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OPINION OF THE SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE) ON

"The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof "

Adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004

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Introduction

In the context of a proposal on priority substances which the Commission is developing in accordance with Article 16 of the Water Framework Directive, DG Environment has sought the Opinion of the CSTEE on a number of issues relating to the setting of environmental quality standards

It is noted that, "*The Commission is not requesting the Committee to systematically review the data, the assessment procedure and the review process related to each substance but where, on the basis of their experience and knowledge the Committee identifies anomalies, inconsistencies, problems, opportunities to introduce the latest scientific findings etc, the Commission would be grateful to receive the Committee's advice*".

The CSTEE has answered the specific questions and commented on the values proposed for individual substances.

Question 1 – General Appreciation of the quality standards being developed by the Commission services

Question to the CSTEE

The approach which the Commission has taken for the derivation of the EQS values is based on standard methodology which has been applied in the context of EU chemicals' legislation). However, the Commission invites the Committee to express an opinion on the approach taken and also, to the extent that it is reasonable to do so, on the EQS values which have been proposed for the individual substances.
The Commission is not requesting the Committee to systematically review the data, the assessment procedure and the review process related to each substance but where, on the basis of their experience and knowledge the Committee identifies anomalies, inconsistencies, problems, opportunities to introduce the latest scientific findings etc, the Commission would be grateful to receive the Committee's advice

CSTEE Response

We note that it is the intent of the Commission to develop a "Manual of the Methodological Framework Used to derive Quality Standards for Priority Substances of the Water Framework Directive" and we were supplied with a draft (15 Jan 2004) of this together with supporting documentation (Final Report of Contract B4-3040/200/30637/MARE/E1 dated 4 Sept 2002). It is obvious that the Manual is a working document and we presume that it will evolve as the work develops. For the sake of transparency and consistency we would urge that the Manual treat the various aspects of the framework in a full and systematic way; for example, as with the Technical Guidance Document used for the assessment of New and Existing Chemicals (TGD)[1]. There are number of sections of the Manual that will need more work in this regard and we draw attention to some of them below.

Turning to the approach itself, we accept that this is based on standard methodology that has been applied in the context of EU chemicals' legislation, and in particular from the Technical Guidance document referring to New and Existing substances and guidance relating to the risk assessment of plant protection products[2]. However, we believe that there are important distinctions between the PNECs (Predicted No Effect Concentrations) and EQSs (Ecological Quality Standards) and that these should be made more explicit in the Manual. In particular PNECs (and the endpoints used in Plant Protection Products (PPP) risk assessments) are often derived as part of a tiered approach, so that those based on a minimum dataset and worst-case conclusions will not usually lead to a management decision but trigger the development of a more refined assessment often on the basis of the collection of more exposure and effects data. We therefore believe that for EQS assessment that leads to standards that are defined legally, and that once so defined can be difficult to change, caution needs to be exercised in basing standards on too little and inappropriate data. This is not made clear enough in the current version of the Manual.

It follows that the databases upon which the EQS assessments are carried out should be as full and up-to-date as possible, and should be appropriately screened for quality and relevance. For a number of the substances addressed in the initial exercise, we are not convinced that this was the case. For example, no invertebrate long-term data are available for some chemicals (e.g. dichloromethane, hexachlorobutadiene) and it is questionable if a seven-ten days test can be assumed to be long-term for other substances (e.g. benzene, fluoranthene). For some chemicals with low solubility in water (e.g.octabromo- and decabromo-diphenylether) experimental information is inadequate and QSAR (Quantitative Structure-Activity Relationships) data for non-polar narcosis are used to assume that NOEC (No Observed Effect Concentration) is higher than water solubility**.**

Moreover, we are of the view that given that EQSs are intended to apply to long-term exposures they should rarely, if ever, be based only on acute endpoints. With small lists of

[1] Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Edition 2. Ispra, 2003

[2] Guidance Document on Aquatic Ecotoxicology under Council Directive 91/414/EEC., DGSANCO, 3268/2001.rev 4 final.

hazardous substances it should always be possible to obtain chronic endpoints. Again we are of the opinion that this is not made sufficiently clear in the Manual and that by including assessment factors designed to deal with acute data only there is encouragement of procedures that are not appropriate for EQS development.

In a similar context, we understand the impetus for making a distinction between industrial chemicals and PPPs, based on history and a requirement to do so arising out of the Water Framework Directive. However, we believe that it is artificial to make this distinction and potentially misleading to do so. The main difference is in terms of the treatment of acute data on algae. Given our opinion that these should only rarely be the basis of EQSs, we are of the view that a common table of assessment factors could be developed excluding the acute only factors. This would be in line with the Harmonisation of Risk Assessment Report (Second Report on the Harmonization of Risk Assessment Protocols. Scientific Steering Committee, European Commission, May 2003) that we have endorsed.

Some particular issues:

- We are supportive of the distinction made between QSs (Quality Standards) referring to annual average concentrations (AA-QSs) and those referring to short-term transient exposure, the so-called maximum acceptable concentration (MAC-QSs). However, we believe that this distinction is too sharp. Long term exposures may be very noisy, possibly including concentrations as high as short-term peaks. This will certainly require judgements to be made in the way that particular substances are monitored. We would urge that explicit advice be given on intelligent monitoring in the appropriate documentation.
- Focussing on the MAC-QSs, the advice is to base theses on EC50s only. We believe that this will not always be appropriate. For example, several of the chronic ecotoxicological studies are conducted in relatively short time periods (e.g. days for algal tests, weeks for invertebrates), and therefore these NOECs should be taken into account. In addition, higher tier methods such as Species Sensitivity Distributions (SSDs) or mesocosms can also provide an appropriate way for setting QSs for episodic exposures. Finally, the use of acute EC50s (Mean Effective Concentrations) is not acceptable for chemicals which can produce long-term responses due to episodic exposures such as endocrine disrupters, chemicals with high bioaccumulation potential and low elimination rates, etc. Therefore the CSTEE suggests that proper guidance be given for setting AA and MAC Quality Standards on the basis of the established and existing information.
- Given our views that EQS assessment should be based on as extensive databases as possible, we would envisage that the SSD approach will be common. In a previous Opinion (TGD Draft revision version on Part 3/B - Environmental Risk Assessment - Marine Part. Opinion expressed by written procedure on 25 January 2002) we have counselled caution in the uncritical use of different datasets in constructing SSDs. In particular we believe that it will often not be appropriate simply to conflate datasets from different taxa into the same SSDs. This will particularly be the case when dealing with substances that have specific modes of action. There are two main options for producing SSDs: the option included in the TGD

combining the information on a limited set of species representing different taxa in a single curve, and the option selected for biologically active chemicals, also employed in the risk assessment of cadmium, which requires the individual analysis of each taxonomic group. Guidance on the use of these options should be provided. It seems that the Manual only includes the TGD approach while in reality the second option has been used for setting the values for some pesticides**.** There are also important statistical issues in defining the form of the distributions and specifying endpoints and their confidence limits. The section on statistical extrapolation (4.4.2) needs to be elaborated with these points in mind.

- We believe that there are some problems with the ways suggested for the use of mesocosm data to calculate EQSs**.** Mesocosm experiments are higher tier studies with very specific design and requiring higher tier interpretations. The aim and results of these studies should be checked individually, and according to the environmental fate and ecotoxicological profile of the molecule. The exposure conditions are critical, and the interpretation should be case-by-case. The experimental design must be considered to check the suitability of the study for setting QS based on continuous or episodic exposures. When the concentration of the tested substance changes significantly through the experiment the suitability of the test for providing information on AA or MAC QSs should be considered. The suggestion for "normalizing" the exposure of all mesocosms on the basis of the time-weighted average concentration is not acceptable, as the effects observed in the test are not necessarily similar to those expected at constant exposure levels. The interpretation of a mesocosms study should not be conducted as an independent exercise, but considering the overall information on the ecotoxicological profile of the substance. The CSTEE is concerned about how mesocosm data have been used in several assessments (e.g. alachlor, atrazine or chlorfenvinphos).
- We have expressed concern about the use of the added risk approach for deriving PNECs and quality standards for metals in a number of previous Opinions. This is rehearsed in more detail in our response to Question 5 below.

In applying the principles to the specific substances the CSTEE considers that the scientific quality of the applied methodology and the proposed values for the QS is diverse. In some cases, the methodology is appropriate, presented in a transparent way and updated, following the current state of the science. In other cases, the data sheets do not present enough information for setting a scientific opinion (e.g. the toxicity endpoints are not described). In yet other cases the Committee disagrees with the proposed methodology, the assessment details and/or selected values. This is addressed further in the section summarising our responses to the QSs proposed for the specific substances.

In addition, the human health related data are written in a very condensed way and, for some chemicals, readily available dataset on toxic responses after oral exposure have not been used. To ensure transparency and a well balanced document, the toxicology of a chemical under consideration needs to be presented in more detail, the

selection of relevant endpoints for extrapolation needs to be justified and uncertainties need to be identified.

At its Final Plenary Meeting the CSTEE was informed that, to prevent it from being overwhelmed with information, the Commission did not make available to the CSTEE all the data that had been used by the Commissions experts to support the proposed QS values.

Question 2 – Appropriate quality standards taking into account drinking water protection

Options
A number of options are under consideration including:
Option 1 : *to base the overall EQS (both AA-QS and MAC-QS) on the quality standards for drinking water as applied by Directive 98/83/EC (amending Directive 80/778/EEC), with adequate consideration given to removal efficiencies.*

Option 2: *to base the EQS exclusively on eco-toxicological criteria whilst leaving the achievement of drinking water limits to the treatment plants for drinking water.*

Option 3: *to base the EQS exclusively on eco-toxicological criteria, and for surface waters intended for drinking water abstraction apply an additional binding MAC-QS taking into consideration drinking water standards and appropriate treatment.*

Question to the CSTEE:

The Commission recognises that the establishment of EQS for priority substances which are also covered in the drinking water legislation is essentially a political and economic question. The Commission invites the Committee to provide scientific/technical insights which might inform the setting of EQS for such substances

CSTEE Response

We believe that whether or not it should be ensured that natural waters are fit for human consumption is largely a socio-political issue. This issue becomes critical in situations where the drinking water standards would be more stringent than the ecological standards. Amongst other considerations it requires a view to be taken about the appropriateness of requiring the economic burdens of cleanup to fall on the polluters or the water treatment facilities.

However, there are some scientific issues that require to be taken into account in making these decisions:

- The relative ease/practicality of removing substances at source or in treatment plants.
- DW standards may not be based on health but on analytical limits. They should therefore be treated with some caution in developing environmental standards.

- We believe that risks to terrestrial vertebrates from drinking from natural waters are not currently taken into account at all in the EQSs. Inclusion of human drinking water standards could help to fill this gap.

We are of the view that three main groups of chemicals should be considered:

The first group includes the majority of chemicals, for which, the QS required for the ecosystem protection are low enough for covering the requirement for humans exposed via drinking water. Obviously, no additional considerations are required for this group.

The second group represents those chemicals that are mostly present in tap water due to their production during the chlorination process (e.g. trichloromethane). For these chemicals, the concentration in drinking water is directly related to the chlorination process and not on the initial concentration in the abstracted water. For this group, the application of drinking water standards is not only irrelevant but also useless for human health protection, as the chemicals will be formed after the abstraction process. Therefore, the CSTEE recommends that these chemicals be monitored directly in tap water and should not be used for setting the overall standards for surface water under the WFD. (This suggestion corresponds to option 2; but measuring concentrations after not before the chlorination process).

The third group covers chemicals the main source for tap water being the initial concentration in the abstracted water. For this group, the CSTEE offers an alternative option to those proposed. Where the drinking water abstraction based QSs are lower than the ecological QSs, the CSTEE recommends that first there should be a careful evaluation of these situations, to clarify the reasons resulting in the discrepancy:

- One reason could be the consequence of a regulatory decision to set drinking water QS to much lower concentrations than required based on a toxicological risk assessment. Under these circumstances, and considering the uncertainty and variability in the efficacy of drinking water treatments for removing the chemicals, the CSTEE recommends application of the ecological QS as overall QS for surface water. However, if the results of monitoring programs indicate that drinking water QS are exceeded in surface waters to be used for the abstraction of drinking water, the authorities should specifically monitor to ensure that drinking water QS are not exceeded in tap water.
- If the drinking water QS are based on the results of toxicology based risk assessment, an in-depth re-evaluation of ecotoxicological figures and the use of mammalian toxicity data for ecotoxicological evaluation are required. Aspects such as oral versus waterborne exposure, acute to chronic ratios, role of specific mechanisms of action including those associated with endocrine disruption in wildlife, among others, must be considered. The reassessment should cover the potential effects for aquatic organisms exposed via food, for the terrestrial ecosystems associated with surface water, including the exposure of wild animals via drinking water if it is not covered by secondary poisoning. The overall QS

should be in all cases protective for humans directly exposed to surface water; e.g. due to recreational uses.

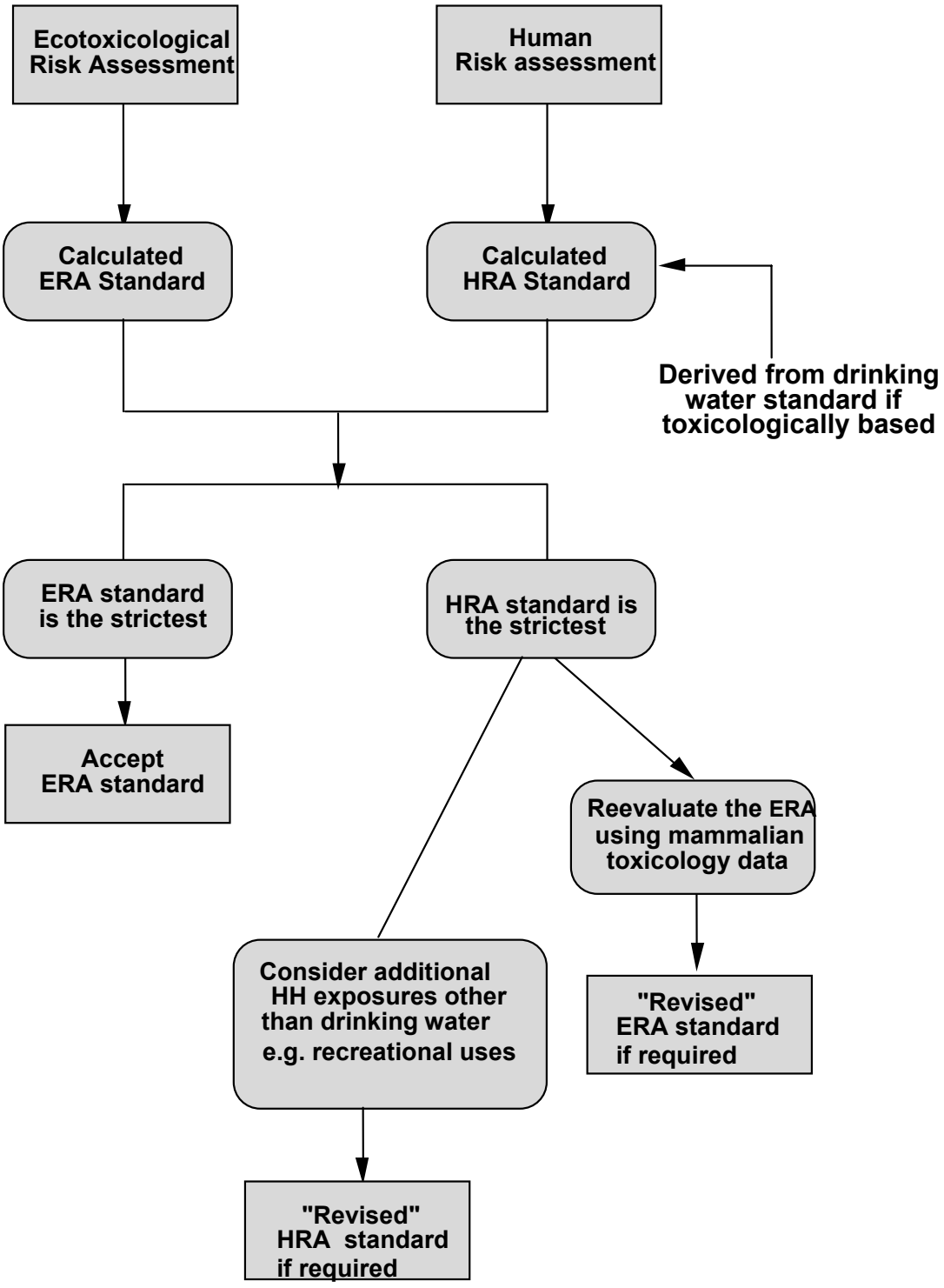

Figure 1: Proposed scheme for the comparison of the standards derived from Ecological Risk Assessments (ERA) and Human Risk Assessments (HRA)

We would also make the point that the process of water quality standard setting initiated by the EU seems to have made limited use of the US EPA activities in this connection. The US EPA (US Environmental Protection Agency) develops water quality criteria for a number of pollutants and a detailed handbook on the US EPA process is available. Quality standards and peer reviewed justifications for these standards are available regarding human health endpoints for some of the priority chemicals considered in the EU-assessment. Consultation of these documents would be helpful in the process of standard setting in the EU.

Question 3 – Quality standards for sediments and biota

T*he Water Framework Directive invites the Commission to present proposals for Environmental Quality Standards for surface waters, sediment or biota. At this stage, the Commission envisages to present Quality Standards only for the water phase. This would include reporting the concentrations of the priority substances in whole water that is including the dissolved fraction as well as the fraction bound to Suspended Particulate Matter. The overall quality standard is furthermore derived to be protective of all compartments, including sediment, biota and secondary poisoning of top predators.*
At this stage, the Commission is not considering presenting specific Quality Standards for sediment and biota for two reasons:

- *data on toxic effects on benthic organisms and biota are of limited availability;*
- *difference in types of sediment matrices, with implications for effects and different contaminant levels in sediment are of varying importance at different locations; as well as,*
- *uncertainties regarding monitoring points, sampling and analytical methods, would make compliance checking in sediment and biota difficult for the purpose of implementation of Community legislation.*

Specific monitoring requirements for sediment and biota to ensure the environmental objective of "no deterioration" are however foreseen to be proposed. The Expert Group on Analysis and Monitoring is furthermore currently developing overview, assessment and guidance of practices required for this purpose.

Question to the CSTEE

The Committee is invited to comment on the Commission's proposed approach for dealing with the issues of sediment and biota.

CSTEE Response

We note that at this stage the Commission envisages presenting Quality Standards only for the water phase and that this would include reporting the concentration of a priority substance in the whole water; i.e. including the dissolved fraction and that bound to suspended organic matter. We believe that there are some difficulties with this being applied uncritically:

- **To base protection on a water column standard ignores many of the biological complexities of exposure through absorption and ingestion by sediment organisms**. Notwithstanding the view that "data on toxic effects on benthic organisms and biota are of limited availability," we believe that information is now more available and should be taken into account whenever possible.

- The exposure of chemicals through the food chain is not only relevant for secondary poisoning in birds and mammals, but also for aquatic invertebrates and fish and the **EQSs based on waterborne exposures are not protective in all cases**. In addition, for chemicals with very low water solubility and/or high binding potential, the monitoring programmes on water column levels can be problematic as the results will depend on the amount of particles in the sample which will give low reproducibility. Some of the substances are also difficult to determine due to the low concentrations. **Monitoring programmes for lipophilic substances should be focussed on biota (and possibly sediment). As the number of chemicals selected as priority substances is very limited, the CSTEE strongly recommends producing the required ecotoxicological information for supporting sound QSs at least for these substances.**

- **Basing exposure concentrations on whole water may be very misleading with regard to bioavailability**. For example the presence of algae and other organic matter in suspension may be important, particularly when there are blooms, and yet the bioavailability of substances in algal biomass is not straightforward**.** The concentrations of lipophilic substances will depend on the amount of suspended particulate matter (SPM) in the sample, which will depend on where, when and how the sample is taken.

- In contrast to the "generic" risk assessments conducted under the TGD, the QSs under the WFD will be applied in a site-specific way, for setting the quality of specific zones in specific rivers. **The use of "generic" partition coefficients, as those suggested in the TGD, are not appropriate for site-specific assessment; where the measured value represents a specific sample of water**, suspended matter or sediment, the use of partition coefficients obtained for a "generic" sediment with properties (which can be very different from those of the actual sampled sediment) can over- or under-estimate the value for the QS which should be associated to that particular sediment. Since the differences in partition coefficients frequently cover several orders of magnitude, the effect of such extrapolations can lead to serious misinterpretations.

As a general conclusion the CSTEE believes that specific quality standards can and should be developed for sediment and biota. This should be based on direct assessment and monitoring of sediments and biota directly (i.e. points 1 to 4 above). The use of partitioning models is more difficult due to the sensitivity of partition coefficients to local circumstances (point 5 above) and hence these should not be applied, due to geographic variability, on a generic EU-wide basis.

Question 4 – Quality standards for transitional waters

Options
The Commission therefore sees two options:
Option 1 - *Inland water EQS (AA and MAC) shall apply also to transitional waters, unless on a case-by-case basis sufficient data is available to assess specific estuary ecosystems, in which case the values may differ.*

Option 2 – *Coastal and Territorial AA QS will apply also to transitional waters. [Although no MAC has been derived for coastal and territorial waters, it will however be necessary to apply a MAC also to transitional waters, which would be based on the inland water MAC-QS with appropriate AF taken into account if deemed necessary]* [3]

Question to the CSTEE

The Commission invites the Committee to give an opinion concerning the establishment of EQSs for transitional waters.

CSTEE Response

We have been critical about the distinction made between marine and freshwaters in the revised TGD (TGD Draft revision version on Part 3/B - Environmental Risk Assessment - Marine Part. Opinion expressed by written procedure on 25 January 2002). In particular we were unconvinced about the need for extra application factors to reflect uncertainties regarding the relative sensitivity of uniquely marine taxa. However we observe that although the general TGD approach for applying an additional factor of 10, when no information on two additional marine invertebrate groups is available, is included in the manual for setting QS under the WFD, **some of the specific assessments have involved a critical evaluation of available information** and thus deviated from the TGD rules. The CSTEE welcomes this approach, and considers that this in-depth evaluation should be applied to all substances.

It is clear that the extent to which a body of water be treated as marine or freshwater will depend on taxonomic composition and its possible influence on SSDs, and the salinity of the system and its possible influence on exposure as well as on the structure of the biological community. **It follows that when values are employed that are different from those used for inland waters, the difference should be identified and justified**. If based on differences in physical-chemical properties, the standards for transitional waters should reflect this, and the values should be related to the salinity, ionic strength, pH, of the water body etc. Alternatively, if the difference is based on the specific sensitivity of some marine organisms, the relevance of those organisms in transitional waters, and the sensitivity of estuarine species should guide the application of the freshwater or the marine standards, or the need for developing specific values. We believe that there was not sufficient clarity on this in the documentation and we were certainly confused about the intent, or not, of a distinction between transitional waters, estuaries and brackish habitats.

[3] Datasheets and overview tables as included in Annexes 3 and 4 currently present option 2.

Question 5 - Background concentrations for metals

The Methodology for the Derivation of Quality standards for Priority Substances sets out a specific methodology for deriving the Quality Standards for metals (section 4.4). Specifically it is proposed to use the Added Risk Approach which takes into account the question of natural background concentrations. The general assumption made is that the ecosystems are adapted to the natural background concentrations, and that the same amount of anthropogenically added metal will cause the same effect. The Quality Standard to be complied with by the Member States should be the background concentration plus the Maximum Permissible Addition (MPA).

$EQS_{add} = C_{background} + MPA$

Opinions differ among the Member States concerning the Added Risk Approach. For Lead and Mercury, the Expert Advisory Forum supports the use of the added risk approach. With respect to Cadmium and Nickel the risk assessment is still being completed. For mercury the potential low value of the Quality Standard is a concern (see also question 7).

The Commission would foresee a flexible approach, where the Member States can apply different background concentrations, based on solid justification. The Expert Group on Analysis and Monitoring is developing commonly agreed methods for establishing background concentrations, including establishing a "default background concentration" that can be applied by the Member State.

Options

There are two options under consideration:

***Option 1 –** the Added Risk Approach is not used for any metal, and the proposed MPA becomes the EQS.*

***Option 2 –** Member States are given the option to use the Added Risk Approach. If not used, then the proposed MPA becomes the EQS.*

Question to the CSTEE

With regard to the establishment of EQS for metals, the Commission invites the Committee to gives its opinion on the use of the Added Risk Approach

CSTEE Response

Aquatic organisms and ecosystems respond to the bioavailable total metal concentration (i.e. $[MPA+Cb]_{bioavailable}$).

The CSTEE is aware that both the added and the total risk approach have been used or are being considered for various completed and ongoing risk assessments of metals. **With the total risk approach, PNEC or EQS may be derived which are below the natural background concentration**. In theory, the use of the added risk approach avoids this potential problem by accounting for the background. The naturally occurring concentration of metals, i.e. the background concentration, in various environmental systems can vary substantially depending on the geographic area/ earth crust composition, soil type and geochemical processes. Table 1 illustrates the variability of the background concentrations of zinc. **With the added risk approach it is thus assumed the background does not**

affect the ecological system and that only the risks posed by the anthropogenic metal addition are assessed.

Table 1: Variability of natural (background) zinc concentrations reported in surface waters (Janssen et al, 2000 in Human and Ecological Risk Assessment 6:1003-1018).

Location	Zn range (µg/L)	Reference
Great Lakes (USA)	0.09-0.28	Nriagu et al., 1989
Mississippi (USA)	0.11-0.27	Shiller and Boyle, 1987
Rivers in calcareous region (France)	0.09-0.12	Whitehead et al., 1988
Meuse and Rhine (Europe)	2.7	Zuurdeeg et al., 1992
Gotä and Nodre river (Sweden)	6-7	Danielsson et al. 1983
Streams 'Nothern Europe'	8-42.7	Zuurdeeg et al., 1992

Two important factors need to be considered.

- It has been shown that it is very difficult to correctly establish the natural background of a particular location and/or a specific region. **The CSTEE is of the opinion that current knowledge on the geographic distribution of metal background concentration in aquatic systems is insufficient to correctly implement the added risk approach**. Further research on the development of standard methods for assessing background concentrations in water and sediments and the establishment of the regional variability is required. **The CSTEE suggests that the establishment of a "default background concentration" will not contribute to the correct assessment of the risks posed by metals.**

- In the original papers describing the added risk approach MPC = MPA + φCb with φ being a bioavailability factor. In risk assessment practice this factor is usually set at 1, i.e. maximum bioavailability of the background. As, at a given location, the anthropogenic metal fraction occurs in the same surface water as the background fraction this implies that all metal is considered 100% bioavailable. Numerous studies have shown that metal bioavailability is depended on environmental characteristics (e.g. pH, hardness, dissolved organic matter, and others for surface water; sulfides, organic matter, and others for sediments) and thus may vary from 0 to 100% depending on environmental factors. The CSTEE is of the opinion that not accounting for φ in both the MPA and Cb fraction results in the incorrect assessment of the risks and thus prevents the establishment of science-based EQS.

The latter bioavailability concerns also apply to the total risk approach. It is, however, **the opinion of the CSTEE that in general the added risk approach, through the lack of accurate information on background variability and on a number of biological/ecological processes (e.g. acclimation/adaptation, field community responses), may increase the overall uncertainty associated with the EQS.**

Based on the above considerations, the CSTEE has concerns with both options proposed by the Commission. **The CSTEE suggests that an accurate assessment of the risks (or EQS) posed by metals should be done by establishing - on a site-specific-, watershed/basin- or regional basis - both the bioavailable total fraction in the**

environmental compartment/medium ($EC_{bioavailable}$) and the bioavailable total no effect concentrations ($PNEC_{bioavailable}$). Tools for assessing and predicting metal bioavailability are available or are being developed for a number of metals including some of the metals considered in this document.

Question 6 – Quality standards for Groups of Pollutants

The Water Framework Directive establishes that specific measures, including quality standards shall be set for individual pollutants or groups of pollutants. The first list of priority substances included a number of groups of substances, notably Polycyclic Aromatic Hydrocarbons (PAHs) where 5 substances are specified, and other groups like Hexachlorocyclohexane (HCH) where the gamma-isomer (Lindane) is specifically highlighted as of importance.
When deriving quality standards for these two substance groups, different proposals for setting such group standards have been proposed, and the Commission is seeking the opinion of the CSTEE on the scientifically best way forward.
The analytical feasibility of compliance checking for those group standards is currently assessed by the Expert Group on Analysis and Monitoring.

Options
i) For HCH

Hexachlorocyclohexane (HCH):	***Option 1*** *– separate standards shall apply to HCH γ-isomer (Lindane) and the sum of the other HCH-isomers (i.e. α-, β-, δ-), as proposed in the data sheets.*
	Option 2 *– one standard is set for the sum of* ***all*** *HCH isomers (i.e. . α-, β-, δ- & γ-), with the quality standard derived for the HCH γ-isomer(Lindane)*

These 2 options could also be expressed as follows;

	Inland and transitional waters AA-QS [µg/l]	*Coastal and Territorial Waters AA-QS [µg/l]*	*MAC-QS [µg/l]*
Option 1			
γ-Isomer (Lindane)	*0.02*	*0.002*	*0.04*
HCH (α-, β-, δ-Isomers)	*0.042*	*0.01*	*0.9*
Option 2			
Σ-HCH (α-, β-, δ- & γ-Isomers)	*0.02*	*0.002*	*0.04*

Expert consultation has lead to a preference for option 2.

ii) For PAHs

Polycyclic Aromatic Hydrocarbons(PAHs)	***Option 1*** *– to set two quality standards, one for 5 ring PAHs and one for 6 ring PAHs*
	Option 2 *– to set three quality standards, one for 5 ring PAHs and one for 6 ring PAHs and one for BaP.*

Expert consultation has lead to a preference for option 2.

Question to the CSTEE

The Commission invites the Committee to give its opinion concerning the establishment of EQS for HCH isomers and PAHs

CSTEE Response

Background to the use of group exposure

The CSTEE understands that quality standards are intended to be set in ecological and human health grounds, which ever is the stricter value. In the practical situation simultaneous exposure will inevitably occur to several priority substances.

Simultaneous exposure to two chemicals may result in an overall effect that simply reflects the independent contributions of each chemical. However for some combinations of chemicals the effect observed indicates interactions that are synergistic or antagonistic. Prediction of synergistic and antagonistic effects is very difficult unless there is detailed knowledge of the mechanisms by which each chemical exerts its effects.

However in respect of the likely simultaneous exposure to members of structurally related chemicals, such as a chemical series (hereafter termed a group) particular consideration should be given to the effects being additive.

A consistent and transparent approach is needed in assessing the risks from groups of chemicals. The CSTEE proposes that a group exposure standard for the protection of human health and/or ecosystems should be applied if:

- Simultaneous exposure to several members of a group of chemicals is likely to occur frequently and the methodology is available to measure the expected levels of several members of the group.
- Several members of the group have been demonstrated to have a common target organ(s)/ cell type and are considered likely to have the same /similar mode of action

These criteria need to be considered for establishing standards for controlling both ecological and human risk. In some cases such as endocrine disrupters the mode of action may be similar across a number of phyla whereas for others such as polycyclic aromatic hydrocarbons the nature of certain impacts is different in vertebrates and invertebrates.

Two main approaches may be employed, depending on the available data, in setting a group exposure standard:

i) TEF (Toxicological Equivalence Factor) approach

The favoured method, where sufficient data is available, is to base the standard on the individual potencies of individual members of the group. This method is now well established for estimating the risk from simultaneous exposure to dioxins and related structures such as dioxin-like PCB's. It is based on the calculation for a shared single endpoint of a relative toxicological equivalence factor (TEF) for each relevant member of

the group, where the most potent member of the group is arbitrarily assigned a value of 1. By using the TEF values and the measured exposure levels the overall impact of co-exposure to several members of the group can be determined. The TEF approach is therefore used to set the exposure standard.

ii) Worst case approach

Where the relative potencies of the important members of the group are unknown or are somewhat similar (i.e. within a 3-5-fold range) a simpler method can be employed. Namely each member of the series has a similar potency. Since a conservative approach is pertinent for setting standards to protect human health and ecosystems, potency should be based on the most toxic member of the group.

This approach has been used by the CSTEE to recommend an exposure standard for organotin compounds (CSTEE 2004).

General considerations in the application of the groups exposure standard approach

A key issue is to ascertain the variation in the likely composition of different members of the group in real samples that reflect exposure. If the relative composition is fairly consistent it may be sufficient to analyse only for one or two representative members of the group. In principle these can be selected on the basis of ease of analysis.

However if the relative composition of the members of the group is rather variable the above approach is inadequate. In this case as a minimum the most potent members of the group need to be analysed for.

In some cases there may be particular concern regarding the measurable release into the environment of a specific chemicals even through the concentrations arising are significantly below the group quality standard. Under these circumstances strictly for risk management purposes it could be appropriate to set a limit to deter bad practice.

Selection of priority chemicals for the application of a group exposure standard

Examination of the list of priority chemicals in the Water Framework Directive report, indicates that a number fall into one of the following distinct groups viz:

- Polycyclic aromatic hydrocarbons (human health and ecological risks will, however, need to be dealt with separately)
- Hexachlorocyclohexane like (ecological modes of action likely to be similar)
- Organophosphorus pesticides (human and ecological modes of action similar)

Further consideration should be given to the possibility of other group standards, for example:

- Long chain alkyl phenols
- Polychlorobenzenes
- Organotin compounds
- Triazine herbicides

The WFD report only considers polycyclic aromatic hydrocarbons and hexachlorocyclohexanes as warranting an assignment of a group exposure standard. If a group exposure standard is to be applied to any of the priority chemicals the approach should be a consistent one. There is no obvious scientific logic that precludes its application to the other chemical groups identified above.

Specific comments

a. In the case of hexachlorocyclohexane, the proposal is to take the sum of the three isomers. It is reasonable to assume a common mechanism. However the gamma isomer (lindane) has the lowest ecotoxicological NOEC. Therefore using the worst case approach set out above; the standard should be set based on lindane.

b. For PAH's the CSTEE has already identified the need for a group exposure standard in respect of creosote exposure and ambient air (Opinion on Cancer risk to consumers from Creosote containing less than 50 ppm benzo-[a]-pyrene and/or from wood treated with such Creosote and estimation of respective magnitude; 8th CSTEE plenary meeting, 4 March 1999; Opinion on Position Paper on Ambient Air Pollution by Polycyclic Aromatic Hydrocarbons (PAH) expressed at the 24th CSTEE plenary meeting, 12 June 2001) based on the likelihood of a common mode of action in mammals. The problem is to identify one or representative members of the group whose concentration(s) consistently reflect the concentrations of the other members of the group across a range of samples from different water bodies. If no member of the group is shown to be representative in this sense it is necessary to measure directly the concentrations of the most potent and prevalent members of the group

c. For PAHs two options to set QSs are presented: One is to use an interim QS of 0.03 µg/l for the group of the 5-ring PAHs B[a]P, B[b]F, and B[k]F and a second QS of 0.0016 µg/l for the 6-ring PAHs. The second is to use a separated B[a]P value of 0.05 µg/l, and two interim QSs for B[b]F and B[k]F of 0.03 µg/l and for 6-ring PAHs 0.0016 µg/l. The first option would limit the PAH content to 0.0316 µg/l, the second to 0.0816 µg/l. CSTEE does not support either of these proposals and refers to its proposal of the group approach for PAHs.

Conclusions:

1. **The CSTEE welcomes the proposal to set a group quality standard for chemicals with a similar mode of toxic action.**
2. **It is important that the criteria are clearly set out to describe where and how a group quality standard should be introduced. In the view of the CSTEE a transparent and consistent application is essential. Suggestions are provided in this opinion.**

Question 7 - Quality standard for mercury

The consultation process has exposed wide divergences of opinion as to which QS should be applied for Mercury. The extremes in the range of suggested values are spread between

0.008 ng/l to 100 ng/ (1:12500). The difference of opinion is due to the uncertainties surrounding the bioaccumulation factor. Given the wide range of options, and the importance of basing the proposal on sound scientific judgement, the Expert Advisory Forum recognised that opinion of the CSTEE would be crucial in reaching a final position.

Question to the CSTEE

The Commission invites the Committee to gives its opinion regarding the bioaccumulation of mercury in biota and through the food-chain and to advise the Commission concerning the establishment of EQS for this metal.

CSTEE Response

As outlined in the section 'Comments on specific substances' of this Opinion, a water quality standard for mercury could not be defined because the numbers for standards proposed by involved stake holders differ by a factor of 12 500. This is due to the many uncertainties regarding transformation of inorganic mercury to methyl mercury and the bioaccumulation of methyl mercury in fish. The complexity of the issue is well outlined in the "Water Quality Criteria for the Protection of Human Health for Methyl Mercury" published by the US EPA in 2001. Due to the many uncertainties, the US EPA did not develop a water quality criterion for methyl mercury (maximal concentration in water) regarding human health effects due to fish consumption. Instead, the EPA developed a maximum residue level tolerable in fish for human methyl mercury exposure. In Europe, more than 90 % of human exposure to mercury is to methyl mercury from dietary sources, mainly fish and residue level have been set (which may not be totally protective based on the EPA evaluation of the available human epidemiology). The approach made by the US EPA is appropriate to follow in the context of this document regarding indirect effects on humans due to methyl mercury consumption from fish. The consultant uses the fish residue level set by the EU of 0.5 mg/kg. The use of the fish residue level of 0.5 mg Hg/kg fish (edible parts) is acceptable since most of the Hg present in fish is in the form of methyl mercury. In comparison the US EPA has developed a fish residue criterion of 0.3 mg Methyl-Hg/kg fish based on average fish consumption in the US.

A similar approach should be conducted for the protection of predators, bearing in mind that the food item is the whole fish/invertebrate and not only the human edible part.

Due to the many uncertainties, the CSTEE concludes that a water quality standard for mercury cannot be defined based on defendable scientific argumentation due to the many uncertainties and knowledge gaps.

Comments on the proposed Quality Standards for specific substances

Following the mandate, the CSTEE has addressed the essential requirements for setting quality standards according to the Water Framework Directive, but including specific examples from the individual data sheets when appropriate. The CSTEE has concentrated the efforts in identifying all relevant issues from the process as a whole. Some issues identified for one substance may be applicable to other substances as well, even if they are not explicitly mentioned in the opinion.

In addition, the CSTEE considers that from a scientific perspective the list of priority substances should be reconsidered. The need for including the pesticides should be re-evaluated following the authorised uses (if any) under Directive 91/414/EC process and the need for including chemicals such as dioxins or PCBs should be considered.

The CSTEE has not checked the completeness of the database used for assessment or definition of NOAELs (No Observed Adverse Effect Levels) or ADIs (Acceptable Daily Intakes) used for the values proposed in the data sheets.

At its final plenary meeting the CSTEE was informed that, to prevent it being overwhelmed with information, the Commission did not make available to the CSTEE all the data that had been used by the Commissions experts to support the proposed QS values.

1. Alachlor

Environmental assessment

The CSTEE finds that the data used in for the deriving the QS for alachlor are, in general, of adequate value. However, the CSTEE is concerned with the procedure used for deriving the AA-OS. The main reasons for this are (1) the lack of transparency concerning how the mesocosm value was derived and (2) the lack of justification for rejecting the NOEC obtained for chironomids. All other environmental QS are deemed to be adequate.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

2. Anthracene

For the environmental and human health assessment the CSTEE recommends the group approach.

Environmental assessment

The CSTEE agrees with the proposed QS. Minor suggestions for clarification were discussed: e.g. on solubility, photolysis and the justification for rejecting one of the effect values.

Human health assessment

The CSTEE agrees with procedures proposed in the human health assessment.

3. Atrazine

Environmental assessment

The CSTEE notes that the report recognises that the assessment of endocrine effects is relevant for this substance and that these effects may result in be the most sensitive endpoint. However, the proposed QS does not cover these effects for reason apparently concerned with reliability of the data. Furthermore, the CSTEE is concerned about the probabilistic approach using mesocosm NOECs. The CSTEE notes an inconsistency of an assessment factor 5 being applied here while for other substances using mesocosm data a factor of 2 has been used. For these latter reasons the CSTEE finds it hard to support the proposed QS and suggests that a re-evaluation is made.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

4. Benzene

Environmental assessment

The CSTEE finds that the data selection criteria are not transparent (e.g. justification for rejection the data of Black et al.).

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

5. Deca brominated diphenlylether (BDE)

Environmental assessment

The CSTEE finds that the proposed triggers for not setting a quality standard for secondary poisoning are not applicable as deca-BDE derivatives have recently been reported in biota. It is proposed that the QS is re-evaluated in the light of new scientific data.

Human health assessment

The CSTEE notes that the HH data are based on a study giving a NOAEL of 1000 mg/kg/day cited in a recent EU-risk assessment. The WFD report refers to experimental results in fish which indicate that deca-BDE does not bioconcentrate. The CSTEE, however, recommends to use an additional safety factor since environmental concentrations of BDEs are increasing and debromination of deca-BDE may occur. As the water solubility of deca-BDE is much lower than the QS proposed in the report the CSTEE suggests that no QS is therefore recommended regarding this endpoint.

6. Octa brominated diphenlylether (BDE)

Environmental assessment

The CSTEE notes that this WFD report is based on the EU RAR (Risk Assessment Report). The RAR states that a chronic study is required and that the PNEC for secondary poisoning could be related to the toxicity of the hexa-bromo component in the commercial octa-bromo. As such, the CSTEE finds that QS derivation is not appropriate. It is suggested that monitoring programmes for all brominated derivatives are conducted and additional effects /accumulation data are obtained prior to setting the QS.

Human health assessment

The CSTEE notes that, despite the fact that the WFD report states that no toxicity data were made available for evaluation, both 28 and 90-day toxicity studies have been published. The report refers to experimental results in fish which indicate that octa-BDE does not bioconcentrate. The CSTEE, however, recommends to use an additional safety factor since environmental concentrations of octa-BDE are increasing and debromination of higher brominated BDEs may occur. For developing the QS for human food uptake, the consultant uses an NOAEL from a reproductive toxicity study in rabbits which gives the lowest NOAEL. This approach is supported.

7. Penta brominated diphenlylether (BDE)

Environmental assessment

The CSTEE supports the AA-QS suggested for the pelagic freshwater community. On the basis of one of its previous opinion (TGD Draft revision version on Part 3/B - Environmental Risk Assessment - Marine Part. Opinion expressed by written procedure on 25 January 2002) the CSTEE questions the use of an additional assessment factor for the marine environment as applied here. The CSTEE is of the opinion that a MAC-QS, which is derived use an application factor of 10 instead of 100 on the acute LC50, should be considered in the light of the persistence and bioaccumulation potential of penta-BDE. It is also suggested that the QS for secondary poisoning is based measurements in biota not in water. The CSTEE has produced an opinion on the RAR for this substance (Opinion on the Environmental Risk Assessment of Pentabromodiphenyl ether [CAS N° 32534-81-9], 13th CSTEE plenary meeting, 4 February 2000). Some of the data requirements identified by the CSTEE are now available.

Human health assessment

The CSTEE supports the use of the NOAEL for penta-BDE taken from a 30 day dietary study (0.45 mg/kg/day) reported in the recent EU-risk assessment. It is noted that the HH QS regarding ingestion of food is lower than the value derived from the protection of the aquatic community. The CSTEE agrees with the drinking water abstraction value proposed in the WFD document.

8. Cadmium and its compounds

Environmental assessment

The CSTEE notes that WFD report is based on the EU RAR for Cd. In its opinion on this RAR the CSTEE has expressed several concerns about the procedures and assumptions used to derive the PNEC for the aquatic environment and about the validity of the model used to assess the secondary poisoning. It is suggested that QS proposed in the WFD report are re-assessed in the light of these comments.

Human health assessment

Since human Cd exposure from a number of sources is rather high and close to concentrations which may cause adverse effects (MOS <10) any QS needs to be well justified. The recent RAR and the CSTEE comments on the RAR should be considered.

9. C10-C13 chloroalkanes

Environmental assessment

The CSTEE notes that the WFD report concludes that biomagnification is relevant for the derivation of the QS for secondary poisoning. The CSTEE suggests that the proposed QS for secondary poisoning should be based on biota concentrations and the application of the more appropriate biomagnification models that we refer to in the Opinion on 'Marine TGD' and 'Chloroalkanes'.

The CSTEE has produced an opinion on the RAR for this substance (Opinion on Alkanes, C10-13, chloro {SCCP}, 6th CSTEE plenary meeting, 27 November 1998).

Human health assessment

The CSTEE notes that QS referring to food uptake by humans and drinking water abstraction, the WFD report is based on a recent EU-risk assessment report. The conclusion that these quality standards are far higher than standards needed to protect the aquatic community and are therefore not integrated into definition of the, is supported by the CSTEE.

10. Chlorfenvinphos

Environmental assessment

The CSTEE has concerns about the proposed QS values as it questions the manner in which some data were used/treated: the use of an time weighted average concentration in the mesocosm study, the inconsistency (across substances) of the application of an assessment factor on the mesocosm NOEC, and the selected mammalian NOEC for deriving the QS for secondary poisoning is not ecologically relevant.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

11. Chlorpyrifos

Environmental assessment

The CSTEE agrees with the proposed QS.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

12. 1,2 dichloroethane

Environmental assessment

The CSTEE questions the validity of the presence of this substance on the priority lists considering the very low toxicity, the rapid dissipation due to volatilisation and potentially biodegradation and the lack of bioaccumulation potential. The CSTEE notes that the NOEC used to derive the PNEC derived in the COMMPS is no longer considered valid in the present WFD document.

Human health assessment

The CSTEE notes that a quality standard for drinking water (10 µg/l) is already set by present regulations for 1,2-dichloroethane. The CSTEE agrees with procedures and the values proposed in the human health assessment.

13. Dichloromethane

Environmental assessment

The CSTEE questions the validity of the presence of this substance on the priority lists considering the very low toxicity, the rapid dissipation due to volatilisation and potentially biodegradation and the lack of bioaccumulation potential. The CSTEE notes that the NOEC used to derive the PNEC derived in the COMMPS is no longer considered valid in the present WFD document.

Human health assessment

The CSTEE would like to state that – unlike reported in the WFD document - oral toxicity data for dichloromethane are available.

14. Di(2ethylhexyl)phatlate (DEHP)

Environmental assessment

The CSTEE notes that the report is based on the RAR and that it has already commented on the fact that toxicity data for fish exposed via food and data on sediment dwelling organisms were not used in the RAR and that no justification was provided (Opinion on the Risk Assessment of Bis (2-ethylhexyl) phthalate (DEHP), 29th CSTEE plenary meeting, 09 January 2002). The key element for the assessment, secondary poisoning due to the

bioconcentration-biomagnification potential, is not properly addressed. Some inconsistencies on data presentation (fish, birds and mammals oral toxicity) and on the selection of values have been found. In particular, the direct use of the human health NOAEL without considering its ecological relevance, not using the BCF observed for freshwater invertebrates, and the assumption of no biomagnification potential based on data not yet evaluated are issues of concern. The CSTEE suggests the derivation QS for biota and sediments (instead of water) would be more appropriate.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

15. Diuron

Environmental assessment

The CSTEE is of the opinion that the QS values for diuron are correctly derived in a transparent and scientifically justified manner.

Human health assessment

The CSTEE finds that QS for food uptake proposed in the report is not supported by data.

16. Endosulfan

Environmental assessment

The CSTEE is of the opinion that the QS values for endosulfan are correctly derived in a transparent and scientifically justified manner.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

17. Fluoranthene

For the environmental and human health assessment the CSTEE recommends the group approach.

Environmental assessment

Clarification on some values (e.g. EC50 growth for Mulinia and endpoint of the mammalian NOAEL) is required. The report properly assesses the relevance of sediment dwelling organisms and that the equilibrium partitioning method is not suitable; however, as the endpoint of the sediment toxicity tests is mortality the CSTEE suggests that sublethal NOECs on sediment dwelling organisms should be required for setting the QS. Additional modelling possibilities for setting the bioaccumulation potential should be explored.

Human health assessment

The CSTEE agrees with procedures proposed in the human health assessment.

18. Hexachlorobenzene

Environmental assessment

The CSTEE has some concerns on the reliability of the selected effect data and notes that the data set is incomplete. It is suggested that a specific assessment of exposure via food for all organisms should be performed.

The CSTEE does not support the proposed MAC-QS due concerns expressed in the response to question 1. The approach used to derive the QS for secondary poisoning is acceptable, but it is suggested - as the factors refers to muscle concentration and whole body will be higher - an additional correction is required. It is suggested to keep the QS based on concentration in biota, rather than the one proposed for water. The equilibrium partitioning method for the derivation of the sediment QS is not acceptable.

Human health assessment

Limited data are presented, however, the CSTEE agrees with the proposed NOAEL.

19. Hexachlorobutadiene

Environmental assessment

The CSTEE notes that the acute effects data clearly indicate that the aquatic invertebrates are the most sensitive organisms. However, no experimental chronic data were used to derive the QS. As such the CSTEE is of the opinion, despite the fact that the PNEC was derived using TGD procedures, that the proposed QS for this priority substance cannot be supported (see response to question 1).

Human health assessment

In the quality standard for food uptake, the consultant bases his calculations on a tolerable daily intake of 0.2 µg/kg b.w., which is a WHO (World Health Organisation) drinking water standard. This standard seems to be based on a rat study with a NOAEL for kidney toxicity of 0.2 mg/kg/day (Kociba et al., 1977) with a safety factor of 1000. The approach used is acceptable for deriving a QS.

20. Exachlorocyclohexanes

Environmental assessment

See recommendation on lindane, option 2.

Human health assessment

The CSTEE notes that published data from rodent studies indicates that the β-isomer has different target organs/cells as compared to lindane and it does consider to have not a similar mode of action.

21. Lindane

Environmental assessment

The CSTEE points out that lindane is a banned substance since 2002 and as such does not understand why QS should be established. If QS are to be established, the CSTEE agrees with option 2 proposed in the document. The CSTEE has concerns that the lowest NOEC used to derive the QS is based on a behavioural endpoint. The reproductive effect endpoint is an order of magnitude higher. We also note that are observations on sediment dwelling organisms that are not considered.

Human health assessment

The CSTEE agrees with procedures and the values proposed in the human health assessment.

22. Isoproturon

Environmental assessment

The CSTEE notes that both for the derivation of the MAC-QS and the marine QS conventional TGD assessment factors were not used. The justification given in the report is considered to be valid. The CSTEE supports the proposed QS.

Human health assessment

Insufficient information is given to allow an assessment.

23. Lead and its compounds

Environmental assessment

The CSTEE notes that some data collected in the context of the ongoing voluntary EU RAR on Pb have been used to prepare the WFD report. The CSTEE would like to express concerns about the following issues: lack transparency of the effects data relevance/quality screening (i.e;. it is not clear how and what type of 'plausibility/validity' checks were made, the absence of bioavailability considerations/corrections, validity of some of the models (e.g. the EQP (Equilibrium Partitioning method) for sediment QS and the model used to calculate secondary poisoning) and the validity of the assessment/extrapolation factors used.

Human health assessment

Conclusions are based on a PTWI (Provisional Tolerable Weekly Intake). Legal drinking water limits are in place.

24. Mecury and its compounds

See response to question 7.

Human health assessment

As outlined in the document, a water quality standard for mercury could not be defined because the numbers for proposed standards by involved stake holders differ by a factor of 12 500. This is due to the many uncertainties regarding transformation of inorganic mercury to methyl mercury and the bioaccumulation of methyl mercury in fish. Due to the many uncertainties, the CSTEE concludes that a water quality standard for mercury cannot be defined based on defendable scientific argumentation due to the many uncertainties and knowledge gaps. The complexity of the issue is well outlined in the Water Quality Criteria for the Protection of Human Health for Methyl Mercury published by the US EPA in 2001. Due to the many uncertainties, the US EPA did not develop a water quality criterion for methyl mercury regarding human health effects due to fish consumptions. Instead, the US EPA developed a maximum residue level tolerable in fish for human methyl mercury exposure. In Europe, more than 90 % of human exposure is to methyl mercury from dietary sources, mainly fish and residue level have been set (which may not be totally protective based on the US EPA evaluation of the available human epidemiology). This approach may also be appropriate to follow in the context of this document regarding indirect effects on humans due to methyl mercury consumption from fish.

Quality standards to protect aquatic organisms may be based on effects of inorganic mercury in the approach defined in the TGD.

25. Naphthalene

For the environmental and human health assessment the CSTEE recommends the group approach.

Environmental assessment

The CSTEE notes that this WFD document mainly refers to the data described in the RAR on Naphthalene that was already object of an Opinion of CSTEE approved February 22nd 2002. Some comments made in the Opinion are also applicable to this WFD report.

The CSTEE accepts the proposed QS despite the fact that the justification for not using one of the NOECs was not clear. The CSTEE found that this apparent inconsistency did not affect the outcome of the assessment.

Human health assessment

A recent RAR on naphthalene has been used but the CSTEE does not support that an individual QS should be set. See response to question 6.

26. Nickel and its compounds

Environmental assessment

The CSTEE notes that the data proposed in the (interim) assessment of the ongoing EU RA on Ni have been used to prepare the WFD report. The CSTEE would like to express concerns about the following issues: lack transparency of the effects data relevance/quality screening, the absence of bioavailability consideration/corrections, validity of some of the

models (e.g. the EQP for sediment QS and the model used to calculate secondary poisoning) and the validity assessment/extrapolation factors used.

Human health assessment

The assessment uses a NOAEL from a two generations reproduction study which needs to be adequately referenced. The approach can be supported by the CSTEE.

27. Nonylphenol

Environmental assessment

The CSTEE notes that this WFD document is mainly based on the RAR on Nonylphenol. It is suggested that the document is updated since a considerable amount of new information on this substance – including an US RAR – has become available. Considering the large amount of toxicity data and a mesocosm NOEC of 5 µg/l does not support the use of an assessment factor of 10 to the lowest single species NOEC (3.3 µg/l).

Human health assessment

The CSTEE notes that the WFD report is based on the RAR. The CSTEE did not comment on the HH parts in their opinion of March, 2001.

The CSTEE agrees with procedures and the values proposed in the human health assessment. New information on HH is available in the recent US RAR.

28. Octylphenol

Environmental assessment

The CSTEE notes that the dataset used in this WFD document is based on the draft UK RAR that was not evaluated by us. On that basis the CSTEE can do no more than note the proposed QS.

Human health assessment

The CSTEE notes that almost no toxicity data are reported in the WFD document. However, the CSTEE finds that a tentative risk assessment ought to have been done for example using the two-generation reproduction study in rats by Tyl et al (1999) as it would have been useful in the comparison with the ecotoxicological quality standards. Despite this shortcoming, the CSTEE agrees that the quality standards for the protection of the pelagic communities would probably be lower than a standard based on health effects due to ingestion of food or drinking water.

29. Pentachlorobenzene

Environmental assessment

The CSTEE believes that the proposed QS should be reconsidered for the following reasons. The relevance of the NOEC for aquatic organisms and mammals is unclear and has not been assessed. The report indicates no difference between freshwater and marine

organisms but still uses the additional factor of 10 as specified by the TGD. Additionally the CSTEE suggests that the bioaccumulation studies should be carefully evaluated and that an appropriate bioaccumulation/biomagnification model is developed (see previous on TGD revision).

Human health assessment

The approach is based on a NOAEL from a 90-day rat study. The assessment should justify why an uncertainty factor of 100 was used. Without this justification the CSTEE has concerns about the proposed QS.

30. Pentachlorophenol

Environmental assessment

The CSTEE notes some deficiencies in this WFD document. The main concerns are: incomplete data sets, unclear data quality and relevance evaluation (for freshwater, sediments and mammalian data) and the application of an assessment factor of 4 to the 5th percentile of the SSD (freshwater). The CSTEE has concerns about the proposed QS.

Human health assessment

The CSTEE notes that no HH QS were developed. The WFD report states that no data relevant for human health effects after oral exposures are available. However, recent summaries the toxicology of pentachlorophenol are available from ATSDR (Agency for Toxic Substances and Disease Registry) as a „Toxicological Profile“and a reference dose has been developed by the US EPA in IRIS (Integrated Risk Information System).

31. PAHs: B(a)P, B(b)F, B(k)F, B(g,h,I)P, I(1,2,4,cd)P

For the environmental and human health assessment the CSTEE recommends the group approach.

Environmental assessment

The CSTEE recognizes that, in general, there is a lack of appropriate toxicity and physico-chemical data for most PAHs. As such it is difficult to derive precise and fully justified QS. We can understand why it is being suggested that an interim standard for B(a)P is being proposed given the research effort required to establish group standards. We refer to the response to question 6.

Human health assessment

The CSTEE notes that information on the mutagenic and carcinogenic properties of the five PAHs listed in the WFD documents are correctly reported as described by IARC 1983. This also holds for anthracene, fluoranthene and naphthalene. However, the CSTEE in its opinion of June 12th 2001 proposes to consider at least 16 PAHs usually present in environmental compartments and apply toxicological equivalent factors to characterize the toxic potency of the mixture. The sum of calculated toxic equivalents provides an estimate of the mixture’s toxic potency. These TEF are derived from toxicological studies in animals and have been designed for PAH mixtures in air. IPCS (1998) stated that they may not be

applicable for PAHs taken up via food. CSTEE recommends to evaluate the relative toxicities of PAHs via oral exposure and establish TEFs to better estimate the combined health impact of PAHs in food and drinking water and to set a QS for the mixture of commonly found PAHs in drinking water.

32. Simazine

Environmental assessment

The evaluation of the available data should be reconsidered. In particular, the relevance of the microcosm/mesocosm studies for setting the QS, and the consideration of the mechanism of action when setting the SSD. Several recommendations for refining the assessment are proposed. It should be also noticed that the report presents discrepancies with the methodology proposed in the manual, in some cases, the discrepancies are in line with the recommendations of the CSTEE (e.g. using chronic NOECs for setting MAC-QS). The CSTEE recommends using consistent approaches among the different substances. The recently submitted reports support the CSTEE recommendations.

Human health assessment

The assessment uses an ADI from a carcinogenicity study of the non-genotoxic agent. The ADI should be supported by a more detailed description. If the ADI is supported, the CSTEE agrees with the approach.

33. Tributyltin compounds

Environmental assessment

The CSTEE notes a number of deficiencies in this WFD document. The main concerns are: unclear data selection (endpoints not reported) for application of the SSD approach, the rejection of the values derived from the SSD analysis, the fact that bioaccumulation was not considered from the derivation of the QS for secondary poisoning. The CSTEE recommends reappraisal of the proposed QS.

Human health assessment

A number of organotins are present in the water. Therefore, the other organotins need to be evaluated with the option of setting a group standard (see upcoming CSTEE opinion).

34. Trichlorobenzenes

Environmental assessment

The CSTEE notes that this WFD document mainly refers to the data described in the RAR on Trichlorobenzenes that was already object of a CSTEE Opinion (1,2,4-Trichlorobenzene CAS N° 120-82-1 20, 25th CSTEE plenary meeting, July 2001). The amount and quality of information for effect assessment was considered acceptable.

The CSTEE finds that procedures used to derive the QS for surface waters, sediments and secondary poisoning are acceptable. However, the MAC-QS (ECO) should be reconsidered

as the use of acute toxicity data for deriving MAC-QS for chemicals with a bioaccumulation potential may not be appropriate. See response to question 1.

Human health assessment

The CSTEE notes that the HH data are taken from the RAR. The CSTEE has agreed on the conclusions of the RAR regarding cancer and mutagenicity and the NOAEL. As such, the CSTEE agrees with procedures and the values proposed in the human health assessment.

35. Trichloromethane

Environmental assessment

The rationale for the derivation of the critical value of 12 ug/l in Directive 86/280/ECC should be provided. The CSTEE supports the fact that conventional TGD assessment factors were not used for the marine QS derivation. The CSTEE supports the derivation of a QS for sediments and the proposed PNEC for the sediment compartment.

Human health assessment

See response to question 2, group 2.

36. Trifluralin

Environmental assessment

The CSTEE notes a number of deficiencies in this WFD document. The main concerns are: unclear toxicity data quality and relevance evaluation, lack of data on environmental dissipation, several issues concerning secondary poisoning and bioaccumulation. The CSTEE recommends reappraisal of the proposed QS.

Human health assessment

The CSTEE notes that no QS is calculated since trifluralin is not labelled with R-phrases that trigger derivation of a QS for HH by fish consumption despite a BCF for fish of 6000. The CSTEE questions this approach and suggest that (at least) a better justification for not deriving a QS is given.