

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

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**FINAL STATEMENT OF REASONS**

CALIFORNIA CODE OF REGULATIONS

TITLE 8: Division 1, Chapter 4, Subchapter 7, Group 16, Article 107,
Section 5155 of the General Industry Safety Orders

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

There are no modifications to the information contained in the Initial Statement of Reasons.

SUMMARY OF AND RESPONSES TO ORAL AND WRITTEN COMMENTS**I. Written Comments:****David Y. Shiraishi, MPH, Area Director, U.S. Department of Labor, Occupational Safety and Health Administration, by letter dated January 11, 2013.**

Comment: Mr. Shiraishi's letter indicated that the amendments proposed to the existing PEL for ethylbenzene appear to be commensurate with the counterpart federal standard.

Response: The Board thanks Mr. Shiraishi for participating in this rulemaking process.

Catherine A. Porter, JD, California Healthy Nail Salon Collaborative, by letter dated December 21, 2012.

Comment: Ms. Porter's letter recommends adoption of a time-weighted-average PEL value for ethylbenzene of 0.5 ppm to reduce the risk of cancer to 1 excess case per 1,000 workers exposed over a working lifetime, and also to protect against potential effects of exposure to this substance on the liver and kidneys, as well as reproductive and developmental damage. Ms. Porter notes that some nail polish manufacturers, as a substitute for toluene, are using xylene which she indicates can contain up to 20 percent ethylbenzene. Ms. Porter's letter also notes that ethylbenzene is used as an intermediate in the production of styrene, as a solvent, and in the plastic and rubber industries.

Response: The Initial Statement of Reasons (ISOR) for this rulemaking fully explicates the possible health basis for a time-weighted-average (TWA) PEL value of 0.5 ppm that the commenter refers to.

The ISOR also summarizes the discussion in, and recommendation of, the Feasibility Advisory Committee (FAC) for the proposed 8-hour TWA PEL of 5 ppm, rather than the 0.5 ppm value the commenter recommends. Beyond reference to particular industries and operations where employee exposure to ethylbenzene may occur, which the Board appreciates the commenter providing, the commenter does not provide any specific information on feasibility to supplement that presented in the FAC meeting of December 8, 2009 at which ethylbenzene was discussed. Therefore, the Board declines to modify the proposed PEL of 5 ppm (8-hour TWA) in response to the request of the commenter.

The Board thanks Ms. Porter for participating in this rulemaking process.

Julia Quint, Ph.D., by letter dated January 17, 2013, with attachment.

Comment JQ1: Dr. Quint comments that the health assessment document for ethylbenzene that she developed as a member of the Health Expert Advisory Committee (HEAC) for PELs in 2009 is not referenced in the ISOR or listed as one of the documents relied upon in the ISOR. Her letter notes that the health assessment document provides a transparent scientific basis for a PEL for ethylbenzene of 0.5 ppm (TWA), and that it was amended to reflect the discussion of ethylbenzene at three HEAC meetings in 2009 and provided to the FAC for PELs for its meeting held December 8, 2009. The letter requests that the October 20, 2009 version of the health assessment document for ethylbenzene be entered into the record of these hearings along with her written testimony.

Response: The Board and the Division recognize and greatly appreciate Dr. Quint's contributions to the work of the HEAC including the extensive research and analysis she applied in developing the HEAC health assessment document for ethylbenzene to which she refers in her letter (the October 20, 2009 version of this document, revised for the discussion at the last of three HEAC meetings to discuss ethylbenzene, can be viewed at the Internet link for [Ethyl benzene](#) under the entry for the FAC meeting of December 8, 2009 at www.dir.ca.gov/dosh/DoshReg/5155Meetings_2009.htm). The ISOR for this rulemaking specifically incorporated Dr. Quint's quantitative analysis of cancer risk for ethylbenzene that appeared in the health assessment document she developed and was discussed extensively in the HEAC meetings on ethylbenzene. The ISOR also notes the reference she cites for the most sensitive non-cancer endpoint for ethylbenzene of hearing loss found in rats. The Documents Relied Upon in the ISOR include the studies forming the basis for the analysis in the assessment document developed by Dr. Quint and; therefore, by implication Dr. Quint's analysis is a central part of the ISOR, albeit without specific attribution.

Comment JQ2: Dr. Quint's letter suggests that the proposed PEL of 5 ppm (8-hour TWA) for ethylbenzene, rather than the 0.5 ppm value derived in the health assessment document she authored and was discussed in the HEAC, is not based on objective evidence that a lower PEL would not be feasible. She said that from the FAC meeting discussion, the only basis for concluding that a PEL of less than 5 ppm could not be met appears to be a FAC committee member's experience that it would be unreasonably costly to achieve in his workplace, which uses xylene in the manufacture of artificial breasts. She said the minutes of the FAC meeting indicate there was no discussion of the feasibility of complying with a PEL lower than 5 ppm in operations using xylene by replacing industrial grade material with analytical xylene that is 98 percent pure, or by obtaining a variance. She said that proposing an 8-hour TWA PEL of 5 ppm, rather than a more health-protective value

does not appear to meet the requirements of Labor Code Section 144.6 that PELs in Section 5155 be developed based upon research, demonstrations, experiments, and other information as may be appropriate.

Response: As noted earlier in response to the comment of Catherine Porter, the decision of the Division to recommend, and the Board to propose, an 8-hour TWA PEL value for ethylbenzene of 5 ppm, as reflected in the ISOR section entitled *Cost Estimates of Proposed Action*, is based primarily on the consensus recommendation of the FAC members present at the meeting at which ethylbenzene was discussed in light of their collective experience. The specific example of exposure to ethylbenzene from use of xylene in the manufacture of artificial breast implants referred to in the comment letter and also discussed in the ISOR is an example of a situation where reducing the PEL to 0.5 ppm might be problematic, but it is not by itself the basis of the PEL value proposed in this rulemaking. The commenter suggests that use of xylene containing less ethylbenzene could possibly reduce exposure levels and the Division and the Board appreciate this suggestion. But without detailed information on the volumes of xylene that various processes in California might employ, and the likely increased cost of more highly purified xylene, the Board is not in a position to use this as the basis for feasibility of an 8-hour TWA PEL value of 0.5 ppm for ethylbenzene. Title 8, Section 5141 provides for a hierarchy of exposure control options to achieve compliance with PELs in Section 5155. In light of this, the Board does not envision the applicability of the variance process to PELs, though obviously it could not be ruled out in advance. When the Division reconvenes the FAC process, it intends to revisit the issue to see if follow-up rulemaking is necessary to further reduce the PEL based on the current state of feasibility for ethylbenzene.

Comment JQ3: Dr. Quint's letter notes that the proposed 8-hour TWA PEL of 5 ppm does not protect against non-cancer effects of ethylbenzene including developmental toxicity, hearing loss, and liver, kidney, and pituitary gland damage. She noted that in the health assessment document she developed, applying uncertainty factors consistent with those used for Cal/OSHA PELs adopted by the Board in 2009, she derived PELs of 1 and 2 ppm for developmental toxicity using two different studies, 0.2 ppm for hearing loss, and 2 ppm for liver, kidney, and pituitary gland damage.

Response: The Board acknowledges Dr. Quint's comment that the proposed 8-hour PEL TWA of 5 ppm would not achieve the same level of worker health protection as her recommended value of 0.5 ppm. However, as discussed in the ISOR itself, and in response to Dr. Quint's Comment JQ2 above, the PEL of 5 ppm being proposed is based on the consensus recommendation of the FAC members present at their meeting of December 8, 2009 at which ethylbenzene was discussed based on their collective experience.

Comment JQ4: In her letter, Dr. Quint supported the proposed revision of the existing 15-minute Short Term Exposure Limit (STEL) for ethylbenzene of 125 ppm, and she agreed with the data and method used to derive the proposed amended STEL value of 30 ppm. However, she supports a STEL value of 16 ppm to be consistent with a TWA PEL value of 0.5 ppm, and urged the Board to adopt both these values to reduce the increased cancer risk from worker exposure to ethylbenzene to 1/1,000 and to protect against serious non-cancer health endpoints of developmental damage, hearing loss, and organ system damage.

Response: The 15-minute STEL value of 16 ppm suggested by Dr. Quint would translate into an 8-hour TWA value of 0.5 ppm where the exposure to ethylbenzene is limited to a single 15-minute period in an 8-hour work shift. However, the definition of the STEL in Section 5155 reads as follows:

Short Term Exposure Limit (STEL). A 15-minute time-weighted average exposure which is not to be exceeded at any time during a workday even if the 8-hour time-weighted average is below the PEL. An averaging period other than 15 minutes may be specified in the footnotes at the end of Table AC-1.

In light of this definition, while any PEL STEL value below the 8-hour TWA value can help limit brief high exposures, which can also then help reduce the 8-hour TWA exposure, the STEL value cannot be translated directly into a PEL value without an assumption as to the number of 15-minute periods in the work shift in which exposure to ethylbenzene is occurring. Where ethylbenzene exposure in an 8-hour work shift is limited to a single 15-minute period, a 15-minute STEL value of 16 ppm as suggested by Dr. Quint would translate into an 8-hour TWA exposure level of 0.5 ppm based on there being thirty-two 15-minute exposure periods in an 8-hour work shift. Since the effect of the STEL value on the 8-hour TWA exposure, and therefore, cancer risk, depends on the number of 15-minute exposures in the work shift, it is problematic to make cancer risk reduction the central basis of necessity for a STEL value for ethylbenzene. In contrast, the evidence for eye and respiratory tract irritation provides a quantitative basis that was used to develop the value of 30 ppm for the 15-minute STEL that is proposed in this rulemaking.

The Board thanks Dr. Quint for participating in this rulemaking process and for her past service as a HEAC member.

Dorothy Wigmore, WorkSafe, at the January 17, 2013 Public Hearing, submitted the following article: Regulatory Toxicology and Pharmacology 58 (2010) 167-169, Clarifying Carcinogenicity of Ethylbenzene.

Comment: See Ms. Wigmore's "second comment" in the Oral Comments at the January 17, 2013 Public Hearing in Oakland, California section of the Final Statement of Reasons.

Response: See the response to Ms. Wigmore's "second comment" in the Oral Comments at the January 17, 2013 Public Hearing in Oakland, California section of the Final Statement of Reasons.

The Board thanks Ms. Wigmore for participating in this rulemaking process.

II. Oral Comments at the January 17, 2013 Public Hearing in Oakland, California:

Catherine Porter, California Healthy Nail Salon Collaborative.

Comment: Ms. Porter said that the Healthy Nail Salon Collaborative had attended the HEAC meetings regarding ethylbenzene. She said that an analysis done by Dr. Julia Quint recommended a PEL for ethylbenzene of 0.5 ppm. She said she is concerned that the Initial Statement of Reasons

does not reflect Dr. Quint's analysis and that the procedure and documentation that are before the Board are inadequate for consideration. She asked the Board to consider a level of 0.5 ppm as recommended in Dr. Quint's analysis.

Response: See the response to Ms. Porter's similar written comment and to Dr. Quint's Comment JQ2.

The Board thanks Ms. Porter for participating in the public hearing on the PEL for ethylbenzene.

Dorothy Wigmore, WorkSafe (First Comment).

Comment: Ms. Wigmore echoed the concerns of Ms. Porter with regard to the analysis done by Dr. Julia Quint, and that the PEL being proposed does not protect workers. She said that even a PEL of 0.5 ppm would not adequately protect workers because it still has a 1 in 1,000 increased cancer risk, and WorkSafe advocates for a PEL that would only have an increased cancer risk of 1 in 100,000. She said the proposed value of 5 ppm would present a 10 in 1,000 cancer risk. She stated that the industry association for ethylbenzene acknowledges that substitution is the best way to reduce exposure, but that was not discussed during the FAC. She said that more coordination is needed between the green chemistry initiative and Cal/OSHA to reduce exposures, and if the FAC does not consider substitution, then it is not a good process. She asked the Board to have more discussion with Cal/OSHA on this matter and to set a PEL based on Dr. Quint's recommendations and accurate data.

Response: The comment speaks to issues beyond the scope of this particular rulemaking. With regard to the appropriate increased cancer risk level on which PELs should be based, the Division has a longstanding practice of using the 1/1,000 increased risk level as at least the starting point for developing possible health based values for PEL proposals. That said, recognizing Ms. Wigmore's concern, if information is available to support feasibility of a PEL for ethylbenzene that would control increased cancer risk below the 10/1,000 level, for example to the 1 in 100,000 level suggested in the comment, then the Division and the Board would consider that in developing a follow-up rulemaking to further reduce the proposed PEL value.

With regard to the industry association recommendation of substitution, Ms. Wigmore did not provide a reference for this assertion, and the Division is not aware of such a recommendation. Finally, the Division and the Board agree that those working on "green chemistry" initiatives such as that in California may be in a position to make positive contributions of information or perspective on the feasibility of particular PELs. The FAC meeting, initiated as a change in the Division's PEL advisory committee process for its latest round of work starting in 2007, is intended as an opportunity for anyone with information relevant to feasibility of a PEL to be able to present and discuss such information in a public meeting.

Dan Leacox, Greenberg Traurig, representing the Styrene Information and Research Center (SIRC).

Comment: Dan Leacox said that based on recent studies of ethylbenzene exposure to mice and rodents, the cancer endpoint is not relevant to humans. He said that ethylbenzene is part of a large

study group and that many factors went into the Division's evaluation and recommendation of 5 ppm as the PEL. He said that an industry group participating in the HEAC discussions had recommended PEL values for different endpoints ranging from 7 to 20 ppm, and even though the Division's recommendation of 5 ppm is outside of that range, it is something that SIRC could still support.

Response: As indicated and addressed in the Initial Statement of Reasons, the relevance of the cancer endpoint for humans from ethylbenzene exposure based on animal test results was discussed extensively in the HEAC as summarized in the minutes for the meetings of that committee in 2009 in which ethylbenzene was discussed.

The Board thanks Mr. Leacox for participating in the public hearing on the PEL for ethylbenzene.

Dorothy Wigmore, WorkSafe (Second Comment).

Comment: Ms. Wigmore said that a study titled "Clarifying Carcinogenicity of Ethylbenzene" contradicts Mr. Leacox's statement that increased cancer observed in animal studies of ethylbenzene is not relevant to humans. She noted that this study says that when a chemical causes cancer in animals, attention should quickly be given to those results rather than ignoring them. She also stated that there is other evidence that contradicts Mr. Leacox's statement and that this evidence should be considered.

Response: As noted in the response to the verbal comment of Mr. Leacox, the relevance of the cancer endpoint for humans based on animal test results was discussed extensively in the HEAC as detailed in the minutes for the meetings of that committee in which ethylbenzene was discussed. With regard to the study noted by Ms. Wigmore, in proposing an 8-hour TWA PEL value for ethylbenzene of 5 ppm, the Board is not taking a position, or basing the proposed PEL, on the potential of ethylbenzene to cause cancer, though being mindful of that risk, a 15-minute STEL is being proposed, in part, to contribute to greater control of full-shift exposures.

The Board thanks Ms. Wigmore for participating in the public hearing on the PEL for ethylbenzene.

Laura Stock, Standards Board Member.

Comment: Ms. Stock said that the Initial Statement of Reasons stated that a PEL of 0.5 ppm for ethylbenzene is not feasible. She asked Mr. Barish representing the Division to explain how that conclusion was reached and what the criteria is for determining feasibility.

Response: The Initial Statement of Reasons for this rulemaking stated in part that "5 ppm appears to be the lowest feasible level to which the PEL can be reduced at the current time." This is not the same as saying that a PEL of 0.5 ppm, or some other value between 0.5 and 5 ppm, is "not feasible." What was intended by the statement quoted above on feasibility in the Initial Statement of Reasons is that no information, or even substantial opinion, was provided in the FAC meeting, or otherwise in the development of the proposed amended PEL for ethylbenzene, that a value below 5 ppm would be feasible for California employers to achieve.

In general, feasibility is viewed first from a technological standpoint of “capable of being done.” Once this most basic hurdle of feasibility determination is reached, the next question is can it be expected that most, a majority, or even a substantial percentage of employers with operations employing the substance in question achieve compliance with the PEL being proposed?

In the particular case of ethylbenzene, air sampling data was provided by one FAC member for one particular operation with which he was familiar from his employment, and these data suggested a PEL of 0.5 ppm could be problematic from the standpoint of feasibility, while a PEL of 5 ppm would probably be feasible in that operation. This was not a definitive determination of infeasibility of 0.5 ppm for the PEL for ethylbenzene, but it probably did contribute to the consensus of the four FAC members present at the meeting at which ethylbenzene was discussed, all experienced industrial hygienists, that 5 ppm should be a feasible PEL for this chemical in California. Again, this consensus should not be read as a firm conclusion that some lower PEL would necessarily be infeasible. However, in the absence of additional data to support feasibility of a PEL lower than 5 ppm, the Division and the Board do not believe they are in a position to propose a PEL below this level at this time. When the Division reconvenes the FAC process, it intends to revisit the issue to see if follow-up rulemaking is necessary to further reduce the PEL based on the current state of feasibility for ethylbenzene.

Hank McDermott, Standards Board Member.

Comment: Mr. McDermott thanked those commenting on the ethylbenzene PEL proposal and stated that he was on the Feasibility Advisory Committee that met in 2009 and discussed ethylbenzene. He said he is looking forward to the Division’s response to the comments received today, but he is concerned that the original discussions were so long ago. He also stated that he is concerned because there is not very much exposure information available on either side of the argument as to whether the PEL should be raised or lowered. He stated that the cost to analyze an air sample for ethylbenzene is about \$50.00, but based on the materials he has been given, as well as the public’s testimony today, it seems no one has collected and analyzed an air sample in the last 5 years to test whether the level should be higher or lower. He said that, as a result of this, the Board has to rely on the Division’s assessment of what was presented during the Health Expert and Feasibility Advisory Committees.

Response: In response to Board Member McDermott’s comment, Division staff reviewed all the comments submitted and even conducted another search for data in the scientific literature that might be relevant to the question of feasibility, to assess if data had become available since the FAC meeting in December 2009 at which the PEL for ethylbenzene had been discussed, and to reassess data that might have been available at the time of the FAC meeting. A number of published articles were found that had air sampling results of public and occupational exposures to ethylbenzene from pumping of gasoline at automobile service stations, from exposure in a petroleum depot, and from situations of environmental contamination including oil spills. The air sampling of occupational exposures from these operations were not considered relevant as their sampling results were much lower than any of the PELs discussed in the FAC. In addition, no relevant reports were identified on exposures in occupational environments where ethylbenzene, or xylene which contains it as a mixture, is used as a solvent, the operation probably of greatest concern in California. Therefore, the Division and the Board believe it is reasonable to rely for guidance, at least in part, on the consensus

recommendation of the FAC with regard to the feasibility of different possible PEL values. The Division will continue to monitor the scientific literature for air sampling data that could be used to support further lowering of the PEL through a future follow-up advisory process and rulemaking.

Bill Jackson, Standards Board Member.

Comment: Mr. Jackson stated that he would like to see the Division address in its response to comments whether or not there is a credible estimate as to how many California employees are exposed to ethylbenzene, and if there is, the level to which they are exposed. He stated that, if lowering the PEL is necessary and appropriate, the Board should lower it to a level that the Division recommends, and if a lower number than that is found to be appropriate, they can do that later. He asked the Board to not put off something better in anticipation of something perfect coming later on.

Response: As stated in the ISOR, sufficient information is available to conclude that there is the potential for exposure to ethylbenzene in a wide range and number of industrial operations in California. Therefore, in the absence of other substantial comments or information to the contrary received in the FAC process that is based on actual workplace exposure data, the Division and the Board believe it is reasonable to rely on the consensus recommendation of the FAC members who attended the meeting at which ethylbenzene was discussed as to the feasibility of the PEL value proposed in this rulemaking.

ADDITIONAL DOCUMENTS RELIED UPON

None.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

None.

DETERMINATION OF MANDATE

This regulation does 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 regulation. 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.