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

Opinion on the results of the Risk Assessment Targeted Report (TRAR) of:

Cadmium oxide as used in batteries

**CAS No.: 1306-19-0
EINECS No.: 215-146-2**

**Carried out in the framework of Council Regulation (EEC) 793/93 on
the evaluation and control of the risks of existing substances¹**

**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), the CSTEE was requested to produce and opinion on the Risk Assessment Report of Cadmium Metal and Cadmium Oxide. This RAR also included a targeted risk assessment for the use of cadmium (oxide) in batteries. 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.*

Introduction

The RA presented in this TRAR is focused on the assessment of cadmium as used in NiCd batteries during the different life stages such as manufacturing, recycling and disposal.

The CSTEE recognizes that for this type of TRAR there is no or limited guidance available in the TGD. As such, the rapporteur developed completely new scenarios with associated underlying assumptions. The TRAR covers several stages of the life-cycle of NiCd batteries, but only the risk associated to Cd is considered.

The main differences with the comprehensive RAR are associated to the assessment of waste disposal, and it should be considered that guidance for this assessment is very limited and the interpretation of available data is very complex. The TRAR focuses on disposal of portable NiCd batteries, those use by general consumers, and exclude the industrial batteries, under the assumption that a recycling close to 100% for industrial batteries is achievable.

For portable NiCd batteries, a 100% of recycling is not expected and two disposal ways, via incineration and via municipal solid waste landfilling are considered. Obviously, NiCd

batteries are not the only source of cadmium in municipal wastes, and monitoring data just reflect the overall amount of cadmium; modeling approaches are required for quantifying the contributions expected from different sources, including the batteries.

Data indicate a large variability in the total cadmium concentration; a significant variability in the contribution from NiCd batteries in municipal wastes is also expected. Several main factors contribute to this variability, including marketing conditions, waste management methods, percentage of batteries recycled, or socio-economic situations. The TRAR has presented the available information and conducted assessments for different options.

General comments

As expected, the TRAR is developed as a follow up of the comprehensive RAR. Therefore, it should be noticed that most CSTEЕ comments on the comprehensive RAR are also applicable to this targeted assessment.

This aspect is particularly important for the effect assessment, as the TRAR just copy the deterministic PNECs presented in the comprehensive RAR. It should be noted that the CSTEЕ does not agree with the PNECs derived for aquatic organisms, sediment dwelling organisms, soil organisms and secondary poisoning used in the comprehensive RAR. As explained in the CSTEЕ opinion on the RAR of Cadmium metal and cadmium oxide the Committee considers that the available information on bioavailability and variability in the expected effects has not been properly considered due to oversimplification.

For the exposure assessment TRAR presents several innovative alternatives, and on the basis of available information, has developed new scenarios for conducting environmental risk assessment for metals disposal via incineration and landfilling. However, the validation/justification of several assumptions is suffering from the limitations of available data.

An additional key problem is that the simplistic risk characterization methodology employed in this TRAR is not appropriate for data-rich chemicals such as cadmium. In particular, the risk of a targeted assessment can be expressed using comparative risk assessment methods, and considering the large amount of information available and the large variability associated to the EU conditions, quantitative (probabilistic) options should be selected as the best option for risk characterization.

A proper management within the risk assessment context of other cadmium sources than the NiCd batteries is required, particularly for land-filling releases and for the contribution of the regional PECs. It is suggested to focus the assessment on comparative approaches, covering the geographical differences (e.g. using the information on the bio-geographical regions produced by the European Environmental Agency for refining the exposure and effect parameters which are affected by environmental conditions) and trying to distinguish between uncertainty and true variability.

Comments on the exposure assessment

Overall, the initial part of the exposure assessment of the TRAR is of good quality and transparent. It offers scenarios for covering the main exposure routes within the life cycle of the NiCd batteries, provides an overview of the variables producing the largest modifications

in the exposure predictions, and presents a rudimentary sensitivity analysis (attempting to determine the key factors affecting the overall conclusions).

However, most of this information is not later used in the risk characterization. In fact, after presenting the large influence of the operational parameters in the estimation of the exposure related to cadmium used in NiCd batteries, the TRAR tries to oversimplify all this information to a single deterministic value.

The CSTEE recognizes the utility of simplified estimations for an initial screening assessment. But the selected assumptions should represent worst-case conditions. A large number of assumptions are made for this simplification process, and the rationale for the selection of several values and triggers is not presented. Many of these unsubstantiated assumptions may be criticized and the finally selected exposure values do not necessarily represent a worst-case situation; mean values are used in some cases, while 90th-95th percentiles or assumed worst cases are used in others parts of the assessment. In conclusion, the CSTEE cannot assess if the estimated exposure levels represent or not worst-case conditions.

It should be noticed that the contribution of cadmium exposure from other sources than NiCd batteries represents the main component in the overall exposure level for most estimations. For example, large differences in the exposure scenario (dilution factors of 20 or 1000; land-filling of 10 or 50% of NiCd batteries; leachate concentrations of 5 or 50 ug/l; direct or indirect discharge, etc.) produce minor changes in the PECs (from 0.11 to 0.12 ug/l, only exceptionally 0.13-0.16) where the PEC_{regional} (a value of 0.11 ug/l is used while the contribution of NiCd batteries to this value is negligible) represents between 90 and 100% of the PEC and therefore of the overall risk in most cases

It should be considered that cadmium natural and man-made backgrounds differs largely within the EU, and that other relevant environmental parameters, affecting the potential for releases, the fate and behavior and/or the bioavailability of cadmium, also present a large variability.

The CSTEE considers that the available information should be used and this variability should be covered in the assessment.

The TRAR directly translate several methodologies, assumptions and values from the comprehensive RAR. Obviously, when relevant, the specific comments included in the CSTEE opinion on the cadmium RAR should be also applied to the TRAR.

General comments on effect assessment

As already mentioned, the effect assessment is based on a set of PNEC values not agreed by the CSTEE. A proper consideration of the bioavailability of cadmium is required.

The effect assessment for the TRAR scenarios on waste disposal should considered the chemical speciation of cadmium released via incineration and landfilling, and should take into account the bioavailability of these releases. For example, in acidic areas, the concentration of Cd in the leachate can be higher due to the higher capacity of acidic draining water to dissolve/extract cadmium and also the bioavailability of cadmium can be higher resulting in effects at lower concentrations.

General comments on risk characterization

The large amount of information produced for the exposure assessment and the large amount of available information on the effect side (presented in the comprehensive RAR but not transferred to the TRAR) is not used in the risk characterization. The efforts for reducing the information to single PEC and PNEC numbers are not scientifically justified.

The CSTEE considers that the available information is enough for producing risk characterizations based on distributions instead of point estimates, or at least, for accounting the variability among European regions. For data-rich chemicals, such as cadmium, reducing the true variability for producing a point estimates is not scientifically justifiable. While uncertainty should be reduced as much as possible, the real variability should be presented in a clear way within the risk assessment, and be transferred to the risk characterization, as the information is essential for risk management decisions

Nevertheless, the CSTEE welcomes the fact, despite the high uncertainty associated with this RA that the report tried to address the variability by using different risk scenarios and sensitivity analyses. The information presented in the TRAR if properly evaluated would allow comparative risk assessment of the different management options, including future scenarios, and could constitute a proper basis for comparing risk management options. Unfortunately, this information has not been properly transferred to the risk characterization.

Even more, the CSTEE wonders if the use of the TGD approach for presenting the outcome of the risk assessment based on the conclusion i); ii) or iii) options is a proper methodology for presenting the results of a targeted risk assessment; particularly when the addressed use just cover a minor part of the local environmental exposure but a generic overall regional contribution.

In conclusion, the CSTEE does not support the conclusions presented in the TRAR and considers that the report offers much more information than that finally used for the risk characterization.

The report should clearly identify the risk associated to the different use conditions; consider the variability of the European situation, and provide a comparative assessment. There are several options for using the available information in a proper way, and several recommendations are presented below.

Recommendations

The CSTEE recognizes the complexity for producing targeted risk assessments, particularly when the target focuses on a specific use of the chemical. The use of the added risk approach is problematic as the contributions from other sources are not considered. Therefore, the CSTEE suggest presenting comparative risk assessments for the overall risk (total risk approach) under different hypothesis/proposals for the emissions associated to the particular use in NiCd batteries. These comparisons would allow the identification of the contribution of NiCd batteries to the overall cadmium risk under different management options.

For cadmium, the use of a lower tier assessment methodology, adding together worst-case estimations at each level, would give the unrealistic outcome that an even natural background

represents a significant environmental risk. The TRAR seems to elude this problem by using combinations of worst-case and average-case situations, which are not justified and reduce the transparency of the assessment.

The CSTEЕ considers that for data rich chemicals there are additional possibilities for conducting the targeted risk assessment that should be explored, such as:

- Conducting fully quantitative (probabilistic) comparative assessments.
- Conducting geographically-based assessments, where the variability is reduced and allows the use of realistic assessments within each geographical area, which are then combined in an overall EU situation using weighting factors.

The first recommendation avoids oversimplifications of the exposure and effect assessments, and produce probabilistic estimations for both, considering the risk with and without the specific use, and where relevant, comparing also different release scenarios and risk management options for the assessed use. Statistical methods can be then applied for comparing the different distributions.

The second recommendation also avoids oversimplifications, but maintains the “simplified assessment” within each region.

Both recommendations can be combined, producing probabilistic assessments for each region which can be then integrated in a simple probabilistic assessment. This should be the preferred option for the CSTEЕ as addresses simultaneously the regional variability and the use of all available information.