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

Opinion on

the Report on *"The risks to health and environment by cadmium used as a colouring agent or a stabiliser in polymers and for metal plating"* (Risk & Policy Analysts Ltd, 2001)

expressed at the 27th CSTEE plenary meeting

Brussels, 30 October 2001

Introduction

Two Reports on the risks to health and environment by cadmium used as a colouring agent or a stabiliser in polymers and for metal plating were prepared for the European Commission by WS Atkins in 1998 (1,2). In assessing these Reports, the CSTEE came to the conclusion that they contained major areas in need of further clarification or amendment, especially as regards the estimation of PEC and PNEC values, the values of human daily intakes employed and the correct value of the human NOAEL (3). The present Report was prepared in order to re-examine the same issues as the WS Atkins (1998) Reports, having in view especially the criticisms of the CSTEE.

Opinion

The CSTEE is in general agreement with the approach, procedures and most of the conclusions of the present Report. In particular, it welcomes the increased transparency compared to previous Reports on the same subject. Furthermore, it endorses and wishes to underline the importance of the statements on uncertainty, resulting from the numerous assumptions, associated with the occurrence of risks from the specific cadmium uses addressed.

The data on occupational exposure to cadmium referred to in the Report are limited and do not justify the Report's conclusion that occupational health risks are limited to workers in pigment and stabiliser manufacture facilities.

The CSTEE notes that the lack of information on long-term emissions of cadmium from landfills constitutes a serious problem and recommends that further research in this field as of high priority. As the cadmium releases from this potentially important exposure route are not considered in this report, the expressions of risk may not reflect the true environmental risks of these cadmium uses.

The CSTEE strongly underlines that the results of this Report cannot be used in isolation, and that the importance of the possible risks of these cadmium uses should be evaluated in a broader context.

Justification of the Opinion

The present Report uses the WS Atkins (1998) Reports as a basis, and re-examines all the specific aspects of cadmium use, emissions, exposures, and toxicity to the environment and humans, using more recent data in some cases. It also examines, where appropriate a number of scenarios regarding disposal and recycling. It makes extensive use of data, analysis and insights provided by the Draft EU Risk Assessment Report (RAR) on cadmium (De Win et al., 1999). In each Section, the criticisms or questions of the CSTEE are specifically addressed.

Environment

Exposure assessment

In the Report, estimates of environmental and human exposure attributable to the three specific uses of interest are made using the methodology of the Technical Guidance Document and the EUSES modelling programme, reviewing the application of EUSES in view of the criticisms stated by the CSTEE.

More recent exposure data have been used on production volumes than those employed in the Atkins (1998) Reports. All PECs were calculated using the EUSES software and thus represent predictions which were not verified using measured data. Apparently this type of data is not available. The uncertainty associated with the PECs may therefore be considerable. The recognition that both the behaviour (exposure) and the effects of cadmium are dependent on the properties of the environment (*e.g.* in aquatic environments: pH, hardness, dissolved organic carbon) and should be accounted for in risk assessments is, supported by the CSTEE. Consequently the fact that the PEC calculations were performed for both a 'general' and an 'acidic' environment not only presents a more realistic assessment but also enhances the transparency of the document.

However, it is unclear to the CSTEE how both types of environments were defined (1) and what the representativeness (% geographic distribution) of these environments is for the EU area (2). It is suggested that the above-mentioned information be provided in the report.

The partition coefficients, used in the Report and required to make the PEC calculations for the different environmental compartments are scientifically justifiable. The CSTEE recognises that for the 'realistic worst case scenario' (acidic environment) the lowest Kp values available in literature were selected thus maximising potential exposure. Although the CSTEE supports this approach, it is unclear if and what type of quality control was applied for the data selection used to derive the bioconcentration factors (BCFs) required to calculate the cadmium transfer to higher trophic levels and to humans (man via food). Uncertainty about the ecological relevance of some of the BCFs used in the various environmental compartments may therefore be large.

As mentioned, various worst case assumptions were made throughout the PEC calculations, this is particularly true for the metal plating use for which no guidance is given in the TGD. As indicated in the report, the results from this analysis are subject to large variability (too many non-verified assumptions) hence the conclusions need to be viewed in this context.

Most of the cadmium used for the purposes covered by the Report will end up in landfills together with cadmium from several other applications. However, because landfills are not addressed in the Technical Guidance Document, the Report states that it was not possible to address the emissions from landfills arising from these specific uses.

The CSTEE notes that the lack of information on long-term emissions of cadmium from landfills constitutes a serious problem and recommends that further research in this field as of high priority. It should be emphasised that without this type of information the exposure concentrations in the various environmental compartments cannot be assessed and consequently the risks arising from cadmium exposure cannot be determined.

Effects assessment

As mentioned above, the Report has extensively relied on the comprehensive data set compiled in the cadmium RAR (De Win *et al.*, 1999). As the same data quality and relevance procedures, the same data sets and the same extrapolation procedures (log-logistic extrapolation model) were applied, the PNECs derived for the various compartments are identical or very similar to those reported in De Win et al. (1999). The CSTEE supports the use of this data set and the methods used. Furthermore, this approach will enhance harmonisation of the use of effect data for specific compounds across different EU initiatives.

The Report briefly discusses the effect of environmental characteristics (*e.g.* pH, hardness, etc…) on the bioavailability of cadmium and concludes that, at present, the influence of these factors on the PNECs cannot be incorporated in the effects assessment. Consequently, PNECs were only derived for one type of environment (not 'acidic' and 'general' as in the exposure assessment).

The CSTEE endorses this approach but it does want to underline the importance of these science-based bioavailability considerations for the development of future risk assessment procedures for metals. The CSTEE recommends that research on metal bioavailability in natural environments is of high priority as it will allow to develop (geographic) environment specific effect assessments.

Human health

Exposure assessment

The present Report contains no more information on measured workplace air concentrations of cadmium than the extremely limited information contained in the WS Atkins (1998) Reports. Hence, the Report's statements that, historically, concentrations in pigment and stabiliser facilities have been of the order of 10-50 µg/m3, while those in plating facilities are much lower (of the order of 1 µg/m3), and that measures to reduce worker exposures are being taken, are not supported by any specific data.

The human toxicology of cadmium is addressed extensively, and most important animal and human studies reviewed. Kidney toxicity is correctly identified as the most sensitive end-point following inhalation as well as oral intake.

Effects assessment

For inhalation exposure of workers, a NOAEL level of 4 µg/m3 8-h TWA for 30 years is adopted [the reference to Järup *et al.*, 1998, given for the derivation of this limit, is wrong, and should be Järup *et al.*, 1988 (4)]. Although the cumulative exposure corresponding to this concentration (120 µg/m3 x years) is acceptable to the CSTEE as a NOAEL, it is noted that the working time normally adopted in estimating lifetime cumulative occupational exposure is longer than 30 years (45 years), which would lead to a lower value of the air concentration. In view of the extremely limited data on workplace air concentrations, noted above, no proper assessment of occupational risks by inhalation can be carried out. Consequently the Report's conclusions that "some adverse effects would be observed amongst long term workers" in pigment and stabiliser facilities (paragraph 7.3.1) and "there would be appear to be a slight risk to health associated with pigment and stabiliser manufacture" (paragraph 9.2, and Executive Summary, p. iii) are not possible to state.

For oral intake, the Report notes that, while older studies suggested a NOAEL of 2 µg/kg/day (corresponding to a renal cortex concentration of 200 µg/g wet weight) for the induction of microproteinuria, recent studies suggest that the critical renal cortex concentration for susceptible individuals may be around 50 µg/g wet weight, leading to a NOAEL of 0.5 µg/kg/day. The CSTEE notes that this lower limit is also supported by a recent Swedish study (5) not cited in the Report, and supports its use to calculate the MOS in the Report. It also notes that this limit corresponds to a NOAEL and not, as stated in the Report, to a TDI. The CSTEE recognises that a full re-evaluation of the NOAEL and ADI of cadmium cannot be carried out in the context of the present study and, in this context, looks forward to the publication of the final Risk Assessment Report on cadmium to be produced in the framework of Regulation 793/93 on Existing substances.

Risk characterisation

The risk characterisation, presented in the Report, was performed according to TGD procedures: i.e. the calculation of PEC/PNEC ratios for the different environmental compartments and scenario (‘acidic’ and ‘general’).

PEC/PNEC ratios larger than 1 were obtained for the surface water at 2 manufacturing plants. For the sediments and the terrestrial compartment all PEC/PNEC ratios were < 1. Risks for secondary poisoning via the aquatic environment were (acidic only) identified for the cadmium plating sites and plated metal use. Risks for secondary poisoning via the terrestrial food chain were also observed for all cadmium uses considered in this report.

Although the risk assessment was performed using procedures outlined in the TGD, the CSTEE wishes to re-iterate that because of the absence of the potential landfill releases and very limited scope of the study (only some cadmium uses) the conclusions of this risk assessment may underestimate the true risks of cadmium in the environment.

Risk calculations for man exposed via the environment indicate that Margin of Safety is < 1 for two pigment manufacturing sites, cadmium plating sites and for waste incineration. As already noted, the suggestion that risks to workers may be present in pigment and stabiliser facilities, but not in metal plating facilities, is not justified using specific data.

References

1. Atkins 1998a
2. Atkins 1998b
3. CSTEE Opinion on Atkins report (expressed at the 7th CSTEE plenary meeting, Brussels, 18 January 1999)
4. Järup *et al.* Cumulative blood-cadmium and tubular proteinuria: a dose-response relationship. Int. Arch. Occup. Environ. Health 60 (1988) 223-229.
5. Järup *et al.* Low level exposure to cadmium and early kidney damage: the OSCAR study. Occup. & Envir. Med. 57 (2000) 668-672.