EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels, C7/GF/csteeop/Cdmet-ox/env/280504 D(04)

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

Opinion on the results of the Risk Assessment of:

CADMIUM METAL AND CADMIUM OXIDE

Environmental part

CAS No.: 7440-43-9 and 1306-19-0

EINECS No.: 231-152-8 and 215-146-2

Carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances[1]

Adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004

[1] Regulation 793/93 provides a systematic framework for the evaluation of the risks to human health and the environment of those substances if they are produced or imported into the Community in volumes above 10 tonnes per year. The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC)1488/94, which is supported by a technical guidance document.

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Terms of Reference

In the context of Regulation 793/93 (Existing Substances Regulation), and on the basis of the examination of the Risk Assessment Report the CSTEE is invited to examine the following issues:

(1) Does the CSTEE agree with the conclusions of the Risk Assessment Report?

(2) If the CSTEE disagrees with such conclusions, the CSTEE is invited to elaborate on the reasons for this divergence of opinion.

According to the Technical Guidance Document on Risk Assessment – European Communities 2003:

- *conclusion i): There is a need for further information and/or testing;*
- *conclusion ii): There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;*
- *conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.*

General comments

Overall, the RAR reviews and discusses most issues very thoroughly. However, one of the main shortcomings of this report is that despite these in-depth descriptive analyses the available information is not or inadequately used. Although for certain crucial aspects (e.g. monitoring data, effects data, bioavailability,...) there are large datasets - which could allow quantification of the associated uncertainty and variability - the RAR does not use this information and reduces the RA conclusions to over-simplistic, deterministic RQ calculations.

In the RAR the variability and uncertainty of both exposure and effects assessments have been reduced to single PEC and PNEC values not always using realistic worst case assumptions. The CSTEE is of the opinion that the final conclusions are not based on all available scientific information (and the uncertainty analysis) and as such do not represent the most optimal type of information for possible chemical management strategies.

The CSTEE was not able to verify that all industrial applications of Cd were covered by the RA. It is noted that other potential exposures not related to the industrial application of Cd and CdO have also been considered. The RAR also presents a proper distinction between natural background concentrations and backgrounds related to natural plus historic pollution. Again, the problems

appear when trying to reduce the expected (and observed) variability to a single number for each environmental compartment.

The CSTEE also notes that the local risk characterisations have addressed only some of the "local" issues for which information is available. For example, the use of local dilution factors implies that the assessment is conducted for a specific industrial facility releasing the effluent to an identified water body. Then, the water hardness of the receiving water and the background Cd concentration upstream the facility should also be considered for assessing the local risk and the contribution of the facility discharge to the overall cadmium risk. The RAR uses site-specific emissions and dilution factors but generic PNECs (i.e. not accounting for the site-specific bioavailability) and regional PECs for calculating the local risks. The CSTEE deems that this mixed approach is not acceptable and does not result in the determination of the true local risks.

The CSTEE notes that total risk approach (vs. added risk approach) was used in this RAR and is of the opinion that this approach is appropriate for a non-essential metal like Cd. This statement, however, does not imply that the CSTEE agrees with the way it has been used in the RAR.

In summary, the CSTEE considers that most of the information presented in the exposure and effect parts of the RAR is well discussed and the choices made for conducting the exposure and effect assessment profiles are transparent. However, the CSTEE does not support the conclusions of the risk characterisation, which are based on over-simplifications and use approaches which cannot be supported by the CSTEE, especially in case of a data-rich substance like Cd. An overview of the main concerns is given under 'Conclusions'. The Committee suggests that the PECs and PNECs presented as probability distributions and creating probabilistic PEC/PNEC distributions will considerably enhance the risk characterisation and provide improved insights and information for potential risk management decisions.

Specific comments

Local exposure

Aquatic compartment

Although the local aquatic exposure has been performed according to the TGD, the CSTEE questions the value of the single Kp (average) used (p. 63-64). Although the EU wide variability of Kp values was characterised, this variability was not used in the calculations. The use of an average Kp is not appropriate as it results in important information loss, and it does not reflect realistic worst case exposure. The CSTEE suggests the available Kp information to be statistically analysed and that the resulting probability distribution is used in the RA. This comment is also valid for the Kp values used for the sediment compartment, in which through the use of the best fit derivation of the Kp, the actual variability of the Kp is negated. The CSTEE notes that for the PEC local calculations the same PEC regional has been added to all sites while for other factors - such as emission and dilution - site-specific data were used. The CSTEE is of the opinion that for the PEC local calculations, site-specific information for all factors (including PEC regional) should be used (e.g. upstream Cd concentration instead of generic regional addition to PEC local).

Terrestrial compartment

The CSTEE cannot support the assumption that the only exposure route is atmospheric deposition as this is not supported by data. Similarly, the statement that sludge is not a route of exposure in the local assessment is not supported by data.

As for the aquatic environment, the PEC local calculations for the terrestrial compartment use some site-specific values (e.g. emission amounts and days) but only consider a single PEC

regional. This approach does not take into account site-specific climatic conditions, soil differences and soil use pattern (e.g. industrial, agricultural …) which do affect the PEC regional.

Regional exposure

Aquatic compartment

The regional PEC derivation for the aquatic compartment is based on monitoring data. Although the CSTEE supports the use of measured surface water concentrations for deriving the PEC, it would like to express concerns on the representativeness (for the whole of the EU) of the monitoring data used. In the RAR, data from only two countries (Germany and The Netherlands) were used to calculate the PEC regional (average of the 90 th percentile of the data). The CSTEE is of the opinion that monitoring data, suitable for 90th percentile calculations, from other EU regions/countries are available. Incorporation of these data in the RA will allow to asses EU-wide geographic differences in regional PECs and thus reduce the uncertainty associated with the currently proposed single PEC value. The CSTEE notes that for soft surface waters scenario the RAR proposes conclusion (i).

Sediment compartment

The regional PEC for the sediment compartment is based on measured concentrations. The CSTEE notes that the PEC regional for the sediment compartment is an average concentration derived from monitoring data. An average was chosen as the PEC sediment (instead of a 90th percentile as is recommended by the TGD and as applied for the aquatic compartment). The CSTEE cannot support this approach. In addition, it is not clear from the RAR how the mean was derived (e.g. is it a weighted average based on the number of samples; were averages of average concentrations calculated?). Similarly to the water compartment, the size and representativeness of databases used to derive the PEC regional for sediments should be clarified (e.g. lakes vs. streams).

No attempt was made to account for geographic differences in the sediment PEC regional.

Arguably, the main short-coming of this section is the fact that no attempt was made to account for the factors affecting (e.g. SEM/AVS) Cd bioavailability in sediments. The CSTEE is of the opinion that without consideration of the main factors affecting Cd bioavailability a scientifically sound risk characterisation cannot be made.

Terrestrial compartment (soil)

The CSTEE welcomes the scientific quality and transparency of the regional exposure assessment for the terrestrial compartment. The RAR presents two approaches for calculating the PEC regional and concludes that the 'alternative' method is preferable to derive the PEC regional. The CSTEE agrees with this approach, but would like to point out a number of significant limitations and/or short-comings:

- The alternative approach is based on agricultural soils. The CSTEE notes that this value is subsequently being used for natural and other soils. This is not appropriate and should be addressed.

- Although, seven different scenarios for PEC soil regional were developed, only one was used for the final risk characterization (i.e. worst case). The CSTEE suggests that all scenarios are taken forward in the RA as this will reflect the EU wide variability of the soil compartment.

- It is noted that these (7) scenarios only cover the Atlantic and Central European region. No scenarios were developed for the Mediterranean region although there are production facilities in this region.

- All scenarios used the same leaching flow, no specific climatic conditions were taken into consideration.

The RAR compares the calculated PEC regional with the average measured concentration (monitoring data) and concludes - from the fact that these values are relatively similar - that this demonstrates the validity of the approach. The CSTEE does not agree with this conclusion as it does not represent the EU-wide variability and does not include a realistic worst case situation.

The concern expressed about the use of a single Kd value for the aquatic environment is also relevant for the terrestrial compartment.

Effect assessment

The CSTEE welcomes the transparent data selection and relevance screening performed in the RAR and agrees with the approach taken.

Aquatic compartment

The RAR attempts at examining the effect of water characteristics on Cd bioavailability and toxicity. However, this in-depth analysis and possible approach was not taken forward in a conclusive way into the final risk characterization. The CSTEE is of the opinion that incorporation of Cd bioavailability will reduce the uncertainty of the RA.

The PNEC aquatic is derived from a SSD. The different methods for constructing the SSD have been examined in detail and the most appropriate method was selected. However, it is noted that an additional safety factor is applied to PNEC. The CSTEE has concerns about this procedure as there is neither scientific rationale nor evidence which allows an objective selection of the factor magnitudes. The CSTEE suggests that if there is additional concern about the PNEC, other more scientifically defensible methods can be used to address this issue.

The CSTEE notes that the RAR has proposed conclusion (i) for soft surface water environment The CSTEE agrees that, at present, insufficient scientific information is available to derive a PNEC aquatic for this type of water.

Sediment compartment

The CSTEE notes that the PNEC sediment is based on only one chronic toxicity NOEC value. The RAR proposes two methods to derive the PNEC: 1) the equilibrium partitioning procedure (EqP) and 2) application of an assessment factor (AF) of 50 to the NOEC. Neither approach is supported by the CSTEE.

EqP has been shown not to be valid for metals. Concerning the AF approach the CSTEE is of the opinion that the reason given (i.e. the number of acute toxicity data showing no differences between species) for reducing the AF from 100 to 50 is not justified. Because of the importance of deriving the PNEC sediment as accurately as possible, the CSTEE recommends that additional chronic toxicity data with benthic species are provided/generated.

Terrestrial compartment

It is unclear from the RAR why the effects data obtained with micro-flora and those obtained with all other organism groups were treated in two separate SSDs. Indeed the data indicate that there is no difference in sensitivity of both groups. The CSTEE is of the opinion that the arguments given in the RAR are not scientifically sound (i.e. functional vs. structural endpoints). It is suggested that this issue is addressed in the RAR and that the PNEC is recalculated.

As for the aquatic compartment, the CSTEE cannot support the use of additional safety factors on PNECs derived from SSD calculations.

As for the aquatic compartment, a good attempt at trying to assess Cd bioavailability is presented in the RAR. However, the available data and science do not allow incorporation of this issue into risk characterization phase. The CSTEE agrees with this conclusion.

Based on the arguments given in the section on secondary poisoning (cf. below), the CSTEE does not support the PNEC soil derived in the RAR.

Secondary poisoning

On the issue of secondary poisoning, the CSTEE questions the appropriateness of the use of the critical Cd concentration in humans for the characterisation of risk to ecosystems. I.e. the aims of human RA and ecological RA are clearly different and not all endpoints (and critical concentrations) from one type of RA can be extrapolated to the other. The CSTEE considers that it is essential to check the ecological relevance of the proposed endpoint before using it in the assessment of secondary poisoning.

The CSTEE would like to express concerns on the use of the SSD-like approach based on extrapolated data for accumulated Cd. This approach is not supported as the extrapolation method is not realistic (as recognised in the RAR) and it does not account for:

- differences in exposure routes (and diets) of the different species or for the same species living at different locations.

- differences in Cd bioavailability in different soils.

The CSTEE would like to suggest that a possible way forward to assess secondary poisoning for wild vertebrates could be (1) to estimate the bioaccumulation in different food items as a function of the Cd concentration and (2) from these data develop a scenario for different birds and mammals feeding on different food items (as suggested in pesticide risk assessment guidelines) and (3) to validate this approach by using field data (as reported in the RAR).

Risk characterization

The risk characterisation is performed according to a very restrictive interpretation of the TGD, i.e. by calculating a RQ for each of the environmental compartments; where both the PEC and the PNEC are represented by a single number.

However, the CSTEE is of the opinion that given:

- the large number of exposure and effects data available,

- the good data analysis and variability characterisation performed in the other sections of the report,

the RAR has not characterised the risk of Cd to the environment in the optimal way, i.e. using all available scientific information and most recent techniques. Considering that the concerns

expressed in this opinion affect most of the PEC and PNEC values, the CSTEE cannot support the final risk conclusions of the RAR.

Conclusions

The CSTEE is of the opinion that the RAR, in general, presents an in-depth descriptive analysis of the available and required information. However, the CSTEE has a number of concerns:

- the limited geographical coverage of the surface water monitoring database used to calculate the PEC regional, which did not allow to assess possible EU-wide differences in Cd exposure

- the very limited geographical coverage of the sediment monitoring data base and the procedures used to calculate the PEC regional sediments

- the application of a single exposure scenario for the terrestrial (regional) risk characterization

- bioavailability considerations/corrections were not taken forward in the risk characterization for the aquatic compartment

- the choice of the assessment factor applied to the PNEC derived from a SSD (aquatic and terrestrial)

- possible bioavailability corrections were not considered for the sediment compartment

- the limited data set and the procedures used to establish the PNEC for the sediment compartment

- the use of two separate SSDs to derive the PNEC for soil organisms

- the data relevance and the procedure used to calculate the risks for secondary poisoning

- the variability and uncertainty in the exposure and effect dataset was not quantified and used in the final risk characterization.

Indeed by not accounting for the uncertainty which could have been quantified, the final conclusions given in the RAR – single PEC and PNEC values – may not reflect the actual risks of Cd.

The CSTEE finds that the RAR contains sufficient good quality scientific information to assess the environmental benefit of potential risk management decisions. It is suggested that the use of probabilistic approaches could have resulted in providing the type of information required to make decisions on potential risk management options.