Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Calcium fluoride

Environmental Part

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Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

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1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report SCHER is invited to examine the following issues:

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

(2) If SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.

(3) If SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1 General comments

The RAR on calcium fluoride (CaF_2) is of good scientific quality and is based on information available in open literature and on data supplied by industry. Like the recent RAR on AlF_3, this report is atypical as it is a targeted assessment focussing on the atmospheric compartment only. The reason for this is that although the EU risk assessment on hydrogen fluoride (HF) (2001) concluded that for a number of HF facilities (production, use and/or processing) local risks to the atmospheric and aquatic compartments were identified, the regional exposure assessment was not performed. This was due to, quote: *'also other F-containing High Production Volume Chemicals and so-called unintentional sources, would significantly contribute to regional emissions of HF into the atmosphere (and water)'*. It was therefore decided to also perform a risk assessment (RA) on AlF_3 and CaF_2 (fourth priority list) to obtain a more balanced regional exposure assessment of fluoride. Furthermore it was decided to make a targeted RA for these substances focussing only on the atmospheric compartment. A number of arguments for not addressing the water compartment are given in the CaF_2 RAR. These include, quote: *'(1) F-emissions from the CaF_2 industry are in general lower that the emissions; (2) no information was received that fluorides constitute a water problem at the regional scale'.*

SCHER, based on the limited information given in the RAR, is of the opinion that these statements do not justify why this RA was limited to the atmospheric compartment and the terrestrial compartment exposed via air.

Recognising the targeted nature of the RAR, SCHER notes that this risk assessment adhered to a large extent to TGD procedures. SCHER could not verify the exposure calculations as not all relevant information was available to the committee.

Although SCHER agrees with the majority of the conclusions presented in the RAR, it does have some concerns about the interpretation of the RCRs obtained for some of the exposure scenarios.

As the RA on CaF_2 has the same focus and has been conducted using the same procedures as those used for AlF_3, the opinion presented here is similar in nature but differs in some of the detail.

3.2 Specific comments

3.2.1 Exposure assessment

The total amount of CaF_2 used in the EU in the year 2000 was 838,482 tonnes (production + import-export). Most of the CaF_2 (91.9%) is used for the production of HF and $CaSO_4$.

The RAR states that the total amount of HF released to the atmospheric compartment in the EU during production and industrial use of CaF_2 is 18 t/y (in 2000). SCHER notes that this value was calculated from HF RAR data using an extrapolation factor. It is unclear to SCHER why this extrapolation was made (insufficient emission data for CaF_2 industry?) and how this extrapolation factor was derived.

For the terrestrial compartment, the RAR concludes that the PEC_{local} values for CaF_2 are, like those for HF (HF RAR, 2001), negligible compared to background concentrations. SCHER supports this conclusion.

As there are no emissions of HF during production, the calculation of a PEC_{local} for the atmospheric compartment is not applicable. SCHER agrees.

The PEC_{local} values for the different industrial/professional uses of CaF_2 with respect to HF production were already covered in the RAR on HF and varied from 0.013 to 2.36 µg/m^3. PEC_{local} values for some other uses calculated in the present RAR ranged from 0.032 to 3.05 µg/m^3.

A good correspondence of predicted and measured levels is demonstrated in the RAR.

To derive the $PEC_{regional}$, the RAR calculated the total emission of the production and use of HF, CaF_2 and AlF_3. It is unclear from the report how this calculation was performed. From this calculation the RAR states that the calculated total emission within the EU (for 2001) of 11,945 tonnes results in a $PEC_{regional}$ for the atmosphere of 0.20 µg/m^3.

3.2.2 Effect assessment

Although some limited aquatic toxicity data are presented, no PNEC was derived for this compartment as this RAR was 'targeted' at assessing the risks for the atmospheric compartment.

The PNECs for the terrestrial and atmospheric compartment used in the RAR are the values taken – without revision – from the risk assessment on HF (RAR HF, 2001). These PNEC are 11 mg/kg for the soil compartment and 0.2 µg/m^3 for the atmospheric compartment (plant-air).

In the CSTEE opinion (2000) on the HF RAR a number of concerns are expressed on the type and quality of data used to derive the PNEC for both compartments. As these same values are used here, the scientific validity of these PNECs is also questioned by SCHER.

The fluoride NOECs used for assessing the non compartment effects on the food chain were also taken – without revision – from the HF RAR. SCHER notes that different atmospheric NOECs for livestock (and plants) are given for the grazing season and the winter season, i.e. 0.8 and 03 µg/m^3.

3.2.3 Risk characterisation

SCHER is of the opinion that the title 'European Union Risk Assessment Report: Calcium Fluoride' might be misleading as this title suggests that the risks to all compartments were assessed. This was not the case in this RAR. It is SCHER's opinion that the targeted nature of this risk assessment should be clearly reflected in the title (front page) and/or clearly stated in the Introduction (and several other places) and Conclusion section of this report.

The following conclusions by SCHER should be considered in the light of the concerns expressed on the PNEC values used and on the committee's inability to verify the presented exposure calculations.

- For CaF_2 production and down-stream users, the RAR proposes conclusion (ii)[1]. SCHER agrees with the rationale given and supports these conclusions.
- For the atmospheric compartment, there is no HF emission during production of CaF_2, therefore conclusion (ii) is proposed. SCHER supports this conclusion.
- The regional PEC/PNEC for the atmospheric compartment is ≤1 and conclusion (ii) is drawn. SCHER supports this conclusion.
- For the use of CaF_2 in the metal industry (based on a realistic worst case emission factor) a PEC/PNEC values of 1.5 is derived. The RAR, however, proposes a conclusion (ii) and justifies it as follows *'in view of the limited contribution of local air concentration to the exceeding of the PNEC'*. SCHER is concerned that despite a RCR > 1, conclusion (ii) is proposed in the RAR. The deviation from normal practice may affect objectivity and consistency of the conclusions presented in other RARs.
- Conclusion (iii) is drawn for the following downstream uses of CaF_2: (1) local environment in the vicinity of the downstream use of CaF2 (HF production): PEC/PNEC > 1 (but the RAR does not state by how much?); (2) eight steel production sites for which a PEC/PNEC of 2 is calculated. Although SCHER support with these conclusions, it would like to express it's concern about the inconsistent interpretation of RCR >1 [cf. above: 1.5= conclusion (ii) vs 2 = conclusion (iii)].
- Conclusion (ii) for non compartment specific effects relevant to the food chain is proposed for CaF_2 production. SCHER supports this conclusion.
- For non-compartment specific effects relevant to the food chain, SCHER does not support the use of different atmospheric NOECs for livestock (0.3 vs. 0.8 µg/m^3) for different down-stream users. This leads to inconsistent statements on risk among the various uses. For this reason, SCHER cannot support the proposed conclusions.

4. LIST OF ABBREVIATIONS

NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RA	Risk Assessment
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
TGD	Technical Guidance Document

5. REFERENCES

European Union Risk Assessment report on Hydrogen Fluoride (2001). 1st Priority List, Volume 8. EC 793/93.

[1] *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