Annex 5

Manual of the Methodological Framework Used to Derive Quality Standards for Priority Substances of the Water Framework Directive

Updated summary of the concept
originally laid down in the Final Report of the Study Contract No. B4-3040/2000/30637/MAR/E1: Identification of quality standards for priority substances in the field of water policy. Towards the Derivation of Quality Standards for Priority Substances in the Context of the Water Framework Directive. By P. Lepper, Fraunhofer-Institute Molecular Biology and Applied Ecology, September 2002.

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1 Background

Article 16 of the Water Framework Directive (WFD, Directive 2000/60/EC) lays down the Community Strategy for the establishment of harmonised quality standards and emission controls for the priority substances and other substances posing a significant risk to, or via, the aquatic environment. In order to achieve the protection objectives of the WFD, the Commission shall submit proposals for quality standards applicable to the concentrations of the priority substances in surface water, sediment or biota.

2 Concept Development

The concept for the derivation of quality standards proposed in this report was presented to the Expert Advisory Forum on Priority Substances (EAF) at different stages of its development. Furthermore, an Expert Group on Quality Standards discussed specific elements of the proposed methodology. Comments received upon the different discussion rounds have been taken into account, where appropriate. The proposed approach was finally endorsed by the EAF at its meeting in March 2002.

In order to develop a scientifically sound and practicable concept and to derive most appropriate quality standards ensuring a good chemical status[1] of the Communities' surface waters, it is necessary to assess and evaluate all three compartments (i.e. water, sediment, biota) in parallel. The starting point for the development of the concept to derive quality standards were the provisions set out in Annex V, section 1.2.6 (Procedure for the Setting of Chemical Quality Standards by Member States) of the Water Framework Directive [1]. However, while the provisions of Annex V may suffice as general scheme to derive quality standards for organic substances in the water body, they do not deal with specific problems arising from the inclusion of sediment quality, protection of top predators from secondary poisoning and human health as objectives of protection, nor do they account for the peculiarities that must be considered if quality standards for metals or for transitional, coastal and territorial marine waters are to be set. Therefore, it was deemed indispensable to take further approaches for effects assessment and quality standard setting into account.

To this end, the EU (i.e. CSTÉ) and Member States methods for the purpose of deriving water quality standards as well as other provisions such as the EU-concepts on risk assessment for new notified and existing substances (Directive 93/67/EEC and Regulation (EC) No 1488/94, as laid down in the Technical Guidance Document) or for plant protection products (Directives 91/414/EEC and 97/57/EC) as well as latest developments in science have been evaluated with regard to their suitability and pertinence to achieve the objectives pursued with the quality standards under the Water Framework Directive. The evaluated methods are described in sections 4 and 5 of the report “Towards the Derivation of Quality Standards for Priority Substances in the Context of the Water Framework Directive” [2].

[1] The WFD aims at the achievement of a good status for surface waters and groundwater bodies (Article 4(1)). The basic idea behind "good status" is that water bodies may be affected by human activity only to the extent that the ecological functions and the community structure of the water body in question are not fundamentally changed, i.e. the long-lasting continuance of populations of naturally occurring species should be ensured by the quality standards to be set.

All approaches for quality standard setting or risk assessment are in so far very similar as the application of assessment factors depending on the quality and quantity of available toxicity data is a common core element. As an alternative to this assessment factor approach, the use of statistical extrapolation methods (i.e. species sensitivity distributions) is recommended, respectively preferred, e.g. in the context of the EU risk assessments [3, 4], if the data requirements for the application of this approach are met.

As no fundamental differences in the national approaches for quality standard setting or the EU methods for risk assessment could be found, it was decided to built the methodological framework for quality standard setting as far as possible on the state-of-the-art, internationally acknowledged, effects assessment procedures used in the EU-risk assessment frameworks for existing substances [6, 38] or plant protection products [8, 15, 35]. In addition, the methodology was supplemented with elements of Member State approaches for quality standard setting or latest findings in research, if deemed pertinent (e.g. in the QS setting procedure for metals).The reasons for this approach are as follows:

- to keep the ecological effects assessment methodology on EU-level as consistent as possible;
- to use, as far as possible, elements for the set up of the quality standard derivation methodological framework that are already accepted and agreed by Member States and introduced on Member State level.

The general approach chosen for the derivation of quality standards in the context of the Water Framework Directive is very similar to the approach for the derivation of EU Water Quality Objectives in the context of Council Directive 76/464/EEC developed by the former CSTÉ [5], as possible impacts on aquatic ecotoxicity, human health effects and bioaccumulation potential are accounted for in setting the standards. However, as effects assessment methodology has been considerably refined in the last decade, it was deemed necessary to use today's state of the art methods in the present exercise.

3 Objectives of the Approach for the Derivation of Quality Standards

The methodological framework elaborated for the derivation of quality standards is intended to concomitantly protect freshwater and marine ecosystems from adverse effects as well as human beings from all impacts on health by drinking water uptake or ingestion of food originating from aquatic environments. To this end, for the entire set of objectives of protection, i.e. the pelagic and benthic communities (≈ water and sediment) in freshwater or saltwater ecosystems, the top predators of these ecosystems and human health, it is assessed by means of pre-defined trigger criteria (see table 1 for triggers) whether a substance may pose a certain objective at risk. For those objectives for which a possible risk (≈ exceeded trigger-value) is identified, specific quality standards are derived. In a subsequent step the lowest of the standards derived for the individual protection objectives is selected as the overall quality standard (however, if deemed justified, distinct quality standards are derived for freshwater and saltwater, respectively).

Thus, a quality standard derived by this approach takes all relevant protection objectives into account. Moreover, all direct and indirect exposure routes in aquatic systems like exposure in the water body via water and sediment or via bioaccumulation as well as possible exposure via drinking water uptake are accounted for. Further, all relevant modes of toxicity are considered, e.g. for ecosystems direct and indirect toxicity (≈ after bioaccumulation) and for man oral toxicity

as well as carcinogenicity, mutagenicity and adverse effects on reproduction (CMR). In addition, effects on endocrine regulation in animals or man are accounted for, if relevant.[2]

Therefore, a quality standard derived by the described conceptual framework is not merely a threshold level ensuring the protection of only a particular protection objective (like, for instance, a Predicted No Effect Concentration for the protection of the pelagic community), but is an overall stand alone value that encompasses the consideration of direct ecotoxicological effects in different habitats (water, sediment), indirect ecotoxicological effects occurring after bioaccumulation in biota (secondary poisoning of top predators) and effects on human health by oral uptake of water and food, including long term toxicity and CMR mechanisms.

In order to cover both long-term and short-term effects resulting from exposure to a chemical, it was deemed pertinent to derive two kinds of quality standards referring to (i) the annual average concentration and (ii) to short term concentration peaks. To this end, a QS has been calculated which is referring to the annual average concentration (AA-QS) and, in addition, the so-called maximum acceptable concentration QS (MAC-QS) referring to short term transient exposure. The MAC-QS is a figure not be exceeded any time. In conjunction, the AA-QS and the MAC-QS are intended to protect the structure and function of the addressed aquatic ecosystems from significant alterations by the impact of chemical substances.

4 Methodological Framework to Derive Quality Standards for Water, Sediment and Biota

4.1 General Procedures for Quality Standard Setting

According to Article 16(7) WFD, the Commission shall submit proposals for quality standards applicable to concentrations in water, sediments or biota. This implies that the setting of quality standards for all the mentioned compartments is optional. Quality standards (QS) for a specific compartment may not be required if – based on the current scientific knowledge - there is no indication that a given substance poses this compartment at risk. For instance, a quality standard for sediment may not be necessary if there is no indication that the substance concerned accumulates in the sediment. Similarly, quality standards for concentrations in biota may not be required if there is no indication for bioaccumulation (≈ secondary poisoning of top predators), or risk to human health by consumption of fishery products.

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. This quality standard is given in a mass per volume unit (e.g. µg/l). However, for hydrophobic or strongly adsorbing substances this quality

[2] Quality Standards derived by the proposed methodological framework do not account explicitly for a possible combined action of pollutant mixtures. Nonetheless, it is assumed that the safety factors applied in the effects assessment do cover the possible occurrence of combined action of pollutants in most instances to a great extent. For the time being, there is apparently no consolidated and validated approach to account for combined action of pollutants available that is applicable in the context of quality standard setting. Therefore, the Commission, has commissioned a research project on the regulation of mixtures of toxic chemicals in the aquatic environment, the so-called BEAM project. The results of this project should be considered in future adaptations of the proposed quality standard setting methodology to scientific progress.

standard is additionally expressed as concentration in suspended particulate matter (µg/kg) if this appears meaningful, e.g. for analytical reasons[3].

In line with the provisions of the TGD on marine effects assessment [3], distinct QS are derived for **freshwater and saltwater** environments, respectively, if the effects data available do not suffice to conclude that both environments can be considered as equally vulnerable. The setting of further quality standards for drinking water abstraction, biota or sediments is triggered by the criteria given in table 1.

The lowest specific standard derived for the different objectives of protection[4] is adopted as **overall quality standard**. However, if different quality standards for the freshwater and the marine environment are derived, the lowest standards relevant for either the marine or the freshwater environment are adopted as specific overall QS_{marine} or $QS_{freshwater}$.

In order to be able to adopt the lowest quality standard as overall standard, it may be required to transform standards from mass per volume to mass per mass units (e.g. µg/l (water) to µg/kg (sediment, biota)) or vice versa using appropriate model calculations and parameters. Similarly, biota quality standards may be transformed to concentrations in water or suspended particulate matter (and be reported as those) in order to avoid routine monitoring (and thus sampling) of biota for compliance checking with quality standards. The respective algorithms for transformation are given in the following sub-sections of chapter 4.2

Quality standards for **sediment** should preferably be derived on the basis of toxicity tests with sediment dwelling organisms. However, as those toxicity tests with benthic organisms are not available for many substances, the so-called equilibrium partitioning method may be used in order to extrapolate a quality standard applicable to the concentration in sediment (for the protection of benthic life) from the quality standard derived for the protection of life in water (see section 4.2.2 for details).

For the purpose of compliance checking, the sediment quality standard may be compared with the substance concentration monitored in suspended particulate matter (SPM). By doing so, compliance of the level in SPM with the sediment quality standard ensures that the material that will eventually settle down and contribute as most important fraction to the build-up of new sediment layers is suitable to fully support sustainable benthic life (i.e. the contaminant level in new sediment will not exceed the no-effect threshold level). In contrast to SPM, sediment samples from the ground of a water body might be a suitable reference for quality standards triggering the need for remediation of seriously contaminated sediments. However, the development of such "remediation standards" is beyond the scope of the current task.

With respect to **drinking water quality**, existing standards will be accounted for, e.g. those given in Council Directive 75/440/EEC concerning the quality required of surface water intended for the abstraction of drinking water [6] or in Council Directive 98/83/EC concerning the quality of water intended for human consumption [7]. Both directives require Member States to ensure that any measures taken in no circumstances have the effect of allowing, directly or indirectly, either

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[3] Thus, for hydrophobic organic substances, the quality standard 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 section 4.2.1 for transformation algorithms).

[4] Objectives of protection: Water quality to support aquatic life or to allow for drinking water abstraction, sediment quality to support benthic life, and quality of biota in order to protect humans or top predators from secondary poisoning by ingestion of food.

any deterioration of the present quality of water intended for human consumption or any increase in the pollution of waters used for the production of drinking water (Article 7, CD 75/440/EEC and Article 4, CD 98/83/EC; see also Articles 7(2,3) and 16(1), WFD). In this sense, the "A1 values" of Council Directive 75/440/EEC referring to "simple treatment" (i.e. filtration and disinfection) to produce drinking water from surface water are considered as minimum quality standard. For those priority substances for which no values are given in CD 75/440/EEC a standard for drinking water abstraction from surface water may be derived by the procedure described in section 4.2.4.

In order to derive the human health related quality standards for **biota** (consumption of food originating from aquatic environments), it is suggested to follow the guidance and models given in the TGD [3] and in the context of Council Directive 91/414/EEC [8] as far as possible (see sections 4.2.3.2 and 4.3). Existing maximum levels such as, e.g., those fixed for cadmium, lead and mercury in Council Regulation (EC) No 466/2001 [43] for fishery products are considered in the derivation of the biota quality standards.

Table 2 gives an overview on the methods proposed for the derivation of quality standards for the different objectives of protection. The methods are outlined in the following sections 4.2 – 4.5.

Table 1a: Environmental protection objectives and triggers to derive quality standards

Water	Sediments (suspended particulate matter)	Biota (secondary poisoning)
No trigger value applies. QS are derived for <u>all</u> priority substances. For hydrophobic / adsorbing substances the QS referring to the concentration in water are additionally reported as concentration in suspended particulate matter (SPM) if this is meaningful. Trigger value: log $Kp_{SPM\text{-}water} \geq 3$	QS are derived for all substances with al log $Kp_{SPM\text{-}water} \geq 3$ The $QS_{sediment}$ refers to suspended particulate matter in order to protect the new sediment.	QS are derived for organic substances and metals with experimental BCF ≥ 100 or BMF >1. If a reliable BCF is not available, the trigger is log Pow ≥ 3 (applies only to organic substances) In order to avoid routine monitoring of biota the concentrations in animal tissue are transformed to concentrations in water or suspended particulate matter, using appropriate model estimates / partition coefficients.

Table 1b: Human health related protection objectives and triggers to derive quality standards

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)) *<u>plus</u>* - harmful or (very) toxic if swallowed or in contact with skin (R-phrases R21, R22, R24, R25, R27 or R28); <u>or</u> - 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): 1. 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 2. 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 3. 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

Table 2: Overview on the methods proposed for the derivation of quality standards in relation to the different objectives of protection

(AF: assessment factor ; CD: Council Directive; DW(S): drinking water (standard); ME: metals; MPA: maximum permissible addition; OC: organic chemicals; PPP: plant protection product; QS: quality standard; SPM: suspended particulate matter; SSD: species sensitivity distribution; TER: toxicity-exposure ratio; TGD: technical guidance document)

Objective of protection	**Type of substance**	**Compartment**	**Method proposed**	**Description in section**
pelagic community	OC	marine water (unfiltered sample) (for hydrophobic substances in addition: corresponding concentration in SPM)	• TGD Assessment Factor method (freshwater AFs) • SSD method (data rich substances)	4.2.1.1 4.2.1.3 & 4.4.2
pelagic community	OC	marine water (unfiltered sample) (for hydrophobic substances in addition: corresponding concentration in SPM)	• TGD Assessment Factor method (saltwater AFs) • SSD method (data rich substances)	4.2.1.2 4.2.1.3 & 4.4.2
benthic community	OC	freshwater sediment (SPM) QS are derived if log $Kp_{sediment\text{-}water} \geq 3$	• TGD Assessment Factor method (freshwater AFs) • Equilibrium partitioning approach (if no or only insufficient data for sediment organisms are available) • SSD method (data rich substances)	4.2.2.1 4.2.1.3 & 4.4.2
bentic community	OC	marine sediment (SPM) QS are derived if log $Kp_{sediment\text{-}water} \geq 3$	• TGD Assessment Factor method (AFs for marine sediment) • Equilibrium partitioning approach (if no or only insufficient data for sediment organisms are available) • SSD method (data rich substances)	4.2.2.2 4.2.1.3 & 4.4.2
pelagic community	PPP	freshwater (unfiltered sample) (for hydrophobic substances in addition: corresponding concentration in SPM)	• Based on Uniform Principles (CD 97/57/EC) and TGD $QS_{water,\ annual} = NOEC_{min} / TER\text{-}trigger_{long\ term}$ or Case by case decision if higher tier data are available	4.3
pelagic community	PPP	marine water (unfiltered sample) (for hydrophobic substances in addition: corresponding concentration in SPM)	• Based on Uniform Principles (CD 97/57/EC) and TGD marine effects assessment $QS_{water,\ annual} = NOEC_{min} / TER\text{-}trigger_{long\ term}$ or Case by case decision if higher tier data are available	4.3; 4.2.1.2
benthic community	PPP	freshwater sediment (SPM)	• QS for sediment derived as for "normal" organic chemicals, under consideration of the argumentation related to this compartment in the risk assessment monograph	4.3 4.2.2.1
benthic community	PPP	marine sediment (SPM)	• QS for sediment derived as for "normal" organic chemicals, under consideration of the argumentation related to this compartment in the risk assessment monograph	4.3 4.2.2.2
pelagic community	ME	freshwater (filtered sample) (corresponding concentration in SPM in addition)	• Added risk approach ($QS = C_{background} + MPA$) • SSD method to derive the MPA for data rich metals • TGD assessment factor method (freshwater AFs) to derive MPA if application of SSD method not possible	4.4.1 4.4.2 4.4.4
pelagic community	ME	marine water (filtered sample) (corresponding concentration in SPM in addition)	• Added risk approach ($QS = C_{background} + MPA$) • SSD method to derive the MPA for data rich metals • TGD assessment factor method (saltwater AFs) to derive MPA if application of SSD method not possible	4.4.1 4.4.2 4.4.4 4.4.6
benthic community	ME	freshwater sediment (SPM) QS derived if log $Kp_{sediment\text{-}water} \geq 3$	• Added risk approach ($QS = C_{background} + MPA$) • SSD method to derive the MPA for data rich metals • TGD assessment factor method (freshwater sediment AFs) to derive MPA if application of SSD method not possible • Equilibrium partitioning approach if no or only insufficient data for sediment organisms available	4.4.1 4.4.2 4.4.5

continued overleaf

Table 2: (continued) Overview on the methods proposed for the derivation of quality standards in relation to the different objectives of protection

Objective of protection	**Type of substance**	**Compartment**	**Method proposed**	**Description in section**
benthic community	ME	marine sediment (SPM) QS derived if log $Kp_{sediment\text{-}water} \geq 3$	• Added risk approach (QS = $C_{background}$ + MPA) • SSD method to derive the MPA for data rich metals • TGD assessment factor method (marine sediment AFs) to derive MPA if application of SSD method not possible • Equilibrium partitioning approach if no or only insufficient data for sediment organisms available	4.4.1 4.4.2 4.4.5 4.4.6
secondary poisoning of top predators	OC, PPP, ME	water (freshwater & saltwater) (for hydrophobic substances in addition: corresponding concentration in SPM) QS only derived if triggers are exceeded (see table 1a)	• Based on the lowest relevant threshold level (e.g. NO(A)EL divided by appropriate AF) and the standard figures given in the TGD for food consumption, concentrations in fish (and/or mussels) are calculated that prevent adverse effects by seafood ingestion. Based on these "safe" levels calculated for fish or mussels, water concentrations are derived using the BCF (preferred) or the octanol water partition coefficient (the latter not for metals) of the substance concerned. The resulting water concentrations are the quality standards for secondary poisoning.	4.2.3.1 (OC) 4.3 (PPP) 4.4.7 (ME)
human health (drinking water consumption)	OC, PPP, ME	freshwater derivation of QS only if no standard is fixed in CD 75/440/EEC	Derivation of DW abstraction QS only if the following cases apply: 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 DWS QS = appropriate DWS / Fract. not removable	4.2.4
human health (food consumption)	OC, PPP, ME	water (freshwater & saltwater) (for hydrophobic substances in addition: corresponding concentration in SPM) Derivation of QS only if triggers are exceeded (see table 1b)	• Based on the lowest relevant threshold level for human health (e.g. NO(A)EL divided by appropriate AF, ADI/TDI or unit risk value) and the standard figures given in the TGD for consumption of fishery products and body weights of humans, concentrations in fish (and/or mussels) are calculated that prevent adverse effects by ingestion of fishery products. Based on these "safe" levels calculated for fish or mussels, water concentrations are derived using the BCF (preferred) or the octanol water partition coefficient (the latter not for metals) of the substance concerned. The resulting water concentrations are the quality standards for human health effects due to food uptake.	4.2.8.3.2 (OC) 4.3 (PPP) 4.4.7 (ME)

4.2 Derivation of Quality Standards for Organic Chemicals (other than Plant Protection Products)

4.2.1 Quality Standards Referring to Substance Levels in the Water Phase

For hydrophobic organic substances (exceeding the partition coefficient triggers given in table 1) the quality standards referring to water are laid down as concentration in the unfiltered water sample (i.e. water plus SPM) and in addition as corresponding concentration in suspended particulate matter (SPM) of the EU standard water as defined in the TGD [3] (15 mg/l SPM dry weight). This approach offers the Member States the option to do compliance monitoring in the matrix (unfiltered water sample or SPM) that is deemed the most suitable (e.g. for analytical reasons).

The algorithms to calculate the concentration in SPM from the total concentration in water and vice versa are as follows:

$$QS_{SPM.wat}\ [\mu g/kg] = \frac{QS_{wat.tot}\ [\mu g/l]}{C_{SPM}\ [mg/l] * 10^{-6}\ [kg/mg] + Kp^{-1}\ [l/kg]}$$

$$QS_{wat.tot}\ [\mu g/l] = QS_{SPM.wat}\ [\mu g/kg] * (C_{SPM}\ [mg/l] * 10^{-6}\ [kg/mg] + Kp^{-1}\ [l/kg])$$

with:

$QS_{SPM.wat}$	Quality standard for water referring to the substance concentration in SPM
$QS_{wat.tot}$	Quality standard for water referring to the total (unfiltered) water sample
C_{SPM}	Concentration of SPM in the water sample (standard water: 15 mg dry weight / l)
Kp	Substance specific partition coefficient SPM – water

In case compliance checking is based on quality standards referring to SPM, the SPM concentration in the water samples should be monitored in addition. The SPM concentration is required to allow for a correction of the $QS_{SPM.wat}$ with the real C_{SPM}.

4.2.1.1 Freshwater

The procedures for aquatic effects assessment and the calculation of the PNEC ($\approx QS_{freshwater}$) by the Assessment Factor method as laid down in section 3.3 of Part II of the TGD [3] are used as standard approach (required also by Annex V WFD), i.e. assessment factors are used to derive the $QS_{freshwater}$ depending on the quality and the quantity of the data available (see table 3).

The assessment factor approach is generally considered as indispensable for substances for which no extensive toxicity data base is available and it is broadly accepted as an in scientifically terms acceptable method to deal with uncertainties arising from limited data availability and knowledge in extrapolating "safe" environmental levels of substances.

However, in cases in which conditions are met to use a statistical extrapolation method for the derivation of quality standards, this approach shall also be applied in accordance with the

provisions layed down in section 3.3.1.2 of Part II of the TGD [3] (see also section 4.4.2 of this document for details).

Table 3: Assessment factors to derive a Quality Standard for freshwater (adaptation from table 16 of [3])

Data set	**Assessment factor**
At least one short-term $L(E)C_{50}$ from each of three trophic levels of the base set (fish, Daphnia, algae)	1000(a)
One long-term NOEC (either fish or Daphnia)	100(b)
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50(c)
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10(d)
Species sensitivity distribution (SSD) method	5-1 to be fully justified case by case(e)
Field data or model ecosystems	Reviewed on a case by case basis(f)

Notes:

(a) The assessment factor 1000 is a conservative and protective factor. For a given substance there may be evidence that the factor 1000 is to high or to low. In these circumstances it may be necessary to vary this factor, leading to a raised or lowered assessment factor depending on the available evidence. However, variation from a factor of 1000 should not be regarded as normal and should be fully supported by accompanying evidence. Except for substances with intermittent releases under no circumstances should a factor lower than 100 be used in deriving a PNEC from short-term toxicity data.

(b) AF 100 applies to a single long-term NOEC (fish or daphnia) if this NOEC was generated for the trophic level showing the lowest short-term L(E)C50. If the available NOEC is from a species which does not have the lowest L(E)C50, it cannot be regarded as protective of the other more sensitive species. Therefore the effects assessment is based on the short-term data with an AF of 1000. However, the resulting PNEC based on short-term data may not be higher than the PNEC based on the available NOEC.

AF 100 applies also to the lowest of 2 NOECs covering different trophic levels when such NOECs have not been generated from that showing the lowest L(E)C50. This should however not apply in cases where the acutely most sensitive species has an $L(E)C_{50}$ value lower than the lowest NOEC value. In such cases the PNEC might be derived by using an assessment factor of 100 to the lowest $L(E)C_{50}$ of the short-term tests.

(c) AF 50 applies to the lowest of 2 NOECs covering different trophic levels when such NOECs have been generated covering that level showing the lowest L(E)C50.

AF 50 applies also to the lowest of 3 NOECs covering different trophic levels when such NOECs have not been generated from that level showing the lowest L(E)C50. This should however not apply in cases where the acutely most sensitive species has an $L(E)C_{50}$ value lower than the lowest NOEC value. In such cases the PNEC might be derived by using an assessment factor of 100 to the lowest $L(E)C_{50}$ of the short-term tests.

(d) AF 10 will normally only be applied when long-term toxicity NOECs are available from at least 3 species across 3 trophic levels. A factor of 10 cannot be decreased on the basis of laboratory studies.

It may sometimes be possible to determine with high probability that the most sensitive species has been examined, i.e. that a further long-term NOEC from a different taxonomic group would not be lower than the data already available (particularly important if the substance does not have a potential to bioaccumulate). In those circumstances, a factor of 10 applied to the lowest NOEC from only two species would also be appropriate. If it is not possible to make this judgement, then an AF of 50 should be applied.

(e) Basic considerations and minimum requirements as outlined in section 3.3.1.2 (of [38],.see also section 5.3.1.2 of this report)

(f) The AF to be used on mesocosm studies or (semi) field data will need to be reviewed on a case by case basis.

4.2.1.2 Transitional, Coastal and Territorial Waters

Transitional waters have normally more characteristics in common with freshwater bodies than with marine waters. For the purpose of quality standard setting, they may therefore be considered as freshwater, i.e. the freshwater QS may apply for transitional waters as well.

The procedures for the marine effects assessment as described in section 4.3 of Part II of the TGD [3] are used as standard approach for coastal and territorial waters, i.e. the assessment factor method together with specific assessment factors for marine effects assessment (see table 4) is applied to derive the $QS_{saltwater}$ and statistical extrapolation methods for the calculation of the PNEC for marine organisms are used as well if sufficient data are available (in analogy to the QS setting for freshwater and in accordance with the provisions of the TGD).

In order to derive quality standards for coastal and territorial waters combined toxicity data sets of marine and freshwater species are normally used as toxicity data reviewed and current marine risk assessment practice suggest a reasonable correlation between ecotoxicological responses of freshwater and saltwater biota [3] (i.e. the same data sets can be used interchangeably for freshwater and saltwater effects assessment and QS setting). Where this appears not justified based on the available evidence, QS for freshwater and marine water must be derived on the basis of distinct data sets for freshwater and marine organisms.

As for the derivation of quality standards referring to marine water the assessment factors for marine risk assessment of the TGD [3] are to be used, the resulting quality standard might be more stringent than the standard derived for the freshwater environment. However, the application of more stringent assessment factors for the marine environment is justified by the requirement to account for additional uncertainty due to peculiarities of the marine ecosystem such as, e.g., greater species diversity or limited data availability for marine species and use of freshwater toxicity data as surrogate. The greater species diversity in the marine environment, including the presence of a number of taxa that occur only in that environment, may mean that the distribution of sensitivities of species is broader. Thus, where only data for freshwater or saltwater algae, crustaceans and fish is available a higher assessment factor than that used for the derivation of the $PNEC_{freshwater}$ should be applied, to reflect the greater uncertainty in the extrapolation. Where data is available for additional taxonomic groups, for example rotifers, echinoderms or molluscs the uncertainties in the extrapolation are reduced and the magnitude of the assessment factor applied to a data set can be lowered [3] (see table 4).

Thus, an additional assessment factor is not automatically applied in the marine effects assessment but only if the data do not appropriately represent the community that dwells in the marine ecosystem. If marine life forms are sufficiently represented in the data set available, the assessment factors to be applied are not different from those used in the freshwater effects assessment.

Table 4: Assessment factors to derive $PNEC_{water}$ for saltwater [3]

Data set	Assessment factor
Lowest short-term $L(E)C_{50}$ from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels	10000(a)
Lowest short-term $L(E)C_{50}$ from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels, + 2 additional marine taxonomic groups (e.g. echinoderms, molluscs)	1000
One long-term NOEC (from freshwater or saltwater crustacean reproduction or fish growth studies)	1000(b)
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish)	500(c)
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels	100(d)
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) + 1 long-term NOEC from an additional marine taxonomic group (e.g., echinoderms, molluscs)	50
Lowest long-term NOECs from three freshwater or saltwater species (normally algae land/or crustaceans and/or fish) representing three trophic levels + 2 long-term NOECs from additional marine taxonomic groups (e.g., echinoderms, molluscs)	10

NOTES

General: Evidence for varying the assessment factor should in general include a consideration of the availability of data from a wider selection of species covering additional feeding strategies/ life forms/ taxonomic groups other than those represented by the algal, crustacean and fish species (such as echinoderms or molluscs). This is especially the case, where data are available for additional taxonomic groups representative of marine species. When substantiated evidence exists that the substances may be disrupting the endocrine system of species, it should be considered whether the assessment factor would also be sufficient to protect against effects caused by such a mode of action.

(a) The use of a factor of 10000 on short-term toxicity data is a conservative and protective factor and is designed to ensure that substances with the potential to cause adverse effects are identified in the effects assessment. It assumes that each of the identified uncertainties described above makes a significant contribution to the overall uncertainty.

For any given substance there may be evidence that this is not so, or that one particular component of the uncertainty is more important than any other. In these circumstances it may be necessary to vary this factor. This variation may lead to a raised or lowered assessment factor depending on the evidence available. Except for substances with intermittent release, under no circumstances should a factor lower than 1000 be used in deriving a $PNEC_{water}$ for saltwaters from short-term toxicity data.

Evidence for varying the assessment factor could include one or more of the following:

- Evidence from structurally similar compounds which may demonstrate that a higher or lower factor may be appropriate;
- Knowledge of the mode of action as some substances by virtue of their structure, may be known to act in a non-specific manner. A lower factor may therefore be considered. Equally a known specific mode of action may lead to a raised factor.
- The availability of data from a variety of species covering the taxonomic groups of the base set species across at least three trophic levels. In such a case the assessment factors may only be lowered if multiple data points are available for the most sensitive taxonomic group (i.e. the group showing acute toxicity more than 10 times lower than for the other groups).

There are cases where there will not be a complete short-term data set even for freshwater algae, crustacean and fish species, for example for substances which are produced at < 1 t/a (notifications according to Annex VII B of Directive 92/32/EEC). In these situations, the only data may be short-term $L(E)C_{50}$ data for *Daphnia*. In these exceptional cases, the PNEC should be calculated with a factor of 10000.

(continued overleaf)

Table 5.5: (continued) Assessment factors proposed for use to derive $PNEC_{water}$ for the marine environment

(b) An assessment factor of 1000 applies where data from a wider selection of species are available covering additional taxonomic groups (such as echinoderms or molluscs) other than those represented by algal, crustacean and fish species; if at least data are available for two additional taxonomic groups representative of marine species

An assessment factor of 1000 applies to a single long-term NOEC (freshwater or saltwater crustacean or fish) if this NOEC was generated for the taxonomic group showing the lowest $L(E)C_{50}$ in the short-term algae, crustacean or fish tests.

If the only available long-term NOEC is from a species which does not have the lowest $L(E)C_{50}$ in the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus, the effects assessment is based on the short-term data with an assessment factor of 10000. However, normally the lowest PNEC should prevail.

An assessment factor of 1000 applies also to the lowest of the two long-term NOECs covering two trophic levels (freshwater or saltwater algae and/or crustacean and/or fish) when such NOECs have not been generated from that showing the lowest $L(E)C_{50}$ of the short-term tests. This should not apply in cases where the acutely most sensitive species has an $L(E)C_{50}$-value lower than the lowest NOEC value. In such cases the PNEC might be derived by applying an assessment factor of 1000 to the lowest $L(E)C_{50}$ of the short-term tests.

(c) An assessment factor of 500 applies to the lowest of two NOECs covering two trophic levels (freshwater or saltwater algae and/or crustacean and/or fish) when such NOECs have been generated covering those trophic levels showing the lowest $L(E)C_{50}$ in the short-term tests with these species. Consideration can be given to lowering this factor in the following circumstances.

It may sometimes be possible to determine with a high probability that the most sensitive species covering fish, crustacea and algae has been examined, that is that a further longer-term NOEC from third taxonomic group would not be lower than the data already available. In such circumstances an assessment factor of 100 would be justified,

A reduced assessment factor (to 100 if only one short-term test, to 50 if two short-term tests on marine species are available) applied to the lowest NOEC from only two species may be appropriate where:

- short-term tests for additional species representing marine taxonomic groups (for example echinoderms or molluscs) have been carried out and indicate that these are not the most sensitive group, and;
- it has been determined with a high probability that long-term NOECs generated for these marine groups would not be lower than that already obtained. This is particularly important if the substance does not have the potential to bioaccumulate.

An assessment factor of 500 also applies to the lowest of three NOECs covering three trophic levels, when such NOECs have not been generated from the taxonomic group showing the lowest $L(E)C_{50}$ in short-term tests. This should, however, not apply in the case where the acutely most sensitive species has an L(E)C50 value lower than the lowest NOEC value. In such cases the PNEC might be derived by applying an assessment factor of 1000 to the lowest $L(E)C_{50}$ in the short-term tests.

(d) An assessment factor of 100 will be applied when longer-term toxicity NOECs are available from three freshwater or saltwater species (algae, crustaceans and fish) across three trophic levels.

The assessment factor may be reduced to a minimum of 10 in the following situations:

- where short-term tests for additional taxonomic groups representing marine species (for example echinoderms or molluscs) have been carried out and indicate that these are not the most sensitive group, and it has been determined with a high probability that long-term NOECs generated for these species would not be lower than that already obtained.
- where short-term tests for additional taxonomic groups (for example echinoderms or molluscs) have indicated that one of these is the most sensitive group and a longer-term NOEC test has been carried out for that species. This will only apply when it has been determined with a high probability that additional NOECs generated from other taxa will not be lower than the NOECs already available.

A factor of 10 cannot be decreased on the basis of laboratory studies only.

4.2.1.3 Application of Statistical Extrapolation Methods to Derive Quality Standards

According to the TGD [3] the effects assessment performed with the assessment factor method can be supported by a statistical extrapolation method if the data basis is sufficient for its application.

Therefore, statistical extrapolation methods in line with the provisions of the TGD are used for QS derivation in case the data base of the substance concerned is sufficient. To this end the same approach can be used as described in section 4.4.2. Supplementary the standard TGD assessment factor method is applied. The decision which of the two quality standards either derived by application of the extrapolation method or by the assessment factor method may be finally adopted as QS should be based on expert judgement.

4.2.2 Quality Standards Referring to Substance Levels in Sediment

4.2.2.1 Freshwater Sediment

If results of long-term toxicity tests with sediment organisms are available, the quality standard is calculated as laid down for the $PNEC_{sediment}$ in section 3.5.4 of Part II of the TGD [3], using the assessment factors given in table 5.

Table 5: Assessment factors to derive a $QS_{sediment}$ (table 19 of [3])

Available test result	**Assessment factor**
One long term test (NOEC or EC10)	100
Two long term tests (NOEC or EC10) with species representing different living and feeding conditions	50
Three long term tests (NOEC or EC10) with species representing different living and feeding conditions	10

However, as toxicity data for benthic organisms are normally lacking for many substances, in such cases the $QS_{sediment}$ is calculated using the equilibrium partitioning method as described in section 3.5.3 of the TGD [3]:

$$\mathbf{QS_{sed.wet\_weight}}\ [mg.kg^{-1}] = \frac{Kp_{SPM\text{-}water}\ [m^3.m^{-3}]}{bulk\ density_{SPM.wet}\ [kg.m^{-3}]} * QS_{water}\ [mg.l^{-1}] * 1000$$

with:

$Kp_{SPM\text{-}water}$	partition coefficient suspended particulate matter – water
$bulk\ density_{SPM.wet}$	1150 $kg.m^{-3}$

As the formula only considers uptake via the water phase, a correction is made for substances with log Kow >5 as significant uptake by food ingestion may take place. To this end, the $QS_{sediment}$ is divided by a factor of 10.

In case there is only a marginal short-term effects data base for benthic organisms available the QS should be derived on the basis of both the short-term effects data (applying an assessment factor of 1000 to the lowest) and the equilibrium partitioning approach. The final QS is set based on expert judgement, taking all available information into account.

4.2.2.2 Marine Sediment in Transitional, Coastal and Territorial Waters

Transitional waters have normally more characteristics in common with freshwater bodies than with marine waters. For the purpose of quality standard setting, they may therefore be considered as freshwater, i.e. the freshwater QS may apply for transitional waters as well.

With respect to the quality standards setting for sediments in coastal and territorial waters the strategy recommended in section 4 of the TGD [3] for effects assessment with marine benthic organisms is followed. This is basically the same approach as outlined in section 4.2.2.1 of this report for freshwater sediment. However, more stringent assessment factors may apply depending on the quality and quantity of toxicity data available; see table 6.

Table 6: Assessment factors for derivation of the $PNEC_{marine\ sediment}$ based on the lowest available $NOEC/EC_{10}$ from long-term tests [38]

Available test results	**Assessment factor** [a)]
One acute freshwater or marine test (LEC_{50})	10000 [*)]
Two acute test including a minimum of one marine test with an organism of a sensitive taxa (lowest LEC_{50})	1000 [*)]
One long term freshwater sediment test	1000
Two long term freshwater sediment tests with species representing different living and feeding conditions	500
One long term freshwater and one saltwater sediment test representing different living and feeding conditions	100
Three long term sediment tests with species representing different living and feeding conditions	50
Three long term tests with species representing different living and feeding conditions including a minimum of two tests with marine species	10

[a)] The general principles of notes (c) and (d) as applied to data on aquatic organisms (table 4) shall also apply to sediment data. Additionally, where there is convincing evidence that the sensitivity of marine organisms is adequately covered by that available from freshwater species, the assessment factors used for freshwater sediment data may be applied. Such evidence may include data from long-term testing of freshwater and marine aquatic organisms, and must include data on specific marine taxa.

[*)] If a $QS_{sediment}$ is calculated with short-term toxicity data an alternative QS must be calculated using the equilibrium partitioning approach (see section 4.2.2.1 of this report). The final QS is set based on expert judgement, taking all available information into account.

4.2.3 Quality Standards referring to Substance Levels in Biota

Quality standards referring to substance levels in biota need to be derived in order to prevent secondary poisoning of top predators as well as adverse effects on human health through ingestion of contaminated food.

The respective quality standards for substance levels in biota are calculated if the triggers given in table 1a or 1b concerning secondary poisoning or human health effects are met.

4.2.3.1 Calculation of Quality Standards referring to Secondary Poisoning of Predators

The standard figures and procedures as laid down in section 3.8.3 and 4.3.3 of the TGD [3] are used.

Only toxicity studies reporting on dietary and oral exposure are relevant as the pathway for secondary poisoning is referring exclusively to the uptake through the food chain. As secondary poisoning effects on bird and mammal populations rarely become manifest in

short-term studies, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth. As toxicity data for wildlife birds and mammals are normally not available, it will - in most instances - be necessary to extrapolate threshold levels for wildlife species from toxicity data of laboratory test species assuming that interspecies correlations exist.

The results of the relevant mammalian or avian tests may be expressed as concentration in food ($mg.kg_{food}^{-1}$) or as dose (mg.kg body weight.day^{-1}) causing no effect. For the assessment of secondary poisoning, the results always have to be expressed as the concentration in food. In case toxicity data are given as NOAEL only, these NOAELs can be converted to NOECs as laid down in section 3.8.3.5 of [3].

$$NOEC_{oral} = NOAEL_{oral} * CONV$$

with:
CONV: conversion factor from NOAEL to NOEC (table 7)

Table 7: Conversion factors from NOAEL to NOEC for several species [3]

Species	Conversion factor (BW/DFI*)
Canis domesticus	40
Macaca sp.	20
Microtus spp.	8.3
Mus musculus	8.3
Oryctolagus cuniculus	33.3
Rattus norvegicus (> 6 weeks)	20
Rattus norvegicus (≤ 6 weeks)	10
Gallus domesticus	8

* BW = body weight (g); DFI: daily food intake (g/day)

The quality standard referring to the concentration in food of the predator ($QS_{secpois.biota} \approx PNEC_{oral}$) is then derived from the $NOEC_{oral}$ applying an assessment factor (table 7).

$$\mathbf{QS_{secpois.biota}} = NOEC_{oral} / AF_{oral}$$

Table 7: Assessment factors for extrapolation of mammalian and bird toxicity data [3]

$\mathbf{TOX_{oral}}$	Duration of test	$\mathbf{AF_{oral}}$
$LC_{50\ bird}$	5 days	3000
$NOEC_{bird}$	chronic	30
$NOEC_{mammal,\ food,chr}$	28 days 90 days chronic	300 90 30

If several $NOEC_{oral}$ for bird or mammal species are available, the lowest of the resulting $QS_{secpois.biota}$ is used as quality standard.

As 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 ($\approx QS_{secpois.water}$), using the safe level in prey ($QS_{secpois.biota}$) and bioaccumulation data

(bioconcentration factor (BCF) and biomagnification factor (BMF)) of the substance concerned[5]. The calculation is done with a transformation of the formulae used in the TGD to calculate the PEC_{oral} (sections 3.8.3.4 and 4.3.3.2 of the TGD). Accounting for the longer food chains in the marine environment, not only biomagnification in the prey of predators (BMF1, as for freshwater) but also in the prey of top predators (BMF2) is considered.

Freshwater

$$\mathbf{QS_{secpois.water}}\ [\mu g/l] = \frac{QS_{secpois.biota}\ [\mu g/kg]}{BCF\ [l/kg] * BMF_1}$$

Marine water

$$\mathbf{QS_{secpois.water}}\ [\mu g/l] = \frac{QS_{secpois.biota}\ [\mu g/kg]}{BCF\ [l/kg] * BMF_1 * BMF_2}$$

The BMFs used should ideally be based on measured data. However, the availability of such data is at present very limited and therefore, in accordance with the TGD, the default values as listed in table 8 are used.

Table 8: Default BMF-values for organic substances [3]

log K_{ow} of substance	**BCF (fish)**	**BMF_1**	**BMF_2**
< 4.5	< 2000	1	1
4.5 - < 5	2000-5000	2	2
5 – 8	> 5000	10	10
> 8 - 9	2000 – 5000	3	3
> 9	< 2000	1	1

4.2.3.2 Calculation of Quality Standards referring to the Uptake of Fishery Products by Humans

With regard to the uptake of fishery products by humans no standard approach or convention exists. The use of a consumer intake model considering all uptake routes was deemed too complex and, moreover, often not possible as not all exposure routes and the contamination levels of the relevant food commodities might be known. Therefore, a rather simple but practicable approach for deriving a respective quality standard is used.

By convention, the uptake of a substance with fishery products shall not exceed more than 10% of the relevant threshold level for humans (e.g. the ADI / TDI / $NO(A)EL_{oral}$).

The quality standard referring to the substance concentration in fishery products ($QS_{hh.food}$) is calculated as follows, using the standard figures of the TGD for human body weight (bw; 70 kg) and consumption of fishery products (115 g/day):

[5] For hydrophobic organic substances (exceeding the triggers given in table 8.1) the biota quality standards may also be given as concentration in suspended particulate matter of the EU standard water; transformation see section 4.2.1.

$$\mathbf{QS_{hh.food}} = \frac{0.1 * \text{threshold level [µg/kg bw]} * 70 \text{ kg (human bw)}}{0.115 \text{ kg seafood consumption}} = \text{µg/kg fishery product}$$

This $QS_{hh.food}$ is transformed to the corresponding concentration in water, applying the same approach as described for the transformation of the $QS_{secpois.biota}$ in section 4.2.3.1 of this report.

$$\mathbf{QS_{hh.food.water}} \text{ [µg/l]} = \frac{QS_{hh.food} \text{ [µg/kg]}}{BCF \text{ [l/kg]} * BMF_1}$$

4.2.4 Quality Standards Referring to Levels in Water Intended for the Abstraction of Drinking Water

In accordance with Articles 7(2,3) and 16(1) of the WFD it is required to protect the possibility of drinking water abstraction from surface waters. The procedure described in the following was devised to permit the derivation of a quality standard addressing this protection objective:

1. In case a "A1 value" referring to simple surface water treatment (e.g. rapid filtration and disinfection) is fixed in the "drinking water abstraction" Directive 75/440/EEC [6] and this "A1 value" is lower than the quality standard required to safeguard the other objectives of protection (freshwater community, sediment quality, and quality of biota in order to protect humans or top predators from secondary poisoning by food ingestion), the "A1 value" is adopted as quality standard for surface freshwater.

   If no "A1 value" has been set in CD 75/440/EEC but a drinking water standard is available according to Council Directive 98/83/EC [8] (concerning the quality of water intended for human consumption) and this drinking water standard is lower than the quality standard required to safeguard the other objectives of protection, the subsequent procedure is followed:

2. An assessment is performed with the objective to derive a quality standard ensuring the possibility of drinking water abstraction by simple treatment (category A1 in CD 75/440/EEC). In this context, the substance specific removal efficiencies of the simple surface water treatment methods in use must be considered. As there is no sufficiently accurate method for the prediction of removal efficiencies for surface water treatment available [3], experts in drinking water processing technology should be involved in the assessment. The final quality standard for drinking water abstraction from surface water should be no higher than the drinking water standard according to CD 98/83/EC divided by the fraction <u>not</u> removable by simple treatment.

3. For those substances on the working list for which "A1 values" or quality standards have not been fixed in the context of Council Directives 75/440/EEC or 98/83/EC, provisional drinking water quality standards are calculated by the TGD-procedure described further below in this section. If this provisional drinking water quality standard is lower than the quality standard required to safeguard the other objectives of protection, in principle the same assessment procedure as described under (2.) is applied:

An assessment is performed with the objective to derive a quality standard ensuring the possibility of drinking water abstraction by simple treatment. Experts in drinking water processing technology should be involved for the reasons given under (2.). In addition, the participation of experts in human toxicology might also be required in order to assess the appropriateness of the provisional standards calculated by the rather simple TGD-procedure, not taking account of possible substance specific toxicological peculiarities. The final quality standard for drinking water abstraction from surface water should be no higher than the concentration in drinking water considered as acceptable in terms of toxicological aspects divided by the fraction not removable by simple treatment.

Calculation of provisional drinking water quality standards according to the TGD

Based on the recommendations given in Part I of the TGD [3] (section 2.4.3 and Appendix III) the quality standards for water intended for human consumption are calculated using assumptions as follows:

Water uptake 2l/d, body weight 70 kg. Threshold level for human health: either ADI/TDI, lowest relevant NOEL*100^{-1} or the 10^{-6} unit risk value for cancer risk. The provisional quality standard for drinking water is calculated with the consideration that uptake by drinking water should in any case not exceed 10% of the threshold level for human health.

$$QS_{DW} = \frac{0.1 * TL_{HH} * BW}{Uptake_{DW}}$$

with:

QS_{DW}	quality standard for drinking water (mg/l)
TL_{HH}	threshold level for human health (ADI/TDI etc. in mg/kg body weight per day)
BW	body weight (70 kg)
$Uptake_{DW}$	uptake drinking water (2 l per day)

4.3 Derivation of Quality Standards for Plant Protection Products

Whereas the quality standards for industrial chemicals (existing as well as new substances) are calculated in line with the provisions laid down for effects assessment in the TGD [3], the effects of plant protection products (PPP) are assessed according to the principles laid down in Council Directives 91/414/EEC [9] and 97/57/EC [10].

The most obvious difference in the aquatic risk assessment protocols for new and existing substances (ESRA) and plant protection products (PPPRA), respectively, is the fact that for new and existing substances a single PNEC is derived which is set in relation with the corresponding PEC, whereas for plant protection products several toxicity exposure ratios (TER) must be established which are compared with corresponding predetermined TER trigger values. The calculated TER values normally must not be lower than the triggers in order to permit the authorisation of the PPP. Thus, the application of safety factors accounting for uncertainties is different although the factors itself are in most instances comparable in size.

Therefore, despite the apparent formal differences, both approaches are in principle equivalent and should - in most instances - for the same data set give the same result with regard to the acceptability of risk, because the TER ratio (toxicity / PEC) is merely the inverse expression of the PEC/PNEC ratio. Also, the strategy followed to refine the results of the risk assessments for the aquatic environment is very similar. In case the risk of a substance appears to be unacceptable in the initial stage of the risk assessment a "refined"

(ESRA) or "higher tier" (PPPRA) risk assessment may be conducted utilising more sophisticated means for exposure and effects assessment such as, e.g., microcosm or mesocosm studies. (see table 5.10 and sections 5.2 and 5.5 of [2] for an overview and comparison of the basic principles and steps in PPPRA and ESRA).

However, with regard to the consideration of toxicity to algae, a difference exists in both risk assessment frameworks that might lead to different results in case algae are the most sensitive organisms. In the PPPRA, only acute toxicity to algae (EC50) is considered whereas in the ESRA also the no-effect level (NOEC, EC10) is taken into account, if respective data are available. Moreover, the safety factors to account for alga toxicity are different in both RA frameworks. In the ESRA, assessment factors of 10 for NOEC/EC10 values and 100 for EC50 data are normally used whereas the respective PPPRA TER ratio for the $EC50_{algae}$ must not fall below 10 (equivalent to AF 10 in ESRA).

Another difference in the notification process is that for plant protection products beneficial effects of the (intentional) use of a PPP are taken into account and, therefore, the risk characterisation in the PPPRA is focused on the acceptability of effects occurring after exposure. To this end, specific consideration is given to the recovery potential of small water courses (e.g. ditches) in the immediate vicinity of the treated area after transient exposure to a PPP [6]. This might be the reason why effects on algae are not considered exactly the same way as any other effects on invertebrates or fish (many alga species have a high recovery potential and recover fast once the toxicant concentration falls below the effect level). Thus, the philosophy and objective of the PPPRA differ to some extent from that followed by the ESRA.

As the aquatic effects assessment according to Directives 91/414/EEC and 97/57/EC is – in principle - equivalent to the aquatic effects assessment as laid down in the TGD, the quality standards for plant protection products are derived in accordance with the respective directives, as far as possible.

Therefore, in case only “lower tier” toxicity data are available (i.e. the required minimum set of short-term and long-term single species tests with algae, daphnia and fish) the lowest long-term NOEC is divided by the long term TER-trigger (10; TER ≈ Toxicity Exposure Ratio) in order to derive a PNEC-equivalent and the QS_{water}.[7]

$$QS_{water,\ PPP} = NOEC_{min} / \text{TER-trigger}_{\text{long term}}$$

Statistical extrapolation methods (species sensitivity distributions) may be used if the data requirements are fulfilled. If higher tier data (e.g. multispecies mesocosm or microcosm studies) are identified as most relevant, the lowest relevant NOEC is used in the derivation of the QS_{water}, according to the principles described in [11, 12, 13, 14].

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[6] The “edge of a field” exposure pattern normally assessed in the PPPRA is different from the exposure situation in larger water bodies for that quality standards are to be set. Moreover, the QS by definition refers to an annual average concentration. Therefore, in contrast to the transient exposure at the edge of a field in the PPPRA, for the purpose of quality standard setting the recovery potential of aquatic ecosystems after transient exposure cannot be taken into account. Differences in the approaches and objectives of the aquatic risk assessment for plant protection products and the concept of the water quality standards in the context of the water framework directive as well as resulting consequences for the interpretation of toxicity data are explained and discussed in [11].

[7] As the long term quality standards refer to "annual average" concentrations it is required to give the algae / aquatic plant toxicity data another weight for the purpose of quality standard setting. Hence, if algae / plants are the most sensitive species, the lowest valid NOEC instead of the EC50 and an assessment factor of 10 (equivalent to the long term TER trigger for aquatic invertebrates or fish) is used to derive the QS_{water}.

Other aspects of aquatic effects assessment such as bioaccumulation and secondary poisoning are addressed in both risk assessment frameworks and the outcome of these assessments can be considered as equivalent. The quality standards addressing the protection of predators from secondary poisoning and humans form adverse health effects due to ingestion of fishery products and drinking water are, in principle, derived as laid down in section 4.2 for “ordinary” organic chemicals.

According to the TGD, freshwater effects data of plant protection products shall normally not be used *in lieu* of saltwater data, because within trophic levels differences larger than a factor of 10 were shown for several PPP. This means that the derivation of quality standards addressing the protection of water and sediment in coastal and territorial waters is not possible if there are no effects data for marine organisms available or if it is not possible to determine with high probability that marine organisms might not be more sensitive than freshwater biota (for some PPP such a prediction may however be possible in view of its specific mode of action).

4.4 Derivation of Quality Standards for Metals

For metals, it could be required to differentiate between freshwater and marine water in quality standard setting. Reasons are of both biological (ecological and physiological) and geochemical (metal phase distribution and speciation) nature. For several metals differences in sensitivity larger than a factor of 10 were found between saltwater and freshwater species of the same taxonomic groups [3]. Therefore, toxicity data sets (as well as BCF data) of marine and freshwater organisms may only be combined if no differences in sensitivities of freshwater and saltwater organisms of the same taxonomic groups exist. Otherwise, it is necessary to set specific quality standards referring to freshwater and marine water bodies, respectively.

4.4.1 Use of the "Added Risk" Approach

Since metals are naturally occurring substances it is proposed to adopt the "added risk" approach as used in the Netherlands [15, 16] for the derivation of EU quality standards for metals. This approach facilitates to account for natural background concentrations in an appealingly simple manner: A maximum permissible addition (MPA) to the background level of a certain metal is calculated. The MPA is the amount of metal that maximally may be added to the background concentration of this metal without adversely affecting the assessed ecosystem.

$$QS_{add} = C_{backg} + MPA$$

Two assumptions are the basis of this approach:

1. It is not relevant to which extent the background concentration of a metal has an impact on ecosystem structure and function since any potential adverse or positive effect of the background concentration can be considered as effect contributing to the natural biodiversity of ecosystems.
2. As species in an ecosystem are adapted to the prevailing background level, it is assumed that the same amount of a metal added by human activities causes in principle the same effect, provided all environmental parameters determining metal toxicity are equal except

the background level of the metal concerned (i.e. not the "absolute" level of a metal is decisive for the occurrence/extent of adverse effects but only the added amount).

The background concentration and the MPA are independently derived values. A concept for the estimation of background levels and the definition of the appropriate level of spatial resolution (e.g. river basin scale) is currently elaborated by the AMPS[8] working group.

With regard to effects assessment, the added risk approach implies that the MPA is derived from toxicity data that are based on the added metal concentration in toxicity tests (i.e. the added metal concentration is considered 100% bioavailable). Thus, the maximum permissible addition and hence the quality standard derived by the added risk approach refer to the "bioavailable" fraction in "real world" samples.

The use of the added risk approach implies further that there is no risk for deficiency of essential metals at the level of the calculated quality standard, as the QS derived in this approach is defined as the maximum permissible addition to the background concentration. By definition, the background concentration in a given ecosystem provides the organisms in that ecosystem with the required essential metals.

4.4.2 Use of Statistical Extrapolation Technique and TGD Assessment Factor Method for Quality Standard Derivation

For metals with large databases (including many long term toxicity data of a range of aquatic species) it is proposed to use a statistical extrapolation method as standard method for the calculation of the maximum permissible addition. The method of Aldenberg and Jaworska (2000) [17] seems most suitable for this purpose as it is possible with this method to calculate a confidence interval (normally the 90% interval) for the 5-percentile cut-off value of the species sensitivity distribution (SSD). The input data used to estimate the SSD should be NOEC data selected according to the criteria recommended in the TGD [3] (cf. section 4.4.2.1).

The 5-percentile cut-off value according to Aldenberg and Jaworska is calculated as follows:

$$\log 5P\text{-}COV = X_m - k * s$$

with:

5P-COV =	5^{th}-percentile cut-off value
X_m=	mean of log-transformed NOEC data
k =	extrapolation constant depending on protection level and sample size (according to Aldenberg and Jaworska [31], see Annex 2 of this report)
s =	standard deviation of log-transformed data

The extrapolation constant *k* is taken from Aldenberg and Jaworska [17]. Three values are given for *k*. The 5-percentile cut-off-value (5P-COV) is calculated with the median estimate for *k* whereas the confidence limits are calculated using the upper and lower estimates of *k*.

According to the recommendation in the TGD [3] the 5P-COV of the SSD is considered as an intermediate value in the determination of the MPA. The final MPA is calculated as 5-percentile cut-off value divided by an assessment factor reflecting further uncertainties identified.

MPA = P5-COV / AF (AF: max. 5 – min. 1; default: 5)

[8] AMPS = Analysis and Monitoring of Priority Substances

In determining the size of the additional assessment factor to be applied in order to derive a MPA based on the 5th percentile, the following points should be used as a guide [3]:

- The overall quality of the database and the end-points covered, e.g., if all the data are generated from ”true” chronic studies (e.g., covering all sensitive life stages);
- The diversity and representativeness of the taxonomic groups covered by the database, including also the variation represented relating to differences in the life forms, feeding strategies and trophic levels of the organisms;
- The mode of action of the chemical;
- Statistical uncertainties around the 5th percentile estimate, e.g., reflected in the goodness of fit or the size of confidence interval around the 5th percentile;
- Comparisons between field and mesocosm studies and the 5th percentile and meso-cosm/field studies to evaluate the laboratory to field extrapolation.

Besides the derivation of the MPA by statistical extrapolation of the SSD, the MPA should be derived using the standard TGD assessment factor approach for PNEC derivation (see sections 4.1.1 & 4.1.2) on the same database. If mesocosm studies are available, they should also be evaluated and a MPA derived following the TGD. A comparison of the two, possibly three points above should be carried out and a final MPA determined with full justification. In case the database is not sufficient to apply statistical extrapolation, it is suggested to follow the standard TGD approaches as recommended.

4.4.2.1 Quality and Quantity of Data required

Where possible and appropriate, a pre-selection of the data should be performed in relation to realistic environmental parameters for Europe. Input data may be all reliable NOECs from chronic/long-term studies, preferably on full life-cycle or multi-generation studies.

Confidence can be given to the MPA derivation based on statistical extrapolation if the database contains preferably more than 15, but at least 10 NOECs, for different species covering at least 8 taxonomic groups (see table 93). Deviations from these recommendations can be made, on a case-by-case basis, through consideration of sensitive endpoints, sensitive species, mode of toxic action and/or knowledge from structure-activity considerations.

It is important to include any available information on the mode of action of the chemical, in order to evaluate the need to include possible other (sensitive) taxonomic groups or exclude possible over-representation of certain taxonomic groups, realising that the mode of action may differ between short term effects and long term effects and between taxonomic groups.

Table 9: Species required to apply statistical extrapolation for freshwater [3] [9]

• Fish (species frequently tested include salmonids, minnows, bluegill sunfish channel catfish, etc.)
• A second family in the phylum Chordata (fish, amphibian, etc.)
• A crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish etc.)
• An insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.)
• A family in a phylum other than Arthropoda or Chordata (e.g. Rotifera, Annelida, Mollusca, etc.)

[9] For saltwater and sediment no specific species requirements (or better: taxonomic groups and foraging strategies) have been defined so far. However, it is evident from the concept of the SSD extrapolation methodology that different taxonomic groups and foraging strategies should be adequately represented in the input data set.

- A family in any order of insect or any phylum not already represented
- Algae
- Higher plants

4.4.2.2 Aggregation of Multiple Data for One Species

It is proposed to follow the recommendations given in the draft report of the "London Workshop", which also have been adopted in the TGD [3]:

1. The full database should be carefully evaluated to extract information (e.g., on sensitive species and/or end-points), which may be lost when ”averaging” the data to a single value (to be used for either the SSD or the ”standard” PNEC).
2. The data of the most sensitive end-point should be used as the representative for the species. In this context, demographic parameters and bio-markers can be used as end-points, if they are relevant in terms of population dynamics.
3. Multiple values for the same endpoint with the same species should be investigated on a case-by-case basis, looking for reasons for differences between the results.
4. For comparable data on the same end-point and species the geometric mean should be used as the input value for the calculation of the SSD. If this is not possible, e.g. because results which are considered valid are too variable, then consider grouping and combining the values, e.g. by pH ranges, and using reduced numbers of values. The full data set could also be used if necessary.
5. Where it is considered that the results are limited to certain conditions (e.g. not appropriate for low pH) then these limitations should be explained.

4.4.2.3 Testing Distributions for Goodness of Fit

Different distributions like e.g. log logistic, log normal or others may be used. The log-normal distribution is a pragmatic choice from the possible families of distributions because of the available description of its mathematical properties (methods exist that allow for most in depth analyses of various uncertainties). The Anderson–Darling goodness of fit test can be used in addition to the Kolmogorov-Smirnov-test, as a criterion for the choice of a parametric distribution for comprehensive data sets, because it gives more weight to the tails of the distribution. [3]

Further guidance is given in the TGD [3]:

- Whatever the fit to a distribution, results should be discussed with regards to the graphical representation of the species distribution and the different p values that were obtained with each test.
- Finally, any choice of a specific distribution function should be clearly explained.
- If the data do not fit any distribution, the left tail of the distribution (the lowest effect concentrations) should be analysed more carefully. If a subgroup of species can be identified as particularly sensitive and if the number of data on this subgroup is sufficient, the distribution can be fit to this subgroup.
- The SSD method should not be used in cases where the data do not fit a distribution.

4.4.3 Consideration of Water Quality Parameters in QS Setting for Metals

For metals, it is important to define the bioavailable concentration, since this is the fraction of the total concentration which is important for toxicity, both in the laboratory tests and in the "real" environment. Due to several physico-chemical processes, metals exist in different chemical forms which might differ in bioavailability. Thus, the bioavailability of metals in both laboratory tests and in the environment may be affected by several physico-chemical parameters [16] such as the pH, hardness of water and the content of dissolved organic matter (DOM).

Although metal bioavailability to different aquatic life forms as well as the modifying influence of water quality parameters are subject of extensive ongoing research programs, there is – for most metals - not yet enough scientific knowledge available to describe quantitatively the influence of water quality parameters on bioavailability and long term toxicity for the different aquatic life forms representing freshwater or marine communities [18] and, hence, to take these parameters into consideration in setting quality standards (for details refer to section 8.6.3 of [2]).

Therefore, for the time being, no account of the influence of the above mentioned physico-chemical parameters on metal bioavailability and, hence, long-term toxicity to different aquatic life forms is taken because of the uncertainties in the data and/or the possible methodological approaches. This applies for the metals, lead, mercury and nickel.

For cadmium the situation is different, as for this metal an (approximate) assessment of bioavailable concentrations might be possible. A regression function based on increasing chronic toxicity values of *Daphnia magna*, *Pimephales promelas* and *Salmo trutta* with increasing water hardness could be established recently and it is suggested in the ongoing cadmium risk assessment [19] to consider this water hardness correction of the $PNEC_{water}$ for risk characterisation at a local or regional scale.

The development of biotic ligand models (BLMs) for Cd, Ni, Pb and other metals (such as Cu and Zn) is in progress and industry expects that BLM models applicable for the prediction of long term effects will be available within 2 years for some of the mentioned metals. If in the future these models and comprehensive data for validation become available, their utility in the assessment of bioavailability and the calculation of appropriate local quality standards should be evaluated carefully.

4.4.4 Calculation of Quality Standards for Metals

Bioavailability of Metals in Toxicity Tests

Metals that are added to the test medium are considered as dissolved and 100% bioavailable under the conditions of laboratory tests (usually very low content of dissolved organic matter and suspended particulate matter, use of flow through test systems with a rapid turnover rate for test media, use of soluble metal salts etc.). Thus, the maximum permissible addition refers (MPA) to the "bioavailable" fraction in "real world" samples. This proposal is in line with the approach followed by the Netherlands [15] and in the draft risk assessments for Cd and Zn.

"Bioavailable" Metal Fraction in "Real World" Water Samples

As for most metals adequate methods / data are lacking to quantitatively determine the fraction of a metal that is bioavailable to the aquatic life forms (i.e. species from various phyla

differing in physiology and feeding types) representing the aquatic community, there may mainly two options be available to address bioavailability of "real world" samples:

1. Only the "dissolved" fraction is considered bioavailable. This is the approach followed in the ongoing risk assessment for Cd and Zn and in the Netherlands.

   ⇒ Total amount of a metal in a water sample is corrected for metal sorption to SPM.

   By convention, the metal fraction present in a water sample after filtration through a 0.45µm filter is considered as "bioavailable". However, it should be noted that not the entire amount in this "dissolved" fraction may be bioavailable as a certain amount of metal may be bound to colloids or be sequestered.

2. The "total" content of a metal in a water sample is considered as bioavailable. This approach is followed by Germany, Norway and Sweden.

   ⇒ Reasons to follow this approach are:
   - Sequestered or otherwise bound / sorbed metals may become bioavailable as physico-chemical water parameters change
   - Organisms like filter feeders may also take up metals from SPM during gastro-intestinal passage

Calculation of the Maximum Permissible Addition (MPA)

As, for the time being, it is not possible to decide whether one of the above described options for the consideration of metal bioavailability in “real world” water samples is generally superior in reflecting metal bioavailability under all possible environmental conditions and for all life forms, two MPAs are calculated, one referring to metal levels in water and one referring to the corresponding levels in suspended particulate matter, using reliable SPM – water partition coefficients.

- A MPA_{water} for water referring to the "bioavailable" (dissolved) metal [µg Metal / l] is calculated based on the underlying toxicity tests (i.e. PNEC derived by the species sensitivity distribution method or by the assessment factor method)
- A MPA_{SPM} for SPM [µg Metal / kg SPM] is calculated based on the MPA_{water} and the relevant $Kp_{water\text{-}SPM}$ ($MPA_{SPM} = MPA_{water} * Kp_{water\text{-}SPM}$)

Calculation of the final QS Referring to Metal Levels in Water Samples:

The background concentration is either added as concentration in water or as concentration in SPM in order to derive a QS_{water} or a QS_{SPM}.

- $QS_{water} = C_{background.water} + MPA_{water}$
- $QS_{SPM} = C_{background.SPM} + MPA_{SPM}$

4.4.5 Quality Standard Derivation for Sediment

The added risk approach as outlined for water in section 4.4.1 applies also to sediment.

If sufficient NOEC data for benthic organisms are available (≥ 10 NOEC data for different species representing different living and feeding conditions) the same statistical extrapolation methodology as described in section 4.4.2 for the MPA_{water} is used to derive the $MPA_{sediment}$.

If not enough data for benthic organisms are available to use the species sensitivity distribution method, the standard TGD approach as - in principle - described for organic substances in sediment (cf. section 4.2.2) is followed (i.e. the assessment factor approach is used to calculate a $MPA_{sediment}$ on the basis of toxicity data for benthic organisms and the equilibrium partitioning method is used for calculation of a $MPA_{sediment}$ on the basis of the MPA_{water}[10]). As for organic substances, a decision whether the $MPA_{sediment}$ derived on the basis of toxicity data of benthic organisms or calculated from the MPA_{water} will be based on expert judgement.

4.4.6 Specific Considerations with Respect to Transitional, Coastal and Territorial Marine Waters

Transitional waters have normally more characteristics in common with freshwater bodies than with marine waters. For the purpose of quality standard setting, they may therefore be considered as freshwater, i.e. the freshwater QS may apply for transitional waters as well.

According to the TGD, freshwater effects data of metals shall normally not be used *in lieu* of saltwater data, because within trophic levels differences larger than a factor of 10 were found for several metals. This means that the derivation of quality standards addressing the protection of water and sediment in coastal and territorial waters is not possible if there are no effects data for marine organisms available or if it is not possible to determine with high probability that marine organisms might not be more sensitive than freshwater biota.

For quality standards referring to coastal and territorial waters, in principle the same approach as described for freshwater and freshwater sediment applies (see sections 4.4.1 to 4.4.5). However, if the assessment factor method is used to derive the MPA for marine water or marine sediment, the specific assessment factors and procedures as set out in the respective sections 4.2.1.2 and 4.2.2.2 for organic chemicals are to be applied.

4.4.7 Metal Quality Standards Referring to Substance Levels in Biota

For metals, in principle the same TGD-based approach should be followed as outlined in section 4.2.3 for organic substances.

With regard to human health, quality standards for levels in biota are already set by Council Regulation (EC) No 466/2001 [43] for cadmium, lead and mercury in seafood. Corresponding metal concentrations in water are derived by using relevant BCFs.

With respect to the use of BCF data it must be taken into account that inverse relationships have been observed for metals where the highest BCF values for metals were found in waters with the lowest metal concentrations (and vice-versa). Thus, BCF values of studies conducted in waters with extremely low (i.e. lower than in the upper range of background levels) or high metal concentrations are not used for the calculation of quality standards. The required BCFs may be either obtained by calculating species specific geometric means from

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[10] In the case of metals, only empirically derived coefficients for the partition between water and sediment (i.e. $K_{water\text{ -suspended particulate matter}}$) should be used.

BCF studies conducted with environmentally relevant metal concentrations in the test media or by using BCFs observed in the field.

4.4.8 Metal Quality Standards Referring to Levels in Water Intended for the Abstraction of Drinking Water

The same approach as described for organic chemicals is followed (see section 4.2.4).

4.5 Derivation of Quality Standards Accounting for Transient Exposure Peaks (MAC-QS)

In order to cover both long-term and short-term effects resulting from exposure to a chemical, a second kind of quality standards referring to short term concentration peaks, the so-called maximum acceptable concentration QS (MAC-QS) is derived. The MAC-QS is a figure not be exceeded any time. In conjunction, the AA-QS and the MAC-QS are intended to protect the structure and function of the addressed aquatic ecosystems from significant alterations by the impact of a chemical.

The derivation of the MAC-QS is based on the provisions of the TGD for substances with intermittent release (section3.3.2 of [3]).

For exposure of short duration only short term effects may need to be considered. An assessment factor of 100 applied to the lowest L(E)C50 of at least 3 short term tests of three trophic levels is normally considered appropriate to derive the MAC-QS for such situations. However, for substances with a potential to bioaccumulate the lowered assessment factor of 100 may not always be justified. For substances with a known non-specific mode of action inter-species variations may be low and therefore a factor lower than 100 appropriate. In no case should a factor lower than 10 be applied to a short-term L(E)C50 value.

5 Selection of Data for the Derivation of Quality Standards

Data identified as valid in finalised risk assessment reports and in (consolidated) draft reports for existing substances (according to Council Regulation (EEC) No. 793/93) as well as for plant protection products (according to Council Directives 91/414/EEC & 97/57/EC) have been preferably used for the derivation of quality standards as they were already subjected to an extensive peer review and evaluation process. No differentiation with regard to the status of the risk assessment report (final or draft) was made in the context of this study. Therefore, quality standards that are proposed on the basis of information and data given in draft reports should be reviewed once the respective risk assessments are finalised.

If PNECs were already established in the risk assessment reports, these PNECs (e.g. for water, sediment or secondary poisoning of top predators) were used for the derivation of the specific standards for the respective objectives of protection. Accordingly, the effects data identified as valid to establish the Toxicity Exposure Ratios (TER) in the RA-monographs for plant protection products (PPP) were used to derive the quality standards for plant protection products as described in section 4.3. In order to set quality standards referring to human health the relevant threshold levels (e.g. NOEL, ADI, TDI etc.) identified in the risk assessment reports were used.

For the priority substances for which the risk assessment reports or monographs were not available, or in case data required to calculate the quality standards could not be retrieved

from the RA reports, data provided by Member States, industry and NGOs were used. These stakeholders were asked in the consultation process to submit only data that were evaluated and considered reliable by themselves. Data selection rules as follows were applied:

1. Only data that can be considered as reliable (see section 9.2 of [2]) are used, irrespective of the source of the data.
2. The relevant data from the different sources available (see Annex 3 of [2]) are collated in the substance data sheet. This means that not all valid data provided by stakeholders were transferred to the data sheet but only those that were considered relevant for quality standard setting.
3. Data collated for quality standard derivation were selected making best use of supplementary information provided along with the data. In case no further ranking of data with regard to their utility and relevance for the derivation of quality standards was possible, the final selection of data was made following the precautionary principle. I.e., usually the lowest acute and long term toxicity data available for the different species and end points are used, or in case of other data, such as partition coefficients, the figures resulting in worst-case assumptions are selected. A justification for the selection of specific data is briefly given in the EQS data sheets.
4. Based on the selected data, the quality standards were derived as described in section 4. If a standard for a specific objective of protection could not be derived since the required data are lacking, this is flagged.

6 References

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