
STP	Sewage Treatment Plant
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
WFD	Water Framework Directive
WQO	Water Quality Objective

List of the Directives mentioned in this document

67/548/EEC	Classification and labelling of dangerous substances
75/440/EEG	Directive for surface water intended for the abstraction of drinking water
76/160/EEC	Bathing Water Directive
76/464/EEC	Directive on pollution caused by certain dangerous substances in the aquatic environment
79/409/EEC	Birds Directive
80/778/EEC	Drinking Water Directive
85/337/EEC	Environmental Impact Assessment Directive
86/278/EEC	Sewage Sludge Directive
91/271/EEC	Urban Waste-water Treatment Directive
91/414/EEC	Plant Protection Products Directive
91/676/EEC	Nitrates Directive
92/43/EEC	Habitats Directive
793/93/EEC	Existing Substances Directive
93/67/EEC	New Notified Substances Directive
1488/94/EC	Directive with principles of risk assessment for existing substances, after 793/93/EEC
96/61/EC	Integrated Pollution Prevention and Control Directive
96/82/EC	Major Accidents (Seveso) Directive
97/57/EC	Directive on placing of PPPs on the market
98/8/EC	Directive on placing of biocides on the market
98/93/EC	Directive on quality of water intended for human consumption
2000/60/EC	Water Framework Directive
466/2001EC	Maximum levels in foodstuffs-Directive
Draft 2003/0210	Groundwater Directive
Non-paper June 2004	Non-paper on priority substances in surface water