



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C – Public Health and Risk Assessment
C7 – Risk assessment

Brussels, C7/VR/csteep/Cr/100903 D(03)

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

Opinion on the results of the Risk Assessment of:

**Chromium trioxide (CAS No. 1333-82-0)
Sodium chromate (CAS No. 7775-11-3)
Sodium dichromate (CAS No. 10588-01-9)
Ammonium dichromate (CAS No. 7789-09-5)
Potassium dichromate (CAS No. 7778-50-9)**

ENVIRONMENTAL PART

**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 39th plenary meeting
of 10 September 2003**

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) and on the basis of the examination of the Risk Assessment Report provided by the European Chemicals Bureau, the CSTE E is invited to examine the following issues:

1. Does the CSTE E agree with the conclusions of the Risk Assessment Report?
2. If the CSTE E disagrees with such conclusions, the CSTE E is invited to elaborate on the reasons for this divergence of opinion.

OPINION

The CSTE E is of the opinion that the Report has not provided transparent and scientifically justifiable information to support the conclusions stated in the RAR. Furthermore the CSTE E notes that a major part of this EU risk assessment (i.e. regional assessment) was not performed.

General and specific comments supporting the CSTE E's opinion and suggestions for improvement are given hereunder.

INTRODUCTION

The risk assessment report evaluates the risk to man and the environment associated with the production and use of five hexavalent chromium compounds: sodium chromate, sodium dichromate, potassium dichromate, chromium trioxide and ammonium dichromate. Production volumes in the EU are 103, 110, 32, 1.5 and 0.85 kilo-tonnes/y, respectively. These compounds are used for the manufacture of chromium containing chemicals, metal treatment, magnetic tapes, montan wax, vitamin K, mordant in wool dyeing, catalysts and other minor uses.

GENERAL COMMENTS

In general, the environmental exposure and effects assessments and the risk characterisation are conducted using procedures recommended by the TGD (1996).

However, the CSTEE wishes to express a number of general concerns.

The RAR considers the effects of the use of five chromium (VI) substances. The RAR then states *'that the releases of chromium (VI) away from any sources are expected to be reduced to chromium (III) in most situations in the environment so that the impact of chromium (VI) is likely to be limited to the area around the source'*. Consequently the risk assessment *'focuses on the local impact of emissions of the production and use of the chromium (VI) compounds'*.

Although the CSTEE agrees with the evidence presented to support the statement that Cr(VI) is reduced to Cr(III), it does not agree with the fact that the impact of the latter is not assessed. The CSTEE is of the opinion that in any EU risk assessment both the local and regional risk of the substance(s) should be evaluated.

The RAR used the added risk approach to assess the risks of chromium in the environment. This approach assumes that only the anthropogenic amount of the substances is relevant for the effect assessment, the possible toxic effects of natural background are ignored. Indeed, it is unclear how the risk characterization based on 'added Cr' can be made with measured data (preferred over calculated values). Measured data are given as total concentrations (background + added) whereas the calculated data are 'added' concentration. For example, the PNEC_{soil} is about 3 mg/kg while total Cr in soils varies 1-100 mg/kg, how can the 'added' component be calculated? The CSTEE is of the opinion that - while the 'added risk approach' is generally discussed in this RAR - this approach cannot be applied for a risk characterization using measured data, e.g. in the soil compartment. The CSTEE also suggests that the added risk approach is only useful when the background variability and metal bioavailability (of both added and background) can be accounted for and incorporated in the RA.

Although the RAR discusses and recognizes the importance of environmental factors such as pH and hardness on the speciation, bioavailability and ecotoxicity of chromium, the CSTEE notes that it does not take these factors into account when evaluating the risks of the substances. Some attempt to take account of the potential variation in environmental properties across the EU has been made by developing an acidic and neutral-alkaline environment scenario. Although this approach can be considered as a good first approximation and illustration of the possible effects of these factors on the risks of chromium (VI), the CSTEE considers this approach is inadequate to fully address this issue in a comprehensive risk assessment required under Regulation EEC 793/93. In this context, the CSTEE is of the opinion that the available literature has not been quantitatively explored and would like to underline that these types of comprehensive evaluations have been or are being made in the ongoing EU risk assessment of zinc and cadmium compounds.

SPECIFIC COMMENTS

1. *Environmental exposure assessment*

The CSTEENotes that several important statements on the release of chromium to the environment are not substantiated by data. E.g. the statement *'sludge application is another potential route to land; however, from comments from producers and users it is more usual for solid waste and sludges to be disposed off to landfill'*, should be supported by data indicating (at least) the amounts of waste/sludge ending up in landfills and being applied to soil. Additionally the CSTEENotes that the fate of chromium waste in landfills has not been evaluated. Although not strictly mentioned in the TGD, this type of evaluation has been or is being performed in other EU risk assessment of metals and metal compounds (e.g. Cd).

The releases of the five chromium (VI) substances during production and the various uses have been mainly performed according to the default scenarios and emission factors described in TGD (B-Tables). For releases for which no emission scenarios are available (e.g. releases from use in wood treatment), alternative and scientifically defensible approaches have been used. The CSTEESupports the methods used to derive these exposure estimates.

As indicated above, although the RAR discusses - at length - the main degradation and transformation processes that may occur for chromium (VI), the CSTEENotes that these processes are not taken into account in the derivation of local concentrations.

The CSTEEWishes to emphasize that not accounting for speciation effects and only considering Cr(VI) exposure, results in an incomplete and potentially incorrect assessment of the risks of chromium to the environment. The excellent summary on the behaviour of chromium (VI) given in the RAR clearly illustrates the importance of environmental variables on the speciation of chromium (and thus toxicity) and further supports the position of the CSTEENotes.

The CSTEEWishes to point out that it is unclear on what scientific evidence some of the important assumptions made in the RAR are based. This is for example the case for the assumption that for acid soils, sediments and waters, 97% chromium (VI) will be rapidly reduced to chromium (III) and that in alkaline conditions the reduction from Cr(VI) to Cr(III) is slow. Although the scientific principles are correct, it is unclear on how this quantitative differentiation was made. Similarly, it is unclear how the adsorption coefficients for suspended solids, sediments and soil were derived.

Specifically for soil the RAR states that *'under anaerobic conditions, Cr(VI) is 'rapidly' reduced to Cr(III)'*. Under aerobic conditions (which are the conditions in most topsoils), Cr(VI) is more stable and is expected to migrate in soil to deeper, anaerobic layers where it is reduced to Cr(III). In the risk assessment, it is assumed that all Cr in the topsoil is present as Cr(III). This seems not in accordance with the above statement that Cr(VI) is more stable in aerobic conditions and thus not *'rapidly'* reduced. However, further on in the RAR (e.g. section 3.2.2.1.3) laboratory toxicity tests confirm that Cr(VI) is reduced to Cr(III) in periods of a few days or weeks. It would be more convincing to mention these studies also in section 3.1.0.2.1. If Cr(VI) is indeed rapidly converted to Cr(III), then also the validity of *'effects data'* of Cr(VI) is questionable, i.e. the transformation can also take place in the tests. This selection is not performed in this RAR.

The CSTEESuggests that additional information be provided which transparently demonstrates the derivation of these respective parameters.

The CSTEESupports the conclusions of the sections on the behaviour of chromium in waste treatment facilities and finds the worst case values used for the removal efficiency of Cr(VI) and Cr(III) justifiable.

The RAR states that the predicted environmental concentrations (PEC) in surface water were calculated in two ways: (1) assuming that all Cr remains as Cr(VI) and (2) assuming that all the Cr is in the form of Cr(III) before it is released. Although, the CSTEEWelcomes this approach as it

allows consideration of both ends of the potential risk spectrum, it did not find any evidence of these calculations in the section on the production of Cr. Additionally, the PECs for the three production facilities cannot be verified as essential information e.g. production amounts, release rates and receiving waters is not given in the RAR. For both of these remarks, this lack of information may be due to the fact that the Annexes were not available.

The CSTEER suggests that the relevant information be provided so that the PECs can be independently verified.

The PECs-water for the uses of chromium (VI) are calculated following the two scenarios indicated above. Assuming all Cr remains in the VI form, PECs vary from 0.32 to 350 µg/l. Conversely, when all Cr is assumed to be released as Cr(III), PECs range from 0.1 to 97 µg/l (acid environment).

The PECs for the sediment range from 0.15 to 152 mg/kg Cr (VI) (acid) and from 1.7 to 1660 mg/kg Cr (III) (alkaline).

PECs for the air compartment were calculated according to the TGD.

PECs for soil vary depending on Cr use (or production) from 0.23 to 232 mg/kg (as Cr(III)) for arable land and from 9.3 to 93 mg/kg Cr (III) for grassland.

Although strict comparison of the calculated and measured concentrations for the different compartments could not be performed, measured concentrations were in most cases lower than the calculated values.

2. Effects assessment

The discussion on the essentiality of Cr(III) is too brief to fully reflect the potential importance of this factor in the context of the natural background variability (not used in this RAR) and the added risk approach. Although the CSTEER recognises that this RAR is on five Cr(VI) compounds, it is of the opinion that, considering the behaviour of Cr(VI) in the environment, the assessment risks of these compounds cannot be performed without consideration of its most frequently occurring transformation products, i.e. the Cr(III) species. In this context it is suggested that a regional risk assessment be performed accounting for the Cr fate after its release in the environment. In this type of assessment background variability, essentiality and bioavailability aspects may become important aspects of the overall RA.

There is no quality screening criterion on the speciation of Cr in the test: i.e. it is unknown if the PNEC of the species truly reflects the added concentration of either Cr III or Cr VI. In contrast we note that in the exposure assessment assumptions are readily made on the speciation of Cr (e.g. assumption that in acidic conditions only 3% remains as Cr VI). There is therefore a possibility that effects concentrations were expressed in terms of one species when the exposure system within the system was more likely to be in terms of the other species.

For the water compartment, toxicity data for algae, invertebrates, fish, other organisms and micro-organisms are summarized and discussed. Very few sediment toxicity data are available.

The CSTEER notes that, although some evidence on the importance of environmental parameters (e.g. hardness) is available for invertebrates and fish, the arguments given why Cr bioavailability modifying factors cannot / should not be included in the RA are not supported by quantitative data or literature references. The CSTEER suggests that this issue is further examined and discussed to quantitatively assess the importance of considering Cr speciation and bioavailability.

Predicted no effect concentrations are derived using both the assessment factor method and the statistical extrapolation approach; the latter is used in the final PEC/PNEC comparison. The CSTEER agrees in principle with the methodology and chronic dataset used in the statistical extrapolation approach. However, caution needs exercising in terms of the choice of taxa and

mixing endpoints in the development of these kinds of models since both can influence the output from this approach (Forbes, V. E. & Calow, P., 2002, Species sensitivity distributions revisited: A critical appraisal in Human and Ecological Risk Assessment, 8, pp. 473-4929.) Moreover it is unclear to the CSTEE how and why an additional assessment factor of 3 was applied to the HC5-50%. Indeed, the CSTEE suggests that a rigorous scientific framework be developed which describes the scientific rationale for the application of an extra assessment factor on statistically derived PNECs.

For Cr(VI) a PNEC_{water} of 3.4 µg/l is derived in this way. The RAR also reports a PNEC_{water} of 4.6 µg/l for Cr(III) derived using the application factor approach and a different dataset (in annexes). From the RAR, it is unclear how these two toxicity datasets (i.e. for Cr(VI) and Cr(III)) were separated when speciation was not evaluated (screened for) when the toxicity data selection was performed. The CSTEE recommends that this be clarified.

The CSTEE cannot support the use of the EQP approach to assess the effects of metals to sediments. It has been clearly established that pore water is not the only possible route of exposure to sediment organisms. Hence the EQP approach does not allow assessing the risks of metals to benthic communities. In addition, like for the soil and water compartment, assessment of metal bioavailability in sediments (both on the exposure and effects side) is crucial for a realistic risk assessment.

The CSTEE recommends that these aspects are considered and incorporated in the RAR on chromates.

In the section on the terrestrial compartment, the following statements:

'the amount of chromium available to plant is usually low ... this means that in terms of determining a PNEC for chromium (VI) species of interest, the background concentration of chromium in soil can be ignored', and *'once released into soil, it is likely that much of the Cr (VI) present will be reduced to Cr (III)...'*; illustrate the importance of accounting for speciation (and bioavailability) when assessing chromium. When speciation is considered the arguments for not accounting for background Cr concentrations may not hold. The CSTEE suggests that, as for similar compounds, the importance of background Cr concentrations is considered.

It is mentioned in the RAR that validity criteria are applied to validate ecotoxicity studies. For the soil compartment it is not clear which validity criteria have been applied. It is for instance not clear if studies that do not report soil data (e.g. Soni and Abbasi, 1981) or where only one concentration has been tested (e.g. Ottabong, 1990) are considered as relevant. We suggest including such criteria in the RAR.

There is no information in the RAR on how NOEC's are calculated (based on article statistics, % inhibition, extrapolation of data ...). Given the importance of NOEC's, we suggest to include a section describing the calculation of NOEC's.

A list of NOEC of Cr(VI) and Cr(III) should be added to increase the transparency.

The PNEC for Cr(III) is based on data collated by Crommentuijn *et al.* (1997). It is not clear from the RAR if all these studies have been checked for reliability by the authors of the RAR. It is also not clear if the study of Juma and Tabatabai (1977), which is a short term exposure test (1.5 h), is considered as reliable. The CSTEE recommends that this information be included in the RAR.

3. Risk characterisation

No regional risk assessment was performed. The CSTEE is of the opinion that for these substances, there are no scientific reasons for not evaluating the potential regional risk.

The local PEC/PNEC ratios were calculated for all compartments.

For the aquatic compartment Clocal were compared to the PNECs for Cr(VI) and Cr(III); for the latter two scenarios were considered: alkaline and acid conditions. The worst case RQ (of Cr(VI) or Cr(III) is used to derive the risk conclusion.

As the EQP method was used to derive both the PEClocal and the PNEC the RQs are the same as for the water compartment.

For the wastewater treatment the Clocal/PNEC were calculated for Cr(III) and Cr (VI).

For the terrestrial compartment the Clocal/PNEC were only calculated for Cr(III). The CSTEE notes that for the exposure (Kp) and effects assessment, PNEC have considered both Cr(III) and Cr (VI), but that the information on the latter is not used in the risk characterisation.

Considering the major concerns surrounding both the exposure and effects outlined in the previous sections, the CSTEE cannot support the conclusions made in the RAR. It recommends that a re-evaluation of the RAR be performed in light of the concerns expressed by the CSTEE.