



Scientific Committee on Health and Environmental Risks

SCHER

OPINION ON

"CADMIUM IN FERTILISERS – REQUEST FOR A SCHER OPINION ON THE RISK ASSESSMENT REPORT FROM THE KINGDOM OF SWEDEN"

The SCHER adopted this opinion via written procedure on 27 February 2012

About the Scientific Committees

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. They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

Scientific Committee members

Ursula Ackermann-Liebrich, Rolf Altenburger, Herman Autrup, Denis Bard, Stella Canna Michaelidou, Wolfgang Dekant, Pim de Voogt, Arielle Gard, Helmut Greim, Ari Hirvonen, Colin Janssen, Renate Kraetke, Jan Linders, Borut Peterlin, Jose Tarazona, Emanuela Testai, Marco Vighi

Contact:

European Commission
DG Health & Consumers
Directorate C: Public Health and Risk Assessment
Unit D3 - Risk Assessment
Office: 4, rue Breydel (B232), 1049 Brussels
Sanco-Scher-Secretariat@ec.europa.eu

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http://ec.europa.eu/health/scientific_committees/environmental_risks/index_en.htm

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Prof. Colin Janssen (chair and rapporteur)
Prof. Pim De Voogt
Prof. Marco Vighi
Prof. Eric Smolders (external expert)

All Declarations of working group members are available at the following webpage:
http://ec.europa.eu/health/scientific_committees/environmental_risks/members_wg/index_en.htm

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1. BACKGROUND

On 17 October 2011, the Kingdom of Sweden has notified the Commission of its intention to reduce its national provision on the cadmium content of mineral phosphate fertilisers from 100 mg Cd/kg P to 46 mg Cd/kg P.

Current EU legislation concerning fertilisers (in particular Regulation (EC) No 2003/2003) does not contain limits on the content of cadmium. In accordance with Article 114 (5) TFEU, Member States are not free to impose limits on cadmium in fertilisers within the scope of the EU fertilisers legislation. However, derogation for introducing national measures may be granted when a Member State provides new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure. A risk assessment report was submitted by the Swedish authorities in support of their request for derogation.

The Commission must decide on the Swedish notification within six months with a decision on whether or not to grant derogation. If justified by the complexity of the matter and in the absence of a risk to human health, the Commission may prolong the period of examination by a further 6 months.

It should be noted that Austria, Finland and Sweden currently have already obtained derogation for setting limits on cadmium in fertilisers that were granted by the Commission on the basis of a CSTE opinion of 2002 on national risk assessments. Information on the risk assessments carried out by several Member States are available at:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/fertilisers/cadmium/risk-assessment_en.htm

Following an initial screening of the documents submitted by the Swedish authorities, risks for aquatic organisms living in extremely soft waters have been identified. The scientific basis of the report should be carefully examined to determine whether the justification submitted by Sweden in support of its request does actually contain evidence that is new (i.e. has arisen after 2003, the date of adoption of the EU Regulation on fertilisers), and relates to the protection of the environment or the working environment on grounds of a problem specific to Sweden¹.

We therefore request that the report should be submitted to SCHER for an opinion. In order to respect the legal deadline of 17 April 2012, an opinion of SCHER would be needed for 31 January 2012.

2. TERMS OF REFERENCE

SCHER is requested to:

1. Assess the overall scientific quality of the Swedish report and identify any significant deficiencies.
2. Comment on appropriateness of the scenarios studied, and on the reliability and validity of the conclusions concerning the identified risks for the environment, or if relevant, the working environment, that are specific to Sweden.

¹ The report submitted by Sweden does also consider risks to human health – however, examination of these is not relevant for requests submitted under Article 114 (5) TFEU.

3. SCHER should in particular evaluate whether the assumptions made in the Swedish report (i.e. that no cadmium is absorbed during its passage through the subsoil and that the dilution factor is low compared to the dilution factors proposed in Technical Guidance Document (2003)² are appropriate for calculating risk in the Swedish environment. (See conclusions of Annex V of the Swedish report).

3. OPINION

3.1. Overall scientific quality of the Swedish report.

Assess the overall scientific quality of the Swedish report and identify any significant deficiencies.

In general the risk assessment report prepared by the Swedish authorities is of good scientific quality. SCHER mainly based this opinion on the information provided in Annex 5 (Bilaga 5, H. Parkman, January 2011). It provides an overview of existing information on the ecotoxicity of Cd summarized in comprehensive reviews (e.g. EU RAR 2007 and others) and some new, more recent data (including field observations) relevant for the risk assessment of cadmium. However, the report contains a number of statements and/or assumptions which are not supported by sufficient evidence. For example the observations given in the fish monitoring studies (page 9) assume a cause-effect relationship although this assumption is not proven. Another example is the assumption of the dilution factor ($= \frac{1}{2}$) used to calculate the Cd concentration in the surface waters of brooks (which is central to this risk assessment). Indeed, the Cd concentration in the brook receiving drainage water is based on a 1:1 dilution of drainage water with brook water upstream of the emission point; no scientific evidence or justification is given to support this factor.

3.2. The scenarios studied and the conclusions.

In general the scenarios studied are appropriate and most parameter values used in the scenarios are acceptable. However, for some scenarios the conditions used for the calculations can be questioned. For example, the calculations presented in Scenario 6 (page 26, Table 7) and made for Class PAL II soils is poorly representative as it corresponds to phosphorus application used in less than 25% of the Swedish soils (page 18, Figure 4 of the Bilaga 4: Sternbeck and Eriksson, January, 2011). Also the calculations of the surface water concentrations in the brooks after drainage (page 26, Table 7) seem problematic and the proposed levels do not correspond with the measured concentrations given elsewhere in the report (page 7). The reason for this discrepancy is the assumed (but not substantiated) low drainage/brook dilution factor (cf. above). In addition, the representativeness and ecological relevance of the described scenarios, with just a 1:1 dilution of the water drained from P-fertilized agricultural soils into the brook is unclear, particularly due to the low percent of arable land (about 7% of the total country area) and because the RCRs are for Cd concentrations maintained in time or equivalent to annual averages (PNEC equivalent to the AA-EQS under the WFD).

The PNECs used in this risk assessment are those suggested in the EU RA on Cd (2007) (and also in the WFD context), and as such can be supported by SCHER. The presented RCRs are thus solely dependent on the exposure assessment, i.e. the predicted Cd concentrations in Swedish surface waters. Since the latter are dependent on the above mentioned, unsubstantiated soil/brook dilution factor, SCHER does not support the RCR for brooks presented in the report.

² http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd/tgdpart2_2ed.pdf

3.3. Evaluation of the assumptions.

As mentioned above, most assumptions used in the calculations seem valid (although sometimes worst-case). However, SCHER does not agree with the assumption that there is no adsorption in the soil. This will only occur when the soil is already heavily contaminated and no *net* adsorption occurs at steady state, which is currently not the case in most Swedish soils. The report also assumes that there is no Cd adsorption in soil occurring deeper than 30 cm; this is also not the case. The latter thus makes that the predicted concentrations in the brooks are over-estimated. Finally, as mentioned above, the soil/brook dilution factor is not substantiated by robust scientific evidence. As such, SCHER cannot support the RCR (Table 7) given in the risk assessment report. Overall, the SCHER does not consider the assumptions made in the Swedish report as appropriate for calculating risk in the Swedish environment.

3.4. Retro acta: additional information on this issue.

SCHER notes that the CSTEE (2002) has published an opinion on the relationship between Cd concentrations in fertiliser and expected Cd concentrations in European soils. The SCHER confirms that these calculations and conclusions are still valid (including for Swedish agricultural soils). However, it is important to recognize that the CSTEE opinion (2002) was based on a stand-still principle, not on a risk assessment as performed in the present opinion.

4. REFERENCES

EU 2003: <http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/fertilisers/>; accessed January 9, 2012