SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)
Opinion on

(I) Some practical implications of the proposed modification to the Water Framework Directive (Annex V) and

(II) Procedure for selection of priority substances with a view to the establishing of a list of Community priority substances

Opinion adopted by written procedure on June 5, 1998

PREAMBLE

The Scientific Committee was in unanimous agreement that the Directive represented an advance over previous legislation in using ecological effects as a basis of control rather than focussing on agents with a potential for adverse effects. The assessment of quality is therefore in terms of the functioning and structure of ecological systems, rather than chemical contamination. On the other hand, defining ecological quality, for communities and ecosystems, is not currently possible from scientific first principles. This means the approach has to be pragmatic and be based fundamentally on the judgements of scientists concerning the levels of quality from "good" to "poor". The implication of this is that the definition of status has to be through the establishment of reference conditions. This will require transparency and careful attention to the design of the sampling programmes and statistical analysis. In our view this should be subject to critical peer review, and be underpinned by a supported research programme.

A. ECOLOGICAL STATUS OF SURFACE WATERS

Terms of reference

The opinion of the Committee is requested on whether the formulation of the normative definitions of high, good and fair ecological status of surface waters is scientifically sound. The opinion of the Committee is further requested on whether the normative definitions specify in a sufficient clear way the borderlines between what is considered a body of water of "high", "good" and "fair" status. Furthermore, the Committee is also requested to comment on the terminology used.

General comments

1. The Working Group acknowledges a number of scientific problems associated with the intent of the Directive as specified in Articles 1 and 4: in particular in defining ecological quality and distinguishing between levels of it from «high» to «fair». This should encourage more fundamental research into defining «functional sustainability» of ecosystems and of specifying the relationship between it and structural characteristics.

2. Within the context of implementing the Directive, most of these issues will be avoided by use of reference sites as normative standards and by measuring deviations from them. Care will be needed in choosing and characterising appropriate sites and in

designing programmes with sufficient power and precision to pick up significant deviations in systems that are likely to show considerable natural variability through space and time.

3. There will be an issue about the extent to which deviations are technique specific. This will need to be considered in pilot studies, that determine the extent to which sensitivity adjustments will be called for. Apparently good correlations between techniques compared in preliminary programmes are encouraging.

4. There will also be issues concerning: how much deviation should signal a change in quality (especially good to fair); and if the same change in structure between «norm» and «observed» (say a 20 % reduction of species) means the same thing in different systems. These revolve around questions concerning the relationship between structure and function. They might be resolved practically by looking for correlations between species compositions and long-term stability and/or by developing a better understanding of the relationship between structure and function (see §1)

Comments on Article 2 of the Directive

Under Article 2 of the Water Framework Directive, all definitions needed for the understanding of the subsequent articles of the Directive are given. In particular, preliminary definitions of ecological status are given. These definitions are sufficiently clear and scientifically sound, and appear adequate at this point of the Directive, where only relatively general statements are needed. Nevertheless some amendments are suggested.
It is usual to make a distinction between contaminants - introduced by human activity but at levels not likely to have harmful effects - and pollutants - contaminants present at levels likely to have harmful effects, i.e. cause pollution. Such a distinction could be made more explicit in definitions 27 and 28 in Article 2. Moreover, since the intention is to eliminate pollution not contaminants (pollutants), i.e. to eliminate harmful effects not necessarily potentially harmful substances (as specified in Recital 18a) in achieving objectives (Article 4), then the wording in Article 13 para 3a is misleading:
"For basic measures covering elimination of ***pollutants***"
would better read
"For basic measures covering elimination of ***pollution***"
Referring to other definitions included in Article 2, an amendment could be suggested at point 6, defining the " Fresh water limit". Instead of "an appreciable increase in salinity", a more precise quantitative threshold could be suggested, based on a defined quantitative value (e.g. an increase of 1g/l of TDS or an increase of 100% compared to medium values of TDS in the river).
If this is not the right point for a quantitative statement, it could be stated in a suitable Annex.
There are no suggestions for the definition of the outer (seaward) limits of estuaries, to be defined by Member States. This could create some problems for the normative definitions of coastal waters (see below).

Normative definitions in Annex V

General comments

The division into four classes is adequate. Probably this could be the right position for a more precise definition of surface water typology.

The definition of ecological water status on the basis of biological, hydromorphological, chemical and physico-chemical parameters is adequate.
Taking into account that differences between high and good status are relatively small**,** in evaluating the suitable methods for monitoring, it might be appropriate to use other ecologically relevant indicators of exposure and effect, besides traditional biological approaches.
In evaluating the suitable methods for monitoring hydrological regimes, especially for rivers, which are subject to impoundment or water abstraction, reference should be made to specific models to calculate minimum flow for the maintenance of natural communities.
Finally, general terms like "slight", "moderate", "significant" should be better defined and it should be made clear if the statistical and/or ecological senses are intended. The quantification of changes depends on the methodology used for the evaluation of the ecological status, which, in some cases are not yet available, at least in standardised form. The quoted terms should be quantitatively defined in function of the methods used.

1.1.2. Normative definitions

Table 1.1.2.1: Normative definitions for high, good and fair ecological status in rivers

General
The proposed definitions are adequate

Biological elements
Aquatic flora
In many European rivers phytoplankton is not a relevant component of the ecosystem. The presence of phytoplanktonic algae is in general the result of drift from lakes or from low-flow stretches of the river. Therefore, the evaluation of the status of a phytoplanctonic community could be problematic and could be not very relevant in defining the ecological status of the river. Moreover, the effects on aquatic flora of the quality of the river system can be better determined through the study of macrophytes and phytobenthos.
Thus, the evaluation of phytoplancton may be suggested only for particular conditions (very large rivers, dead zones).
The definitions for high, good and fair ecological status for macrophytes and phytobenthos are adequate.
Fish fauna
The definition of good quality is not comparable with other biological elements. It seems that more relevant changes are accepted for the fish community in comparison to flora and to invertebrates.
The following amendment are suggested:

> " Only slight changes in species composition, abundance, biomass and age structure, compared to type-specific conditions, are allowed, even if it could be accepted that a few typical species are missing (except for "keystone" species for the autochthonous community and endangered species).
> The presence of species untypical of the ecotype or stocked species must not significantly interfere with the autochthonous fish population."

In the definition of fair quality, there is a discrepancy between the first sentence (Some species or a whole group of species are missing) and the third sentence (A moderate

proportion of the expected sensitive species....). The first seems stronger than the third. We propose the following amendment:

> "There would be a significant/moderate change in species composition, abundance, biomass and age structure.
> A moderate proportion of the expected sensitive species would be absent or of very low abundance.
> The reproduction of some species can be significantly affected.
> Species untypical of the ecotype or stocked species can be found which significantly interfere with the autochthonous fish population."

Benthic invertebrate fauna
The definition of good quality is adequate.

Hydromorphological elements
Definitions are adequate. In rivers, which are subject to impoundment or water abstraction, reference should be made to specific models to calculate the instream flow needs.

Chemical elements
For the definition of good quality for substances under Annex VIII not included under general parameters, it is better to use environmental quality standards instead of NOEC (acute, chronic?). The following amendment are suggested:

> "Concentrations not exceeding environmental quality standards[2] without prejudice to Directive 91/414/EC. (≤ eqs)"

[2] Established according to the procedure established in section 1.1.2.5

Table 1.1.2.2: Normative definitions for high, good and fair ecological status in lakes

For fish fauna and for chemical elements the same amendments as for rivers are suggested.
Other definitions are adequate.

Table 1.1.2.3: Normative definitions for high, good and fair ecological status in estuaries

Biological elements
Aquatic flora
The definition of good quality for phytoplancton is the same as for lakes, but, in the case of lakes, it is referred to the whole aquatic flora, while, in this case, it is referred only to the phytoplanctonic component. Thus, we suggest deleting the sentence: "and higher forms of plant life".
Nevertheless, the possibility of accelerated growth or changes in species composition due to eutrophication, at least in the shallow parts of the estuary, should be taken into account also for macroalgae and angiosperms. Thus, we suggest changing the definitions of good and fair quality for these elements as follows:

> Good quality (Macroalgae, Angiosperms)
> "Only slight changes in the expansion and species composition and abundance compared to type-specific conditions.

No significant changes (increase or decrease) in biomass due to anthropogenic activity."

Fair quality (Macroalgae, Angiosperms)
"Species composition and abundance significantly differ from type-specific conditions.
Significant changes (increase or decrease) in biomass due to anthropogenic activity."

Benthic invertebrate fauna
The definition of quality refers to high number of taxa. Compared to what? In general, transition ecosystems (such as estuaries) are characterised by a reduced diversity in comparison to other systems (e.g.: rivers, coastal waters). We suggest the following amendments:

High quality
"The number of taxa, total abundance and biomass correspond totally or nearly totally to type-specific conditions.
Typical/key indicator species of unimpacted state would be present."

Good quality
"Only slight changes in the number of taxa, total abundance and biomass compared to type-specific conditions.
Most typical/key indicator species of unimpacted state would be present."

Fair quality
"Significant/moderate changes in the number of taxa, total abundance and biomass compared to type-specific conditions.
Species indicative of impact (for example organic pollution) would be present."

Fish fauna
Also in this case, it seems that for fish higher changes in quality could be accepted. We suggest a few changes in the definitions:

Good quality
"Sustainable resident fish populations with slightly changed composition, reduced abundance and biomass.
Sustainable fisheries exist upstream, also if a slight hindrance to fish migration could occur.
Sustainable nursery fishery, only slightly below optimal recruitment."

Fair quality
"Resident fish population significantly changed in composition, abundance and biomass.
Significant hindrance to fish migration, fisheries upstream significantly affected.
Fish breeding significantly affected."

Chemical elements
For chemical elements the same amendments as for rivers are suggested.

Table 1.1.2.4: Normative definitions for high, good and fair ecological quality for coastal waters

General
The proposed definitions are adequate

Biological elements
Only the aquatic flora is taken into account in the proposal. The complexity of the marine biota and the variety of communities could justify this, also in function of the structure of the substrate (sandy, rocky, etc.). Moreover, there is a lack of standard methods for the evaluation of community structure and functions comparable to those available, for example, for rivers. Nevertheless, at least benthic invertebrates should be mentioned.
Aquatic flora
Phytoplancton
It is true that chlorophyll concentration must be *in general* very low. Nevertheless, in particular situations, such as shallow coastal areas, areas influenced by river inputs, etc., higher productivity may occur also in unimpacted coastal waters. This is also matter of the extension of the outer (seaward) limits of estuaries, to be defined by Member States, but without any suggestion in the definitions of Article 2 of the Directive. How large could be an estuary in shallow coastal areas?
The mention of the Mediterranean as an example could be adequate because it is a naturally oligotrophic sea, but some naturally productive areas are present in the Mediterranean too. Even if historical records are taken into account, before pollution phenomena of the last decades, chlorophyll and transparency of Italian Northern Adriatic are not comparable to values typical for Thyrrenian Sea.
We suggest the following amendments:

> High quality
> "Concentration of Chlorophyll-a (μg/l) is, in general, very low (for example in the Mediterranean <1μg/l); for naturally productive areas (e.g.: shallow waters, areas close to estuaries, etc.), it is adequate to the natural trophic status.
> No exceptional phytoplanctonic blooms.
> High transparency (for example in the Mediterranean >20m) with the exception of naturally productive areas (see above)."
>
> Good quality
> Definition is adequate. Delete the sentence "or higher forms of plant life".
>
> Fair quality
> "Significant increase of concentration of Chlorophyll-a compared to the type-specific natural condition.
> Occurrence of phytoplanctonic blooms.
> Significant reduction of transparency."

Macroalgae and angiosperms
Besides the sentence on indicator species, a sentence on community composition and abundance could be added. We suggest the following amendments:

> High quality

"Species composition and abundance correspond totally or near totally to type-specific natural conditions.
Presence of indicator species (of unimpacted conditions) with very high density."

Good quality
"Only slight changes in the species composition and abundance compared to type-specific conditions.
Presence of indicator species (of unimpacted conditions) with high density."

Fair quality
"Species composition and abundance significantly differ from type-specific conditions.
Presence of indicator species (of unimpacted conditions) with medium density."

Benthic invertebrate fauna
We suggest including the following definitions:

High quality
"Species composition and abundance correspond totally or near totally to type-specific natural conditions."

Good quality
"Only slight changes in the species composition and abundance compared to type-specific conditions."

Fair quality
"Species composition and abundance significantly differ from type-specific conditions."

Hydromorphological parameters
Alterations of hydromorphological parameters in coastal waters depend mainly on structures such as harbours, marinas, dams, piers, wharves, etc., capable to modify natural conditions either directly (by modifying the structure of the sea shore) or indirectly (through alterations of current and tide regime, affecting coastal erosion or sediment deposition, etc.).
This is not completely clear in the definitions. These could be simplified by grouping the three parameters (Hydrological regime, Continuity and Morphological elements) in a single definition. In this case, the definition of high quality could indicate coastal areas completely free from human changes. This is not unrealistic, as for rivers or lakes, because many stretches of European coasts are totally unaffected by hydromorphological changes of human origin.
Finally, definitions of good and fair quality should not refer only to the biological community, taking into account the difficulties to define it in the marine ecosystems.
We suggest he following amendments:

Hydrological regime, Continuity and Morphological elements

High quality
"The structure of the sea shore reflects totally the natural conditions, without any human intervention capable to modify directly the shoreline, to alter the continuity of the ecosystem, to modify water regime (tides, currents) and sediment deposition"

Good quality
"The natural structure of the shoreline is moderately changed by human installations.
These installations does not alter significantly water and sedimentation regimes, does not interrupt the continuity of the system in such a way to produce significant obstacles to migrations of biota."

Fair quality
"The natural structure of the shoreline is significantly changed by human installations (piers, wharves, etc.).
The water and sedimentation regimes may be significantly modified.
The biological community may be significantly affected by these changes."

Chemical elements
For chemical elements the same amendments as for rivers are suggested.

1.1.2.5 Procedure to be followed for the setting of chemical quality standards

The proposed procedure is based on the application of safety factors on a relatively reduced set experimental data and is comparable to other procedures proposed for setting environmental standards or objectives (see for example CSTE, 1994). Nevertheless, at least a major criticism could be made.
The concept that long term data on only one or two organisms could be used, with an appropriate safety factor, may be accepted only for non-specific toxicants. For chemicals with specific mode of action or acting as biocides on a specific target, such as pesticides, long-term data are compulsory for the more sensitive organism.
Moreover it must be specified that field data or model ecosystems must be referred to a specific body of water.

Conclusions

With the proposed amendments, the normative definitions of high, good and fair status may be considered as adequate. Nevertheless, one must be aware that these are "general" definitions.
For practical, regulatory purposes, there is the need for more precise and quantitative definitions of environmental quality, even if, on a strictly scientific point of view, severe objections could be made on this rigid and pragmatic approach.
In other words, there is the need for standard methods, capable to express quantitatively, (in enough acceptable terms) the structure and function of ecosystems. In some cases (as for invertebrate benthic fauna of rivers) some acceptable, standardised and enough reliable methods still exist, but for some natural communities suitable methods must be developed.
This aspect must be clarified in defining the methodology for monitoring. In function of this methodology and of the precise and quantitative definition of reference conditions, threshold values of EQR for the different quality levels may be set up.

B. STATUS OF GROUNDWATER

Terms of reference

The opinion of the Committee is requested on whether the formulation of the definition good quantitative and chemical status of groundwater is scientifically sound and whether the definition is sufficiently clear to determine whether a body of groundwater complies with the required good status and to ensure at least the same level of protection as existing Community legislation, and in particular the Groundwater Directive (Council Directive 80/68/EEC)

Introduction.

The proposal establishes two basic aspects for groundwater that must be protected: quantity and quality.
Quantity is considered under the Quantitative groundwater status, defined as an expression of the degree to which a body of groundwater is permanently depleted by direct and indirect abstractions and alterations to its natural rate of recharge.
The environmental objective required to meet (Article 4) is good quantitative status, defined in terms of long-term sustainable natural recharge. Sustainability is referred to the ecological quality in associated surface waters and as potential damage to associated terrestrial ecosystems.
Quality is considered under the Groundwater chemical status, defined as an expression of the degree to which a body of water is polluted. In addition, pollution is defined in terms of harmful to (human health and) the quality of the environment. This formulation could be confusing for groundwater, as no specific definition for «quality of the environment» is included.
The environmental objective required to meet (Article 4) is good chemical status, defined in terms of comparison between the concentrations of pollutants and their environmental quality standards. Concentrations should not exceed the standards and monitoring data should not suggest that the standards could be exceeded in the future.

Comments

The objectives for groundwater protection also cover the protection of the associated surface waters, wetlands and terrestrial ecosystems. This point is specifically covered regarding the quantitative status. Both, the formulation and the monitoring programme focus on the sustainability of the associated ecosystems.
However, the situation is absolutely different regarding quality. The concepts of «ecological quality» defined for surface waters, as their capability to maintain ecosystems (populations) cannot be applied to groundwater. In fact, no additional information on the rationale for this proposal has been included if the provided information.
The quality of groundwater is therefore only defined by the chemical status. In my opinion the selection of a restricted list of pollutants in not enough for the protection of groundwater and associated ecosystems.

Proposal.

An additional parameter, toxicity to aquatic organisms, should be included to cover the potential risk of non-detected pollutants and synergistic effects due to mixtures of several pollutants. The parameter should be considered as an additional aspect «toxicological status».
The definition of an additional condition: «groundwater quality status» is proposed. This condition should incorporate the physicochemical parameters included in the quantity status, the specific reference for nitrates and chlorides-conductivity, the chemical status and the toxicological status.

The toxicological status should be evaluated by the current methodologies for ambient water toxicity tests. The use of concentration-fractionation procedures should be considered for the specific detection of persistent and bioaccumulable pollutants. The environmental objective for high status should be no toxicity in concentrated and no concentrated samples. The environmental objective for good status should be no toxicity (either acute or chronic) in non concentrated samples, and less than 50% of effect in acute toxicity tests for samples concentrated by a factor of 1000, and no effect in chronic toxicity tests for samples concentrated by a factor of 10.

C. SUBSTITUTION OF THE SURFACE WATER DIRECTIVE (COUNCIL DIRECTIVE 75/440/EEC), THE FISH WATER DIRECTIVE COUNCIL DIRECTIVE 78/659/EEC) AND THE SHELLFISH WATERS DIRECTIVE (COUNCIL DIRECTIVE 79/923/EEC)

C.1) THE SURFACE WATER DIRECTIVE (COUNCIL DIRECTIVE 75/440/EEC)

Terms of reference

The opinion of the Committee is requested on whether the definition of good ecological status ensures at least the same level of protection as the Surface Water Directive as regards the implications for compliance with the Drinking Water Directive.

General comments

A first question is: to which category of water according to Directive 75/440 (A1, A2, A3) should a good ecological status, defined by the Water Framework Directive, correspond? Reasonably, it should be A1, even if at least for some toxic compounds some discrepancies between A1 category of Directive 75/440 and levels required by the Drinking Water Directive (80/778/EEC) exist. It must be emphasised that A1 water may be used for drinking purposes after a simple filtration and disinfecting. This treatment doesn't have any effect on toxic microcontaminants. For example, for pesticides, the limit of Directive 75/440 is 1 μg/l, not in agreement with the 0.1 μg/l limit of Directive 80/778.
Having regard to both Directives, some preliminary comments should be made.

A) Comments similar to those made for the Shellfish Directive below can be made. In the Water Framework Directive, there is no mention of the control of microbiological parameters. It is obvious that, if all other pollution parameters are controlled, the probability of a relevant faecal contamination is remote, but possible. Thus, for water bodies intended for abstraction of drinking water this aspect is extremely important. Therefore, microbiological controls must be included at least for waters intended for this purpose.

B) Taking into account physico-chemical parameters of Directive 80/778, some levels considered as undesirable for drinking water (see for example, Ca, Mg, total hardness, etc.) may naturally occur in surface fresh water without any relevant adverse effect for biological communities. Therefore, good quality water, according to the new Directive, need not be perfectly suitable for drinking purposes.

C) For some toxic substances, Directive 80/778 is based on the "precautionary principle"; in particular, for pesticides. The Maximum Admissible Concentration (MAC) of 0.1 μg/l could

be, for some pesticides, far below an ecotoxicologically based Water Quality Objective, even if, for other pesticides, the WQO can be lower than 0.1.

C.2) THE FISH WATER DIRECTIVE (COUNCIL DIRECTIVE 78/659/EEC) AND THE SHELLFISH WATERS DIRECTIVE (COUNCIL DIRECTIVE 79/923/EEC)

Terms of reference

The opinion of the Committee is requested on whether the definition of good ecological status ensures at least the same level of environmental protection as the Fish Water Directive and the Shellfish Waters Directive.

The Fish Water Directive

The Fish Water Directive (76/659/EEC) is based on the definition of water quality for two typologies of fresh water bodies (Salmonid and Cyprinid waters) in respect of a series of physical and chemical parameters. No mention is made of the biological and hydromorphological parameters.
On a strictly physico-chemical basis, the Water Framework Directive should ensure a comparable level of protection, because the definition of good quality refers to environmental quality standards for general physico-chemical parameters and for specific pollutants. Obviously these standards must be established in order to ensure, for the different type-specific biological communities, the same level of protection of the previous directive.
Moreover, the Water Framework Directive is strongly oriented toward the control on ecological quality, on the basis of biological parameters and takes into account the role of hydromorphological parameters that must be such as to ensure a negligible/moderate deviation of the biological community in comparison to reference conditions. In theory, this should ensure a higher level of environmental protection.
Nevertheless, to make this level of protection real and not only theoretical, the points highlighted in the final recommendations must be carefully evaluated.

The Shellfish Waters Directive

The requirements for water quality in the Shellfish Water Directive (79/923/EEC) are based on some physico-chemical and microbiological parameters.
Taking into account the terms of reference, it seems implicit that only waters classified as "good ecological status" could be used for shellfish production or fishing.
The definition of good ecological status, in particular for estuaries and coastal waters, ensures a level of environmental protection much higher in comparison to those required by the previous Directive.
Nevertheless, in the Water Framework Directive, there is no mention of the control of microbiological parameters. The same comments apply then as for drinking water, and microbiological controls must be included also for waters intended for shellfish production and fishing.
Moreover, the problem of toxins produced by algae is of growing concern in many European coastal waters. In waters of good ecological status the likelihood of problems due to these toxins should be low. Nevertheless, the presence of toxic algae is not necessarily incompatible with the definition of good ecological status. Therefore, the control of algae toxins must also be included for waters intended for shellfish production and fishing.

D. MONITORING REQUIREMENTS OF ANNEX V

Terms of reference

The opinion of the Committee is requested on the adequacy of the proposed monitoring requirements and regimes.

General Concepts

The rationale for the monitoring programme is considered compatible with the aim of the Directive. The protection of the "supported" ecosystems is considered the basic criterion for the protection of water, under the concept that the protection of these ecosystems is not only a requisite for the protection of the environment, including human populations, but also a guarantee for the protection all water uses.

The description of the monitoring programme in the proposal presented to this Committee is not detailed enough to allow a specific opinion on its scientific basis. It is impossible to formulate an appropriate opinion on the way in which type I and type II errors are considered and taken into account, on the expected precision when establishing differences among the different categories, and particularly between good and fair status which are recognised as the critical difference, or even on the convenience of the proposed monitoring frequency. More detailed information on the specific parameters, selection of reference and monitoring sites, data interpretation, etc. will be required for a further analysis.

Until this information could be available, the Committee only has the possibility of preparing general comments on the conceptual validity of the proposed monitoring programme and recommending additional possibilities not included yet in the proposal.

The importance of monitoring is valid from a scientific point of view, and the Commission is encouraged to continue in this line. Anthropogenic impacts, either physical or chemical, significantly reducing the water quality and/or quantity will produce alterations/modification in the conditions of the supported community. In fact, the threshold for "significantly" under an environmental concept could be defined by the occurrence of these alterations.

The second aspect of the proposed monitoring conditions is to focus on the direct assessment: measuring the situation of the biological community and a set of supporting parameters considered essential for their maintenance. Again the rationale is scientifically valid, if within a specific area the monitoring programme can confirm an undisturbed ecological status, no additional concerns are required.

The key feature of the Directive is that it measures quality in ecological terms; i.e., in terms of the structure and functioning of natural ecosystems. However, this will not always be possible; e.g. in areas seriously modified. Under these circumstances consideration should be given to direct toxicity assessment using systems that are demonstrably relevant indicators of the absence of adverse effects on populations and communities.

The use of direct toxicity assessment in both water and sediment should be always incorporated in the monitoring programmes of those areas where the failure to achieve good ecological status should be considered as entirely due to heavily modified physical characteristics.

The use of the green dashes superimposed on the appropriate colour code should not be allowed without the confirmation of the absence of pollution using direct toxicity assessment.

Ecosystems exposed to continuous impacts, either physical or chemical, can be adapted to such changes, either by the development of adaptation mechanisms at the species level or by the replacement of the most sensitive species. Although the level of detail in the present wording for annex V does not allow an in depth assessment, it is feasible that the achievement of a "good ecological status" could be observed in areas exposed to certain chemicals to which the community can be adapted. The Committee considers that the condition of "good ecological status" must be assumed in all cases when the ecological parameters indicate that the biological communities fulfil the requisites for this condition, even if evidence of adaptation to a certain level of contamination is identified. However, this problem is particularly relevant when considering that the ecological status of the aquatic community is also used as indicator for the protection of human health and associated terrestrial and wetlands ecosystems. When the adaptation of the aquatic community plays a significant role in the achievement of good ecological status, the Commission and the M.S. must check that the required protection of human health and associated terrestrial and wetlands ecosystems is achieved using additional monitoring programmes under this Directive or other EU regulations.

Chemical status and chemical quality standards.

A second comment focuses on the interpretation of chemical data. The proposal establishes that chemical status is simply the question of compliance with all quality standards. Point 1.1.2.5. Includes a procedure for setting chemical quality standards, which follows the procedure described in the Technical Guidance Document on risk assessment. Both, the experience of the CSTE and the discussions at the Technical Meetings on risk assessment clearly indicate that setting these standards under a scientific basis is not an easy task.

It is recommended to include in the proposal a mechanism for consultations on the established (or proposed) quality standards, avoiding the risk of setting different values as the general quality standard for a chemical among different Member States or even River Basins.

For chemicals which toxicity/bioavailability is highly dependent on water quality conditions (i.e., heavy metals, nitrites, etc.) Site Specific Quality Standards could be a better approach than the general ones. The incorporation of specific procedures for this development should be considered.

In these cases, the estimation of real exposure conditions from the simple measurement of the chemical concentration in water can be difficult. A potential solution could be the use of biochemical biomarkers for those groups of chemicals for which validated markers are currently available. The recommendation includes metallothioneins and the induction of Cyt P-450 activities for heavy metals and organic planars (PCBs, PAHs, chlorinated dioxins, etc.) respectively.

Summary of recommendations:

1.- The further development of the preliminary proposal included in the present version of Annex V should be reviewed as soon as available.

2.- The assessment of the ecological status should be considered as the essential part of the monitoring programme whenever possible. A transparent and scientifically based approach to the critical elements of the monitoring programme, such as selection of reference sites, availability of ecological information, development of structure/function relationships, intercalibration procedures, etc., is considered the keystone of the appropriate application of the proposed Directive.

3.- Whenever the ecological status could be significantly affected by problems other than water quality, i.e. due to physical modifications of the river basin or any other reason disturbing significantly the ecosystems such as the presence of exotic species, direct toxicity assessments should be considered as additional parameters for an adequate estimation of the "water chemical status".

Inclusion of ambient water and sediment toxicity tests as a complement to the chemical analysis of priority and other pollutants should be studied. The use of specific concentration/fractionation procedures for persistent/bioavailable chemicals should also be considered. This is particularly important for water bodies with good and less-than-good status as well as for the identification and confirmation of the relevance of the pollutants detected at the River Basin inventory when problems on the ecological parameters or concentrations above the quality standards are observed. The advantages and disadvantages of these direct toxicity assessments should be investigated and guidelines on when and how combine chemical analysis and direct toxicity assessment should be developed.

Similarly, other biological approaches, should be considered wherever the inventory reveals specific pollution problems related to chemicals for which bioavailability, and therefore potential danger, is importantly affected by water quality conditions. The capability of the combination of chemical analysis on water and biochemical biomarkers (mostly on fish populations) as monitoring tools in those areas in which heavy metals or persistent planar organic chemicals constitute a relevant problem according to the River Basis Inventory should be investigated. This aspect is particularly important for zones with a fair status.

4.- Direct toxicity assessments should be used to confirm the lack of chemical pollution in those areas where the failure to achieve good ecological status should be considered as entirely due to heavily modified physical characteristics.

5.- There should be procedures for European co-ordination when developing those Quality Standards which are not available and must therefore be developed by the Member States.

6.- There should also be procedures for establishing Site Specific Quality Standards and guidance on the appropriateness of general versus site-specific quality standards.

E. PRESENTATION OF RESULTS AND CLASSIFICATION OF WATERS

Terms of reference

The opinion of the Committee is requested on the adequacy of the proposed requirements for presentation, classification and comparability regime.

Main comment

The directive requires a very simple presentation of the results, using a letter/colour code for ecological status and a GOOD/NO GOOD presentation for chemical status and for the presentation of data on groundwater. The proposal puts more emphasis on the presentation of ecological status (five levels with separate representations of biological, hydromorphological and chemical qualities) versus other conditions (mostly described as good or not good status). These differences are considered scientifically sound as, when feasible, the monitoring of the ecological status should be recognised as the essential element in the definition of the environmental quality.

The Committee recognises that these very simple presentations can be helpful for a rapid overview of the water status within the European Union, but expresses its concern on the loss of information associated with this excessive simplification. In particular, the presentation of results as environmental quality ratios potentially hides variance in both observed and expected measurements. This should be taken into account in deciding if the EQR differs significantly from 1. Methods are available for carrying these analyses out (e.g. Monte Carlo simulations). It should be made explicit that these analyses would be excepted routinely and when they are not carried out this should be justified.

A possible solution to avoid the loss of essential information could be to incorporate a tiered presentation of monitoring results, with three different levels. Additional information should be included when the lower tier data indicate significant differences from the reference (or high) conditions.

Other general comments

The presentation of monitoring results for ecological status covers five possibilities, from high to bad. However, in the present proposal normative definitions only cover three classes, from high to fair. So no information on the conditions associated to poor and bad status has been presented. The Committee considers that it is useful to have criteria discriminating between fair, poor and bad status, but also recognises the scientific problems of achieving this level of detail.

Although the aim of the directive is to reach good status in all European waters in a relatively short period, the Committee considers that the information provided with the presentation of results is particularly important for areas with fair, poor or bad status. In these cases, the presentation must provide information not only on the status itself, but also on the conditions/parameters responsible for this status.

Specific comments

Presentation of monitoring results and classification of ecological status.

The proposal includes separated classifications for biological quality, hydromorphological quality and physico-chemical quality, and assumes that the overall ecological status of the water body shall be the lowest of the three. This is considered appropriate for the present state of the art of ecological monitoring. However, the research effort required for the implementation of this directive should aim for a fully integrated monitoring programme and results presentations, where the biological condition should represent the main weight in the assessment.

The achievement of high or good status is considered enough for the direct interpretation of the quality of the water body. High or good status means that all conditions are acceptable; thus the situation for each parameter is clear. However, the information provided for those water bodies presenting fair, poor or bad status is not sufficient. The presentation of the results must indicate the reason(s) interfering with the achievement of good status. I.e., large differences (both, in the situation and in the required management) exist between water bodies failing to achieve good status in the fish population due to the effect of introduced species versus water bodies failing to achieve good status for temperature due to the emission of hot effluents. The use of a tiered system for the presentation of the results is a potential solution. Tier 1 could be restricted to the basic status, from high to bad, and is basically the present proposal. Tier II should be applied to the fair to bad status and could incorporate the parameters failing to achieve good status. Tier III should be applied when there are more than one parameter responsible for the unacceptable status; and would provide all the basic information for each parameter below the good status.

The research programme required for the implementation of this directive should include the establishment of appropriate guidance for setting quantitatively the deviation from the reference conditions and the estimation of biological consequences.

Presentation of data for water bodies with heavily modified physical characteristics.

The proposal indicates that for the areas where failure to achieve good ecological status is entirely due to physical modifications of the basin, a set of green dashes shall be superimposed on the appropriate colour code.

The Committee expressed its concern on the criteria to identify heavily modified areas. As expressed in the opinion on point D, the monitoring programme of these areas should include direct toxicity assessment of water and sediment to confirm the absence of relevant levels of chemical pollution. Criteria should be developed on how to interpret these toxicity assessments. In any case, the green dashes should never been used without this confirmation of the lack of chemical pollution.

Definition of quality classes for chemical parameters

The interpretation of chemical parameters is presented in a very simple way. The establishment of numerical standards is considered possible only for the high and good status. Comparability of the numerical standards established by the Members States must be assured before these values can be used. For fair, poor and bad status, the interpretation of the results required a diagnostic approach of the expected consequences of the observed deviation for the biological community. The consequences are affected by a set of variables; therefore numerical standards cannot be established. Diagnostic protocols must be established after implementation and intercalibration procedures to assure the required comparability among the interpretation of these data.

Presentation of monitoring results for chemical status

The presentation of the results only includes a single YES/NO statement regarding the achievement of good status. The Committee considers that when good conditions are not achieved, the data presentation should also include the chemical(s) which are above the standards and an indication of their potential risk.

The method selected for setting the Environmental Quality Standard for chemicals, the TGD method, combines the relevance of the endpoint and the amount of information to select the uncertainty factor. Thus, the distance between the measured value and the EQS does not offer equivalent information for all chemicals.

The use of probabilistic approaches is recommended for the presentation of this information. The percentage of species potentially affected by the measured level of pollution can be considered as a good parameter. When the toxicological information on a specific pollutant is too scarce to allow probabilistic approaches, the data presentation should at least indicate if the monitored results is higher or lower that the chronic and the acute toxicity observed for the most sensitive species.

Presentation of monitoring results for groundwater.

The presentation of the monitoring results for the status of groundwater should be modified according to the changes suggested in part B. The results can be presented as a set of two letters representing the quantity and quality status respectively. The Committee considers that when good conditions are not achieved, the data presentation should also include the chemical(s) and/or toxicological parameters that are above the standards/criteria and an indication of their potential risk.

Comparability of biological monitoring results.

The implementation of the directive and the intercalibration network requires an extensive scientific input. The results of this exercise must be interpreted not only on a statistical basis but also, and particularly, on an ecological basis. Additional research must be considered to allow a further comprehensive connection between the biological results and the hydromorphological and chemical «supporting» parameters.

The proposal establishes the quality of a water body as the «distance» between the present situation and the reference conditions. This distance is quantified by the so-called Environmental Quality Ratios (EQR). This concept is included in the annex but it is not used for the definition of boundaries between quality classes. Therefore, instead of numerical values for the EQR, quality classes are defined by verbal expressions. The Committee considers that this decision is appropriate, as not enough information is available for a scientifically sound classification based on EQR.

An intercalibration exercise is proposed to assure the comparability among the different methods selected by Member States. Although not clearly expressed in the main document, a peer review of the base documents presented indicates that this exercise will be mostly focused on two specific aspects:

- The comparison between the method currently available/employed by Member States for the same parameter.
- The establishment of comparable boundaries between good and fair status.

The Committee recognises the key role of both aspects, but expresses its concern on the possibility that the efforts focussed on these two aspects could lead to a poor definition of other essential needs.

In particular, some biological parameters are not so well established as others are, and therefore the consequences for the biological community derived from a certain level of deviation from reference conditions must be carefully evaluated. The intercalibration exercise should be designed to set comparable levels not only between different methods for the same parameter, but also for the assessment of ecological relevance and capability to discriminate between polluted and not polluted communities for different biological parameters. The intercalibration exercise should also be the starting point to establish, on a scientific basis, the appropriate role of the ecological *versus* the supporting (hydromorphological and chemical) parameters.

II) PROCEDURE FOR SELECTION OF PRIORITY SUBSTANCES WITH A VIEW TO THE ESTABLISHING OF A LIST OF COMMUNITY PRIORITY SUBSTANCES.

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Terms of reference

The opinion of the Committee is requested on the technical procedure for the selection of priority substances pursuant to Article 21 of the proposed Water Framework Directive as outlined in working document M0223WD1.

General comments

As a whole, the approach followed with a view to include a given substance in a priority list as dangerous for the aquatic environment, is logical and sound, and consistent with those used elsewhere. In particular the association of a "monitoring based" concept with a "modelling based" one makes sense. In this respect, this approach should be supported.

According to the objectives of the Commission, the priority setting and assessment of substances in the framework of Directive 'COM(97)614, final' should follow the methodologies of Regulation 793/93 as much as possible.

However, the following comments have been made:

1. Lack of data and use of defaults often dominate the output of prioritisation schemes. It is not clear how it was intended that this would be handled. It must be stressed that the lack of toxicity data may result in an unnecessary elevated score for a substance, due to the application of the precaution principle. Clearly, the IPS method which was originally proposed for priority setting (selection of substances) should be followed as much as possible, but less defaults should be used and more monitoring data should be introduced in the procedure.

2. Prioritisation schemes need to be designed to reach their goal as simply as possible; they should be transparent and easy to apply. This does not seem to be the case in this document where the proposed approach is rather laborious. The goals can also be achieved by:

- taking the substances which are on the lists proposed in the paper (step 1 pg. 7),
- using HEDSET data and filling relevant gaps by literature search,
- running the substances through the IPS method (environment part),
- taking e.g. the top 100 of the resulting list (top x depending on length of list required and reviewing the sequence of substances and length of the list (e.g. bringing it back to a top 40) on the basis of monitoring data (selected on the basis of quality and representativeness;

top x depending on length of list foreseen) using expert judgement and a MS interest discussion.

This is closer to regulation 793/93 and seems more practical.

3. There is a discrepancy between the text of the directive which is clearly intended to protect the aquatic environment and the desire to introduce the concept of the hazard to human in the procedure to establish a priority list. This makes the proposal unclear suggesting (1) to take into consideration human toxicology data, but with a rather low weight, or (2) to use them only in the final selection step.

4. Generation of candidates from existing lists and combination of MECs and PECs is sound. However, most of the PNECs will derive from acute effects and this might underprioritise substances that, though not necessarily having lethal effects, may nevertheless have longer term sub-lethal effects, e.g. endocrine disrupters. Furthermore, setting a priority list by taking candidates from existing lists such as OSPARCOM, is sound but must necessarily include an expert judgement.

Detailed comments.

Pg. 4, para 2: (also fig. 1, fig. 2, pg. 20 para 2): Article 21 of the final proposal for the Directive and the priority setting proposal say that substances which in the framework of Regulation 793/93 have been decided to require risk reduction for the aquatic compartment are in any case included in the final priority list. In the framework of Regulation 793/93 strategies for limiting the risks are produced which describe which type of measure is most appropriate for reducing the risks involved. For substances which require aquatic risks reduction, sometimes the "water directive", sometimes other frameworks (e.g. the marketing and use directive 76/769/EEC) may be more appropriate. This depends on the case; no general rules can be given. Putting such substances on the priority list of the water directive may not always be the right way forward.

Pg. 7, para 1: Monitoring based approach is also hampered by the lack of monitoring data and the limited number of substances which are monitored in a useful way (useful depends on type of monitoring, (number of) places of monitoring, monitoring method, etc, etc.).

Pg. 12, para 6-8: Here it gets quite complicated (bearing in mind that the procedure foreseen should be very transparent and is probably going to be done on a regular basis): substances not detectable in surface waters will not enter the modelling-based ranking. However, further on it says that substances not monitored but with a high toxicity will enter the modelling procedure. However, even if they would pass that procedure with priority, they are very unlikely to be selected in the final step (see chapter 7).

P12. Without wishing to question the principle stated in this paragraph, the example chosen (pyrethroids) does not seem to be a good one given that such compounds are metabolised very quickly. Under such circumstances their absence in the aquatic medium can be dependent upon degradation and not to insufficient analytical power to detect them.

P13: Step A suggests that for all substances on the lists a PNEC is derived. In this stage, this is quite laborious (requires e.g. review of ecotox data, filling of data gaps, selection of appropriate ecotox data, selection of appropriate AF and finally derivation of the PNEC). Furthermore, it can be questioned whether it is necessary to make an inventory of detection

limits of all listed substances, since only some will become candidates for the monitoring-based ranking.

Pg. 15, para 3: Based on the monitoring information received from Members States, a distribution may be derived. From such a distribution, it would be preferable to use the 90-percentile of measured concentrations instead of mean (see TGD Regulation 793/93).

Pg. 15 last para: This can be written in a more transparent manner. Reflecting that out of all relevant/good acute toxicity data for the substance, the lowest is chosen. Similarly the lowest of all chronic toxicity is chosen. Each of them are divided by an AF, depending on the test duration and number of trophic levels, resulting in two values of which the lowest resembles the PNEC.

P18. Treating metals separately is a good idea. The principles set out to take into consideration the degree of oxidation and the metallic forms actually present are conceptually sound. However, from a practical standpoint, the applicability of such principles seems much more difficult given the scant data available.

P18. Using bioaccumulation criteria in the context of an effect search is likely to be made difficult in the case of the so-called "essential" metals. It is very useful indeed for the human body to be able to accumulate the metals which are necessary to its metabolism.

Pg. 17, 18: Alternative: the choice seems to be more political than scientific.

Pg. 20, para 4: The word "refine" is not appropriate, better use "compare".

Pg. 20/21 : Also the expert judgement phase should not be overly laborious (see e.g. step 2 "careful reassessment").

FINAL RECOMMENDATIONS FOR THE IMPLEMENTATION OF WATER FRAMEWORK DIRECTIVE

As stated in the preamble, the Committee is fully in agreement with the philosophy and the general objectives of the Directive. Nevertheless, the need for a precise definition of some key points and for a detailed description of some methodological aspects is strongly envisaged for the implementation of the Directive. In particular:

1. The “reference conditions” must be very carefully selected. They must represent a “natural” (or almost natural) condition for all different typologies of water bodies. This is not an easy task; in particular for biological parameters. The variability of biological communities depends on a number of factors, sometimes not completely understood. It is very important to define not only a suitable series of reference conditions for the different water bodies and for the different ecoregions, but also the level of variability that could be accepted in order to consider a biological community “corresponding to the type-specific conditions” in terms of structure and function.

2. Methods for the evaluation of biological quality must be carefully selected. There is a need for methods capable of evaluating, in quantitative terms, the deviation of structure and function from a reference condition. For some biological components, enough reliable and standardised methods are available, but for others they are not and should be developed.

3. To assess the possibility of exposure to contaminants that may not be detected by chemical monitoring, direct toxicity assessments should be considered as additional parameters for an adequate estimation of the "water chemical status". Direct toxicity assessments should also be used to confirm the lack of chemical pollution in those areas where the failure to achieve good ecological status should be considered as entirely due to physical characteristics. Moreover, to evaluate exposure to low levels of contaminants, the use of early warning systems of biological response (e.g. biomarkers) could be suggested.

4. Suitable methods to evaluate the role of hydromorphological parameters must be carefully selected. Cause-effect relationships between changes in these parameters and the effects on the biological community must be evaluated. Environmental quality standards, comparable to those set up for physico-chemical parameters should be proposed.

5. Precise procedures must be developed either for European co-ordination of general Quality Standards or for establishing Site Specific Quality Standards.

6. Precise and detailed procedures must be set up for the monitoring programmes. These procedures must give precise indications on time of sampling and location of stations in function of the different typologies of water bodies and on the methods to be used for evaluating environmental status (ecological, chemical, hydromorphological).

Finally, taking into account the complexity of the ecological and ecotoxicological problems faced by the Directive, it is the opinion of the Committee that a research programme specifically oriented to provide a scientific basis required for the fully implementation of this Directive must be activated on several key items. For example:

- Defining functional characteristics of different surface water ecosystems (rivers, lakes, estuaries, coastal waters) which are more relevant for the evaluation of ecosystem quality in a sustainable sense and the definition of cause-effect relationships between functional changes and both chemical and hydromorphological changes.
- The extent to which the "structure" of the aquatic ecosystem is related to anthropogenic alterations of the environment, on the one side, and to ecosystem function on the other side.
- The development of "habitat quality" assessment criteria, incorporating all aspects of physical and chemical constituents along with the biotic interactions. Protocols for Habitat Assessment have been proposed for some particular ecosystems (e.g. for rivers), but no information is available for most typologies of aquatic environments.
- The development of methods for the evaluation of ecological quality, in quantitative terms, for the different typologies of aquatic ecosystems, and the integration of biological and abiotic parameters to define sustainable ecosystem properties and processes.
- The improvement of biological methods for the direct toxicity assessment of groundwater, which could also be applied to monitor chemical pollution in surface waters in which the ecological community is significantly affected by physical disturbance.

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