



State of New Jersey

Jon S. Corzine
Governor

Department of Environmental Protection

Mark N. Mauriello
Acting Commissioner

Office of Science
PO Box 409
Trenton, NJ 08625

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Michael Baes
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1515 Clay St., 16th floor
Oakland, California 94612
Attention: PHG Project

Dear Mr. Baes,

The New Jersey Department of Environmental Protection (NJDEP) is pleased to comment on California EPA's Draft Public Health Goal (PHG) for hexavalent chromium in drinking water. These comments were prepared by the NJDEP toxicologists responsible for developing the New Jersey oral slope factor for hexavalent chromium (A.S.) and for the development of New Jersey health-based drinking water standards and guidance (G.P.).

We agree that the results of the recently completed National Toxicology Program (NTP, 2007) chronic drinking water study indicate that hexavalent chromium is carcinogenic by ingestion. We also agree that development of an oral cancer slope factor for hexavalent chromium based on a non-threshold approach is appropriate, and that the data from the NTP (2007) study provide an appropriate basis for developing such an oral cancer slope factor. Prior to the completion of the NTP (2007) study, several laboratory animal and human epidemiology studies suggested that hexavalent chromium could be carcinogenic by the oral route, but no study showing this definitively or providing data suitable for quantitative risk assessment was available.

New Jersey has also developed an oral cancer slope factor for hexavalent chromium (NJDEP, 2009) based on NTP (2007) for use as the basis for an ingestion criterion for hexavalent chromium in soil. This slope factor has been peer-reviewed by scientists with relevant expertise and has been finalized by NJDEP. The slope factors developed by New Jersey ($0.5 \text{ (mg/kg/day)}^{-1}$) and proposed by California ($0.6 \text{ (mg/kg/day)}^{-1}$) are very similar numerically, and the basis for the difference is minor.

The document supporting NJDEP's oral slope factor development is available on the web at <http://www.state.nj.us/dep/dsr/chromium/soil-cleanup-derivation.pdf>. For some specific aspects of the California risk assessment, the NJDEP document provides additional analysis and

information that may strengthen the arguments you present. We have noted these below with the page numbers corresponding to the posted version of the NJDEP document.

1. Body weight, water consumption, and dehydration (NJDEP pg. 5-7) - We agree with your conclusion (echoing the NTP conclusion) that decreased water consumption was a contributing factor to decreased body weight compared to controls in the high-dose male and female mice. Additional information supplied to us by NTP provides evidence that for the high dose female mice there was also a systemic component to decreased body weight. In addition, since the issue of possible dehydration and the possibility of its contribution to the neoplasia was raised in the initial peer review of the NTP study, the NJDEP document addresses this question. You may want to consider, likewise, addressing this issue

2. Denominator of the incidence ratio in mice (NJDEP pg. 10) - There are some small and essentially non-significant differences between the values you identified for the denominator of the incidence ratio and those identified in the NJDEP analysis. However, additional information from NTP that is presented in the NJDEP document may simplify this issue in your presentation.

3. Consideration of exceedence of the maximum tolerated dose (MTD) (NJDEP pg. 5-6) - You may want to include the observations in our discussion that support self-restriction of water intake in high dose males, but not high dose females, and the related conclusion that the significant decrease in body weight in the high-dose females was a systemic effect indicating a possible exceedence of the MTD rather than a result of palatability issues.

4. Issues relating to the reduction capacity of the mouse stomach (NJDEP – Appendix A) - We agree with your conclusion that the doses in the NTP study did not exhaust the reduction capacity of the stomach. This is a critical point for establishing the relevance of the NTP findings to risk at the lower doses to which humans are exposed. The in-depth discussion of the evidence in support of this conclusion in the NJDEP document can be useful to you in making a more thorough argument in support of this conclusion.

Overall, your qualitative and quantitative conclusions with respect to cancer potency of Cr^{+6} by ingestion are remarkably close to those derived in our NJDEP document. In particular, both assessments based their quantitative assessments on the NTP (2007) study; both assessments chose male mice as the most appropriate species and sex for the quantitative assessment; both assessments employed benchmark dose modeling to derive the point-of-departure (POD); both assessments derived nearly identical values for the cancer potency (0.6 and $0.5 \text{ (mg/kg/day)}^{-1}$); and both assessments agree that Cr^{+6} was available to the mouse small intestines following oral exposure and that this availability did not result from the doses in the NTP study having overwhelmed the reduction capacity of the mouse stomach.

As you are aware, the current Federal drinking water standard (Maximum Contaminant Level, MCL) for total chromium of 100 ug/L is based on a non-cancer Reference Dose using the No Observed Adverse Effect Level in a chronic drinking water study of hexavalent chromium in rats (MacKenzie et al., 1958). We agree that an oral slope factor

based on the NTP (2007) study provides an appropriate basis for a health-based drinking water criterion for hexavalent chromium such as California's proposed PHG.

New Jersey's Drinking Water Quality Institute (NJDWQI), a legislatively mandated advisory body charged with recommending drinking water standards to the NJDEP Commissioner, plans to review the basis for the current Federal MCL for chromium and the recent New Jersey oral cancer risk assessment for hexavalent chromium in order to determine whether to recommend a revision of the New Jersey drinking water standard for chromium. New Jersey's Safe Drinking Water Act specifies that drinking water standards for carcinogens be based on a health-based goal of one in one million, the same risk level used by California for its proposed PHG. New Jersey health-based drinking water values also use the same oral exposure assumptions used by California to develop its PHG. Any recommendation by the NJDWQI for a regulatory drinking water standard (MCL) will consider analytical limitations and available treatment removal methods in addition to the health-based goal. Although New Jersey's drinking water legislation does not provide for consideration of inhalation and dermal exposures from drinking water in developing health-based drinking water values, California's analysis indicates that the cancer risk from inhalation of water droplets during showering and from dermal absorption are insignificant compared to the risk from ingestion, and consideration of these exposure routes does not impact the proposed PHG. Thus, if it is decided that the oral slope factor is an appropriate basis for a New Jersey MCL recommendation, the approaches and assumptions used by New Jersey for carcinogens would result in a health-based drinking water goal (called Health-based MCL in New Jersey) very close to the California PHG.

Thank you for the opportunity to comment on California's proposed PHG for hexavalent chromium. If you have any questions or need further information, please contact Dr. Alan Stern at alan.stern@dep.state.nj.us or Dr. Gloria Post at gloria.post@dep.state.nj.us.

Sincerely,

Gary Buchanan, Ph.D.
Manager
Office of Science