EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

Brussels, C7/VR/csteeop/copper/190903 D(03)

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

"COMPLAINT 1999/5056/NL – RESTRICTIONS TO THE USE OF COPPER CONTAINING ANTI-FOULINGS ON PLEASURE CRAFT"

Adopted by the CSTEE by written procedure on 19 September 2003

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

"COMPLAINT 1999/5056/NL – RESTRICTIONS TO THE USE OF COPPER CONTAINING ANTI-FOULINGS ON PLEASURE CRAFT"

Adopted by the CSTEE by written procedure on 19 September 2003

SUMMARY

The Dutch Government is proposing to forbid the application of copper-based antifouling preparations on pleasure crafts in the Netherlands. The Commission has requested the CSTEE to give an opinion on aspects of the risk assessment and the conclusions drawn from it under three specific questions concerning, in turn, the justification of the environmental quality standards, the soundness of the risk assessment methodology and the consequent conclusions concerning risks to environment:

(1) The CSTEE was not convinced that the environmental quality standards (Maximum Permissible Risks [MPRs]) used by the Dutch authorities in the assessment were scientifically justified. This was based on two substantial concerns. First there was a lack of transparency in how data were selected for inclusion in the effects assessment. Second, there was no explicit account taken of bioavailability; yet this is of critical importance in considering the impact of metals on organisms in test systems.

(2) The CSTEE was of the view that risk assessment methodology used by the Dutch authorities was sound in principle, but suffered from a number of problems in application. First, there were the uncertainties associated with the effects assessment already specified above. Second, there were similar problems with exposure assessment in that uptake was not adequately addressed. Also there was inconsistency in the way that background was included in effects and exposure assessments. Moreover, there were difficulties in interpreting exposure calculations and we had concerns about the scientific basis of some of these data. Most of the risk assessments gave results of marginal concern, except when total copper in the environment, i.e. from all sources not just antibiofouling paints, was taken into account. We were not convinced that this approach, involving total copper, was a sound basis for risk assessment of copper derived from a particular use.

(3) Because of all this uncertainty, the CSTEE was not convinced that the Netherlands has provided sufficient scientific justification to show that copper-based antifouling products present environmental risks. We recommend that the conclusions be revisited in the light of more up-to-date data and modern methodology currently being developed as part of a voluntary programme for the risk assessment of copper in the context of the Existing Substances Regulation.

INTRODUCTION

This Opinion relates to a complaint received by the Commission concerning a measure by the Dutch Government to forbid the application of copper-based antifouling preparations on pleasure craft in the Netherlands. Copper-based antifoulings are biocidal products classified under product type 21 under Directive 98/8/EC concerning the placing of biocidal products on the market. However, the Commission notes that, "the use of copper-based antifouling products is not (yet) harmonised at Community level and that therefore the restrictions at issue have to be examined in the light of Articles 28 and 30 of the EC Treaty". Even so there is concern that the Dutch authorities are using appropriate risk assessment procedures under Directive 98/8/EC especially since DG ENV is in the process of developing procedures for conducting these risk assessments.

Terms of Reference:

The CSTEE has therefore been asked for Opinion on the following questions:

(1) Is the CSTEE of the opinion that the environmental quality standards [Maximum Permissible Risk (MPR)], used by the Dutch Board for the Approval of Pesticides (C.T.B.) as the basis of the environmental risk assessment of copper based antifouling products and in particular, a MPR of 1.7μg/l for copper in solution and 4.3μg/l for total copper content, as stated in the report of the National Institute of Public Health and the Environment "Striving for values" are justified?

(2) Is the CSTEE of the opinion that the methodology followed and the assumptions made by the Netherlands in the context of their environmental risk assessment are consistent and adequate?

(3) In the light of the CSTEE's conclusions on points 1and 2 and all the submitted information, including industry's comments, as well as other possible available information, is the CSTEE of the opinion that the Netherlands have provided sufficient sound scientific evidence to show that the use of copper-based antifouling products presents environmental risks? If so, is it possible to quantify these risks or give an indication if they are a cause for concern, which would require risk reduction measures such as those introduced by the Netherlands?

The Committee has based its opinion on an original document (REF no.1999-5056/NL and attachments) from the Dutch Authorities together with supporting materials that included industry comments, plus a later submitted Dutch Notification (2003 0201 NL) on the restrictions of the use of antifouling paints submitted by the Dutch under the "technical standards" Directive 98/34/EC.

We address each of the questions in turn below.

QUESTION 1

Is the CSTEE of the Opinion that the environmental quality standards [Maximum Permissible Risk (MPR)], used by the Dutch Board for the Approval of Pesticides (C.T.B.) as the basis of the environmental risk assessment of copper based antifouling products and in particular, a MPR of 1.7μg/l for copper in solution and 4.3μg/l for total copper content, as stated in the report of the National Institute of Public Health and the Environment "Striving for values" are justified?

The environmental quality standards are based on the maximum permissible (or tolerable) risks (MPR) specified in the Dutch pesticide legislation. These appear to be derived from Beek (1996; RIZA Werkdocument 96,129X Normstelling Koper en Zink) and developed further in

Crommentuijn (RIVM REPORT no. 601501001) but the exact source of the estimates used by the Dutch was not very clear. Nevertheless, the approach uses a species sensitivity distribution to represent the responses to copper and the endpoint is supposed to take account of background (but whether or not it does will, amongst others, depend on the data selection criteria and we were unable to check this). In Crommentuijn the endpoint is referred to as an MPA and added to background (of 0.44 μg/l for copper in surface waters) to give an endpoint similar to that used in the risk assessment. It turns out that the results from Crommentuijn are somewhat lower than those of Beek and since the Dutch risk assessment was based on Beek, this tends to add further support to the conclusions arrived at by the Dutch authorities.

However, we have expressed a view on the Crommentuijn conclusions in a previous Opinion (On the Justification of a Notification by the Netherlands to Introduce National Measures Concerning Wood treated with Copper Substances, September 2002). Our major concern in the use of this approach is in terms of the bioavailabilty of copper in the test systems and the environment (see under Question 2 below) and the selection of data for use in the SSDs.

We are aware of the difficulties of incorporating metal bioavailability in a risk assessment. However, we suggest the reasons given in Crommentuijn for not doing this are no longer justified in the light of recent scientific developments. Indeed, we suggest that the algorithms and models presently available for accounting for metal availability in the environment are sufficiently robust to be incorporated into risk assessment exercises. The CSTEE wishes to point out that these developments: (1) have been, or are being, applied in recently completed and ongoing metal risk assessments conducted under the Existing Substances Regulation (ESR) and (2) are being considered in the ongoing technical developments in the context of the Water Framework Directive. In the light of these facts and based on the scientific evidence available the CSTEE is of the opinion that without proper consideration of Cu bioavailability, the environmental risks of Cu cannot be correctly assessed.

Of even more pertinence in the risk assessment than the MPRs for water is the MPR for sediment. This is again derived from Beek as 60mg/g with a slightly lower value again noted from Crommentuijn. This is equivalent to the MPA plus background figure discussed above for the water column and is derived from it by a partitioning method. The MPC for sediments is derived using equilibrium partitioning from the water phase ecotoxicity data. Although, this approach has been suggested and used in the past, it has also been shown that it is poorly applicable to metals. As such we suggest that the MPR derived for sediments may not accurately predict the true risk of Cu to sediments. The acute and chronic toxicity of Cu to benthic organisms has been (recently) reported and it is suggested that the MPR is revised using this type of approach. Again, the CSTEE wishes to point out the importance of metal bioavailability. For sediments it has been demonstrated that this is dependent on a number of factors of which the SEM/AVS concentration seems to be one of the most important. Although, also mentioned in the Crommentuijn document, it was not considered in the MPR derivation. The CSTEE is aware of the fact that this concept is presently being considered for use in at least one ongoing metal risk assessment and believes that this incorporation of metal availability in sediments will contribute to the scientific validity and accuracy of the risk assessment.

Issues relating to bioavailability are elaborated further under **QUESTION 2.**

In conclusion, then, with respect to **QUESTION 1** the CSTEE is of the view that because of lack of transparency in the way that the data were selected for inclusion in the effects assessment and the failure to take proper account of bioavailability, the uncertainties associated with the MPRs are such that they cannot be used credibly in a risk assessment. We are aware that a voluntary risk assessment is currently being carried by an industry consortium, in the context of ESR. This is

using more up-to-date data and methodology than in the Dutch assessment. We are of the firm view that there should be cross-referencing between the two approaches.

QUESTION 2

Is the CSTEE of the opinion that the methodology followed and the assumptions made by the Netherlands in the context of their environmental risk assessment are consistent and adequate?

The risk assessments are carried out on the basis of MECs for all compartments apart from the water column in marinas. In the latter, the availability of few measurements led to the use of back calculation from sediment MECs. For all compartments the proportion of MEC likely to be derived from biofouling paints was estimated and this value was compared with the MPR to give a risk quotient. For all compartments these risk quotients were below 1 (indicating unlikely harm) for average values of MECs (except for water beds in marinas), but were above 1 (indicating likely harm) for maximum MECs in all compartments. Excedance levels range from 1.3 to 3.0 (not large).

We draw attention to a number of important uncertainties associated with these calculations:

(1) We believe that the database used to assess the Cu exposure concentrations is too limited to allow a correct assessment of the risk posed by Cu originating from anti-fouling paints.

(2) We note that MECs were not corrected for background, so that the portion due to biofouling paints will contain some background. This is compared with MPA plus background. This therefore conforms with the so-called added risk approach – which is sound in principle, if in practice the background used for both effects and exposure are the same. That used in the effects calculation was a standard (see above). On the other hand, "natural background" is likely to be variable and so it is difficult to assess what effect this will have had on the assessment of risk.

(3) We are also concerned that exposure and effect scenarios for metals depend crucially on bioavailability and this, in turn, varies from one environmental situation to another and their physicochemical characteristics. Due to several physico-chemical processes, copper will exist in different chemical forms, some of which are more bioavailable than others. It should thus be realized that the bioavailability of copper in both laboratory tests and in the environment may be affected, to a much larger extent than other metals, by several physico-chemical parameters, such as pH, alkalinity, hardness and the presence of other elements. For copper, differences in bioavailability/toxicity may vary up to 3 orders of magnitude due to these factors. This means that it is important that both effects and exposure concentrations used in one risk assessment are from the same physico-chemical, and hence bioavailability scenarios. The bioavailability of copper has apparently not been taken into account in this way for exposure and effects estimates in this report. Again, it is difficult to know what effect this might have on the assessment of risk.

(4) Finally there are problems with some of the assumptions used in assessing the proportion of the total MECs attributable to antibiofouling paints. For example, they are based on the presumption that leaching from vessels is 10 $\mu g/cm^2$/year (equivalent to 36g/m^2/year). However, based on an average composition of 150g copper/kg paint, and the application of 1kg of paint per 5m^2, we estimate that the maximum amount of copper that could leach would be in the order of 30g and this would occur over a period longer than one year. Moreover we believe that the amount of time that leisure vessels remain in marinas may be overestimated at 94% total time; this would give them only 20 days per year out of marinas. In our view both these factors will serve to reduce the MECs attributed to antibiofouling. More generally we

should also note that we have concerns about the reports on which the exposure assessments were based in that they appeared to contain a considerable amount of information that was not well substantiated.

Another set of risk quotients is calculated by the Dutch authorities on the basis of "new insights" that effectively uses total MECs representing background and inputs from all anthropogenic sources (i.e. not only from antifouling paints but also drinking water pipes and a large number of sources of smaller contributions). The rationale is that it is total MEC that poses the risk and that if this exceeds MPR there would be grounds for controlling emissions from biofouling paints even if their specific contribution was below MPR. The effect of this is to lead to risk quotients greater than 1 in more compartments viz: the average value for surface waters (1.9 max now 7.9). Excedances now range from 1.7 to 7.9.

The difference in philosophies between the original and the "new" approaches is in terms of assessing risks from a particular source and managing them or assessing risks from a particular contaminant and managing them by applying controls across all emission sources without necessarily paying attention to the magnitude of contributions. Both approaches might be justified on management grounds. However, which method is being used and for what reasons needs to be clear. We are of the firm view that the assessments carried out under the heading of "new insights" are not sufficiently detailed to enable credible substance-based (i.e. not source-based) assessments, for example as required under the Existing Substances Regulation (ESR).

QUESTION 3

In the light of the CSTEE's conclusions on points 1and 2 and all the submitted information, including industry's comments, as well as other possible available information, is the CSTEE of the opinion that the Netherlands have provided sufficient sound scientific evidence to show that the use of copper-based antifouling products presents environmental risks? If so, is it possible to quantify these risks or give an indication if they are a cause for concern, which would require risk reduction measures such as those introduced by the Netherlands?

There are a number of important uncertainties in the Dutch assessments; chief amongst which are the inconsistencies and limitations in the ways the exposure assessments have been performed and the facts that background levels and bioavailabilty (in the two aquatic compartment) are not consistent in the effects and exposure assessments. This makes it difficult to gauge if the assessments represented worst-case scenarios and, in that event, if they were realistic worst cases. Our judgement is that there are sufficient scientific doubts about the risk assessments carried out by the Dutch Authorities to mean that they should not be used as a credible basis for the development of management programmes.

With this in mind it is also important to note that the risk assessments were marginal in terms of suggesting likely risk when MECs attributed to anti-biofouling agents alone were considered (exceeding 1 marginally for average MECs representing sediments in marinas, and maximum MECs for all compartments). The assessment indicated more likelihood of harm if total MECs representing copper from all sources were taken into account. It therefore becomes important to be clear about the management rationale behind these different kinds of assessments and the extent to which it corresponds with the intent of the legislation.

It is our view that if the risk assessment is based on MEC for antifouling substances only, the cause for concern is marginal.

CONCLUSIONS

Our fundamental concerns with the Dutch assessment are: that there was a lack of clarity in the selection of both effects and exposure data on which it was based; that insufficient account was taken of bioavailability issues that are of particular importance for copper; that PEC/PNEC ratios were only marginally in excess of one apart from when total environmental concentration, rather than that due to antibiofouling paints, was taken into account. On the latter, we believe that even if total MECs were considered a justified basis for a risk assessment, as in the ESR, the assessment would need to be carried out in a more detailed and scientifically substantial way than that carried out by the Dutch authorities.

On this basis, therefore, we do not believe that currently the Netherlands has provided sufficient sound scientific evidence to show that the use of copper-based antifouling products presents significant environmental risks.

Rather we would recommend that account be taken of the new data and approaches that are being developed in the voluntary programme on the risk assessment of copper in the environment referred to above and that the Dutch authorities reconsider their assessments and conclusions in this light.