

March 31, 2006

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Submitted electronically: bbarish@dir.ca.gov

RE: Comments Regarding the Proposed Policy and Procedures for the Advisory Process of Setting Permissible Exposure Limits (PELs) in California

Dear Dr. Barish:

The American Composites Manufacturers Association (ACMA) appreciates the opportunity to provide comments to the Division of Occupational Safety and Health (“DOSH” or “the Division”) on the Draft PELs Process Document issued for public comment on February 28, 2006. ACMA is the national trade association representing companies that make products using combinations of styrene-containing thermoset polyester resin, glass or carbon fiber, and other materials. Approximately 10,000 Californians are employed by composite manufacturing companies.

The objective of the PELs Advisory Committee Process is ultimately to assist the Standards Board in adopting PELs that satisfy the requirements of Section 144.6 of the California Labor Code in an open, fair and cost-effective manner. With that objective in mind, ACMA strongly supports DOSH’s efforts to establish a balanced and more formal process for developing and adopting appropriate PELs that is transparent to all interested parties.

1. Background

The adoption of PELs by the Standards Board in California is governed by two state laws. Section 144.6 of the Labor Code provides that, in setting standards, the Board shall:

... adopt that standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to a hazard regulated by such standard for the period of his working life. Development of standards ... shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to ... health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the reasonableness of the standards, and experience gained under this and other health and safety laws.

Section 11350 of the Government Code provides, in part, as follows:

(b) In addition to any other ground that may exist, a regulation . . . may be declared invalid if . . . the agency's determination that the regulation is reasonably necessary to effectuate the purpose of the statute . . . is not supported by substantial evidence.

Section 144.6 closely mirrors Section 6(b)(5) of the Federal Occupational Safety and Health Act, which reads:

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Further, Section 11350 imposes on DOSH the same “substantial evidence” test imposed on OSHA under Section 6(f) of the Federal act, which reads, in part:

The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

Based on decisions of the U.S. Supreme Court and the federal appellate courts construing statutory language substantially the same as that found in Section 144.6 of the Labor Code, we believe determinations made by DOSH and the Standards Board with respect to the technical, economic and analytical feasibility issues must be performed with the same care and rigor, and are reviewed under the same “substantial evidence test,” as the health-based determinations.¹

2. The process advocated by SIRC provides a balanced approach to the PELs development process

We have carefully reviewed the Division’s draft PELs Process Document with a view toward establishing a balanced approach that avoids the complexities of the federal OSHA PELs process yet ensures the

¹ See, e.g., *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 531 (1981)(*Cotton Dust* case); *AFL-CIO v. OSHA*, 965 F.2d 962, 980-983 (11th Cir. 1992)(*PELs* case); *National Grain and Feed Association v. OSHA*, 866 F.2d 717, 737 (5th Cir. 1988)(*Grain Dust* case).

promulgation of standards that are demonstrably justified based on substantial evidence. We believe the approach recommended by the Styrene Information and Research Center (SIRC) meets that need in a practical and straightforward manner that captures the spirit of the process described in the draft PELs Process Document offered by DOSH.

Specifically, where a stakeholder or other interested person presents credible concerns to DOSH regarding either the underlying health-related evidence (e.g., the TLV, toxicology, epidemiology) for a particular substance, or the feasibility (technical, economic, or analytical) of complying with a reduced PEL, that substance would be referred to a Substance-Specific Advisory Committee. That committee would be charged with the responsibility of addressing all issues relevant to the recommendation of a PEL for that substance.

In most every case, the need for a substance-specific committee would be determined at the planning stage of the process. DOSH would provide public notice² of the substances up for review in the next cycle with a brief explanation of the reason for including that substance in the review. DOSH would request all stakeholders to comment on priorities, issues and concerns raised by this notice, whether they intend to participate actively in the process for a specific substance, the nature of their intended participation,³ the need for a Substance-Specific Advisory Committee, and nominations for participants in a Substance-Specific Advisory Committee.

In unusual cases, the existence of a highly sensitive, controversial, or complex issue unique to the substance might not become apparent until after the Technical Expert Advisory Committee had formulated a health-based exposure limit recommendation. If that situation were to arise, the proper course of action would be to refer that substance to a Substance-Specific Advisory Committee along with whatever information had been developed to date, but with the understanding that the Substance-Specific Advisory Committee would be taking a fresh look at all of the issues relevant to recommending a new or revised PEL.

3. The use of the traditional advisory committee process is critical to the effectiveness of the Substance-Specific Advisory Committee

The draft PELs Process Document specifies the proposed structure, composition and operating practices of the health-based Technical Expert Advisory Committee, but does not provide such specifications for the Substance-Specific Expert Advisory Committees. Furthermore, we have significant concerns regarding the suggested limits on the size of the Technical Expert Advisory Committee, the suggested informality of its deliberations and process for making recommendations, and the fact that it does not reflect the recognized attributes of an advisory committee. Our concern would be even greater if that approach was carried over to the Substance-Specific Advisory Committee process.

As a matter of good government and sound public policy, we believe the PELs Process Document should generally follow the official “Staff Guidelines On Using Advisory Committees To Develop A Rulemaking Process” (the “Staff Guidelines”), which is posted on the Standards Board website at <http://www.dir.ca.gov/oshsb/acguidelines.html>. Adherence to the Staff Guidelines established by the Standards Board is particularly appropriate in this situation where DOSH is functioning as the staff of the Standards Board. DOSH is performing functions assigned to the Standards Board by Section 144.6 of the

² The notice would be posted on the DOSH website and communicated by email to all organizations or individuals identified by DOSH as being interested in the PELs process.

³ That might include a description of the type of information that the stakeholder intends to provide during the process – e.g., health hazard data, technical feasibility analyses, cost estimates, etc.

Labor Code and apparently delegated to DOSH by the Standards Board under a memorandum of understanding (MOU) between DOSH and the Standards Board. Finally, it appears that the attached 1984 MOU (which we believe to be current) generally requires DOSH to use a more formal committee structure and ensure the committee works by consensus.

Some of the more critical attributes of a Substance-Specific Advisory Committee include the following:

- 1) The committee membership must represent the affected industry(s) and, to the extent practical, the committee should be balanced between management and labor. However, that objective must yield where adherence to it would prevent any interest from being a member and fully participating in the process. Technical experts from other state agencies, academic institutions, professional associations, or other interested groups should be considered for membership.
- 2) The Substance-Specific Advisory Committee must be given the opportunity and support needed to carefully review the available data relevant to all issues raised by the adoption of a new or revised PEL: health effects, technical and economic feasibility, cost impacts, analytical feasibility and any other significant issues. All legally required determinations must be well-supported by substantial evidence.
- 3) The advisory committees must operate by consensus. Every reasonable effort should be made to achieve a consensus on a recommended PEL. (The ANSI process for developing consensus standards may be a useful guide in determining how the Substance-Specific Advisory Committee should function.) If a consensus is not reasonably achievable, the DOSH staff should prepare a report describing the different points of view and justifications provided for each. The Substance-Specific Advisory Committee members should be permitted to provide short discussions to be attached to the staff report submitted to the Standards Board.

4. Over-reliance on ACGIH TLVs is inconsistent with Staff Guidelines

Given the reliance apparently placed by the Division and the Standards Board on the Threshold Limit Values (TLVs) adopted by the American Conference of Governmental Industrial Hygienists (ACGIH), we believe that it is important to address the significant concerns raised by that practice. The setting of TLVs by ACGIH has become a highly controversial activity.

ACGIH was initially created, funded and managed by U.S. federal and state agencies and their employees. For almost four decades, ACGIH developed TLVs using open and transparent procedures, welcoming input from all parties and fostering sound science. At the conclusion of that process, the TLVs were formally adopted by the vote of the entire membership. ACGIH and its publications continue to benefit from this positive “brand” recognition, even though ACGIH and its procedures have evolved into a secretive, closed process that does not resemble any accepted scientific method, nor the open, consensus-building process which earned ACGIH its reputation.

We believe the fundamental flaws of the TLV process have been well documented by the information obtained through discovery in pending litigation brought by several industry interests against ACGIH and the U.S. Department of Labor (DOL, as the parent agency of federal OSHA).⁴ Information obtained

⁴ International Brominated Solvents Association et al. v. ACGIH and U.S. Department Of Labor, Docket 5:04CV394, U.S.D.C. for M.D. of Georgia.

through depositions of members of the ACGIH Board and TLV Committee, and DOL personnel (which has been formally presented to the Secretary of Labor), as well as information publicly available on the ACGIH web site, paints the following picture of the ACGIH TLV process:

- 1) The development of a TLV and the associated background document is assigned to a single author, on the ACGIH TLV Committee, whose identity is not disclosed and whose bias and conflicts of interest are unknown;
- 2) ACGIH has no established minimum qualifications for the author of the TLV;
- 3) ACGIH has an official “ACGIH Policy and Process on Bias and Potential Conflicts of Interest”, which has not been effectively enforced to, for example, prevent a government regulatory official from working on or voting on a TLV for a substance while at the same time working on an agency rulemaking on that substance. On the other hand, ACGIH has followed the provisions of its conflicts policy that generally exclude individuals with a financial interest in the substance for which a TLV is being developed (i.e., an “owner, employee, or paid consultant to an organization or corporation that could be impacted by an ACGIH recommendation or practice guideline”) from TLV Committee participation, and bar them from voting on the proposed TLV. In other words, the people with the most significant knowledge of the chemical, current exposures and practices are excluded from participating in the TLV process for that chemical. That approach is totally contrary to the generally recognized consensus standards processes, such as the one supported by organizations such as the American National Standards Institute, which are based on achieving a balance among the participating interests rather than excluding the interest most affected by the decision;
- 4) Under the ACGIH Bylaws, at least 75% of the members of the TLV Committee must be from government agencies or academia;
- 5) Interested outside parties are permitted input to the TLV process only through written communications that are almost never read by the ACGIH leadership adopting the TLV, and sometimes not even by the author of the TLV; and
- 6) Each year, a large group of proposed new or revised TLV’s is presented to the ACGIH TLV Committee and the ACGIH TLV Board for approval, and routinely approved in fairly summary fashion in secret, closed meetings.

In sharp contrast to the ACGIH TLVs as currently developed, “voluntary consensus standards” are developed or adopted by voluntary consensus standards bodies, both domestic and international. These bodies plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. These procedures include: openness, a balance of interests, due process, an appeals process, and consensus (general agreement and a process to fairly consider and attempt to resolve objections). The American National Standards Institute (ANSI) approves voluntary consensus standards processes. ACGIH explicitly disclaims any intent to be a consensus standards organization that attempts to work through a balancing of bias and interests.

Even if the TLV Committee did not have these inherent structural flaws, its mandate, in contrast to that of DOSH and the Standards Board, is to generate recommended exposure levels without any consideration of technical, economic or analytical feasibility. As stated in the official ACGIH Statement of Position at <http://www.acgih.org/TLV/PosStmt.htm>:

Since ACGIH® TLVs® and BEIs® are based solely on health factors, there is no consideration given to economic or technical feasibility. Regulatory agencies should not assume that it is economically or technically feasible for an industry or employer to meet TLVs® or BEIs®. Similarly, although there are usually valid methods to measure workplace exposures at TLVs® and BEIs®, there can be instances where such reliable test methods have not yet been validated. Obviously, such a situation can create major enforcement difficulties if a TLV® or BEI® was adopted as a standard.

Beyond its structural flaws and lack of concern for feasibility, ACGIH does not reliably provide a rational scientific basis for the adopted TLVs, styrene being a notable example where there is no apparent relationship between the TLV and the studies offered as justification for setting the TLV. Given all of the foregoing, we are duly concerned about DOSH and the Standards Board relying on TLVs developed by ACGIH.

5. Conclusion

ACMA supports the efforts of the Division to establish an open, balanced and more formalized process for developing recommendations on PELs for consideration by the Standards Board, and believes the recommendations presented by SIRC would achieve that objective. We would be happy to discuss any questions you may have, and to provide any additional information that would be helpful in refining and finalizing this important document.

Sincerely yours,



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Attachment: 1984 MOU