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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS
SCHER

Opinion on

"Risk to the environment and human health resulting from the use of phosphate fertilizers containing cadmium"

Report 285 - Czech Republic -November 2005

Adopted by the SCHER
during the 13th plenary of 19 September 2006

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1. BACKGROUND

The Czech Republic has notified the Commission that it wishes to maintain its pre-accession upper limit of 50mg Cd/kg P_2O_5 for phosphate fertilizers. Member States are not permitted to impose limits on cadmium under the EU legislation on fertilizers, but derogations may be granted by the Commission if there are valid scientific reasons for doing so. A report entitled "Study to assess risks to the environment and health resulting from the use of phosphate fertilizers containing cadmium" was submitted by the Czech authorities in support of their request for derogation.

The Commission must reply to the Czech notification within six months with a decision on whether or not to grant derogation. Austria, Finland and Sweden currently enjoy derogations on cadmium that were granted by the Commission on the basis of an opinion by the CSTEE in 2002 on national risk assessments carried out to the same methodology.

As the Czech report concludes that there is a risk factor very close to 1 (PEC/PNEC = 0.93), the scientific basis of the report needs careful evaluation.

2. TERMS OF REFERENCE

SCHER is requested to:

(1) Assess the overall scientific quality of the Czech report and identify any major deficiencies. Has the methodology of the ERM report been followed, and is the quality of the report comparable to those of Austria, Finland and Sweden that were evaluated by the CSTEE in September 2002?

(2) Comment on appropriateness of the scenarios studied, and on the reliability and validity of the conclusions concerning the accumulation of cadmium in the soil.

(3) Comment on the reliability and validity of the conclusions concerning the current risk to human health and to the environment, and on the corresponding risks after 100 years. In particular, is the choice of a $PNEC_{soil}$ of 0.18 $mg.kg^{-1}$, for which risks are reported for two scenarios, appropriate for calculating risk in the Czech Republic, and is the reported PEC/PNEC ratio of 0.93 the most appropriate value to describe that risk?

3. OPINION

3.1 Question 1

Comments

In general, the Czech report follows a similar methodology for exposure assessment, based on a mass balance model, as suggested by ERM and applied by Sweden, Finland and Austria.

There are elements, particularly some additional input sources, that are included here and that were not included in the other reports and *vice versa*. These differences, however, will not lead to significant differences in the final soil concentrations.

The values of important soil characteristics (soil pH, organic matter content, etc...) used for the calculations of the Cd accumulation in Czech soils are mean values based on databases containing nation-wide monitoring results. The latter data are not available to the SCHER.

Despite this apparent abundance of available monitoring data, the SCHER is of the opinion that these were not used in an optimal manner to address the question 'are there present future risks for the environment and human health due to the use of Cd containing phosphate fertilizers in the Czech Republic?'

Indeed, using a single (mean) value for these parameters does now allow to explore the possible variation of the Cd soil concentrations as a function of soil characteristics (scenario's) and does not provide a quantitative estimate of how much of the arable land in the Czech is or could be at risk. It should be noted that the Swedish, Finish and Austrian reports did include this type of information in the development of the various scenarios relevant for their respective countries. As such the latter studies were able to provide quantitative estimates of the % land surface at risk for different types of fertilizer applications. The Czech report suggests the availability of sufficient national information to allow a similar type of assessment and/or to perform a probabilistic risk assessment using distributions instead of averages. The SCHER would welcome quantitative (probabilistic) risk assessments for these situations, covering the natural variability and if possible the uncertainty of each estimation.

A second major issue concerns the PNEC values used for the determination of the environmental risk characterisations ratios (PEC/PNEC).

The present Czech report used the PNEC values reported in the ERM (2000) report which are clearly different than those proposed by the EU draft RAR on Cd oxide and metal (July, 2003). Although the CSTEE (May 2004) has expressed concerns on the validity of the procedures and values of the PNEC (for soil organisms and secondary poisoning of mammals) derived in the RAR, the SCHER would like to suggest that the influence of these 'alternative' PNECs on the risk characterisation ratios derived in the Czech report is examined.

The SCHER proposes that the scientific quality of the human health assessment may be improved substantially by adopting some of the scientific findings proposed in detail in the CSTEE opinion on the human health assessment of CdR RAR (CSTEE, 2004). E.g. in this opinion it was suggested to use 95% percentiles of the intake and effect levels to ascertain the degree of uncertainty. It is also noted that the Czech Republic report estimated a TDI of 15 to 25 µg/day which is not consistent with the ADI of 40 to 70 µg/day used in the RAR. The relevant endpoint associated with carcinogenicity/genotoxicity and possibly reprotoxicity should be mentioned as a concern.

It should be noted that the CSTEE opinion - on a similar issue - adopted in September 2002 focused on the potential for accumulation, not on the risks for human health and the environment.

Response to question 1:

The SCHER is of the opinion that the Czech report has some deficiencies but has used methods similar to the methodology proposed in the ERM report. However, the Czech report has not made full use of the data which are apparently available. Unlike reports presented by Sweden, Finland and Austria, the Czech report has not developed in sufficient detail soil dependent scenario's which would allow to assess the 'extent' (e.g. area of % of arable land) of the risks. It is also suggested that the human health part can be considerably improved and that information from the Cd RAR and the CSTEE opinion (2004) on that document should be used. In this document Table 1 a detailed set of scenario's and MOS values are calculated for that Cd-U of

2.5 µg/g creatinine correspond to about 50 mg/kg in kidney cortex or assuming that 2.5 µg/g creatinine correspond to a long-term daily intake of 50 µg/day.

3.2 Question 2

Comments

Results of the calculations of the accumulation of cadmium in soil as a result of application of Cd containing phosphate fertilizers are consistent with those discussed in the CSTEE opinion of 24 September 2004.

In this opinion it is suggested that an annual application of 23 kg P_2O_5 kg/ha with a fertiliser containing 20, 40 and 60 mg Cd/kg P_2O_5 results in no, very low (<5%) and low (10%) cadmium accumulation after a 100 year application period, respectively. As such the present scenario in the Czech Republic, i.e.14.5 kg.ha/a application with 17.7 mg Cd/kg P_2O_5, will not lead to long term accumulation. The second scenario presented in the Czech report, i.e. 40 kg.ha/a application with 50 mg Cd/kg P_2O_5, is – according to the CSTEE opinion - expected to lead to net accumulation in most but not all scenarios.

However, it should be stressed that in the Czech report only 3 combined 'application and fertilizer Cd content' scenarios are assessed. The influence of important soil characteristics (such as pH, organic matter content) and other input parameters (such as atmospheric deposition and annual drainage) on the long term Cd accumulation is not assessed.

It is noted that the Czech scenario includes parallel increases in Cd content (from a current average of 17.7 to an average of 50 and 90 mg/kg P_2O_5) and of the consumption pattern of fertilizers (from the current value of 14.5 kg P_2O_5 /ha to 40 kg).

Independent scenarios for each increase related to the different realistic combinations of the environmental factors reflecting the conditions in the Czech Republic are needed to fully ascertain the consequences of application Cd containing phosphate fertilizers.

Response to question 2:

The SCHER is of the opinion that the scenario's assessed in the Czech report are too scant to allow a reliable evaluation of the long term Cd accumulation due to application of phosphate fertilizers to Czech soils. It is suggested that realistic scenario's are developed and assessed which reflect both (1) the variability of the soils characteristics (and their relationship with arable soil area) and (2) the potential combinations of the Cd content and the annual fertilizer application quantity. The SCHER also suggests that the human health part of the Czech report can be improved by including more detailed information on the actual intake of cadmium by the Czech population or by using worst case scenario's.

3.3 Question 3

Comments

There are two major problems associated with the Czech report which affect the reliability and validity of the conclusions concerning the current and future risks to human health and the environment.

The first is the lack of detail in the exposure assessment scenarios. The information presented in the report does not allow assessment of the influence of different application rates and different Cd containing phosphate fertilizers on the various types of arable land present in the Czech Republic (cf. above). The use of nation-wide averages rather than percentiles (preferably related to % Czech arable land area) of soil characteristics and other model input parameters does not allow assessing the importance of different application/Cd content scenarios for environmental conditions present in the Czech Republic. Incorporating more detail in the analysis will allow the determination of the importance, relevance and uncertainty associated with the relevant exposure scenario's and conditions.

The second problem is related to the effects assessment. For the environment, the Czech Republic has used the PNECs proposed in the ERM (2000) of which the lowest PNECsoil was 0.18 mg Cd/kg. As such it should be concluded that this report used a generic PNEC and not a value derived for a typical Czech environment as was done in the Swedish and Finnish reports. The Austrian report also used the lowest PNECsoil proposed by ERM (2000). In their reports, Sweden and Finland, however, derived an alternative PNECs which are assumed to be more representative for their environments: i.e. 0.25 mg Cd/kg and 0.06 mg/kg. The value of and the arguments given to support these 'alternative' PNECs may be questioned.

As mentioned above, the draft EU RAR on Cd oxide and metal has become available in 2003. The PNEC values proposed in this RAR, which are based on an in-depth evaluation of all available literature, are not consistent with the values used in the ERM report (and thus the Austrian and Czech reports) and those proposed in Swedish and Finnish documents.

In the draft Cd RAR a PNEC value - based on the toxicity to terrestrial mammals through secondary poisoning – of 0.9 mg Cd/ kg dw soil (approximately 0.8 mg Cd/ kg soil ww) is used to assess the risks of Cd to the terrestrial compartment. This value is approximately 5 times higher, 3.6 times lower and 15 times lower than the values used in the Austrian and Czech Republic, Swedish, and Finnish reports, respectively. As such, the Czech report used a PNEC value will less conservative than the one used on the Finish report and more conservative that the PNECs used in all other reports.

Based on this comparison, the SCHER wishes to underline the uncertainty associated with the derivation of PNEC using the currently available methods. This uncertainty should be considered when deciding on the acceptability of the risk characterization results. The risk quotient approach, i.e; using a single PEC/PNEC value, for presenting the risk characterization should be used with care to conclude on the presence or absence of risk. Quantitative (probabilistic) approaches covering the natural variability and uncertainty should be considered as alternative tools for the risk characterization. Using the PNECsoil proposed by the draft Cd RAR, the PEC/PNEC ratios for the limited scenario's assessed in the Czech report would have varied from 0.18 to 0.24. If, however, the PNEC proposed in the Finnish report is used, PEC/PNEC ratios would be in the range from 13 to 18. The SCHER considers that, as a minimum, the relevance of the selected PNEC for addressing the characteristics of the Czech soils, and the uncertainty associated with this assessment, should be presented.

Response to question 3

The SCHER is of the opinion that the PNEC used in the Czech report is a rather conservative 'generic' value which has not been extensively peer-reviewed. More recent data and discussions reported in the EU draft RAR on Cd (2003) were not taken into account. As such, and given the non-quantified uncertainty associated with both the PEC and PNEC values, the SCHER is of the opinion that the risk quotients presented in the Czech report may not be the most appropriate

values to describe the presence or absence of the risk of Cd to soil resulting from the application of the Cd containing phosphate fertilizers.

The SCHER should emphasize again that the CSTEE opinion adopted on September 2002 focused on the Cd accumulation in soil only, and not on the risk for human health and the environment caused by the application of Cd containing fertilisers to soils.

4. LIST OF ABBREVIATIONS

ADI	Allowable daily intake
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
MOS	Margin of safety
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RAR	Risk Assessment Report
TDI	Tolerable Daily Intake

5. REFERENCES

CSTEE 2002, Risk assessment to health and the environment from cadmium in fertilizers. Opinion adopted on 24 September 2002.
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CSTEE 2004 Risk Assessment of Cadmium Metal and Cadmium Oxide, Environmental part CAS N°: 7440-43-9 and 1306-19-0. Opinion adopted on 28 May 2004.
http://ec.europa.eu/health/ph_risk/committees/sct/documents/out228_en.pdf

ERM 2000 “Procedures for the Assessment of Risks to Health and the Environment from Cadmium in Fertilizers” (ETD/99/502247).
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