

Office of Environmental Health Hazard Assessment



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Secretary of Environmental Protection

March 27, 2009

Arnold Schwarzenegger
Governor

NIOSH Docket Office
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03-31-09A06:02 RCVD

RE: Comments on the *NIOSH Draft Criteria Document Update: Occupational Exposure to Hexavalent Chromium – September 2008*

Dear Sir or Madam:

I am pleased to provide comments on behalf of the Office of Environmental Health Hazard Assessment (OEHHA), an office within the California Environmental Protection Agency. We have reviewed the National Institute for Occupational Safety and Health (NIOSH) *Draft Criteria Document Update: Occupational Exposure to Hexavalent Chromium* dated September 2008 (hereafter referred to as the Criteria Document) with regard to effects on reproduction and development. OEHHA released an evaluation of the developmental and reproductive hazards of hexavalent chromium (Cr(VI)) in September 2008. Our remarks below reflect considerations from this recent evaluation. In addition, based on previous work completed by OEHHA, we provide a comment on the carcinogenic effects discussed in the Criteria Document.

With regard to carcinogenic effects of Cr(VI), we applaud NIOSH's decision to include all Cr(VI) compounds in the recommendation for limiting airborne exposure to Cr(VI) compounds, as stated on lines 62-63 of chapter 1, and for reducing the recommended exposure level (REL). Cr(VI) is a potent carcinogen, and scientific evidence supports the inclusion of all Cr(VI) compounds in the new, lower REL. We also agree with NIOSH's statement that residual risk of lung cancer exists at the new REL (Chapter 1, lines 59-60), and urge NIOSH to encourage use of the most stringent controls possible, including the use of substitute compounds, to further reduce exposure to Cr(VI) in the workplace and its release into the ambient environment. OEHHA's evaluation of the cancer potency of airborne Cr(IV) identified a unit risk factor of $1.5 \text{ E-1 } (\mu\text{g}/\text{m}^3)^{-1}$, and a slope factor of $5.1 \text{ E+2 } (\text{mg}/\text{kg}/\text{day})^{-1}$ (OEHHA, 1999. Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II: Technical support document for describing available cancer potency factors, p 210-215.). Using these values to calculate the risk faced by exposed workers would result in a more health protective standard than that arrived at in the Criteria Document.

California Environmental Protection Agency

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption.

The NIOSH draft document's treatment of the data relevant to reproductive toxicity of Cr(VI) is not complete, and thus fails to identify a serious hazard posed by occupational exposure to Cr(VI). OEHHA's recent evaluation, *Evidence on the Developmental and Reproductive Toxicity of Chromium (hexavalent compounds)* dated September 2008 (found at http://www.oehha.ca.gov/prop65/hazard_ident/pdf_zip/chrome0908.pdf) presents in detail the scientific evidence supporting an identification of Cr(VI) as a reproductive and developmental toxicant. Only a few of the relevant studies summarized in OEHHA's document are referenced in the NIOSH Criteria Document (Chapter 4, lines 589-597; Chapter 3, lines 293-302). A panel of scientific experts, the Developmental and Reproductive Toxicant Identification Committee (DART Identification Committee) of the OEHHA Science Advisory Board, considered the evidence presented in the OEHHA document in November 2008. They determined that chromium (hexavalent compounds) has been "clearly shown, through scientifically valid testing according to generally accepted principles, to cause developmental toxicity, male reproductive toxicity and female reproductive toxicity". As a result, effective December 19, 2008, chromium (hexavalent compounds) was listed as known to the State of California to cause reproductive toxicity. Regulations governing the criteria for listing of chemicals by the "state's qualified experts" (DART Identification Committee) are set out in Title 27, California Code of Regulations, section 25305(b)(1) (formerly Title 22, California Code of Regulations, section 12305(b)(1)).

OEHHA's document includes in its consideration of male reproductive effects 16 epidemiologic studies of men occupationally exposed to chromium compounds, primarily through welding exposure, and includes an examination of the issues contributing to the variation in findings noted in the NIOSH Criteria Document (Chapter 4, line 593-596). In addition, all but one of the 16 animal studies showed adverse effects on some aspect of the male reproductive system, regardless of species or whether Cr(VI) was given in drinking water, in feed, by gavage, or by i.p. injection. The NIOSH Criteria Document notes in Chapter 5 (lines 167-170) that "Chronic inhalation studies provide the best data for extrapolation to occupational exposure." In the absence of such data from animals studies, however, it is not scientifically appropriate to ignore experimental studies that were carried out using other routes of exposure. For reproductive effects, it has been empirically demonstrated that Cr(VI) exposure by oral or other routes poses a hazard. Careful consideration should be given to toxicokinetic extrapolation from such empirical studies to potential adverse reproductive effects resulting from inhalation exposures.

As a consequence of the hazard of reproductive effects from Cr(VI) exposure, OEHHA recommends that workers be warned of the potential adverse impact on their reproductive success posed by exposure to Cr(VI).

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We appreciate the opportunity to provide these comments, and hope that NIOSH's final document will reflect these considerations.

Sincerely,

A handwritten signature in cursive script that reads "McMarty for Alexeeff".

George V. Alexeeff, Ph.D., D.A.B.T.
Deputy Director for Scientific Affairs