

CCMEC

CALIFORNIA CEMENT MANUFACTURERS ENVIRONMENTAL COALITION

TXI Riverside Cement, Post Office Box 51479, Ontario, CA 91761-0079, Phone: 909/635-1826

Via email

February 15, 2011

Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, CA 94612

RE: PROPOSED MADL FOR HEXAVALENT CHROMIUM (ORAL)

To Whom It May Concern:

The California Cement Manufacturing Coalition (CCMEC), consisting of environmental professionals representing all cement manufacturers operating within California, via this cover letter resubmits its September 27, 2010, comments on OEHHA's proposed MADL for Hexavalent Chromium.

Concluding the September 27th submittal, CCMEC stated:

"We understand that while many of these comments may reflect current science, they may not be consistent with current OEHHA or Prop 65 practice. We respectfully suggest this discrepancy reinforces the need for the Agency to continually revisit its risk assessment procedures in light of best available information and scientific practice. We ask that OEHHA prepare a revised rule using the most current principles, practices and methods available and used by public health professionals experienced in the fields of epidemiology, toxicology, and risk assessment. This should result in a MADL that is at least two orders of magnitude greater than that currently proposed, without any compromise to human health and safety."

Reviewing the revised December 2010 Public Health Goal for Hexavalent Chromium in Drinking Water, it is apparent that OEHHA has not considered CCMEC's suggestion to consider the application of best available information and scientific practice in its suggested MADL for Hexavalent Chromium (Oral).

CCMEC remains of the opinion that, absent the use of current state-of-the-art risk assessment methodologies, OEHHA continues to suggest artificially low standards which have no sound basis in science and therefore, if applied, will result in needlessly low regulatory thresholds with no beneficial health impacts and additional adverse financial impacts on California's residents.

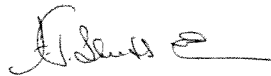
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Again, thank you for reconsidering CCMEC September comments,

Sincerely,



Frank T. Sheets, III
Chairman, CCMEC

cc: Dr. George Alexeeff, Acting Director, OEHHA, Sacramento, CA
Mr. Bob Houston, The Houston Group, Sacramento, CA
Ms. Kathryn E. Kelly, DrPH, Delta Toxicology, Inc., Crystal Bay, NV

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27 September 2010

Ms. Susan Luong
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento , California 95812-4010

RE: PROPOSED MADL FOR HEXAVALENT CHROMIUM (ORAL)

Dear Ms. Luong:

The California Cement Manufacturers Environmental Coalition (CCMEC) is pleased to submit these comments regarding the proposed Maximum Allowable Dose Level (MADL) for hexavalent chromium (oral).

By way of background, we would like to note that since Roman times, the concrete made with cement is the world's most widely used building material. Annual global cement production is about 1.25 billion tons.ⁱ Cement is used in the buildings in which we work, in the roads we drive to work on, and in the foundations of our homes. Annual global cement demand stood at 250 kg per person in 2000 for the six billion people on the planet.ⁱⁱ Of this, California production capacity is approximately 13 million tons annually.ⁱⁱⁱ

Yet despite the ubiquity of concrete and the ongoing presence of hexavalent chromium in cement raw materials (in trace quantities typical of naturally occurring metals in rocks and minerals), cement is not associated with significant public or occupational risks. This observation is supported by independent epidemiological studies of cement works near residential areas (for example, Roberts et al^{iv}). For more information on cement and concrete, we would refer you to www.cement.org.

This positive history of minimal occupational and public health risk associated with cement is not by accident; the cement industry works diligently to ensure the large quantities of cement are manufactured safely for our workers and are safe for the general public to use. CCMEC consists of environmental professionals from all of the cement manufacturers operating in California. Companies with operations in California include Cemex, Mitsubishi Cement Corp., CalPortland Company, National Cement, Lehigh Southwest, and TXI Riverside Cement. One role of this organization is to proactively monitor and participate in the development and implementation of all state legislative and regulatory environmental issues affecting the California cement industry. As such, CCMEC feels it is important to comment on the proposed OEHHA regulation of dosage levels on hexavalent chromium. Our comments:

1. The MADL is expressed as 8.2 ug/day for a 58 kg female. We would like to note that although Prop 65 states otherwise, a dose is more properly expressed in units of ug/kg body weight/day, and as such should be represented as X ug/kg/day (in this example, 0.142 ug/kg/day).

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2. We question the use of a 58 kg female given there are more studies of reproductive and developmental effects in males than females (and in fact no usable studies of adverse effects due to hexavalent chromium exposure in female workers).^v The most sensitive study of health effects involved female mice, but there are also developmental and reproductive effects in male mice. Accordingly, a mean body weight for all adults (male and female, all age groups) combined should be used, i.e., 71.8 kg per Table 7-2 of the U.S. EPA Exposure Factors Handbook.^{vi}
3. Furthermore, the studies of the adverse effects in male workers that involve inhalation should be tied to an inhalation threshold and not confused with the ingestion criteria, as there is no basis given for extrapolating ingestion results to inhalation exposures. (Per Section 25803(a)(5), "the results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.")
4. There is an unsupported discrepancy in the proposed rule. "The proposed regulation would adopt into Section 25805 the following regulatory level for chromium (hexavalent compounds), chemicals known to cause reproductive toxicity:

Chemical	MADL, in units micrograms per day
Chromium (hexavalent compounds)	8.2 (oral)"

but the supporting document says "for the purpose of Proposition 65, exposure by the oral or inhalation routes or via multiple routes that leads to an absorbed dose equal to that resulting from oral exposures to 8.2 µg/day should be considered the MADL."^{vii} There is no justification or evidence given in the supporting document to include inhalation or multiple routes in calculating overall exposure to 8.2 ug/day. Reference to other routes should be excluded and these non-oral exposures reflected in the appropriate route-specific exposure limits, per Section 25803 (a) (5) which states "the results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant." Inhalation and/or multiple routes are not relevant.

5. There are several factors (only some of which are listed here) that suggest there are (per §25803) "principles or assumptions scientifically more appropriate based on available data" that would supersede the use of default assumptions as used in the OEHHA risk assessment approach.^{viii} This was anticipated in the Final Statement of Reasons for this section which states "'safe harbor" risk assessments need not be performed in a rigid fashion. Rather, it is intended that each default assumption or principle set forth in section 12803 apply only in the absence of a scientifically more appropriate principle or assumption."

In accordance with good risk assessment practice and §25803, we would request the proposed rule reflect more scientifically appropriate principles and assumptions. There should also be more discussion of the overall uncertainty in the analysis, including the major assumptions made, scientific judgments employed, and an estimate of the degree of conservatism involved. At a minimum, this would include consideration and discussion of the following, and incorporation of "scientifically more appropriate data" where applicable:

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- a. Given its 1,000-fold effect on the proposed exposure level, it would be appropriate to include discussion of the nature of the scientific concern over the appropriateness of the basis of the safety factor of 1,000 that is applied to the NOEL as part of the discussion on uncertainty, and in particular whether this default should be revised in light of the additional points raised below.
- b. In the discussion on uncertainty, kindly include discussion of the fact that there is an additional order of magnitude between the lowest observed effect level of 5 ppm in the Murthy study and the next lower dose of 0.5 ppm used as the NOEL that is reflected in the MADL.
- c. Please include the definition of "sufficient" quality as used in Section §25803(a)(4) and whether a study (such as the Murthy study) that does not provide chemical ingestion rates as a basis for developing oral exposure concentrations can meet the criterion of "sufficient quality." This lack of information apparently led OEHHA to rely on body weight and water consumption rates from another study (Junaid 1996) instead, and even the water consumption rate from Junaid was for the control group rather than the treated mice, which might have had a different water and therefore chemical consumption rate. A difference of 10% in consumption rates alone would have a significant effect on the resulting MADL and should be included in a discussion of the uncertainty underlying the proposed MADL, if indeed the Murthy study is deemed to be of sufficient quality to be the foundation of this MADL given this lack of important consumption data.
- d. Please discuss the appropriateness of extrapolating a 90-day exposure period in the Murthy study (i.e., 4.5 gestation cycles) to likely human exposure conditions. Three plus years of equivalent human exposure seems unreasonably high and bears discussion.
- e. The averaging period for MADLs for developmental and reproductive toxicity that do not affect the fetus is not specified in the regulation and should be. Kindly include discussion of the age range to which this proposed reproductive and developmental toxicity criterion applies, as it is certainly less than lifetime exposure. (Per 25721(d)(2), "for an exposure reasonably anticipated to affect a certain subpopulation of the general population in any geographic area, specific data (if available) relating to that subpopulation shall be used to determine the level of exposure.")
- f. There should be more complete discussion of the negative results of human studies for reproductive or developmental toxicity (e.g., Aschengrau 1993, Eizaguirre-Garcia 2000^x). The highest relative risk noted in these studies was 1.5, whereas the relative risk should be above 3 by epidemiological standards to be of any public health significance.
- g. Consideration should be given to the available human studies of exposure to hexavalent chromium, such as Desert Sierra Cancer Surveillance Program (DSCSP), Community Cancer Assessment in Hinkley, California, 1988-1993, updated June 15, 2000, and the lack of reproductive effects seen at these known high exposures to hexavalent chromium. While the human data on hexavalent chromium toxicity provide only a limited basis for establishing a quantitative dose-response relationship, they can be used as part of a weight-of-evidence approach to decrease the several orders of

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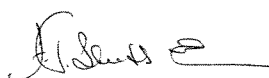
- h. magnitude of uncertainty reflected in the MADL. This would of course require revising the OEHHA approach to be more consistent with best scientific practice, which is also recommended.
 - i. Discussion of the relevance of the fact that per OEHHA, virtually all foods contain some chromium, ranging from 20-590 ug/kg.^x These foods contain varying quantities of hexavalent chromium, yet widespread exposure to chromium to date has not been associated with adverse reproductive or developmental effects. Understanding that absence of evidence does not mean evidence of absence, it is still noteworthy that widespread exposure to ingested hexavalent chromium has not been identified with adverse reproductive or developmental effects.
 - j. Discussion of the finding of the Institute of Medicine regarding the safety of chromium picolinate, which is known to contain up to 12 ppb of hexavalent chromium.^{xi} The IOM found “there is neither consistent evidence of reasonable expectation of harm from chromium picolinate nor sufficient evidence to raise concern regarding the safety or toxicity of chromium picolinate when used in the intended manner for a length of time consistent with the published clinical data,” up to 1.6 mg chromium picolinate per day for 3-6 months.^{xii} In short, there is orders of magnitude greater exposure to hexavalent chromium in currently approved dietary supplements without evidence of adverse reproductive effects.
 - k. Discussion of the overall weight of evidence that hexavalent chromium likely does not cause adverse human reproductive or developmental effects within several orders of magnitude of the proposed MADL.
6. We note that “in accordance with Government Code Section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by OEHHA or that has otherwise been identified and brought to the attention of OEHHA would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.”^{xiii} In light of the above, we would ask that the proposed rulemaking consider other reasonable alternatives, such as no action, in light of the absence of a clear threat of hexavalent chromium to reproductive or developmental health at these very low levels of exposure, in accordance with best available science. At a minimum, more scientifically appropriate principles and assumptions should be reflected in the derivation of the hexavalent chromium ingestion MADL as noted above.
7. Finally, we object to the statements contained in the Notice of Proposed Rulemaking that “adoption of the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of our businesses to compete with businesses in other states”^{xiv} or with other countries. This proposed rule could ultimately have significant negative economic consequences for the cement industry in California. On the same grounds we strongly disagree that “the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.”^{xv} The short time allowed for public comment (given the months of development underlying these proposed rules) prevents a more detailed description of the extent of the inevitable and significant adverse economic impacts created by this proposed rule.

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We understand that while many of these comments may reflect current science, they may not be consistent with current OEHHA or Prop 65 practice. We respectfully suggest this discrepancy reinforces the need for the Agency to continually revisit its risk assessment procedures in light of best available information and scientific practice. We ask that OEHHA prepare a revised rule using the most current principles, practices and methods available and used by public health professionals experienced in the fields of epidemiology, toxicology, and risk assessment. This should result in a MADL that is at least two orders of magnitude greater than that currently proposed, without any compromise to human health and safety.

Sincerely yours,



Frank T. Sheets, III
Chairman, CCMEC

cc: Dr. Joan E. Denton, Director, OEHHA, Sacramento, CA
Mr. Bob Houston, The Houston Group, Sacramento, CA
Kathryn E. Kelly, DrPH, Delta Toxicology, Inc., Crystal Bay, NV

ⁱ History of Cement. <http://www.rumford.com/articlemortar.html> Retrieved 20 September 2010

ⁱⁱ What is Cement? International Cement Review. <http://www.cemnet.com/cement-history/portland-cement.aspx> Retrieved 20 September 2010

ⁱⁱⁱ F Sheets, personal communication, 23 September 2010.

^{iv} Roberts RJ, Steward J, John G. Cement, cancers and clusters: an investigation of a claim of local excess cancer risk relative to a cement works. *Journal of Public Health Medicine* 25(4):351-357. 2003.

^v California EPA. Evidence on the Developmental and Reproductive Toxicity of Chromium (Hexavalent Compounds). OEHHA Reproductive and Cancer Hazard Assessment Section. August 2009.

^{vi} U.S. EPA. Exposure Factors Handbook (Final Report) 1997. U.S. Environmental Protection Agency, Washington, DC, EPA/600/P-95/002F a-c, 1997

^{vii} Ibid.

^{viii} Title 27, Article 8, Section 25803(a).

^{ix} California EPA. Evidence on the Developmental and Reproductive Toxicity of Chromium (Hexavalent Compounds). OEHHA Reproductive and Cancer Hazard Assessment Section. August 2009.

^x Ibid.

^{xi} The patent at <http://www.patentstorm.us/patents/5846581-fulltext.html> notes "presently available forms of bioavailable chromium, such as chromium picolinate or chromium yeast, evidence at ~12 ppb of chromium (VI)."

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^{xii} IOM (2004). Prototype Monograph on Chromium Picolinate. Dietary Supplement Ingredient Prototype Monographs. Developed as Examples for the Report - Dietary Supplements: A Framework for Evaluating Safety. Washington, D.C., IOM Committee on the Framework for Evaluation Safety of Dietary Supplements. Food and Nutrition Board.

^{xiii} California EPA, OEHHA, Notice of Proposed Rulemaking, Title 27, California Code of Regulations, Amendment to Section 25805, Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity. 12 August 2010.

^{xiv} Ibid.

^{xv} Ibid.