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November 30, 2000

Dr. C.W. Jameson  
Report on Carcinogens  
NIEHS MD EC-14  
79 Alexander Drive  
Building 4401, Room 3118,  
P.O. Box 12233  
Research Triangle Park, NC 27709

RE: National Toxicology Program (NTP) Board of Scientific Counselors' Report on Carcinogens (RoC) Subcommittee Meeting, December 13-15, 2000, at the Wyndham City Center, 1143 New Hampshire Ave., Washington, DC 20037

Dear Dr. Jameson:

The October 17, 2000 Federal Register (65FR65352) announced the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors' Report on Carcinogens (RoC) Subcommittee is to be held on December 13, 14, & 15, 2000, at the Wyndham City Center, 1143 New Hampshire Ave., Washington, DC 20037. In this announcement, the NTP would welcome receiving additional information (including completed human or experimental animal cancer studies, studies of mechanism of cancer formation, current production data, human exposure information, and use patterns) on any of the listed nominations.

The National Paint & Coatings Association, Inc. (NPCA) is the pre-eminent trade association representing the interests of paint and coatings manufacturers and suppliers of paint raw materials. Established in 1888, NPCA has over 400 members that collectively manufacture more than 90% of the annual US production of paint and coatings products. NPCA closely follows the NTP review process for listing in the RoC as it directly impacts industry compliance with the requirements of the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29CFR1910-1200). Under that standard, NTP listed carcinogens must be identified on product Materials Safety Data Sheets (MSDS) and offer appropriate label warnings when they are present in product mixtures above 0.1% by weight. As a result, NPCA and the paint industry are critically aware of the deliberations of the NTP Board of Scientific Counselors' and their Report on Carcinogens (RoC) Subcommittee.

At the December 13-15, 2000 meeting NPCA has a particular interest in the planned evaluation of talc, including both asbestiform and non-asbestiform types. The paint industry uses a significant amount of talc products in the formulation of industrial and architectural coatings and has been actively involved in talc-related occupational health hazard assessments for its workforce, and in particular cancer mortality. Attached is a copy of a January 1981 Journal of Occupational Medicine (JOM) article entitled "A General Mortality Study of Production Workers in the Paint and Coatings Manufacturing Industry" by R. Morgan, S. Kaplan, and W. Gaffrey. This study reviewed records on a cohort of some 16,243 individuals who were employed in the manufacture of paints and coatings and found no evidence of increased cancer mortality. These workers had occupational exposure to a number of carcinogens and other hazardous



materials during their employment, as well as exposure to talc, an extender pigment. NPCA has used this study as foundation for additional cancer hazard evaluations, including support for the International Agency for Research on Cancer (IARC) efforts in 1990 which led to the publication of a monograph on cancer risk from occupational exposures in the painting trades and paint manufacturing. In that monograph, IARC concluded that workers in the paint manufacturing industry are not at increased risk of cancer. Based on these findings, NPCA has continued to promote good industrial hygiene practices in manufacturing facilities and had been particularly diligent in evaluating new evidence of cancer hazards associated with paint raw materials.

In undertaking our hazard assessment efforts, NPCA has used the established criteria to evaluate toxicology data on carcinogens, mutagens and teratogens published in *Regulatory Toxicology and Pharmacology* 7:1-20 (1987). This publication (attached), contains additional criteria for inferring causation from epidemiology data including *strength of association, consistency, specificity, relationship in time, coherence of evidence, biological gradient and plausibility, and experimental verification*. NPCA believes that detailed evaluations of epidemiology data on talc using such criteria will provide a meaningful assessment of the underlying cancer hazard and not indicate a need to include both asbestiform and non-asbestiform talc in the RoC. We strongly urge the Subcommittee to carefully consider these criteria as well as any comments offered by independent epidemiology experts on the studies NTP has referenced in the notice.

It is our understanding that the primary and secondary scientific review (on both types of talc) by the National Institute of Environmental Health Sciences (NIEHS)/NTP Report on Carcinogens Review Committee (RG1 and RG2) have been completed and the third (or "external" public peer review) will be the focus of the NTP Board of Scientific Counselors (BSC) RoC Subcommittee meeting in December. Furthermore it is our understanding that following the completion of these reviews and solicitation of public comments through announcements in the Federal Register and other media, the independent recommendations of the three scientific peer review groups and all public comments will be presented to the NTP Executive Committee for review and comment. All recommendations and public comments are submitted to the Director, NTP, who reviews them and makes a final recommendation to the Secretary, DHHS, concerning the listing or delisting of chemicals or exposure circumstances in the RoC, and ultimately the Secretary has final review and approval. Pending completion of the NTP review, NPCA has committed to undertake, where feasible, a detailed assessment of talc exposures arising from paint application tasks, including sanding and abrasive paint removal. NPCA's recently completed exposure assessment project for crystalline silica (and IARC human carcinogen found in paint and a myriad of other products) has shown no discernable exposure to respirable dust or crystalline silica while spray applying or sanding latex painted wall surfaces. Given a similar study design, NPCA believes that exposures to talc will be consistently low or non-existent.

We thank you for this opportunity to comment on the upcoming Subcommittee deliberations.

Please contact our offices if you have any questions.

Sincerely,



Stephen R. Sides, CIH  
Vice President, Environmental, Health and International Affairs

Attachments