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

Opinion on the

"Revision of the 1996 Technical Guidance Document (TGD) in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) 1488/94 on risk assessment for existing substances [also being extended to provide guidance on risk assessment for biocides under 98/8/EC (excluding human exposure evaluation)]"

submitted for CSTEE opinion on 23 August 2001

Draft revision version on

PART 3/B – ENVIRONMENTAL RISK ASSESSMENT – MARINE PART

CSTEE opinion expressed by written procedure on 25 January 2002

SUMMARY OPINION

1. The CSTEE welcomes the extension of risk assessment procedures to chemicals in the marine environment.
2. However, the CSTEE is concerned about inconsistencies in the approaches advocated for the marine environment and those developed for freshwater and being developed for the terrestrial environment.
3. The CSTEE remains committed to risk assessment as a sound basis for environmental protection, and in contrast to suggestions in the draft TGD believe that in principle there is no reason why it should not be applied to chemicals in all the marine compartments.
4. The CSTEE accepts that in certain situations it may be necessary to act in advance of scientific understanding. But then it is difficult to give a scientific view about the precautionary principles applied. The CSTEE does, nevertheless, make some critical remarks about the PBT criteria advocated in the TGD.
5. The proposals for assessing biodegradation need reconsideration. Estimates based on laboratory observation on half-lives are flawed. This is also the case for freshwater and research is needed to develop more relevant techniques. However, the specific rates proposed in the TGD are too slow and need critical review.
6. In making predictions about environmental concentrations the CSTEE advises caution in relying on local and regional water column estimates since substances that adsorb to suspended matter and sediment may well represent significant sources of exposure for particle feeders, and also by sediment transport can accumulate in areas outside the coastal region used in the models.
7. The CSTEE is dubious about adding extra application factors to represent increased uncertainty in estimating PNECs in marine as compared with freshwater systems. There is little evidence that marine taxa are any more sensitive than freshwater and terrestrial systems.
8. In considering the likelihood of biomagnification, the CSTEE does not believe that on average food chains are longer in marine as compared with other ecosystems. For all systems there ought to be a consideration of at least 4 trophic levels and development of appropriate biomagnification models. This would require a reconsideration of the TGD for freshwater systems.

1. INTRODUCTION

This chapter of the TGD seeks to lay down principles and concepts that should drive an assessment of the impacts of industrial chemicals on the marine environment. It is accepted that schemes already developed “to address risks which might arise from emissions to the terrestrial and/or limnic aquatic environment……. must…act as a starting point for the development of a comprehensive approach to risk assessment of substances in the marine environment”. However, “ due recognition is also given to the many differences in technical detail and general approaches which may be necessary” for marine systems. The *Introduction* goes on to assert that “there are…….. additional concerns for the risk assessment of the marine environment that may not be adequately addressed by the methodologies used for the inland environmental risk assessment. These are:

a. the concern that hazardous substances may accumulate in parts of the marine environment and that:
    (i) the effects of such accumulation are unpredictable in the long–term;
    (ii) that such accumulation would be practically difficult to reverse;
b. the concern that remote areas of the oceans should remain untouched by hazardous substances from human activity, and that the intrinsic value of pristine environments should be protected."

In this *OPINION* the CSTEE first considers the scientific basis of the arguments for treating marine systems in a different way from freshwater and terrestrial systems (*i.e.* concentrating on a(i) and a(ii) above) before considering the extent to which the different technical approaches to the standard risk assessment are justified for implementation in the marine environment.

2. ASSESSMENT OF ARGUMENTS FOR DEPARTURE FROM THE STANDARD (*PEC/PNEC*) APPROACH

2.1 The Rationale

The basic rationale is not expressed very clearly within the draft TGD but the CSTEE understands it as follows:

1. For substances in general, application of the standard approach to local and regional situations should be adequately protective for these and the more open seas (beyond 10 km offshore) because a PEC/PNEC (= RQ)>1 will signal the possible need for risk management and would not be greater in open ocean because of the dilution. Similarly, measures to manage risk, *e.g.* by limiting emissions, with respect to the local and regional situations should also work for the open ocean.
2. This is why methodology for standard risk assessments is only given in the TGD for local and regional situations not for continental/oceanic situations.
3. But, it is argued in the TGD, there are substances that irrespective of the analysis as described in #1 (*i.e.* have RQs<1 before or after any management is applied) give cause for concern because of their capacity to persist, bioaccumulate and be very toxic. This is because of presumed fundamental uncertainties of their behaviour, especially, globally, in the open oceans, viz:
    (i) their capacity to move and accumulate in the seas
    (ii) their capacity to persist especially in deep waters
    (iii) their capacity to have long term effects.

2.2 The Scientific Position

The CSTEE is of the view that, notwithstanding the challenges, there is no reason in principle why risk assessment should not be applied to all substances in all situations in the marine environment. Where these models and predictions can be formulated risk assessments should be carried out irrespective of the intrinsic properties of the substance and the environment likely to be exposed. The logical extension of this view is that management should then be carried out on the basis of the risk assessment. However, where it is not possible to carry out a risk assessment because the science is not yet sufficiently developed it could be legitimate to consider the precautionary approach as proposed in the Commission 'White Paper' (Communication from the Commission on the Precautionary Principle. COM(2000) 1).

2.3 The PBT approach

The PBT approach as advocated in the TGD is not a risk assessment but is based on the intrinsic properties of substances. The CSTEE is therefore uncomfortable with it being presented in a document that is clearly labelled as guidance on risk assessment. Moreover because the PBT approach is proposed on the basis of the precautionary principle it is difficult to give a scientific view on it. The CSTEE, however, believes that the PBT approach would be useful as a means of prioritising substances for further actions.

Nevertheless, the CSTEE has concerns about the definitions of PBT given in TABLE 7 of Section 9 of the TGD on the following grounds:

1. There seems to be little difference between the PBT and vPvB definitions
2. PBT definitions are somewhat subjective and arbitrary so there can be differences between those used in different jurisdictions – care should be taken to explain why those in the table differ from any of the others.
3. In addition, the CSTEE is concerned about the scientific validity of the approaches used for setting the PBT and vPvB triggers. The use of DT_{50} values assumes first-order kinetics; guidance should be given when this is not the case. The criteria for bioaccumulation should consider parameters other than BCF, particularly for covering bioaccumulation from oral exposures.
   For a PBT chemical, long-term food chain exposures should be considered the relevant exposure route. Therefore, toxicity should be based on chronic oral toxicity studies. A low water-borne toxicity value does not necessarily indicate low toxicological concern. In addition, specific triggers rather than reference to classification phrases, should be used in the definition of PBT chemicals.

3. ASSESSMENT OF THE TECHNICAL DETAILS OF THE STANDARD APPROACH

3.1 Marine Degradation (Section7.3 of the TGD)

The Opinion here centres largely on TABLE 2 and addresses issues that are generally applicable to estimates of biodegradation irrespective of environment and those that relate to the specific half lives advocated for use in marine systems.

First the general:
It is scientifically indefensible to make a distinction between substances that are “readily” or “inherently” biodegradable, or to use half-lives determined in screening tests to predict biodegradation. All depends on the interaction between substances and degrading microbes and adaptation of the degraders is crucial. Finding better ways of predicting biodegradation in any aquatic system should be considered and will undoubtedly require further research.

Second, the specific issues:
Notwithstanding the general problems, the figures given in Table 2 for all the aquatic systems suggest rates that are slower than they are likely to be by a factor of up to 50 times. These should therefore be subject to critical review. As well, we note that though it is argued that biodegradation is lower even in estuaries as compared with freshwater systems in 7.2.2 this is

not reflected in the table. Our view is that such a difference is not well established anyway (Appendix 1).

3.2 PEC (local).(Sections 7.4.2 & 7.4.3)
Our main concern here is that there is no explicit spatial definition of "local" in these sections. Unless it is close to source the standard default dilution factor of 100 for PEC aquatic is likely to be underestimated. Whilst we understand the difficulties of being too prescriptive for circumstances that are very site specific, some examples might be helpful with attention being drawn to the need to keep the dilution factor under review dependent on local circumstances.

The calculation of PEC-seawater excludes adsorption on suspended matter (see Clocal seawater equation) and therefore the concentration only accounts for the dissolved fraction. However, chemicals adsorbed on the suspended matter can be bioavailable through food exposure. As a screening approach, the CSTEE suggests that the PEC-seawater should be based on the total concentration (dissolved + adsorbed), and to compare this PEC value with the PNEC (derived from water-borne exposures). If a potential risk is identified, a refinement should consider the toxicity of the dissolved and the adsorbed fractions, using for the latter toxicity tests on relevant species (filtering organisms) exposed to contaminated suspended matter.

3.3 PEC Regional (Section 7.5)
The model presented as FIGURE 1 in this Section is generally sound. However, there is one deficiency. No assessment is suggested for sediment, yet PEC sediment can be at least as important a source of exposure as PEC water column for the regional scenario for certain chemicals. Moreover, substances might adsorb to sediment and be subject to transport leading to concentration both within the regional compartment and far outside. Hence PEClocal and PECregional for sediments may be lower than for more remote locations where fine sediments accumulate (*e.g.* Norwegian Trench). Hence a specific assessment might be needed for these circumstances.

The CSTEE is of the view that both these problems need addressing in the revision of the TGD. The committee is also of the view that it would be useful to give some guidance on the plethora of models that are available in the open literature for predicting environmental concentrations in the regional scenarios envisaged in the TGD.

3.4 Derivation of PNEC (Section 8.1.3)
The CSTEE's comments here centre on TABLE 3 of the Section and in particular on the raising of the assessment factor by a factor of 10, compared with the usual values used for freshwater risk assessments, when extrapolating from information only on freshwater or saltwater representatives of algae, crustaceans and fish species. These are reduced if data are available on 2 additional marine taxa and examples are given as echinoderms and molluscs. This is justified in the TGD on the basis of the well-documented increased biodiversity of marine as compared with freshwater systems.

However, though there are more taxa in the marine environment as a whole, there is no evidence that particular communities are consistently more diverse than those in freshwater or terrestrial systems, and that there are consistent differences in sensitivity between marine taxa and those in other environments (Appendix 2). The CSTEE is therefore of the view that there are no scientific grounds for raising the application factors for marine systems as

compared with those already used for freshwater systems in the situation where toxicity results are only available for algae, crustaceans and fish. However, the CSTEE is also of the view that :

(a) in general application factors should be kept under review and subject to revision as more information becomes available;
and

(b) as a general rule, if there are grounds for believing that the sensitivity of different taxa toward a certain chemical is likely to be different (*e.g.* from an understanding of mechanism of action or large discrepancies between responses of taxa tested) then this should always require more testing on additional taxa.

3.5 Secondary poisoning (Section 8.3.3)

Most of our comments here centre on FIGURE 2 of the section:

1. Starting the food chain with fish is ecologically incorrect. This also applies to freshwater systems.
2. The model food chain contains one extra (top predator) level to that used in the analysis of freshwater systems. This is justified on the basis of a belief that food chains are longer in marine systems (see Section 8.3.1). But the evidence that marine food chains are *on average* longer than those in freshwater ecosystems is not very strong. In both systems we therefore need to use biomagnification based on at least 4 levels (including 3 levels with vertebrates).

The CSTEE does not understand how the default values given in Table 6 were calculated since in one of the references used to support the calculation the BMF was higher than 100 for some chemicals in one of the steps.

There is no mention in the TGD of possible differences in BMF between gill breathing and lung breathing (mammals, birds) animals. There is evidence in the literature of differences of 2-3 orders of magnitude between concentrations of chemicals with biomagnification potential in top predator with comparable behaviour belonging to the two different groups (*e.g.* biomagnification in dolphins much higher than in tuna).

In mammalian top predators, the assessment of a BMF is important to assess internal concentrations and possible transfer to milk, producing toxic effects on young specimens. Marine mammals transfer large amounts of fat soluble and persistent substances to their offsprings during periods of lactation which may last from a couple of weeks (certain seal species) to 2 years (polar bear). The milk has a fat percentage ranging from 30-60%. Thus, marine mammal offspring are potentially exposed to a large amount of fat soluble substances during periods of development and maturation of vital organs.

The CSTEE recognises the difficulties in obtaining PNEC values for predatory marine birds and mammals in estimating food chain effects. However, the committee would council caution in extrapolating too readily from laboratory animals since there are major differences in physiology between these and the marine species that ought to be taken into account. This is also true for freshwater species, but it is probably much more important for marine species. Major differences occur between laboratory species like rats, mice and chicken and marine mammals and seabirds. For example, marine mammals during a year undergo dramatic changes in their nutritive condition, and have a very unique fat dynamics. Seals undergo long periods of fasting during moulting and pup production. Also delayed implantation is practiced.

3.6 Use of QSARs

We note that there is little reference to the use of QSARs in the TGD. However, the CSTEE believes that sufficient work has now been carried out on them to allow their more routine use within risk assessments. The CSTEE is of the view that this could be helpful in accelerating the process, minimising the use of animals in testing, and facilitating a more cost-effective approach. The CSTEE therefore believes that serious consideration should be given to the integration of QSARs into the risk assessment associated with new and existing substances and that this should be reflected by the provision of specific advice in the TGD (Appendix 3).

3.7 More research

The critical appraisal of the draft TGD has suggested a number of research topics that need attention.

(1) Review of existing models and development of new models to predict fate of organic chemicals in oceanic systems, with particular reference to sediment transfer.
(2) Development of more relevant methods for assessing degradation, taking account of adaptation in microbes.
(3) The development of models that appropriately represent biomagnification in at least 4 levels, including 3 levels of vertebrates.
(4) Assessment of similarities/differences in extrapolating from observations on laboratory mammals, to food-chain effects in marine mammals.

CONCLUSIONS

The CSTEE welcomes the extension of risk assessment to chemicals in marine systems. However, it remains committed to a scientific basis for this and are uncomfortable with the suggestion, implicit in the draft TGD, that an approach based only on the intrinsic properties of chemicals alone (PBT) represents a proper risk assessment. The CSTEE does not see why in principle estimates of effects and exposure cannot be made for any environmental compartment, including the open ocean. Nevertheless, the committee accepts that action will sometimes be necessary in advance of a complete scientific understanding, but since this depends to a large extent on subjective judgements it is difficult to give a scientific assessment of criteria. The CSTEE does, nevertheless, draw attention to some specific concerns with the PBTs being proposed in this context.

With respect to the PEC/PNEC ratio: The CSTEE has general reservations about the way decomposition rates are estimated and believe those suggested for estuaries are too low; the CSTEE has concerns about relying exclusively on water column concentrations in local or coastal waters as predictors of exposure; the committee does not believe a case is made for using bigger application factors in marine systems as compared with freshwater to calculate PNECs. In assessing potential for biomagnification it is also of the view that the grounds for treating food chains as longer in marine as compared with other ecosystems are not firm. Irrespective of system it is more appropriate to consider that all consist of at least 4 levels and to develop models on that basis. This would require reconsideration of models used for freshwaters.

All the above raises a number of questions that can only be addressed by more research. The CSTEE suggests some topic areas that deserve attention.

APPENDICES

1. Blok, H.[no.1] First draft for a proposal for long term research on biodegradation rates in the marine environment.
   Blok, H.[no. 2] Questions about biodegradation rates in the marine environment in the scope of risk assessment and the review of TGD [NB not circulated generally yet
2. Janssen, C. Biodiversity and sensitivity of marine systems.
3. Van Leeuwen, K. Comments on the TGD concerning the use and application of QSARs.