Scientific Committee on Health and Environmental Risks

SCHER

Risk arising from the use of copper-based antifouling paints used in leisure boating

Dutch notification 2003/0201/NL

The SCHER adopted this opinion at its 15th plenary on 30 January 2007

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SCHER

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1. BACKGROUND

On 13 June 2003, the Dutch authorities notified within the framework of the "98/34 procedure for the provision of information in the field of technical standards and regulations and of rules on information society services" a draft text by which the Pesticides Licensing Board (PLB) intends to extend application of the standards and criteria laid down in the Decree on environmental licensing requirements for pesticides.

The Commission decided to consult the Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) about several aspects of the notified draft. The CSTEE adopted the related opinion in its plenary meeting of 19 September 2003.

Based on the CSTEE opinion, the Commission delivered a detailed opinion pursuant to article 9.2 of Directive 98/34/EC against the Dutch draft on 27.11.2003. Therein, the Commission mainly concluded that the Dutch risk assessment has not provided sufficient sound scientific evidence to show that the use of copper-based antifouling products presents significant environmental risks to support the envisaged measure.

In its reply of 19.4.2004 to the Commission's detailed opinion, the Dutch government rejected the arguments put forward by the CSTEE.

In its analysis of the reaction of the Dutch authorities to its detailed opinion, the Commission came on 13.1.2005 to the conclusion that several important issues raised in the CSTEE's opinion have not been addressed fully in the Dutch reply. This concerns in particular the partly outdated database used in the risk assessment and the failure to take bioavailability into account. The Commission concluded that, being confronted with contradictory scientific information, no final position could be taken at that point in time.

In its reply of 18 January 2006, the Dutch Government provided the Commission with two additional documents on approaches to address bioavailability in the case of copper in risk assessments.

In its communication of 3 February 2006 the Commission indicated to the Dutch authorities that it needed to analyse the above mentioned RIVM Reports before taking a position. Having examined the reports and having heard the opinion of the interested economic operators, the Commission services decided to submit additional questions to the SCHER.

2. TERMS OF REFERENCE

The SCHER is requested to examine the following questions:

1. Is the SCHER of the opinion that the analysis of the four methods to determine bioavailability described in the RIVM report is scientifically sound and comprehensive, in particular with respect to the assessment criteria established by RIVM?

2. Does the SCHER share the conclusion drawn in the RIVM reports, in particular with respect to the uncertainties associated with the individual methods and their suitability to determine the bioavailability of copper in the context of environmental risk assessments for regulatory purposes?

3. Is the SCHER of the opinion that the additional information provided by the Dutch Government in its letter of 19 April 2004 now provides sufficient information on how the data for the effect assessment performed in the disputed risk assessment has been selected?

4. In the light of the SCHER's conclusion on questions 1 to 3, and all the submitted information including industry's comments', as well as other possible available information, does the SCHER maintain its opinion that the risk assessment performed by the Dutch government to justify the draft measure notified to the Commission does not

provide sufficient sound scientific evidence to show that the use of copper-based antifouling paints in leisure boats presents significant environmental risks?

3. OPINION

3.1 General remarks

The SCHER has revisited the previous CSTEE opinion and the comments submitted by the Dutch Authorities, and as a general conclusion considers that the concerns expressed by the CSTEE have only partially been covered by the Dutch response.

The CSTEE was concerned by the lack of transparency in the selection of the effect assessment data. The Dutch response focuses mostly on the applicability of SSD approaches for setting quality standards such as the MPR employed by the Dutch authorities. It should be clear that both, the SCHER and the CSTEE are fully supportive of the SSD approach when feasible and have recommended this methodology in several occasions.

The concern expressed by the CSTEE was related to the selection of data, not to the methodology itself. This selection is particularly relevant for an essential metal such as copper, particularly when bioavailability corrections have not been taken into account.

The clarification presented now by the Dutch authorities provides some clarification regarding the criteria for checking the quality of the data, but not on the selection criteria required for a metal and particularly for an essential metal.

Regarding the availability of data, the ongoing voluntary risk assessment for copper under the existing substances legislation clearly confirms the CSTEE statement indicating that there is a significantly amount of data on copper ecotoxicity that has not been included in the Dutch assessment. It should be noted that this information is available to all Member States.

The SCHER fully supports the CSTEE opinion regarding the need for considering bioavailability issues in the risk assessment of copper; this approach has been employed for other metals as well as in the voluntary risk assessment of copper under the Existing Substances regulation.

A similar situation should be considered for the exposure assessment part. The main concern from the CSTEE was the lack of justification for some assumptions included in the report. The SCHER welcomes the clarifications, but still considers that data and assumptions should be clearly presented and the rationale for the selected values should be well justified. The main role of the Scientific Committees is to address the scientific quality of the assessments, including methodologies and input data, and the lack of transparency means that the Committee is unable to do this.

Regarding the measured data, the information provided by the Dutch authorities indicates that all measurements have been done in the same area, and all water measurements inside the yacht area are from the same location. Regardless the total number of measurements, the monitoring programme is very limited in terms of spatial cover, and the relevance of the site, not only in terms of emissions of copper from anti-fouling paints but from all other sources.

Regarding the methodology employed for the risk characterization, the Dutch authorities present a long discussion on the rationale for the approach, suggesting a misunderstanding from the CSTEE. The method considers the relative contribution of the source, copper in antifouling paints, but the same correction is applied to the exposure and the effect assessments. As stressed by the CSTEE, this approach in reality means that independent of the contribution of each source, the proposed method assumes that the risk of any specific source is finally expressed as "the total measured concentration divided by the total MPR", as recognised in the Dutch comments.

In the opinion of the SCHER, this approach is useful for an overall assessment of the risk coming from all sources, but, as pointed out by the CSTEE, this approach is not useful for addressing the risk of independent sources, as it allocates exactly the same risk to a contribution representing 0.01% or less of the total emissions as to a contribution representing 50% or more; risk management measures on sources contributing 0.01% or 50% of the total emission would have obvious differences on the overall risk.

Therefore the SCHER suggests that other alternatives should be selected for quantifying the risk of each source by considering their specific contribution above background levels.

Finally, as stressed by the Scientific Steering Committee (2000 and 2003) the risk characterization should consider not only the risk estimation but also the uncertainty associated with the assessment. From a scientific perspective, the assumption that a risk quotient of 0.99 is perfectly acceptable and a risk quotient of 1.01 is fully unacceptable cannot be supported. Obviously, the consequences of being slightly above the trigger or orders of magnitude above the trigger are not similar.

The SCHER may agree that actions should be taken when the risk quotients exceeds the regulatory trigger, but the actions should be different for a risk quotient based on conservative approaches which slightly exceed the threshold than for a risk based on realistic estimations and indicating a high likelihood for effects on populations and communities. The uncertainty assessment and the options for risk refinement are particularly relevant when the risk quotients are close to the trigger.

3.2 Questions 1 and 2

1. Is the SCHER of the opinion that the analysis of the four methods to determine bioavailability described in the RIVM report is scientifically sound and comprehensive, in particular with respect to the assessment criteria established by RIVM?

2. Does the SCHER share the conclusion drawn in the RIVM reports, in particular with respect to the uncertainties associated with the individual methods and their suitability to determine the bioavailability of copper in the context of environmental risk assessments for regulatory purposes?

Response to questions 1 and 2

Four methods for assessing bioavailability in freshwater systems (one for sediments and three for the pelagic compartment) are presented in the RIVM report.

Of the three methods for the water, the first one represents the procedure used by the Dutch Board for the Authorisation of Pesticides (CTB), based on total metal concentrations and thus does not account for bioavailability. The second method (Kopertox) is based on the empirical relationship between Cu toxicity and dissolved organic carbon (DOC) concentrations and can thus be considered as a simplification of the third method: i.e. the Biotic Ligand Model (BLM) approach.

The SCHER considers that only this latter method represents the state-of-the science and as such the committee will only comment on the analysis of the scientific soundness and comprehensiveness of this part of the report.

The SCHER notes that the RIVM report does not present a balanced or complete review of all available data. For example, the report states *'It must be concluded that the most problematic aspect is that although the BLM method is in principle usable, a valid BLM for copper is not currently available for certain trophic levels.[ ] This means that for the second-line assessment, too, the influence of bioavailability cannot currently be included in the risk assessment for surface water.'* The SCHER would like to point out that this statement is not correct, as chronic BLMs have been developed and validated for all three trophic levels and have subsequently been successfully used and validated for other species such as rotifers, various other crustaceans and algal species (Bossuyt et al. 2004a, 2004b, 2005; De Schamphelaere and Janssen 2004a, 2004b, 2006; De Schamphelaere et al. 2004, 2005, 2006; Villavicencio et al. 2005).

Concerning the numerous remarks on the uncertainties associated with for example DOC, lab to field extrapolations and relevance of the physico-chemical characteristics of the surface waters tested in the various validation studies, the SCHER finds that some data were misinterpreted and not all available data were taken into consideration. This has lead to an incorrect assessment of the uncertainty associated with the use of BLMs.

Irrespective of the numerous factors which may affect bioavailability assessment the value of any method/model is - as noted in the criteria set out in the RIVM report - in the predictive capacity of the method/model under realistic conditions. An objective evaluation of all available data and literature demonstrates that, both using laboratory test media and real surface waters that the chronic BLMs (for fish, crustaceans and algae) accurately predict copper toxicity for approximately 80 to 90 % of the samples tested. This means that the species-specific variability of a factor 10 to 100 observed when using total Cu concentrations is reduced, through the use of BLMs, to a factor of approximately 2. This predictive capacity is, despite the concerns expressed in the RIVM report, obtained with most types of waters and natural DOC tested so far.

The evaluation also shows that the models were developed with and validated for waters which cover the 10 and 90 percentile of the EU range of the main factors affecting Cu bioavailability (pH, hardness and DOC). Taking into account the water characteristics of the majority of Dutch surface waters it is concluded that these models are applicable to Dutch waters.

Finally the SCHER notes that bioavailability has been accounted for in the EU risk assessments (RA) of Cd (hardness correction) and Zn (BLMs) and is presently being considered the EU RAs of Ni and Cu (both through BLMs).

On the assessment of copper bioavailability in sediments the RIVM report states *'In relation to sediment, bioavailability, including correction for AVS, is conceptually important. The AVS method is, however, not yet suitable for use in the generic risk assessment for copper owing to the risk of temporal variation in AVS (AVS only plays a role under anaerobic conditions), which means that metals nevertheless become available.* The RIVM report consequently concludes that no bioavailability assessment of copper in sediments can be made.

In the draft EU RAR on copper, to which the RIVM refers, a clear relationship between AVS and chronic Cu toxicity to several benthic organisms was established. A similar relationship was found between sediment organic carbon content and Cu toxicity. Because of experimental and analytical problems, however, this dataset does not allow to quantitatively develop a robust AVS –copper toxicity model which may be useful for RA purposes. The RAR did demonstrate that accounting for sediment organic carbon (OC) content and assuming low AVS significantly reduced the variability in the dataset, illustrating that – for copper - OC normalisation may be a useful method to account for it's bioavailability in sediments. It should be clear that this approach is, because of the low AVS assumption, conservative in nature.

The SCHER notes that the Acid Volatile Sulphide model was used in the RA of zinc under the Existing Substances Regulation.

In conclusions, the SCHER is of the opinion that the analysis of bioavailability models described in the RIVM report is insufficiently comprehensive and sometimes lack scientific rigor to support the conclusion that bioavailability cannot be taken into account in the environmental risk assessment of copper.

The SCHER is of the opinion that the 'total metal' approach (not accounting for bioavailability) - as currently used by CTB – does not accurately assess the environmental risks of copper from antifouling paints and that incorporation of bioavailability will reduce the uncertainty associated with the current assessment.

3.3 Question 3

Is the SCHER of the opinion that the additional information provided by the Dutch Government in its letter of 19 April 2004 now provides sufficient information on how the data for the effect assessment performed in the disputed risk assessment has been selected?

Response to question 3

It is opinion of the SCHER that in the document of the Dutch Government sufficient additional information is not provided to reply to the objections posed by the CSTEE Opinion of 19 September 2003.

In particular, no answers have been provided to the request for more transparency on the criteria for the selection of data for inclusion in the effects assessment.

In the Dutch reply it is confirmed that the MPR was based on the application of the SSD approach, assuming a protection level of 95% of the species of the ecosystem. For applying the SSD approach it is also confirmed that data from the Crommentuijn (1997) report were used. Nevertheless, there is no mention on the criteria used for the selection of data.

Even if the SCHER supports the scientific validity of the approach used, it must also be highlighted that, for the SSD application, the transparency of criteria for data selection is a key point to ensure the validity of the results.

Moreover, a revision of the assessment is also mentioned, but the rationale for that is not clarified.

It is confirmed, without any additional justification, that the equilibrium partitioning method for sediment effect assessment was used. In the CSTEE Opinion it of was highlighted that the equilibrium partitioning method is poorly applicable to metals for deriving the MPR for sediments. The suggestion of the CSTEE of using some recent toxicity data on benthic organisms has been totally ignored.

Therefore, it is opinion of the SCHER that all uncertainties connected with the derivation of MPR still exist.

Besides doubts on effects, many aspects need to be clarified about exposure. This is particularly relevant if one takes into account that PEC/PNEC ratios were only marginally in excess of one. In these cases, there is the need for a higher-tier assessment, by reducing unrealistic worst case assumptions, in order to confirm the occurrence of a risk.

In the Dutch document, it is stated that the assessment is a higher-tier assessment, being based on measured exposure data. However, many objections can be made on that.

1. If the risk assessment is based on measured data, the contribution from antifouling paints cannot be assessed. To evaluate the real role of antifouling paints, an assessment of many factors is needed (leaching rate, time that pleasure crafts spend in port, etc.). It is opinion of the SCHER that all these items are overestimated. No satisfying answers have been provided to the questions posed in the CSTEE Opinion.
2. Measured data refer to total copper, without any assessment of bioavailability. The relevance of this point has been underlined under questions 1 and 2.
3. The Dutch document states that the assessment is based on more than 500 experimental data. It appears that:
    - most of these data refer to sediments outside of marinas and a minor amount refer to water outside of marinas;
    - only 8 samples are available for sediments inside of marinas;
    - only in one sampling station the water column was measured inside of a marina;

- corrections are made for background values, but inconsistencies between the "standard" background used for effects and those used for exposure are not clarified;
- it was assumed that outside marinas copper contribution from antifouling is 35% of the total, but this assumption is not adequately supported.

Therefore it is opinion f the SCHER that exposure has not been adequately evaluated for a higher tier assessment.

3.4 Question 4

In the light of the SCHER's conclusion on questions 1 to 3, and all the submitted information including industry's comments', as well as other possible available information, does the SCHER maintain its opinion that the risk assessment performed by the Dutch government to justify the draft measure notified to the Commission does not provide sufficient sound scientific evidence to show that the use of copper-based antifouling paints in leisure boats presents significant environmental risks?

Response to question 4

The SCHER confirms the previous opinion of the CSTEE and considers that the Dutch authorities have not properly addressed the concerns expressed by the CSTEE.

The Committee suggests that the risk assessment for copper in anti-fouling paints:

- Should be based on a transparent use of all available information
- Must consider the bioavailability issue following the methodology agreed for other metals at the EU level, and
- Requires a proper risk characterization for addressing the risk of copper in anti-fouling paints in combination with other copper sources, expressing the contribution of the source to the overall risk.

These issues have not been properly considered in the assessment conducted by the Dutch authorities; therefore, the SCHER concludes that the risk assessment performed by the Dutch government to justify the draft measure notified to the Commission does not provide sufficient sound scientific evidence to show that the use of copper-based antifouling paints in leisure boats presents significant environmental risks.

4. CONCLUSIONS

The SCHER concludes that the risk assessment performed by the Dutch government to justify the draft measure notified to the Commission does not provide sufficient sound scientific evidence to show that the use of copper-based antifouling paints in leisure boats presents significant environmental risks.

5. LIST OF ABBREVIATIONS

NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TGD	Technical Guidance Document
WWTP	Waste Water Treatment Plant

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