

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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Attachment No. 2

INITIAL STATEMENT OF REASONS**CALIFORNIA CODE OF REGULATIONS**

Title 8: Division 1, Chapter 4, Subchapter 7, Article 107, Section 5155
of the General Industry Safety Orders

Airborne Contaminants: Ethylbenzene**SUMMARY**

Labor Code, Section 144.6 requires that the Occupational Safety and Health Standards Board (Standards Board), when dealing with standards for toxic materials and harmful physical agents, adopt standards which most adequately assure, to the extent feasible, that no employee suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard for the period of their working lifetime. This section also requires that the Standards Board base standards on research, demonstrations, experiments and other information as may be appropriate. Labor Code, Section 144.6 also lists other considerations such as the latest scientific literature, the reasonableness of the standards, and experience gained under this and other health and safety laws.

Existing Section 5155 establishes minimum requirements for controlling employee exposure to specific airborne contaminants. This section specifies several types of airborne exposure limits, including limits on exposures as an 8-hour time-weighted average (TWA), short term exposure limits (STELs), and ceiling limits. Section 5155 also requires that, for specified substances which may be absorbed into the bloodstream through the skin, mucous membranes or the eye, appropriate clothing be provided for and used by employees as necessary to prevent skin absorption. Section 5155 also contains requirements for measurement of workplace airborne exposures and, in certain situations, medical surveillance.

On an ongoing basis with the assistance of an advisory committee, the Division of Occupational Safety and Health (Division) develops proposals to amend these airborne exposure limits known as Permissible Exposure Limits (PELs). This ongoing review is necessary to take into account changes in the information available to assess the health effects of exposures to airborne substances that can be present in the workplace.

The Standards Board is proposing to reduce the existing 8-hour TWA for ethylbenzene of 100 parts per million in air (ppm) to 5 ppm. The Standards Board believes that this PEL is necessary to reduce the risk of cancer and non-cancer health effects. Due to feasibility issues, the Standards Board is not at this time proposing a PEL of 0.5 ppm which would control the excess cancer risk to 1/1,000. The Standards Board is further proposing to amend the existing 15-minute STEL for this substance from 125 ppm to 30 ppm to prevent respiratory and eye irritation.

This proposal was developed by the Division pursuant to its mandate in Labor Code Section 147.1 to maintain surveillance and propose standards to the Standards Board. This proposal is a result of identification of ethylbenzene by the Office of Environmental Health Hazard Assessment (OEHHA) as a substance that should be regulated in the workplace based on its potential to cause cancer. Ethylbenzene was also on a July 2007 list of recommendations to the Division for new and revised PELs developed by HESIS (the Hazard Evaluation System and Information Service of the California Department of Health Services).

The Division, in developing this and past proposals for amendments to Section 5155, has convened advisory committees to consider and make recommendations on the substances in the base list. These advisory committees assist the Division in evaluating and interpreting the studies and other scientific information listed in the Documents Relied Upon section that form the factual basis of proposals for revisions to Section 5155. The advisory committees for PELs also provide an additional avenue for involvement in the rulemaking process by employers and worker representatives, and by other communities that can be affected by revisions to Section 5155.

The health basis of the PEL for ethylbenzene was taken up by the Division's Health Expert Advisory Committee (HEAC) for PELs at its meetings on March 25, June 24, and September 10, 2009. With assistance from OEHHA, the HEAC discussed scientific information on both cancer and non-cancer risks presented by exposures to ethylbenzene. After the HEAC discussions on ethylbenzene concluded, feasibility and cost issues were taken up at a meeting of the Division's Feasibility Advisory Committee (FAC) on December 8, 2009. Minutes of the HEAC and FAC meetings are posted on the internet. The website address for 2009-2010 meetings is http://www.dir.ca.gov/dosh/DoshReg/5155Meetings_2009.htm.

SPECIFIC PURPOSE AND FACTUAL BASIS OF THE PROPOSED ACTION

This regulatory proposal is intended to provide worker safety at places of employment in California.

The proposed rulemaking action:

- Is based on the following authority and reference: Labor Code Section 142.3, which states, at subsection (a) (1) that the Board is "the only agency in the state authorized to

adopt occupational safety and health standards.” When read in its entirety, Section 142.3 requires that California have a system of occupational safety and health regulations that at least mirror the equivalent federal regulations and that may be more protective of worker health and safety than are the federal occupational safety and health regulations.

- Differs from existing federal standards, in that the PEL value proposed for ethylbenzene is lower than that found in the federal air contaminants standard at 29 CFR 1910.1000. Labor Code section 147.1(c) mandates with respect to occupational health issues not covered by federal standards that the Division maintain surveillance, determine the necessity for standards, and develop and present proposed standards to the Standards Board. For a variety of reasons, the federal standards for air contaminants have remained largely unrevised since their promulgation in the early 1970s, with the exception of substances for which individual comprehensive chemical hazard control standards have been promulgated, primarily for carcinogens. The federal air contaminant standard for ethylbenzene has not been revised in over 40 years. During that time, considerable scientific evidence has developed supporting concern with potential effects on worker health including cancer, as well as non-cancer health effects most notably on the auditory system (hearing loss) with exposure to ethylbenzene at levels lower than the federal standard. The Standards Board believes the Division appropriately carried out its mandate under Labor Code section 147.1 to present to the Standards Board the PEL proposed for ethylbenzene in this rulemaking, including a determination of necessity for the proposed amendment. In addition, the Standards Board believes that with this proposal, it is carrying out its mandate under Labor Code section 144.6 to adopt standards dealing with toxic materials which most adequately assure, to the extent feasible, that no employee will suffer material impairment of health or functional capacity, taking into account the latest available scientific data in the field and the reasonableness of the standard.
- Is not inconsistent or incompatible with existing state regulations. This proposal is part of a system of occupational safety and health regulations. The consistency and compatibility of that system’s component regulations is provided by such things as the requirement of the federal government and the Labor Code to the effect that the State regulations be at least as effective as their federal counterparts.
- Is the least burdensome effective alternative. This rulemaking proposal was developed with the assistance of two technical advisory committees: one that considered scientific data on health risks associated with exposure to ethylbenzene, and a second that considered concerns of cost and feasibility of implementation in the workplace. These committees were comprised of subject matter experts with expertise relevant to the concerns they were considering and from a range of different institutional orientations most notably health and chemical exposure science, industry, medicine, and government. In addition, a stakeholder organization with a specific interest in the subject under consideration, the American Chemistry Council, was contacted and it responded by sending a scientific representative to present and discuss information and

recommendations with the health committee. The PEL proposed is performance based and thus is consistent with the preference stated for this type of standard in Labor Code section 144.6 when dealing with toxic materials.

The PEL for ethylbenzene is proposed to be lowered from 100 ppm as an 8-hour time-weighted average (TWA), to 5 ppm 8-hour TWA and a 15-minute STEL value of 30 ppm. A reduction in the existing 15-minute STEL from 125 ppm to 30 ppm is also proposed.

Participants in the FAC meeting at which ethylbenzene was discussed indicated that it is found most commonly in mixtures with xylene, a widely used organic solvent. It is also found commonly as a solvent in coatings materials.

For the purposes of the Division's PEL amendment process, identification of ethylbenzene as a substance with potential for workplace exposure and presenting a risk of cancer was made by OEHHA in a report released in December 2007 (OEHHA, 2007a).

Over the course of the three HEAC meetings where the health effects of ethylbenzene were reviewed, the discussion focused on the conclusions drawn from the results of an animal bioassay reported in 1999 by the U.S. National Toxicology Program (NTP, 1999) indicating that ethylbenzene can cause cancer and whether these results supported a PEL of 0.5 ppm 8-hour TWA based on an inhalation unit risk value of $2.5 \times 10^{-6} \text{ (ug/m}^3\text{)}^{-1}$ derived by OEHHA (2007b), translating into an increased cancer risk of 210 cases per 1,000 workers exposed at the current PEL of 100 ppm as an 8-hour TWA.

The inhalation unit risk value derived by OEHHA was based on the male rat kidney data in the NTP bioassay. There was also discussion initiated by a HEAC member of ototoxicity (damage to the hearing function) induced by ethylbenzene and a PEL of between 0.2 and 1 ppm to protect against this effect identified in rats by the study of Gagnaire et al., 2007.

In the HEAC discussions of ethylbenzene, representatives of the Ethylbenzene Panel of the American Chemistry Council (ACC) questioned the relevance to humans of the NTP animal bioassay results for kidney cancer used by OEHHA as the basis for its inhalation unit risk value. It was noted that similar comments from the ACC had already been responded to by OEHHA in the rulemaking in which a No Significant Risk Level (NSRL) for cancer was developed for the ethylbenzene listing under the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly referred to as Proposition 65). The ACC recommended that an appropriate PEL for ethylbenzene would be in the range of 7 to 28 ppm, based on mouse lung tumors found in the NTP, 1999 study, non-cancer effects on the liver seen in the same NTP bioassay, or on the hearing loss found in rats in the Gagnaire, et al., 2007 study.

At its September 10, 2009 meeting, the HEAC discussion of ethylbenzene concluded without agreement among committee members on a single value for a recommendation for a health-based PEL. As a result, the values considered by the FAC at its December 8, 2009 meeting ranged

from 0.5 ppm 8-hr TWA based on the NTP bioassay and OEHHA risk assessment noted above, to 7 ppm 8-hr TWA based primarily on the effect on hearing found in test animals. At the FAC meeting held on December 8, 2009, a committee member discussed data on exposures to ethylbenzene he had assessed at his workplace involving manufacture of artificial breast implants suggesting that a PEL of less than 5 ppm 8-hour TWA might be unreasonably costly to achieve in this and similar operations. He noted that the exposure to ethylbenzene, as is common, resulted from its presence in a mixture with the widely used solvent xylene of similar structure and identical molecular weight. Labor representatives at the FAC meeting asserted that it was the burden of industry users of ethylbenzene to show with credible data that a PEL of 0.5 ppm, as discussed by the HEAC based upon the OEHHA cancer risk assessment, was not feasible or would be excessively costly and that this had not been done. A comment letter dated November 18, 2009 was submitted to the FAC by WorkSafe noting a number of current applications where safer alternatives could be substituted for ethylbenzene including aerosol cleaners used in automotive repair, polishes used in nail salons, coatings and adhesives. FAC members considered the data that was presented as well as their own experience and concluded that a PEL of 0.5 ppm may be unreasonably low but that a PEL of 5 ppm 8-hour TWA was likely to be reasonably feasible to achieve.

After completion of the HEAC/FAC process, the Division identified scientific evidence to support amending the existing 15-minute STEL for ethylbenzene of 125 ppm. A STEL of 30 ppm is proposed based on findings in a controlled exposure of human volunteers to ethylbenzene (Bardodej and Bardodejeva 1961). A summary translation of this report into English was obtained from the U.S. Environmental Protection Agency. Consistent with that translation, the EPA and the National Research Council in documentations for interim and final recommendations respectively for graded sets of specialized exposure limits for ethylbenzene, both cite the results of this study identifying a No Observed Adverse Effect Level (NOAEL) of 100 ppm for eye and respiratory tract irritation in an exposure study of nine volunteers. These documentations also indicate that in this study, eye and respiratory tract irritation was observed in volunteers exposed to 200 ppm ethylbenzene. For the purposes of their specific mandates, in developing recommendations for limiting short-term human exposures to ethylbenzene to 33 and 30 ppm, respectively, the EPA and the National Research Council both indicated in their documentations that they applied an uncertainty factor of 3, for intraspecies variability, to the NOAEL value for eye and respiratory tract irritation of 100 ppm for human volunteers identified in the Bardodej and Bardodejeva (1961) study. In addition to the Bardodej and Bardodejeva (1961) study results, a STEL value in the range proposed is also supported by observation of pre-narcotic effects of increased motility in male rats exposed to 400 ppm ethylbenzene for one to four hours (Molnar et al., 1986).

In proposing to amend the 8-hour TWA PEL for ethylbenzene, the Standards Board accepts the recommendation of the FAC of 5 ppm based on feasibility of achievement. The Standards Board believes that amending the 8-hour TWA PEL is necessary to reduce cancer risk and that 5 ppm appears to be the lowest feasible level to which the PEL can be reduced at the current time. A 15-minute STEL value of 30 ppm is also proposed to prevent respiratory tract and eye irritation.

This regulatory proposal is intended to provide worker safety at places of employment in California.

DOCUMENTS RELIED UPON

1. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. *Occupational Health Hazard Risk Assessment Project for California: Identification of Chemicals of Concern, Possible Risk Assessment Methods, and Examples of Health Protective Occupational Air Concentrations*. December 2007a.
<http://www.cdph.ca.gov/programs/hesis/Documents/riskreport.pdf>
2. Office of Environmental Health Hazard Assessment. Notice of Adoption of Unit Risk Value for Ethylbenzene. November 14, 2007b, available at:
http://www.oehha.ca.gov/air/hot_spots/pdf/111407memo.pdf
3. The technical report underlying the memo above, *Long-term Health Effects of Exposure to Ethylbenzene*, can be accessed directly at:
http://www.oehha.ca.gov/air/hot_spots/pdf/Ethylbenzene_FINAL110607.pdf
4. California Code of Regulations, Title 24, Final Statement of Reasons, No Significant Risk Level for Ethylbenzene Under Proposition 65 (Health and Safety Code, Section 25249.5 *et seq.*), with Comments Received from Sharon H. Kneiss, American Chemistry Council, 2009.
http://oehha.ca.gov/prop65/law/pdf_zip/NSRLethyl050709.pdf
5. Gagnaire, F., et al. Ototoxicity in rats exposed to ethylbenzene and to two technical xylene vapours for 13 weeks. *Arch. Toxicol.* 2007. 81:127-143.
6. National Toxicology Program Technical Report on The Toxicology and Carcinogenesis Studies of Ethylbenzene (CAS No. 100-41-4) in F344/N Rats and B6C3F₁ Mice (Inhalation Studies), January 1999, NTP TR 466, NIH Publication No. 99-3956, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health:
http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr466.pdf (228 pages)
7. Letter from Worksafe, November 18, 2009, with comments regarding PELs for Substances before Feasibility Advisory Committee Pursuant to Title 8, Section 5155 of the California Code of Regulations.
8. Bardodej, Z. and Bardodejeva, E. Usefulness and application of exposure tests. X. Exposure test for ethyl benzene. *Cesk Hyg (in Czech)*. 1961. 6:537-545.
9. Electronic mail from Ernest Falke, August 3, 2011, U.S. Environmental Protection Agency, Acute Exposure Guideline Levels Program, with attached summary translation of Bardodej and Bardodejeva (1961).

10. Technical Support Document for Interim Acute Exposure Guideline Level for Ethylbenzene. U.S. Environmental Protection Agency. September 2009.

http://www.epa.gov/oppt/aegl/pubs/ethylbenzene_interim_sep_09.v1.pdf

11. Spacecraft Maximum Allowable Concentrations for Selected Airborne Contaminants: Volume 3 (1996). National Research Council, Subcommittee on Spacecraft Maximum Allowable Concentrations. National Academy Press, 1996. Available at:

http://books.nap.edu/catalog.php?record_id=5435

12. Molnar, J., et al. Changes in the Rat's Motor Behaviour During 4-Hr. Inhalation Exposure to Prenarcotic Concentrations of Benzene and Its Derivatives. *Acta Physiological Hungarica*. 1986. 67(3): 349-354.

13. Draft Meeting Summary of the HEAC on March 25, 2009, with a list of Members, Assisting Agencies, and Interested Parties.

14. Draft Meeting Summary of the HEAC on June 24, 2009, with a list of Members, Assisting Agencies, and Interested Parties.

15. Draft Meeting Summary of the HEAC on September 10, 2009, with a list of Members, Assisting Agencies, and Interested Parties.

16. Meeting Summary of the FAC on December 8, 2009, with a list of Members, Assisting Agencies, and Interested Parties.

These documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the Standards Board Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, California. For those documents that are available on the internet, the website links to these documents are listed for your convenience.

REASONABLE ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES

No reasonable alternatives were identified by the Standards Board and no reasonable alternatives identified by the Standards Board or otherwise brought to its attention would lessen the impact on small businesses.

SPECIFIC TECHNOLOGY OR EQUIPMENT

This proposal will not mandate the use of specific technologies and equipment.

COST ESTIMATES OF PROPOSED ACTION

This rulemaking proposes to amend the existing PEL for ethylbenzene in workplace air. Employers with workplaces where there may be worker exposures to ethylbenzene operate primarily in the private industrial and chemical sectors. The amended PEL proposed for ethylbenzene is supported by scientific findings of which professional health and safety staff and consultants of these employers would be expected to be cognizant. Many of the employer entities that would be affected by the proposed amended PEL for ethylbenzene already seek to control employee exposures to hazardous airborne contaminants to levels well below their existing PEL in the interest of business continuity, other more general requirements to protect worker health and safety, and minimization of tort and workers' compensation liability.

For the FAC meeting at which ethylbenzene was discussed, comment letters for this meeting were received from WorkSafe and from the Western States Petroleum Association (WSPA). The WSPA letter did not directly address cost or feasibility of the proposed amended PEL for ethylbenzene. The 2009 WorkSafe letter was more specific, suggesting that effective and less hazardous alternative to the use of ethylbenzene as a cleaning solvent are available, as well as for xylene in which ethylbenzene is a frequent significant component and which can be found used in nail salons. At the FAC meeting, a committee member presented workplace air sampling data which had been gathered at the location where he then worked, which he asserted suggested that complying with a PEL for ethylbenzene of less than 5 ppm in uses similar to those which he evaluated could impose significant costs on employers to achieve. The FAC concluded based on its members' own experience measuring workplace solvent exposures, supported in part by the data provided by the FAC member, that a PEL of 5 ppm for ethylbenzene is reasonable from the standpoint of cost and feasibility given the information available. The Standards Board concurs with that assessment in proposing 5 ppm as the amended PEL-TWA for ethylbenzene in this rulemaking.

The Standards Board also believes a STEL of six times the PEL-TWA as is being proposed is reasonable with respect to feasibility as it is consistent with the widely recognized industrial hygiene goal of maintaining short term exposures at not more than about 4 times the TWA value. Therefore, no significant cost is anticipated with the proposed STEL value of 30 ppm.

Costs or Savings to State Agencies

No costs or savings to state agencies will result as a consequence of the proposed action.

Impact on Housing Costs

The Standards Board has made an initial determination that this proposal will not significantly affect housing costs.

Economic Impact Analysis

The Standards Board has made a determination that this proposal will not result in a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

For the FAC meeting at which ethylbenzene was discussed, a committee member presented workplace air sampling data which had been gathered at the location where he then worked, which he asserted suggested that complying with a PEL for ethylbenzene of less than 5 ppm in uses similar to those which he evaluated could impose significant costs on employers to achieve. The FAC concluded based on its own experience measuring workplace solvent exposures, supported in part by the data provided by the FAC member, that a PEL of 5 ppm for ethylbenzene is reasonable from the standpoint of cost and feasibility given the information available. The Standards Board concurs with that assessment in proposing 5 ppm as the amended PEL for ethylbenzene in this rulemaking.

In light of the limited economic impact of the proposal (as a result of the FAC feasibility determination), the adoption of the proposed amendments to these standards will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand businesses in the State of California.

This regulatory proposal is intended to provide worker safety at places of employment in California.

Cost Impact on Private Persons or Businesses

The Standards Board is not aware of any cost impact that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Costs or Savings in Federal Funding to the State

The proposal will not result in costs or savings in federal funding to the state.

Costs or Savings to Local Agencies or School Districts Required to be Reimbursed

No costs to local agencies or school districts are required to be reimbursed. See explanation under "Determination of Mandate."

Other Nondiscretionary Costs or Savings Imposed on Local Agencies

This proposal does not impose nondiscretionary costs or savings on local agencies.

DETERMINATION OF MANDATE

The Occupational Safety and Health Standards Board has determined that the proposed standard does not impose a local mandate. Therefore, reimbursement by the state is not required pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the proposed amendments will not require local agencies or school districts to incur additional costs in complying with the proposal. Furthermore, the standard does not constitute a “new program or higher level of service of an existing program within the meaning of Section 6 of Article XIII B of the California Constitution.”

The California Supreme Court has established that a “program” within the meaning of Section 6 of Article XIII B of the California Constitution is one which carries out the governmental function of providing services to the public, or which, to implement a state policy, imposes unique requirements on local governments and does not apply generally to all residents and entities in the state. (County of Los Angeles v. State of California (1987) 43 Cal.3d 46.)

The proposed standard does not require local agencies to carry out the governmental function of providing services to the public. Rather, the standard requires local agencies to take certain steps to ensure the safety and health of their own employees only. Moreover, the proposed standard does not in any way require local agencies to administer the California Occupational Safety and Health program. (See City of Anaheim v. State of California (1987) 189 Cal.App.3d 1478.)

The proposed standard does not impose unique requirements on local governments. All state, local and private employers will be required to comply with the prescribed standard.

EFFECT ON SMALL BUSINESSES AND RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Standards Board has determined that the proposed amendments may affect small businesses. However, no adverse economic impact is anticipated. The feasibility and cost of implementation of the proposed PEL for ethylbenzene was discussed by the FAC. This committee concluded that a PEL at the lower end of the range recommended on a health basis to address cancer risk may not be economically feasible. The committee recommended, and the proposed regulatory limit reflects, this judgment on cost and feasibility resulting in a proposed PEL that is a factor of 10 higher than that level discussed in the health advisory as being appropriate to address cancer risk. In light of this, the Standards Board believes there will be no adverse economic impact on small businesses.

ALTERNATIVES THAT WOULD AFFECT PRIVATE PERSONS

No reasonable alternatives have been identified by the Standards Board or have otherwise been

identified and brought to its attention that would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Labor Code section 144.6 provides that standards dealing with toxic materials be adopted that are most adequately protective of employee health “to the extent feasible.” Discussions were held in public meetings with advisory committees for both health and feasibility assessment. These discussions addressed a number of possible alternative PEL levels as summarized above and these different alternatives were considered in developing the PEL proposed in this rulemaking. These discussions are fully described in the minutes included in Attachment No. 4. Labor Code section 144.6 also provides that whenever practicable, standards for toxic materials be expressed in terms of objective criteria and of the performance desired. The proposal in this rulemaking is consistent with that stated preference in that it does not require particular specified equipment or methods for exposure level control, but rather provides an objectively stated performance criteria with affected employers determining the alternatives to use to achieve compliance in their particular operations involving employee exposure to the toxic material. The preference of Labor Code section 144.6 for performance based standards for toxic materials is consistent with the same stated preference contained in such Government Code section 11340.1(a).