Strategy Report on Challenges, Opportunities and Research needs arising from the Definition, Assessment and Management of Ecological Quality Status as required by the EU Water Framework Directive based on the workshop EQS and WFD versus PNEC and REACH - are they doing the job?

27 – 28 November 2003, Budapest

Workshop Report No. 2

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ECETOC WORKSHOP REPORT No. 2

EQS and WFD versus PNEC and REACH – are they doing the job?

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EXECUTIVE SUMMARY

This report arises out of a workshop that focussed on the concept of ecological quality status in terms of its definition, assessment and involvement in environmental management. The immediate motivation was the adoption and implementation of the EU Water Framework Directive (WFD) where it forms a central concept, but it was also the view that it ought to be the basis of assessment endpoints for all ecological protection instruments.

The aim was to identify challenges, opportunities and research needs arising from the more explicit use of ecological quality status in environmental protection. The recommendations listed at the end of this report are intended for the community of stakeholders in general; but it is presumed that they will be considered particularly by the ECETOC Scientific Committee and prioritised for further action by ECETOC.

An important general conclusion was that the definition of ecological quality status is elusive. It can only be defined comparatively: by reference to systems deemed to be little disturbed. Recommendations arising for the community of stakeholders as a whole were to ensure that monitoring systems were designed with sufficient power to distinguish adverse changes from natural noise, to ensure that appropriate monitoring tools are developed for all appropriate aquatic systems, to be clear about the relative sensitivity and ecological importance of elements assessed in the monitoring programmes, and to obtain a better understanding of the relationship between ecological structure and function in aquatic systems. Given the pace of implementation of the WFD these areas need to be addressed with some urgency.

The implication of an explicit focus on ecological quality status for ecological risk assessment is that the effects endpoints used should be protective of 'good ecological quality status'. In general it was considered that these effects endpoints would be likely to be overconservative relative to the protection goals. It was recommended that population level risk assessment should be considered as a more appropriate basis for management decisions, that attention should be given to mismatches between quality judged on the basis of chemical concentrations exceeding standards established from effects assessment and the results of ecological monitoring, and that it will be necessary to develop ecological models that can predict the likelihood of recovery following remediation.

Once deviations from 'good' quality status have been properly identified in aquatic ecosystems it will be necessary to identify the causes, if appropriate management is to be deployed. Ascribing causation retrospectively involves use of relatively new

eco-epidemiological techniques. This was identified as an area where there was an urgent requirement for further work and for priority attention by industry groups. In particular there is a need for a critical review of existing techniques and for the compilation of user-friendly guidance. It will also be important to develop methods for validating outputs of eco-epidemiological analyses based on field data, and it is likely that micro-/meso-cosms will play an important part in this.

Remediation of ecosystems to 'good' status will undoubtedly involve considerable expenditure. There was therefore a recommendation to compile and review techniques and case studies deploying cost-effectiveness and cost-benefit analyses in ecological remediation. A major challenge here was recognised to be the appropriate valuation of ecological resources.

BACKGROUND

In ecological risk assessment we tend to measure what we can and what we have been measuring for the past 50 or so years. But as the regulatory focus shifts to assessing and managing the quality of real ecological systems, as it is for example in the Water Framework Directive (WFD), then increasingly there will be a need to reconsider the relevance of what is being done. This is quite apart from raising the most fundamental question of all – what is meant by ecological quality? - and this raises a number of other questions that are not just of theoretical importance.

For example:

- To what extent are the assessments used in current chemicals legislation, and intended in REACH (Registration, Evaluation and Authorisation of Chemicals), likely to be over- or under-protective of good ecological status?
- Is the drive for achieving good ecological status in water bodies, as required by the Water Framework Directive, likely to be achieved by application of currently used quality objectives and standards?

This workshop dealt with the general issues that centre on ecological quality – its definition and measurement – with the aim of putting principles into practice.

The specific objectives were:

- To assess critically what is meant by ecological quality status as used in the WFD.
- To consider the implications of protecting ecological status for what we do in new and existing chemicals legislation currently and under REACH.
- To consider the relationship between water quality objectives, water quality standards, Predicted No Effect Concentrations (PNECs) and the requirement to achieve good ecological status.
- To consider how the complex, multiple exposure scenarios that will undoubtedly drive influences on ecological status can be addressed in risk management.
- To review critically and recommend tools to identify causes of divergence from good quality.
- To examine the value and cost/benefit of returning habitats to good status.

WORKSHOP STRUCTURE

Over 40 participants with backgrounds in ecotoxicology and eco-epidemiology representing governments, academia, consultancies and industry met for a 2-day workshop. The broad aim was to refine understanding of the concept of ecological quality status that is made explicit in the EU Water Framework Directive but that ought to be implicit in all aspects of ecological risk assessment and management. The workshop consisted of three syndicate sessions. Each session began with one or two presentations.

The workshop was held in Budapest on 27 and 28 November 2003 and was organised by ECETOC and sponsored jointly by ECETOC, the Environment Agency of England and Wales and the CEFIC Long-Range Research Initiative (LRI).

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WORKSHOP OVERVIEW

Introduction

All ecological regulatory instruments aspire to protect aspects of ecological quality status; yet what is intended by this is rarely made very explicit. This changed with the adoption of the EU WFD (EC, 2000), which seeks to define ecological quality and manage EU surface- and ground-waters on that basis.

The WFD requires that surface waters be classified through the assessment of ecological status (or in the case of heavily modified or artificial water bodies, ecological potential), and surface-water chemical status. Annex V of the WFD defines the quality elements that must be used to assess status for rivers, lakes, transitional waters and coastal waters and explicitly defines ecological status, for each of the quality elements, in each of five status classes ranging from high, through good, moderate and poor, to bad. This is the first time that normative definitions of ecological quality status have been made explicit in primary, environmental protection legislation.

The challenges for implementation of the WFD are considerable but they also have implications for other aspects of environmental protection regulations. For example, the presumption must be that chemical (environmental) water quality standards (EQSs) and PNECs protect against changes in ecological quality status outside those allowed by the WFD. Hence, the ecological risk assessments (ERAs) upon which both EQSs and PNECs are based must be presumed to protect ecological quality status appropriately.

This strategy report will review aspects of the principles and practices involved in defining and assessing ecological quality status especially within the context of WFD, but also in terms of ERAs; consider how to identify causes of divergences from the required ecological quality status when they are picked up in monitoring programmes; and examine how the value of improving ecological quality might be balanced against the costs of achieving enhanced status through management and remediation programmes.

Specifically the aims will be: to identify challenges in implementation of WFD both for the regulated and regulatory communities; to point to some of the important gaps in our understanding and methodologies; and to suggest some key areas for research.

Further details of the programme, summaries of outputs from the syndicates and a list of participants are given in Appendices 1-5. All references from the main body of the report and the appendices are given in the bibliography.

Defining ecological quality status

The normative definitions of the WFD provide the basis for classifying the ecological status of water bodies. For natural water bodies the values of the relevant biological elements at high status reflect those normally associated with that category under undisturbed conditions. For good ecological status the relevant elements show low levels of distortion resulting from human activity, but deviate only slightly from those normally associated with undisturbed water bodies. For moderate ecological status, the values of the biological quality elements will differ moderately from the type-specific communities.

The meanings of slight and moderate deviations are under consideration as part of the inter-calibration exercise being carried out by Member States and will be addressed in terms of the issues associated with detecting deviations from the required status. The important point to note, though, is the presumption that norms exist for the biological elements in undisturbed conditions.

There are two caveats that need to be made here that derive from ecological understanding. The first is that it is not possible to define ecological quality, on first principles, from ecological theory. Where predictions are made, they are based on established correlation models: (e.g. the River Invertebrate Prediction and Classification System - RIVPACs - used in the UK) rather than mechanistic models. The second caveat is that in ecology there is a general presumption against making precise predictions of the states of particular ecological systems due to an expectation of considerable dynamics through space and time (Lawton, 1997). This natural variation can be caused by natural disturbances and/or the internal dynamics of ecological systems and both of these sources will vary with ecosystem. They could be especially prevalent in so-called high-energy systems such as rivers, estuaries and exposed coastal systems. One of the major challenges undoubtedly will be to distinguish levels of natural variations (i.e good quality) from variation that is derived from external pressures in disturbed systems.

An important conclusion, therefore, is that there is a need to establish the level of natural variation in undisturbed or slightly disturbed systems. This might be achieved through direct monitoring, or by mining the databases that provide information on species composition, and sometimes abundance, in some aquatic systems (see Appendix 3).

The quality elements to be monitored for all categories of water body are defined broadly in Annex 5 of the WFD; however, details are to be left to individual Member States and there are already considerable differences between Member States in terms of the state of development and kinds of measurement tools that they are using (see Appendix 3). Furthermore there are considerable differences in the extent of coverage of different environmental compartments. Whereas flowing waters are relatively well covered in terms of assessment techniques, in general these indices have been developed to detect effects of organic loading and it remains to be seen if these are appropriate for picking up the effects of other stressors. Certainly standing freshwater bodies, estuarine and marine systems are poorly covered by existing techniques. **Hence there is a need to develop appropriate assessment tools for lakes, estuaries and coastal waters, to keep the assessment tools for rivers under review, and to develop appropriate sampling guidelines for each type of environment.**

The dynamics of different quality elements will vary, as will their sensitivity to different anthropogenic pressures. Moreover, the relative importance of different biological quality elements for the stability and resilience of the whole system are likely to vary between systems. For example, the removal of some species from some systems can cause massive changes in the species composition of the system. These are so-called keystone species and clearly ought to be subject to special attention in any programme that purports to protect ecological quality. However, it is probable that not all ecosystems have keystone organisations. The loss of other species may have little or no consequences for the dynamics of the whole system, and this will be discussed further below.

Hence more information is needed on the relative sensitivity and relative importance for taxonomic organisation of the different biological quality elements referred to in Annex V of the WFD. It would also be useful to have information on the distribution of keystone organisations through the ecosystems subject to WFD. Again this might be achieved either by review or direct observation.

Most of the quality elements in Annex V WFD, and the suggested parameters by which they are to be measured, are structural; for example presence/absence of taxa, species richness and diversity, abundance, age structure and so on. An exception is productivity in phytoplankton. However, the WFD also purports to protect functioning (Article 2, para. 21 'Ecological status' is a statement of the quality of the structure and functioning of aquatic ecosystems…). The definition of 'functioning' is nevertheless unclear. Ecosystems do not function in the sense of having a 'role in Nature', but they do involve processes of energy flow and material cycling and they can be considered to deliver services to society (Calow, 1998). It is presumed that the WFD intends 'functioning' in both these senses. The relationship between structure and processing has been the subject of much ecological debate (e.g. Kareiva, 1996). The tightness of the coupling is likely to vary between systems, and redundancy, where species might be lost from a system with no obvious functional consequences, could be widespread. For this and other reasons, functioning (in the broad sense) is likely to be less sensitive to disturbances than structure. It is often on this basis that a focus on structure in ecological protection, as in Annex V of the WFD, is justified. This might be thought of as an ecological manifestation of the precautionary principle.

On the other hand, it is through ecological processes that services are delivered to society; e.g. as biomass through production; as maintenance of soil quality and productivity through the biogeochemical cycles and so on. So it might be argued that if a prime aim of protecting ecological quality is to maintain the delivery of these services, then the benefits of protecting structure to overprotect services could be called into question. The problem that we have at present, however, is that there is considerable uncertainty about the couplings between structure and process, and process and service.

Hence, important research ventures for ecology in general are programmes not only concerned with the relationship between species diversity and process delivery but also with the relationship between process and service delivery. Energy flows and material cycling can, for example, be studied in mesocosms or in natural surface waters as reported by Peterson *et al.* (2001).

Finally and more pragmatically, it is important that the assessment tools used in the programme should be sufficiently robust to be deployed routinely and to be understood by a variety of stakeholders. **Hence there will be a need to translate complex ecological measures of effect to more simple ones that sufficiently capture the extent of the effect and which can be deployed cost effectively.**

Implications for ERAs

PNECs and EQSs are derived from ecotoxicological endpoints divided by factors that represent the uncertainties in extrapolating from laboratory to field. The implication is that these will lead to exposure concentrations that are compatible with good ecological quality. Thus the risk assessments associated with new or existing chemicals should lead to environmental concentrations, at regional and local levels, that do not impair ecological quality (PNECs). Similarly, effluent releases from point sources that conform to EQSs should also not impair ecological quality in the receiving environment especially since these are generally calculated in an even more conservative way than the PNECs (see Appendix 3 for a comparison of definitions of PNECs and EQSs).

The ecotoxicological endpoints that are in general use are variables that refer to survival, reproduction and development of individuals. For ecological systems we are usually more concerned about groups such as populations, communities and ecosystems. These are certainly the focus of the WFD. The limited information that is currently available suggests that the most sensitive individual-level endpoints are generally more sensitive to toxicants than variables that relate to whole population responses, such as population growth rates (PGRs) (e.g. Forbes and Calow, 1999; and Appendix 4). The same is likely to be true for community structure and ecosystem process variables. Hence, PNECs and EQSs derived from individual level variables may well be conservative relative to the ecological organisations and processes that they are supposed to protect. This is probably even more likely for endpoints based on suborganismic responses, i.e. biomarkers, for there are various homeostatic responses that modulate impacts on molecular, cellular and physiological processes relative to the well being of the individual organism. Indeed some of the biomarkers that are measured reflect the deployment of these homeostatic responses. Precautionary endpoints should be favoured, but as uncertainties are reduced and more attention is given to costs as well as benefits of particular management options then it may well be important to put the emphasis on more ecologically relevant endpoints in the derivation of PNECs and EQSs.

Attention therefore needs to be given to assessing if PGRs can be calculated from data in existing ecotoxicological databases and to comparing these with ERAs based on more traditional endpoints using appropriate sensitivity analyses.

Similarly attention should be given to any mismatches between water chemistry analyses, that will be compared with PNECs and EQSs to predict likely effects, and the observed effects, or absence of them, inferred from the biological monitoring driven by WFD. There are a number of possible reasons for mismatches, that include: differences in the relative power of chemical and biological sampling designs to pick up adverse effects; the conservatism in ecotoxicological endpoints; failure of the ecotoxicological analyses to take account of indirect effects, long-term consequences of short-term exposure (e.g. pulses of pesticides entering streams) and the effects due to exposure to complex mixes of chemicals and other stressors. Hence there will need to be a systematic treatment of the detection and explanation of mismatches that should be used to inform the future design of monitoring programmes and ecotoxicological assays (see ECOSTAT 2003).

Another likely requirement to arise out of full implementation of WFD is the ability to predict the time course and extent of recovery of systems of less than good quality after remediation. Here it is important to note that the ecotoxicological models that are deployed routinely to define PNECs and EQSs are designed to predict effect and no-effect concentrations (NOECs) and not necessarily to predict detailed, whole-system responses. Work carried out to date suggests that whereas adverse effects on ecosystems may be stressor specific their recovery may be independent of the stressor but a function of the life-history features of the populations (e.g. Barnthouse, 2004).

Hence, it may be necessary to develop models that are more capable of predicting the detailed response dynamics of aquatic systems that have been subject to remediation. These will likely be more specific than the ecotoxicological models in routine use.

Detecting deviations

The WFD requires that any water body that is found to deviate from good quality status should be subject to remediation. It is presumed that a pressures and impacts analysis will be used to identify water bodies where this is likely and that these must then be considered within the operational monitoring programmes for the river basin. The monitoring programme will essentially compare observed states for specific quality elements with those expected for good or better quality status (see ECETOC 2003b). The observed values will be subject to the natural variations discussed above and to measurement errors. The WFD requires that Member States achieve an adequate level of confidence that water bodies are assigned to their true status classes and that this is reported in the River Basin Management Plans (Annex V, para.1.3). However, the Directive does not specify the levels of precision and confidence required in this process, so that will depend on judgements made in Member States. The level of confidence that can be put into statements about deviations from norms will depend on the design of sampling programmes and in particular on the number and positioning of replicates through space and time. It will also be important to consider the relative importance of picking up deviations when they do not occur, as compared with not picking up deviations when they do occur.

There is considerable ecological literature on these aspects of sampling design (e.g. Underwood, 1997) so that there is no need for primary research effort. However, care will be needed in the implementation of particular sampling programmes. As a general rule it is likely that considerably more effort will need to be put into the design of monitoring programmes than at present if acceptable levels of confidence are to be achieved. This will be costly. On the other hand the costs of misclassification might be even more considerable; this

could derive from either performing unnecessary remediation or not performing necessary remediation possibly leading to unacceptable effects on ecosystems or human health. Developing appropriate cost-benefit procedures, and ways of discussing them in appropriate stakeholder forums, is therefore likely to be of considerable importance.

Since the monitoring programmes will consider more than one quality element at a time there will be a need to develop techniques for combining and weighting information. This is addressed in ECOSTAT (2003).

Identifying causes

The WFD requires that once a deviation from good status is detected a programme of remediation be put in place. This presupposes that the cause or causes of the deviation are identified with reasonable confidence, otherwise time, effort and resources may be wasted in addressing the wrong pressures. The basic problem here, then, is being able to identify causes of effects, once they have occurred, from monitoring programmes. This can never be achieved with absolute confidence because of fundamental constraints on retrospective analyses of this kind. Nevertheless, confidence in ascribing causation can be achieved by systematically and transparently weighing available evidence according to rules that have been established for human health epidemiology; in consequence this kind of exercise is increasingly referred to as eco-epidemiology (see Appendix 5). Eco-epidemiology helps in assessing the correlations between chemical and ecological parameters in an environmental compartment. These correlations can identify potential stressors (e.g. habitat change, chemical insult) responsible for a suboptimal quality status of the rivers considered. But cause/effect relationships can only be confirmed experimentally with adequate testing facilities, e.g. mesocosms.

There is a developing literature on eco-epidemiological techniques (e.g. Suter *et al*, 2002; Forbes and Calow, 2002; Menzie *et al*, 1996). However, there is a need for a compilation and critical review of these techniques in a way that tests their effectiveness and cost-effectiveness through case studies that will be of relevance to the WFD.

Key to the establishment of causation, particularly in situations involving complex mixtures of potential agents, will be the use of whole effluent toxicity and toxicity identification evaluation techniques. These are reasonably well developed, but a critical review should be carried out on available techniques and their strengths and weaknesses in deployment as part of an eco-epidemiological analysis. It is very likely that there will be a requirement for

the development of more specific diagnostic tools that involve agent-specific biomarkers.

Moreover, there is an urgent need to develop techniques that allow evidence derived in eco-epidemiological studies to be weighed in as objective a way as possible, hopefully leading to specifications of the levels of certainty/ uncertainty associated with the conclusions derived from them. It will also be important to develop user-friendly guidance material.

Methods should be developed to validate (1) the epidemiological conclusions and (2) existing and new ecological risk assessment approaches. This will involve considering evidence that supports or falsifies cause-effect hypotheses arising from monitoring studies. One possible way of addressing these hypotheses would be to use high tier ecotoxicological testing facilities, e.g. experimental streams. Other approaches will be to test hypotheses using single species toxicity tests, TIEs and reviews of toxicity databases.

Balancing costs and benefits of remedial action

Once the causes of deviations from good quality status have been identified the WFD requires remediation to good status. This will usually involve considerable expenditure, for example in the construction of more effective treatment of effluents from sewage treatment works (STWs) and industrial sources, in requiring adjustments to agricultural practices to ameliorate the effects of diffuse sources, and in rectifying the effects of physical habitat destruction. So there will be a need to develop and deploy cost-effectiveness analyses that might select between different methods of addressing the same problem and/or that select the optimum way of managing a deterioration caused by several different causes.

Ultimately it is also possible that society might start asking questions about the rationale for remediating all sites, in the EU to good ecological status, if only because the overall costs may be very considerable. This will require ways of transparently balancing the value that society puts on natural resources with the costs of protecting them from harm and the costs of remediating any harm that has been deemed to occur within them as a result of anthropogenic pressures. This requires that there are appropriate stakeholder forums for having these kinds of discussions on costs and benefits, and appropriate ways that the discussions can be facilitated.

One approach is to attempt to value both costs of remediation and ecological resources in the same terms; i.e. in financial units. This is the subject area of ecological economics, a discipline that bridges between the social and ecological sciences. Putting economic value on remedial constructions and actions is reasonably straightforward, as is judging between techniques to achieve cost-effectiveness in solutions. However, putting economic values on ecological resources so that cost-benefit analyses can be carried out currently raises many challenges. Nevertheless some approaches have been developed and deployed with relevance for the WFD (e.g. Balmford *et al*, 2002).

There is a need to compile and review techniques and case studies deploying both cost-effectiveness and cost-benefit analyses with, if appropriate, the development of user-friendly guidance materials. Moreover, much of the evaluation of ecological resources to date has been carried out by revealed preferences; e.g. by gauging increased price of properties close to a good quality river. Yet stakeholders are likely to have poor understanding of the direct impact of ecological services on the economy. Hence, there is a real need for ecological science to inform the debate on cost-benefit analyses by making explicit the links between ecological structural status, the processes that go with it and their impact on services and hence the economy.

General conclusion

A general conclusion from this workshop is that ecological quality is an elusive term (see Appendix 3). Most ecologists would agree that it would not make much sense to suggest that there are certain properties of ecosystems that might be defined as intrinsically good. What it probably amounts to is that we define quality in terms of features that we want to protect; e.g. services in the broad sense of not only contributing to the economy but also to our aesthetic and ethical requirements.

The WFD takes a practical approach of focussing on elements that can be measured, and that have been measured in monitoring programmes. It also seems to apply the precautionary approach by focussing on the protection of structure rather than process. Yet as the economic arguments are brought more into focus this might change. In that event there needs to be a forum where there can be debate leading to decisions on what quality criteria should be applied. This ought to involve a broad cross-section of stakeholders with scientists informing the discussion by indicating possible implications of selecting various criteria for the system as a whole and for the delivery of services, and also giving advice on the practicalities of measuring these criteria.

SUMMARY OF MAJOR RECOMMENDATIONS

This reiterates the major recommendations that are marked in bold in the text in the order in which they appear and is therefore not intended to signify priorities. However following each recommendation there is a commentary on which body should be responsible for taking the work forward (general scientific community, regulatory community and industry, possibly through CEFIC LRI) and suggestions on the the relative importance of the recommendations. The commentary is emphasised in bold.

- There is a need to establish the level of natural variation in undisturbed or slightly disturbed systems. This might be achieved through direct monitoring, or by mining the databases that provide information on species composition, and sometimes abundance, in some aquatic systems. **The regulatory community is largely responsible for monitoring work and keeping databases, but industry may well have information on ecosystems in proximity to their operations. In any case, industry should be involved in the analysis of this kind of information since it may well have an influence on the extent to which sites are judged to have diverged from good status. Given the pace of implementation of the WFD this kind of work should be given moderate priority**.
- There is a need to develop appropriate assessment tools for lakes, estuaries and coastal waters, to keep the assessment tools for rivers under review, and to develop appropriate sampling guidelines for each type of environment. **These aims should now be actively pursued by the regulatory community as part of the implementation of WFD. Industry should maintain a watching brief to ensure that the measurement tools developed are fit for purpose. It will also be important to engage the general scientific community in these developments possibly through the support of funding programmes arising in Member States and at EU level.**
- More information is needed on the relative sensitivity and relative importance for taxonomic organisation of the different biological quality elements referred to in Annex V of the WFD. **A first step would be to identify what species might be keystones in different community types and what features to look for in order to determine whether a species is a keystone in the kinds of systems to come under WFD. It would also be useful to have information on the distribution of keystone organisations through the ecosystems subject to WFD. Again this might be achieved either by review or direct observation. There may be some opportunity to address this through existing ECETOC and LRI databases and so some attention should be given to this by industry. Otherwise it is clearly an issue that should be addressed by the general scientific community. It is likely to represent a medium-term research goal.**

- Programmes are needed to not only address the relationship between species diversity and process delivery but also the relationship between process and service delivery. Energy flows and material cycling can, for example, be studied in mesocosms or in natural surface waters as reported by Peterson *et al* (2001). **These are questions that should be addressed by the general community of science. But industry should be seeking to encourage this kind of work and keep a watching brief on developments given their importance to the 'quality agenda' and in cost-benefit analysis. These represent long-term research programmes.**
- There will be a need to translate complex ecological measures of effect to more simple ones that sufficiently capture the extent of the effect and which can be deployed cost effectively. **This should be a responsibility of regulators supported by the general scientific community.**
- Attention needs to be given to assessing if PGRs can be calculated from data in existing ecotoxicological databases and to comparing these with ERAs based on more traditional endpoints using appropriate sensitivity analyses. **It may well be possible to make use of existing ECETOC (ECETOC, 2003a) and CEFIC LRI (WRc, 2001) databases to address these issues, so industry could take a lead. Given its importance in the development of ERAs and EQSs this work should be given reasonably high priority.**
- Attention should be given to any mismatches between water chemistry analyses, that will be compared with PNECs and EQSs to predict likely effects, and the observed effects, or absence of them, inferred from the biological monitoring driven by WFD. There are a number of possible reasons for mismatches, that include: differences in the relative power of chemical and biological sampling designs to pick up adverse effects; the conservatism in ecotoxicological endpoints; failure of the ecotoxicological analyses to take account of indirect effects, long-term consequences of short-term exposure (e.g. pulses of pesticides entering streams) and the effects due to exposure to complex mixes of chemicals and other stressors. Hence there will need to be a systematic treatment of the detection and explanation of mismatches that should be used to inform the future design of monitoring programmes and ecotoxicological assays. **This is something that is being addressed by the regulatory community as a matter of urgency in the implementation of the WFD (see ECOSTAT, 2003). Industry needs to keep a watching brief and, if necessary, develop programmes to explore the general basis of any mismatches that might be identified.**
- It may be necessary to develop models that are more capable of predicting the detailed response dynamics of aquatic systems that have been subject to remediation. These will likely be more specific than the ecotoxicological models in routine use. **This should be a concern for the general scientific community. However, industry might seek to encourage this kind of work in national and EU research programmes. It will be long-term research.**

- Care will be needed in the implementation of particular sampling programmes. As a general rule it is likely that considerably more effort will need to be put into the design of monitoring programmes than at present if acceptable levels of confidence are to be achieved. This will be costly. On the other hand the costs of misclassification might be even more considerable; deriving from either the carrying out of unnecessary remediation or not carrying out necessary remediation possibly leading to unacceptable effects on ecosystems or even to human health. Developing appropriate cost-benefit procedures, and ways of discussing them in appropriate stakeholder forums, is therefore likely to be of considerable importance**. There is considerable ecological literature on sampling design (e.g. Underwood, 1997) so that there is no need for primary research effort. But the regulatory community will need to be aware of theses issues in the implementation of the WFD and industry needs to keep a close watching brief.**
- There is a developing literature on eco-epidemiological techniques (e.g. Forbes and Calow, 2002; Suter *et al*, 2002; Menzie *et al*, 1996). However, there is a need for a compilation and critical review of these techniques in a way that tests their effectiveness and cost-effectiveness through case studies that will be of relevance to the WFD. **Both the regulatory communities and industry need to take the initiative here. Given the importance of appropriately ascribing cause to effect in the rapidly evolving regulatory context, this kind of work should be given a high priority.**
- Key to the establishment of causation, particularly in situations involving complex mixtures of potential agents, will be the use of whole effluent toxicity (WET) and toxicity identification evaluation (TIE) techniques. These are reasonably well developed, but a critical review should be carried out of available techniques and their strengths and weaknesses in deployment as part of an eco-epidemiological analysis. **Industry could take an initiative here. The review may well show a requirement for the development of more specific diagnostic tools that involve agent-specific biomarkers. This should be given as much priority as the eco-epidemiological programme.**
- There is also an urgent need to develop techniques that allow evidence derived in eco-epidemiological studies to be weighed in as objective a way as possible, hopefully leading to specifications of the levels of certainty/uncertainty associated with the conclusions derived from them. **This ought to be a concern for both the regulatory community and industry. It will be important to develop user-friendly guidance material to ensure the development of good eco-epidemiological practice. ECETOC should facilitate this as matter of priority by the commissioning of a Task Force.**
- Methods should be developed to validate (1) the epidemiological conclusions and (2) existing and new ecological risk assessment approaches. This will involve considering evidence that supports or falsifies cause effect hypotheses

arising from monitoring studies. One possible way of addressing these hypotheses would be to use high tier ecotoxicological testing facilities, e.g. experimental streams. Other approaches will be to test hypotheses using single species toxicity tests, TIEs and reviews of toxicity databases. **It is therefore recommended that all the various stakeholders involved in the implementation of REACH (EC, 2003) and the WFD be involved in these developments. It could be useful to set up a multi-stakeholder task force to consider how the cause-effect basis of eco-epidemiological assessments can be strengthened. The programme will inevitably be long term.**

- There is a need to compile and review techniques and case studies deploying both cost-effectiveness and cost-benefit analyses with, if appropriate, the development of user-friendly guidance materials. Moreover, much of the evaluation of ecological resources to date has been carried out by revealed preferences; e.g. by gauging increased price of properties close to a good quality river. Yet stakeholders are likely to have poor understanding of the direct impact of ecological services on the economy. Hence, there is a real need for ecological science to inform the debate on cost-benefit analyses by making explicit the links between ecological structural status, the processes that go with it and their impact on services and hence the economy. **This is clearly an area that should involve the community of science as a whole, but industry needs to keep a close watching brief and might want to encourage developments through CEFIC LRI and SETAC initiatives and also through EU programmes. The research programme is long term but should be given some priority given its potential impact on regulatory decisions in general.**

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APPENDIX 2: WORKSHOP PROGRAMME

Thursday 27 November 2003

08.30 – 09.00	**Registration**	
09.00 – 09.15	**Introduction**	Peter Calow
09.15 – 09.45	**Ecological Quality** Ecological quality in current and developing chemicals control legislation	David Taylor
09.45 – 11.15	**What is Ecological Quality?** Aquatic ecology Terrestrial ecology A Hungarian perspective	 Theo Brock Nico van Straalen Béla Csányi
11.15	Coffee	
11.30 – 13.00	**Syndicate Session I** Implications of protecting ecological status	
13.00 – 14.00	Lunch	
14.00 – 15.30	**Feedback from Syndicate Session I**	
15.30	Coffee	
15.45 – 16.30	**Ecological Relevance** Ecological relevance	Valery Forbes
16.30 – 18.00	**Syndicate Session II** Moving from individual to population level and population versus species specific risk assessment	
19.30	Workshop dinner	

Friday 28 November 2003

08.15 – 09.15	**Feedback from Syndicate Session II**	
09.15 – 10.15	**Biological Monitoring and the Role of Eco-epidemiology**	
	Artificial stream studies	Ali Temara
	Biological monitoring	Mark Crane
10.15	Coffee	
10.30 – 11.30	**Syndicate Session III**	
	Role of eco-epidemiology	
11.30 –12.30	**Feedback from Syndicate Session III**	
12.30	Lunch	
13.30 – 14.45	**Regulatory Perspective**	
	Using science to find smarter ways of assessing ecological status	Geoff Brighty
	UBA presentation	Christiane Markard
	Netherlands presentation	Remi Laane
14.45 – 15.30	**Conclusions from Workshop with some Reference to Cost-Benefit Analysis**	Peter Calow

APPENDIX 3: OUTPUT FROM SYNDICATE SESSION I

Implications of protecting ecological status

The workshop agreed that, currently, it was not possible to define precisely what is meant by 'good ecological status' but that because of the time pressures associated with implementation of WFD there was a need to take forward the biological methods that were currently available and look to refine and improve them over time.

For example, in the UK, tools are being refined and/or developed that comply with WFD requirements and that can be used to predict status, determine whether boundaries are crossed, predict reference conditions, and develop EQRs - for each biological quality measure (RIVPACS/NUPHAR/DARES). In the Netherlands measurements are being carried out at 40 organisations/sites and there is a 50-year dataset available. In Portugal there are few reference condition data, and although chemical data exist there are limited biological data.

Clearly for some environments (e.g. freshwater) there are methods across many taxonomic groups and datasets. However there are major problems with other environments particularly – estuaries and coastal waters.

In summary it was agreed that:

- Some tools are available - but there is not the data available to validate them i.e. to ensure that they are fit for purpose;
- there is a predominance of qualitative as compared with quantitative indicators;
- simplification of the complexity is needed: in particular, can simple instruments based on results of studies of complex ecosystems be developed?
- no single indicator is available to identify all stressors, and one option is to group indicators and group stressors;
- it will be necessary to ensure that the new science outcomes can be taken up as the WFD activities mature.

It will be important to be able to separate the effects of chemical stressors from natural fluctuations in a water body.

Figure 1: This shows possible variation in an ecological quality indicator through time due to both natural causes and an anthropogenic stressor.

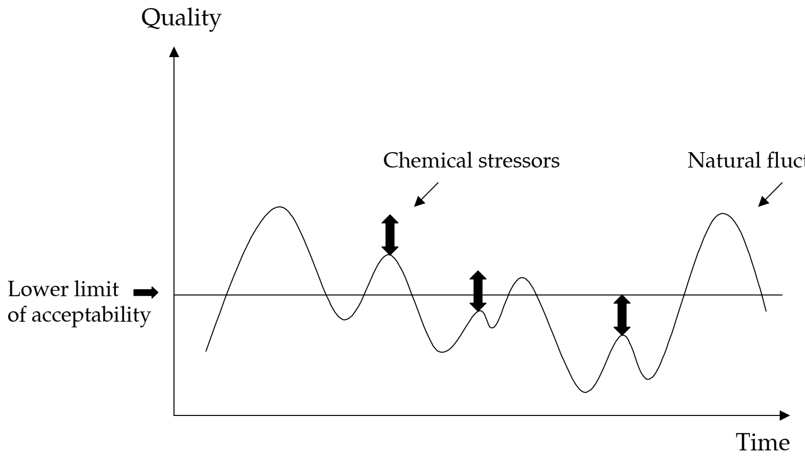


Figure 1 illustrates the need for greater understanding of the variability in samples over time and from that to develop understanding of the boundary condition such that decisions can be justified on how much of a community shift is needed to achieve a particular status. For example, fish populations can be inherently variable, driven by climatic conditions. The measure used to assess status (RIVPACs; phytobenthos; LEAFPACS; phytoplankton in lakes (NUPHAR)) must be fit for purpose - species composition may be the only option but this may not be compliant with WFD. One suggestion was to move to functional groups to help define boundaries and classify sites. Whatever is decided, identifying the boundaries between status classes will be very significant in the debate.

More clarity is needed about the criteria for setting EQSs - how they will be derived from the PNEC and if other factors such as secondary poisoning will be considered. The following points were made:

- EQSs tend to be aimed at achieving pristine quality and to be precautionary;
- EQSs can be site specific; PNECs are not site specific;
- PNECs can be readily updated to reflect new information – standards, once set, tend not to be updated;
- more realistic EQSs could be achieved by using mesocosm studies and understanding mixture toxicity effects;
- EQSs are only available for a limited number of substances;
- EQSs may not properly allow for biological 'resilience' (toxicity versus resilience)
- EQSs do not deal with mixtures.

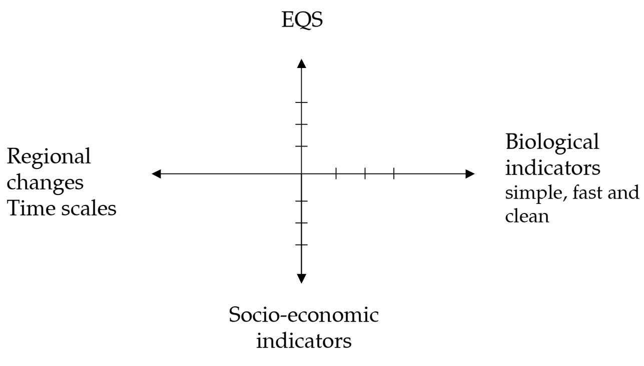
The derivation of EQSs was considered to be highly conservative, one possible consequence of which is that a stretch of river is classified as of 'good' ecological status on the basis of biological monitoring even when EQSs are exceeded. In this case should chemical status override biological status as it appears to do under the terms of the WFD? There may also be the situation where 'adaptation' has occurred i.e. where the local fauna have evolved mechanisms to allow occurrence in the presence of one or more stressors. There is also the possibility that the opposite occurs i.e. there is no individual chemical EQS failure – but the ecology is 'poor', perhaps because of mixture toxicity.

- More research is needed to understand the ecological relevance of the EQS and how this relates to natural fluctuations and changes in human impact over time.

The different factors that could be considered when protecting ecological quality status are summarised in Figure 2 and include:

- Biological indicators - which are efficient, easy to use and interpret;
- socio-economic factors;
- regional changes and timescales within the EU and also globally.

Figure 2: Diagram to indicate the different dimensions that could be considered when defining ecological quality status



Another important aspect to consider is environmental impacts from countries outside the EU, such as acid rain or pollution problems from neighbouring countries that share the same river basin. There is also potential for imbalance in decisions - socioeconomic components must be included.

Misdirected investment – a programme of measures may require investment in treatment to achieve EQS, even though the ecological status is good. Is this wasted resource?

APPENDIX 4: OUTPUT FROM SYNDICATE SESSION II

Moving from individual to population level and population versus species-specific risk assessment

The WFD is now demanding the protection of ecosystems and the communities they contain. Population level risk assessment (PLERA) is a step in this direction. Laboratory tests aim to protect populations, but they are based on measurements at the individual level. It is recognised that some jurisdictions enforce protection at the population level (e.g. fish, protected species).

The PLERA approach might be relevant to chemical standards and regulation, the specific relationship between activity and impact, and subsequently for developing a programme of mitigation measures. It is more difficult to envisage how the approach might be applied directly to defining good ecological status as required by the WFD. Not enough data exist to move effectively from individual-based risk assessment to assessment of risk to field populations. In addition the assessment factor approach is not necessarily the right way to address this since it would reinforce the weak foundation of existing extrapolation. Regulators should not generally accept an overestimation of the PNEC, while overly conservative estimation might lead to excessive costs for society.

Individual level risk assessments may well be overestimating effects on populations and this might be improved by moving to population effects assessments. In general population measures of effect tend to be less conservative than individual measures of effect. This does not mean that all tests should be carried out at the population level: PLERA may be based on effects measured at the individual level. There are also some individual endpoints that invoke public concern (e.g. cancerous lesions) and which would probably result in regulatory action despite no known population effects. It is also important to keep in mind that a prime requirement is to have understanding of community and ecosystem effects. These are not necessarily directly linked to population level effects. Hence micro/mesocosms may be more predictive than individual populations (e.g. ECETOC 1997). Finally predictions based on models might also be employed but much depends on whether their aim is to make specific predictions about the real world or to provide mechanistic understanding of key processes/relationships.

By making explicit the relationship between responses at the individual level and the consequences for population level effects, knowledge of demographics should help to refine and improve the assessment factors used in the calculation of PNECs and EQSs.

There remains the question of which species/populations to consider; should the focus be on keystone species, those responsible for maintenance of community stability and function? The most sensitive organisms to toxicants may not always be the most relevant ecologically. Protecting populations should obviously be an aim of chemical RA, although individuals of conservation importance should also be protected.

Some critical issues and potential problem areas remain to be solved: can we extrapolate from population effect RAs to real-life community response? What is the impact of exposure pathways, multiple stressors, and considering functional responses? Since changes in community structure (i.e., species composition, relative abundance) arise because of changes in the dynamics of the populations in the community, the link should be straightforward, however complications arise because PLERAs often do not take account of interactions involving competition and predation.

A range of indicator species could be linked to the protection goals. As these protection goals vary, so will the (group of) indicator species. However it is also important to select species in a way that covers the diversity of life-cycle strategies within communities e.g. to ensure that both K- as well as r-strategists are taken into account. It seems unlikely that a regulator would ignore significant effects on demographic parameters (survival, growth, reproduction) when there was no significant effect on r because the results are for test species that are surrogates for all potentially exposed species, most of which will be un-tested. Thus a tiered approach might be considered to derive EQS/PNECs first and then to move up to PLERAs if necessary.

Thus the conclusion is that PLERAs are likely to be a useful step towards more relevant community/ecosystem protection but must be developed carefully, to ensure that the assumptions are valid and relevant.

The population level approach can either be used to make projections from laboratory data (prospective risk assessment) or to monitor populations in the field (retrospective risk assessment) and the latter can be a more reliable measure of population effects. However, uncertainties exist in both prospective and retrospective risk assessment.

Mathematical models as well as experimental test systems exist which enable the move to population models, at least in terms of the WFD. For experimental systems, it is necessary to establish the benefit of using these over individual species tests with extrapolation factors in terms of PNECs/EQSs. Mesocosms are already a good tool for population risk assessments of chemicals. They can provide general patterns of community and functional responses but not precise population responses. Further validation needs to be carried out.

The group noted that there was a recent Pellston population level-ecological risk assessment workshop (www.setac.org/eraag/era_pop_pellston.htm) where these and other issues have been addressed. The workshop proceedings shall provide detailed guidance on empirical and modelling approaches to population-level risk assessment as well as discussion of its strengths, limitations, and application in overall ERAs.

The following research needs were highlighted:

- Improve understanding of population measures and development of models for specific application within the context of WFD;
- development of diagnostic capability based on mechanistic understanding of individual-to-population linkages;
- improve understanding of exposure scenarios involving individual - population - metapopulation - food chain interactions;
- more consideration should be given to which population(s) to choose for risk assessment purposes;
- improve use of available data (in particular, data from chronic tests that could provide input into demographic models);
- make more systematic comparisons between PNECs/EQSs and mesocosm effects to determine how conservative each one of them is.

APPENDIX 5 OUTPUT FROM SYNDICATE SESSION III

Role of eco-epidemiology and monitoring

Eco-epidemiology seeks to identify the causes, magnitude and extent of adverse effects on individuals, populations and assemblages of wildlife in the field. It is still in its infancy although as a technique it is already employed in a number of areas. Ideally it should be used to establish causal relationships, but how this can be done is still under investigation. There are no standard protocols but scientific understanding is improving. Many tools are available; however a lack of data is still a major problem. Furthermore, there is a challenge in translating the findings to ecological status?

Currently good case studies exist but only for specific issues (e.g. eutrophication, where cause-effect relationships are well understood). Studies on the Elbe, Rhine and in the State of Ohio (DeZwart *et al* 2004) have been used to show the distinction between the adverse impacts of habitat disruption and chemicals on ecological status. Knowledge will increase with increases in chemical monitoring, but the sensitivity of the technique (in terms of false negatives) needs to be kept under review. There will be a need to develop protocols for epidemiological studies that are approved by regulatory authorities.

A number of different designs exist depending on for example whether the aim is identification of exposure or impact assessment. Since only correlations can be established, there is a need to test hypotheses on the cause-effect basis of these. However, stressors rarely come alone: the link between stressors and effects can often be established using multivariate analysis techniques and the most likely stressors identified. Implications of eco-epidemiology for environmental monitoring to detect cause and effect are that studies should be extensive rather than intensive and become part of a tiered approach. To ensure effectiveness of any remedial action they should continue when the apparent stressor has been removed. (Forbes and Calow, 2002; Suter *et al*, 2002).

The workshop agreed that eco-epidemiology studies would be most appropriately deployed as diagnostic tools in situations where biological and chemical measurements are fully co-ordinated (see also ECETOC 2003b). However it should be remembered that monitoring *per se* is not epidemiology; there has to be an attempt to establish correlations and causality.

The main objective of monitoring programmes should be to inform on ecological status; however the planning and execution of monitoring should be carried out in a way such that the data can also be of value for eco-epidemiology and model development. Eco-epidemiology studies will generally be expensive and this needs to be taken into account for routine application.

Mixtures

In many cases, departures from good ecological quality at particular sites may be attributable to a mixture of agents. Assumptions of additivity seem to hold for most substances (ECETOC 2001). Eco-epidemiological analyses should lead to suggestions about which combinations of chemicals are the causal agents. These hypotheses might be explored further by the application of whole effluent toxicity (WET) and toxicity identification evaluation (TIE) techniques. Tools are now reasonably well developed for the implementation of TIEs, but their deployment can be resource intensive. There may nevertheless be a need for more specifically diagnostic tools involving agent-specific biomarkers.

Physical stressors versus chemical stressors

The group considered if eco-epidemiological studies could be applied where physical stressors might be implicated. They concluded that this may be possible for relatively simple cases or when there are no strong confounding variables. Even for simple causes if there is spatial and temporal variation this may lead to a requirement for complex eco-epidemiological studies.

Research needs

A number of areas for further research were identified. These were grouped into three major categories.

- Critical review/compilation of tools including WET and TIE, and case studies that involve both chemical and physical disturbances. Understand the 'noise' of methods (e.g. bioassays, WET);
- Development of Standards and Guidelines - a number of areas related to monitoring practice were proposed for future research. Given the huge amount of monitoring that was foreseen to meet the requirements of the WFD, the need to minimise the resources currently needed to obtain results was highlighted. In particular the concept of 'good monitoring practice' was raised. This would involve the harmonisation of approaches to monitoring via standardised procedures/guidelines. Areas where harmonisation could be considered include:

- design monitoring programme;
- focus on case studies;
- focus on a number of organisms;
- analysis, interpretation and communication of data;
- integration of biological and chemical parameters;
- integration of laboratory tests.

- Develop more specific diagnostic tools (e.g. biomarkers) to understand mixture toxicity

APPENDIX 6: LIST OF ABBREVIATIONS

CEFIC	The European Chemical Industry Council
EQS	Environmental Quality Standards
EQR	Ecological Quality Ratio
ERA	Ecological Risk Assessments
EU	European Union
PGR	Population Growth Rate
PLERA	Population Level Risk Assessment
PNEC	Predicted No Effect Concentration
RA	Risk Assessment
REACH	Registration, Evaluation, Authorisation of Chemicals
RIVPACS	River Invertebrate Prediction and Classification System
SETAC	Society of Environmental Toxicology and Chemistry
STW	Sewage Treatment Works
TIE	Toxicity Identification Evaluation
WET	Whole Effluent Testing
WFD	Water Framework Directive

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ECETOC PUBLISHED REPORTS

Workshop Reports

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No. 1	Workshop on Availability, Interpretation and Use of Environmental Monitoring Data 20 – 21 March 2003, Brussels