

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

2520 Venture Oaks, Suite 350
Sacramento, CA 95833
(916) 274-5721
FAX (916) 274-5743
www.dir.ca.gov/oshsb

**FINAL STATEMENT OF REASONS****CALIFORNIA CODE OF REGULATIONS**

TITLE 8: Chapter 4, Subchapter 7, Group 16, Article 107, Section 5155 of the General Industry
Safety Orders

Airborne Contaminants**MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM
THE 45-DAY PUBLIC COMMENT PERIOD**

Other than correction of a nonsubstantive technical error noted in the response to comments below, there are no modifications to the proposal or the information contained in the Initial Statement of Reasons. Public comment received in writing and orally during the public hearing is summarized and responded to below.

The proposed nonsubstantive modification to correct a technical error in the original proposal consists of a modification of the value of the proposed amended Permissible Exposure Limit (PEL) for 2-butoxyethanol expressed in terms of milligrams per cubic meter of air (mg/M^3). Because 2-butoxyethanol is present in air as a vapor (rather than an aerosol) its concentration in air is normally expressed in terms of parts per million (ppm). However, for completeness and ease of translation of air sampling results among other factors, Table AC-1 in Section 5155 also provides PEL values in terms of mg/M^3 . With the exceptions of mixtures of solvents, PELs for solvents and other substances that exist in air primarily as gasses are expressed in terms of ppm. Therefore, the PEL in terms of ppm was the actual proposal. The proposal in terms of mg/M^3 is simply a conversion from the ppm value. That conversion was incorrect in the original proposal and presented as $80 \text{ mg}/\text{M}^3$. It is proposed to correct that error and provide the value in terms of mg/M^3 that is mathematically correct, i.e., $97 \text{ mg}/\text{M}^3$.

Summary and Response to Oral and Written Comments:

Oral comments were received at the September 15, 2005, public hearing in Sacramento, California.

2-Butoxyethanol**Comment:**

Susan Anderson Lewis, of the American Chemistry Council by letter dated September 8, 2005. The letter supported the Occupational Safety and Health Standards Board's (Board's) proposal to adopt a Permissible Exposure Limit (PEL) of 20 ppm for 2-butoxyethanol consistent with the Threshold Limit Value (TLV) of the American Conference of Governmental Industrial

Hygienists (ACGIH). The commenter also noted that the PEL in the proposal expressed as mg/M^3 is incorrect, saying that it should be $97 \text{ mg}/\text{M}^3$ rather than the indicated $80 \text{ mg}/\text{M}^3$.

Response:

The Board thanks the commenter for participating in the rulemaking process and for the suggested nonsubstantial correction to the proposal which will be made as discussed above so that the values for the PEL are equivalent in terms of both ppm and mg/M^3 .

Glutaraldehyde

Comment:

Written and oral comments were received in support of the proposed amendments to the (PEL) for glutaraldehyde from the following:

Thomas E. Tremble, AdvaMed, by letter dated September 13, 2005

David L. Gollaher, California Healthcare Institute, by letter dated September 12, 2005

Judith S. Freyman, Organization Resources Counselors, by letter dated September 9, 2005

Hamilton Fairburn, Organization Resources Counselors, in an oral comment

Jim Lane, SEIU - United Healthcare Workers, in an oral comment

Arthur Lawyer, Technical Services Group, in an oral comment

Roger Richter, California Healthcare Association, in an oral comment

Susan Ripple, Dow Chemical Company, in an oral comment

Paul Brownson, Dow Chemical Company, in an oral comment

Tom McNall, Medtronic Heart Valves, in an oral comment

The letters from Mr. Tremble and Mr. Gollaher also specifically supported the two-year delay in the date for the amended PEL to take effect as a ceiling limit in recognition of the time needed to establish and test the engineering control measures they believe will be necessary to achieve compliance by these means with the PEL as a ceiling limit.

Response:

The Board thanks all of these commenters for their participation in the rulemaking process.

The following five commenters are listed above as making statements in support of the proposed amendment to the PEL for glutaraldehyde but also provided additional comments:

David L. Gollaher, California Healthcare Institute

Comment:

Mr. Gollaher's letter also stated that member companies of his organization project investments in the range of \$250,000 to \$1,000,000 each to establish and validate engineering controls necessary to comply with the proposed standard.

Response:

The Board appreciates Mr. Gollaher and his organization providing a cost estimate range for engineering controls to achieve the PEL for glutaraldehyde in this rulemaking with a 2-year delay period for the ceiling limit to reflect the consensus reached at the third of three public advisory meetings held in 2004. It is not possible for the Board to respond meaningfully to the compliance cost estimate in Mr. Gollaher's letter without specific details on (1) the types and numbers of operations requiring additional control measures and (2) the basis of the cost estimate of the engineering controls to control employee exposures to the proposed PEL. Additionally, as noted below in the response to the comment of Mr. Tom McNall of MedTronic Heart Valves, Title 8, Section 5141 allows employers to use administrative controls to achieve compliance when engineering controls are not feasible or are not sufficient to achieve full compliance with the PEL. Section 5141 also allows employers to use respiratory protective equipment for compliance during the period necessary to install or implement feasible engineering controls where feasible engineering and administrative controls fail to achieve full compliance; and in emergencies.

Arthur Lawyer, Technology Sciences Group, Inc., in an oral comment at the public hearing.

Comment:

Dr. Lawyer said that the cost estimate in the documentation for the rulemaking should reflect statements made in the advisory committee by Kaiser Permanente that the amended PEL would impose a \$24 million impact on their operations, and the statements of a medical device manufacturer that the cost for their operation could be \$250,000 to \$1,000,000. Dr. Lawyer also suggested that the initial statement of reasons should be modified to clarify the concept of "susceptible population."

Response:

The Board appreciates the commenter's suggestion to add the employers' statements to the record from the advisory meeting with respect to the costs to comply with the proposed amended PEL for glutaraldehyde. Cost estimates submitted by Kaiser Permanente as part of the formal rulemaking process are described and discussed below. With respect to the reference to use of the term "susceptible workers," the Board believes that this term is sufficiently clear and that its meaning is generally understandable even to those not expert in the field of occupational health.

Roger Richter, California Healthcare Association, in an oral comment at the public hearing.

Comment:

Mr. Richter said that with state seismic safety mandates and the special governmental review process required for structural modifications to hospitals as could be required to comply with the amended PEL for glutaraldehyde, the delay in implementation should be extended from two years to at least three, and as many as five. Mr. Richter's comments noted an estimate for the total cost of state seismic safety mandates for hospitals of about \$32 billion. He expressed concern that a hospital could be faced with making a structural modification to comply with the amended PEL and then have to redo it as part of a required seismic mandate.

Response:

This comment is responded to below along with that provided by Tom McNall.

Tom McNall, Medtronic Heart Valves, in an oral comment at the public hearing.

Comment:

Mr. McNall said that two years would not be sufficient time for medical device manufacturers to come into compliance with the amended PEL for glutaraldehyde as a ceiling limit. Mr. McNall's company is regulated by the U.S. Food and Drug Administration and the two-year effective date is not feasible. He said that the effective date for the PEL for glutaraldehyde as a ceiling limit should be extended to three years.

Response:

The Board recognizes the concerns of employers with respect to the costs and timing of implementation of control measures to achieve compliance with the amended PEL by means of engineering controls alone. The Board applauds the desire of employers to control employee exposures to glutaraldehyde by engineering controls. However, it is important to note that Title 8, Section 5141 allows employers to use administrative controls to achieve compliance when engineering controls are not feasible or sufficient to achieve full compliance. Section 5141 also allows employers to use respiratory protective equipment for compliance during the time period necessary to install or implement feasible engineering controls where feasible engineering controls and administrative controls fail to achieve full compliance; and in emergencies. The Board fully anticipates that some employers will want or need to use administrative controls and respiratory protective equipment to supplement engineering controls to be fully confident of compliance, especially with the proposed amended PEL to be a ceiling limit after two years rather than a time-weighted average level of exposure, and with many uses of glutaraldehyde in hospitals and other industries being of a short-term intermittent nature. With the flexibility provided by Section 5141 in choosing control approaches and timing, the Board is confident that employers can come into reliable compliance with the amended PEL ceiling of 0.05 ppm within the proposed two-year timeframe that was generally agreed upon by all parties at the Division of Occupational Safety and Health's (Division) advisory meeting of October 14, 2004.

Susan Ripple, Dow Chemical Company, in an oral comment at the public hearing.

Comment:

Ms. Ripple supported all of the proposed PEL amendments, but noted that the Board's discussion of financial impact did not address the increased cost of air monitoring that will be associated with the amended PEL for glutaraldehyde. She said that at the level of the amended PEL, passive air sampling techniques (sampling "dosimeters" or "badges") could not be used, and that this could result in up to a five-fold increase in cost for the sampling process from its current level of about \$50 per sample.

Response:

The Board appreciates Ms. Ripple bringing this issue to its attention. It is not clear from the comment what aspect of the different sampling process would increase costs, especially to a five-fold level. It is the understanding of the Board that the cost of analyzing air samples for glutaraldehyde is the same whether they are collected using passive methods or using a portable air-sampling pump and coated glass fiber filters as in the OSHA 64 method. The Board understands that active collection methods will require use of a sampling pump and associated equipment for calibration. However, amortization of the expense of this equipment over a large number of samples, as would be expected to be collected in a hospital or medical device manufacturing location, or by a consultant for a smaller employer, should minimize the per sample cost of such equipment. Passive samplers with their ease of use do enable an industrial hygienist or technician to potentially collect many more samples in a given period of time. However, under this approach, the industrial hygienist would still be required to monitor and observe the employees' individual activities in order to properly account for the sampling results (e.g., sampling results were low, but no pouring was conducted). The Board believes that the main limiting factor in the number of breathing zone air samples for glutaraldehyde, or most other substances, that can be collected in a given period is not the time required to calibrate and deploy air sampling pumps (rather than the simpler process of using passive samplers), but is the number of samples that can be reliably tracked at any one time so that the operation associated with their collection can be accurately and meaningfully recorded. This is especially relevant when the PEL is a ceiling limit and operations are short-term and intermittent in nature. Without close tracking and accurate recording of individual employee activities associated with particular air samples, results are not only of little use for informing decisions on control measures, but would also not provide the employer with meaningful guidance as to their level of compliance or non-compliance with the PEL. Therefore, the Board anticipates that switching from passive samplers to sampling pumps and filter media should not, in most instances, significantly increase the time required or the expense to collect the same number of air samples with the requisite associated information to make them meaningful and useful in the control of employee exposures to glutaraldehyde.

Kaiser Permanente Estimation of Financial Impact from Glutaraldehyde Exposure Limit Reduction, by letter dated September 9, 2005, and submitted by Barry Foose, EH&S Specialist, Kaiser Western Region.

Comment:

This written comment pertains to the potential financial impact of the proposed amended PEL for glutaraldehyde on the Kaiser Permanente system of healthcare facilities. The comment indicated that the initial cost of achieving the proposed PEL of 0.05 as a ceiling limit would be \$12,639,600. The vast majority of this cost (\$12,000,000) was estimated to be associated with the addition of local exhaust ventilation to automated endoscope reprocessing (AER) operations. Attached with the comment was a paper copy of a PowerPoint presentation that was given at one of the three special advisory meetings held by the Division in 2004 to discuss proposed amendment of the PEL for glutaraldehyde.

Response:

The Board appreciates the commenter providing their estimate of the cost impact of the proposed amended PEL for glutaraldehyde on their operations.

The Board applauds the intention of the commenter to control all employee exposures to glutaraldehyde below the proposed PEL by means of engineering controls such as local exhaust ventilation. The Board notes that the stakeholder consensus from the advisory meeting process for glutaraldehyde in 2004 was a two-year delay in the effective date for the PEL as a ceiling limit. This delayed effective date for the PEL to take effect as a ceiling limit will not only provide additional time for installation and testing of control equipment, but also for detailed industrial hygiene air sampling and operational analysis that can facilitate targeting of scarce resources for engineering controls where they are most needed, or will be most effective, in controlling employee exposures to glutaraldehyde.

Methyl bromide

Anne Katten, California Rural Legal Assistance Foundation, in an oral comment.

Comment:

Ms. Katten said that her organization supports the proposed amended PEL for this substance. She said that the minutes of the PEL advisory committee meetings reflect that she and her organization would support an even lower PEL, but that adoption of the proposed PEL would be a positive step that would contribute to protecting workers' exposure to methyl bromide in agricultural and manufacturing operations.

Response:

The Board thanks Ms. Katten for participating in the rulemaking process.

Methyl methacrylate

Daniel Leacox of Livingston & Mattesich Law Corporation in a letter dated September 12, 2005, and reiterated in an oral comment at the public hearing.

Comment:

The Methacrylate Producers Association supports the Board's proposal to adopt a PEL for methyl methacrylate consistent with the ACGIH TLV.

Response:

The Board thanks Mr. Leacox for participating in the rulemaking process.

Propylene oxide

Courtney M. Price, CHEMSTAR, American Chemistry Council, by letter dated August 18, 2005.

Comment:

The letter was written in support of the Board's proposal to adopt a PEL for propylene oxide consistent with the ACGIH TLV.

Response:

The Board thanks Ms. Price for participating in the rulemaking process.

Morris Warren, ABERCO, Inc., by letter dated September 13, 2005.

Comment:

Mr. Warren's comments, in summary, were as follows:

1. Mr. Warren does not believe the Board has established a health-based justification for reducing the PEL below 3 ppm. Mr. Warren based this comment on three points:
 - a. The 1994 EPA Risk Assessment for propylene oxide does not support a PEL for propylene oxide below 3.6 ppm.
 - b. The 2001 ACGIH Background Document for propylene oxide does not support a PEL for propylene oxide below 3.0 ppm.
 - c. Previous industry submissions should be interpreted to oppose a PEL below 2 ppm and not to support a PEL of 2 ppm.
2. The Standards Board has not developed the evidence necessary to support a determination that the proposed action will not have a significant adverse economic impact on California businesses as required by Government Code Section 11346.
3. Section 147.1 of the Labor Code does not give the Division of Occupational Safety and Health the authority to initiate amendments to Section 5155 with respect to substances covered by Federal OSHA standards.

The Board's responses to these comments are as follows:

Response to 1a:

The commenter first asserts that the value for a PEL in parts per million (ppm) based on the 1994 EPA Risk Assessment level of 0.3 mg/M³ for an increased risk level of 1 in 1,000 for the general public was not properly recalculated for the difference in exposure for the general public and workers. While the figures provided by the commenter to be used for the conversion are correct, the commenter makes an error in converting from the EPA's 0.3 mg/M³ to a level in ppm. As suggested by the commenter, to correct the differences in exposure duration and frequency between the general public for whom the EPA level was calculated and the workplace population, one must multiply the EPA risk level in parts per million by 5.11. Rounding upwards, the result of this calculation is 0.7 ppm which was the level recommended by the Air Contaminants Advisory Committee.

Beyond the question of calculation of the PEL from the EPA estimate for the 1 in 1000 increased risk exposure level, the commenter asserts that the EPA risk assessment is outdated and tends to overestimate the risk from human exposure to propylene oxide because it relies on an overly

conservative EPA methodology that assesses the human risk from animal bioassay using a linearized multistage model to extrapolate from experimental animal doses to human use doses. The commenter refers to studies cited by the ACGIH TLV documentation for propylene oxide indicating that a threshold response of cell proliferation is a prerequisite to the development of the nasal cancer observed in test animals. While the ACGIH documentation for the TLV for propylene oxide did make note of this finding, it was only one of a number of factors considered in reaching the TLV of 2 ppm.

Response to 1b:

The commenter asserts that even though the ACGIH TLV committee recognized 30 ppm as the lowest scientifically supported No Observed Adverse Effect Level (NOAEL), it chose a TLV of 2 ppm rather than 3 (based on a usual safety factor of 10 for animal studies) because its preferred TLV values are 1, 2, and 5 ppm. While the TLV documentation for propylene oxide does make reference to these “preferred” TLV values in its conclusion, it goes on to discuss at some length the cancer risk posed by propylene oxide. The Board views the ACGIH choice of 2 ppm rather than 3 ppm for the TLV as the reasonable application of an additional safety factor for a substance that is a confirmed animal carcinogen and a confirmed mutagen in in-vitro studies. The Board believes such a cautious approach is prudent.

Moreover, it is important to recognize that while the Board looks to the ACGIH as a starting point for review of information on substances under consideration, the Board is not bound by the conclusions of the ACGIH TLV Committee.

Response to 1c:

The Board appreciates that the commenter has taken the time to review previous submissions in the Division’s PEL process, referring specifically to an American Chemistry Council (ACC) letter dated March 2, 2004. This letter was submitted to the Division in response to its announcement of a special public advisory meeting on March 30, 2004. This meeting was held to provide opportunity for additional stakeholder comments with regard to a number of recommendations of the Air Contaminants Advisory Committee that were withdrawn from a proposal to the Board originally considered at its meeting of December 18, 2003. As noted above, the American Chemistry Council has submitted another letter as part of this rulemaking process, dated August 18, 2005. The ACC letter states, in part, with regard to the Board’s proposed PEL of 2 ppm for propylene oxide: “This value is consistent with several occupational exposure levels for propylene oxide recently adopted internationally, which as detailed in the Panel’s March 2, 2004, comment, range from 2 to 5 ppm.” It is clear from the remainder of the letter that the American Chemistry Council was concerned with the PEL committee’s recommendation of 0.7 ppm based on the 1994 EPA risk assessment. While the Board cannot rule out the commenter’s interpretation of the March 2, 2004, ACC letter, the Board does not view it as a substantive comment on the proposed rulemaking. The Board takes at face value the ACC’s more recent letter’s statement that it “supports this change” to the PEL for propylene oxide.

Response to 2:

In response to concerns from the public with respect to the initially proposed PEL for propylene oxide and a number of other substances in this rulemaking, the Division convened a special advisory meeting on March 30, 2004, specifically to receive comments on the initially proposed PELs for these substances at levels below the ACGIH TLV. At that meeting representatives of Dow Chemical Company and ISP Food Ingredients gave presentations with regard to the proposed PEL for propylene oxide. Additionally, representatives of the American Chemistry Council attended with regard to other substances on the agenda. The Board believes that this process, along with the meeting process of the PEL Advisory Committee in which industry representatives actively participated on a number of different substances, adequately considered the question of the economic impact of the current proposal.

The Board also notes that the commenter has not provided in his detailed letter any information to suggest that a PEL of 2 ppm would in fact have a significant adverse impact on California businesses.

Response to 3:

This comment is apparently in reference to a statement (page 2) in the Initial Statement of Reasons for this rulemaking. Labor Code Section 147.1 addresses mandated, rather than simply authorized, activities of the Division of Occupational Safety. The Division's activities with respect to hazardous chemical substances are not limited only to those specifically mandated in Labor Code Section 147.1. Furthermore, Section 147.1 does not address the authority of the Board to adopt new or amended Permissible Exposure Limits. The authority of the Board to adopt, amend, or repeal occupational safety and health standards is granted by Labor Code Section 142.3 which is referenced at the end of the proposal.

The Board thanks Mr. Warren for his participation in the rulemaking process and expresses appreciation for the detailed letter provided to the Board.

ADDITIONAL DOCUMENTS RELIED UPON

None.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

None.

DETERMINATION OF MANDATE

These standards do not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

ALTERNATIVES CONSIDERED

The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed standards. No alternative considered by the Board 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 adopted action.