CPMA
COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

September 21, 2001

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Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens
Building 4401, Room 3118
79 Alexander Drive
P. O. Box 12233
Research Triangle Park, North Carolina 27709

Re: Comments of the Color Pigments Manufacturers Association, Inc. on the National Toxicology Program; Call for Public Comments on 16 Substances, Mixtures and Exposure circumstances Proposed for Listing in the Report on Carcinogens, Eleventh Edition, 66 Fed. Reg. 38430

Dear Dr. Jameson:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to the National Toxicology Program ("NTP"); Call for Public Comments on 16 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Eleventh Edition, 66 *Fed. Reg.* 38430. These comments are specifically addressed to the Proposed Listing of Occupational Exposure to Lead or Lead Compounds in the Report on Carcinogens, Eleventh Edition.

The CPMA is an industry trade association representing color pigment companies in Canada, Mexico, and the United States. CPMA represents small, medium, and large color pigments manufacturers throughout Canada, Mexico and United States, accounting for 95% of the production of color pigments in North America. Color Pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, colored cement products, textiles, cosmetics, and artist's colors. Color pigments 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.

For background, the NTP indicates in the Federal Register Notice that Occupational Exposure to Lead or Lead Compounds is proposed for listing in the Report on Carcinogens because of, "[R]ecent published data that indicate an excess of cancers in workers exposed to lead and lead compounds". NTP describes the major occupational exposures for lead and lead compounds to be the lead smelting and refining industries, battery manufacturing plants, steel welding or cutting operations, construction, and firing ranges.

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We have reviewed the references NTP is citing as its support for undertaking this analysis of lead and lead compounds. These include:

> Steenland, K., and Boffetta, P., "Lead and Cancer in Humans: Where are We Now", Amer. Journal of Ind. Med., Vol. 38, (2000) pp. 295-299 and,
>
> Vainio, H., "Lead and Cancer Association or Causation", Editorial, Scand. Journal of Worker Environ. Hlth., Vol. 23 (1997) pp. 1-3.

Both of these references are literature reviews of various studies which have been conducted on populations of lead exposed workers in various countries. Both Vainio and Steenland emphasize, and analyze in depth, studies which have commenced since 1987.

Even if these two papers are read in a manner most favorable to the obvious bias shown by the authors, neither the two surveys cited above nor the extensive epidemiological studies underway present any convincing new evidence that lead exposure in the workplace is carcinogenic. Putting aside the extensive flaws and uncontrolled confounding factors, there is no documented statistically significant cancer risk which can be attributed to occupational lead exposure. Even a cursory reading of the Steenland conclusion would confirm this assessment.

Why has NTP Undertaken to Identify an Exposure that no Longer Exists as Carcinogenic?

As stated in the conclusion of the Steenland Study:

> "Despite the fact that lead is one of the earliest recognized occupational toxins, there exist relatively few studies of cancer among lead-exposed workers with well documented high exposures. Such studies are the most informative for identifying whether lead causes cancer." (Steenland p. 299)

Steenland goes on to point out that there are eight principal studies with well documented "high exposures". The strongest supportable statement Steenland can make regarding whether lead is a cause of cancer among workers is "the evidence is somewhat suggestive of an association with lung cancer and stomach cancer, but remains limited".

This analysis begs the question, if there have already been eight recent studies of very high historic exposures and these exposures no longer occur in modern workplaces, why is NTP undertaking to establish a carcinogenicity label on exposures which no longer occur? How can it be assumed that, even if some link could be substantiated between very high exposure to lead (and other substances) over a long period of time and cancer, any conclusion could be rationally made regarding modern workplace exposures which are a fraction of that studied? Does NTP intend to qualify its analysis, conclusions

and listing to clearly indicate to the public that only historic exposures with little or no relevance to current standards were considered in the NTP analysis? Since the exposure levels are not relevant to modern occupational exposures and standards and since no dose-response data exist, which would be a better basis for inference, there is no basis for concluding that any of this recent and wholly inconclusive work has any relevance to current exposure and the risks, if any, posed by current exposures.

Therefore, by its own terms and description, NTP is not proposing to analyze whether currently exposed workers face a significant risk of cancer. NTP is rather studying whether or not very high, currently irrelevant exposures to lead could have posed a significant risk of cancer. The description, therefore, of what is being researched should be amended to reflect the analysis NTP proposes to undertake. Rather than the current prospective description:

> "Occupational exposure to lead and lead compounds" 66 *Fed. Reg.* 38432

NTP should accurately describe the strongest conclusion conceivable from the data available which would be:

> historic and very high occupational exposure to lead or lead compounds in specific industries, lead smelting, battery manufacturing etc. (which may be supported by the recent epidemiological studies)

By their own terms and descriptions the studies cited by Steenland are not relevant to modern exposures and animal data using massive doses of highly soluble compounds have not been shown relevant to human exposure to solid, largely insoluble particles, such as those found in lead chromate pigments. Furthermore, since the relevance of this exercise must be questioned, resources placed on this project may be better spent in other areas.

The CPMA Supports the Conclusion Made on this Issue by the International Lead Zinc Research Organization.

We have reviewed draft comments on this issue prepared by the International Lead Zinc Research Organization ("ILZRO"), in particular a summary position paragraph which concludes that the data presented indicate that occupational exposure to lead compounds does not pose carcinogenic risk. The conclusions shown in the ILZRO comments on this subject, both those to be submitted to this docket and the prior comments of ILZRO submitted for NTP's previous analysis of lead as a carcinogen, are supported by CPMA and incorporated as if set forth herein.

Lead Chromate Pigments should not be included in NTP's Analysis of the Carcinogenicity of Occupational Exposure to Lead and Lead Compounds

The discussions presented by Vainio and Steenland provide no new evidence of human carcinogenicity regarding lead chromate pigments, which are insoluble. Nor do these studies present any new animal

evidence regarding lead chromate pigments. A discussion of the available information regarding the carcinogenicity of lead chromate pigments is provided in the attached copy of CPMA's "Petition of the Color Pigments Manufacturers Association, Inc. on the 9th Report on Carcinogens to Amend the Language Discussing the Status of Lead Chromate Pigments". We also enclose the May 1, 1996 letter submitted to the Environmental Protection Agency Integrated Risk Information System.

There have been several epidemiological analyses of lead chromate pigment workers, as well as many animal assays. In no case has any of these studies concluded that a significant increase in cancers resulted from exposure to lead chromate pigments.

Therefore, since NTP's analysis is specific to certain lead industries where new data has been developed, these studies have no relevance for the manufacture and use of lead chromate pigments. Lead chromate pigments, both in their manufacture and use, should not therefore be included in the industries which describe NTP's analysis and should not be included in any description which is included in the "Report on Carcinogens".

Conclusion

In conclusion, we find that there is no compelling evidence for reopening, again, the analysis of lead as a carcinogen including the analysis of lead exposures in the workplace. Indeed, the language of the references cited by NTP for undertaking this analysis provides no support for this activity.

Furthermore, to the extent that any conclusion could be drawn from the references cited, such data involve exposures that the authors admit is not relevant to modern workplace exposures. Any conclusion drawn from such data must be qualified to the specific historic exposures studied. To imply that workers currently exposed to lead face an increased risk of cancer, based upon the irrelevant exposure studies and the results of controversial animal studies involving massive doses of soluble lead, is inappropriate.

We hope these comments are helpful to you in your analysis of the occupational exposure to lead and lead compounds.

Please call if there are any further questions or comments.

Sincerely,

J. Lawrence Robinson
President

JLR:jldd

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