

**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: Naphthalene**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 August 15, 2013.**

Comment: Mr. Shiraishi's letter indicated that the proposal to amend Section 5155 by adding a new PEL for naphthalene appears to be commensurate with the counterpart federal standard.

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

Peter Grass, President, Asphalt Institute (AI), by letter dated August 13, 2013.

Comment: AI believes the proposed PEL of 0.1 ppm to protect employees from excess cancer risk and non-cancer health effects is not based upon the most current scientific literature regarding naphthalene as an airborne contaminant. More recent published information suggests the evidence supporting the revised PEL is irrelevant to actual human risk. Based upon the new information, the Health Council of the Netherlands stopped developing a more stringent classification for naphthalene. The Documents Relied Upon listed in the Initial Statement of Reasons are dated from 1992 to 2009 and do not include more current and compelling relevant findings. A 2010 publication [Rhombert, et al.] notes the challenges of applying animal studies to humans, often extrapolating high dose to low dose exposures; focusing on research related to naphthalene exposure and cancer. The authors concluded there is no systematic epidemiological evidence of human naphthalene exposure and cancer and questioned extrapolating high dose

rodent exposures to human risk. This article caused the Health Council of the Netherlands to reverse its original conclusion and decided the available animal data does not provide sufficient evidence for naphthalene to be declared a human carcinogen. Indeed, the Health Council's subcommittee decided that naphthalene's mode of carcinogenic action in rodents was not relevant for humans. AI further notes that the American Conference of Government Industrial Hygienists (ACGIH) 2012 draft Threshold Limit Value (TLV) recommendation for naphthalene declared there was inadequate epidemiological evidence to determine whether naphthalene caused cancer in humans. The ACGIH has also returned its TLV value for naphthalene to 10 ppm. The AI requests the Board to review this most recent research which demonstrates the proposed PEL may be based upon flawed premises.

Response: The Board appreciates AI's participation in this rulemaking process and has carefully considered the points AI raises in its comments and attachments. The Board notes that, although the commenter asserts that there is a lack of human data, the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the Office of Environmental Health Hazard Assessment (OEHHA) continue to categorize naphthalene as either reasonably anticipated or suspected to be a human carcinogen. Recently, NTP reaffirmed its categorization of naphthalene as reasonably anticipated to be a human carcinogen. In reviewing the Rhomberg, et al, article provided by AI, the Board finds that it is a proposal for a particular methodological way of thinking about carcinogenic modes of action utilizing the case of naphthalene as an example, but the article suggests no new modes of action for naphthalene that were not already known and discussed in the available literature. The questions the Rhomberg, et al, article raises and the explicit assumptions it makes are by no means the only mechanistic questions that could be asked, nor are they the only assumptions that could be made about naphthalene's modes of action. In any event, there is no consensus in the scientific community that the hypothesis-based weight of evidence tool should be the utilized (let alone be the single definitive model utilized) by those scientific bodies evaluating potential carcinogens such as the NTP. The Netherlands and the American Conference of Governmental Industrial Hygienists (ACGIH) decision not to lower its exposure limits are not relevant to this proposal in that they have different scientific review and advisory process that may or may not have taken into account the documents our advisory process relied upon.

Finally, the PEL of 0.1 ppm has also been derived by the advisory committee process as the level both necessary and feasible to protect against both cancer and non-cancer health effects. The Board believes this derivation as summarized in the 2008 Quint document is consistent with the latest research on both cancer and non-cancer endpoints for naphthalene, which include many other effects other than the lung and nasal hyperplasia that are the initiating points for the cancer discussion. With regard to more recent data becoming available since the advisory process on the substance was concluded in 2009, when the Division reconvenes the Division's Health Expert Advisory Committee (HEAC) and the Division's Feasibility Advisory Committee (FAC) process, it intends to revisit the issue to see if follow-up rulemaking is necessary to further revise the PEL based on the current state of the scientific evidence and/or feasibility data for naphthalene.

Anne LeHuray, Ph.D., Executive Director, Naphthalene Council (NC), by letter dated August 14, 2013.

Comment: The NC, a non-profit trade association of naphthalene producers, supports the comments of the Asphalt Institute. The NC believes the scientific evidence supports maintaining the PEL at 10 ppm TWA. This PEL has been found to effectively protect those exposed to naphthalene in industrial settings, and has, after several years of deliberation, been determined to be appropriate by the ACGIH TLV Committee. The NC participates with other trade associations and individual companies in the Naphthalene Research Committee (NRC), which sponsors research to help improve naphthalene risk assessment and to ensure publishing of quality data in peer-reviewed journals to reduce use of default assumptions in naphthalene risk assessment. In 2006, a symposium was held to review NRC sponsored research on naphthalene carcinogenicity and genotoxicity. The symposium resulted in the publication of six scientific articles, which NC lists here. An additional 14 articles describing more recent research on modes of action of naphthalene carcinogenicity are also listed; many of these articles were also based on NC sponsored research. The most current research demonstrate the proposed PEL may be based on premises now shown to be incorrect or default values for which naphthalene-specific data now exists.

Response: The Board thanks NC for its comments and participation in the advisory process. Please see the Board's responses to the similar comments by the AI. In regard to the recent articles listed in the NC letter, as stated in the AI response, the Board notes that the recent NTP reaffirmation of its view of naphthalene carcinogenicity encompasses the publication dates of most of those articles and the Division will reconsider if any further changes are needed when the HEAC and FAC process is reconvened.

Catherine A. Porter, JD, Policy Director, California Healthy Nail Salon Collaborative, by letter dated August 5, 2013.

Comment: Every workday, nail salon workers, predominately women of reproductive age, are exposed to numerous harmful chemicals in nail care products, including naphthalene. Naphthalene is a polycyclic aromatic hydrocarbon (PAH) derived from coal tar. Studies show naphthalene linked to rat nasal cancer and to non-cancer respiratory problems, while PAHs have been shown to increase risk for breast cancer. Healthy Nail Salon Collaborative recommends a PEL of 0.025 ppm as proposed by Julia Quint in her HEAC comments. This PEL represents a risk of cancer calculated as 1/1000.

Response: The Board thanks the Healthy Nail Salon Collaborative for its comments and participation in the advisory process. Please see the Board's responses to the comments of Dr. Quint.

Julia Quint, PhD, by letter dated August 13, 2013.

Comment: While Dr. Quint commends the Board for proposing to lower naphthalene's current PEL of 10 ppm, the Board should adopt a PEL of 0.03 ppm, the same value proposed by the Hazard Evaluation System and Information Service (HESIS) when she was its Chief. HESIS recommended this PEL of 0.03 ppm to reduce cancer risk to workers. Based upon a 2007 report prepared by the Cal/EPA OEHHA under contract to HESIS, a PEL of 0.03 ppm would reduce cancer risk for occupational exposure to naphthalene from 330 excess cases/1000 workers at the current PEL, to only one excess cancer per thousand. This exposure limit will also protect against naphthalene-induced chronic respiratory system damage as documented in the 3/25/2009 comments to HEAC on derivation of a non-cancer endpoint PEL. Both the cancer and non-cancer PEL of 0.03 ppm are based on quantitative risk analyses (QRAs) consistent with methodology utilized with other recently promulgated Cal/OSHA PELs as well as methodologies of federal EPA and OSHA, Cal/EPA and OEHHA. The QRA used to derive a PEL for naphthalene of 0.03 ppm is consistent with two federal court decisions about PELs for carcinogens and chemicals causing respiratory system damage. Identification of naphthalene as a carcinogen is consistent with Proposition 65 and the findings of the NTP and the International Agency for Research on Cancer findings. The Board has not presented sufficient evidence that the PEL of 0.03 ppm is not feasible, and instead should be 3-fold higher. At the FAC, no current exposure data or information about feasibility was received from affected employers regarding a PEL of 0.03 ppm. The FAC's conclusion regarding feasibility was based upon monitoring data listed in an article by Price and Jaycock, who described the data as "limited." These authors found that operations had exposures exceeding 0.04 ppm, from which the FAC drew its conclusion. However, the article did not address the feasibility of these operations achieving lower air levels of naphthalene through the application of industrial hygiene controls. The low range of exposures (0.02 to 0.06 ppm) found in California refining and asphalt industries suggest a PEL of 0.03 ppm is feasible.

The Board's rationale for proposing a PEL of 0.1 ppm is unclear, since this level is on the higher end of the range of reported values for which control measures are typically required. In the Initial Statement of Reasons (ISOR), 0.1 ppm naphthalene is the median exposure level of US Air Force fuel maintenance workers whose work includes entering fuel tanks. Air supplied respirators would be required for such confined space entry, so such workers' actual inhalation exposure would be negligible. The median exposure level of workers conducting moderate fueling activities is 0.002 ppm, indicating that a 0.03 ppm is feasible as well. Thus, without objective evidence, the Board's proposal is not in keeping with its mandate to ensure workers do not suffer material impairment of health from naphthalene. As then Chief of Cal/OSHA, Len Welsh stated at a December, 2009 FAC meeting, PEL feasibility determinations should include consideration of respiratory protection and the extent to which engineering controls may be effective. To help ensure transparency of the PEL development process, the HEAC PEL recommendation document and the attached written comments recommending alternative, lower naphthalene PEL should be added to the list of documents relied upon in the FSOR. Finally, citation 6 on page 7 of the naphthalene ISOR needs to be revised to indicate that Dr. Quint

submitted the updated written comments pertaining to the October 27, 2008 HEAC PEL recommendation document to the HEAC on March 25, 2009.

Response: The Board thanks Dr. Quint for her participation in the advisory process and for her comments on the scientific basis for and support of lowering PEL for naphthalene. Regarding the concern about the proposed PEL not being as low as the 0.03 recommended by the HEAC, the Board acknowledges that the proposed PEL leaves a remaining increased lifetime risk for development of cancer in excess of the 1/1000 level reported by Dr. Alexeef of OEHHA in his letter of March 16, 2009. The Board also acknowledges the remaining risk for non-cancer health effects over a working lifetime of exposure at the PEL. However, the Board notes that the proposed PEL reduces exposure by a factor of 100, lowering substantially the risk of both cancer and non-cancer health effects. The Board further notes first, that the proposed PEL is half of the human equivalent of the Lowest Observed Adverse Effect Level for rat nasal lesions due to chronic inhalation exposure. Secondly, as explained in the ISOR, for some operations for which the potential naphthalene exposure could be significant, median exposures are documented at two orders of magnitude below the PEL. The ranges of documented exposure thus contribute to our current understanding of a PEL that is capable of being reached in California.

The Board acknowledges that additional experimental data, exposure information or epidemiological data could provide an impetus for a further lowering of the naphthalene PEL, but this would be the subject for future additional rulemaking. When the Division reconvenes the HEAC and FAC process, it intends to revisit the issue to see if follow-up rulemaking is necessary to further revise the PEL based on the current state of scientific evidence and feasibility for naphthalene. Finally, the Board acknowledges that No. 6 of the Documents Relied Upon is the same document distributed to HEAC members in 2009 but declines to modify the ISOR as the title is sufficiently descriptive for the regulated public to obtain the document from the Board and see that it is the same document posted on our HEAC website at <http://www.dir.ca.gov/dosh/DoshReg/naphthalene-10-27-08.doc>

Dorothy Wigmore, Occupational Health Specialist, Worksafe, by letter dated August 14, 2013.

Comment: Worksafe congratulates the Board for proposing to reduce the PEL for this carcinogenic and respiratory system toxin. Naphthalene as is on the “Substitute It Now” list in Europe for being an endocrine disruptor; on the Global Automotive Declarable Substances List according to which it must be declared at any concentration; included on the European Union’s Water Framework Directive List of Priority Substances; on the German UBA master list as carcinogenic, mutagenic and toxic for reproduction; on the US EPA’s Extremely Hazardous Substances List; and its use is required by the Massachusetts Toxic Use Reduction Act to be reduced and reported. Naphthalene is also one of 40 substances on the Danish EPA’s List of Undesirable Substances whose use should be reduced or ended and it is on the Swedish Chemicals Agency’s list of priority risk reduction substances and has been named by Nokia as a substance the company has banned, restricted or aims to stop using in its products.

Given these listings and the derived unit risk value for naphthalene submitted to HEAC, Worksafe cannot support the proposed PEL; it is simply too high and will not protect workers from excess risk of cancer or respiratory effects. While Worksafe could support a PEL of 0.03 ppm with a skin notation, as explained very well in Dr. Quint's August 13, 2013 letter to the Board, even this level's excess cancer risk of 1 per 1000 workers exposed over a working lifetime is too high, as this is the upper bound permitted by the Supreme Court's Benzene Decision (the lower bound is 1 in 1,000,000 excess cancers). The feasibility argument for justifying a PEL of 0.1 instead of 0.03 ppm has no evidence behind it. No evidence from industry was submitted to the FAC, and only one limited study of a high hazard Air Force job was adduced by Cal/OSHA as justification for the 0.1 ppm proposal. At the FAC meeting discussing naphthalene in 2009, there was disagreement about what should be the basis for determining feasibility. One participant believed feasibility should be the level currently being achieved or capable of being achieved with currently used technology. Worksafe agrees with another FAC participant that stated feasibility is not about what is currently achievable, but about reduction of workers' exposures through use of the precautionary principle utilizing primary public health prevention approaches and technology-forcing requirements for controls. Just as important, both the FAC and Cal/OSHA need publically available prevention oriented criteria for feasibility determinations, and Cal/OSHA needs adequate staffing and funding to accomplish the necessary tasks for preparing PELs.

Response: The Board thanks Worksafe for its participation in the advisory process and for these comments. Please see the Board's responses to Dr. Quint's letter.

II. Oral Comments at the July 18, 2013 Public Hearing in Costa Mesa, California:

Ms. Wigmore stated that Worksafe is pleased that the PEL is being reduced 100-fold in this proposal, but they believe that it is still too high and should be lowered even further to 0.03 ppm with a skin notation. She said that naphthalene is currently listed on several different hazardous chemical lists around the world, and because of that, as well as the derived unit risk value for naphthalene that was presented to the HEAC, Worksafe cannot support the proposed PEL. They feel that it will not protect workers against cancer and respiratory effects and will create one excess cancer risk for every 1,000 workers exposed to naphthalene over a working lifetime, which is unacceptable to them.

Response: Please see the Board's responses to the written comments of Dr. Quint.

Ms. Stock stated that this proposal is another example for why a better job needs to be done when defining feasibility. She said that strong and clear evidence is needed to justify not going with the most protective PEL and that she did not see any evidence in the FAC minutes to justify not using the 0.03 PEL, which is the most protective level. She stated that the FAC should

change to more concretely define PEL levels and their criteria in a way that will guide the Board moving forward.

Response: The Board thanks Ms. Stock for her input and process recommendations for the Division's PEL advisory process. When the Division reconvenes the HEAC and FAC process, it will consider those process suggestions and intends to revisit the issues raised during this rulemaking to see if follow-up rulemaking is necessary to further revise the PEL based on the current state of scientific evidence and/or feasibility data for naphthalene.

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

No reasonable alternatives have been identified by the 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.