CPMA®

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

March 17, 2009

NIOSH Docket Office
Robert A. Taft Lab
4676 Columbia Parkway
Cincinnati, Ohio 45226
Docket Number: NIOSH-144

Re: Draft Comments of the Color Pigments Manufacturers Association. Inc. on the NIOSH Hexavalent Chromium Criteria Document Update, External Review Draft, September, 2008

Dear Sir or Madam:

Thank you for the opportunity to comment on the NIOSH Hexavalent Chromium Criteria Document Update, External Review Draft, September 2008 ("Draft Criteria Document"). The following comments are provided on behalf of the Color Pigments Manufacturers Association, Inc ("CPMA").

The CPMA is an industry trade association representing color pigment companies in Canada, Mexico and the United States. CPMA also represents small, medium and large color pigment manufacturers throughout Canada, Mexico and the United States, accounting for 95% of the production of color pigments in these countries. Color pigment manufacturers located in other countries with sales in Canada, Mexico and the United States, and suppliers of intermediates, other chemicals and other products used by North American manufacturers of color pigments are also members of the Association. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists' colors.

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NIOSH Basis for Revised Recommended Exposure Limit

In the Draft Guidance document, NIOSH proposes revising the Recommended Exposure Limit (REL) from 1 ug Cr(VI)/m^3 to 0.2 ug Cr(VI)/m^3 for a 40 hour workweek. (See Chapter Seven, Recommendations for an Exposure Limit)

SUMMARIES OF THE BASIS AND COMMENTS

(Quotations from the Draft Criteria Document are identified by [Chapter # and Line #].)

LIMIT OF 1 ug/m^3

The basis for the prior REL of 1 ug/m^3 was the quantitative limitation of the analytical method available for measuring workplace exposures to Cr(VI) at that time. [C7,L65]

LIMIT OF 0.2ug/m^3

Epidemiological Studies on Soluble Compounds Background

The primary basis for the revised NIOSH REL is the results of the Park et al. [2004] quantitative risk assessment of lung cancer deaths of Baltimore MD chromate production workers. The revised REL has an associated excess risk of lung cancer death of approximately one per 1000 workers which is a level of risk consistent with those for other carcinogens in recent OSHA rules. [C7,L255]

This cohort was originally studied by Gibb et al. [2000a]. [C7,L291]

The risk assessment of Park et al. [2004] was used to derive the current REL because it analyzes a more extensive database of workplace exposure measurements that includes smoking data on most workers. [C7,L337]

Epidemiologic studies were often unable to identify the specific Cr(VI) compound responsible for the excess risk of cancer. However, these studies have documented the carcinogenic risk of occupational exposure to soluble Cr(VI). Gibb et al. [2000a] and Luippold et al. [2003] reported the health effects of chromate production workers with sodium dichromate being their primary Cr(VI) exposure. These studies, and the risk assessments done on their data, demonstrate the carcinogenic effects of this soluble Cr(VI) compound. The NIOSH risk assessment on which the REL is

based evaluated the risk of exposure to sodium dichromate [Park et al. 2004].

Although there is inadequate epidemiologic data to quantify the risk of human exposure to insoluble Cr(VI) compounds, the results of animal studies indicate that this risk is likely as great, if not greater than, exposure to soluble Cr(VI) compounds [Levy et al. 1986]. [C7,L346]

CPMA Comments

The Gibb study included workers employed from 1950, and the Luippold study from 1940. [C7,L119 & 137] At that time, most chromate production operations used calcium carbonate in their processes, presumably leading to sodium dichromate mixed with calcium chromate. Is it not possible that the studies measured the toxicity of calcium chromate, and not sodium dichromate, assuming that calcium chromate is more toxic than sodium dichromate [Levy, 1986]? This would mean that some of the (very) insoluble chromates (e.g. lead chromate) might be even less toxic than sodium dichromate [Levy, 1986], and far less toxic (if at all) than the substances present in chromate manufacturing.

Additionally, Draft Criteria Document indicates an unwarranted editorial bias when describing lead chromate For example Page 88 - summary of animals studies when describing the Levy study the Draft Criteria Document states "[S]oluble CrVI compounds produced tumors but "not statistically significant". When describing the available data for lead chromates, lead chromate compounds were also described as producing tumors which were "not statistically significant". However, the authors add the gratuitous statement "but may be relevant" for lead chromates, without explanation or substantiation.

Analytical Considerations
Background

Additional considerations in the derivation of the REL include analytical feasibility and the ability to achieve exposure concentrations to the REL in the workplace. [C7,L261]

There are several validated methods to quantify airborne exposures to Cr(VI) in workplace air. The limits of detection (LODs) for NIOSH Methods 7605, 7604, and 7600 are 0.02 ug, 3.5 ug, and 0.05 ug per sample, respectively [NIOSH 1994a,b; NIOSH 2003b]. OSHA Method ID-215 has an LOD of 0.01 ug per sample. NIOSH methods 7605 or 7600, or OSHA Method ID-215, can quantitatively assess worker exposure to Cr(VI) at the REL of 0.2 ug Cr(VI)/m3. Thus,

monitoring exposures over a work shift poses no problem in assessing exposures at the NIOSH REL. [C7,L376]

CPMA Comments

LODs quoted above are at best 1/20th of the proposed REL. It seems unlikely that "monitoring…poses no problem".

Even if the LODs do not pose a problem, taking samples of such small amounts likely will.

The cost per sample would be high, and many samples are likely to be required. Monitoring may indeed pose problems for many operations.

Controlling Exposure
Background

Elimination of and substitution for Cr(VI) compounds, and the use of engineering controls and good work practices for controlling Cr(VI) exposure should be the highest priorities. However, the use of respirators may be required for some workers exposed to Cr(VI) compounds. Respirators may be required for those industries or job tasks where there are routinely and unavoidably high Cr(VI) concentrations, or where the airborne concentration of Cr(VI) is unknown, unpredictable, or highly variable. [C7,L386]

The Draft Criteria Document also states:

> "…in some industries a large percentage of workers would need to wear respirators at an exposure limit of 0.25 ug/m3 for a full-workshift TWA exposure to Cr(VI) in air." [C7,L394]

CPMA Comments

NIOSH freely acknowledges the difficulties of working to the proposed REL. OSHA's policy of restricting the use of respirators would make it even more difficult to achieve control to the REL.

Past reviews of OSHA's and NIOSH's call reports revealed that many appeared to be of insufficient quality upon which to base even a considerably higher REL such as 5.0 mg/m3.

Recent Molecular Toxicology Studies (and The Applicability of the REL to All Cr(VI) Compounds [C7,L341])

Background

A further (although not included at [C7,L261]) consideration seems to be that: Recent molecular toxicology studies provide support for classifying all Cr(VI) compounds as occupational carcinogens. (Due to the similar mechanisms of action of soluble and insoluble Cr(VI) compounds.) [C7,L275 & 281] See also [C7,L361]

Recent molecular toxicology studies provide further support for classifying all Cr(VI) compounds as occupational carcinogens without providing sufficient data to quantify different RELs for specific compounds [NIOSH 2005a]. The cytotoxicity and genotoxicity of both soluble (sodium chromate) and insoluble (lead chromate) Cr(VI) compounds have been demonstrated in human lung cells [Wise et al. 2002]. Phagocytosis is one mechanism by which lead chromate particles, an insoluble Cr(VI) compound, may enter cells and cause damage [Leonard et al. 2004]. Barium chromate is the only Cr(VI) compound for which IARC concluded that there were insufficient data from animal studies to evaluate its carcinogenicity. However, the cytotoxicity and genotoxicity of this compound has been demonstrated in human lung cells [Wise et al. 2003]. With the data currently available for Cr(VI) compounds it is prudent public health practice to include all Cr(VI) compounds in the revised REL. There is inadequate data to exclude any single Cr(VI) compound from this recommendation. [C7,L361]

CPMA Comments

NIOSH may not be familiar with a recent paper by E.R. Nestmann and B. Zhang, Mutation Research 633 (2007) 126-132. Pre-publication drafts of this study were submitted to the OSHA docket by CPMA. The Abstract reads:

> "Lead chromate pigment in the form of the commercial pigment, Pigment Yellow 34, CAS No. 1344-37-2, used in the plastics and coatings industries, did not induce chromosome aberrations in Chinese hamster ovary (CHO) cell line WB(L). Lead chromate pigment is essentially insoluble in water, and in an effort to test the material under realistic conditions, no attempt to solubilize the pigment was made. These results are significant because others have reported lead chromate to cause genotoxicity in various assays, but only under conditions in which its aqueous solubility was artificially enhanced."

Although containing significant amounts of lead chromate, Pigment Yellow 34 particles are a complex substance with a core of a mixed crystal of lead chromate and lead sulfate, with various metal oxides precipitated on the surface. This structure provides very different properties compared to the pure (or "reagent grade" or "laboratory grade") lead chromate used in the studies quoted by NIOSH.

According to the logic used above by NIOSH [C7,L361], it may be reasonably concluded that the pigment form of lead chromate is not carcinogenic. OSHA's statement above should therefore be revised to read:

> "With the data currently available for Cr(VI) compounds it is prudent public health practice to include all Cr(VI) compounds, but not lead chromate in the form of pigment, in the revised REL."

For further discussion on the applicability of the REL to all Cr(VI) compounds, see the next section.

Epidemiological Studies on Insoluble Compounds
Background

The Draft Guidance states:

> "…there is inadequate epidemiologic data to quantify the risk of human exposure to insoluble Cr(VI) compounds…" [C7,L278]

CPMA Comments

Virtually all epidemiologic studies NIOSH (and other government agencies) quotes on this topic relating to lead chromate deal with exposures to lead chromate and chromates known to be carcinogenic. Only three studies relating to exposures to lead chromate alone are known to exist. These include Davies [1984], Kano [1993], and one not in the NIOSH references, Cooper [1983]. All of these studies are available in the OSHA docket for the Final Rule Regulating Hexavalent Chromium in the Workplace docket number H054a.

NIOSH does not anywhere refer to Davies [1984] in this context, only [C4,L228], and Table 4-2, nor to Kano [1993], only [C4,L620].

The studies are relatively small, but can be combined if two assumptions are made. The Kano study includes four plants, two of

which manufactured only lead chromate. The number of employees is given only for the total of the four plants.

One assumption is that the two lead chromate plants account for half of the 660 employees. (Person-years are not provided at all.) The other assumption is that these are similar to the other two studies, an average of twenty years.

The following overall picture is thus obtained for lung cancer deaths relating to lead chromate pigment exposure:

	observed deaths	**expected deaths**	**SMR**	**# Employees**
Davies:	4	5.07	0.79	180
Kano	1	2.14	0.47	330 (est.)
Cooper	3	2.3	1.30	247
Total	8	9.51	0.84	757 (est.)

In other words, about 700 people with the greatest exposure to lead chromate pigment i.e. those working in a production plant, showed no increase in lung cancer.

The employees of producers of colored products, including paint and plastics concentrate producers, would work with lead chromate pigments for a much smaller part of their working time (likely 1% - 10%) compared to pigment manufacturers, and would have a much smaller exposure.

Much of the exposures analyzed in the studies discussed above was during a period in which dust control technology and respiratory protection were far inferior to that used today, so that exposures were significantly greater than would be the case today.

CONCLUSION

Although NIOSH has gone to considerable lengths in its Draft Criteria Document to conclude that the REL should apply to all hexavalent chromium compounds, the molecular toxicology study by Nestman and Zhang [2007], taken together with the epidemiological studies on workers exposed to lead chromate pigment alone, show that at least one commercial substance, lead chromate pigments, CAS# 1344-37-2 and CAS# 12656-85-8 should not be subject to the proposed REL of 0.2ug/m^3.

We hope these comments are helpful in correcting the Draft Criteria Document.

Please call if we can be of further assistance.

Sincerely,

J. Lawrence Robinson
President